GE Healthcare

Lunar enCORE

Safety and Specification Manual

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CE 0197

DPX Series	YZB/USA 2099 SFDA(I) 20023301115
Prodigy Series	YZB/USA 0509 SFDA(I) 20043301375
iDXA	YZB/USA 1104-2007 SFDA(I) 20073302084

GE Medical Systems LUNAR recommends viewing the instructions for navigating the Lunar iDXA, PRODIGY™, PRODIGY™ Advance, PRODIGY™ Primo, PRODIGY™ Pro, DPX™ NT/Pro/MD+/Duo/Bravo™ Safety Information and Technical Specifications before proceeding through the online guide for the first time.

Table of Contents

Introduction

This manual contains safety and maintenance information, and technical specifications, for your bone densitometer.

This manual should be used with the Lunar enCORE™ Online Help you received with your system.

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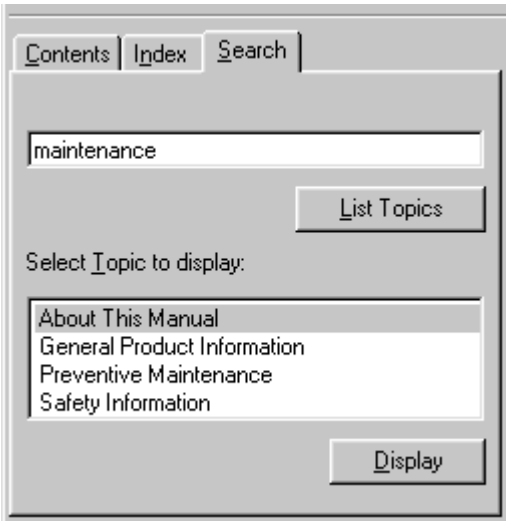
Search

You can search for topics and content within the online help.

1. Click the **Search** tab in the online help window.



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General Product Information

The bone densitometer is designed to estimate the bone mineral density and body composition (lean and fat tissue mass) of patients when medically indicated by their physicians. The manuals provide instructions for operating the software and scan table, system information, and maintenance information.

Variables Affecting Scan Results

Scan results can be affected by operator technique and patient variability:

1. Operator technique refers to patient positioning and scan analysis. To minimize technique variables, 1) establish consistent positioning and scan analysis routines by using anatomical landmarks when positioning patients, and 2) during analysis, manipulate raw scan data only when absolutely necessary.

2. Patient variability refers to changes in the patient's medical history, metabolism, and diet. It also refers to diagnostic procedures that involve radionuclide uptake and medical treatment, and the presence of external radiation (particularly the use of other radiation-generating devices in the vicinity of the system). To minimize patient variability, 1) thoroughly familiarize yourself with the patient's history, and 2) install the scanner in an environment effectively shielded from other sources of external radiation.

CAUTION: United States Federal Law restricts this device to the sale, distribution, and use by or on the order of a physician (USA only).

Training Information

GE Medical Systems Lunar or authorized GE Medical Systems Lunar distributors provide individual, hands-on training as part of the installation procedure for your system. (GE Medical Systems Lunar distributors provide training for systems installed outside the United States.) An Applications Specialist provides information on software and hardware operations, and reviews the warnings and cautions in the manuals.

IMPORTANT: Only trained technologists should operate the system. New technologists should receive training prior to unsupervised operation of the system. Additional training sessions are available on request for a nominal fee. For more information, contact the GE Medical Systems Lunar Customer Service Department at 800-334-5831, or your local GE representative.

Cautions for DEXA Determinations

You should be aware of the following factors which may affect the clinical accuracy of DEXA spine estimates: marked distortions of skeletal architecture-e.g., osteophytes, degenerative disc disease, spinal arthritis, spondylolisthesis, kyphoscoliosis, and vertebral fractures-and significant calcium deposits in the aorta can falsely elevate spine bone mineral values. Regions that contain these dystrophic calcifications can be excluded from the scan analysis in some cases. The scanner can be used to monitor changes in bone mineral over time in patients with these disorders, but caution must be taken in interpretation. Use DEXA estimates as an aid to other methods in the evaluation of patient bone mineral status in the clinical setting.

In addition, spine estimates will be difficult to interpret for patients with orthopedic metal devices and previous surgical interventions, such as bone grafts. Radiographic contrast material and radiopharmaceuticals used for myelograms, barium enemas, and other diagnostic tests prevent accurate estimates. Barium clears the body within a few days, but the oil-based dyes used in myelograms several years ago may remain within the body for years. A three-day waiting period is sufficient time for barium and most radiopharmaceuticals to be completely discharged from the body.

Femur estimates will be difficult to interpret for patients with orthopedic metal devices and previous surgical interventions. The most common complicating factors for femur estimates are prosthetic devices and surgical implants in the region of the bone scan. Results may be adversely affected if the patient has difficulty with the desired 25° inward rotation of the leg or with maintaining this position without movement.

Total Body estimates require consistent patient positioning for accurate results and will be difficult to interpret for patients with orthopedic metal devices and previous surgical interventions. The operator should pay particular attention to the location of the patient's arms, keeping the positioning the same for each scan. Results may be affected if the patient moves during the scan.

Precautions for Standard Operating Procedures

1. Do not attempt to operate the scanner without first reading this manual.
2. Do not remove the assembly panels or attempt any repairs without prior instructions from authorized GE Medical Systems Lunar personnel.
3. Perform the Quality Assurance procedure each morning. If any test fails, check the position of the calibration block and rerun the QA procedure. If a test fails again, contact GE Medical Systems Lunar Support. Also, call GE Medical Systems Lunar if more than two failures occur in a one-week period. If the room temperature changes more the 5°C during the day, then perform another Daily QA.
4. If the patient is or might be pregnant, always contact the patient's physician before performing a scan.
5. Remain in the room with the patient while a scan is in progress. Assure the patient does not move during the measurement. Minimize the amount of time the patient lies flat on the scan table.
6. Restrict access to the room to authorized personnel.
7. Do not attempt to service any of the system's electrical components while the scan table is turned ON. High voltage is used to produce x-rays.
8. Radiation safety information is located within this manual you received with your system. Review this information before operation.
9. **To stop the scanner in an emergency**, press the emergency stop button on the scan arm. **DO NOT** use the emergency stop button to routinely abort a scan.
10. Remove any fluids which are spilled on pad or any surface of table immediately.
11. All surfaces should be cleaned to meet site's guidelines for handling blood and body fluids. Pad material may be damaged by certain chemicals Use appropriate hospital grade disinfectant followed by mild detergent.
12. Do not generate x-rays through the use of remote applications.

13. Protect the computer against malicious logic and unauthorized network access. Only allow authorized user access. Prevent virus attacks through the use of firewalls, anti-virus software and software patch updates. Contact your local GE representative for more information.

14. DPX Duo: Extend the step the full distance to provide maximum surface area for the patient to get on and off the table without risk of injury.

15. DPX Duo: Do not place an excessive load on foot rest (stirrup), drawers, or leg extension.

16. DPX Duo: Do not sit on leg extension table.

Patents

This product is covered by the claims of one or more of the following patents:

U.S. patents #5,040,546, #5,306,306, #5,480,439, #5,533,084, #6,038,281, #6,081,582, #U520050249331A1, #U520050247882A1, #U520050247880A1

Standard Operating Procedures

1. **Quality Assurance:** Every morning, before you start patient measurements, complete the daily Quality Assurance procedure. Refer to chapter 2 of the enCORE Operator's Manual. Make sure you save your printed results for future reference.

2. **Measure Patients:** If time allows, enter the Primary, Secondary, and Additional data for the patients you expect to measure during the day. Refer to chapter 3 of the enCORE Operator's Manual to measure a patient.

3. **Analyze Results:** Analyze and print results immediately after each patient measurement if time allows. Otherwise, analyze all of the patient files after the last patient has been measured. Refer to chapter 4 of the enCORE Operator's Manual to analyze results.

4. **Archive image files:** Archive your image files before you leave for the day. In the unlikely event of a computer malfunction, it is very important that you have archived files of all of your patient measurements to rebuild your database. Refer to Archive image files on page 30 for archive procedures.

5. **Shut down computer:** At the end of the day, select Exit from the Main screen, select Shut Down from the Close window, and click OK to close the program.

   Note: Do not turn off the scanner at the end of the day for stationary systems.

Scanner Table Assembly

Note: Do not attempt to service the scanner table assembly. Please call GE MEDICAL SYSTEMS Lunar Support or your GE MEDICAL SYSTEMS Lunar distributor.

Scanner table

The scanner table is used to support the patient during a measurement or general examination (DPX Duo). In addition, the x-ray source assembly and other electronics are contained inside the scanner table.

Scanner arm

The laser light, emitted from an aperture on the scanner arm, helps you locate the measurement start position. Positioning switches let you move the scanner arm until the laser light is located at the correct start position. The start position is different for each measurement type.

The DPX Duo and DPX Bravo scanner arm has a release and locking mechanism allowing the upper arm to swivel when the scanner is idle. The scanner arm must be in the locked position over the scanner table to perform a measurement.

Display panel

The following describes the indicators located on the scanner arm display panel:

Indicator	Status (on)
Green (power)	Power is supplied to the scanner table.
Yellow (x-ray)	X-ray tube assembly is supplying x-rays.
Yellow (shutter)	Shutter is open.
Amber (laser)	Laser is on.

Emergency stop button

Push the red emergency stop button to stop the scanner arm and immediately shut down x-rays in an emergency. Do not use the emergency stop button to routinely stop the scanner during normal operation.

Positioning switches

The positioning switches move the scanner arm and detector to the measurement start position (the laser light indicates the position of the detector). The Back/Front switch moves the detector across the width of the scanner table. The Left/Right switch moves the scanner arm down the length of the scanner table.

Swing arm position sensing switches (DPX Duo, DPX Bravo)

The swing arm position sensing switches detect the locking status of the swing arm and the swing arm latch. The swing arm latch must be locked and the swing arm must be in the locked position over the scan table before a measurement can be performed. Release of the swing arm latch during a measurement will abort the scan and the measurement data will be lost.

iDXA Start Scan button

The start scan button initiates the patient measurement. The start scan button is located on the display panel near the positioning switches.

System Safety

Obey these safety guidelines at all times:

- Read the manual before you operate the scanner.
- The technologist operating the scanner must remain in the room with the patient during the measurement.
- Do not attempt to service the scanner. Please call GE MEDICAL SYSTEMS Lunar Support or your GE MEDICAL SYSTEMS Lunar Distributor.
- When the scanner is not in use, make sure the Shutter Open, X-ray, and Laser lights are off.
- Do not put excessive pressure on the scanner arm.
- Use the scanner table for patient measurements and examinations (DPX Duo) only: do not sit, stand or lie on the table for other purposes.
- Do not let liquids touch the computer or scanner table mechanics and electronics.

Operator Safety

Personnel monitors

Personnel monitors are not necessary to operate the scanner.

It is not likely that you can receive more than 25% of the maximum permissible x-ray dose from the scanner. However, some facilities choose to use personnel monitors. Refer to your city, county or state Health Department or Radiation Safety Officer for your facility's policy.

Film badges and thermal luminescent dosimeter (TLD) badges are obtained from a supplier accredited by the National Voluntary Laboratory Accreditation Program for personnel dosimetry processing.

The following is a sample situation for a clinic measuring an AP spine and Dual Femur on 5 subjects per day with an exposure rate of 0.18mR/hr at a distance of 2 meters estimated from the iDXA isodose curves.

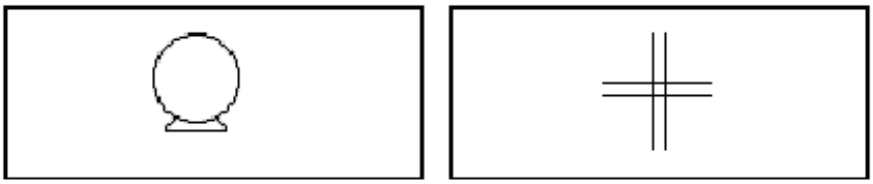
Sample Calculation for Estimated Exposure per Year from Scatter with iDXA Densitometer

Scan Type	Mode	Average Scans/Day	Scan Time/Day (sec/day)	Equivalent 2.5 mA Scan Time/day (sec/day)
AP Spine	Standard	5	260	260
Dual Femur	Standard	5	535	535
2.5 mA Scan Time per Day (sec)				795
2.5 mA Scan Time per Day (hours)				0.221
2.5 mA Scan Time per Week (hours)				1.11
2.5 mA Scan Time per Year (hours)				57.5
2.5 mA Exposure from Isodose Plots (mR/hr)				0.18
Total Exposure for 1 Year (mR)				10.3
Total Absorbed Dose for 1 Year (mRad) 0.92 Rad/R				9.5

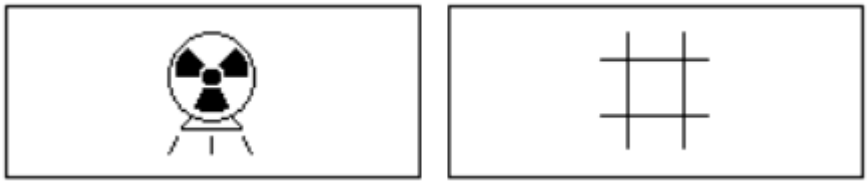
X-ray and shutter graphics

During a measurement or Quality Assurance procedure, x-ray and shutter graphics are shown on the computer monitor. The graphics are green to indicate x-rays are off and the shutter is closed, and yellow to indicate x-rays are on and the shutter is open.

*X-rays off and shutter closed (**green**):*



*X-rays on and shutter open (**yellow**):*



X-ray shutter

When power to the scanner is interrupted during a measurement or Quality Assurance procedure, the shutter closes and the x-ray tube stops generating x-radiation.

X-ray power supply

The x-ray tube assembly uses high voltage to generate x-rays. **DO NOT** touch internal components. **DO NOT** attempt to service internal components.

Patient Safety

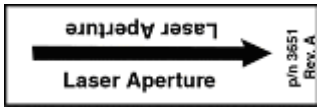
Pinch points

The Warning label identifies the location of possible pinch points.

When the scanner arm is in motion, make sure possible pinch point areas are clear at all times. Patient limbs must remain inside the boundaries of the table top. A pinch point is possible between the scanner arm and table.

Laser Safety

DO NOT STARE INTO THE LASER BEAM during patient positioning and Quality Assurance procedures. The label that follows is located on the scanner arm and shows the location of the laser aperture.



Radiation Safety

X-ray exposure: The system makes radiation when electric voltage is supplied to, and current flows through, the x-ray tube. During a measurement, the shutter opens to let a beam of radiation pass through the scanner table and patient. The nominal radiation field at the iDXA scanner table top is 18.4 mm x 3.3 mm, at the Prodigy table top is 19.5 mm x 3.4 mm and at the DPX series table top it is 2 mm. Lead oxide shielding surrounds the x-ray tube insert inside the tube housing assembly and reduces radiation levels around the scanner table.

Skin entrance dose: A Victoreen model 530 Precision Electrometer/ Dosemeter with a Model 660-5 Ion Chamber was used to measure the X-ray entrance dose. Refer to the "Current and Typical Dose Tables" for irradiation times and skin entrance doses.

Measurement modes

Patient thickness determines the appropriate measurement mode. The program selects the appropriate mode based on the patient's height and weight.

Lunar enCORE Systems

	iDXA, PRODIGY, PRODIGY Advance	DPX Series
Mode	**Patient thickness**	**Patient thickness**
Thick	>25 cm	>25 cm
Standard	13-25 cm	15-25 cm
Thin	<13 cm	<15 cm

Current and typical dose information for Lunar iDXA modes

Site	Mode[A]	Current (mA) [B]	Typical Measurement Area L x W cm x cm [C,D]	Irradiation times (sec)[C,D,E]	Estimated Skin Entrance Dose (µGy)[F,G]
AP Spine	Thick	2.500	19.0 x 18.0	109	329
AP Spine	Standard	2.500	19.0 x 18.0	52	146
AP Spine	Thin	0.625	19.0 x 18.0	52	37
AP Spine	QuickView	2.500	19.0 x 18.0	23	47
Femur	Thick	2.500	20.5 x 17.0	112	329
Femur	Standard	2.500	20.5 x 17.0	54	146
Femur	Thin	0.625	20.5 x 17.0	54	37
Femur	QuickView	2.500	20.5 x 17.0	24	47
DualFemur	Thick	2.500	2 x 20.5 x 17.0	224	329
DualFemur	Standard	2.500	2 x 20.5 x 17.0	107	146
DualFemur	Thin	0.625	2 x 20.5 x 17.0	107	37
DualFemur	QuickView	2.500	2 x 20.5 x 17.0	48	47
APVA[H]	Thick	2.500	42.7 x 18.0	117	146
APVA[H]	Standard	2.500	42.7 x 18.0	117	146
APVA[H]	Thin	0.625	42.7 x 18.0	117	37

Forearm	Standard	0.188	14.2 x 10.0	24	10
Hand	Standard	0.188	25.3 x 18.0	69	10
Total Body	Thick	0.188	196.8 x 66	796	6
Total Body	Standard	0.188	196.8 x 66	436	3
Total Body	Thin	0.188	196.8 x 66	436	3
LVA[H]	Standard	2.500	42.7 x 20.0	271	329
LVA[H]	Thin	0.625	60.0 x 20.0	381	82
Lateral Spine	Standard	2.500	19.0 x 18.0	104	329
Orthopedic Femur	Thick	2.500	23.7 x 15.0	109	329
Orthopedic Femur	Standard	2.500	23.7 x 15.0	53	146
Orthopedic Femur	Thin	0.625	23.7 x 15.0	53	37
Small Animal	Standard	0.188	75.8 x 25.0	264	10

[A] All modes are 100kV, ±1kV.
[B] Tube current is ±1% at the maximum current.
[C] Imaging time measured from shutter open to shutter close, 90% to 100% of indicated value.
[D] Sizes of measurement areas and irradiation times will be less than those listed above if you use the SmartScan feature.
[E] Measurement lengths and times are dependent on patient height and product version.
[F] Dose measurements are constrained by Daily QA limits.
[G] Irradiation times and dose values do not consider a "sweep retry" feature which can double the dose for a single transverse sweep within an entire scan. If a retry occurs a slight increase in irradiation time and skin entrance dose would be expected. The retry feature reduces need to rescan entire patient.
[H] The activation of the spine geometry application permits a maximum scan length up to 69.5 cm.

Current and typical dose information for Lunar PRODIGY, PRODIGY Advance, PRODIGY Pro modes

Site	Mode[1]	Current (mA) [2]	Typical Measurement Area L x W cm x cm [4,5]	Irradiation times (sec)[3,4,5]	Estimated Skin Entrance Dose (µGy)[6,7]
AP Spine	Thick	3.000	15.1 x 12.1	56	83
AP Spine	Standard	3.000	15.1 x 12.1	28	37
AP Spine	Thin	0.750	15.1 x 12.1	28	9
AP Spine	QuickView	3.000	15.1 x 12.1	14	12
Femur	Precise	3.000	15.1 x 12.1	56	83
Femur	Thick	3.000	15.1 x 12.1	56	83
Femur	Standard	3.000	15.1 x 12.1	28	37
Femur	Thin	0.750	15.1 x 12.1	28	9
Femur	QuickView	3.000	15.1 x 12.1	14	12
DualFemur	Thick/Precise	3.000	2 x 15.1 x 12.1	112	83
DualFemur	Standard	3.000	2 x 15.1 x 12.1	55	37
DualFemur	Thin	0.750	2 x 15.1 x 12.1	55	9
DualFemur	QuickView	3.000	2 x 15.1 x 12.1	28	12

Forearm	Standard	0.150	13.4 x 10.0	21	2
Hand	Standard	0.150	23.5 x 18.0	61	2
Total Body	Thick	0.150	151.5 x 60	532	0.8
Total Body	Standard	0.150	151.5 x 60	295	0.4
Total Body	Thin	0.150	151.5 x 60	295	0.4
Lateral BMD	Standard	3.000	15.1 x 12	56	83
LVA	Standard	3.000	38.7 x 15.0	175	83
APVA	Thick	3.000	38.7 x 15	85	37
APVA	Standard	3.000	38.7 x 15	85	37
APVA	Thin	0.750	38.7 x 15	85	9
Orthopedic Femur	Thick	3.000	20.2 x 15	91	83
Orthopedic Femur	Standard	3.000	20.2 x 15	44	37
Orthopedic Femur	Thin	0.750	20.2 x 15	44	9
Small Animal	Standard	0.15	75.7 x 25.0	261	1.8

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Current and typical dose information for Lunar PRODIGY Primo modes

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Site	Mode[1]	Current (mA)[2]	Typical Meas-urement Area L x W cm x cm[4,5]	Irradiation times (sec)[3,4,5]	Estimated Skin Entrance Dose (µGy)[6,7]
AP Spine	Thick	1.500	15.1 x 12.1	96	74
AP Spine	Standard	1.500	15.1 x 12.1	56	42
AP Spine	Thin	0.375	15.1 x 12.1	56	10
Femur	Thick	1.500	15.1 x 12.1	96	74
Femur	Standard	1.500	15.1 x 12.1	56	42
Femur	Thin	0.375	15.1 x 12.1	56	10
DualFemur	Thick	1.500	2 x 15.1 x 12.1	193	74
DualFemur	Standard	1.500	2 x 15.1 x 12.1	112	42
DualFemur	Thin	0.375	2 x 15.1 x 12.1	112	10
Forearm	Standard	0.150	13.4 x 10.0	21	2
Total Body	Thick	0.150	151.5 x 60	532	0.8
Total Body	Standard	0.150	151.5 x 60	295	0.4
Total Body	Thin	0.150	151.5 x 60	295	0.4
Lateral BMD	Standard	3.000	15.1 x 12	56	83
LVA	Standard	3.000	38.7 x 15.0	175	83
APVA	Thick	3.000	38.7 x 15	85	37

APVA	Standard	3.000	38.7 x 15	85	37
APVA	Thin	0.750	38.7 x 15	85	9
Orthopedic Femur	Thick	3.000	20.2 x 15	91	83
Orthopedic Femur	Standard	3.000	20.2 x 15	44	37
Orthopedic Femur	Thin	0.750	20.2 x 15	44	9

Current and typical dose information for Lunar DPX-PRO/NT/Duo/Bravo modes

Site	Mode[1]	Current (mA) [2]	Typical Measurement Area L x W cm x cm [4,5]	Irradiation times (sec)[3,4,5]	Estimated Skin Entrance Dose (µGy)[6,7]
AP Spine	Thick	1.500	15.1 x 12.1	215	41
AP Spine	Standard	1.500	15.1 x 12.1	108	20
AP Spine	Thin	0.375	15.1 x 12.1	215	5
AP Spine	QuickView	Not Available			
Femur	Precise	1.500	14.0 x 12.0	221	41
Femur	Thick	1.500	14.0 x 12.0	221	41
Femur	Standard	1.500	14.0 x 12.0	132	20
Femur	Thin	0.375	14.0 x 12.0	221	5
Femur	QuickView	Not Available			
DualFemur	Thick/Precise	1.500	2 x 14.0 x 12.0	443	41
DualFemur	Standard	1.500	2 x 14.0 x 12.0	264	20
DualFemur	Thin	0.375	2 x 14.0 x 12.0	443	5
DualFemur	QuickView	Not Available			
Forearm	Standard	0.050	11.5 x 10.0	286	3
Hand	Standard	Not Available			
Total Body	Thick	0.100	151.5 x 60	1337	0.3
Total Body	Standard	0.100	151.5 x 60	670	0.2
Total Body	Thin	0.100	151.5 x 60	900	0.2
Lateral BMD	Standard	1.500	12.0 x 12.0	189	41
LVA	Standard	Not Available			
APVA	Thick	Not Available			
APVA	Standard	Not Available			

APVA	Thin	Not Avail-able			
Orthopedic Femur	Thick	1.500	20.1 x 15.0	385	41
Orthopedic Femur	Standard	1.500	20.1 x 15.0	223	20
Orthopedic Femur	Thin	0.375	20.1 x 15.0	385	5
Small Animal	Standard	Not Avail-able			

Current and typical dose information for DPX-MD+ modes. Note, Standard mode is replaced with Standard-MD mode.

Site	Mode[1]	Current (mA)[2]	Typical Measurement Area L x W cm x cm[4,5]	Irradiation times (sec)[3,4,5]	Estimated Skin Entrance Dose[6] (µGy)
AP Spine	Standard-MD	0.750	15.0 x 12.0	212	20
Femur	Standard-MD	0.750	15.0 x 12.0	236	20
Orthopedic Femur	Standard-MD	0.750	15.0 x 12.0	336	20

[1] All modes are 76kV, ±1kV.
[2] Tube current is ±1% at the maximum current.
[3] Imaging time measured from shutter open to shutter close, 90% to 100% of indicated value.
[4] Sizes of measurement areas and irradiation times will be less than those listed above if you use the SmartScan feature.
[5] Measurement lengths and times are dependent on patient height and product version.
[6] Dose measurements are constrained by Daily QA limits. For example, the maximum spine (standard mode) range is 30 to 85µGy for Prodigy densitometers and 8 to 28µGy for DPX series densitometers.
[7] Irradiation times and dose values do not consider a "sweep retry" feature which can double the dose for a single transverse sweep within an entire scan. If a retry occurs a slight increase in irradiation time and skin entrance dose would be expected. On Lunar Prodigy scanners DF+12000 and above, all Prodigy Advance, and DPX+NT scanners running version 8 software and newer, a sweep may be retried one time during acquisition. A maximum of two sweeps can be retried per scan. The retry feature reduces need to rescan entire patient.

Mechanical Safety

The scanner arm moves down the entire length of the scanner table. Make sure the patient does not interfere with the movement of the scanner arm to prevent possible injury. In addition, make sure that there are no objects behind the scanner table that might obstruct movement of the scanner arm.

Weight applied to the Lunar iDXA must not exceed 204kg (450 pounds). Weight applied to the Lunar DPX-Pro/NT/MD+ scan table bed must not exceed 136kg (300 pounds). Weight applied to the Lunar PRODIGY, PRODIGY Advance, PRODIGY Primo, DPX-Duo/Bravo scan table bed or footstep (DPX Duo) must not exceed 159kg (350 pounds).

External Symbols

Attention: shows the Operator's Manual contains important safety information such as the location of pinch points.

Emergency Stop Button: shows the location of the emergency stop button.

Laser On: shows the location of the Laser On indicator.

Shutter Open: shows the location of the Shutter Open indicator.

X-ray On: shows the location of the X-ray On indicator.

Type B Equipment: shows that the scanner has Type B protection against electrical shock.

Power On: shows the location of the Power On indicator and the switch position for Power On.

Power Off: shows the switch position for Power Off.

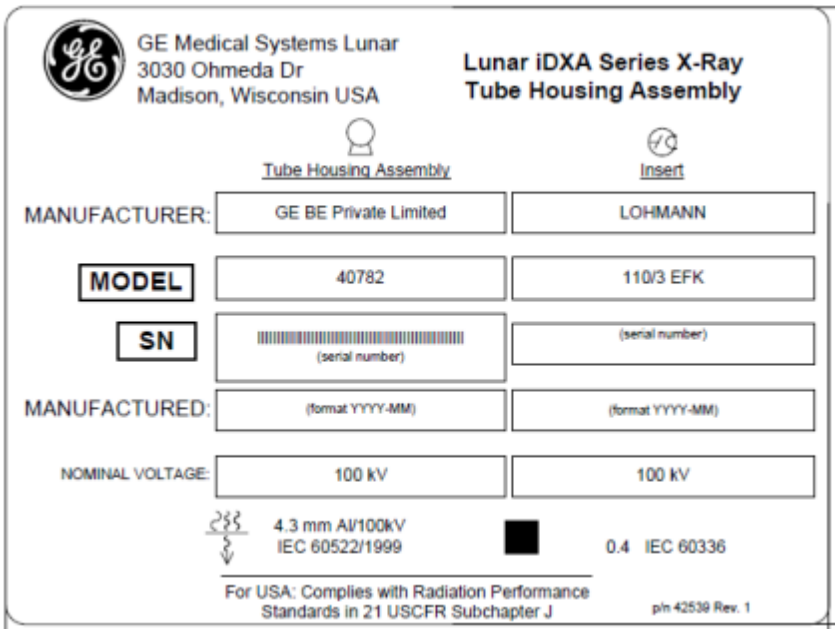
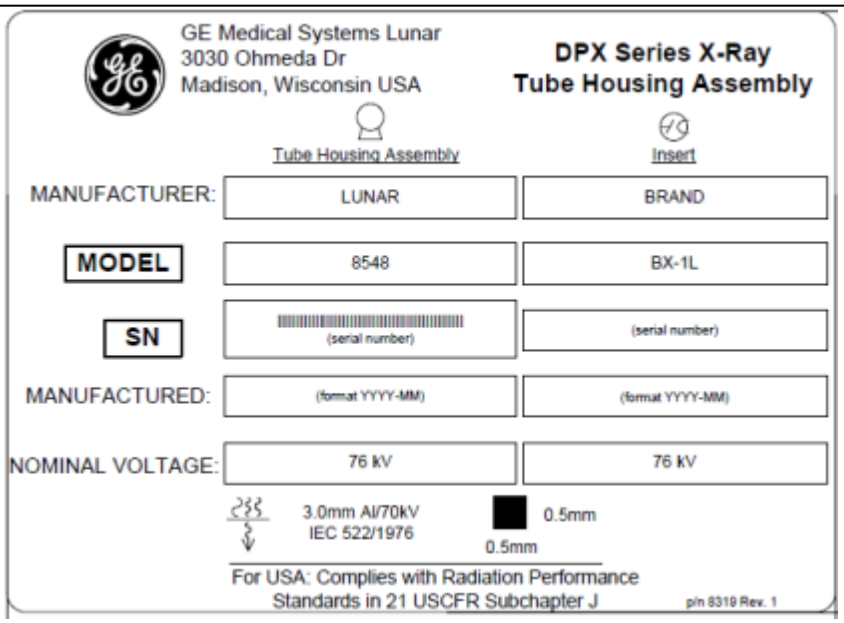
Internal Symbols

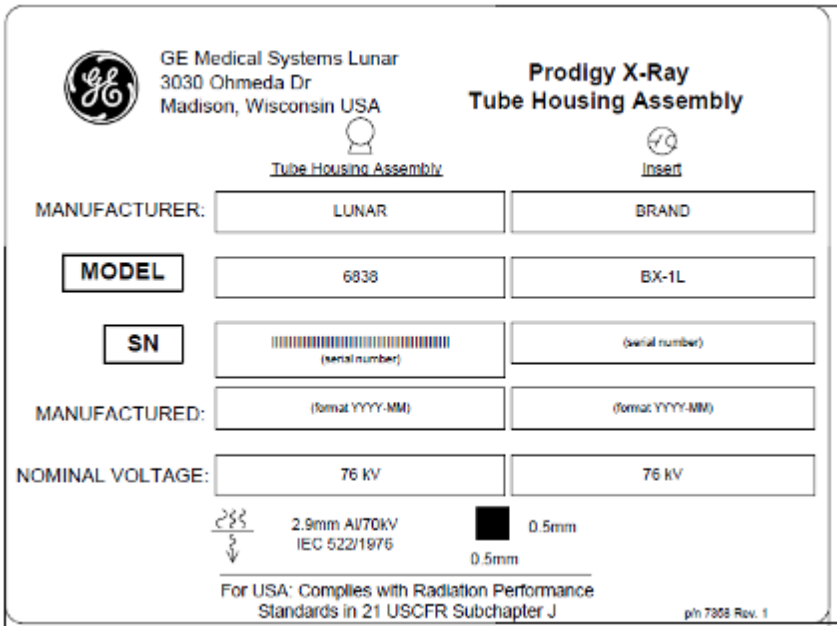
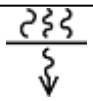
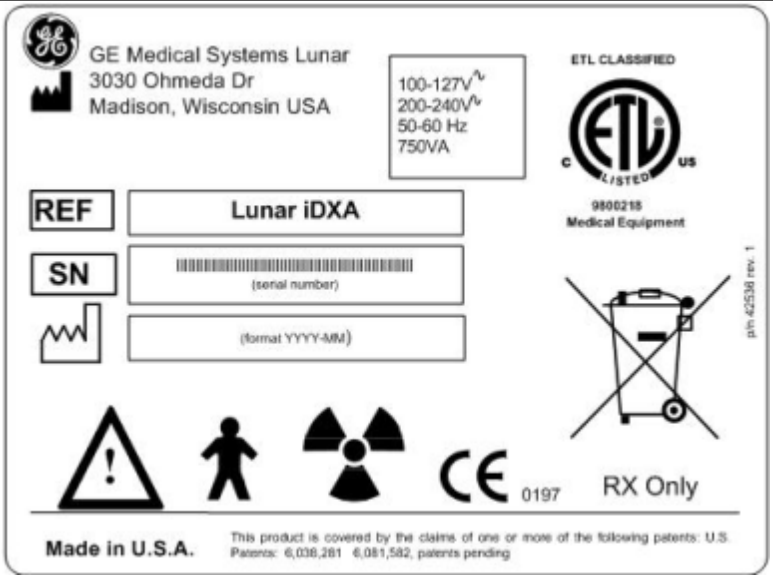
Protective Earth: shows the location of a Protective Earth terminal.

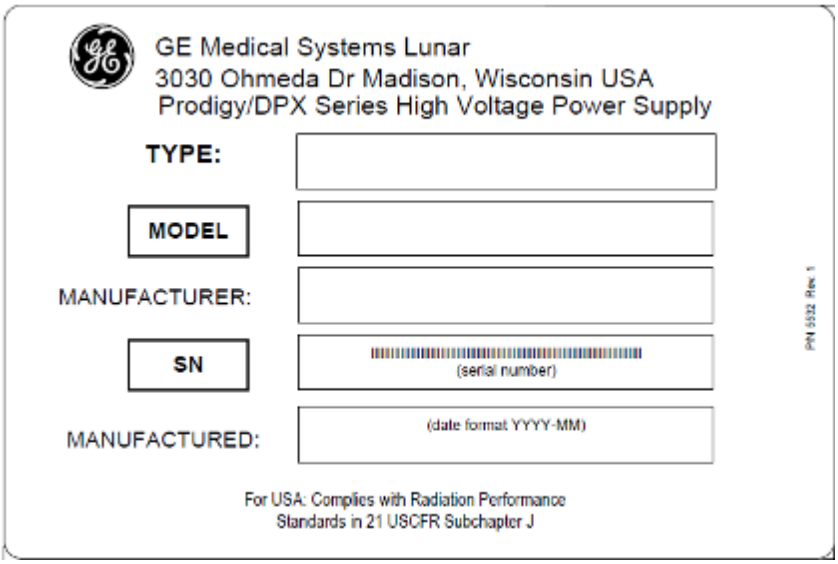
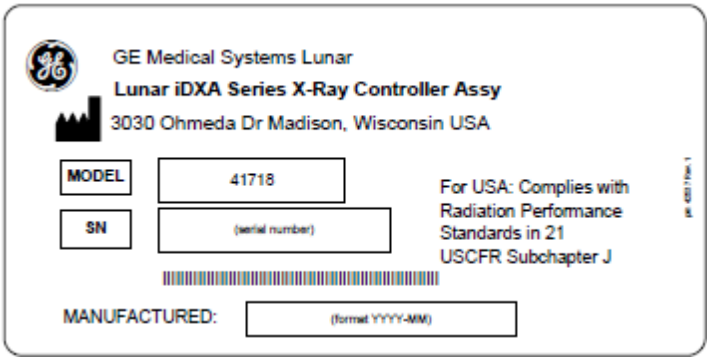
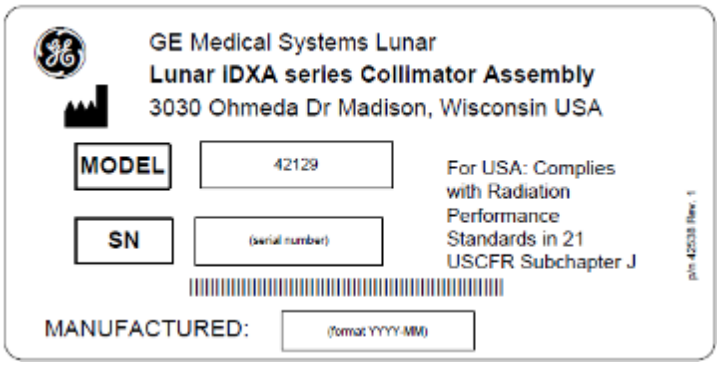
Functional Earth: shows the location of a Functional Earth terminal.

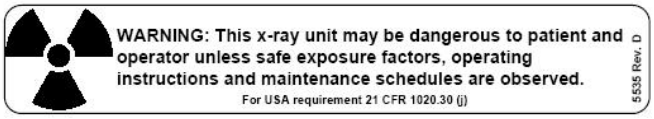
Labels

	**Laser Caution and Ionizing Radiation Label**: Shows that the scanner uses a Class II laser. The label includes the required symbols and precaution (Laser Radiation: Do not stare into beam. Class II Laser Product).

	**Tube Head Assembly "Lunar iDXA" Label:** This label gives tube head assembly and x-ray source char-acteristics information. It is located on the tube head assembly and the foot panel of the scanner. The label appearance may vary from the one displayed here. The Lunar iDXA series label covers appro-priate Tube Head Assembly for Lunar iDXA scanners.
	**Tube Head Assembly "DPX Series" Label:** This label gives tube head assembly and x-ray source characteristics information. It is located on the tube head assembly and the foot panel of the scanner. Tube Head Assembly label covers DPX-NT, DPX-MD+, DPX Bravo, and DPX Duo.

	**Tube Head Assembly "Prodigy Series" Label:** This label gives tube head assembly and x-ray source characteristics information. It is located on the tube head assembly and the foot panel of the scanner. The label appearance may vary from the one displayed here. The Prodigy series label covers appropriate Tube Head Assembly for Prodigy and Prodigy Advance scanners.
	**Inherent Filtration:** Symbol from EN60417-1, 5381
	**Tube Insert:** Symbol from EN60417-1, 5337
	**X-ray Source:** Symbol from EN60417-1, 5338
	**Focal Point:** Symbol from EN60417-1, 5327
	**System Label:** This label gives system input power requirements and compliance information. It is located on the foot panel of scanners. The Attention symbol indicates need to read accompanying documents. Person symbol refers to Type B applied part for degree of electric shock protection per EN60601-1. The Fan symbol denotes ionizing radiation is generated. The CE mark shows compliance with the Medical Device Directive 93/42/EEC. The ETL mark shows compliance to UL 60601-1 and CAN/CSA C22.2 No. 601 The Waste Receptacle mark indicates that the waste of electrical and electronic equipment must not be disposed as

	unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
	**High Voltage Power Supply:** This label gives high voltage power supply (x-ray generator) information. It is located on the high voltage power supply and foot panel of the scanner. Prodigy/DPX series High Voltage Power Supply label covers all the latest Lunar products since they use the same HVPS part number.
	**X-ray Controller:** This label shows x-ray controller compliance. It is located near the x-ray controller and on the foot panel of the scanner. The Lunar iDXA X-ray Controller Assembly label covers all the Lunar iDXA products. Prodigy/DPX series X-ray Controller Assembly label covers all the latest Lunar products. Labels show model/serial number for that specific product.
	**Collimator Assembly**: This label gives collimator assembly information. It is located on the collimator and foot panel of the scanner. The Lunar iDXA Collimator Assembly label covers all Lunar iDXA products. Prodigy/DPX series Collimator Assembly label covers latest Lunar products. Labels show model/se-

	rial number for that specific product.
	**Warning Label and Radiation Symbol:** The Warning label shows that the system uses ionizing radiation. It is found only on systems delivered in the United States. Always obey instructions for safe operation.
	**Grounding Reliability Label:** This label states that grounding reliability can only be maintained when using a "Hospital Grade" or "Hospital Only" receptacle. It is found on all power cords of systems delivered in the United States.

Emergency Stop Button and Failsafe Circuit

If the hardware malfunctions, the scanner has two safety features for operator and patient safety: an Emergency Stop button and a Failsafe Circuit.

	**CAUTION:**	Be prepared to abort the scan in the unlikely event arm motion stops with the x-rays on.

Emergency stop button

The emergency stop button is the round, red button located on the scanner display panel.

NOTE: When the Emergency Stop Button is pushed, data is not saved to the database. You must measure the patient again.

1. Push the Emergency Stop button to stop a measurement in an emergency. Power to the scanner table motors, x-ray tube head, shutter, and laser is turned off.

   NOTE: Do not use the emergency stop button to routinely stop the scanner during normal operation.

2. Select **OK** in the message window on the computer screen.

   NOTE: If there is a hardware problem, **DO NOT** try to measure a patient. Call GE Medical Systems Lunar Support or your GE Medical Systems Lunar distributor.

Failsafe circuit

During a diagnostic failure, the Failsafe Circuit stops power to the scanner motors and closes the x-ray shutter. A message is shown on the computer that describes the failure. Call GE Medical Systems Lunar Support or your GE Medical Systems Lunar distributor and provide the failure description.

Registration

Government health departments can require medical facilities to register diagnostic x-ray equipment. Many municipal and state health agencies require medical health facilities to employ certified radiologic technologists to operate diagnostic x-ray devices. Contact your local regulatory authorities or GE representative for registration guidelines and regulation compliance.

Facilities

Install a **"Caution X-Radiation"** sign in the area or room where the system is operated. Because of low leakage levels of radiation from the x-ray tube assembly, additional shielding in the walls, floor, or ceiling is not necessary. However, call your state or local health and radiation safety departments for shielding requirements.

Electrical Safety

	**WARNING:**	Insulate patient from any metal associated with the DPX Duo by using a nonconductive material during cauterization or similar treatments to avoid shock or burns. Do not plug additional outlet strips or extension cords into power connected to scanner.

IEC and UL/CSA certification

To maintain electrical safety, all computer equipment and accessories connected to the scanner must meet all requirements for safety. U.S.A. and Canada require UL/CSA and FCC certification. European countries require CE mark certification. Other countries should follow their local requirements for computer equipment and accessories certification. Declarations of conformity to the required standards should meet or exceed the requirements of EN 60950, "Safety of Information Technology Equipment" and EN 55024 "Information Technology Equipment - Immunity Characteristics".

Electromagnetic interference

Although the scanner meets safety standards regarding electromagnetic interference (EN60601-1-2), you may still experience a loss of performance under extreme electromagnetic conditions. Maximize the distance between the scanner and other equipment. Use a dedicated power line to avoid interference to and from the scanner.

Electromagnetic Compatibility (EMC) Performance

All types of electronic equipment may characteristically cause electromagnetic interference with other equipment, either transmitted through air or connecting cables. The term EMC (Electromagnetic Compatibility) indicates the capability of equipment to curb electromagnetic influence from other equipment and at the same time not affect other equipment with similar electromagnetic radiation from itself. Proper installation following the service manual is required in order to achieve the full EMC performance of the product. In case of issues related to EMC, please call your service personnel.

Declarations of Immunity and Emissions - iDXA, Prodigy Series, DPX Series

Immunity Type	Standard	Test	Input Voltage	Frequency	Test Compliance
EMS	IEC 61000-4-2	ESD	230 VAC	50 Hz	+/- 6kV Contact, +/- 8kV Air Direct/Indirect-Contact +/- 2,4,6kV Direct-Air +/-2,4,8kV
EMS	IEC 61000-4-3	Radiated RF	230 VAC	50 Hz	3 V/ m 80 MHz to 2.5 GHz
EMS	IEC 61000-4-4	EFT	230 VAC	50 Hz	+/- 2kV PS Line, +/- 1kV I/O lines
EMS	IEC 61000-4-4	EFT	100 VAC	60 Hz	+/- 2kV PS Line, +/- 1kV I/O lines
EMS	IEC 61000-4-5	Surge	230 VAC	50 Hz	+/- 1kV Diff.Mode +/- 2kV CommonMode
EMS	IEC 61000-4-5	Surge	100 VAC	60 Hz	+/- 1kV Diff.Mode +/- 2kV Common Mode
EMS	IEC 61000-4-6	Conducted RF	100 VAC	60 Hz	3 Vrms 150 KHz to 80MHz
EMS	IEC 61000-4-8	Power Frequency, Magnetic Field	230 VAC	60 Hz	3 A / m
EMS	IEC 61000-4-8	Power Frequency, Magnetic Field	230 VAC	50 Hz	3 A / m
EMS	IEC 61000-4-11	Voltage Dip, short interruptions and voltage variations	230 VAC	50 Hz	< 5% Ut for 0.5 cycle 40 % Ut for 5 cycles 70% Ut for 25 cycles <5 % Ut for 5 sec
EMS	IEC 61000-4-11	Voltage Dip, short interruptions and voltage variations	100 VAC	50 Hz	< 5% Ut for 0.5 cycle 40 % Ut for 5 cycles 70% Ut for 25 cycles <5 % Ut for 5 sec
EMI	IEC 61000-3-2	Harmonics	230 VAC	50Hz	Class A
EMI	IEC 61000-3-3	Flicker	230 VAC	50 Hz	Compliant
EMI	CISPR 11 / EN 55011 Group 1 Class B	Conducted Emission	230 VAC	50 Hz	0.15 - 0.5 MHz = 66(QP), 56 (Avg) 0.5 - 5 MHz = 56 (QP), 46 (Avg) 5 - 30 MHz = 60 (QP), 50 (Avg)
EMI	CISPR 11 / EN 55011 Group 1 Class B	Conducted Emission	100 VAC	60 Hz	0.15 - 0.5 MHz = 66(QP), 56 (Avg) 0.5 - 5 MHz = 56 (QP), 46 (Avg) 5 - 30 MHz = 60 (QP), 50 (Avg)
EMI	CISPR 11 / EN 55011 Group 1 Class B	Radiated Emission	230 VAC	50 Hz	30 - 230 MHz = 30(QP) 230 - 1000 MHz = 37 (QP)
EMI	CISPR 11 / EN 55011 Group 1 Class B	Radiated Emission	100 VAC	60 Hz	30 - 230 MHz = 30(QP) 230 - 1000 MHz = 37 (QP)

EMC Environment and Guidance

-Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

-A UPS (uninterruptable power supply) is required to pass 61000-4-11 test at the 100V level for iDXA.

-Mains power quality should be that of a typical commercial and/or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the system be powered through a UPS.

-Separation distance to radio communication equipment must be maintained according to the method in the following table.

-NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

-The Lunar densitometer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Recommended Separation Distance between portable and mobile RF communications equipment and the Lunar densitometer

The Lunar iDXA is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Lunar iDXA can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Lunar densitometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter in meters		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.8
1.0	1.2	1.2	2.4
10	3.7	3.7	7.4
100	11.7	11.7	23.3

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Peripheral configurations

WARNING:

The correct connection of the computer and all peripherals is necessary to maintain electrical safety. The signal cable of the scanner is intended only for connection to an approved computer. Call GE Medical Systems Lunar Support or your GE Medical Systems Lunar distributor before adding peripherals.
Operator shall not touch patient and computer or peripherals simultaneously.

Standard room configuration

The computer, peripherals, and all other equipment must be located more than 1.5 m or 1.83 m (U.S.A and Canada) from the scanner. Use an outlet strip to power the computer and all peripherals. The outlet strip must be mounted off the floor so that it does not touch other equipment. If your outlet strip was provided by GE Medical Systems Lunar, it has a maximum output of 15A, 120VAC. Only system-related equipment should be powered by the outlet strip.

A modem and/or network connection can be made at any time if you are using the standard room configuration.

Small room configuration

You must power the computer, peripherals, and all other equipment with an isolating transformer if the room is too small to maintain at least 1.5 m or 1.83 m (U.S.A and Canada) of separation between the scanner and all other equipment.

The isolation transformer supplied by GE Medical Systems Lunar has a maximum output of 400/500VA. Only system-related equipment should be powered by the isolation transformer. Failure to use an isolation transformer can cause leakage currents in excess of 100 microamperes.

A modem and/or network connection can only be made in the small room configuration if all exposed metal surfaces of the computer and peripherals are out of the patient environment.

Lunar PRODIGY system no. DF+11999 and lower

Scanner power output configuration: GE Medical Systems Lunar recommends that you use scanner power output to provide isolated power to the computer and all peripherals. The power strip must be mounted off the floor such that it does not touch other equipment. The computer and ALL peripherals must be powered by the scanner. All other equipment must not be powered by the scanner and must be located more than 1.5 m or 1.83 m (U.S.A and Canada) from the scanner. Failure to use scanner power output can cause leakage currents in excess of 100 microamperes.

If a network and/or modem connection is needed, refer to the wall outlet configuration.

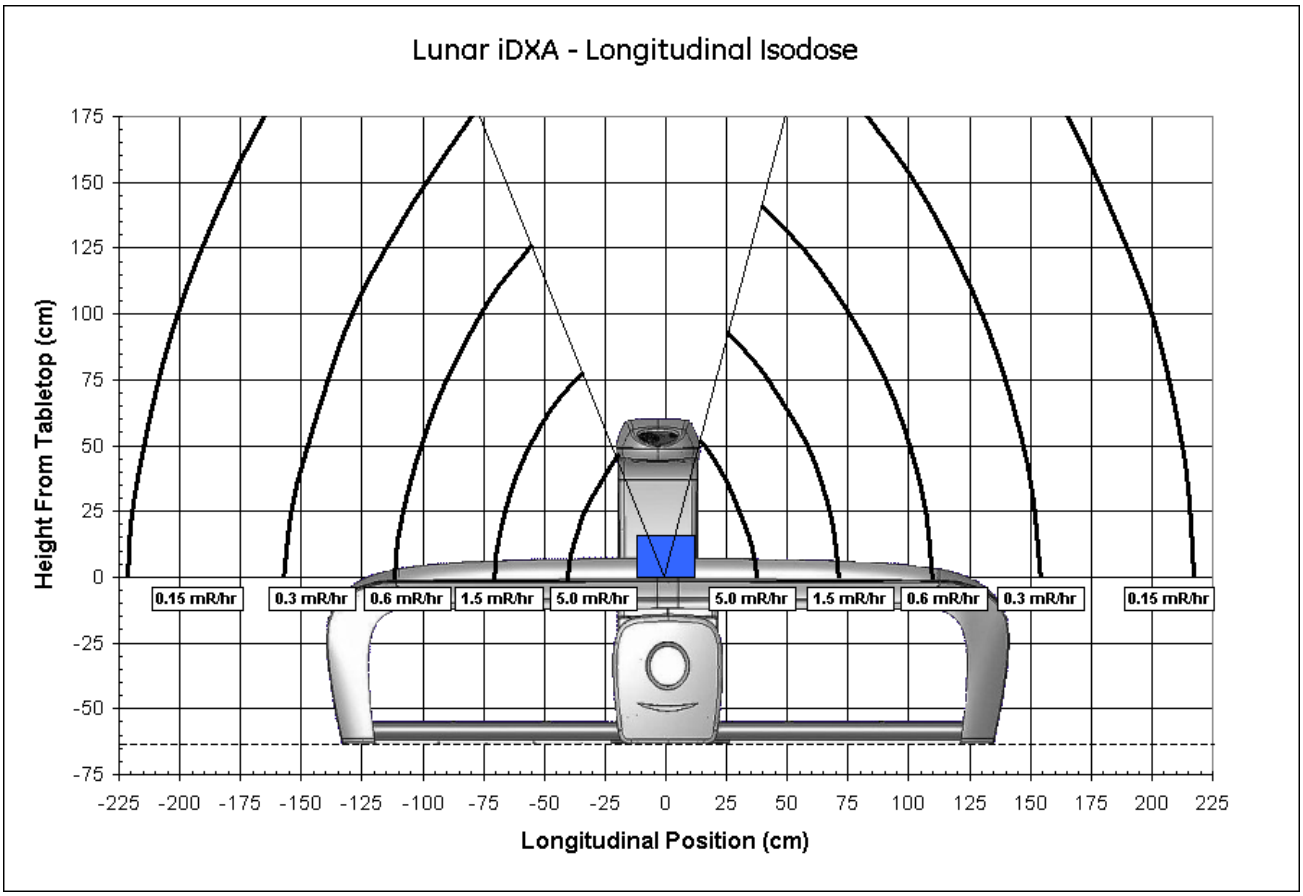
Wall outlet configuration: As an option to scanner power output, a wall outlet can be used to power the computer and peripherals. Isolated power from the scanner must not be used to power any equipment if a wall outlet is used. All exposed metal surfaces of the computer, peripherals, and other equipment must be located more than 1.5 m or 1.83 m (U.S.A and Canada) from the scanner.

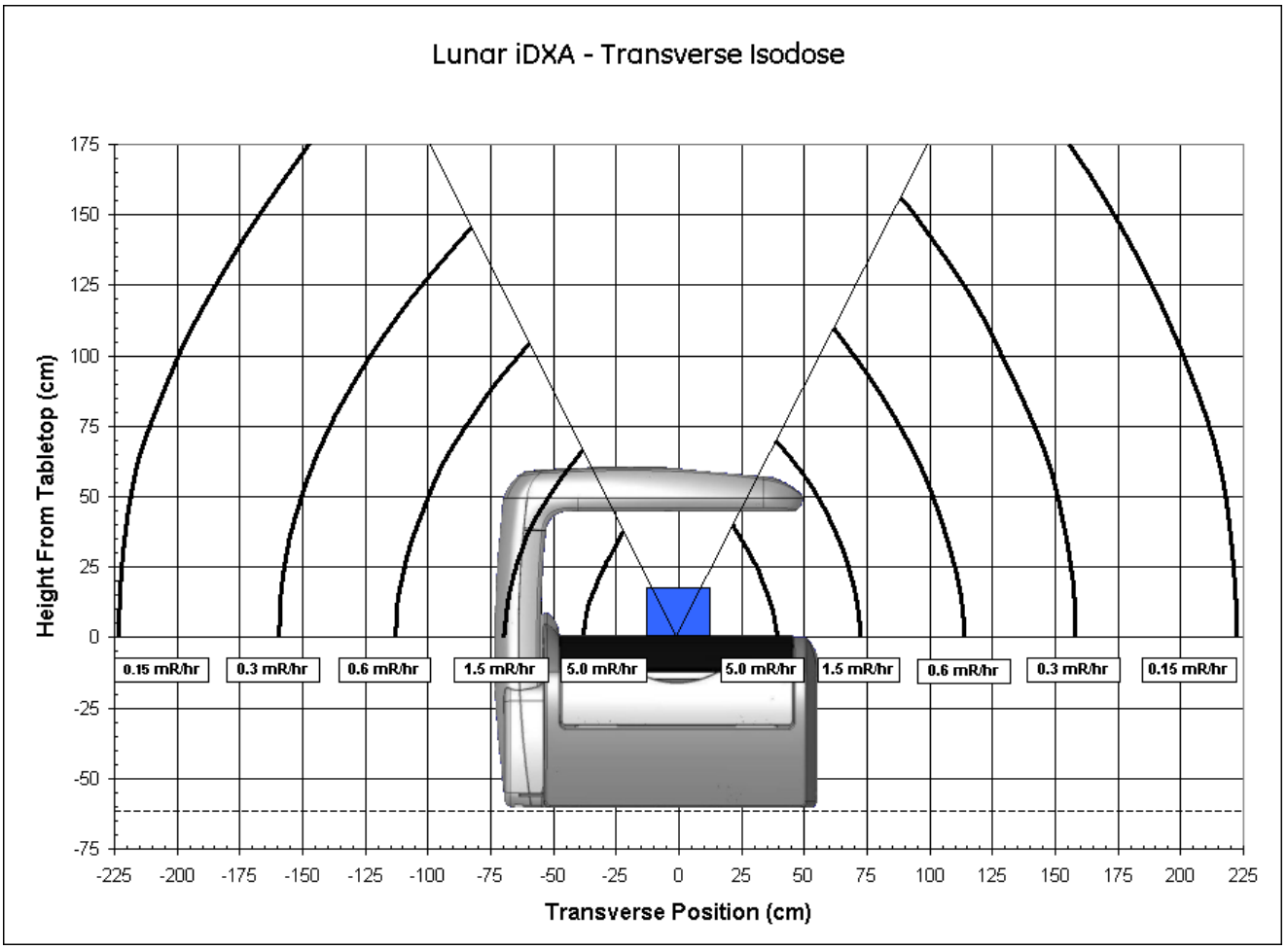
A network and/or modem connection can be made to the computer if power is supplied from a wall outlet as described above.

Scatter Radiation

The following display isodose diagrams of the Lunar iDXA full size scanner scatter radiation. The measurements conformed to the IEC 60601-1-3:1994 standard and were taken with a Victoreen 6000-532 400cc Ion Chamber Paddle Probe. The beam was attenuated according to Clause 29.208.6 section a) which specifies a water target with dimensions 25x25x15 cm with container walls equivalent to less than 1 cm of polymethyl-methacrylate (PMMA), otherwise known as Lucite. Each measurement consisted of a static exposure at the maximum X-ray tube current and voltage of 2.5mA and 100kV.

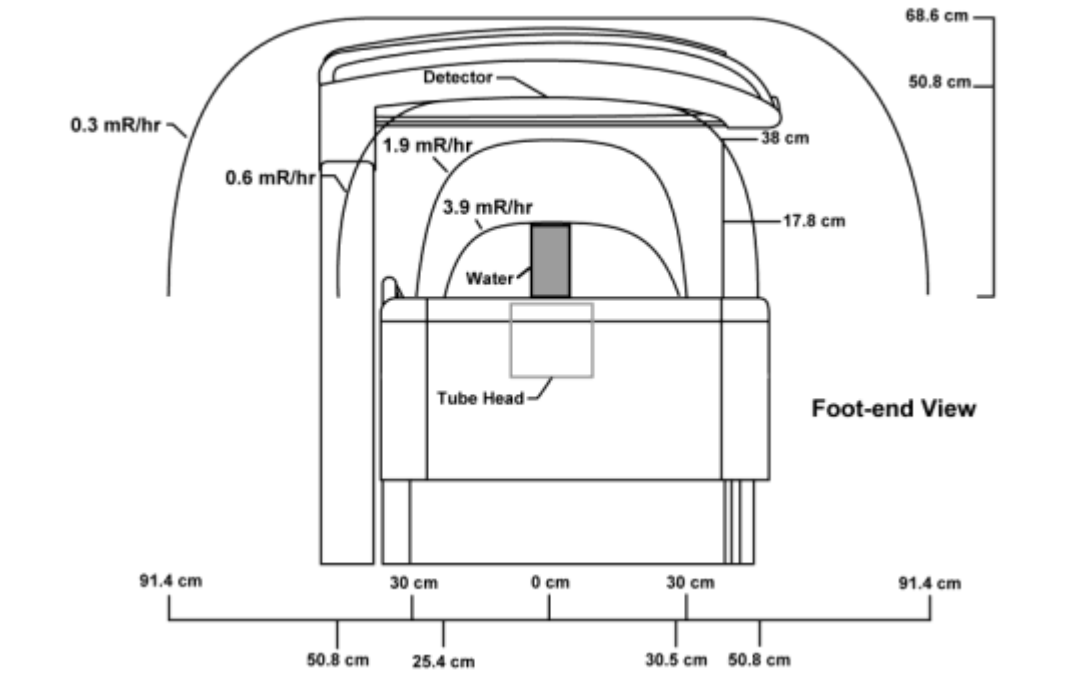
Isodose diagram - Lunar iDXA Full Size Table

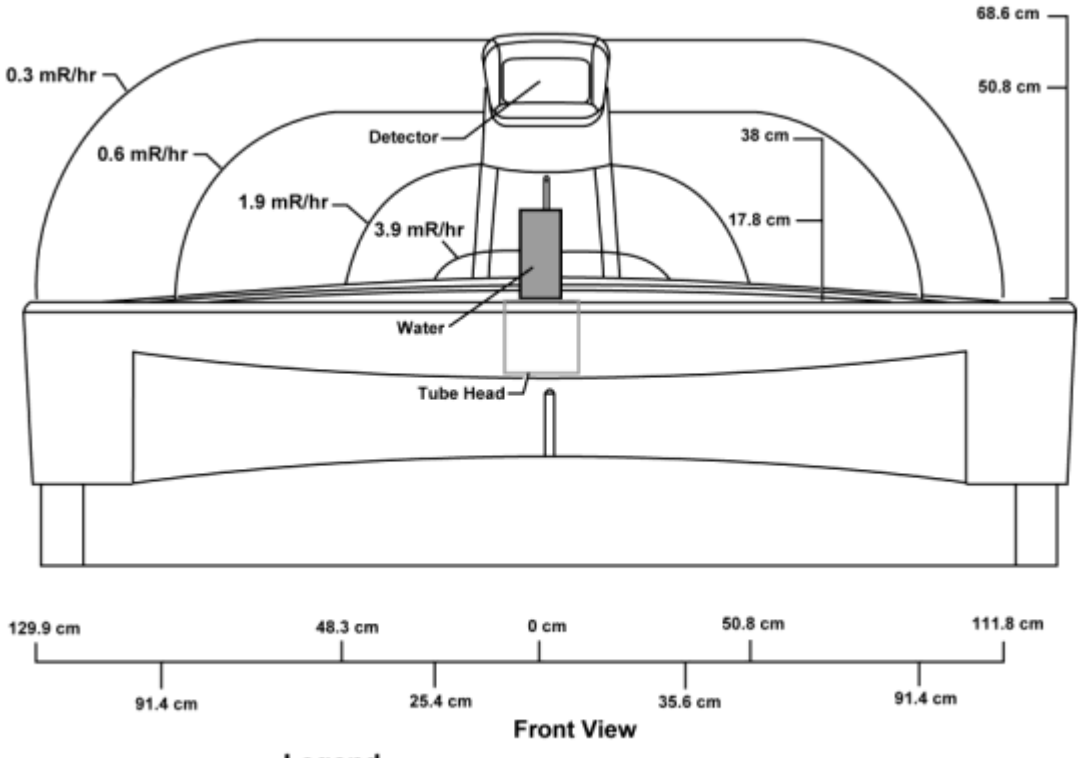




The following display isodose diagrams of the Lunar PRODIGY and PRODIGY Advance full size and compact scanner scatter radiation. The measurements were taken with a Victoreen 470A. The beam was attenuated through a 20.32 cm water phantom.

Isodose diagram - Lunar PRODIGY, PRODIGY Advance, PRODIGY Primo, PRODIGY Pro Full Size Table

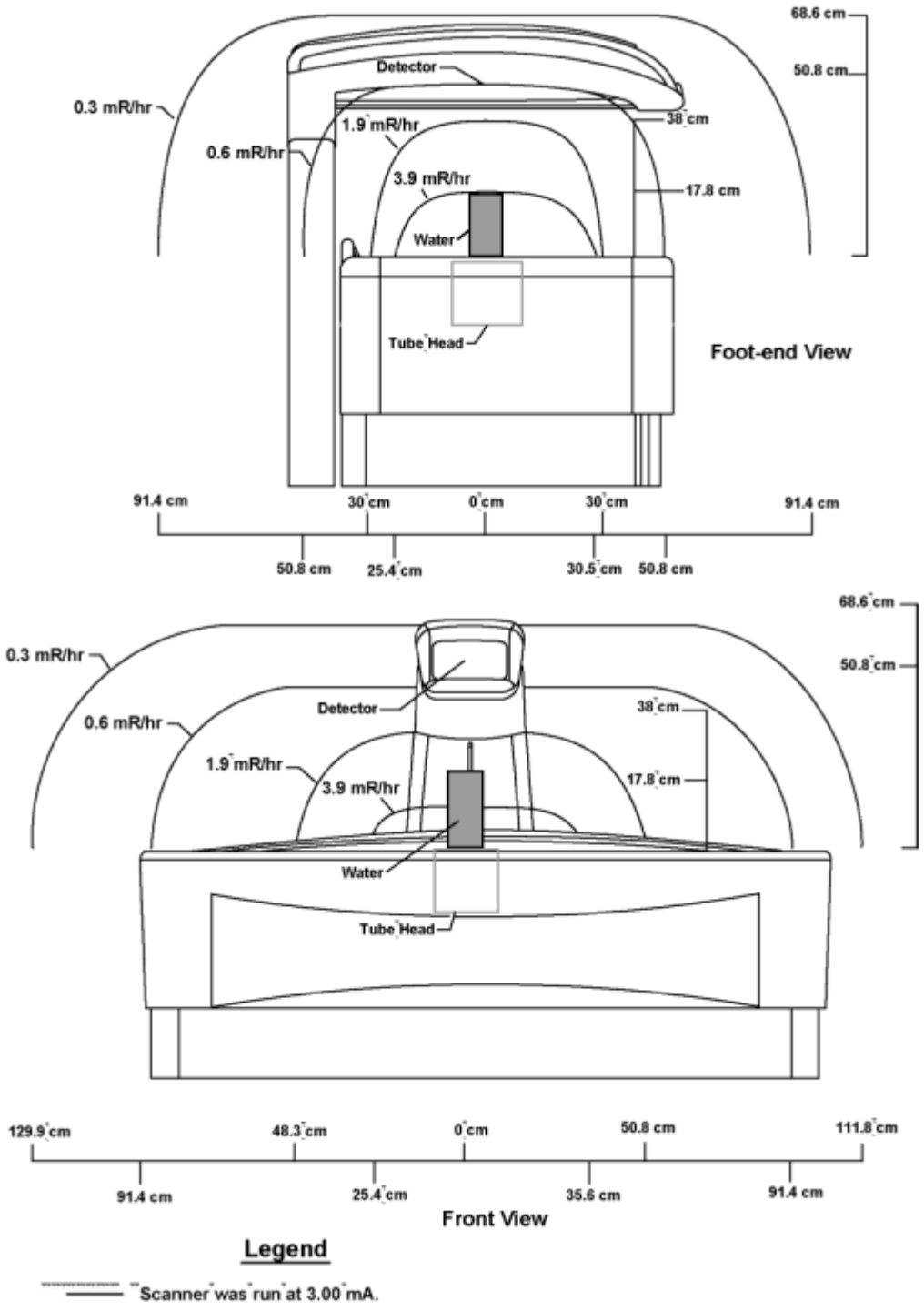




Legend

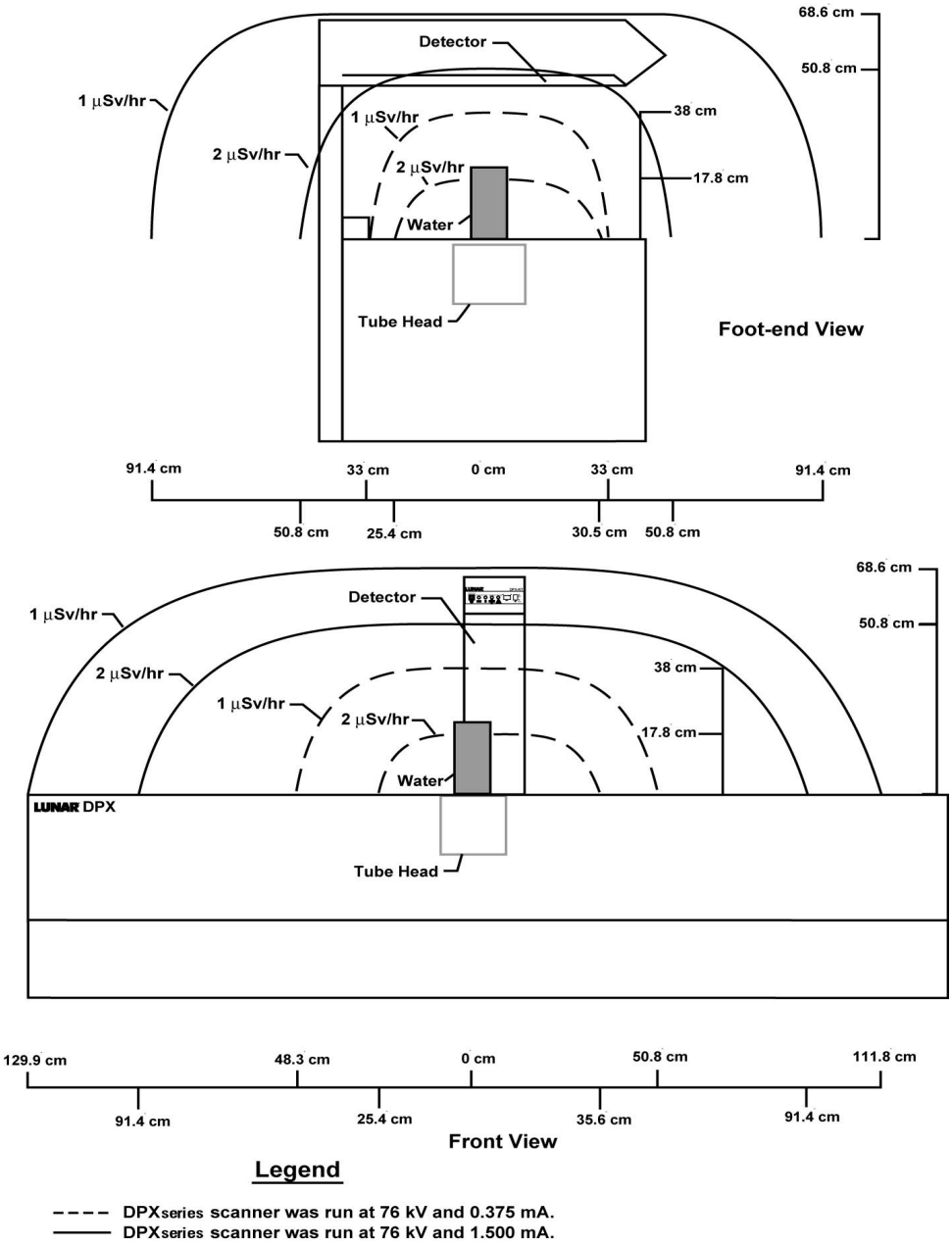
——— Scanner was run at 3.00 mA.

Isodose diagram - Lunar PRODIGY, PRODIGY Advance, PRODIGY Primo, PRODIGY Pro Compact Table

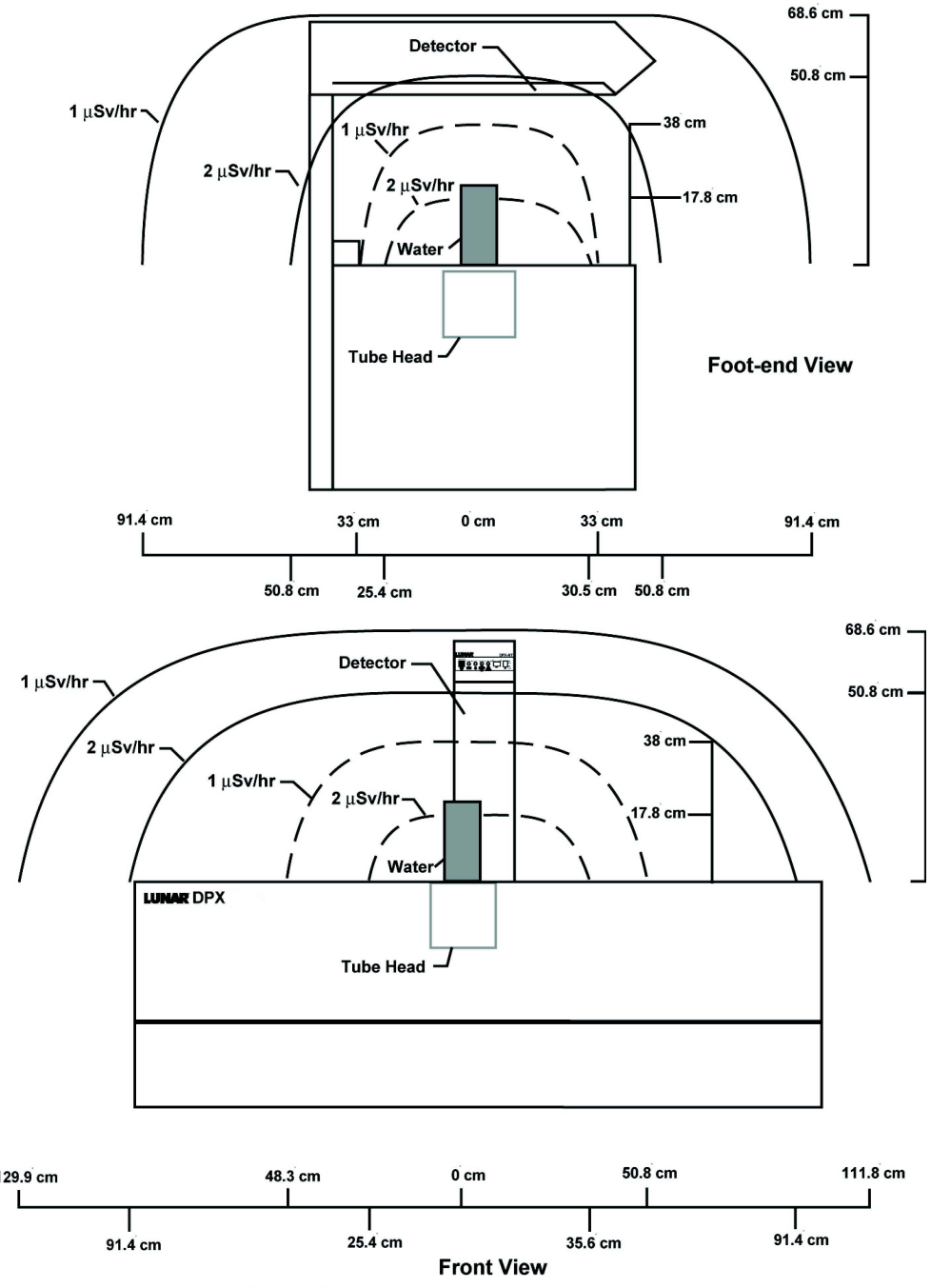


The following display isodose diagrams of scatter radiation for the full-size and compact Lunar DPX-NT/Pro and MD+ scanners, the DPX Duo and DPX Bravo scanners. The measurements were taken with a Victoreen 470A. The beam was attenuated through a 20.32 cm water phantom.

Isodose diagram - Lunar DPX-Pro/NT/MD+ Full Size Table



Isodose diagram - Lunar DPX-Pro/NT/MD+ Compact Size Table, DPX Duo and DPX Bravo



System Maintenance

Clean Scanner Table Environment

Vacuum and dust the system site weekly. Dust the surface of the system regularly and use nonabrasive cleaners to remove dirt. Do not let liquids inside the scanner table.

NOTE: DO NOT connect a vacuum cleaner to the same electrical outlet as the scanner.

	**WARNING:**	Proper cleaning and handling procedures must be followed to prevent the possibility of cross-infections between subjects scanned on the same system. Clean and disinfect the system according to your local and country specific hygienic regulations. Protect table pad and table top from wetness and prevent the ingress of liquid into the scanner by protectively covering the scanner with a waterproof material.
	**CAUTION:** (Small Animal Option)	Device software for investigational use on laboratory animal or for other tests that do not involve human subjects.

Unauthorized network access

Today, the delivery of healthcare to patients increasingly relies on modern information technology (IT) to electronically collect, process, distribute, display, and store patient data. Any computer connected to a network is vulnerable to network virus and/or other malicious attacks. Owners and operators of any medical device that is connected to a network are responsible for protecting their computers from these malicious attacks.

Virus protection software with enCORE

You can protect your computers by following standard computer practices used for all information technology. Virus checker programs are an appropriate measure to assure electronic media and files are virus free before being introduced to your computer or network. The latest operating system updates should also be installed. Contact your local GE representative for more information. However, contact your service representative before performing any operating system update to assure full compatibility. Active virus checker programs should be installed and active on the enCORE computer operating the bone densitometer. However, virus scanners have significant drawbacks including the following:

- Do not initiate an anti-virus scan when operating the bone densitometer. Certain files will be marked read-only.
- Anti-virus software may act inappropriately on false positives. Double check quarantine status before taking any permanent action. Medical image files can be damaged because the virus scanner attempts to fix what it falsely identified as a virus.
- enCORE software may not operate properly if the virus scanner consumes too much memory or system resources.

Archive Image Files

Each day, archive new image files from your computer hard drive to an archive disk. This procedure creates free space on your hard drive.

The program identifies archived files by labeling them with the drive location and the number of the archive disk: the program begins with number 1. For example: the third archive disk located in drive A is labeled "A:A3." Labels for archive disks are shown in the Label column of the Image file list on the Directory screen.

It is important that you label (write) the archive number on each archive disk. If it is necessary to restore archived files to the hard drive or rebuild your database, the program requires that you use the appropriate archive disk(s) according to its label.

1. Select **Directory** from the Main screen or the Common tool bar.

2. Complete one of the procedures that follow:

- **Archive all images for all patients-**1) select Archive from the Directory tool bar and 2) select "Archive all images for all patients" in the message box that is shown.
- **Archive all exams for all patients in the current search results-**1) select a search field from the dropdown menu, 2) enter search criteria in the field provided, 3) click the search button, 4) select Archive from the Directory tool bar, and 5) select "Archive all exams for all patients in the current search results" in the message box that is shown.
- **Archive all images for selected patient-**1) select a patient from the Patient List, 2) select Archive from the Directory tool bar, and 3) select "Archive all images for selected patient" in the message box that is shown.
- **Archive selected exam-**1) select a patient from the Patient List, 2) select the patient image file you want to archive, 3) select Archive from the Directory tool bar, and 4) select "Archive selected image" in the message box that is shown.

3. Select **OK**. The program archives the image files from the computer hard drive to the archive disk or external hard drive. The archive number for the file is located in the Label column of the Image list.
4. If an archive storage source needs to be initiated, the program prompts you to insert a labeled archive disk in the appropriate disk drive. Insert a new or labeled disk as indicated.

   NOTE: Refer to the enCORE Operator's Manual on changing the drive location used to archive files.

Test Emergency Stop Button

Test the emergency stop button once a month. Refer to the procedure that follows:

1. Start a standard total body measurement. Do not have a patient on the table.
2. Push the emergency stop button. Make sure the X-ray and Shutter lights are off and that a message on the computer monitor indicates the emergency stop button is activated.
3. Push the emergency stop button again to reset the system (Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo only).
4. Do not save the patient measurement.

   NOTE: If the emergency stop procedure does not work, call GE Medical Systems Lunar Support or your GE Medical Systems Lunar distributor.

Preventive Maintenance

X-ray tube and laser assemblies

There are **NO USER-SERVICEABLE COMPONENTS** inside the x-ray tube head and laser assemblies. **DO NOT** attempt on-site servicing. Call GE Medical Systems Lunar Support or your GE Medical Systems Lunar distributor immediately if the system malfunctions.

DO NOT attempt to maintain or repair the components and scanner table. Doing so voids all current warranty and service contracts.

Daily Quality Assurance procedure

Complete Quality Assurance procedures daily. Make sure each QA procedure passes. Refer to the enCORE Online Help for detailed instructions.

If your system does not pass a test, check the position of the calibration block and complete the Quality Assurance procedure again. If the procedure fails a second time, call GE Medical Systems Lunar Support or your GE Medical Systems Lunar distributor.

Annual maintenance

GE Medical Systems Lunar recommends that you schedule annual preventive maintenance from an authorized GE Medical Systems Lunar service engineer after your warranty period expires. Contact GE Medical Systems Lunar or your GE Medical Systems

Lunar distributor.

Dispose of Materials

The scanner contains lead (for x-ray shielding) and either sodium iodide or cadmium zinc telluride (used for x-ray detection).

	**WEEE Label:** This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

If you contract with GE Medical Systems Lunar for the disposal of your scanner, GE Medical Systems Lunar will properly dispose of these materials. If you choose to dispose of your scanner yourself, both substances must be disposed of in accordance with local regulations. Contact your local GE representative for more information.

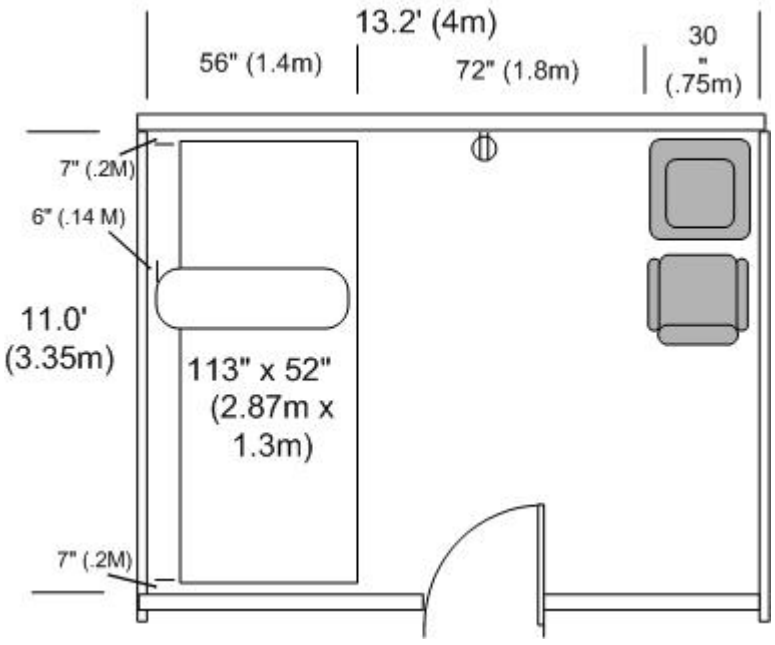
Space Requirements

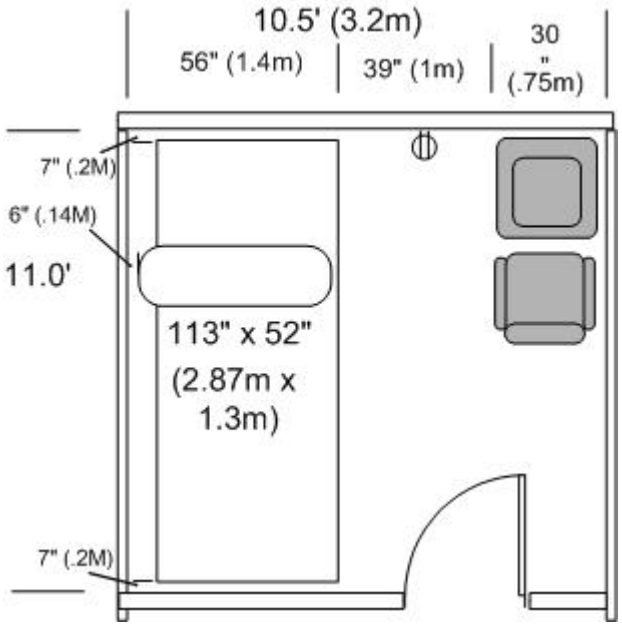
For safety reasons, the computer and all peripherals must be in the same room with the scanner.

Lunar iDXA Full size Table

Standard room configuration: The computer and peripherals must be located more than 1.5 m or 1.83 m (U.S.A and Canada) from the scanner. Recommended room dimensions are: 4.0 meters x 3.35 meters (13.2 feet x 11 feet)

Small room configuration: Room dimensions must be at least 3.2 m x 3.35 m if the computer and peripherals are powered by an isolation transformer. Equipment powered by an isolation transformer can be located anywhere in the room with the scanner. The isolation transformer and scanner must be plugged into the same dedicated line outlet.





Lunar PRODIGY, PRODIGY Primo, PRODIGY Advance, PRODIGY Pro, DPX-Pro, DPX-NT, DPX-MD+ Full size Table

Standard room configuration: The computer and peripherals must be located more than 1.5 m or 1.83 m (U.S.A and Canada) from the scanner. Recommended room dimensions are: 3.7 meters x 3.7 meters (12 feet x 12 feet)

Small room configuration: Room dimensions must be at least 3.0 m x 2.4 m if the computer and peripherals are powered by an isolation transformer. Equipment powered by an isolation transformer can be located anywhere in the room with the scanner. The isolation transformer and scanner must be plugged into the same dedicated line outlet.

Lunar PRODIGY system no. DF+11999 and lower

Scanner power output configuration: It is recommended that the computer and all peripherals be powered by the scanner (scanner power output). If scanner power output is used, the computer and peripherals can be placed anywhere in the room. Room dimensions must be at least 3.0 m x 2.4 m.

Lunar PRODIGY, PRODIGY Primo, PRODIGY Advance, PRODIGY Pro, DPX-Pro, DPX-NT, DPX-MD+, Compact Table and DPX Bravo Tables

Standard room configuration: The computer and all peripherals must be located more than 1.5 m or 1.83 m (U.S.A and Canada) from the scanner. Recommended room dimensions are 2.3 meters x 3.7 meters (7.5 feet x 12 feet).

Small room configuration: Room dimensions must be at least 2.3 m x 2.4 m (7.5 feet x 8 feet) if the computer and peripherals are powered by an isolation transformer. Equipment powered by an isolation transformer can be located anywhere in the room with the scanner. The isolation transformer and scanner must be plugged into the same dedicated line outlet.

Lunar DPX Duo Table

Standard room configuration: The computer and all peripherals must be located more than 1.5 m or 1.83 m (U.S.A and Canada) from the scanner. Recommended room dimensions are 2.3 meters x 3.7 meters (7.5 feet x 12 feet).

Small room configuration: Room dimensions must be at least 2.4 m x 2.8 m (8 feet x 9 feet) if the computer and peripherals are powered by an isolation transformer. Equipment powered by an isolation transformer can be located anywhere in the room with the scanner. The isolation transformer and scanner must be plugged into the same dedicated line outlet.

Component Specifications

Specifications for standard components shipped with the system.

Component	Specifications
Lunar iDXA Scanner table Full Size Table	Dimensions: 287 cm x 131 cm x 125 cm (L x W x H) Weight: approximately 360 kg Maximum patient weight supported: 204 kg (450 pounds)
Lunar PRODIGY Advance, PRODIGY Primo, Scanner table* Full Size Table Compact Table	Dimensions: 262.3 cm x 109.3 cm x 128.3 cm (L x W x H) Weight: approximately 272.16 kg Maximum patient weight supported: 159 kg (350 pounds): Dimensions: 201 cm x 109.3 cm x 128.3 cm (L x W x H) Weight: approximately 254 kg Maximum patient weight supported: 159 kg (350 pounds):
Lunar PRODIGY, PRODIGY Pro Scanner table* Full Size Table Compact Table	Dimensions: 262.3 cm x 109.3 cm x 128.3 cm (L x W x H) Weight: approximately 272.16 kg Maximum patient weight supported: 159 kg (350 pounds): Dimensions: 201 cm x 109.3 cm x 128.3 cm (L x W x H) Weight: approximately 254 kg Maximum patient weight supported: 159 kg (350 pounds):
Lunar DPX-Pro/NT/MD+ Scanner table* Full-size table Compact table DPX Duo DPX Bravo	Dimensions: 242 cm x 103 cm x 128 cm (L x W x H) Weight: approximately 272 kg Maximum patient weight supported: 136 kg (300 pounds) Dimensions: 181 cm x 103 cm x 128 cm (L x W x H) Weight: approximately 254 kg Maximum patient weight supported: 136 kg (300 pounds) Dimensions: 186 cm x 86 cm x 147 cm (L x W x H) Weight: approximately 275 kg Maximum patient weight supported: 159 kg (350 pounds): Dimensions: 186 cm x 86 cm x 130 cm (L x W x H) Weight: approximately 202 kg Maximum patient weight supported: 159 kg (350 pounds)
Console table	78.5 cm x 63.3 cm x 48.1 cm

*Depth is measured from the front edge of the scanner table to the back edge of the scanner arm. Height is measured from the top of the scanner arm to the bottom of the scanner arm.

Functional Specifications

General specifications

	Focal spot to detector distance (cm)	Focal spot to pad surface distance (cm)	Focal spot to table top distance (cm)	Focal spot to source collimator distance (cm)
iDXA:	71.5	24.5	22	19
PRODIGY, PRODIGY Advance, PRODIGY Primo, PRODIGY Pro:	67.2	24.8	22.3	19
DPX-Pro/NT/MD+:	57.1	14.9	12.4	7.25
DPX-Duo/Bravo:	57.1	16.2	13.7	7.25

Lunar iDXA Maximum scan area (long x transverse)

- AP Spine Measurements: 39.5 cm x 22 cm
- Femur Measurements: 20.5 cm x 18 cm
- Total Body Measurements: 197.5 cm x 66 cm measurement field
- Forearm Measurements: 39 cm x 15 cm
- Lateral Spine Measurements: 55.3 cm x 22 cm

Lunar PRODIGY, PRODIGY Advance, PRODIGY Primo, PRODIGY Pro Maximum scan area (long x transverse)

- AP Spine Measurements: 40.9 cm x 22 cm
- Femur Measurements: 20.9 cm x 18 cm
- Total Body Measurements*: 197.5 cm x 60 cm measurement field
- Forearm Measurements: 40.9 cm x 10 cm
- Lateral Spine Measurements**: 40.9 cm x 22 cm

Lunar DPX-Pro/NT/MD+/Duo/Bravo Maximum scan area (long x transverse)

- AP Spine Measurements: 40.9 cm x 22 cm
- Femur Measurements: 20.9 cm x 17.9 cm
- Total Body Measurements*: 195 cm x 60 cm measurement field
- Forearm Measurements: 40.9 cm x 10 cm
- Lateral Spine Measurements**: 40.9 cm x 22 cm

* Prodigy, DPX-Pro/NT/MD+ Full size tables only
** Prodigy, DPX-Pro/NT/MD+ tables only

Software Features

Depending on the scanner model and number of options you purchased, not all of the software features listed below may be included with your software:

- AP spine measurement and analysis
- Pediatric spine measurement and analysis
- OneScan measurement application
- QuickView measurement application
- Femur measurement and analysis
- DualFemur measurement and analysis
- Total body measurement and analysis.
- Total body and regional tissue quantitation
- Pediatric total body measurement and analysis
- Pediatric Femur measurement and analysis
- Forearm measurement and analysis
- Lateral spine measurement and analysis
- Dual-energy Vertebral Assessment: (Lateral and AP)
- Spine Geometry
- Orthopedic femur measurement and analysis (with extended Gruen Analysis)
- Hand measurement and analysis

- Small animal total body measurement and analysis
- ScanCheck™ (formerly known as Computer Aided Densitometry)
- Composer Reporting Tools
- Practice Management Tools
- DICOM and HL7 interface capability
- SQL Server application
- TeleDensitometry
- Multi-user database capability
- OneVision capability
- AHA - Hip Strength Analysis

Environmental Specifications

Operational Environment

Adhere to the specifications that follow during scanner operation:

- **Ambient Space (Interior Subcomponents)** - For scanner operation and servicing, do not block the area around the scanner table. Make sure there is a minimum clearance of 30.5 cm (24 cm for iDXA) at the head and foot ends of the scanner table, at least 15.2 cm for the arm side, and 45.7 cm for the operator side.

- **Ambient Space (Ventilation)** - Do not block the cooling vents on the computer and scanner table. Make sure there is 15.2 cm from the console table to the wall for cable clearance and computer plugs.

- **Dust, Fumes and Debris** - Install the system in a clean, ventilated area. Dust and other airborne debris can cause the diskette drive heads and other sensitive mechanical components to malfunction. GE MEDICAL SYSTEMS recommends that you do not smoke in the scanner room.

- **Humidity** - Make sure the humidity for the scanner area is 20%-80%, non-condensing.

- **Power Consumption** - The iDXA scanner requires a dedicated 20A 100-127 VAC $\pm$10%, 10A 200-240 VAC $\pm$10% circuit, (single duplex outlet) with isolated ground, THD<5% 750VA. The outlet should be located behind the Host PC. The Lunar iDXA scanner will draw 40VA when idle and less than 750VA during a patient scan (100kV / 2.5mA). See Declarations of Immunity and Emissions table for power quality guidance.

  The Prodigy Series, DPX-Pro/NT/MD+/Duo/Bravo scanners require a dedicated 100-240 VAC - 20A 100-120 VAC, 10A 220-240 VAC circuit, (single duplex outlet) with isolated ground, THD<5% 600VA. The outlet should be located behind the Host PC.

  The Lunar PRODIGY and PRODIGY Advance scanner will draw 40 watts when idle and approximately 450 watts during a patient scan (76kV / 3mA).

  The Lunar DPX-Pro/NT/MD+ scanner will draw approximately 25 watts when idle and 250 watts during a patient scan (76 Kv / 1.5mA).

  The Lunar DPX Duo or DPX Bravo scanner will draw 40 watts when idle and approximately 450 watts during a patient scan (76kV / 1.5mA).

  The Host PC (typical PC with a 17" monitor) will draw approximately 110 watts when powered on.

- **Distortion** - Sinusoidal waveform, less than 5% THD

- **Heat Output** - The Lunar iDXA scanner will output approximately 150 BTU per hour when idle and 1500 BTU per hour when actively scanning. The Lunar PRODIGY and PRODIGY Advance scanner will output 150 BTU per hour when idle and 1500 BTU per hour when actively scanning. The Lunar DPX-Pro/NT/MD+/Duo/Bravo scanner will output 90 BTU per hour when idle and approximately 900 BTU per hour when actively scanning. The Host PC (PC with 17" monitor) will output approximately 400 BTU per hour when powered on.

- **Static Electricity** - Install and operate the system in a static-free area. Adhere to minimum humidity requirements to prevent malfunctions caused by static electricity.

- **Shock and Vibration** - Make sure the scanner table does not receive shock greater than 1G for more than 1 millisecond. Make sure the scanner table does not receive vibrations greater than 0.25 G at 1-100 Hz.

- **Temperature** - Make sure the temperature during system operation is 65°F-81°F (18°C-27°C).

  NOTE: When the scanner is turned off for more than an hour, or there is a power failure, you must turn the system on and let it warm for one hour. After one hour, complete a Quality Assurance procedure.

Storage and transport environment

Adhere to the specifications that follow for scanner storage and transportation:

- Humidity, 0% to 95% non-condensing.
- Atmospheric pressure, 500 to 1060 hPa.
- Temperature, -30° to 65° C.

Power Specifications

Leakage current

Computer and peripherals with Isolation Transformer: <100 microamperes.

Scanner Table alone: <500 microamperes.

Scanner input power

iDXA

The scanner has rated input of 100-127 or 200-240 VAC, 50-60 Hz, 750VA. Voltage may fluctuate ±10% from the rated input without a loss of scanner performance. The input power must meet IEEE 519-1992 for power quality and total harmonic distortion (THD <5%).

Lunar PRODIGY Primo, PRODIGY Advance, PRODIGY systems no. DF+12000 and higher, DPX-Pro/NT/MD+ systems no. 72000 and higher or 90000 and higher, DPX Duo, DPX Bravo

The scanner has a rated input of 100-240 VAC (100-120 for US, Canada). Voltage may fluctuate ±10% from the rated input without a loss of scanner performance. The input power must meet IEEE 519-1992 for power quality and total harmonic distortion (THD <5%).

Lunar PRODIGY systems no. DF+11999 and lower, DPX-Pro/NT/MD+ systems number 70000-71999

The scanner has 4 different nominal inputs: 100, 115, 230, and 240 VAC. During installation, the scanner is configured for the nominal input which best matches the voltage on site. Voltage may fluctuate ±10% from the nominal value without a loss of scanner performance. The nominal input (range of inputs) can be found on the system label. The input power must meet IEEE 519-1992 for power quality and total harmonic distortion (THD <5%).

Scanner output power

Lunar PRODIGY systems no. DF+11999 and lower, DPX-Pro/NT/MD+ systems number 70000-71999

The scanner has 3 different nominal outputs: 100, 120, 240 VAC. The nominal voltage output of the scanner is shown on the system label. The computer and all peripherals which use the scanner output power must be rated for this voltage. The maximum power output is 400 VA.

X-Ray Generator Specifications

Lunar iDXA X-Ray Generator

Lunar iDXA X-Ray generator technical information:

Classification	Class 1 Equipment	EN 60601-2-7 5.1
Degree of protection against electrical shock	Type B Equipment	EN 60601-2-7
Protection against ingress of liquids	Ordinary medical electrical equipment	EN 60601-2-7 5.3
Connection to supply mains	Medical grade power cord and isolation transformer	EN 60601-2-7 6.1g)
Mode of operation	Continuous	EN 60601-2-7 6.1m)
Rated mains voltage	85-144 VAC	EN 60601-2-7 6.1j)1
Number of phases in mains	1	EN 60601-2-7 6.1j)2
Mains frequency	45 - 66 Hz	EN 60601-2-7 6.1j)3
Required over-current releases	15 Amp dedicated mains service (for iDXA system)	EN 60601-2-7 6.1j)5
Allowable tube head assemblies	PN 40782 - GE Medical Systems Lunar iDXA X-Ray Tube Head Assembly	EN 60601-2-28 6.8.3 aa) 2)
Manufacturer	GE BEL Pvt. Ltd.	EN 60601-1 6.1 e)
Model	2374276	EN 60601-1 6.1 f)
Original language of accompanying documents	English	EN 60601-2-28 6.8.1
Maximum continuous kV, mA at nominal rated kV	100kV, 1.5mA	EN 60601-2-7 6.8.2 1)
Maximum intermittent kV, mA at nominal rated kV	100kV, 3.0mA	EN 60601-2-7 6.8.2 1)
Maximum continuous kV, mA at maximum mA	50kV, 3.0mA	EN 60601-2-7 6.8.2 2)
Maximum intermittent kV, mA at maximum mA	100kV, 3.0mA	EN 60601-2-7 6.8.2 2)
Continuous kV, mA for maximum electric output power	100kV, 1.5mA	EN 60601-2-7 6.8.2 3)
Intermittent kV, mA for maximum electric output power	100kV, 3.0mA	EN 60601-2-7 6.8.2 3)
Nominal electric power	0.3kW, 100kV, 3mA	EN 60601-2-7 6.8.2 4)
Lowest current time product	0.38mAs. Parameters: 100kV, 0.19mA, 2 seconds	EN 60601-2-7 6.8.2 5)
Nominal shortest irradiation times	2 seconds	EN 60601-2-7 6.8.2 6)
X-Ray Tube Assembly Reference Axis	Line normal to X-Ray Tube Head Assembly x-ray port, centered on x-ray port as shown in reference axis figure.	EN 60601-2-28 6.8.3 aa) 2)
X-Ray Tube Head Assembly Longitudinal Axis	Line intersecting and normal to both the Reference Axis and X-Ray Tube Longitudinal Axis, as shown in reference axis figure.	EN 60601-2-28 6.8.3 aa) 4) IEC 60336 4.2
Reference loading conditions	100kV, 1.5mA	EN 60601-1-3 29.204.2

Maximum heat content	1853kJ	EN 60601-2-28 6.8.2 bb) 1)
Maximum continuous heat dissipation	150W	EN 60601-2-28 6.8.2 bb) 4)
Leakage radiation load conditions	100kV, 3.0mA	EN 60601-2-28 6.8.3 bb) 7)
Focal spot to Image Receptor distance	715mm fixed	EN 60601-1-3 29.203.2
Attenuation equivalence of patient support table.	<1.2mm Al	EN 60601-1-3 29.206.2
Inherent filtration, minimum	X-Ray Tubehead Assembly: 0.9mm Al (aluminum) equivalent	EN 60601-1-3 29.201.3
Fixed added filtration, minimum measured @100kV	Sm (samarium) k-edge filter: 4.0mm Al	EN 60601-1-3 29.201.3
Total filtration, minimum	4.3mm Al (aluminum)	EN 60601-1-3 29.201.3
Maximum overall Dimensions (mm)	265L x 380W x 325H mm	EN 60601-2-28 6.8.3 bb) 5)
Mass	< 32 kg $\pm$ 0.3 kg	EN 60601-2-28 6.8.3 bb) 6)

Lunar PRODIGY Advance, PRODIGY Primo, PRODIGY, PRODIGY Pro X-Ray Generator

PRODIGY Advance, PRODIGY Primo, PRODIGY Pro, PRODIGY DF+12000 and higher

Lunar PRODIGY Advance, PRODIGY Primo, PRODIGY, Prodigy Pro X-ray generator technical information:

Classification	Class I Equipment	IEC 601-2-7 5.1
Degree of protection against electrical shock	Type B equipment	IEC 601-2-7 5.2
Protection against ingress of liquids	Ordinary medical electrical equipment	IEC 601-2-7 5.3
Connection to supply mains	Power supply cord	IEC 601-2-7 6.1g)
Mode of operation	Continuous	IEC 601-2-7 6.1m)
Maximum X-ray tube voltage	76 kV	IEC 601-2-7 6.1m)
Maximum X-ray tube current	3 mA	IEC 601-2-7 6.1m)
Rated mains voltage	100-240 VAC	IEC 601-2-7 6.1j)1
Number of phases in mains	1	IEC 601-2-7 6.1j)2
Mains frequency	50/60 Hertz	IEC 601-2-7 6.1j)3
Required over-current releases	15 Amp dedicated service	IEC 601-2-7 6.1j)5
Heat dissipative components	X-ray tube dissipates 243W max. into surrounding air through forced air convection. Flow rate: 36 m3/h (approx.) Temp. rise of air stream 25° C (approx.)	IEC 601-2-7 6.1t)
Allowable high voltage supplies	Spellman SBD40PN280X2890 or Bertan 2907.	IEC 601-2-7 6.8.1 and 50.2.101-102
Allowable tube head assemblies	GE MEDICAL SYSTEMS model 8743 or equivalent	IEC 601-2-7 6.8.1 and 50.2.101-102
Original language of accompanying documents	English	IEC 601-2-7, IEC 601-2-28, IEC 601-2-32, 6.8.1
Maximum continuous kV, mA at	76 kV, 3 mA	IEC 601-2-7 6.8.2 1)

nominal rated kV		
Maximum intermittent kV, mA at nominal rated kV	76 kV, 3 mA	IEC 601-2-7 6.8.2 1)
Maximum continuous kV, mA at maximum mA	76 kV, 3 mA	IEC 601-2-7 6.8.2 2)
Maximum intermittent kV, mA at maximum mA	76 kV, 3 mA	IEC 601-2-7 6.8.2 2)
Continuous kV, mA for maximum electric output power	76 kV, 3 mA	IEC 601-2-7 6.8.2 3)
Intermittent kV, mA for maximum electric output power	76 kV, 3 mA	IEC 601-2-7 6.8.2 3)
Nominal electric power	0.243 kW	IEC 601-2-7 6.8.2 4)
Lowest current time product	0.20 mAs. Parameters: 76 kV, 0.10 mA, 2 seconds.	IEC 601-2-7 6.8.2 5)
Nominal shortest irradiation times	2 seconds.	IEC 601-2-7 6.8.2 6)
Method of x-ray tube voltage measurement	Voltage divider in high voltage power supply.	IEC 601-2-7 50.106.1
Method of x-ray tube current measurement	Shunt resistor in high voltage supply return line.	IEC 601-2-7 50.106.2
X-ray tube assembly reference axis	Line normal to the tube port, centered on tube port as shown in reference axis figure.	IEC 336
Reference loading conditions	8.21 x 105 Joules, 3 mA, 76 kV for 1 hour.	IEC 601-1-3 29.204.2
Focal spot to Image Receptor distance	67 cm	IEC 601-1-3 29.203.2
Attenuation equivalence of patient support table.	0.7 mm Al	IEC 601-1-3 29.206.2

DF+11999 and lower

Lunar PRODIGY X-ray generator technical information:

Classification	Class I Equipment	IEC 601-2-7 5.1
Degree of protection against electrical shock	Type B equipment	IEC 601-2-7 5.2
Protection against ingress of liquids	Ordinary medical electrical equipment	IEC 601-2-7 5.3
Connection to supply mains	Power supply cord	IEC 601-2-7 6.1g)
Mode of operation	Continuous	IEC 601-2-7 6.1m)
Maximum X-ray tube voltage	76 kV	IEC 601-2-7 6.1m)
Maximum X-ray tube current	5 mA	IEC 601-2-7 6.1m)
Rated mains voltage	100, 110, 115, 120, 125, 127, 200, 220, 230, 240, 250, and 254 volts	IEC 601-2-7 6.1j)1
Number of phases in mains	1	IEC 601-2-7 6.1j)2
Mains frequency	50/60 Hertz	IEC 601-2-7 6.1j)3
Required over-current releases	20 Amp dedicated service	IEC 601-2-7 6.1j)5
Heat dissipative components	X-ray tube dissipates 305W max. into surrounding air through forced air convection. Flow rate: 36 m3/h (approx.) Temp. rise of air stream 25° C (approx.)	IEC 601-2-7 6.1t)
Allowable high voltage supplies	Spellman X2112/X2113/ rev. K and higher. Bertan 2411P and 2411N rev. A and higher. GE MEDICAL SYSTEMS p/n 0311 and 0312.	IEC 601-2-7 6.8.1 and 50.2.101-102

Allowable tube head assemblies	GE MEDICAL SYSTEMS model 6838 or equivalent	IEC 601-2-7 6.8.1 and 50.2.101-102
Original language of accompanying documents	English	IEC 601-2-7, IEC 601-2-28, IEC 601-2-32, 6.8.1
Maximum continuous kV, mA at nominal rated kV	76 kV, 4 mA	IEC 601-2-7 6.8.2 1)
Maximum intermittent kV, mA at maximum kV	76 kV, 5 mA	IEC 601-2-7 6.8.2 1)
Maximum continuous kV, mA at maximum mA	61 kV, 5 mA	IEC 601-2-7 6.8.2 2)
Maximum intermittent kV, mA at maximum mA	76 kV, 5 mA	IEC 601-2-7 6.8.2 2)
Continuous kV, mA for maximum electric output power	76 kV, 4 mA	IEC 601-2-7 6.8.2 3)
Intermittent kV, mA for maximum electric output power	76 kV, 5 mA	IEC 601-2-7 6.8.2 3)
Nominal electric power	0.4 kW	IEC 601-2-7 6.8.2 4)
Reference current time product	7.89 mAs. Parameters: 76 kV, 2.63 mA, 3 seconds.	IEC 601-2-7 6.8.2 5)
Nominal shortest irradiation times	3 seconds.	IEC 601-2-7 6.8.2 8)
Repetition rate for loading during tests	No specific wait period was imposed. Time between tests was approximately 20 seconds.	IEC 601-2-7 50.104.4
Method of x-ray tube voltage measurement	Voltage divider in high voltage power supply.	IEC 601-2-7 50.106.1
Method of x-ray tube current measurement	Shunt resistor in high voltage supply return line.	IEC 601-2-7 50.106.2
X-ray tube assembly reference axis	Line normal to the tube port, centered on tube port as shown in reference axis figure.	IEC 336
Reference loading conditions	1.09 x 106 Joules, 4 mA, 76 kV for 1 hour.	IEC 601-1-3
Leakage radiation was measured at the following loading factors.	3mA, 76 kV	IEC 601-1-3
Focal spot to Image Receptor distance	67 cm	IEC 601-1-3
Attenuation equivalence of patient support table.	0.7 mm Al	IEC 601-1-3

Lunar DPX-Pro/NT/MD+/Duo/Bravo X-Ray Generator

NT±/MD±72000 and higher, NT±/MD±90000 and higher, Duo and Bravo

Lunar DPX-Pro//Pro/MD+/Duo/Bravo X-ray generator technical information:

Classification	Class I Equipment	IEC 601-2-7 5.1
Degree of protection against electrical shock	Type B equipment	IEC 601-2-7 5.2
Protection against ingress of liquids	Ordinary medical electrical equipment	IEC 601-2-7 5.3
Connection to supply mains	Power supply cord	IEC 601-2-7 6.1g)
Mode of operation	Continuous	IEC 601-2-7 6.1m)
Maximum X-ray tube voltage	76 kV	IEC 601-2-7 6.1m)

Maximum X-ray tube current	3 mA	IEC 601-2-7 6.1m)
Rated mains voltage	100-240 VAC	IEC 601-2-7 6.1j)1
Number of phases in mains	1	IEC 601-2-7 6.1j)2
Mains frequency	50/60 Hertz	IEC 601-2-7 6.1j)3
Required over-current releases	15 Amp dedicated service	IEC 601-2-7 6.1j)5
Heat dissipative components	X-ray tube dissipates 243W max. into surrounding air through forced air convection. Flow rate: 36 m3/h (approx.) Temp. rise of air stream 25° C (approx.)	IEC 601-2-7 6.1t)
Allowable high voltage supplies	Spellman SBD40PN280X2890 or Bertan 2907.	IEC 601-2-7 6.8.1 and 50.2.101-102
Allowable tube head assemblies	LUNAR model 8548 or equivalent	IEC 601-2-7 6.8.1 and 50.2.101-102
Original language of accompanying documents	English	IEC 601-2-7, IEC 601-2-28, IEC 601-2-32, 6.8.1
Maximum continuous kV, mA at nominal rated kV	76 kV, 3 mA	IEC 601-2-7 6.8.2 1)
Maximum intermittent kV, mA at nominal rated kV	76 kV, 3 mA	IEC 601-2-7 6.8.2 1)
Maximum continuous kV, mA at maximum mA	76 kV, 3 mA	IEC 601-2-7 6.8.2 2)
Maximum intermittent kV, mA at maximum mA	76 kV, 3 mA	IEC 601-2-7 6.8.2 2)
Continuous kV, mA for maximum electric output power	76 kV, 3 mA	IEC 601-2-7 6.8.2 3)
Intermittent kV, mA for maximum electric output power	76 kV, 3 mA	IEC 601-2-7 6.8.2 3)
Nominal electric power	0.243 kW	IEC 601-2-7 6.8.2 4)
Lowest current time product 0.20 mAs.	Parameters: 76 kV, 0.10 mA, 2 seconds.	IEC 601-2-7 6.8.2 5)
Nominal shortest irradiation times	2 seconds.	IEC 601-2-7 6.8.2 6)
Method of x-ray tube voltage measurement	Voltage divider in high voltage power supply.	IEC 601-2-7 50.106.1
Method of x-ray tube current measurement	Shunt resistor in high voltage supply return line.	IEC 601-2-7 50.106.2
X-ray tube assembly reference axis	Line normal to the tube port, centered on tube port as shown in reference axis figure.	IEC 336
Reference loading conditions	8.21 x 105 Joules, 3 mA, 76 kV for 1 hour.	IEC 601-1-3 29.204.2
Focal spot to Image Receptor distance	57 cm	IEC 601-1-3 29.203.2
Attenuation equivalence of patient support table.	0.7 mm Al	IEC 601-1-3 29.206.2

NT±/MD±70000 - 71999

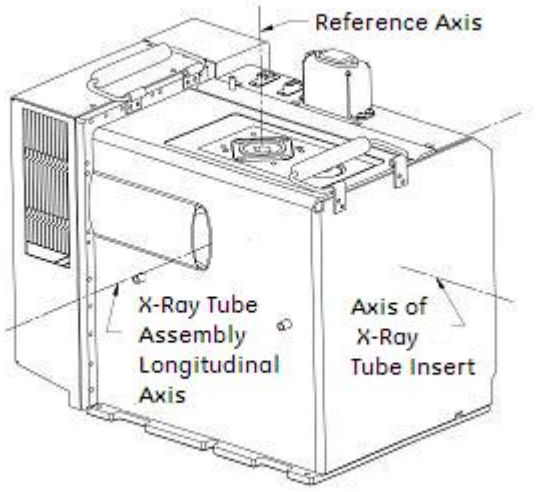
Lunar DPX-NT X-ray generator technical information:

Classification	Class I Equipment	IEC 601-2-7 5.1
Degree of protection against electrical shock	Type B equipment	IEC 601-2-7 5.2
Protection against ingress of liquids	Ordinary medical electrical equip-	IEC 601-2-7 5.3

	ment	
Connection to supply mains	Power supply cord	IEC 601-2-7 6.1g)
Mode of operation	Continuous	IEC 601-2-7 6.1m)
Maximum X-ray tube voltage	76 kV	IEC 601-2-7 6.1m)
Maximum X-ray tube current	5 mA	IEC 601-2-7 6.1m)
Rated mains voltage	100, 115, 230, and 240 volts	IEC 601-2-7 6.1j)1
Number of phases in mains	1	IEC 601-2-7 6.1j)2
Mains frequency	50/60 Hertz	IEC 601-2-7 6.1j)3
Required over-current releases	15 Amp dedicated service	IEC 601-2-7 6.1j)5
Heat dissipative components	X-ray tube dissipates 305W max. into surrounding air through forced air convection. Flow rate: 36 m3/h (approx.) Temp. rise of air stream 25° C (approx.)	IEC 601-2-7 6.1t)
Allowable high voltage supplies	Bertan 2411P and 2411N rev. A and higher.	IEC 601-2-7 6.8.1 and 50.2.101-102
Allowable tube head assemblies	LUNAR model 8297 or equivalent	IEC 601-2-7 6.8.1 and 50.2.101-102
Original language of accompanying documents	English	IEC 601-2-7, IEC 601-2-28, IEC 601-2-32, 6.8.1
Maximum continuous kV, mA at nominal rated kV	76 kV, 4 mA	IEC 601-2-7 6.8.2 1)
Maximum intermittent kV, mA at maximum kV	76 kV, 5 mA	IEC 601-2-7 6.8.2 1)
Maximum continuous kV, mA at maximum mA	61 kV, 5 mA	IEC 601-2-7 6.8.2 2)
Maximum intermittent kV, mA at maximum mA	76 kV, 5 mA	IEC 601-2-7 6.8.2 2)
Continuous kV, mA for maximum electric output power	76 kV, 4 mA	IEC 601-2-7 6.8.2 3)
Intermittent kV, mA for maximum electric output power	76 kV, 5 mA	IEC 601-2-7 6.8.2 3)
Nominal electric power	0.4 kW	IEC 601-2-7 6.8.2 4)
Reference current time product 7.89 mAs.	Parameters: 76 kV, 2.63 mA, 3 seconds.	IEC 601-2-7 6.8.2 5)
Nominal shortest irradiation times	3 seconds.	IEC 601-2-7 6.8.2 8)
Repetition rate for loading during tests No specific wait period was imposed.	Time between tests was approximately 20 seconds.	IEC 601-2-7 50.104.4
Method of x-ray tube voltage measurement	Voltage divider in high voltage power supply.	IEC 601-2-7 50.106.1
Method of x-ray tube current measurement	Shunt resistor in high voltage supply return line.	IEC 601-2-7 50.106.2
X-ray tube assembly reference axis	Line normal to the tube port, centered on tube port as shown in reference axis figure.	IEC 336
Reference loading conditions	1.09 x 106 Joules, 4 mA, 76 kV for 1 hour.	IEC 601-1-3
Leakage radiation was measured at the following loading factors.	1.5mA, 76 kV	IEC 601-1-3
Focal spot to Image Receptor distance	57 cm	IEC 601-1-3
Attenuation equivalence of patient support table.	0.7 mm Al	IEC 601-1-3

GE MEDICAL SYSTEMS X-Ray Tube Head Assembly

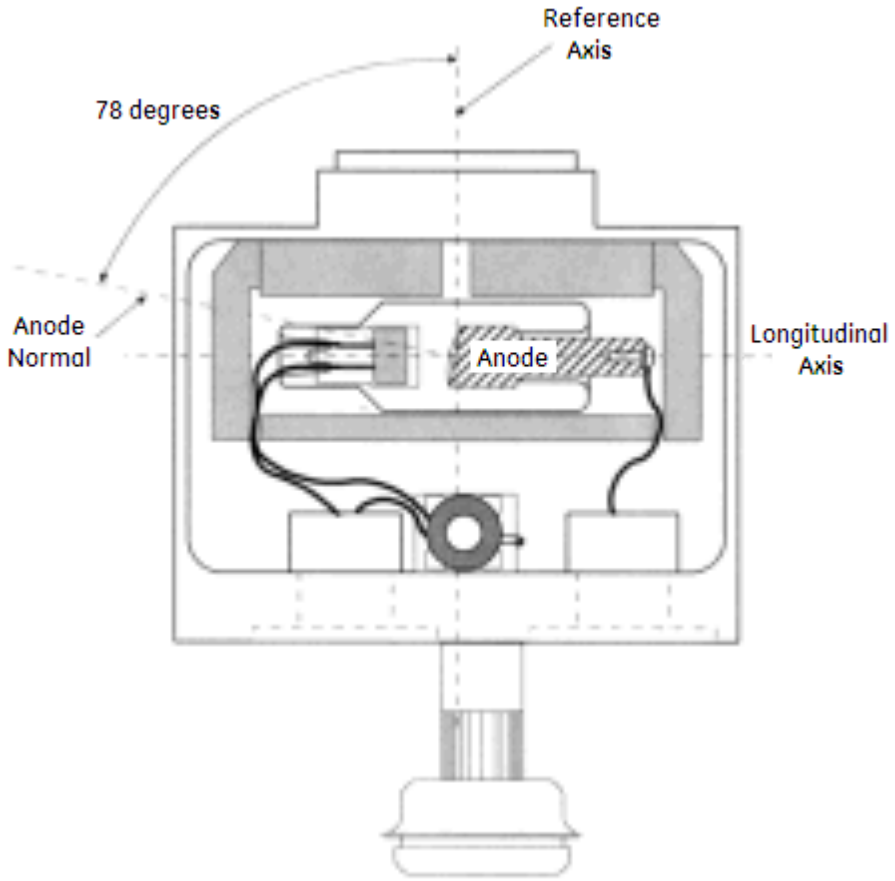
Reference Axis and Target Angles for Tube Head Assembly - iDXA



iDXA Insert Specifications

Manufacturer	Lohmann X-ray GmbH	EN 60601-2-28 6.8.3 aa)
Model	110/3 EFK	EN 60601-2-28 6.8.3 aa)
Nominal x-ray tube voltage	110 kV	EN 60601-2-28 6.8.3 aa) 6)
Nominal anode input power	330 W	EN 60601-2-28 6.8.2 aa) 1)
Maximum anode heat content	50 kJ	EN 60601-2-28 6.8.2 aa) 2)
Anode target material	(W) Tungsten	EN 60601-2-28 6.8.3 aa) 1)
Target angle	10°	EN 60601-2-28 6.8.3 aa) 3)
Nominal focal spot values	0.4 IEC 60336	EN 60601-2-28 6.8.3 aa) 4)
Actual focal spot dimensional limits. Length parallel to Longitudinal Axis of X-Ray Tube Head Assembly	Width 0.25 mm to 0.42 mm Length 0.60 mm to 0.85 mm	
Inherent filtration	0.55 mm of Aluminum equivalent	EN 60601-2-28 6.8.3 aa) 5)

Reference Axis and Target Angles for Tube Head Assembly - Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo



GE Medical Systems 8022 X-ray tube technical information

Nominal anode input power	361 Watts	IEC 613/1989
Maximum anode heat content	18300 Joules	IEC 613/1989
Anode heating and cooling curves	Refer to Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo Anode heating/cooling curves	IEC 613/1989
Anode target material	Tungsten	IEC 601-2-28
Reference axis	Refer to reference axis figure	IEC 601-2-28
Target angle 78°	(reference to normal)	IEC 601-2-28
Nominal focal spot values	0.5	IEC 336/1982
Maximum useful voltage	95 kVp	Not Applicable
Maximum filament current	2.2	Amperes Not Applicable

GE Medical Systems 8743 X-ray tube technical information (DF+12000 and higher)

Beam filtration is permanently fixed with a minimum 2.9 mm Aluminum-equivalent.

Inherent filtration	>2.9 mm Al/70 kV	IEC 522/1976
Filament characteristics	Refer to Filament emission characteristics - Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo figure	IEC 613/1989
Nominal x-ray tube voltage	76 kV - Anode to Cathode 38 kV - Anode to Earth 38 kV - Cathode to Earth	IEC 613/1989
Single load rating	228 W (3 mA, 76 kV) for up to 15 min.	IEC 613/1989
Serial load rating	228 W (3 mA, 76 kV) for up to 15 min.	IEC 613/1989
Maximum x-ray tube assembly heat content	260 kJoules	IEC 613/1989
X-ray tube assembly heating and cooling curves	Refer to the Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo X-Ray Tube Assembly Heating and Cooling Curves	IEC 613/1989
Maximum continuous heat dissipation	243 Watts (3mA x 76kV + 15W filament)	IEC 613/1989
Maximum symmetrical radiation field	3.4 mm/19.5 mm at a distance from the focal spot of 223 mm.	IEC 806/1984
Dimensions	17 cm x 19.4 cm x 11 cm	IEC 601-2-28
Weight	8.6 kg	IEC 601-2-28

GE Medical Systems 6838 X-ray tube technical information (DF+11999 and lower)

Beam filtration is permanently fixed with a minimum 2.9 mm Aluminum-equivalent.
NOTE: Beam quality has a minimum first half-value layer of 3.2 mm of Al at 76 kV.

Inherent filtration	>2.9 mm Al/70 kV	IEC 522/1976
Filament characteristics	Refer to Filament emission characteristics - Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo figure	IEC 613/1989
Nominal x-ray tube voltage	76 kV - Anode to Cathode 38 kV - Anode to Earth 38 kV - Cathode to Earth	IEC 613/1989
Single load rating	361 W (3.00 mA, 76 kV) for up to 4 min., 59 sec.	IEC 613/1989
Serial load rating	361 W (3.00 mA, 76 kV) for up to 4 min., 59 sec.	IEC 613/1989
Maximum x-ray tube assembly heat content	260 kJoules	IEC 613/1989
X-ray tube assembly heating and cooling curves	Refer to the Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo X-Ray Tube Assembly Heating and Cooling Curves	IEC 613/1989
Maximum continuous heat dissipation	361 Watts	IEC 613/1989
Maximum symmetrical radiation field	3.4 mm/19.5 mm at a distance from the focal spot of 223 mm.	IEC 806/1984
Dimensions	17 cm x 19.4 cm x 11 cm	IEC 601-2-28
Weight	8.6 kg	IEC 601-2-28

GE Medical Systems 8548 X-ray tube technical information (DPX-Pro/NT/MD+ 72000 and higher, DPX Duo, DPX Bravo)

Beam filtration is permanently fixed with a minimum 3.0 mm Aluminum-equivalent.

Inherent filtration	>3.0 mm Al/70 kV	IEC 522/1976
Filament characteristics	Refer to Filament emission characteristics - Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo figure	IEC 613/1989
Nominal x-ray tube voltage	76 kV - Anode to Cathode 38 kV - Anode to Earth 38 kV - Cathode to Earth	IEC 613/1989
Single load rating	228 W (3 mA, 76 kV) for up to 15 min.	IEC 613/1989
Serial load rating	228 W (3 mA, 76 kV) for up to 15 min. with a 5 min. cool down time between measurements.	IEC 613/1989
Maximum x-ray tube assembly heat content	260 kJoules	IEC 613/1989
X-ray tube assembly heating and cooling curves	Refer to the Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo X-Ray Tube Assembly Heating and Cooling Curves	IEC 613/1989
Maximum continuous heat dissipation	243 Watts (3mA x 76kV + 15W filament)	IEC 613/1989
Maximum symmetrical radiation field	Diameter = 6.3 mm	IEC 806/1984
Dimensions	17 cm x 19.4 cm x 11 cm	IEC 601-2-28
Weight	8.6 kg	IEC 601-2-28

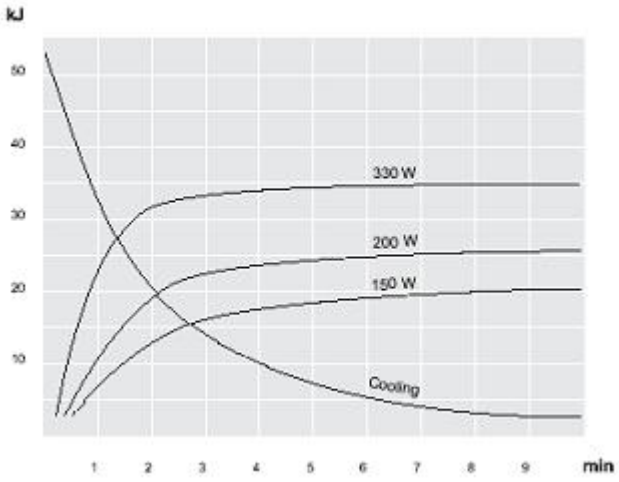
GE Medical Systems 8297 X-ray tube technical information (DPX-NT 70000-71999)

Beam filtration is permanently fixed with a minimum 3.0 mm Aluminum-equivalent.

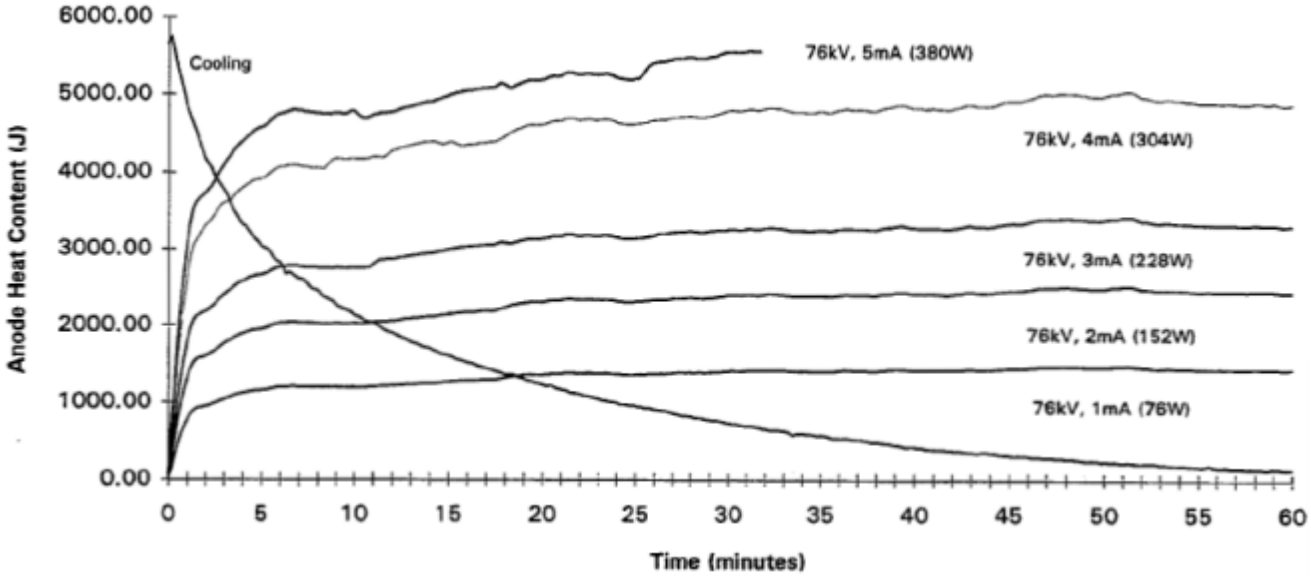
Inherent filtration	>3.0 mm Al/70 kV	IEC 522/1976
Filament characteristics	Refer to Filament emission characteristics - Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo figure	IEC 613/1989
Nominal x-ray tube voltage	76 kV - Anode to Cathode 38 kV - Anode to Earth 38 kV - Cathode to Earth	IEC 613/1989
Single load rating	361 W (4.75 mA, 76 kV) for up to 4 min., 59 sec.	IEC 613/1989
Serial load rating	361 W (4.75 mA, 76 kV) for up to 4 min., 59 sec. with a 10 min. cool down time between measurements.	IEC 613/1989
Maximum x-ray tube assembly heat content	260 kJoules	IEC 613/1989
X-ray tube assembly heating and cooling curves	Refer to Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo X-Ray Tube Assembly Heating and Cooling Curves	IEC 613/1989
Maximum continuous heat dissipation	361 Watts	IEC 613/1989
Maximum symmetrical radiation field	Diameter = 6.3 mm	IEC 806/1984
Dimensions	17 cm x 19.4 cm x 11 cm	IEC 601-2-28
Weight	8.6 kg	IEC 601-2-28

Anode heating/cooling curves

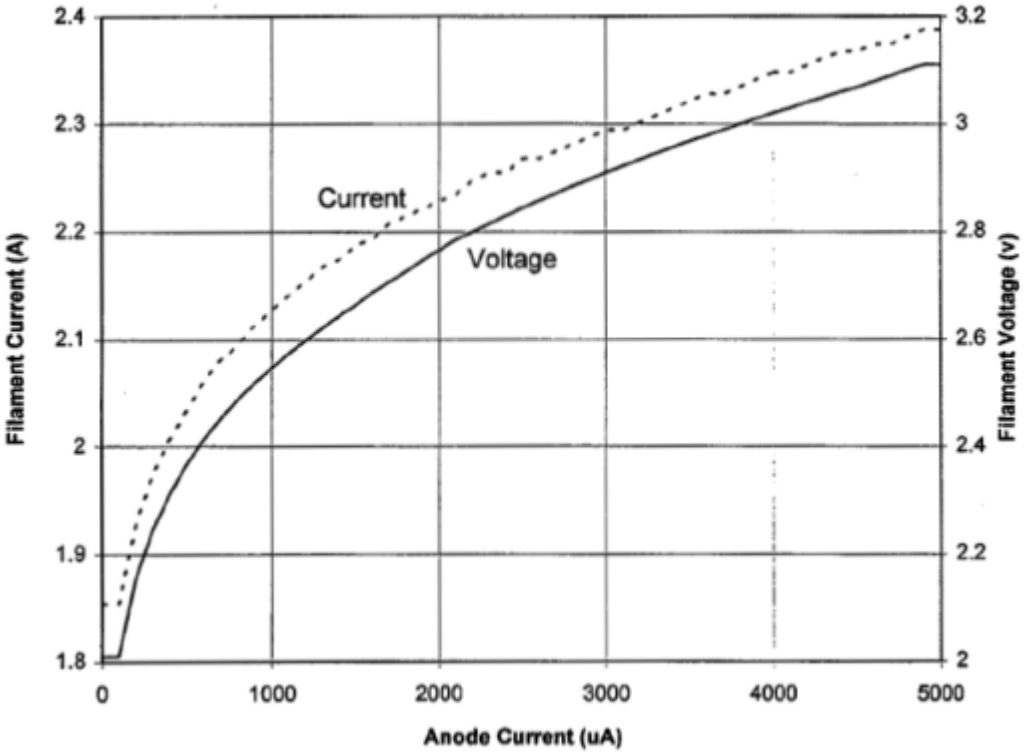
iDXA



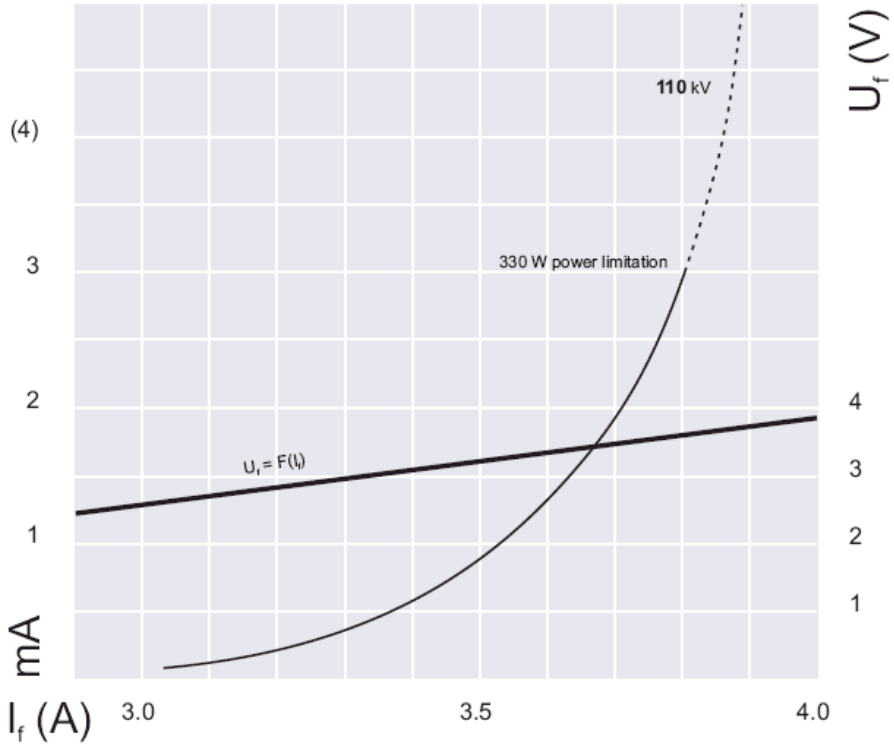
Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo



Filament emission characteristics - Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo

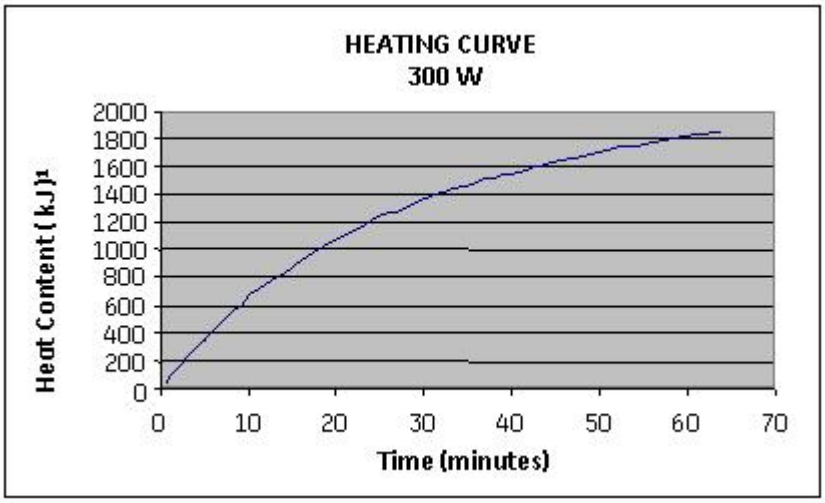


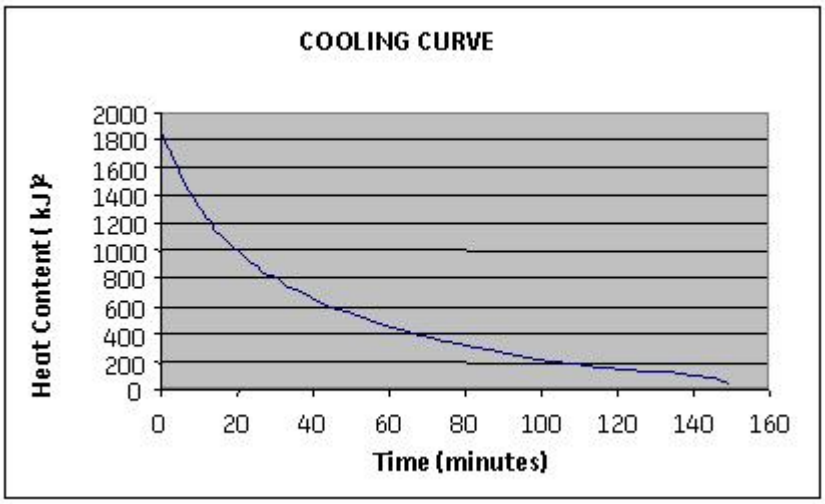
Filament emission characteristics - iDXA



X-ray tube assembly heating/cooling curves

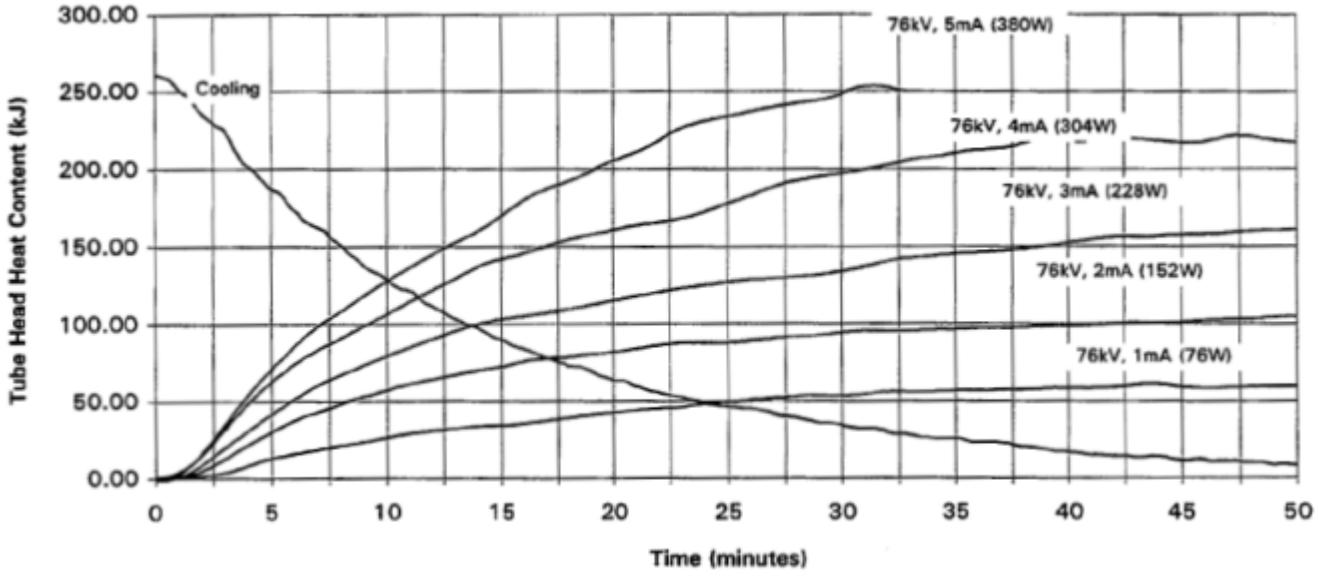
iDXA[12]





1. Total energy input with cooling - actual heat content is lower
2. Energy content values shown are taken from heating curve and represent actual stored energy content which is lower.

Prodigy Series, DPX-Pro/NT/MD+/Bravo/Duo



Compatible Components

For customers located internationally, make sure the computer is certified to local requirements. v. 13 is compatible with existing Windows XP OS, however, for new DXA units, the computer must meet the minimum requirements that follow:

Prodigy Series, DPX-NT/Pro/MD+/Duo/Bravo Bone Densitometer configuration - Windows XP

- Greater than 1 GHz processor
- 1 GB RAM
- Greater than 80 GB Hard Disk
- CD-RW/DVD-R
- 17" SVGA monitor with at least 1024x768x32-bit color
- Audio capable with speakers or monitor (with speakers)
- Service Pack 3
- Internet Explorer version 7.0
- Full height PCI slot for fast Serial I/O board (GE Medical Systems part number 7151) - Prodigys only with system numbers less than 300101
- HP 2280, 2300, 5650, KD5400, 8000 or equivalent printer
- Media for archive and backup

Prodigy Series, DPX-NT/Pro/MD+/Duo/Bravo Bone Densitometer configuration - Windows Vista

- Greater than 1 GHz processor
- 2 GB RAM
- Greater than 80 GB Hard Drive (40 GB drive for OS partition and 15 GB free to install)
- CD-RW/DVD-R
- 17" SVGA monitor with at least 1024x768x32-bit color
- Audio capable with speakers or monitor (with speakers)
- Service Pack 1
- Internet Explorer version 7.0
- Full height PCI slot for fast Serial I/O board (GE Medical Systems part number 7151) - Prodigys only with system numbers less than 300101

- HP 5650, KD5400, 8000 or equivalent printer
- Media for archive and backup

iDXA Bone Densitometer configuration - Windows XP

- Greater than 2.8 GHz processor
- 2 GB RAM
- Greater than 80 GB Hard Disk
- CD-RW/DVD-R
- 17" SVGA monitor with at least 1024x768x32-bit color
- Audio capable with speakers or monitor (with speakers)
- Service Pack 3
- Internet Explorer version 7.0
- 2 100 Mbit ethernet connectivity
- HP 2280, 2300, 5650, KD5400, 8000 or equivalent printer
- Media for archive and backup

iDXA Bone Densitometer configuration - Windows Vista

- Greater than 2.8 GHz processor
- 2 GB RAM
- Greater than 80 GB Hard Drive (40 GB drive for OS partition and 15 GB free to install)
- CD-RW/DVD-R
- 17" SVGA monitor with at least 1024x768x32-bit color
- Audio capable with speakers or monitor (with speakers)
- Service Pack 1
- Internet Explorer version 7.0
- 2 100 Mbit ethernet connectivity
- HP 5650, KD5400, 8000 or equivalent printer
- Media for archive and backup

FDA Certified Components

The following give components certified to the FDA for use with Lunar iDXA scanners. The tables are updated periodically. Contact GE Medical Systems Lunar for a current listing of compatible components.

Lunar iDXA

Component	Description	GE Medical Systems Lunar Model #
Tube Head Assembly	GE Medical Systems Lunar iDXA X-Ray Tube Head Assembly	LU40782
X-ray controller	GE Medical Systems Lunar iDXA X-ray Controller	LU41718
Collimator	GE Medical Systems Lunar iDXA Collimator Assembly	LU42129

The following give components certified to the FDA for use with Lunar PRODIGY, PRODIGY Advance and PRODIGY Primo scanners. The tables are updated periodically. Contact GE Medical Systems Lunar for a current listing of compatible components.

Lunar PRODIGY Advance PA+/- 301000 and higher, PRODIGY DF+/- 301000 and higher, PRODIGY Primo

Component	Description	GE Medical Systems Lunar Model #
X-ray Controller	GE Medical Systems Lunar single board controller	41170
High Voltage Power Supplies	Bertan[1] Model: 2907 Spellman[2] Model: SBD40PN280X2890	7681 7681
Tube Head Assembly	GE Medical Systems Lunar X-Ray Tube Head Assembly	8743
Collimator	GE Medical Systems Lunar PRODIGY Collimator Assembly	8915

[1] Bertan High Voltage Corp., 121 New South Road, Hicksville, NY
[2] Spellman High Voltage Electronics Corp., 475 Wireless Boulevard, Hauppauge, NY

Lunar PRODIGY Advance PA+/- 40000-141999, PRODIGY Pro, PRODIGY DF+/- 12000-130999

Component	Description	GE Medical Systems Lunar Model #
X-ray Controller	GE Medical Systems Lunar single board controller	7635
High Voltage Power Supplies	Bertan[1] Model: 2907 Spellman[2] Model: SBD40PN280X2890	7681 7681
Tube Head Assembly	GE Medical Systems Lunar X-Ray Tube Head Assembly	8743
Collimator	GE Medical Systems Lunar PRODIGY Collimator Assembly	8915

[1]Bertan High Voltage Corp., 121 New South Road, Hicksville, NY
[2]Spellman High Voltage Electronics Corp., 475 Wireless Boulevard, Hauppauge, NY

Lunar PRODIGY DF+/- 11999 and lower

Component	Description	GE Medical Systems Lunar Model #
X-ray Controller	GE Medical Systems Lunar PRODIGY single board controller	5447
High Voltage Power Supplies	Spellman[1] Models: PTV40N200X2113 PTV40P200X2112	 0311 0312
	Bertan[2] Models: 2411 N 2411 P	 0311 0312
Tube Head Assembly	GE Medical Systems Lunar X-Ray Tube Head Assembly	6838
Collimator	GE Medical Systems Lunar PRODIGY Collimator Assembly	6893

[1]Spellman High Voltage Electronics Corporation Hauppauge, NY
[2]Bertan High Voltage Corp., 121 New South Road, Hicksville, NY

The following give components certified to the FDA for use with Lunar DPX-NT/PRO/MD+ scanners. The tables are updated periodically. Contact GE Medical Systems Lunar for a current listing of compatible components.

Lunar DPX-NT/PRO/MD+/- 72000 and higher/90000 and higher

Component	Description	GE Medical Systems Lunar Model #
X-ray Controller	GE Medical Systems Lunar single board controller	7634
High Voltage Power Supplies	Bertan[1] Model: 2907 Spellman[2] Model: SBD40PN280X2890	7681 7681
Tube Head Assembly	GE Medical Systems Lunar X-Ray Tube Head Assembly	8548
Collimator	GE Medical Systems Lunar DEXA Collimator Assembly	7767

[1]Bertan High Voltage Corp., 121 New South Road, Hicksville, NY
[2]Spellman High Voltage Electronics Corp., 475 Wireless Boulevard, Hauppauge, NY

Lunar DPX-NT 70000-71999

Component	Description	GE Medical Systems Lunar Model #
X-ray Controller	GE Medical Systems Lunar DPX-NT single board controller	7844
High Voltage Power Supplies	Bertan[1] Models: 2411 N 2411 P	 0311 or 8531 0312 or 8532
Tube Head Assembly	GE Medical Systems Lunar X-Ray Tube Head Assembly	8297
Collimator	GE Medical Systems Lunar DEXA Collimator Assembly	2898

[1]Bertan Associates, 121 New South Road, Hicksville, NY

Lunar DPX Duo, DPX Bravo

Component	Description	GE Medical Systems Lunar Model #
X-ray Controller	GE Medical Systems Lunar single board controller	41500
High Voltage Power Supplies	Spellman[1] Model: SBD40PN280X2890	7681
Tube Head Assembly	GE Medical Systems Lunar X-Ray Tube Head Assembly	8548
Collimator	GE Medical Systems Lunar DEXA Collimator Assembly	7767

[1]Spellman High Voltage Electronics Corp., 475 Wireless Boulevard, Hauppauge, NY

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