Performix™ 160 A X-ray Tube Assembly
Technical Reference Manual

This manual is applicable to the following product names:

Performix™ 160 A

This manual is applicable to the following X-ray Tube Assembly Model Number:

2216500 (Catalog Number: D2801A)

CE 0459

Performix™ 160 A
Technical Reference Manual, English
Original Version: English

2216500-1EN
Revision: 1

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Revision History

Revision	Date	Reason for change
1	17 OCT 2014	Initial Release of Document

Table of Contents

Chapter 1 Important Precautions

Section 1-1: Safety Definitions

The x-ray tube assembly has no known existing contraindication that would limit use.

This manual uses the following conventions to identify potential safety hazards, and highlight important information.

DANGER **DANGER IDENTIFIES HAZARDOUS CONDITIONS OR ACTIONS THAT COULD CAUSE SERIOUS INJURY OR DEATH.**

WARNING **A WARNING IDENTIFIES HAZARDOUS CONDITIONS OR ACTIONS THAT COULD CAUSE SEVERE INJURIES.**

CAUTION **A Caution identifies hazardous conditions or actions that may cause minor personal injury, damage the hardware, or corrupt the software or databases.**

NOTICE **A notice contains information that saves time by pointing out the potential for user errors. Notices may also contain important reminders and non hazardous warnings.**

Note: Notes provide additional clarifying information to the user.

Section 1-2: Safety

1-2.1 Electric Shock Hazard

WARNING **TO AVOID THE RISK OF ELECTRIC SHOCK, THIS X-RAY TUBE ASSEMBLY MUST ONLY BE CONNECTED TO A GE HEALTHCARE HIGH VOLTAGE GENERATOR WITH PROTECTIVE EARTHING.**

1-2.2 X-ray Protection

CAUTION **Improperly used x-ray equipment may cause injury. Read and understand the instructions in this book and in the associated system manual before you attempt to operate this equipment. If you fail to follow safe X-ray practices or ignore the advice presented in the manuals, you and your patient risk exposure to hazardous radiation. The General Electric Company, GE Healthcare Group, will gladly assist and cooperate in placing this equipment into use.**

Although this x-ray tube assembly incorporates a high degree of protection against radiation other than the useful beam, no practical design of equipment can provide complete

protection. Nor can any practical design compel the operator to take adequate precautions to prevent the possibility of any person carelessly exposing themselves or others to radiation.

Everyone having anything to do with x-ray must receive proper training and become fully acquainted with the recommendations of the National Council on Radiation Protection (NCRP) and Measurements, and the International Commission on Radiation Protection.

NCRP reports are available from:

NCRP Publications
7910 Woodmont Avenue
Room 1016
Bethesda, Maryland 20814
USA

CAUTION **Everyone having anything to do with X-ray must take adequate steps to insure protection against injury.**

All persons authorized to use the equipment must understand the dangers posed by excessive x-ray exposure. The equipment is sold with the understanding that the General Electric Company, GE Healthcare, its agents, and representatives have no responsibility for injury or damage which may result from improper use of the equipment.

GE Healthcare recommends the use of protective materials and devices.

Section 1-3: Regulatory Requirements

This product complies with the regulatory requirements of the following:

- Council Directive 93/42/EEC concerning medical devices bearing the following CE marking of conformity:
  CE 0459
- Code of Federal Regulations, Title 21, Part 820 – Quality System Regulation
- Code of Federal Regulations, Title 21, Subchapter J - Radiological Health
- IEC 60601-1:1988/2005 ; AAMI ES60601-1; CSA C22.2#60601-1
- IEC 60601-1-3:1994/2008
- IEC 60601-2-28:1993/2010
- Medical Industry Standards of the People's Republic of China, YY/T 0609-2007
- Medical Industry Standards of the People's Republic of China, YY/T 1099-2007

NOTICE The individual CE marking on the 2216500 only applies to the x-ray tube assembly.

This x-ray tube assembly may be used in a medical system with or without a CE marking.

Please refer to the accompanying system documentation to verify the compatibility of this x-ray tube assembly, and for information concerning CE marking of the system.

In summary, installing a CE marked x-ray tube assembly does not imply CE certification for the entire system.

Original language of editing: English.

GE Medical Systems is ISO 9001 (2008) and ISO 13485 (2003) certified.

Section 1-4: Damage in Transportation

All packages should be closely examined at time of delivery. If damage is apparent, the notation “Damage in Shipment” should be written on all copies of the freight or express bill before delivery is accepted or signed for by a General Electric representative or a hospital receiving agent. Whether noted or concealed, damage MUST be reported to the carrier immediately upon discovery, or in any event, within 14 days after receipt, and the contents and containers held for inspection by the carrier. A transportation company will not pay a claim for damage if an inspection is not requested within this 14-day period.

Call Traffic and Transportation, Milwaukee, WI (414) 827-3449 / 8*285-3449 immediately after damage is found. At this time be ready to supply name of carrier, delivery date, consignee name, freight or express bill number, item damaged and extent of damage.

Complete instructions regarding claim procedure are found in Section "S" of the Policy & Procedure Bulletins (6/17/94).

Section 1-5: Certified Electrical Contractor Statement

The purchaser of GE Healthcare equipment shall hire only qualified personnel (i.e., GE Healthcare field engineers, personnel of third-party service companies with equivalent training, or licensed electricians) to service the electrical connections of the equipment.

Section 1-6: Omissions & Errors

Customers, please contact your GE Healthcare Sales or Service representatives.

GE personnel, please use the current complaint process to report all omissions, errors, and defects in this publication.

Section 1-7: Technical Manual Updates

When operating or servicing GE Healthcare products, please contact your GE representative for the latest revision of product documentation. Product documentation may also be available on-line at the GE Healthcare support documentation library.

Chapter 2 Product Information

Section 2-1: Description

The x-ray tube assembly generates x-rays for GE Healthcare vascular imaging systems.

The mode of operation for the x-ray tube assembly is continuous operation with intermittent loading according to IEC60601-1:1994 and non-continuous according to IEC60601-1:2005. See load ratings for duty cycle in Table 3-2, Table 3-3, Table 3-4, Table 3-5, Table 3-6 and Table 3-7.

The model number for the x-ray tube assembly described in this document is 2216500. The product name for this model number is the Performix™ 160 A X-ray Tube Assembly. Table 2-1 shows this x-ray tube assembly number with the corresponding x-ray tube and x-ray tube housing model number:

Table 2-1: X-ray Tube Assembly model number with tube and housing numbers.

X-ray Tube Assembly Model Number	X-ray Tube Model Number	X-ray Tube Housing Model Number
2216500	2216450	2216500-2

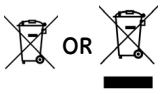
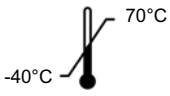
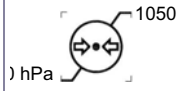
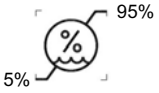
NOTICE Multiple GE Healthcare vascular systems use this x-ray tube assembly. Vascular systems may use different mounting hardware. Please refer to the individual system documentation for detailed installation/deinstallation, calibration, conditioning, and use instructions.

NOTICE Please consult the system manual for the operating environment recommended for using the GE Healthcare vascular system.

Section 2-2: Symbols

The assembly/packaging may have labels with one or more of the following symbols.

Table 2-2: List of symbols used in the x-ray tube assembly and/or packaging.

Symbol	Standard Description	Symbol	Standard Description
Class 1	Type of Protection against Electrical Shock		Caution
	Compliance mark for Waste Electrical and Electronic Equipment Directive (WEEE)		Radiation Filter or Filtration (Permanent Filtration)
	Black: Manufacturer White: Date of Manufacture		Authorized representative in the European Community
	Temperature limits for shipment and storage		Compliance mark for Restriction of Hazardous Substances (RoHS) regulations for China (EFUP)
	Atmospheric pressure limitations for shipment and storage		REF: Model Number SN: Serial Number
	Fragile, Handle with care		Focal Spot: Large Focal Spot: Intermediate Focal Spot: Small
	This end up		Humidity limitations for shipment and storage
	General warning sign		Keep dry

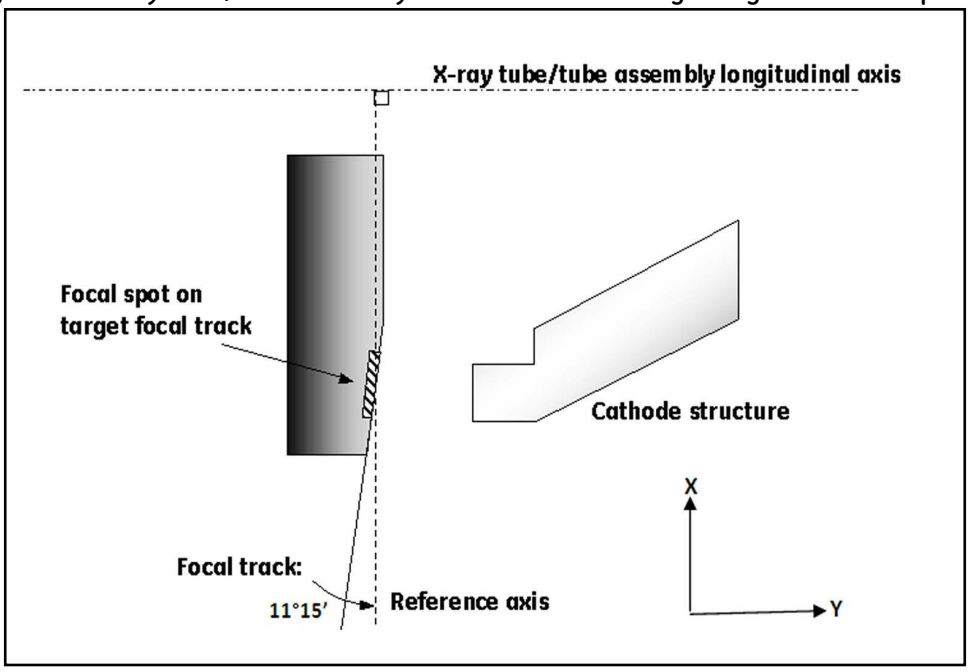
Chapter 3 X-ray Tube

Section 3-1: Description

This chapter contains a general description of the x-ray tube, which consists of a metal frame with a 160 millimeter (mm) diameter rotating anode.

The reference axis for the target angle and focal spot dimensions is normal to the longitudinal axis of both the x-ray tube and the x-ray tube assembly, and passes through the focal spot as shown in Figure 3-1.

Figure 3-1: X-ray Tube/Tube Assembly Reference Axis for Target Angle and Focal Spots



Refer to Figure 4-4 for electrical connections of the x-ray tube. The x-ray tube is grid controlled.

Section 3-2: Specifications

Table 3-1: X-ray Tube Specifications

Subject	Specifications	Reference Standards[1]
Target Material	Tungsten-Rhenium focal track on a molybdenum alloy substrate backed by graphite	IEC 60601-2-28
Nominal Anode Input Power[2]	112.9 kW (Large FS) 55.8 kW (Intermediate FS) 20.0 kW (Small FS)	IEC 60613:2010
Maximum Anode Heat Content	2740kJ (3.70MHU)	IEC 60613:2010
Nominal Focal Spots - Small Focal Spot[3]	0.3	IEC 60336:2005
Nominal Focal Spots - Intermediate Focal Spot[3]	0.6	IEC 60336:2005
Nominal Focal Spots - Large Focal Spot[3]	1.0	IEC 60336:2005
Target Angle with Respect to the Reference Axis[4]	11°15'	IEC 60601-2-28
Anode Rotation (Anode Drive Frequency)	130Hz +0Hz/-10Hz (7800rpm+0rpm/-600rpm)	IEC 60601-2-28
X-ray Tube Minimum Inherent Filtration[5]	0.01mm Al/70kV	IEC60601-1-3
Anode Heating and Cooling Curves	See Figure 3-2	IEC 60613:2010
Single Load Ratings	See Table 3-2, Table 3-3 and Table 3-4	IEC 60613:2010
Serial Load Ratings	See Table 3-5, Table 3-6 and Table 3-7	IEC 60613:2010
Cathode Emission Characteristics (Filament Emission Curves)	See Figure 3-3, Figure 3-4, Figure 3-5 and Figure 3-6	IEC 60613:2010

1. Reference standard means that compliance with this standard is confirmed.
2. The Continuous Anode Input Power is shown for an equivalent anode input power of 100W.
3. Electron emission from the 0.6 focal spot is controlled by grid up to 125 kV at Vg1 = -370 +/- 6%.
4. The reference axis is normal to the longitudinal axis of the x-ray tube.
5. Determined according theoretical method of calculating from BIRCH and MARSHALL.

3-2.1 Identification Labeling

The x-ray tube assembly labels identify the manufacturer, model number and serial number of the x-ray tube assembly and the x-ray tube, in compliance with IEC Standard 60601-2-28.

This marking is designed to remain legible when the x–ray tube is removed from the x–ray tube assembly after a period of normal use.

Section 3-3: Curves and Charts

This section contains the curves and charts referenced in Table 3-1.

Figure 3-2: : X-Ray Tube Anode Heating and Cooling Curve (X-Ray performances can be limited by associated systems)

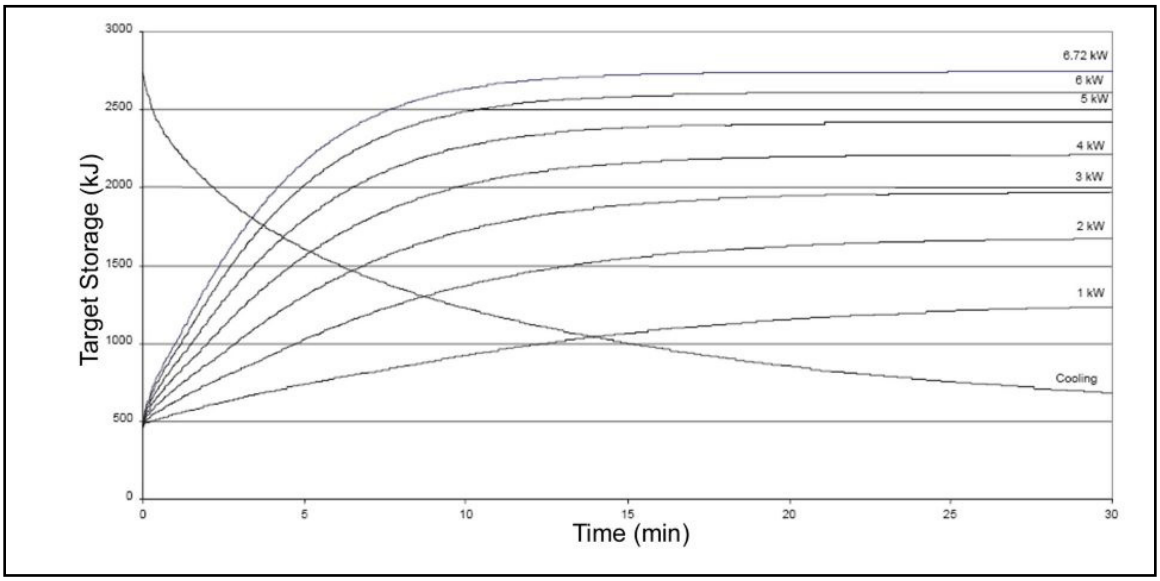


Table 3-2: Single Load Rating - Small Spot: 0.3

POWER (kW)	EXPOSURE TIME (s)
20.0	0.01
18.9	0.05
18.3	0.1
17.6	0.2
16.7	0.5

Table 3-3: Single Load Rating - Intermediate Spot: 0.6

POWER (kW)	EXPOSURE TIME (s)
55.8	0.01
50.6	0.05
47.3	0.1
43.2	0.2
39.3	0.5

Table 3-4: Single Load Rating - Large Spot: 1.0

POWER (kW)	EXPOSURE TIME (s)
112.9	0.01
97.0	0.05
86.9	0.1
75.3	0.2
63.6	0.5

Note: Maximum series run time assumes series starts with 80% of a node storage available.

Table 3-5: Serial Load Rating - Small focal spot: 0.3 (results are Run-Time in seconds)

EXPOSURE TIME (s)	FRAME RATE (frames/s)	POWER (kW)		
		12	14	16
0.02	10	600	600	213
	7.5	600	600	325
	4	600	600	600
	1	600	600	600
0.05	10	287	117	28
	7.5	498	186	56
	4	600	523	167
	1	600	600	600
0.1	10	80	23	1
	7.5	131	47	3
	4	394	150	35
	1	600	600	353

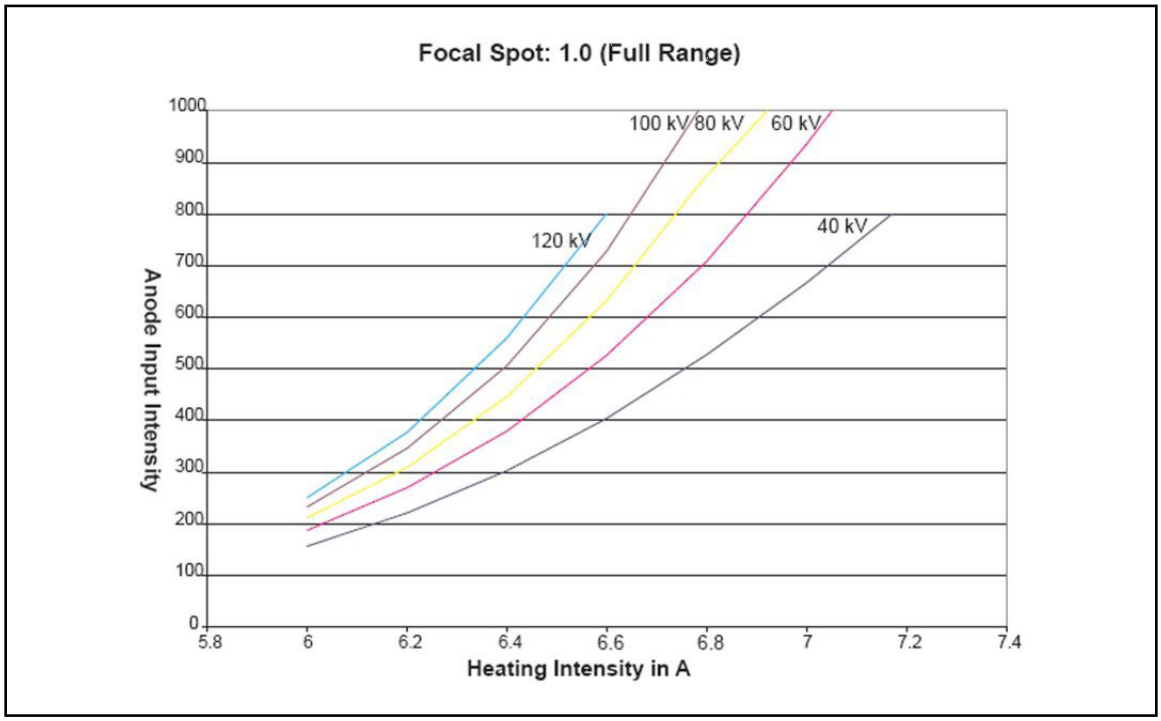
Table 3-6: Serial Load Rating - Intermediate focal spot: 0.6 (results are Run-Time in seconds)

EXPOSURE TIME (s)	FRAME RATE (frames/s)	POWER (kW)		
		20	30	40
0.02	10	600	565	104
	7.5	600	600	161
	4	600	600	429
	1	600	600	600
0.05	10	329	82	7
	7.5	600	134	18
	4	600	429	78
	1	600	600	600
0.1	10	96	14	0
	7.5	163	31	1
	4	600	108	8
	1	600	600	147

Table 3-7: Serial Load Rating - Large focal spot: 1.0 (results are Run-Time in seconds)

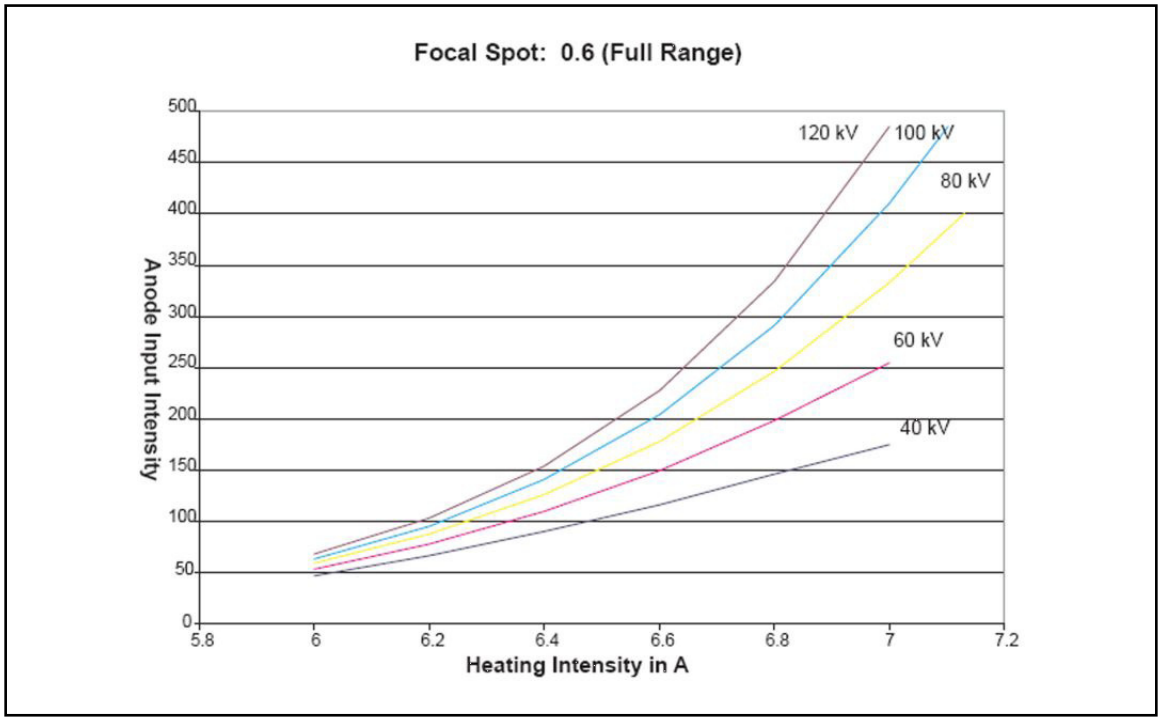
EXPOSURE TIME (s)	FRAME RATE (frames/s)	POWER (kW)		
		60	80	100
0.02	10	139	27	0
	7.5	229	51	0
	4	600	149	3
	1	600	600	95
0.05	10	14	0	0
	7.5	32	2	0
	4	113	12	08
	1	600	172	0
0.1	10	1	0	0
	7.5	3	0	0
	4	20	0	0
	1	252	13	0

Figure 3-3: Cathode Emission Curves: Large Focal Spot (112.9kW)



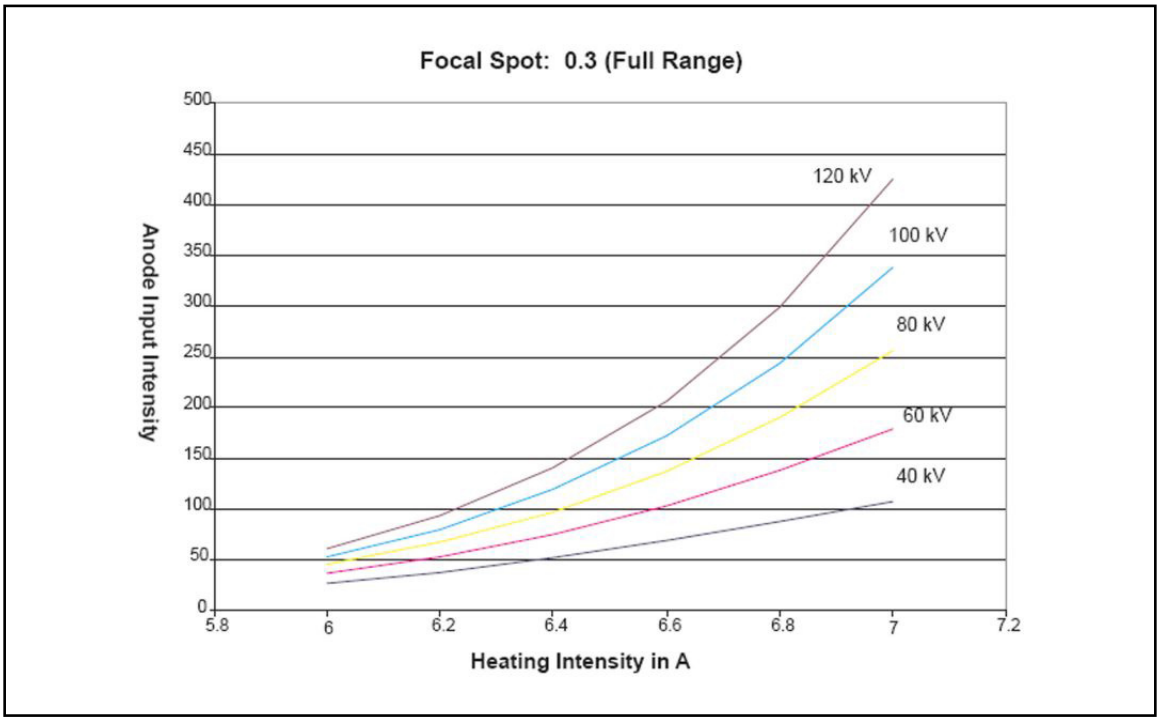
Note: The anode Input Intensity is in mA.

Figure 3-4: Cathode Emission Curves: Intermediate Focal Spot (55.8kW)



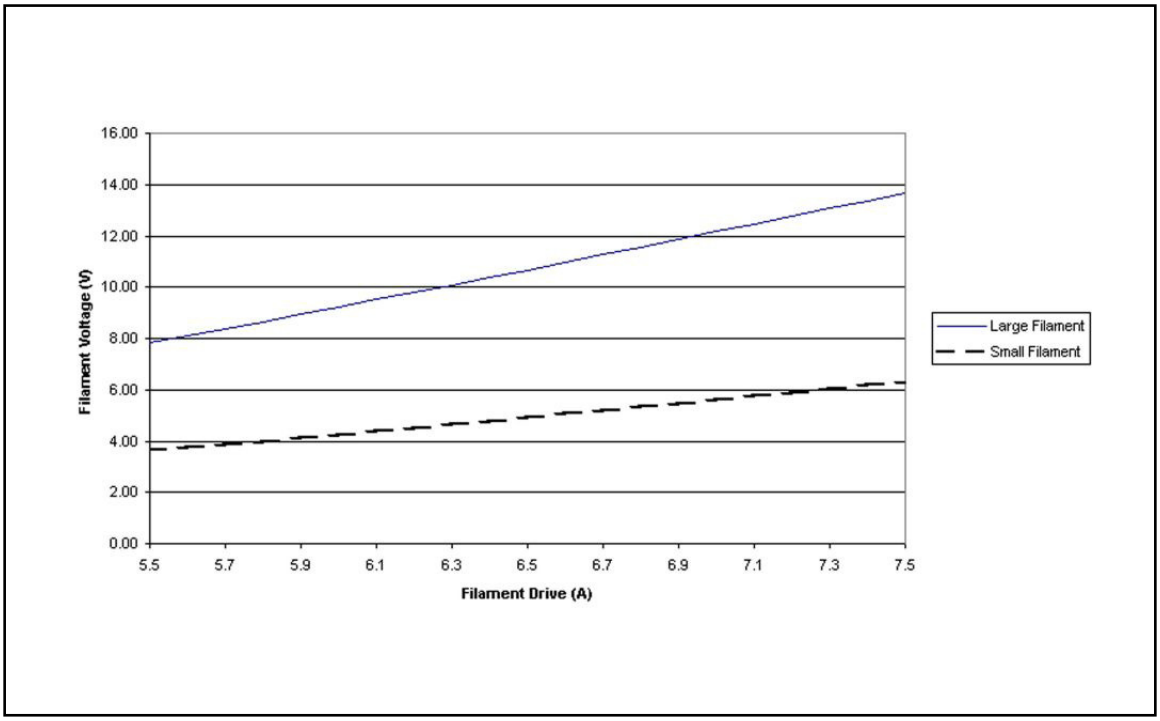
Note: The anode Input Intensity is in mA.

Figure 3-5: Cathode Emission Curves: Small Focal Spot (20.0kW)



Note: The anode Input Intensity is in mA.

Figure 3-6: Typical Voltage/ Current Curves



Chapter 4 X-ray Tube Assembly

Section 4-1: Description

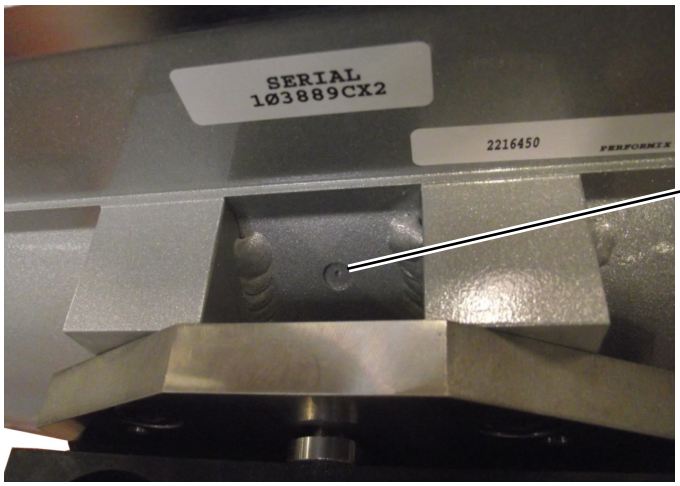
The X-Ray tube assembly is configured mechanically and electrically to operate in GE Healthcare vascular systems. When applicable, the x-ray tube assembly also carries labels to certify compliance with regulation of addressee states (US Federal Regulation 21 CFR Sub-Chapter J, UL, CSA and CE Marking).

The x-ray tube assembly is shipped with mounting hardware for installation on the GE Healthcare vascular system. For installation instructions, please refer to the appropriate GE Healthcare vascular system service manual.

Figure 4-1: X-Ray Tube Assembly label locations - Example shown for 2216500

1	English and Chinese Rating plate	4	WEEE Labels
2	Cathode (-) Label	5	RoHS
3	CE Mark	6	Anode (+) Label

Figure 4-2: Focal Spot location - Example shown for 2216500



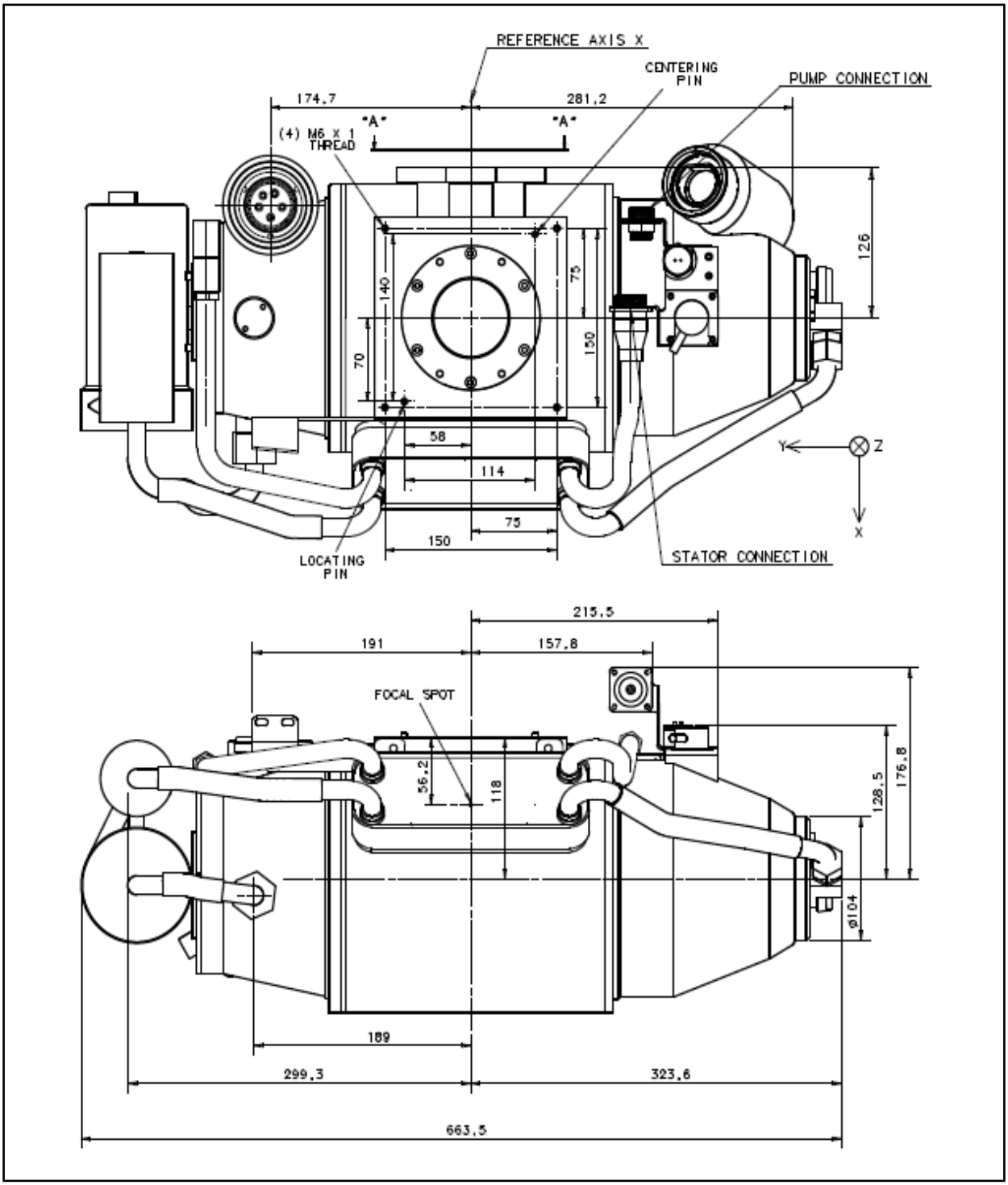
7 Focal Spot localization

Note: The focal spot localization mark is engraved on the X-ray Tube assembly.

The position of the focal spot within the x-ray tube assembly is shown in Figure 4-3.

Principal dimensions (height, width, depth) are also shown in Figure 4-3. All dimensions are in millimeters. The focal spot position is engraved on the X-ray Tube housing.

Figure 4-3:X-Ray Tube Assembly Focal Spot Location and Principal Dimensions



Section 4-2: Specifications

Table 4-1: X-ray Tube Assembly Specifications

Subject	Specifications	Reference Standards[1]
Non-Operating Environment - Temperature Limits for Shipment and Storage	-40°C to +70°C	IEC 60601-2-28 YY/T 1099-2007
Non-Operating Environment - Relative Humidity (RH) Limitations for Shipment and Storage	5% to 95% RH	IEC 60601-2-28 YY/T 1099-2007
Non-Operating Environment - Atmospheric Pressure Limitations for Shipment and Storage	50kPa to 106kPa	YY/T 1099-2007
Operating Environment - Temperature Limits for Operation	+10°C to +40°C	YY/T 0609-2007 IEC60601-1
Operating Environment - Relative Humidity Limitations for Operation	≤ 75% RH non-condensing	YY/T 0609-2007 IEC60601-1
Operating Environment - Atmospheric Pressure Limitations for Operation	700hPa to 1060hPa	YY/T 0609-2007 IEC60601-1
Loading factors concerning leakage radiation	125 kV, 25.6 mA	IEC 60601-1-3 IEC 60601-2-28 21 CFR 1020.30(h)(2)
Maximum Leakage Radiation from X-ray Tube Assembly	≤ 50mR/hr	IEC 60601-1-3 IEC 60601-2-28 21 CFR 1020.30(h)(2)
Permanent Filtration, Total Filtration[2]	1.0mm Al/70kV	See Note 2.
Type of Protection Against Electrical Shock	Class 1	IEC 60601-2-28:2010 IEC 60601-2-28:1993
Reference Axis for Target Angle and Focal Spots	See Figure 3-1	IEC 60601-2-28
Focal Spot Location and Principal Dimensions	See Figure 4-3	IEC 60601-2-28:2010 IEC 60601-2-28:1993
Start-up Time of Rotating Anode (Acceleration)	Stop to fluoro (need 12 Hz running speed) ≤ 2 s Stop to record (need 125 Hz run speed) ≤ 10 s	IEC 60601-2-28
Nominal Tube Voltage	125kV	IEC 60613
Mass of X-ray Tube Assembly	54 ± 1 kg	IEC 60601-2-28
X-ray Tube Assembly Heating and Cooling Curves	See Figure 4-5	IEC 60613:1989 21 CFR 1020.30(h)
Nominal Continuous Input Power of X-Ray Tube Assembly	4kW	IEC 60613:2010 IEC 60613:1989
X-ray Tube Assembly Heat Content (Heat Storage Capacity)	5.14MJ (6.94 MHU)	IEC 60613:1989
Size of radiating field 1 meter away from focal spot	Ellipse at 0° tilt: 82.82cm in X-direction, 61.44cm in Y-direction The area of the ellipse that the beam creates: 3996.47cm2	YY/T 0609-2007

Subject	Specifications	Reference Standards[1]
Power of X-ray Tube Assembly	112.9kW (Large Focal Spot) 55.8kW (Intermediate Focal Spot) 20.0kW (Small spot)	YY/T 0609-2007

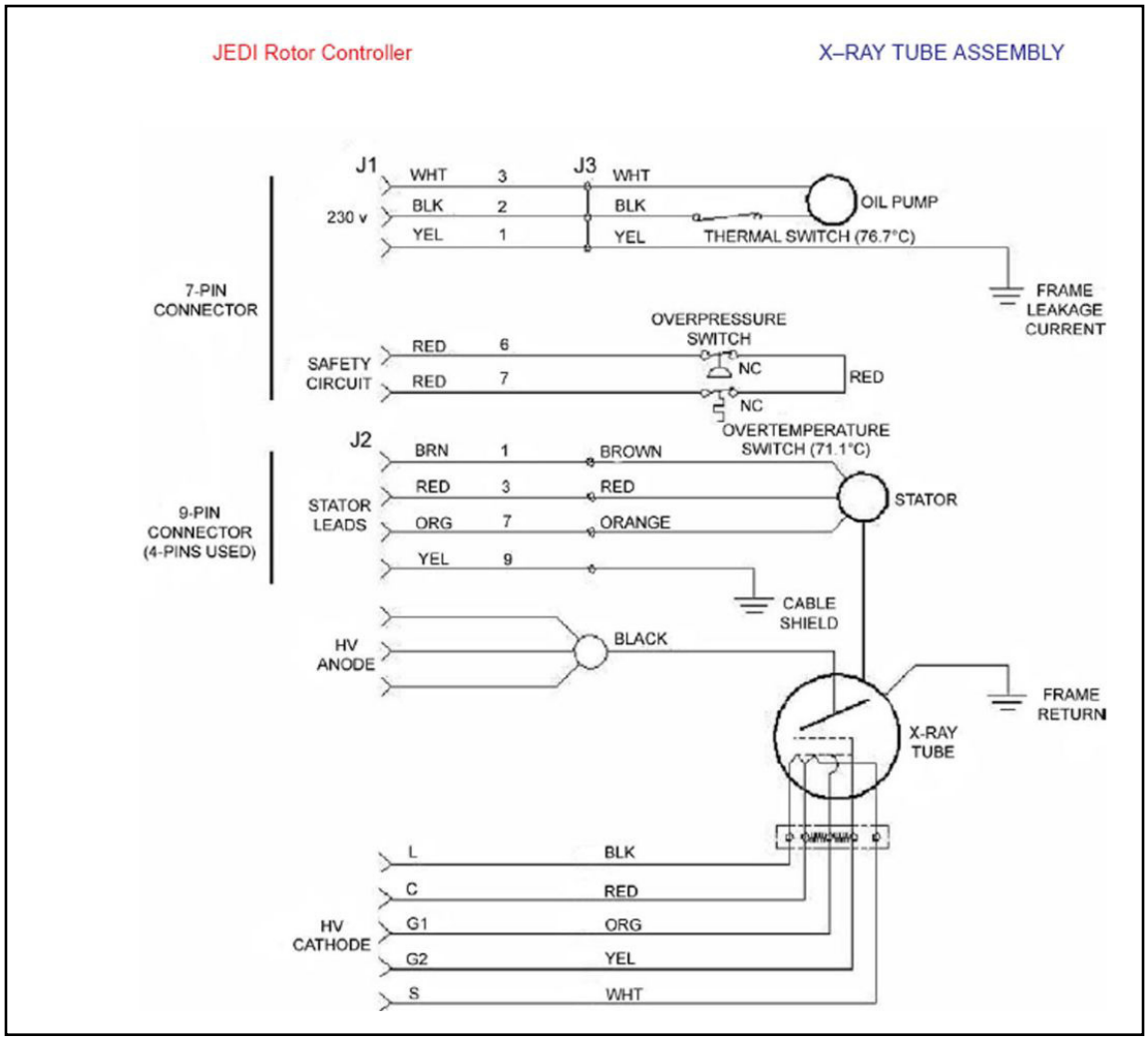
1. Reference standard means that compliance with this standard is confirmed.
2. Determined according to the theoretical method of calculating of Birch and Marshall.

4-2.1 High Voltage (HV) and Electrical Connections

The x-ray tube assembly is a bipolar x-ray tube assembly. The anode (+) and cathode (-) high voltage cables are connected to the x-ray tube assembly with 3-conductor and 5-conductor connectors. This x-ray tube assembly is designed for use with the GE Healthcare vascular high voltage generator. For a complete list of generator identifications, please refer to the appropriate system documentation.

The accessible metal parts of the x-ray tube assembly body and flexible conductive housing of high-voltage cables must be connected to the conductive enclosure of the high voltage generator. For detailed HV connection installation instructions, see the associated GE Healthcare vascular system service manual.

Figure 4-4: X-ray Tube Assembly Connection Diagram



4-2.2 Construction

The X-ray tube assembly consists of two basic components: the X-ray tube and its lead-lined light alloy housing. The X-ray tube is also called an insert because it is mounted inside the housing. The Performix™ 160 A X-Ray Tube consists of a cathode and a rotating anode enclosed under a vacuum metal frame. The housing is filled with specially processed insulating oil. The assembly also provides mounting brackets, a pump for oil circulation, heat exchangers using water cooling system.

Refer to Figure 4-3 for the x-ray tube assembly principal dimensions.

4-2.3 Electrical Specifications

4-2-3.1 Power Supply

The maximum x-ray tube voltage between poles is 125kV peak value, on a rectified or constant voltage generator balanced relative to ground. The x-ray tube assembly is originally designed for use with a GE Healthcare HV generator with an allowable output voltage range of 40kV to 125kV and voltage variation of ± 3,2%. The power capacity of the GE Healthcare HV generator is not greater than 100kW. In addition, the GE Healthcare HV generator provides a voltage of 250Vrms±10% to rotate the anode at approximately 130Hz during clinical scanning. For a complete list of generator identifications, please refer to the appropriate system documentation.

During clinical use, the x-ray tube assembly voltage ranges from 40kV to 125kV. The x-ray tube assembly has an over-voltage limit of 138kV, 0mA for at least a 3 minute test duration. This voltage represents 110% of the maximum operating voltage.

4-2-3.2 Type Designations of Suitable Anode Rotor Driving and Control Equipment

The X-ray tube assembly is designed for use only with the Rotor Controller of the GE Healthcare Vascular System high voltage generator.

Please consult the appropriate system manual for a complete list of compatible high voltage generators.

4-2-3.3 Beam Limiting Devices

The Performix™ 160 A X-Ray Tube Assembly must be equipped with beam-limiting devices. The Performix™ 160 A X-Ray Tube Assembly must not be used as X-Ray source assembly as standalone. It should always be used with the appropriate beam-limiting device in order to meet requirements for the largest X-Ray beam required for its specified applications.

The beam-limiting devices compatible with the x-ray tube assembly are listed in the appropriate system manual.

Any x-ray tube assembly having beam limiting devices other than those listed in the appropriate system documentation is obliged to be checked by qualified personnel for compliance examination for beam quality and leakage radiation according to the requirements of IEC Standard 60601-1-3 and 21 CFR 1020.30(k)(m).

4-2-3.4 Pressure and Thermal Management

The X-Ray Tube Assembly is equipped with a safety loop and a pressure sensitive switch connected in series with a normally closed (nc) contact. The pressure-sensitive switch actuates at 5 psi +/- 1 psi.

The thermostat actuates at 71.1°C +/- 2.8°C.

The actuation of the thermal switch at 76.7°C +/- 2.8°C makes the oil pump stop.

4-2-3.5 Cooling Method & Power Requirement

An insulated oil circuit cools the X-Ray Tube Assembly.

The oil cooling system is composed of the following:

- **Plate Heat Exchanger**

  This is located outside the X-Ray Tube Assembly and consists of several stainless steel plates brazed together with copper.

  The principle is based on two independent sealed circuits each carrying a different fluid in opposite directions. In the Performix™ 160 A, one fluid is oil from the X-Ray Tube Assembly to be cooled while the other fluid is water from an external cooling source maintained at stable temperature.

  Recommended conditions at the water inlet of the heat exchanger: Minimum flow rate: 8.5 liters/min and maximum temperature: 26°C.

- **Oil-Circulating Pump**

  A centrifugal pump circulates the oil.

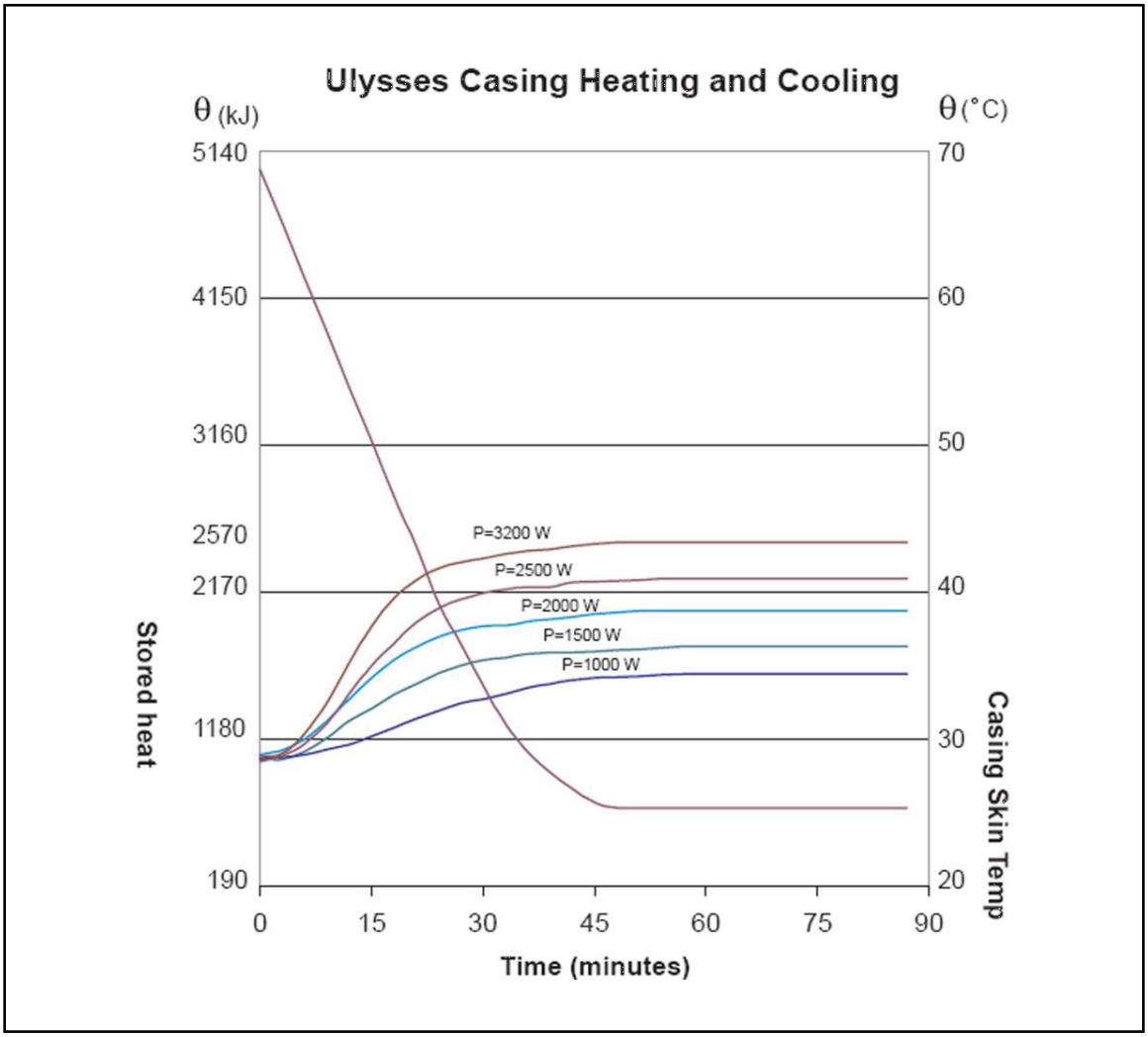
  - Electrical characteristics: 230 V, 1.7 A
  - Flow rate when connected to the X-Ray Tube Assembly and heat exchanger is 252cm3/s at 138 kPa @ 60 Hz.

CAUTION **The x-ray tube assembly may become hot during extended operation. To prevent injury, allow the x-ray tube assembly to cool for at least three hours without operating before attempting to work on the x-ray tube assembly.**

Section 4-3: Curves and Charts

The cooling curve in Figure 4-5 reflects the maximum tube performance. The individual GE Healthcare vascular system software ultimately limits x-ray tube assembly operation. The applied power in the heating curves does not include stator, filament, and pump power.

Figure 4-5: X-ray Tube Assembly Heating and Cooling Curves (based on anode input power)



Section 4-4: Environmental Health & Safety (EHS) Information

The x-ray tube assembly contains potentially hazardous materials, but does not present any danger as long as it is neither opened nor disassembled.

WARNING **DO NOT DISCARD THE X-RAY TUBE ASSEMBLY WITH INDUSTRIAL WASTE OR DOMESTIC GARBAGE. FOLLOW LOCAL GUIDELINES TO RETURN THE X-RAY TUBE ASSEMBLY TO THE DESIGNATED GE HEALTHCARE FACILITY.**

WARNING **TO PREVENT UNINTENDED CONTACT WITH HAZARDOUS MATERIALS, A DAMAGED X-RAY TUBE ASSEMBLY SHOULD NOT BE DISPATCHED THROUGH THE NATIONAL POSTAL SERVICE.**

Your local GE Healthcare field service will advise you on the suitable means of disposal. The x-ray tube assembly to be discarded should be forwarded to the GE Healthcare Service network, and it will be disposed of in a GE Healthcare recycling center.

4-4.1 Hazardous Materials

The x-ray tube assembly contains the following potentially dangerous materials:

Lead (Toxic):

- Lead salts are toxic and their ingestion may cause serious problems. The working of lead is subject to regulations.

Oil (Non-Toxic):

- Univolt 54 or Crosstrans 206 or Electrol B or Shell Diala S3 ZX-IG or equivalent mineral oil are not toxic, but the prevailing environmental regulations should be observed for their disposal or recuperations. For example, it is forbidden to dispose of these oils in the wastewater or sewage system or in the natural environment.

4-4.2 Precautions

Take all the necessary precautions for the personnel handling the recovery or destruction of x-ray tube assemblies, and in particular against the risks due to lead. These personnel must be informed of the danger involved and of the necessity to observe the safety measures.

Section 4-5: CFDA Regulatory Requirements

Table 4-2 highlights the individual CFDA regulatory status for each x-ray tube assembly identified in this manual. For a complete list of registered system types, please consult the system sales representative.

Table 4-2: Regulatory status of each X-ray Tube Assembly

X-ray Tube Assembly Model Number	Product Registration Standard (PRS) No.	CFDA Certification No.
D2801A (2216500)	YZB/USA 1404-2014	CFDA(I) 20142311789

Note: Table 4-3 shows the list of GE Healthcare vascular systems used in China along with the corresponding X-ray Tube Assembly used on the system in China.

Table 4-3: GE Healthcare vascular Systems with corresponding X-ray Tube Assembly used on that system

GE Healthcare vascular System Model	X-ray Tube Assembly used on system in China
Innova 2100-IQ	2216500
Innova 3100-IQ	2216500
Innova 4100-IQ	2216500
Innova 2121-IQ	2216500
Innova 3131-IQ	2216500

Section 4-6: X-ray Tube Assembly Manufacturer Address

Manufacturer (Made for):

GE Medical Systems, LLC
4855 West Electric Avenue
Milwaukee, WI 53219
USA

Manufactured at (Made by):

GE MEDICAL SYSTEMS SCS
283 RUE DE LA MINIERE
78530 BUC FRANCE

Note: Abbreviations for addresses may be used in this manual or on product labeling to identify the made for and made by addresses. Example: West may be abbreviated as W. and/or Avenue may be abbreviated as Ave.

Chapter 5 Maintenance & Troubleshooting

Section 5-1: Renewal Parts

To order a replacement x-ray tube assembly, please contact your GE Healthcare Sales or Service representatives with the catalog numbers shown in Table 5-1.

Table 5-1: X-ray Tube Assembly Catalog Part Numbers

Catalog Number	X-ray Tube Assembly Model Number
D2801A	2216500

Section 5-2: Routine Maintenance

Refer to the applicable GE Healthcare vascular system Service Manual for details on Routine Maintenance.

Section 5-3: Troubleshooting

For troubleshooting the x-ray tube assembly and diagnosing specific issues that may occur during system operation, consult the applicable system service documentation.

Section 5-4: Packaging

Use GE Healthcare transport packaging during shipment and storage. Commercial airline shipment is permissible.

China Post-sales Service Agent:

GE Medical Systems trade & Development (Shanghai) Company, Ltd.
Building 1, 96 Yiwei Road, Wai Gao Qiao Free Trade Zone
Shanghai 200131, China
+(86) 800-810-8188

Authorized representative for Europe/European registered place of business:

GE MEDICAL SYSTEMS SCS
283 RUE DE LA MINIERE
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