SV Product Family

Function Description

X-ray Tube Assembly

SV 150/40/80C-100; 100L; 100F; 100LF

SIEMENS Healthineers

Document Version

Siemens Healthcare GmbH reserves the right to change its products and services at any time.

In addition, manuals are subject to change without notice. The hardcopy documents correspond to the version at the time of system delivery and/or printout. Versions to hardcopy documentation are not automatically distributed.

Please contact your local Siemens Healthineers office to order a current version or refer to our website http://www.siemens-healthineers.com.

Disclaimer

The contents of this document may be published under a system integrator's/ manufacturer's label, but it is the sole responsibility of the system integrator of the finished medical device that content and safety measures described within this document are maintained and clear to the end user. The system integrator is responsible for translations of this document and to provide the language versions that might be required under country specific regulations. These components and configurations are not finished medical devices. The system integrator is responsible for complying with all laws and regulations that are applicable to finished medical devices with respect to marketing, sales and installation.

Copyright

1 Introduction

1.1 General Information

1.1.1 Product Information

This Instruction for Use applies only to X-ray tube assemblies with double-focus rotating anode of the SV product family and was prepared on the basis of the applicable German and international standards, see section “Laws, Standards, and Regulations”.

In this document the X-ray tube assembly SV 150/40/80C-100; 100L; 100F; 100LF is generally described.

This X-ray tube assembly consists of a metallic (e.g. steel, aluminum alloy) case that hous- es an X-ray tube to provide appropriate limits for X-ray leakage and adequate insulation to avoid electric risks during a diagnostic X-ray procedure. It includes sheet lead surrounds at appropriate locations to shield unwanted X-ray radiation and collimators near the aperture; it is usually filled with oil to prevent electrical arcs from the high-voltage components of the X-ray tube. The housing also includes attachment points, cooling means, high-voltage cables, and supports for the tube and cable receptacles..

Features

- Long-term high dose yield
- Single-angle composite anode with graphite
- Focal spots are superimposed
- Compact tube assembly housing

1.1.1.1 Types of X-ray tube assemblies

Table 1 Types of the X-ray tube assemblies

Type	Model No.
SV 150/40/80C-100	4802349
SV 150/40/80C-100L	4803263
SV 150/40/80C-100F	11270466
SV 150/40/80C-100LF	11270460

Table 2 Protection class of the X-ray tube assemblies

Standard	Protection class
X-ray tube assembly according to IEC 60601-2-28:1993	Class I Type B
X-ray tube assembly according to IEC 60601-2-28:2017	Class I

1.1.1.2 Type Coding

Table 3 Legend of naming

Naming	Meaning
-100	Housing for tubes with anode disk diameters of 100 mm, 3-phase drive and standard collimator interface.
-100L	Housing for tubes with anode disk diameters of 100 mm, 1-phase drive and standard collimator interface.
-100F	Housing for tubes with anode disk diameters of 100 mm, 3-phase drive and collimator interface with thread
-100LF	Housing for tubes with anode disk diameters of 100 mm, 1-phase drive and collimator interface with thread
150	Nominal voltage 150 kV
40	Nominal input power of small focus F1: 40 kW
80	Nominal input power of large focus F2: 80 kW
C	Graphite composite anode.
SV	SV product family.

1.1.1.3 Intended Purpose

The X-ray tube assemblies SV 150/40/80C-100; 100L; 100F; 100LF are intended to be used in diagnostic X-ray systems for radiographic and fluoroscopic applications.

- The X-ray tube assembly must be used only according to its intended purpose; the notes in the operator manual of the equipment manufacturer for the operation and maintenance of the X-ray tube assembly apply.

1.1.1.4 Intended User

Information with regard to intended user: X-ray tube assemblies are intended to be integrated into diagnostic X-ray systems by a system integrator, for whom it is required to have specific technical and medical knowledge and skills, including but not limited to radiation protection, electrical and mechanical safety and clinical procedures for which the finalized system is released. Integrated into the diagnostic X-ray system, X-ray tube assemblies are intended to be operated by adequately trained clinical users. Instructions for use of these devices address exclusively the system integrator and are not intended being handed over to the clinical operators. All information and advices for the clinical operator are to be included in the instruction for use and accompanying documents of the finished diagnostic X-ray system in which the X-ray tube assembly is integrated.

1.1.1.5 Improper Use

- The use of the X-ray tube assembly is prohibited if any mechanical, electrical or radiation-related damage is detected.
- The X-ray tube assembly is equipped with devices for monitoring certain operating parameters to prevent an overload or damage of the X-ray tube assembly, if necessary. Any manipulation of these security devices is prohibited.
- The load limit values listed in this operator manual must not be exceeded.
- The operation of the X-ray tube assembly is not permitted in environment with inflammable gas mixtures.

1.1.1.6 Essential performance

The entity X-ray tube assembly itself does not have essential performance. Whether char- acteristics of an X-ray tube assembly shall be considered essential performance, depends on the X-ray system and high-voltage generator characteristics combined with the X-ray tube assembly.

1.1.2 Document Information

1.1.2.1 Purpose of this Document

This document is supposed to serve as input for authoring the system manual. It is not intended as a manual for the end-user.

This document provides the necessary information for installing, starting up, adjusting, servicing, and maintaining the SV 150/40/80C-100; 100L; 100F; 100LF X-ray tube assemblies. The instructions are designed for the engineer integrating the X-ray tube assembly into the system and transferring all data to the system operator manual.

1.1.2.2 Text Layout

Note:

Example of a Note

A note emphasizes important information without there being any direct danger and helps you to operate the product properly and to avoid errors. It also provides additional useful explanations about a subject..

How Safety Information Is structured:

NOTICE
Cause/Source of danger. **Possible consequnces** • **Precautions or remedles**

Classification:

Warning	Indicates a hazard that if disregarded can cause death or serious in- jury.
Caution	Indicates a hazard that if disregarded can cause minor or moderate injury.
Notice	Indicates a situation that if disregarded can cause damage to the product or something else in your environment

The following are pictograms and their meanings as they may apply to your product (IEC standard):

Pictograms:

Torque: Note about a threaded connector with a torque value.

Voltage: Dangerous electrical voltage > 25 V AC or > 60 V DC.

Large Focus

Small Focus

1.1.2.3 Illustrations

All illustrations of the equipment in this document are examples only.

Differences in detail may occur in your product due to the installed options, configurations and constant development of the product.

Reproduction of images can cause loss of detail.

Pictures in this document do not therefore provide any indication of the image quality

1.1.2.4 Value Statements

All technical data are typical values unless specific tolerances are stated.

1.1.2.5 Original Language

This document was originally written in English.

1.1.3 Acronyms and Abbreviations

CFR	Code of Federal Regulations
EMC	Electromagnetic Compatibility
ESD	Electrostatic Discharge
F1	Small Focus
F2	Large Focus
HU	Heat Unit
HV	High Voltage
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
OEM	Original Equipment Manufacturer
kV	Kilovolt
kW	Kilowatt
mA	Milliampere
XTA	X-ray Tube Assembly

1.1.4 General Statements

Unauthorized changes to this product are not allowed and compromise the safety and the performance of the product.

1.1.4.1 Quality System Regulations

The Siemens Healthcare Power & Vacuum Technology Center is ISO 9001 and ISO 13485 certified, manufactures in accordance with the Quality System Regulations (QSR) as de- fined by the U.S. Food and Drug Administration (FDA), and endeavors to comply with legal requirements concerning the environmental compatibility of its products.

1.1.4.2 Artifact Content

Siemens Healthcare GmbH reserves the right to modify the design and the specifications contained herein without prior notice. All rights reserved, particularly in connection with patent applications or registrations of utility model or design. This document is not considered to be a contractual specification. Kindly contact Siemens Healthcare GmbH prior to using this information for equipment design. The information in this document contains general descriptions of the technical options available, which do not always have to be present in individual cases. The required features should therefore be specified in each individual case at the time of closing the contract. The components are labeled as “Manufactured by Siemens Healthcare GmbH”. However, the buyer shall not market the components using the “Siemens Healthineers” brand name and/or trademark. The buyer may integrate these components into a system using its own brands and labels. The product names and/or brands referred to are the property of their respective trademark holders. This document shall not be made available to healthcare professionals or to the general public

1.1.5 Laws, Standards, and Regulations

This product has been manufactured and developed in agreement with the following laws, directives and design regulations:

- Council Directive RoHS directive 2011/65/EU with 2015/863 on the restriction of the use of certain hazardous substances in electrical and electronical equipment, following the requirement of standard IEC 63000:2016.
- ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes.
- ISO 14971:2007 Medical devices - Application of risk management to medical devices / Corrected and reprinted in 2007.
- 21 CFR Part 1020.30 Performance standard for ionizing radiation emitting products, (USA).
- 21 CFR Part 820 Quality System Regulation, (USA).
- International Electrotechnical Commission (IEC), the following standards are considered in particular:

Table 4 Laws, standards and regulations

Standard	Titel
IEC 60336:2005 + C1:2006 eq EU: EN 60336:2005	Medical electrical equipment -X-ray tube assemblies for medical diagnosis – Characteristics of focal spots
IEC 60522:1999 (equivalent to:2003) eq EU: EN 60522:1999	Determination of the permanent filtration of X-ray tube assemblies
IEC 60526:1978 + C1:2010 eq EU: EN 60526:2004	High-voltage cable plug and socket connections for medical X-ray equipment
IEC 60601-1:2012 +C1:2012 eq EU: EN 60601-1:2006 + AC:2010 + A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-3:2008 + A1:2013 eq EU: EN 60601-1-3:2008 + AC:2010 + A1:2013 + A11:2016	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-28:2017 eq EU: EN IEC 60601-2-28:2019	Medical electrical equipment - part 2-28: Particular require- ments for basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60613:1989 eq EU: EN 60613:1990	Electrical, thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis
IEC 60613:2010 eq EU: EN 60613:2010	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis
IEC 63000:2016 eq EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

If a standard is referenced without year, all versions listed in the table applied.

1.1.6 Adress Information

Legal manufacturer	Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen Germany
Address for further inquiries	Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen Germany Telephone: +49 9131 / 84-0 siemens.com/healthineers
Publisher for USA	Siemens Medical Solutions USA, Inc. 40 Liberty Boulevard Malvern, PA 19355-9998 USA Phone: +1-888-826-9702 usa.siemens.com/healthcare
Original language	English

1.2 Safety Information

NOTICE

Risk of improper use of the X-ray tube assembly.

When performing the work steps and checks, the general safety information for medical products must be observed.

- **Before handling the X-ray tube assembly, please carefully read the safety information contained in this document.**

1.2.1 Staff Qualification

The X-ray tube assemblies of the SV product family may only be operated by persons with the necessary special knowledge in accordance with the country specific regulations.

The X-ray tube assembly may be exchanged for safety reasons only by service personal of the manufacturer or by service personal trained by the manufacturer.

1.2.2 Safety Instructions for X-ray Tube Assemblies

The following safety information must be followed!

CAUTION

X-ray tube assembly works outside of specification.

Risk of injuries due to damaging of the X-ray tube assembly!

- **The X-ray tube assembly is to use only with specified ratings**
- **The X-ray tube assembly may be operated only with a connected overpressure switch**

WARNING

Wrong installation may cause death or serious physical injury.

Risk of electrical shock!

- **To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth**

CAUTION

Improper use by interrupted or reduced supply of cooling air.

Risk of injury, damage to property!

- **The X-ray tube assembly is only allowed to operate at locations with sufficient or specified air circulation. The air circulation may not be impaired**

CAUTION

Overpressure inside housing.

Risk of burns, damage to property!

- **The X-ray tube assembly is only allowed to operate with a connected pressure switch**

CAUTION

The housing temperature of the X-ray tube assembly can exceed 85 °C at maximum utilization of the X-ray tube assembly.

Risk of burns!

- **The operator must inform the patient prior to the examination that he or she must not touch the housing of the X-ray tube assembly, since this can become very hot during operation and lead to burns**

CAUTION

Breakage of the collimator flange if mechanical load is too high.

Risk of injury due to falling components!

- **The permissible weight load of the collimator flange of 300 N (30 kg; 66 lbs) must not be exceeded**

The X-ray tube assembly may be operated only in agreement with the safety instructions of this operator manual. The system owner is responsible for compliance with the regulations that apply for the installation and operation of an X-ray system.

For safety reasons the X-ray tube assembly may only be replaced by the service personnel of the manufacturer or by personnel trained by the manufacturer.

In extreme modes of operation there is a risk that the temperature of the X-ray tube assembly rises above 100 °C. For this case the X-ray tube assembly has an overpressure switch which shuts down the X-ray generator for safety reasons (pressure switch trigger level at 1.4 ± 0.05 bar, this corresponds to approximately 100°C). An examination that is in progress can then only be continued after the X-ray tube assembly has cooled down sufficiently. This case is to be avoided by corresponding operating pauses and observing the technical data, especially the maximum continuous heat dissipation of the X-ray tube assembly. The heat storage capacity of the X-ray tube assembly may not be exceeded under any circumstances.

Before using the equipment for examination, the user must ascertain that all safety-related devices on and for the tube assembly function correctly and that the product is ready for operation. If a cover panel is designated on the system side, the X-ray tube assembly may be only operated with an attached casing!

1.2.3 Cleaning and Disinfection

The X-ray tube assembly is not a sterile product. The housing surfaces are designed for easy cleaning (damp cloth). A disinfection of the X-ray tube assembly is possible. Use only agents that are approved in the system documentation (e.g. ethanol or isopropanol).

1.2.4 Radiation Protection

This product fulfills the requirements of IEC 60601-1-3, and US 21 CFR 1020.30. This Xray tube assembly emits X-ray radiation in operation. Only qualified and trained personnel is therefore allowed to operate the X-ray tube assembly, see also section “1.2.1Staff Qualification”.

1.2.5 Electromagnetic Compatibility (EMC)

Radio signals of radio-frequency communication devices such as mobile telephones or other mobile radio devices can influence the correct functioning of a medical- electrical device. This X-ray tube assembly is subject to special precautionary measures with regard to EMC and may be installed and put into operation only according to the installation instructions. All cables necessary for the connection are provided by Siemens Healthcare. Other cables may be used if the function of other cable types is approved. Correct func- tioning cannot be guaranteed if accessories other than the components sold by Siemens Healthcare are used and no release of these parts is available.

This medical electrical component cannot be operated on its own, but only in combination with a generator or a radiological diagnostic system. According to IEC standards the proof of compliance with the requirements of IEC 60601-1-2 with regard to electromagnetic compatibility should be provided by system manufacturer.

1.2.6 Maintenance

The X-ray tube assembly is maintenance free. There are no hazards whatsoever for persons and environment in the case of proper use. X-ray tube assemblies are not subject to repair activities but are exchanged as entity in case of need.

CAUTION

Qualification of service personnel insufficient.

Risk of injury due to electric shock!

- **Inspections (e.g. electrical checks and the protective conductor test) must be carried out exclusively by trained service personel**

1.2.7 Checks

The following checks must be performed at regular intervals. In the case of visible or re- ported damage don’t start the operation of the system.

The following inspections have to be carried out by the operator of the plant prior to the start of operation.

Visual check with the generator turned off:

- Check the X-ray tube assembly for external damage.
- Check the X-ray tube assembly for oil leakages daily.

Mechanical check with the generator being switched off

- Check the fastening of the freely accessible X-ray tube assembly. The X-ray tube assembly must be firmly seated in the holder - ensure that it is not loose!
- Check the fastening of the freely accessible collimator, the collimator must be firmly seated on the flange
  – ensure that it is not loose!
- Check all exposed high-voltage plugs to ensure that they are firmly seated, tighten the union nuts.

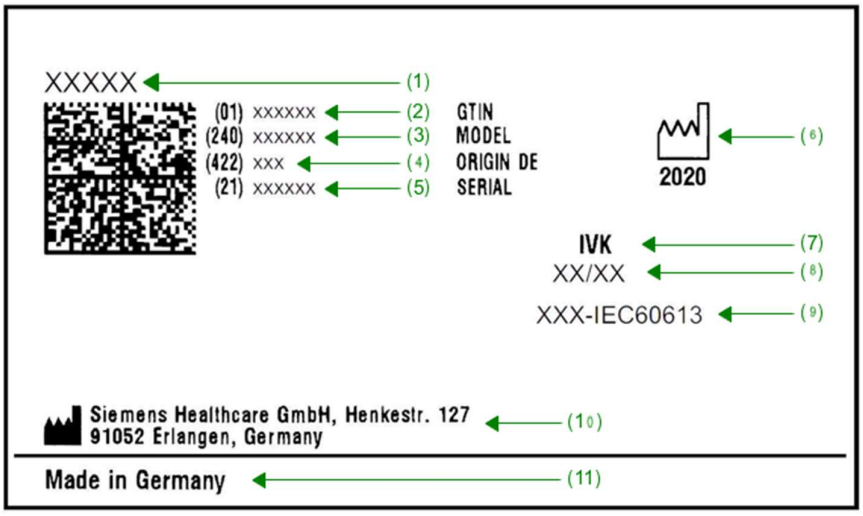
1.2.8 Labels and Pictograms on the Product

Table 5 Labels and pictograms

Label	Meaning
	Symbol for marking the anode of the high voltage cable inlets. A symbol for marking the high voltage cable inlet for the anode with positive sign. The symbol is at the corresponding inlet.
	Symbol for marking the cathode of the high voltage cable inlets. A symbol for marking the high voltage cable inlet for the cathode with negative sign. The symbol is at the corresponding inlet
	Symbol Caution - dangerous voltage The symbol “Caution - dangerous voltage” is attached in two places: 1 x on the connection plate and 1 x at the cover panel on the anode side of the X-ray tube assembly.
	Symbol earth conductor An earth conductor symbol is at the metal surface besides the connection point at the connection board on the anode side of the X-ray tube assembly.
	Follow Instruction for Use A symbol as an instruction for the customer to read the operator manual before using the X-ray tube assembly. It is on the opposite side of the HV cable inlet on the cathode side.
	UL label Medical-application electromagnetic radiation equipment with respect to electrical shock, fire and mechanical hazards only in accordance with: ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), CAN/ CSAC22.2 No. 60601-1 (2014), IEC 60601-1-3 (2013), CSA CAN/CSA-C22.2 No.60601-1-3-09 (2014) + AMD1 (2015), IEC 60601-1-6 (2013), CAN/CSA-C22.2 No. 60601-1-6A:11 + AMD1 (2015), IEC 60601-2-28 (2017), CAN/CSA-C22.2 No. 60601-2-28:12; E347424
	Symbol Caution - hot surface The symbol “Caution - hot surface” is attached on the housing.

1.2.8.1 Description of Identification Label for X-ray Tube Assembly

The type label of the X-ray tube assembly are described in the following figure:



(1) Product name

(2) Global trade identification number

(3) Model number

(4) Code of the country of the manufacturer

(5) Serial number

(6) Year of manufacturing

(7) Identifier of selected system components or parts for product traceability

(8) Minimum specified permanent filtration

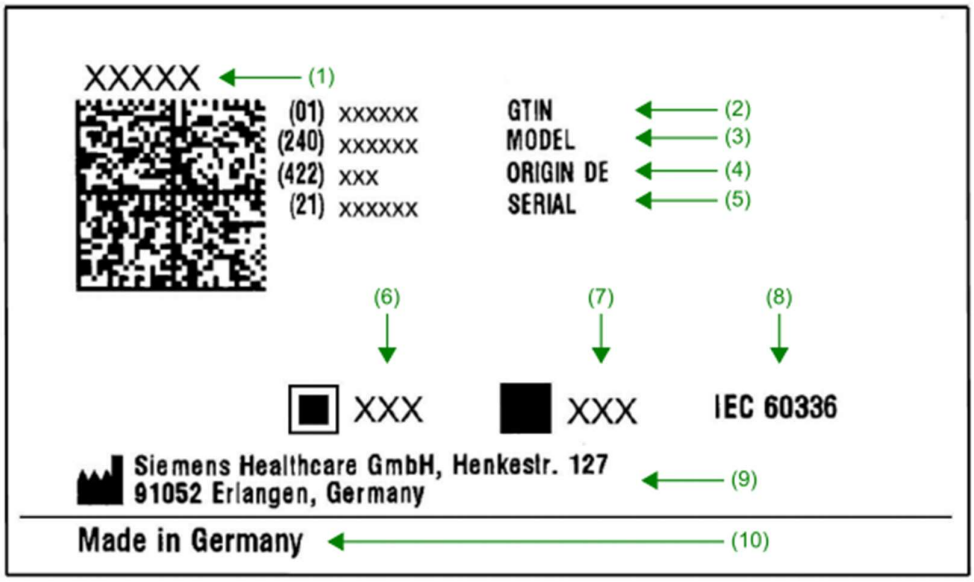
(9) Nominal input voltage

(10) Address of the manufacturer

(11) Country of the manufacturer

1.2.8.2 Description of Identification Label for X-ray Tube

The type labels of the X-ray tube are described in the following figure:



(1) Product name

(2) Global trade identification number

(3) Model number

(4) Code of the country of the manufacturer

(5) Serial number

(6) Nominal focal spot size small focus

(7) Nominal focal spot size large focus

(8) Standard for measuring focal spot

(9) Address of the manufacturer

(10) Country of the manufacturer

1.2.9 Disposal

CAUTION

Improper disposal due to user's lack of knowledge.

Risk of environmental pollution!

- **The manufacturer possesses the required technical knowledge and will take back the X-ray tube assembly for disposal**

The X-ray tube assembly as well as the tube contain materials such as oil and heavy metals for which environmentally friendly and proper disposal in accordance with the valid national legal regulations must be assured. Disposal as domestic or industrial waste is forbidden. The manufacturer possesses the required technical knowledge and will takes the X-ray tube assembly back for disposal. Please contact your Siemens Healthcare Customer Service for this purpose.

The manufacturer possesses the required technical knowledge and will take back the Xray tube assembly for disposal.

In the interest of complying with legal requirements concerning the environmental compatibility of our products (protection of natural resources, avoidance of waste) we endeavor to reuse components and to return them to the production cycle. Reused parts are qualified as good as new.

2 Technical Data

2.1 Specifications

All Information in the following table is according to:

IEC 60601-2-28

Property	Specification	
Focus	F1 ▣	F2 ■
Nominal focal spot value IEC 60336: 2005	0.6	1.0
Nominal anode input power for the equivalent anode input power of 300 W [1]	40 kW	80 kW
Nominal power (calculated) thermal anode reference power of 0 W [1]	52 kW	103 kW
Nominal radiographic anode input power IEC 60613:2017	47 kW	85 kW
Pulsed fluoroscopy		
Rotary frequency of the anode	50 ± 5 Hz	
Permissible nominal voltage	110 kV	
Pulse width / frame rate / pulse power	max. (7±0,5) ms / max. 30 f/s / max. 2.0 kW max. (15±1) ms/ max. 15 f/s / max. 2.0 kW max. (15±1) ms/ max. 7.5 f/s / max. 4.0 kW max. (15±1) ms/ max. 6.0 f/s / max. 4.0 kW max. (15±1) ms/ max. 4.0 f/s / max. 4.0 kW max. (15±1) ms/ max. 3.0 f/s / max. 8.0 kW max. (15±1) ms/ max. 2.0 f/s / max. 8.0 kW max. (15±1) ms/ max. 1.0 f/s / max. 8.0 kW max. (15±1) ms/ max. 0.5 f/s / max. 8.0 kW	
Anode heat storage capacity[1]	450 kJ (600 kHU)	
Maximum cooling capacity of the anode[1]	120 kJ/min 165 kHU/min	
Heating curve, cooling curve of the anode	See diagram in section “Heating and cooling curves of the anode”	
Single and series loading IEC 60613:2017	See diagram in section “Single-Load **Rating** and Serial Loading”	

Heat storage capacity of the X-ray tube assembly [1]		
Without fan		
▪ X-ray tube assembly horizontal or changed during the examinations	1 800 000 J = 2 530 000 HU	
▪ X-ray tube assembly only vertical	1 350 000 J = 1 900 000 HU	
With fan		
▪ X-ray tube assembly horizontal or vertical	1 800 000 J = 2 530 000 HU	
Heating and cooling curve of the X-ray tube assembly[1]	See diagram in section "Heating and cooling curves of the X-ray tube assembly"	
Continuous anode input power	**Ambient temperature**	
	20-25 °C	**40 °C**
▪ Without fan	200 W	130 W
▪ With fan	350 W	210 W
IEC 60613:2017		
Nominal continuous input power of the Xray tube assembly	**20-25 °C**	**40 °C**
▪ Without fan	300 W	230 W
▪ With fan IEC	450 W	310 W
IEC 60613:2017		
Maximum symmetrical radiation field	Maximum symmetrical radiation field (See figure in chapter Maximum radiation field)	
Anode focal track material	Tungsten-Rhenium	
Reference axis of the X-ray tube	Perpendicular to the tube axis	
Reference axis of the X-ray tube assembly	Perpendicular to the tube axis	
Anode angle (Ref: reference axis) X-ray tube and X-ray tube assembly	12°	
Permanent filtration of the X-ray tube assem- bly (+ additional filtration) IEC 60522 IEC 60601-1-3	1.5 mm Al / 75 kV + 1 mm Al[2]	
Nominal X-ray tube voltage IEC 60613 (2017)	150 kV	
Generator connection or supply units	see section "Staff Qualification"	

Data on cathode heating	≈ AC-voltage, < 20 kHz	
	F1	F2
	5.1 A	5.1 A
	11.9 V~	18.7 V~
Emission characteristics of the cathode IEC 60613 (2017)	See diagram in section “Emission Curves of the Cathode”	
Data on anode drive, Anode rotary frequency ▪ Exposure, cine pulse: ▪ series fluoroscopy: ▪ pulsed fluoroscopy:	150/180 Hz (approx. 8500 to 10800 rpm) 20 to 30 Hz (1200 to 1800 rpm) 45 to 55 Hz (2700 to 3300 rpm) Connection values for stator See section “Tube assembly connection plates”	
Maximum anode frequency	180 Hz	
Electrical connections and cables	See section “Connection diagram” and over pressure protection See also section “Oil Pressure Switch”	
Main dimensions and interfaces	See Dimensional drawings	
X-ray tube assembly weight	Approx. 26 kg	
Leakage radiation at 150 kV / 450 W in 1 m distance IEC 60601-1-3	≤ 0.8 mGy/h	
Information on auxiliaries	n.a. There are no auxiliaries Trunnion rings belong to system Fans belong to system	
High voltage connection + - IEC 60526:1978 + C1:2010	3-pin 3-pin	

[1] measured according to IEC 60613:1989

[2] The X-ray tube assembly is delivered with a permanent filtration of 1.5 mm Al and additional filtration 1 mm Al (two disks 0.5 mm Al). The additional filters are only removable or mountable with tools. If necessary the additional filter(s) can be dismounted by the manufacturer of the X-ray system. The total filtration is tested and labelled by the manufacturer of the X-ray system. The Al-filtration of the tube refers to 75 kV (IEC 60522).

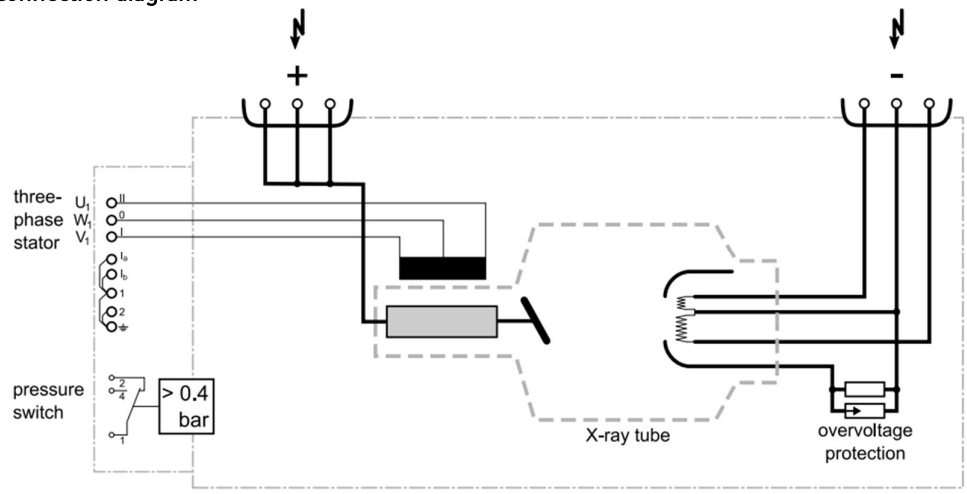
2.2 Environmental Conditions for Operation, Storage and Transport

	Operation	Transport and storage
Ambient temperature	10 °C to 40 °C	- 20 °C to + 70 °C
Relative Humidity	30 % to 75 %	10 % to 95 %
Barometric pressure	700 hPa to 1060 hPa	500 hPa to 1060 hPa

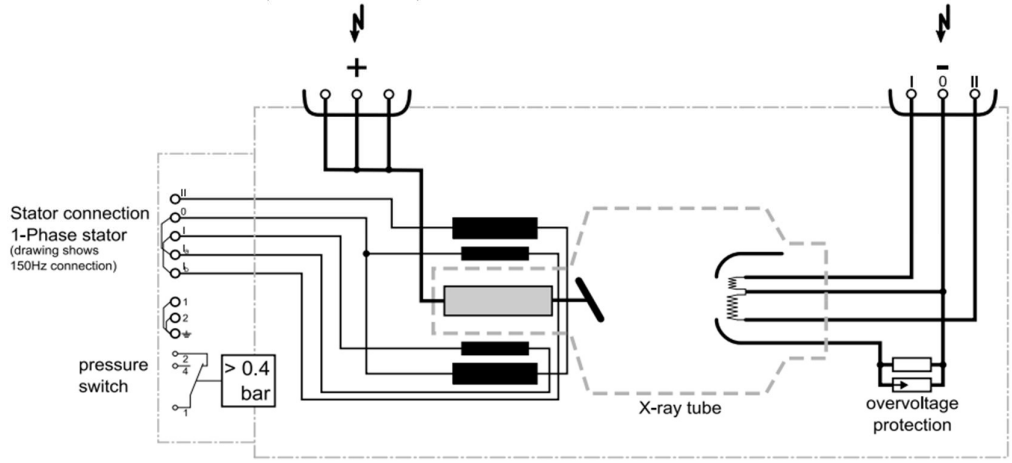
The specified ambient conditions must be maintained for such a time that no humidity is at the X-ray tube assembly. Otherwise, the conditions are the same as for the operation of the system.

2.3 Connection Diagram

2.3.1 Connection diagram



SV 150/40/80C-100; -100F (3-Phase stator)

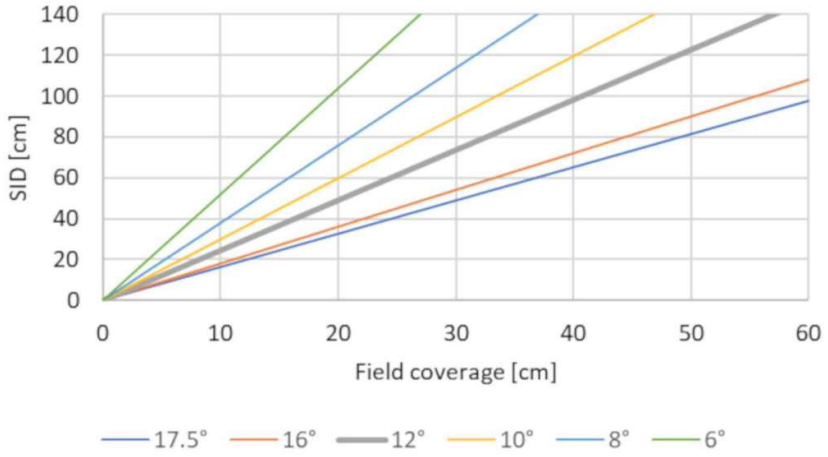


SV 150/40/80C-100L; -100LF (1-Phase stator)

2.3.2 Maximum radiation field

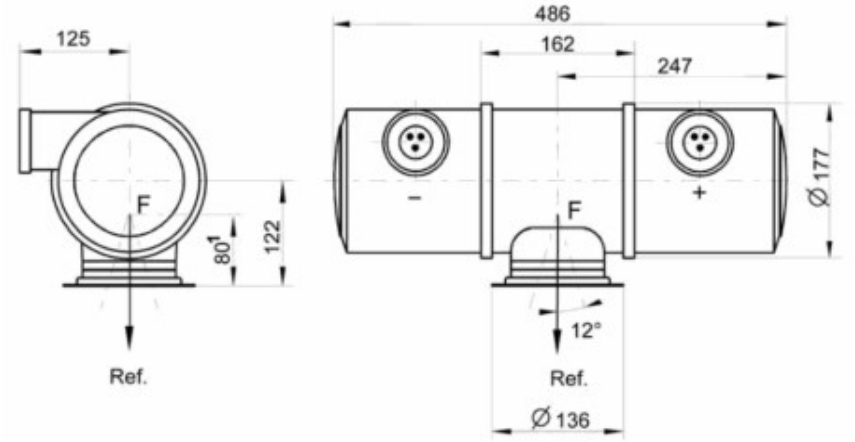
The field coverage depends on the source-image distance (SID) and the anode angle. For example, field coverage of 40 cm x 40 cm can be achieved at 1 m SID with this tube as- sembly (12 ° anode angle).

Figure 1: Maximum radiation field



2.4 Dimensional drawings

2.4.1 Dimensional drawing SV 150/40/80C-100; 100L



[1]Tolerance (+ 2.0 / - 0.5)

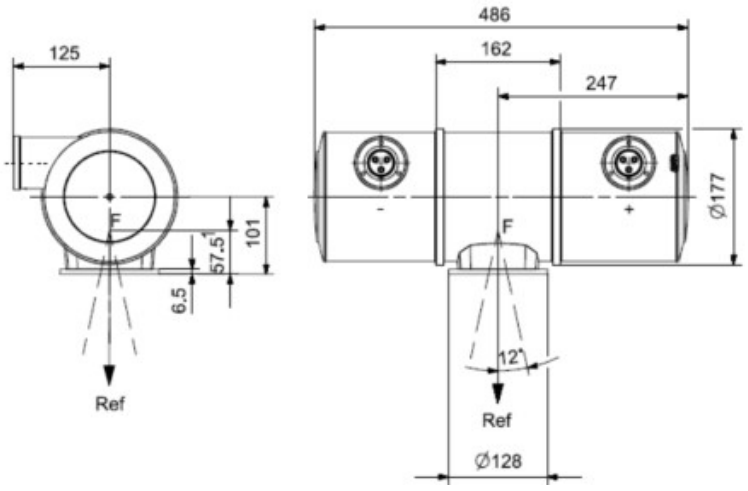
F = Focus position

Ref. = Reference axis

Dimensions are given in mm.

All dimensions are appropriate.

2.4.2 Dimensional drawing SV 150/40/80C-100F; 100LF



[1]Tolerance (0 / - 0.5)

F = Focus position

Ref. = Reference axis

Dimensions are given in mm.

All dimensions are approximate

2.5 Interfaces

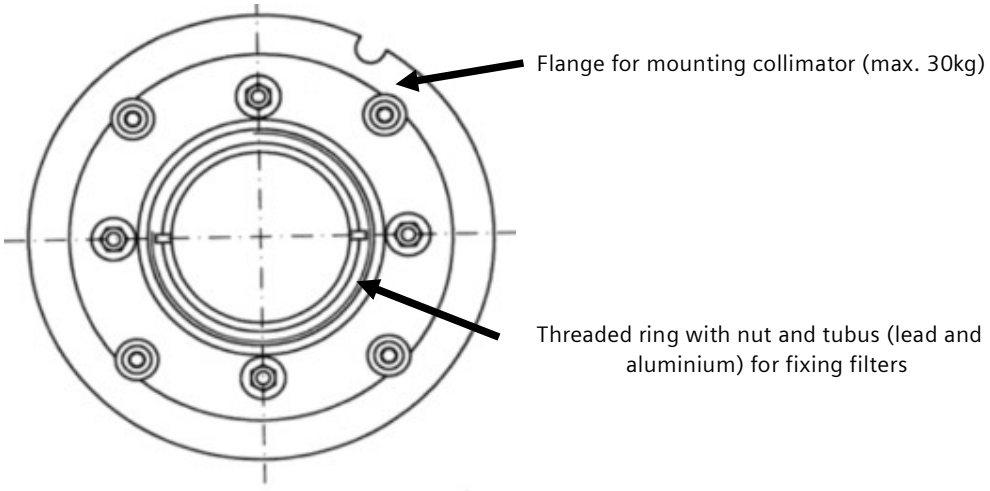
General ESD directives must be followed when handling the system. Follow instructions for installing, handling, tune-up etc. and/or refer to the operator manual of the X-ray tube assembly.

2.5.1 Collimator Flange Interface

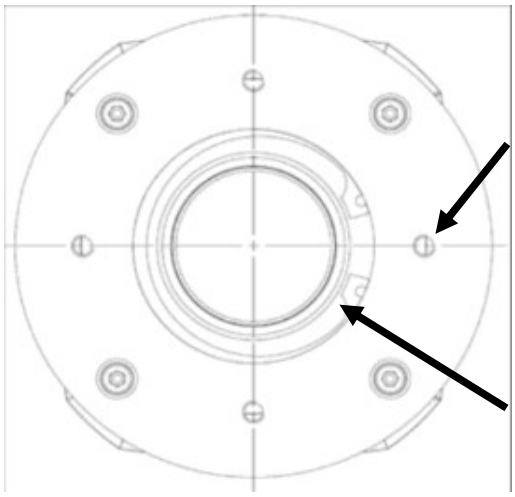
Do not loosen locked screws!

- Flange is exactly adjusted at reference axes, recognizable by red identification with thread sealant.
- Exact adjustment of reference axis is only possible at the manufacturer.

Collimator Flange Interface for SV 150/40/80C-100; 100L:



Collimator Flange Interface for SV 150/40/80C-100F; 100LF:



Thread hole M6 (4x) at divided circle of 92 mm diameter for mounting collimator flange (max.

Snap-ring fixing filters and tubus (lead and aluminium)

2.5.2 Tube assembly connection plates

The electrical connections of stator and sensors are located under the decoration cap on the anode side on the connection plate . To connect cables, remove the decoration cap and connect cables according to the labels under the decoration cap. Before operating the X-ray tube assembly, the decoration cap has to be mounted again in an orientated way to inlet of cables.

CAUTION

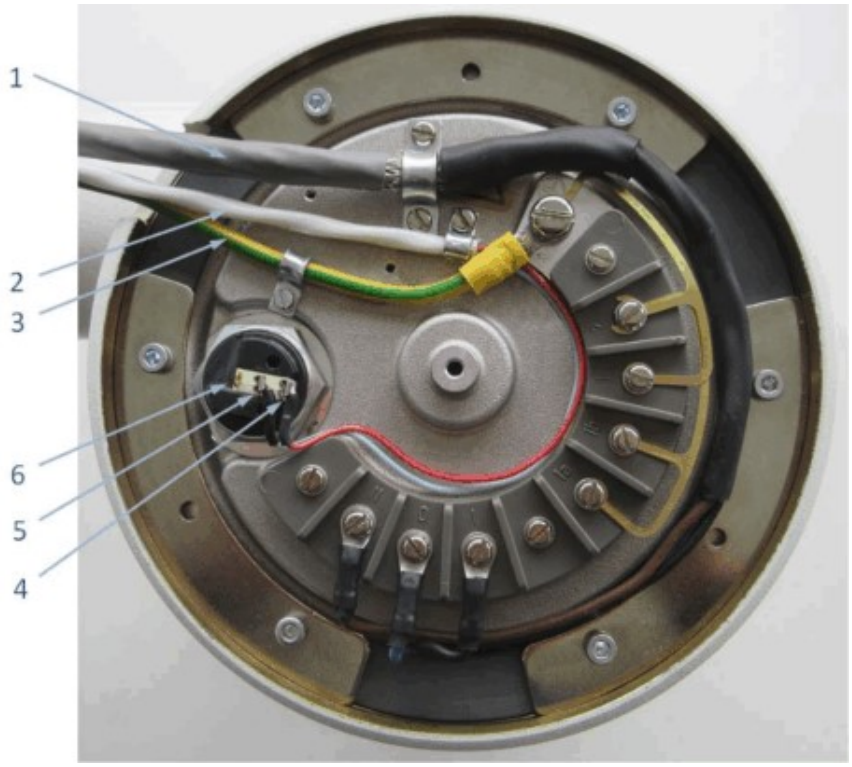
Free accessibility of live parts.

Risk of injury due to electric shock!

- **The requirements for the dielectric strength of the cables, the minimum cable strengths and the temperature resistance (the connection plate can reach temperatures of up to 100 °C, see section "Safety Instructions for X-ray Tube Assemblies") must be strictly observed when attaching the X-ray tube assembly to the electrical system.**

2.5.3 Stator Specifications

2.5.3.1 Three-phase-stator for SV 150/40/80C-100; 100F



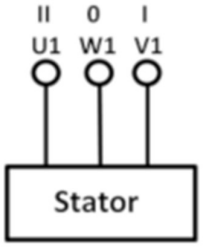


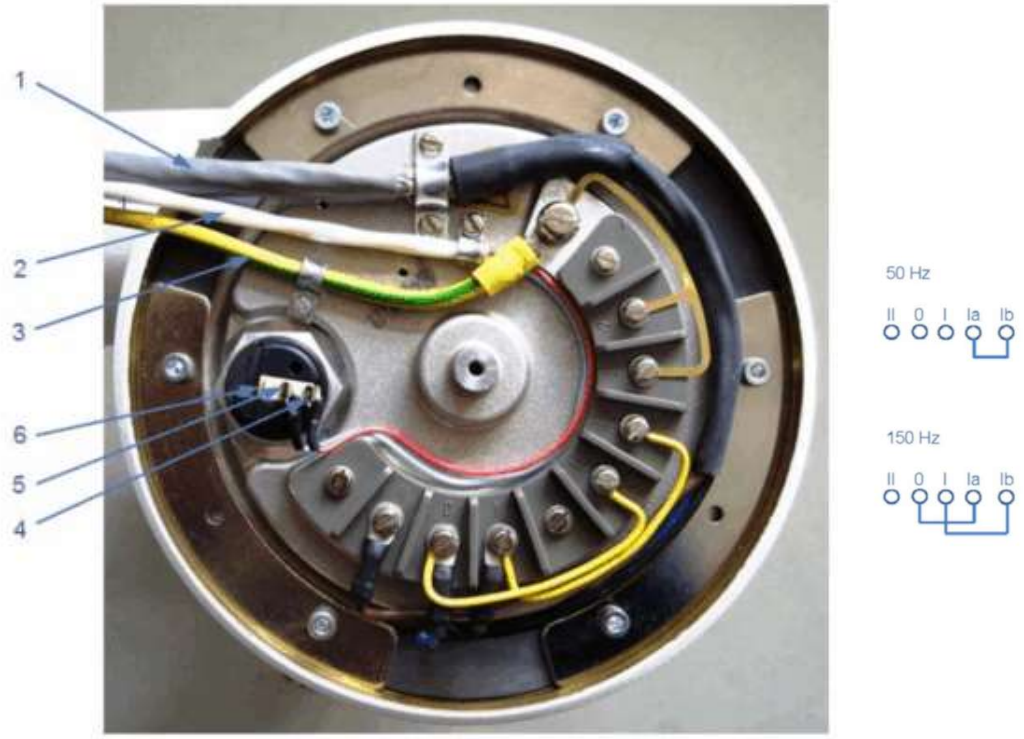
Table 6 3-phase operation

1	Stator connection - Double-shielded cable - Minimum diameter of the cable jacket 11.0 mm - Maximum Stator-pulse voltage1500 V~	**2**	Pressure switch connec- tion - Minimum diameter of the cable jacket 5.0 mm	**3**	Protective ground wire connection - Minimum diameter of the cable jacket 3.0 mm
4	Pressure switch PIN 1 (common)	**5**	Pressure switch Pin 2 (normally closed)	**6**	Pressure switch Pin 4 (normally open)

Table 7 Stator check

Test Point	0-I	0-II	I-II
Winding resistance	≈2.0.....2.6Ω	≈2.0.....2.6Ω	≈2.0.....2.6 Ω

2.5.3.2 Single-phase-stator for SV 150/40/80C-100L; 100LF



1-phase operation (image shows 150Hz connection)

Table 8 3-phase operation

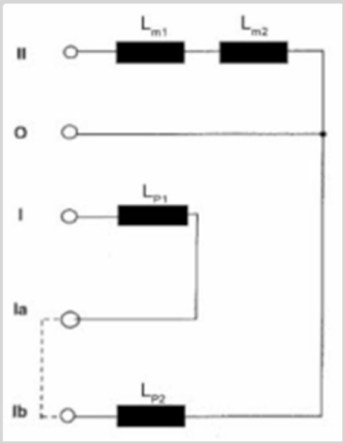
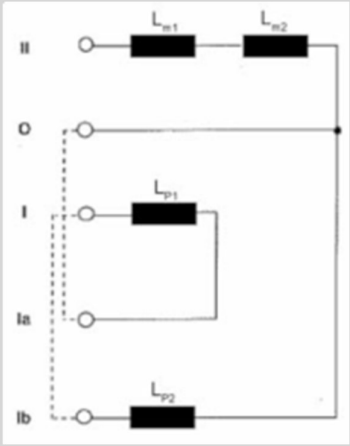
1	Stator connection - Double-shielded cable - Minimum diameter of the cable jacket 11.0 mm - Maximum Stator-pulse voltage1500 V~	**2**	Pressure switch connection - Minimum diameter of the cable jacket 5.0 mm	**3**	Protective ground wire connection - Minimum diameter of the cable jacket 3.0 mm
4	Pressure switch PIN 1 (common)	**5**	Pressure switch Pin 2 (normally closed)	**6**	Pressure switch Pin 4 (normally open)

Table 9 Stator check

Test Point	0-I	0-II	I-II
Winding resistance	≈18,0.....20,0Ω	≈13,0.....16,0Ω	≈31,0.....36,0 Ω

2.5.3.3 Stator characteristic

Only valid for SV 150/40/80C-100L; 100LF

Configuration a for 50/60 Hz	Configuration b for 150/180 Hz	Explanation
		0 = Common I = Phase shift II = Main *Paramter with tube

	Winding resistance [Ω]	Winding inductance [mH]
L_{m1} (Main-winding)	6.9	29.5*
L_{m2} (Main-winding)	6.9	29.5*
L_{p1} (Phase-shifted-winding)	37	280*
L_{p2} (Phase-shifted-winding)	37	280*

	Configuration a	Configuration a	Configuration b	Configuration b
Frequency of anode [Hz]	50/60	150/180	50/60	150/180
Voltage Common-main [V_{rms}]	240	not possible	240	380
Current Common [A_{rms}]	9.4		14.4	7.8
Current Main [A_{rms}]	9.2		9.2	5.6
Phase shift [A_{rms}]	2.6		5.5	2.2
Capacitor (Phase-shifting) [µF]	10		32	6
Voltage Phase shift capacitor [V]	700		460	323

Voltage Starting power Common-main [V_{rms}]	200-240		200-240	280-450
Voltage Running power Common-main [V_{rms}]	40-80		40-80	80-120

Please note that the power (energy) of the stator will interact the performance of the whole X-ray tube assembly.

2.5.4 Oil Pressure Switch

The oil pressure switch responds at an overpressure of approx. 0.4 bar in the housing.

Connections of the pressure switch

2	Opening
1	Common
4	Closing

2.5.4.1 Recommendation of electrical connection of the pressure-switch:

Plug connection:

- contact the pressure-switch by plugging both ready made receptacles (Siemens Healthcare material number 10665047 on the pressure switch contacts
- make sure that both receptacles are completely pushed up against the microswitch body of the pressure switch
- make sure that both receptacles do not contact each other

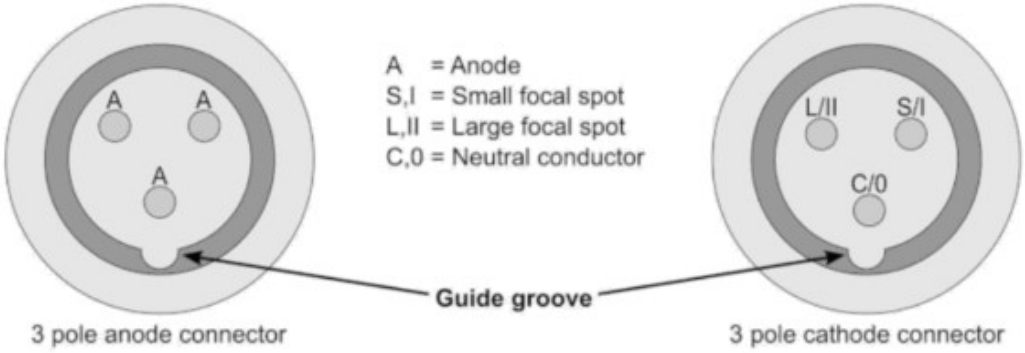
2.5.4.2 Alternative method for connection of pressure switch

Soldering of the connection of the pressure switch:

- To protect the pressure switch the max. temperature of the solder process must not exceed 380 °C
- The recommendation is: soldering time max. 2 s, solder with flux (e.g. wire-diameter D = 1 mm)

2.5.5 High-voltage Connectors

The X-ray tube assembly SV 150/40/80C-100; 100L; 100F; 100LF is provided with a 3-pin high-voltage socket at anode and cathode side. The HV cable length must not exceed 30m due to the cable capacity. The enclosed corona disks must be covered with the silicone oil and slipped over the plug contacts



The diagram shows the configuration of the plug contacts.

The contacts are for high voltage (voltage for electrodes) and voltage for filaments.

2.5.6 Tube Assembly Filtration

CAUTION

Radiation protection component or prefiltration components incorrectly assembled.

Unnecessary radiation exposure!

- **It is important to ensure that the lead cone is reinstalled after removing or exchanging the filters**
- **The configuration of the radiation outlet regarding the filtration must be performed in accordance with the terms of section "Filter replacement"**

2.5.6.1 Filter replacement

The total tube assembly filtration is at least 2.5 mm Al equivalent. Additional filtration comprises two filter disks (2 x 0.5 mm aluminium). The protection cone (0.7 mm alumini- um) is part of the inherent filtration and must be remounted after the removal of the filter plates during assembly of the collimator.

CAUTION

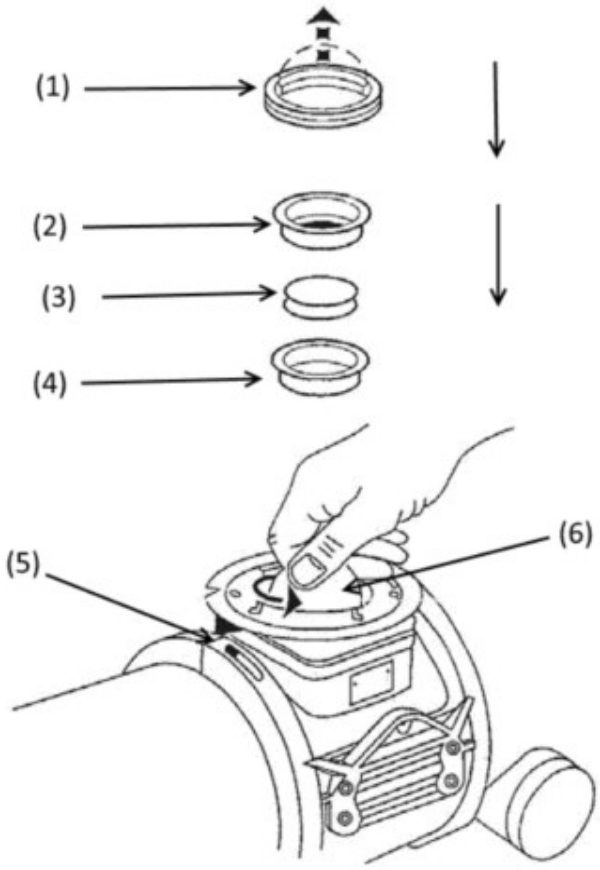
A contact with unprotected lead is possible during the replacement of the filter plates. The inside of the protection cone in the radiate exit window is unpainted.

Risk of contamination in case of skin contact with lead!

- **Be careful with unprotected lead**
- **Do not damage the varnish protection on the outside of the lead part**

The replacement of the filter disks and of the lead cone for image intensifier adaption can be done as follows:

Figure 2 Illustration for changing filter disks



1	Threaded ring with nut for types without letter "F" (-100 and -100L). Snap-ring for types with letter "F" (-100F and -100LF).	**2**	Protection cone (aluminium)
3	Filter disks (2 x 0.5 mm / aluminium)	**4**	Lead cone
5	Holder rings with mounting flange (not included in delivery)	**6**	Tool for disassembling and assembling: - Threaded ring with nut: use flattened disk (included in delivery) - Snap-ring: use usual snap-ring assembly pliers (not included in delivery)

2.5.6.2 Image intensifier - cone adaption

To increase the image quality during standalone image intensifier operation, use of a lead cone with a circular beam exit is recommended. The lead cone set art. no. 8952699 contains lead cones with different hole diameters (14, 20, 22 mm, 1 x unpierced) for optimized beam limitation to the corresponding image intensifier diameter. Cone hole diameter (D) and corresponding image intensifier sizes with 80 cm SID are listed in the following table

RBV/ Image intensifier	D
17 cm / 7 "	9 mm
23 cm / 9 "	11 mm
27 cm / 10 "	14 mm
33 cm / 13 "	20 mm
40 cm / 16 "	22 mm

For distances Ax deviating from 80 cm, the necessary cone hole diameter D_x can be calculated:

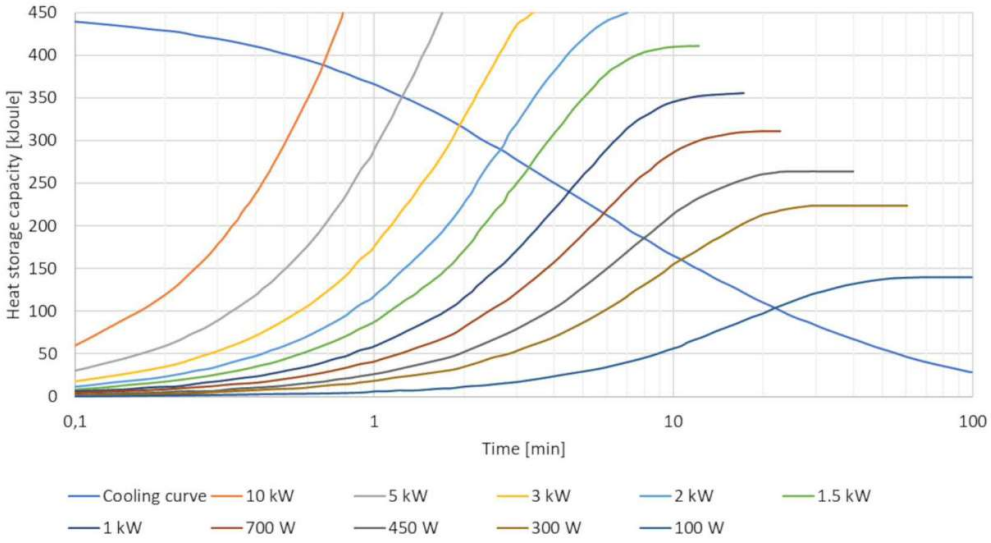
D_x [mm] = (80cm/A_x) * D [mm]

3 Curves and Tables

3.1 Heating and cooling curves

3.1.1 Heating and cooling curves of the anode

In accordance with IEC 60613 (1989)

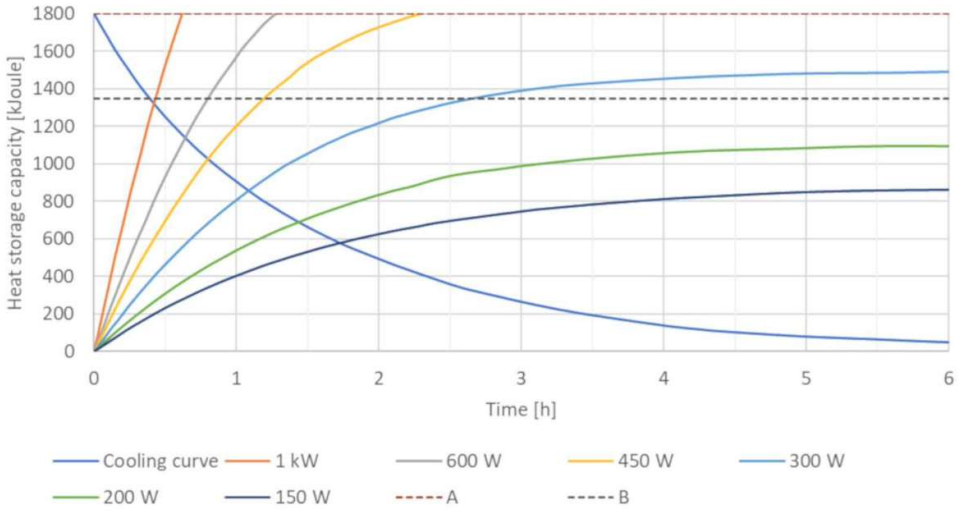


3.1.2 Heating and cooling curves of the X-ray tube assembly

3.1.2.1 X-ray tube assembly without fan

Curves in accordance with IEC 60613 (1989)

A		B	
X-ray tube assembly in horizontal position Position changed during operation		X-ray tube assembly only in vertical position	

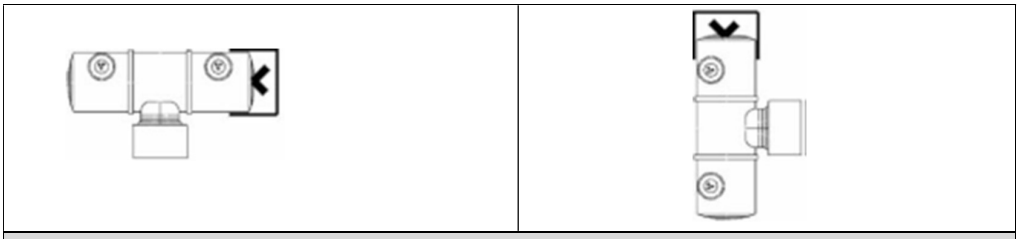


The heating curves include the power loss of the cathode and the stator, e.g. 150/180 Hz

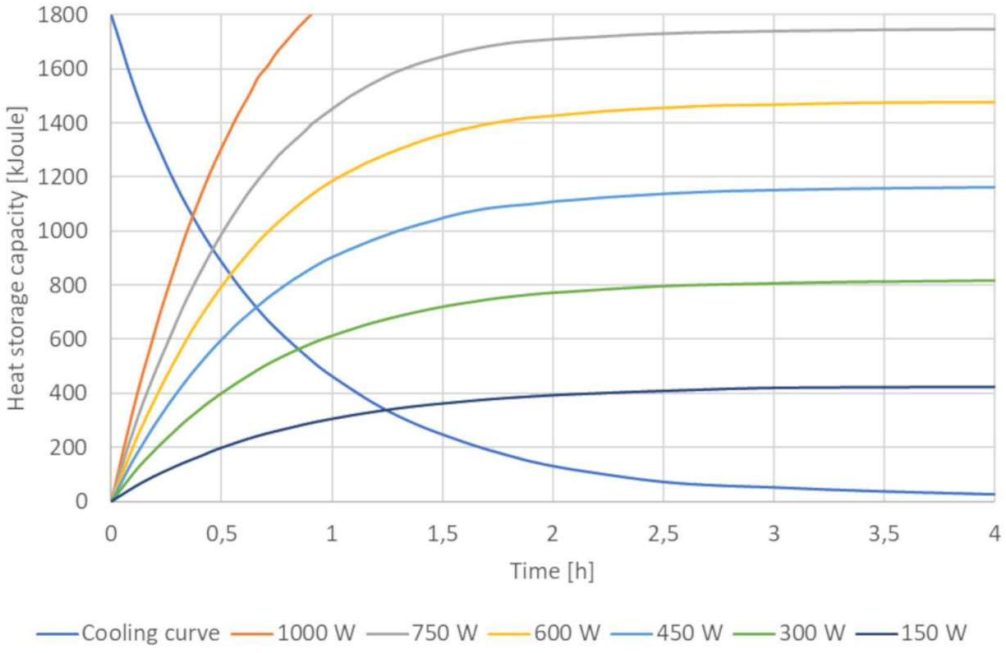
- anode drive ≈ 6000 J / start-up to stop
- 25 Hz anode drive for fluoroscopy ≈ 90 W
- 50 Hz anode drive for pulsed fluoroscopy ≈ 100 W

3.1.2.2 X-ray tube assembly with fan

Curves in accordance with IEC 60613 (1989)



X-ray tube assembly with fan horizontal or vertical with fan on top



The heating curves include the power loss of the cathode and the stator, e.g. 150/180 Hz

- anode drive ≈ 6000 J / start-up to stop
- 25 Hz anode drive for fluoroscopy ≈ 90 W
- 50 Hz anode drive for pulsed fluoroscopy ≈ 100 W

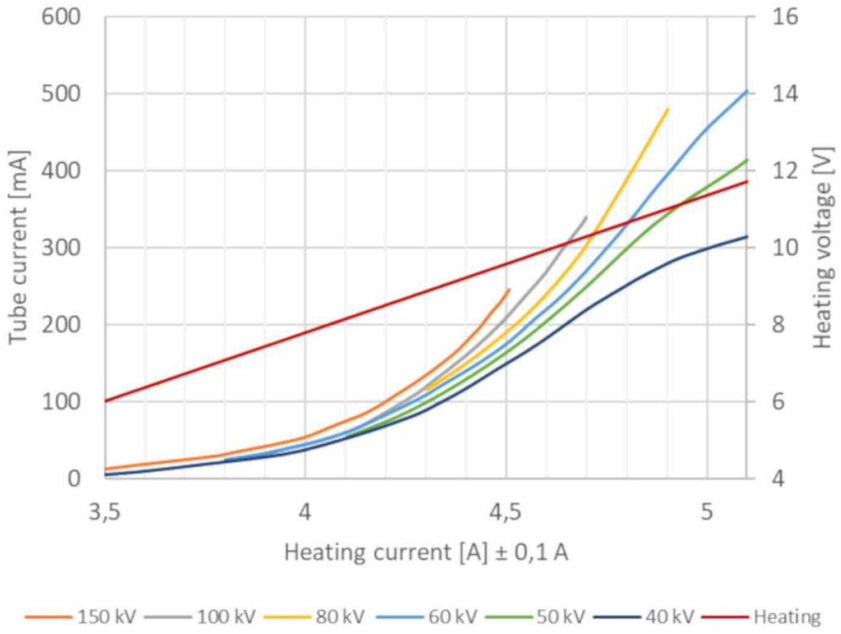
3.2 Emission Curves of the Cathode

Anode drive 150/180 Hz

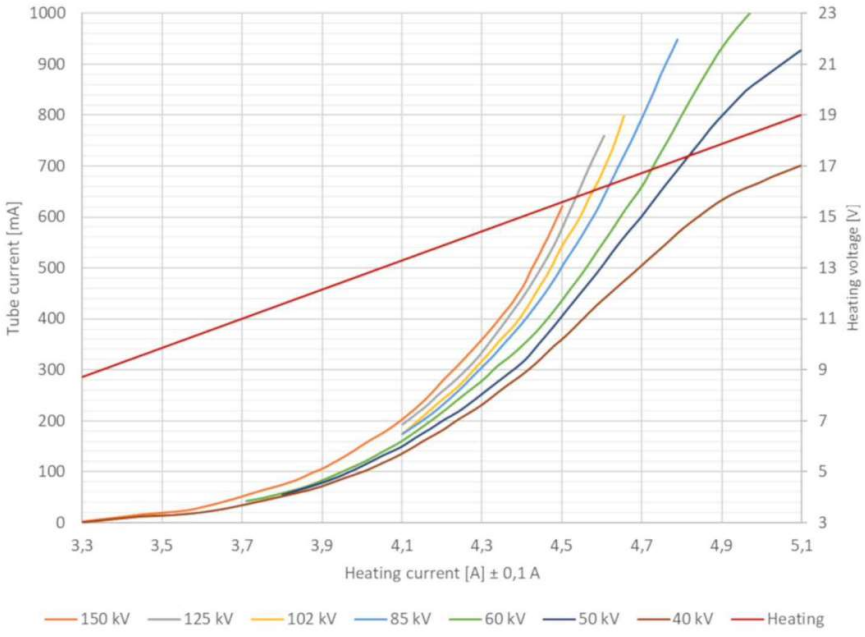
Thermal anode reference power 300 W

Curves in accordance with IEC 60613 (2010)

Small focus 0.6



Large focus 1.0



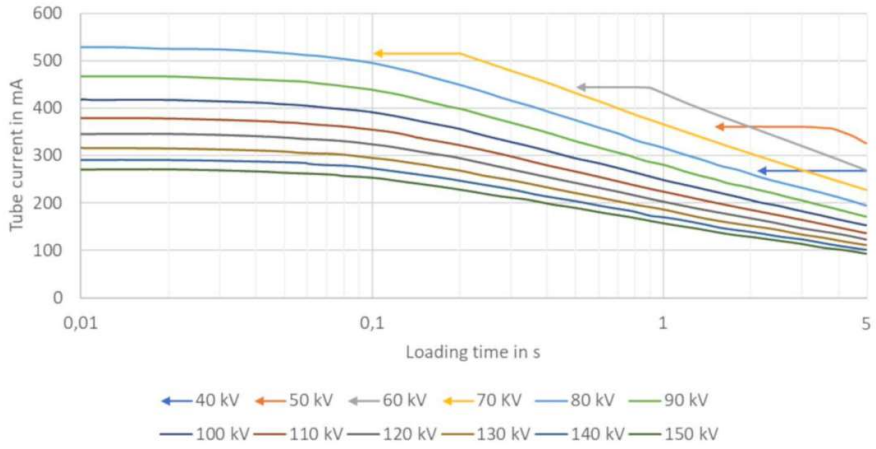
3.3 Loading Curves

3.3.1 Single-Load Rating

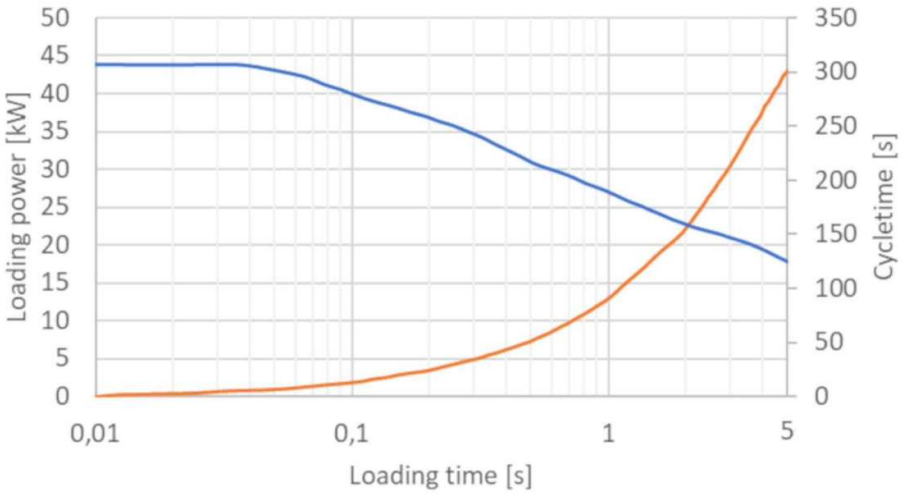
3.3.1.1 Single loading curve with focal spot 0.6

- Anode drive 150/180 Hz
- Thermal anode reference power 300 W

Curves in accordance with IEC 60613 (1989)



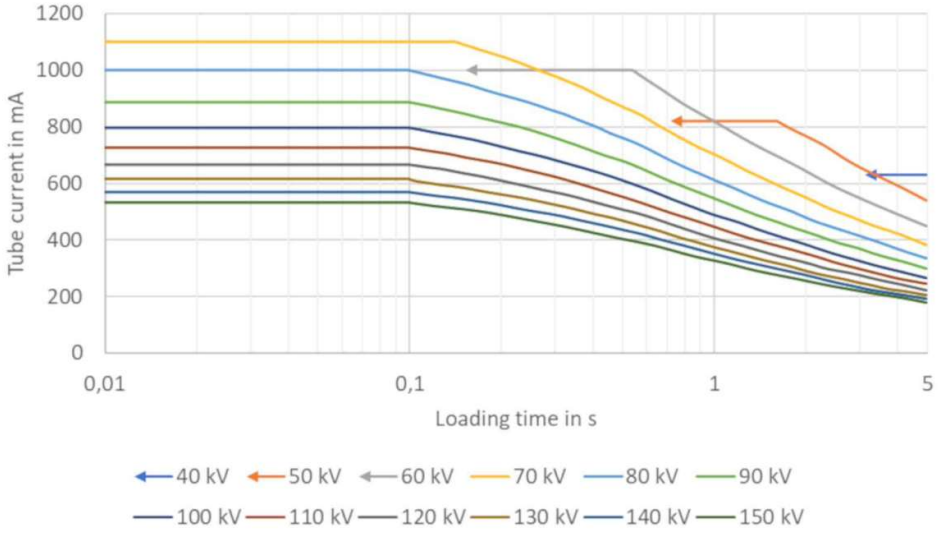
Curves in accordance with IEC 60613 (2010)



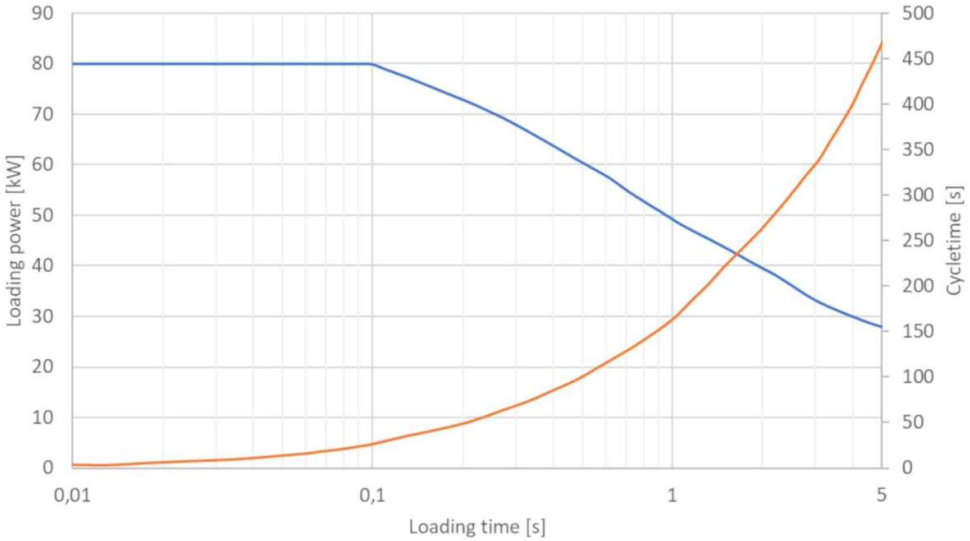
3.3.1.2 Single loading curve with focal spot 1.0

- Anode drive 150/180 Hz
- Thermal anode reference power 300 W

Curves in accordance with IEC 606013 (1989)



Curves in accordance with IEC 60613 (2010)



3.3.2 Serial Loading

- Anode drive 150/180 Hz
- Thermal anode reference power 300 W

3.3.2.1 Series pulse mode with focal spot 0.6

▣ 0.6	Series duration (IEC 60613:1989)									
Pulse width (ms) x framerate (s^{-1})	**1s**	**2s**	**4s**	**6s**	**10s**	**16s**	**25s**	**40s**	**63s**	**120s**
50	40.0	40.0	39.9	39.9	39.8	39.5	39.0	38.5	37.6	34.7
100	39.5	39.4	39.0	38.8	38.5	37.8	36.7	35.5	33.4	25.5
150	37.9	37.6	36.6	36.0	35.0	33.9	32.4	30.7	27.0	17.1
200	36.4	35.3	33.9	33.1	31.8	30.4	28.6	26.4	22.5	12.8
250	35.1	33.6	31.8	30.7	29.1	27.4	25.7	23.2	19.1	10.2
300	33.9	32.1	29.9	28.7	27.0	25.2	23.1	20.5	16.2	8.5
350	32.9	30.7	28.3	26.9	25.0	23.1	21.1	18.3	13.9	7.3
400	32.0	29..4	26.9	25.3	23.3	21.5	19.3	16.4	12.2	6.4
450	31.2	28.4	25.6	23.9	22.0	20.0	17.9	14.9	10.8	5.7
500	30.5	27.5	24.6	22.8	20.9	18.7	16.6	13.6	9.7	5.1
550	29.9	26.7	23.7	21.9	19.9	17.5	15.4	12.4	8.9	4.6
600	29.4	26.0	22.8	21.0	18.9	16.5	14.3	11.2	8.1	4.2
650	28.9	25.3	21.9	20.1	17.9	15.5	13.2	10.3	7.5	3.9
700	28.4	24.6	21.1	19.2	16.9	14.5	12.2	9.4	6.9	3.6
750	27.9	23.9	20.3	18.3	15.9	13.5	11.2	8.7	6.5	3.4
800	27.4	23.2	19.5	17.4	14.9	12.5	10.2	8.0	6.1	3.2
850	27.0	22.6	18.7	16.5	13.9	11.5	9.3	7.4	5.7	3.0
900	26.7	22.1	18.0	15.7	13.0	10.5	8.5	6.9	5.4	2.8
	Pulsed power in kW									

▣ 0.6	Series duration (IEC 60613:1989)									
Pulse width (ms) x framerate (s^{-1})	**1s**	**2s**	**4s**	**6s**	**10s**	**16s**	**25s**	**40s**	**63s**	**120s**
50	6.7	13.3	26.6	39.9	66.3	105.3	162.5	256.7	394.8	694.0
100	13.2	26.3	52.0	77.6	128.3	201.6	305.8	473.3	701.4	1020.0
150	19.0	37.6	73.2	108.0	175.0	271.2	405.0	614.0	850.5	1026.0
200	24.3	47.1	90.4	132.4	212.0	324.3	476.7	704.0	945.0	1024.0
250	29.3	56.0	106.0	153.5	242.5	365.3	535.4	773.3	1002.8	1020.0
300	33.9	64.2	119.6	172.2	270.0	403.2	577.5	820.0	1020.6	1020.0
350	38.4	71.6	132.1	188.3	291.7	431.2	615.4	854.0	1021.7	1022.0
400	42.7	78.4	143.5	202.4	310.7	458.7	643.3	874.7	1024.8	1024.0
450	46.8	85.2	153.6	215.1	330.0	480.0	671.3	894.0	1020.6	1026.0
500	50.8	91.7	164.0	228.0	348.3	498.7	691.7	906.7	1018.5	1020.0
550	54.8	97.9	173.8	240.9	364.8	513.3	705.8	909.3	1028.0	1012.0
600	58.8	104.0	182.4	252.0	378.0	528.0	715.0	896.0	1020.6	1008.0
650	62.6	109.6	189.8	261.3	387.8	537.3	715.0	892.7	1023.8	1014.0
700	66.3	114.8	169.9	268.8	394.3	541.3	711.7	877.3	1014.3	1008.0
750	69.8	119.5	203.0	274.5	397.5	540.0	700.0	870.0	1023.8	1020.0
800	73.1	123.7	208.0	278.4	397.3	533.3	680.0	853.3	1024.8	1024.0
850	76.5	128.1	211.9	280.5	393.8	521.3	658.8	838.7	1017.5	1020.0
900	80.1	132.6	216.0	282.6	390.0	504.0	637.5	828.0	1020.6	1008.0
	Cycletime in s									

3.3.2.2 Series pulse mode with focal spot 1.0

1.0	Series duration (IEC 60613:1989)									
Pulse width (ms) x framerate (s^{-1})	**1s**	**2s**	**4s**	**6s**	**10s**	**16s**	**25s**	**40s**	**63s**	**120s**
50	80.0	79.8	79.7	79.6	79.2	78.0	75.8	70.9	64.9	51.0
100	77.6	76.6	75.8	74.3	71.9	68.3	62.9	56.3	46.7	25.5
150	73.2	71.4	70.0	68.0	63.7	59.5	53.3	45.2	32.4	17.0
200	70.0	67.8	65.5	62.7	57.7	52.8	44.7	35.1	24.4	12.8
250	67.0	64.3	61.1	57.5	52.3	46.7	38.0	28.3	19.4	10.2
300	64.3	61.1	56.7	52.4	47.1	41.4	32.6	23.5	16.2	8.5
350	62.7	58.0	52.4	48.0	42.5	36.8	27.5	19.9	13.9	7.3
400	61.0	55.8	49.0	44.8	39.3	33.6	24.3	17.7	12.1	6.4
450	59.4	53.6	46.2	41.9	36.4	30.7	22.0	16.2	10.8	5.7
500	57.9	51.8	43.8	39.2	33.7	27.8	19.8	14.7	9.7	5.1
550	56.5	50.1	41.6	36.8	31.3	24.9	18.2	13.3	8.9	4.6
600	55.3	48.4	39.6	34.8	34.8	29.3	16.8	12.1	8.1	4.2
650	54.2	46.7	37.6	33.0	27.4	21.2	15.5	11.0	7.5	3.9
700	53.1	45.0	35.7	31.2	25.5	19.7	14.2	10.1	6.9	3.6
750	52.0	43.3	33.9	29.4	23.7	18.2	12.9	9.2	6.5	3.4
800	51.0	41.6	32.3	27.7	21.9	16.6	11.6	8.6	6.1	3.2
850	50.1	40.0	30.7	26.0	20.2	15.0	10.7	7.9	5.7	3.0
900	49.3	38.5	29.2	24.4	18.6	13.5	10.0	7.4	5.4	2.8
	Pulsed power in kW									

1.0	Series duration (IEC 60613:2010)									
Pulse width (ms) x framerate (s^{-1})	**1s**	**2s**	**4s**	**6s**	**10s**	**16s**	**25s**	**40s**	**63s**	**120s**
50	13.3	26.6	53.1	79.6	132.0	208.0	315.8	472.7	681.5	1020.0
100	25.9	51.1	101.1	148.6	239.7	364.3	524.2	750.7	980.7	1020.0
150	20.0	71.4	140.0	204.0	318.5	476.0	666.3	904.0	1020.6	1020.0
200	46.7	90.4	174.7	250.8	384.7	563.2	745.0	936.0	1024.8	1024.0
250	55.8	107.2	203.7	287.5	435.8	662.7	791.7	943.3	1018.5	1020.0
300	64.3	122.2	226.8	314.4	471.0	662.4	815.0	940.0	1020.6	1020.0
350	73.2	135.3	244.5	336.0	495.8	686.9	802.1	928.7	1021.7	1022.0
400	81.3	148.8	261.3	358.4	524.0	716.8	810.0	944.0	1016.4	1024.0
450	89.1	160.8	277.2	377.1	546.0	736.8	825.0	972.0	1020.6	1026.0
500	96.5	172.7	292.0	392.0	561.7	741.3	825.0	980.0	1018.5	1020.0
550	103.6	183.7	305.1	404.8	573.8	730.4	834.2	975.3	1028.0	1012.0
600	110.6	193.6	316.8	417.6	586.0	736.0	840.0	968.0	1020.6	1008.0
650	117.4	202.4	325.9	429.0	593.7	734.9	839.6	953.3	1023.8	1014.0
700	123.9	210.0	333.2	436.8	595.0	735.5	828.3	942.7	1014.3	1008.0
750	130.0	216.5	339.0	441.0	592.5	728.0	806.25	920.0	1023.8	1020.0
800	136.0	221.9	334.5	443.2	584.0	708.3	773.3	917.3	1024.8	1024.0
850	142.0	226.7	347.9	442.0	572.3	680.0	757.9	895.3	1027.5	1020.0
900	147.9	231.0	350.4	439.2	558.0	648.0	750.0	888.0	1020.6	1008.0
	Cycletime in s									

4 Conditioning of the X-ray tube assembly

4.1 Conditioning of the X-ray Tube

CAUTION

The adjustment of the X-ray tube assembly can change due to longer storage periods as a result of global spare parts management.

Risk of injury of high radiation exposures (new exposure necessary), image inter- ferences by discharging of the tube!

- **The operator is obliged after longer storage periods to arrange for qualified service personnel to check the adjustment of the tube**
- **The service personnel has to carry out the post conditioning program in accordance with the details of these this operator manual**

After the tube has not been used for a while, it is required to perform warm-up procedures.

Depending on the idle time, different sequences should be run. The standard tube warm-up, which should be done on a daily basis during system start, is described in chapter 4.2.1

In case the tube was not used for a longer period of time (more than two weeks) it is re- quired to perform the procedure described in chapter 4.2.2 in addition to daily warmup routine.

If tube is operated the first time, than the procedure in chapter 4.2.3 must be applied in addition to the previous two.

If you experience arcings in the tube during the described procedures, stop the procedure and repeat it after a cool down of 30 minutes. If the arcing is still present, the tube must be replaced

During conditioning, ensure that the radiation protection safety precautions are taken; an existing image intensifier must be protected against radiation (e.g. place a lead apron in the beam path).

4.2 Conditioning process of the X-ray tube assembly

4.2.1 Conditioning program (for starting with cold anode)

If fluoroscopy mode is available than (F2, large focus)

Switch on fluoroscopy with 40-70 kV (depending on type of generator). Increase to 110 kV / 4.1 mA within approx. 1 minute and maintain this value for 10 minutes, this is up to about 45% of max. anode heat storage capacity.

If no fluoroscopy mode is available than select exposure mode (F2, large focus)

- 40kV, 50mA, 0,5 s, pause after each exposure 5 s, 3 exposures
- 50kV, 50mA, 0,5 s, pause after each exposure 5 s, 3 exposures
- 60kV, 50mA, 0,5 s, pause after each exposure 5 s, 3 exposures
- 70kV, 50mA, 0,5 s, pause after each exposure 5 s, 3 exposures
- 80kV, 50mA, 0,5 s, pause after each exposure 5 s, 3 exposures
- 90kV, 50mA, 0,5 s, pause after each exposure 5 s, 3 exposures
- 100kV, 50mA, 0,5 s, pause after each exposure 5 s, 3 exposures
- 110kV, 100mA, 0,5 s, pause after each exposure 8 s, 50 exposures

4.2.2 After an extended idle time of the X-ray tube assembly (more than 2 weeks)

- Select exposure mode with F2 (Large focus)
  - 70 kV, 100 mAs, - 2 exposures
- Pause after each exposure = 30 s
  - 90 kV, 400 mAs, - 2 exposures
- Pause after each exposure = 120 s
  - 109 kV, 400 mAs, - 2 exposures
- Pause after each exposure = 150 s

4.2.3 Perform only for installation of a new X-ray tube assembly

Perform procedure in section 4.2.3 only for installation of a new X-ray tube assembly additionally after you have done section 4.2.1 and section 4.2.2

- Pause after each exposure = 30 s
  - 125 kV, 63 mAs, - 2 exposures
- Pause after each exposure = 30 s
  - 150 kV, 50 mAs, - 2 exposures

If the tube tends to repeatedly and strongly arc, abort the procedure.

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Phone: +49 9131 84-0
siemens-healthineers.com

Legal Manufacturer
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany

Publisher for USA
Siemens Medical Solutions USA,
Inc. 40 Liberty Boulevard
Malvern, PA 19355-9998
USA
Phone: +1-888-826-9702
usa.siemens.com/healthcare

Confidential Published by Siemens Healthcare GmbH · Print No. R76-020.140.71.13.02· Doc. Gen. Date: Dec. 2020