

Manual

Technical Description – Operator Manual

RV



This product bears a CE marking in accordance with the provisions of regulation 93/42/EEC of June 14, 1993 for medical devices.



STRATON MX P

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1 General data

X-ray tube assembly in accordance with IEC 60601-2-28 Class I Equipment / Type B

Type	Model No.	For use with CT System
Straton MX P	10141780	SOMATOM DEFINITION AS
	Consisting of:	
	X-ray tube assembly 10141785	
	Cooling unit 10141790	
Straton MX P	X-ray deflection control 08401296	SOMATOM Flash DS
	10430571	
	Consisting of:	
	X-ray tube assembly 10414539	
	Cooling unit 10414538	
	X-ray deflection control 08401296	

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Address of legal manufacturer	Siemens AG Wittelsbacherplatz 2 D - 80333 München Germany
Language of original	English

2 Laws, standards and regulations

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

- Directive 93/42/EEC dated June 14, 1993 for medical devices (CE marking).
- ISO 13485/2003 Medical devices – Quality management systems
- ISO 14971/2007 Medical devices - Application of risk management to medical devices
- 21 CFR Part 1020, 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 especially:

IEC	Title
60336:2005	X-ray tube assemblies for medical diagnosis – Characteristics of focal spots
60522:1999	Determination of the permanent filtration of X-ray tube assemblies
60526:1978	High-voltage cable plug and socket connections for medical X-ray equipment
60601-1:1988+ A1:1991+A2:1995	General requirements for safety
60601-1-2/2001	Electromagnetic compatibility – Requirements and tests
60601-1-3/1994	General requirements for radiation protection in diagnostic X-ray equipment
60601-2-28/1993	Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
60613/1989	Electric, thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis
60788/2004	Medical radiology - Terminology
60806/1984	Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis
62309/2004	Dependability of products containing reused parts – requirements for functionality and tests

3 Description

X-ray tube assembly Straton MX P for use in X-ray equipment for diagnostic purposes.

The STRATON MX P rotating envelope X-ray tube system consists of X-ray tube assembly, deflection electronics and cooling unit. It is intended for use in SIEMENS SOMATOM DEFINITION AS (10141780) and SOMATOM Flash DS (10430571) computer tomographs. The X-ray tube assembly contains an X-ray tube with directly cooled anode. The X-ray tube is a largely rotation-symmetrical rotating envelope X-ray tube in metal-ceramic design. It is driven directly by a motor. The cathode is a single emitter system with selectable settings. The deflection electronics control the size and position of the focus. The emitter is heated by inductive current transmission. The ceramics on the cathode side insulate the entire tube voltage. The anode is part of the tube envelope. In this way direct convective cooling of the anode and, in comparison with conventional tubes, a very low anode temperature are facilitated. The anode consists of the TZM copper sandwich structure with W/Re coating in the area of the focal path. This guarantees low aging and thus high and constant dose values over a long operating life.

The cooling system is separated mechanically from the X-ray tube assembly and connected with this by flexible oil pipes. Because of the direct anode cooling and the associated maximum cooling capacity of the anode of 4.8 MJ/min (6.5 MHU/min), the capacity of the STRATON MX P tube is higher than that of a conventional tube (with rotating anode) with a heat storage capacity of 50 MHU, in which the stored heat is dissipated essentially by thermal radiation from the anode system.

4 Notes

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. We guarantee the functioning, quality and life of these components by taking extensive quality assurance measures including all test procedures, just as for brand new components.

The requirements of IEC 62309 are fulfilled.

Safety information

The X-ray tube assembly may be operated only in agreement with the safety information 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.

- The use of the X-ray tube assembly is approved only in the following SIEMENS system: SIEMENS SOMATOM DEFINITION AS (10141780) and SOMATOM Flash DS (10430571). It may not be connected with assemblies, components or systems other than those recommended by SIEMENS.
- The X-ray tube assembly shall be used only in compliance with its intended purpose; the instructions of the operating instructions of the system manufacturer for operation, servicing and care as well as maintenance of an X-ray system apply. In particular, the tube assembly is not approved for operation in environments with combustible gas mixtures.
- Use of the X-ray tube assembly is forbidden if signs of mechanical, electrical or radiation-related defects are present.
- For monitoring certain operating parameters, the X-ray tube assembly is equipped with means for preventing a possible overload of or damage to the X-ray tube assembly. Any manipulation to these safety devices is prohibited. The load limit values listed in this manual may not be exceeded.
- For safety reasons any part of the X-ray tube assembly may be replaced only by the service personnel of the manufacturer or by personnel trained by the manufacturer.
- When the STRATON MX P rotating envelope system is operated in the vicinity of an MR system, the recommendations of the MR manufacturer must be observed. If a magnetic field of 5 mT on the surface of the tube assembly is exceeded, then the correct functioning of the rotating envelope system is no longer guaranteed.

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Radiation protection

This product fulfills the requirements of IEC 60601-1-3, as well as of the American 21 CFR Part 1020. This X-ray tube assembly emits X-ray radiation in operation. Only correspondingly qualified and trained personnel are therefore allowed to operate the X-ray tube assembly.

Operating conditions

Before the initial start-up of the X-ray tube assembly or after a longer standstill period, proceed according to the instructions of the service documents of the system manufacturer. Refer to section 5.3 for the operating conditions.

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 component 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 Medical Solutions. No other cables may be used. Correct functioning cannot be guaranteed if accessories other than the components sold by SIEMENS Medical Solutions are used.

This medical electrical component cannot be operated on its own, but only in combination with the above named radiological diagnostic system. The proof of compliance with the requirements of IEC 60601-1-2 with regard to electromagnetic compatibility has been provided by SIEMENS Medical Solutions as manufacturer.

Therefore please refer to the operator manual of the X-ray system for all data, guidelines and manufacturer's declarations on electromagnetic emission.

Maintenance

The X-ray tube assembly is maintenance free. There are no hazards whatsoever for persons and environment in the case of proper use.

Checks

Special checks concerning the tube assembly do not have to be performed. Please refer to the operator manual of the X-ray system for all instructions.

Disposal

The X-ray tube assembly as well as the tube contains 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 refuse is forbidden. The manufacturer possesses the required technical knowledge and will take the tube assembly back for disposal. Please contact your Siemens Customer Service for this purpose.

Instructions to service personnel

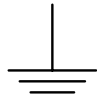
General ESD directives must be complied with when handling the system.

The correct tightening torques of the screw connections must be complied with when installing the tube assembly, the deflection electronics and the cooling unit. Connect the system ground corresponding to the instructions of the system manufacturer. The shield of the high-voltage cables and the parts connected electrically with it have no protective ground potential. These parts must not be touched during radiation operation. Pulled out electrical plug connections can be live when the X-ray system is not de-energized. Temperatures of up to 130°C can develop in normal operation on the tube assembly, the cooling unit and the oil pipes. On installation in the gantry make sure that the cooling hoses are not crushed. Deformation of the oil pipes can lead to leaks and must therefore be strictly avoided. Defective fuses are a sign for defective components. These components shall be replaced and returned to the manufacturer, do not change fuses. Instructions for installing, handling, tune-up etc. and/or reference to the operator manual of the X-ray system.

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Pictograms

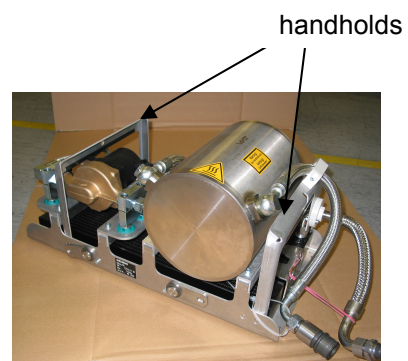
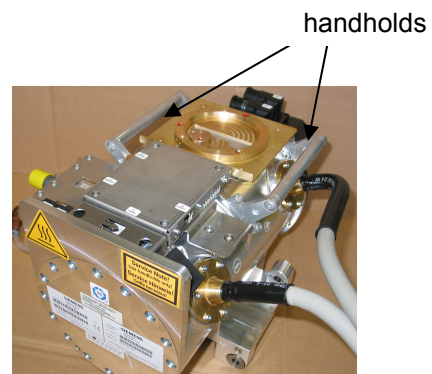
A grounding symbol is affixed in the area of the right-hand connection point on the carrier plate of the tube assembly housing.



A pictogram as warning sign for hot surfaces is located on the cathode-end cover of the tube assembly housing and on the x-ray tube cooling unit.



A label as Service Note is located on the cathode-end of the tube assembly housing and on the x-ray tube cooling unit. The handholds shall be used to lift the device. Lifting at other position might damage the x-ray tube assembly.



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5 Technical Data

Data corresponding to IEC 60601-2-28

5.1 X-ray tube / tube assembly

Property	Specification		Standard
Nominal anode input power at thermal anode reference power 4.6 kW**			IEC 60613
	F1 (small UHR focus)	F2 (small focus)	
	48 kW***	100 kW***	
Maximum anode heat content	400 000 J (500 000 HU) The indication of the maximum anode heat content may not be used for the assessment of the performance capacity of the tube. Refer to the explanation in section 3.		IEC 60613
Maximum cooling capacity of the anode	> 4 800 000 J/min (> 6 500 000 HU/min)		
Anode heating curve, Anode cooling curve	Not reasonable, see *		IEC 60613
Single and series load rating	See table in section 6.4		IEC 60613
Maximum heat content of the X-ray tube assembly	Indication of the heat content of the tube assembly is not meaningful, since the tube assembly is forced cooled by the CT system.		IEC 60613
Heating and cooling curve of the X-ray tube assembly	See figure in section 6.1		IEC 60613
Continuous heat dissipation of the tube assembly	4.6 kW**		IEC 60613
Maximum symmetrical radiation field in distance of the focal spot	See figure in section 8.1		IEC 60806
Anode top coating 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		
	See chapter 8		
Anode angle (Ref: reference axis) X-ray tube and X-ray tube assembly	7 °		IEC 60788
Focal spot nominal values	F1 (small UHR focus)	F2 (large focus)	IEC 60336

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Ref: Reference axis	0.7 x 0.7	0.9 x 1.1	
Permanent filtration of the X-ray tube assembly (Al equivalent)	≥ 6.8 mm Al / 145 kV		IEC 60522 IEC 60601-1-3
Nominal X-ray-tube voltage	145 kV		IEC 60613
Generator connection or supply units	See released documents of the SOMATOM DEFINITION AS SOMATOM Flash DS X-ray system (section 4)		

Data on cathode heating	See released documents of the SOMATOM DEFINITION AS SOMATOM Flash DS X-ray system (section 4)		
Cathode Emission characteristics	See curves section 6.3		IEC 60613
Data on anode drive / rotating anode motor	See released documents of the SOMATOM DEFINITION AS SOMATOM Flash DS X-ray system (section 4)		
Maximum anode frequency	160 Hz		
Electrical connections and cables	See connection wiring diagram section 7		
Main dimensions and interfaces	See dimension drawings section 8		
X-ray tube assembly weight 10141785 10414539	38kg 37,5kg		
Leakage radiation at (145 kV / 4.6 kW in 1m distance)	<0.8 mGy/h		IEC 60601-1-3
High-voltage connections 10141785 +/-	Three-conductor cable connection IEC526		IEC 60526
High-voltage connections 10414539 +/-	1-pin / 1-pin		

* It is not possible to measure heating and cooling curves of the anode according to IEC 60601-2-28, since the anode is an integral and rotating part of the rotating envelope tube and neither the front inside the metal envelope nor the back in the oil is accessible. There are also necessarily very high temperature differences because of the direct cooling of the anode with oil. Thus up to 2400°C is present in the focal spot at maximum power, whereas a maximum of 270°C is reached on the back of the anode. Statement of an anode temperature or of heating and cooling curves is therefore neither possible nor meaningful.

** Limited by the cooling capacity of the CT system.

*** The specified nominal input power (for a loading time of 1 s) is limited by the generator output of the CT system.

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5.2 Cooling system

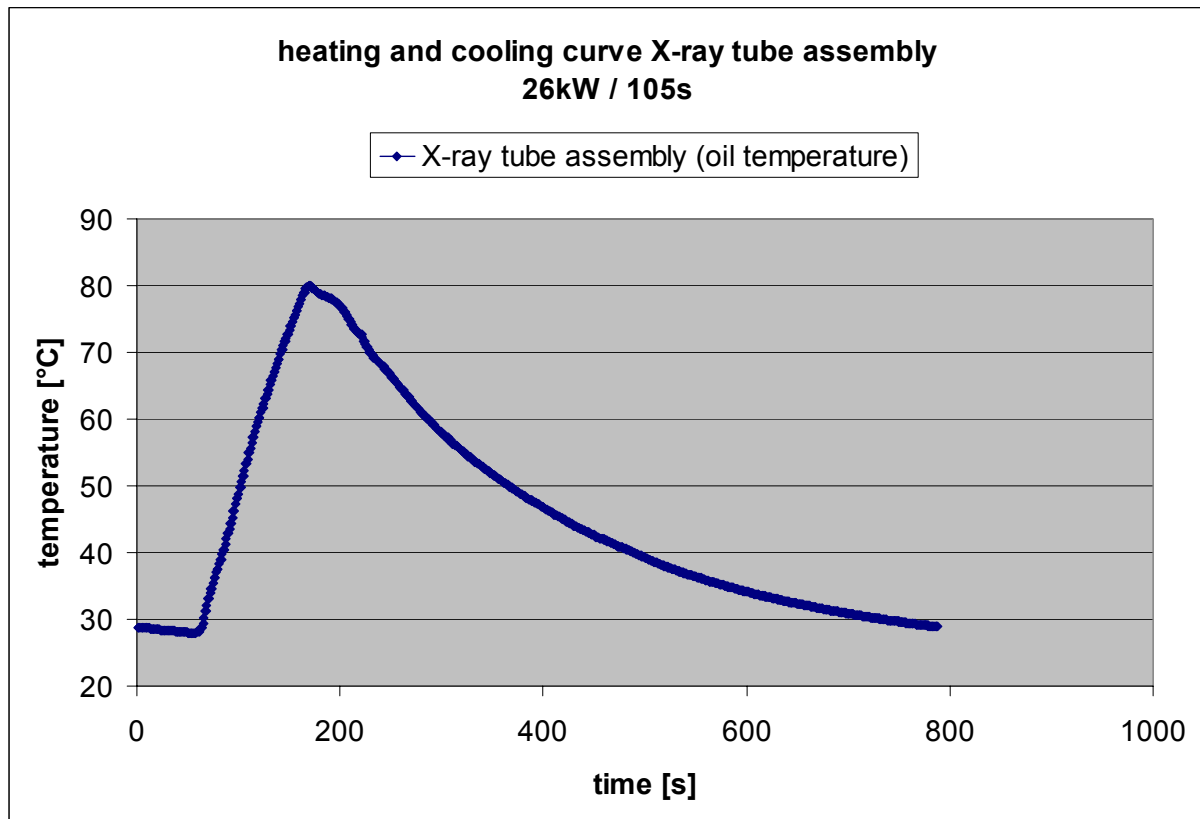
Cooling medium	Insulating oil DIN 57370 part 1
Flow rate	22 l/min
Coolant volume (X-ray tube assembly incl. cooling unit)	11.5 l
Weight (cooling unit)	~ 30kg

5.3 Conditions for operation, storage and transport

	Operation	Transport and storage
Ambient temperature	From 18°C to 30°C	From -20°C to 70°C
Rel. humidity	From 20% to 75%	From 10% to 90%
Barometric pressure	From 700hPa to 1060hPA	From 700hPa to 1060hPA

6 Curves and tables

6.1 Heating and cooling curve of the X-ray tube assembly

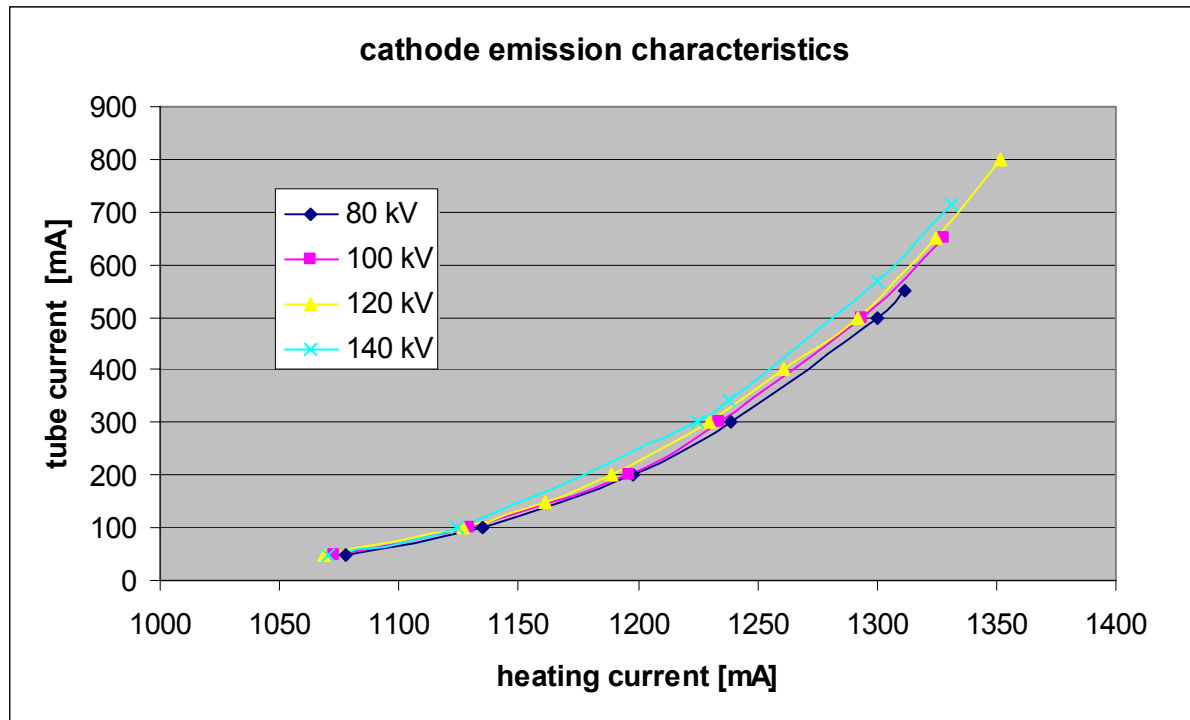


6.2 Anode heating, anode cooling curve

Not reasonable, see * in chapter 5.1

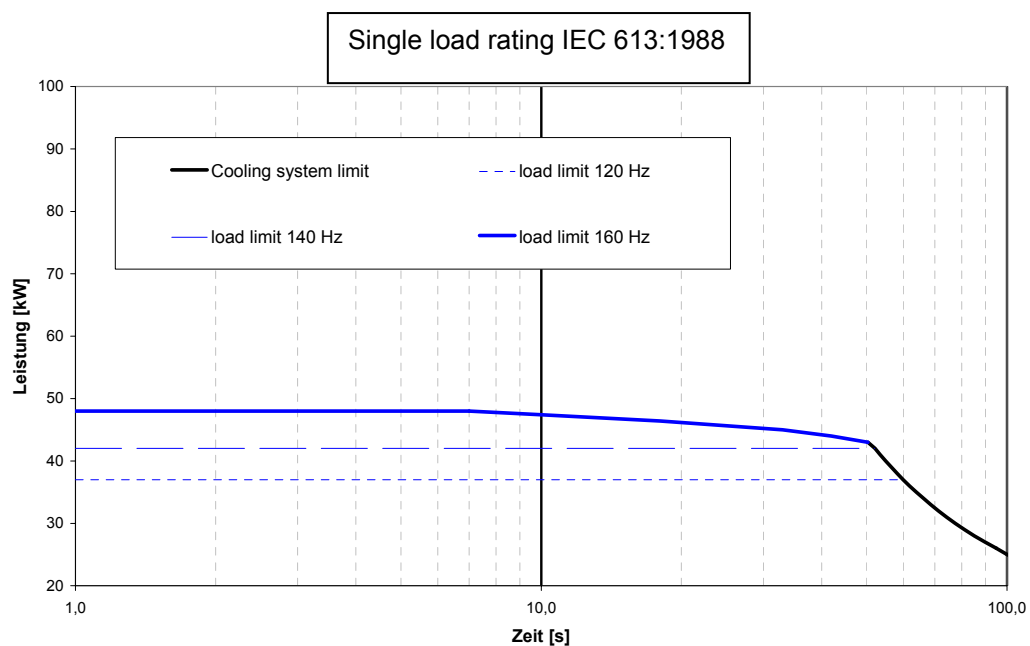
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6.3 Cathode emission characteristics

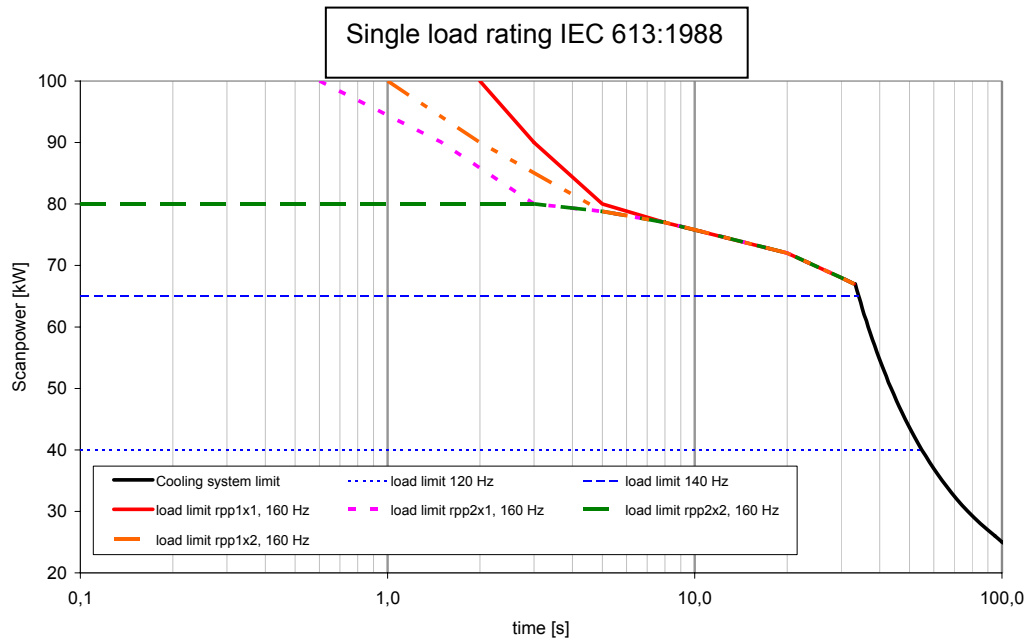


6.4 Single and series loads

Single loads (load limit curves) for the small UHR focus F1
(thermal anode reference power 4.6kW)



Single loads (load limit curves) for the small focus F2
(thermal anode reference power 4.6kW)

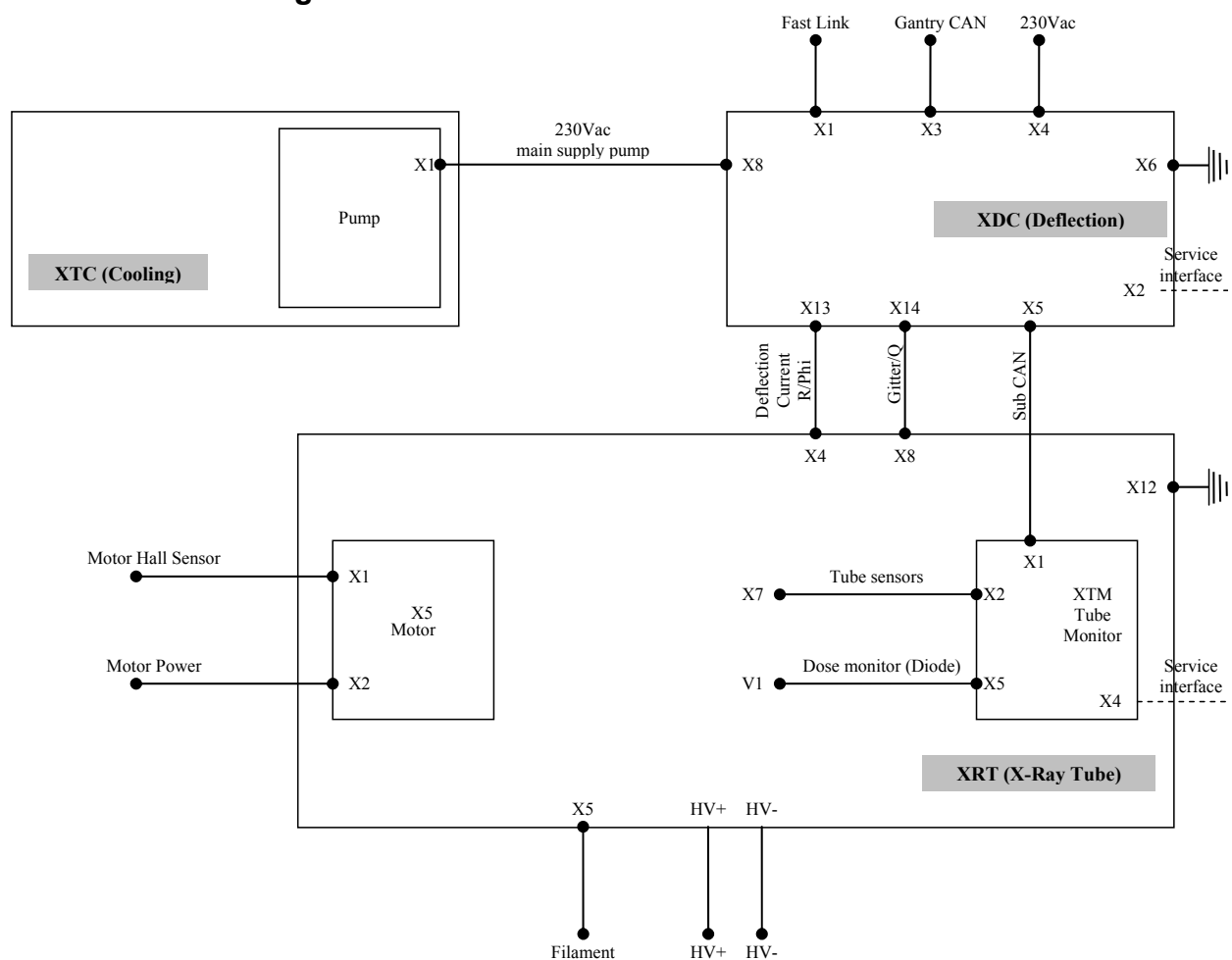


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Serial loading														
scan time [s]	repetitions	rot. time [s]	voltage [kV]	current [mA]	focus	rpp	scan power [kW]	sequence break [s]	break [s]	anode frequency [Hz]	total scan time in repetitions [s]	cycle time [s]	energy [kW/s]	average power / kW
14		0,5	120	540	small	1x2	64,8	n.a.	25	140	14	39	907,2	
14		0,5	120	540	small	1x2	64,8	n.a.	10		14	24	907,2	
14		0,5	120	540	small	1x2	64,8	n.a.	537		14	551	907,2	4,5
13		0,5	140	490	small	1x2	68,6	n.a.	25	160	13	38	891,8	
13		0,5	140	490	small	1x2	68,6	n.a.	10		13	23	891,8	
13		0,5	140	490	small	1x2	68,6	n.a.	539		13	552	891,8	4,5
12		0,3	120	616	small	2x2	73,9	n.a.	181	160	12	193	887,0	4,6
16		1	120	300	small UHR	2x2	36	n.a.	110	160	16	126	576,0	4,6
0,5	40	0,5	80	500	small	1x2	40	0,5	5	120	20	45	800,0	
2	20	1	80	495	small	1x2	39,6	3	200		40	300	792,0	4,6
14		0,5	120	600	small	1x2	72	n.a.	205		14	219	1008,0	4,6
50		0,3	80	550	small	1x2	44	n.a.	430	140	50	480	2200,0	4,6

The above table shows a few examples of series loads for Straton MX P.

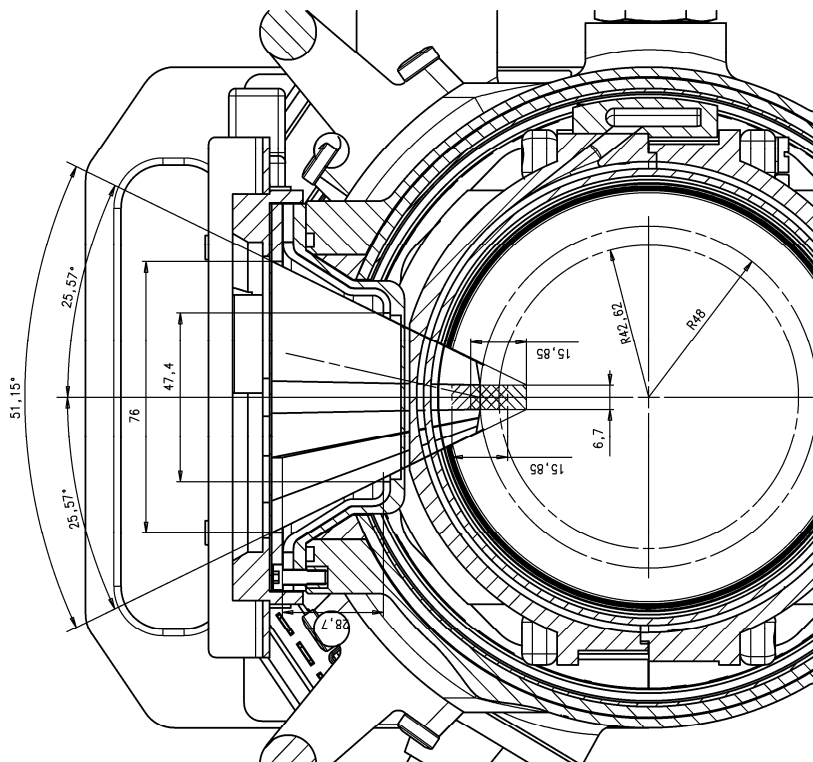
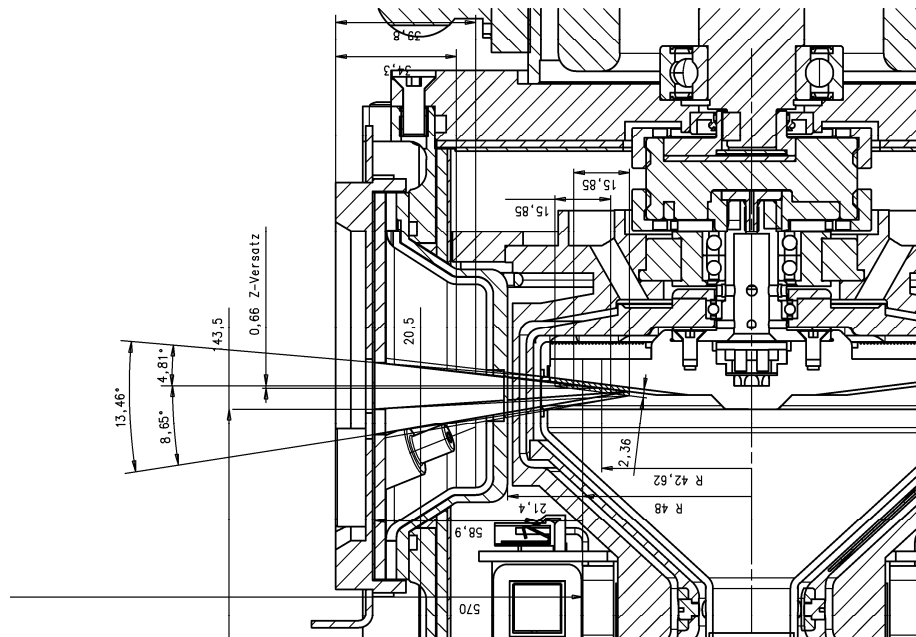
7 Connection diagram



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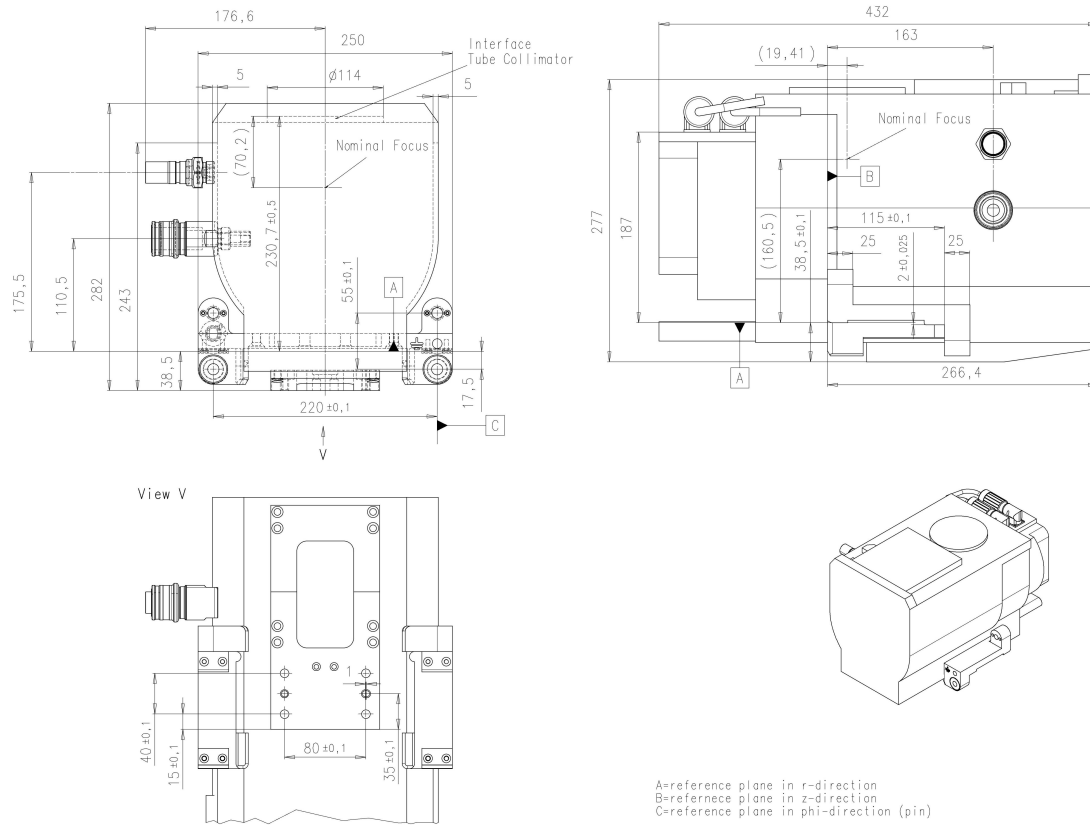
8 Dimensional drawings

8.1 Maximum radiation field



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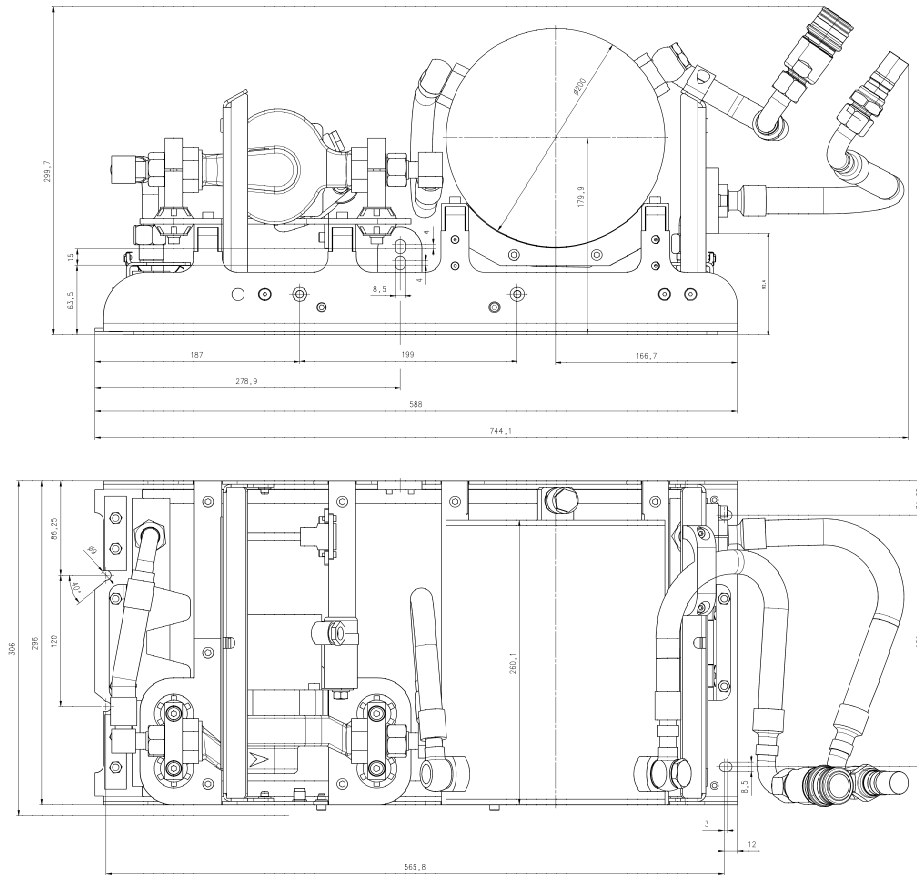
8.2 Tube assembly dimensional drawing



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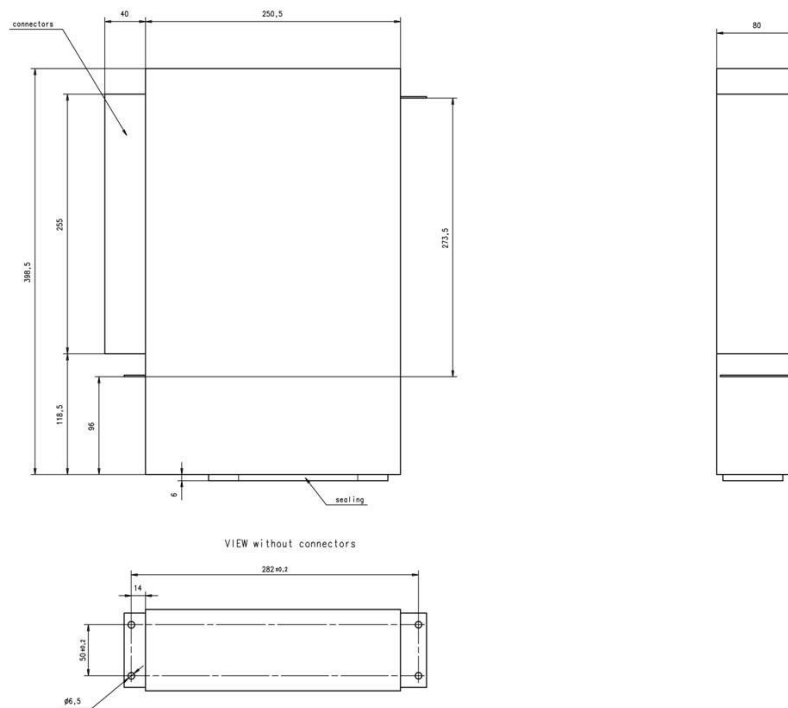
8.3 Cooling unit dimensional drawing

Flexible connecting hoses differ between cooling unit 10141790 and 10414538



8.4 Further components dimensional drawing

X-ray deflection control



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