

**OPERATION MANUAL
X-RAY TUBE ASSEMBLY
0.7/1.2JG326D-265**

Read this operation manual thoroughly before you use the product. Keep this operation manual for future reference.



Thank you for purchasing a SHIMADZU medical equipment. Before using the equipment, please read this manual thoroughly and use the equipment correctly.

NOTE

The precautions and prohibitions seen through the manual are classified as follows:

DANGER

Indicates an imminently hazardous situation which, if not avoided, will result in serious injury or death.

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in moderate to serious injury or possibly death.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor to moderate injury equipment damage.

NOTE

Emphasizes additional information that is provided to ensure the proper user of this product.

This manual is originally drafted and approved and supplied in English by the manufacturer.

Revision history

Rev.	Description	Date
D	Comply with RoHS. Add Revision history.	2013-10
E	Revise 1.4, 1.5, 1.6, 2.1, 2.3 and 7.3.	2015-02
F	Revise 1, 1.7.	2018-02
G	Revise 1.6, 1.8.	2018-11
H	Revise 1.8, 1.9.	2019-02
J	Revise Table 3.	2019-05
K	Revise 1.2, 1.6.2 and 11.	2019-07

Operating Precautions

"Operating Precautions (for both the Safety and the Prevention of Danger) in the Use of Electric Medical Equipment"

1. Nobody without the following experience and knowledge should use the system.
 - (1) Medical (radiographic) training (if particular qualifications are required in the country concerned, those qualifications must be held).
 - (2) The capacity to read and understand the operation manual.
2. When installing the equipment, pay attention to the following items:
 - (1) Do not install system near water faucet or similar equipment.
 - (2) Install it away from potential sources of problems such as abnormal pressure, temperature or humidity, drafts, direct sunlight, dust chlorine or sulfur gas.
 - (3) During transportation and operation of the equipment, avoid tilting, vibration and any impact against it.
 - (4) Keep the equipment away from the areas where chemicals or gases are stored.
 - (5) Use only the correct electrical power source with matching frequency, voltage and current (or wattage).
 - (6) Check the condition of the battery power source (power and polarity) before operating the equipment.
 - (7) Properly ground the equipment
3. Before operating the equipment, pay attention to the following items:
 - (1) Check the conditions of switch contacts, polarity, dial settings, and meters, and make sure the equipment performs correctly.
 - (2) Confirm that the ground is connected properly.
 - (3) Check all wiring for proper and correct connections.
 - (4) Pay attention when using more than one unit at a time, because it may lead to an incorrect diagnosis and cause danger.
 - (5) Check the condition of the external electric circuit, which will be directly connected to a patient.
 - (6) Check the condition of the battery power source.
4. While operating the equipment, pay attention to the following items:
 - (1) Do not over-exceed time or the amount of equipment use needed for diagnosis or therapy.
 - (2) Observe the equipment and patient continuously for early detection of problems.
 - (3) When a problem is detected with the equipment, take proper action to stop the equipment without harming the patient.
 - (4) Do not let the equipment touch the patient.

5. After operating the equipment, pay attention to the following items:
 - (1) Turn off the switches and return the dial to their original before use in the prescribed order.
Then, turn off the main power switch.
 - (2) Do not pull the power cable forcibly from the outlet.
 - (3) When storing the equipment, pay attention to the following factors:
 - (i) Keep it away from the water.
 - (ii) Store it away from the potential causes of problems such as abnormal pressure, temperature or humidity, draft, direct sunlight, dust chlorine or sulfur gas.
 - (iii) During transportation and storage of the equipment, avoid tilting, vibration and sharp impact against it.
 - (iv) Store the equipment away from areas where chemicals and gases are stored.
 - (4) Clean all attachments, cables and contacts, and store them in one place.
 - (5) Keep the equipment clean to avoid problems during the next use.
6. When the equipment is found to be out of order, do not try to repair it. Display an appropriate sign to indicate that the equipment is out of order, and call a certified repair technician for repair.
7. Do not modify and part of the equipment.
8. Preventive maintenance
 - (1) The equipment and its parts should be periodically checked.
 - (2) If the equipment has not been in operation for an extended period of time, test it prior to actual operation to make sure it works correctly and safety.
9. Concerning other items, operate properly according to the operating manual.

WARNING

The responsibility for management of use and maintenance of a medical equipment lies in a user.

This device is restricted to use by, or on the order of, a diagnostic radiology technician or a person with a certificate indicating equal proficiency.

Repair and inspection of the inside of the equipment is dangerous. Make sure to contact our service agency for repair and inspection.

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

NEVER MODIFY THE EQUIPMENT!

In general, almost all of the modifications are strictly prohibited by the Regulatory requirements of the law of the country where device is installed.

Please contact our service agency if it is needed to modify the device.

PERFORM PERIODIC INSPECTION!

Preventive maintenance is required to maintain safety and performance of this system for a long time.

This manual gives detailed description of occasional and periodic maintenance and inspection that a user should perform.

As to the maintenance and inspection that specially trained Specialists exclusively can perform, utilize the maintenance Agreement offered by our company.

WARNING

Do NOT perform any maintenance work of the equipment during study.

The patient may be injured.

Shimadzu Limited Product Warranty

The system is warranted to be free from defects in material and workmanship for one year from the date of delivery. If found to be defective, the system must be offered to Shimadzu for inspection and examination. Upon examination, Shimadzu, at its sole option, will repair or replace at no charge, the system or any part found to be defective. Components which wear are not warranted.

This warranty extends to original purchaser or the lessee of the new system only. If the system is to be resold or delivered to a third party, such third party must be provided with a copy of this manual, the installation manual and the technical manual supplied with the system.

This warranty does not apply to the following:

1. Failure or damage due to any installation, relocation, or service not provided by the SHIMADZU service representative or a SHIMADZU designated contractor.
2. Failure or damage caused by the product of other companies (except those purchased from SHIMADZU).
3. Failure or damage due to repairs using non-SHIMADZU certified service parts.
4. Failure or damage due to non-compliance with the notices and procedures set forth in this manual.
5. Failure or damage due to any operating environment deviating from the requirements set forth in this manual.
6. Failure or damage due to natural disasters such as power surge, rain, fire, earthquake, flood, and thunder.

Service after the expiration of the warranty is available at a reasonable cost and should be performed by the SHIMADZU service representative.

IN NO EVENT SHALL SHIMADZU AND ITS AFFILIATED ENTITIES BE LIABLE TO ANY PERSON OR ENTITY FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, ANY DAMAGES RESULTING FROM LOSS OF USE, BUSINESS INTERRUPTION, LOSS OF PROFITS, LOSS OF SAVINGS, THE COST OF PROCUREMENT OF SUBSTITUTED GOODS, SERVICES OR TECHNOLOGIES OR FOR ANY MATTER ARISING OUT OF OR IN CONNECTION WITH THE USE OR INABILITY TO USE THE SYSTEM.

In some jurisdictions, some of the foregoing warranty disclaimers or damage limitations may not apply.

Shimadzu will be indemnified for any claim, liability, or damage arising out of the misuse or non-compliance with this manual by the purchaser or lessee of the system.

CAUTION

Federal law restricts this device to sale by or on the order of physician.
(This caution is the prescription language required by Federal Regulations in U.S.A.)

CAUTION

Contact your Shimadzu service representative for installation and relocation of the equipment.

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PREFACE

Thank you very much for your purchase of this X-ray tube assembly 0.7/1.2JG326D-265.

This apparatus is designed for Digital angiography, gastro-intestinal examination and other applications requiring high anode heat storage capacity.

The characteristics of this X-ray tube are as follows.

- (1) The target disk of this X-ray tube uses Rhenium-Tungsten faced Molybdenum and its heat content is 530kJ {750kHU}.
- (2) High cooling rate heat exchanger separated from X-ray tube assembly main unit improves following advantages.
 - a) Wider operator operating area in vicinity of the X-ray tube assembly main unit.
 - b) No burden on patients such as hot air generated from the heat exchanger.
 - c) High performance in operation under continuous repetitive load.
 - d) Safety operation is further assured, since X-ray tube assembly does not reach higher temperature.
- (3) By use of grid control, useless X-ray is cut off under pulse-fluorography and skin dose is reduced.

Please be sure to read this operation manual carefully prior to your use of this apparatus to assure its best operating conditions.

WARNING

Do not operate this unit if there is any uncertainty as to the proper functioning of the system. Refer all servicing to qualified service personnel.

1 GENERAL DESCRIPTION

1.1 INTENDED USE

0.7/1.2JG326D-265 is intended to be used as a X-ray tube assembly for medical diagnosis for radiographic and fluoroscopic examinations.

1.2 DETAILS OF COMPONENTS

This X-ray tube assembly 0.7/1.2JG326D-265 has two variations shown in Table1.

The difference of two types is combined heat exchanger.

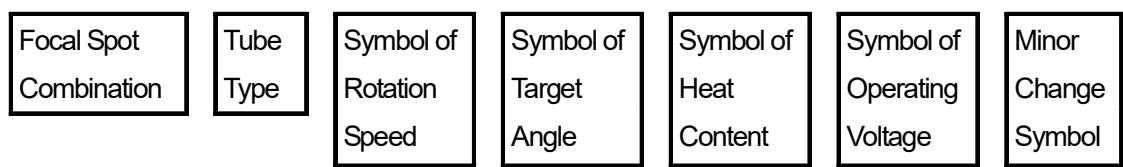
Table 1 COMPONENTS

Description	Model	Type1	Type 2
X-ray tube assembly	0.7/1.2JG326D-265	○	○
Trunnion ring ^{*1}	B-22A	(○)	(○)
Heat exchanger	HE-12S	○	
	HE-05S		○
Oil vessel	—	○	○
Accompanying document	Operation Manual	○	○
	Installation Manual	○	○
	Inspection Certification	○	○

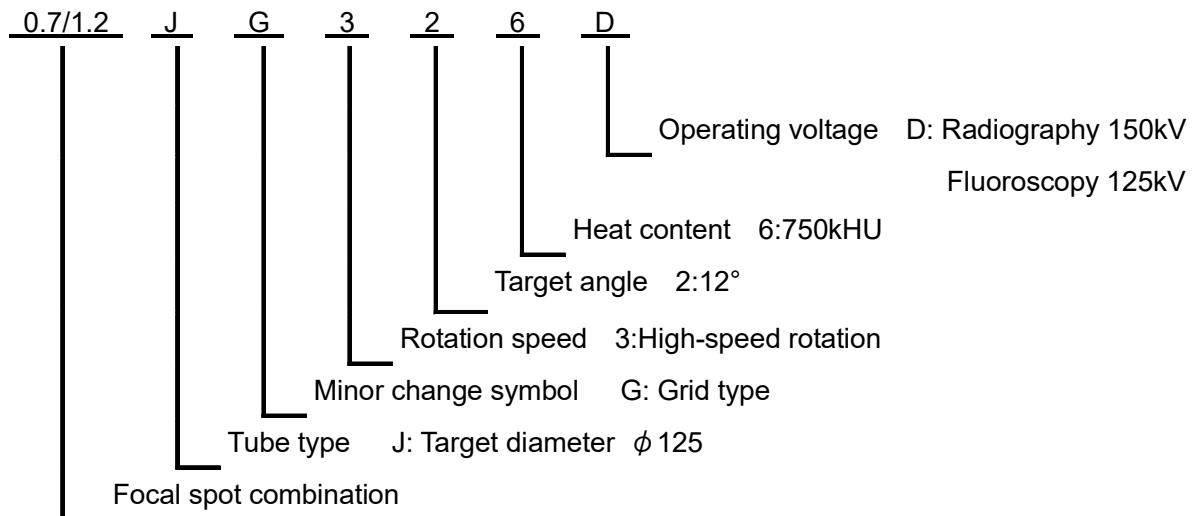
*1 Optional parts. In some cases, it is not included in replacement X-ray tube assembly.

1.3 NOMENCLATURE OF X-RAY TUBE

Nomenclature of X-ray tube is as follows.

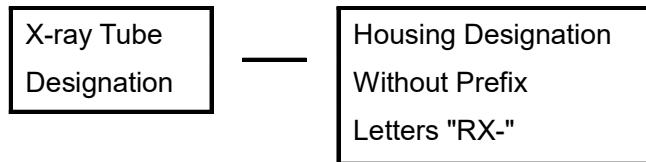


In case of 0.7/1.2JG326D

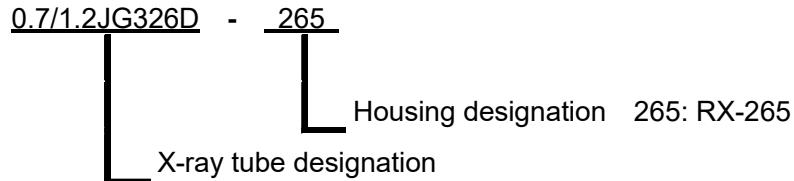


1.4 NOMENCLATURE OF X-RAY TUBE ASSEMBLY

Nomenclature of X-ray tube assembly is as follows.



In case of 0.7/1.2JG326D-265



1.5 APPEARANCE

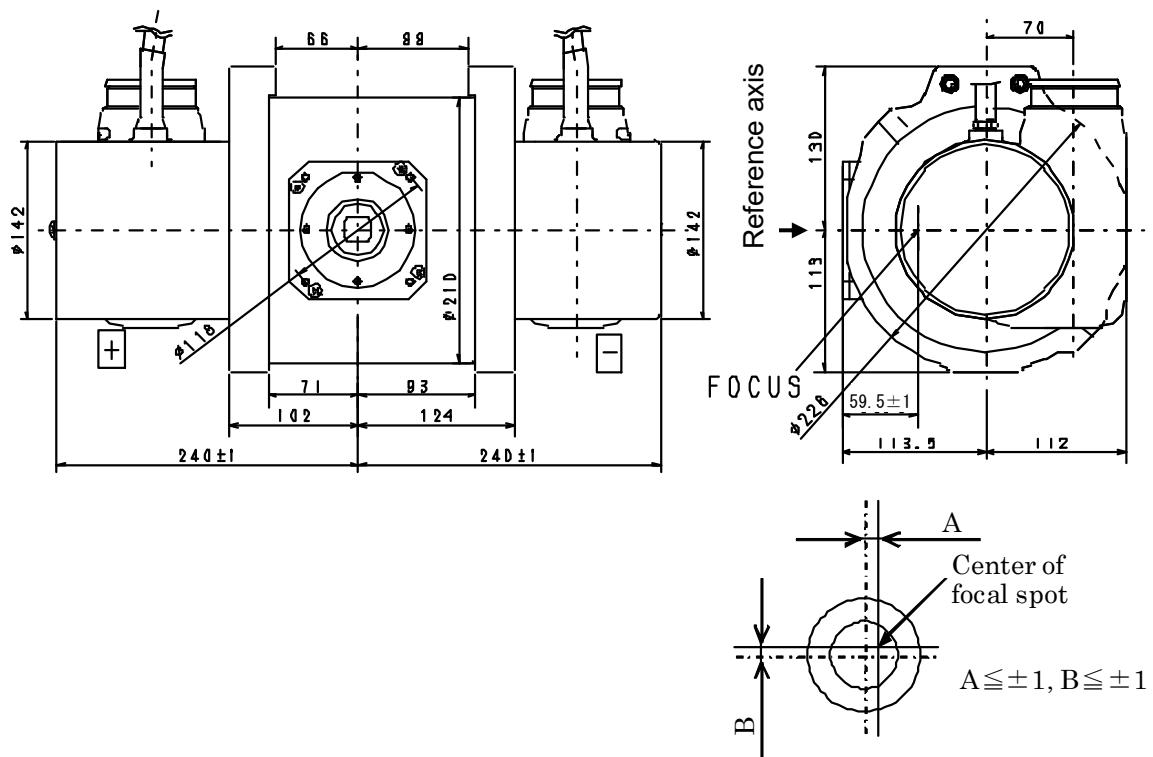


Fig. 1 X-RAY TUBE ASSEMBLY

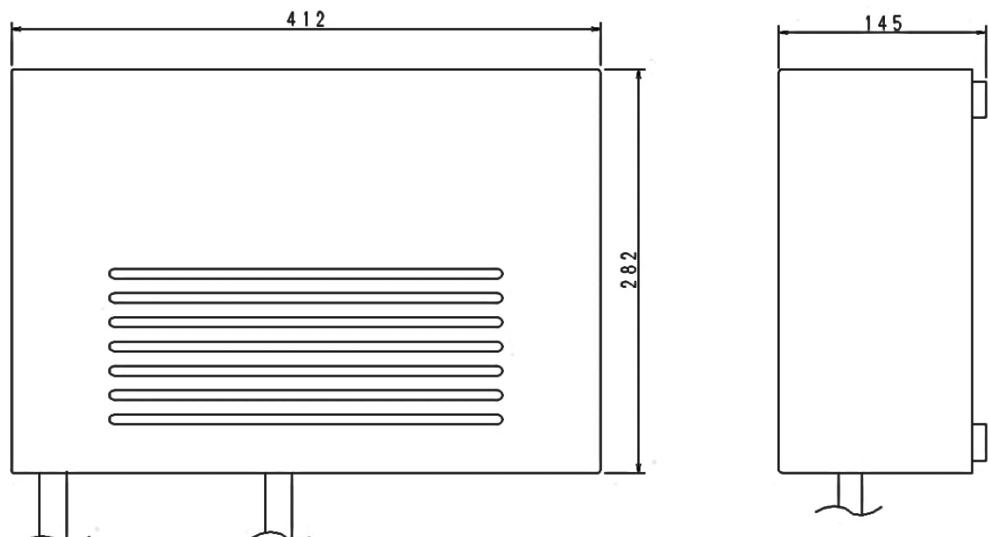


Fig. 2 HEAT EXCHANGER HE-12S

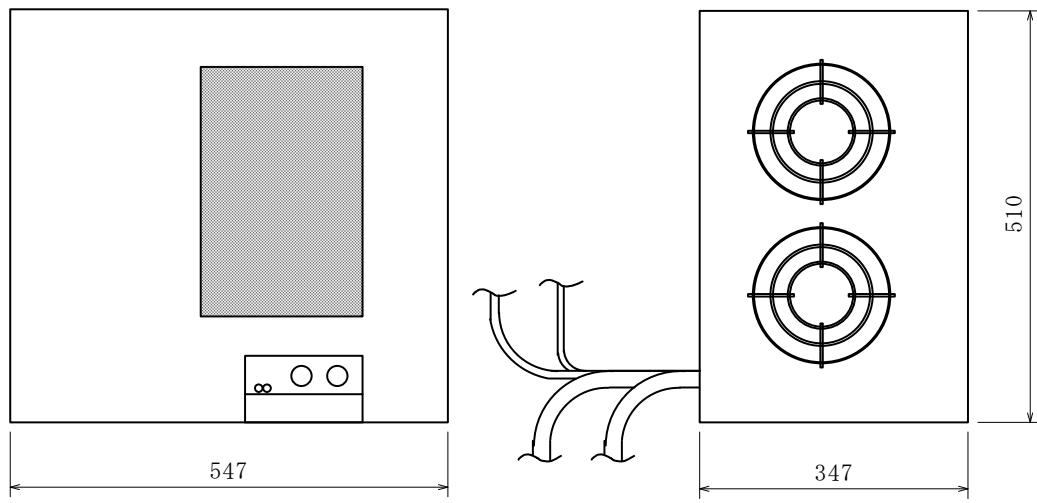


Fig. 3 HEAT EXCHANGER HE-05S

1.6 LABELS

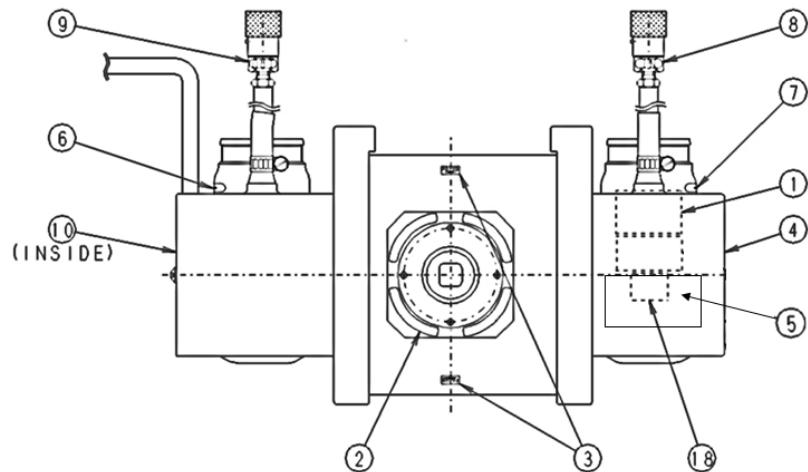


Fig. 4 LABELS ON X-RAY TUBE ASSEMBLY

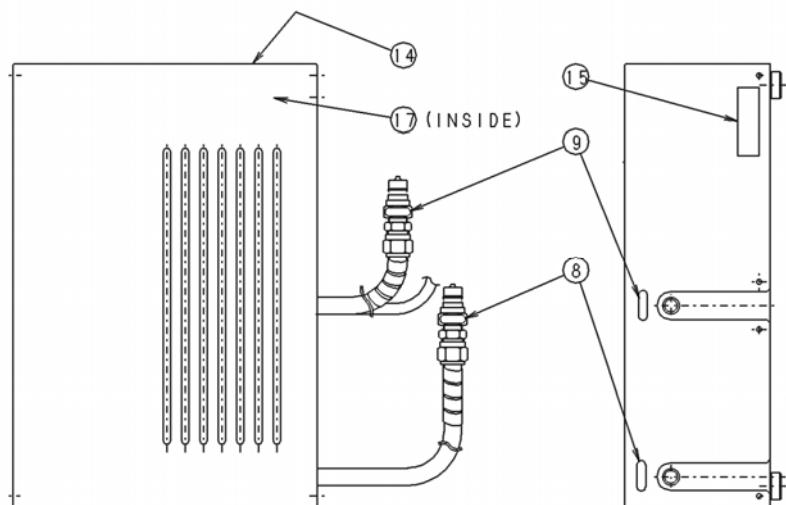


Fig. 5 LABELS ON HEAT EXCHANGER HE-12S

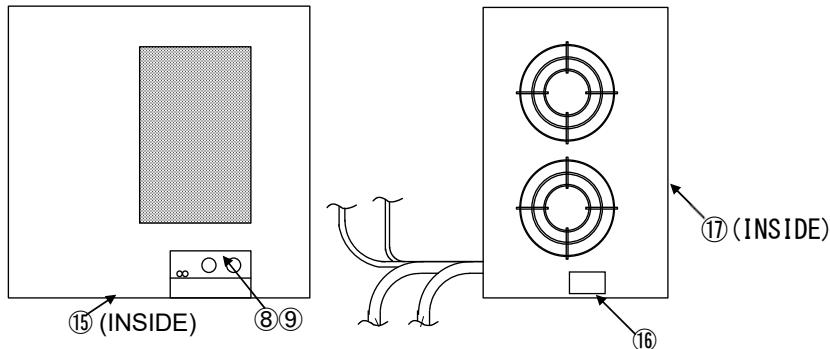
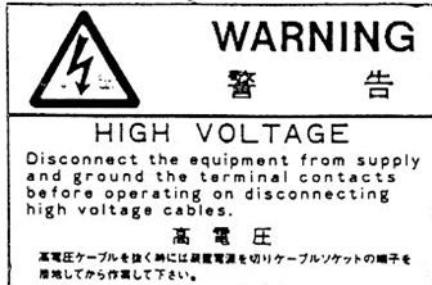


Fig. 6 LABELS ON HEAT EXCHANGER HE-05S

1.6.1 WARNING LABELS



⑩⑯ Warning Label (Electrical shock)



1.6.2 OHTER LABELS

④ Identification Label (X-ray tube assembly)



⑯Identification Label (HE-12S)



⑯ Identification Label (HE-05S)



③ Focus Label *1



⑥⑦ Polarity of high voltage label



⑧⑨ Polarity of oil hose label



*1 According to the surface color of X-ray tube assembly, a position of focal spot is indicated by a hollow on the surface instead of ③ Focus Label.

⑯ Indication Label of fuse rating

250V 2A

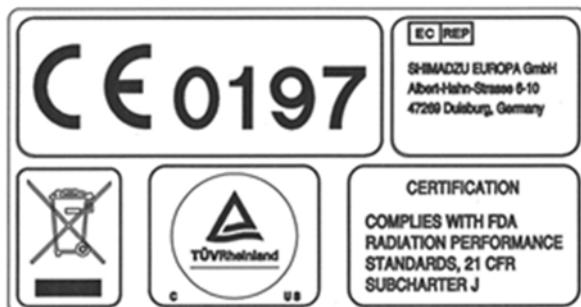
250V 5A

⑰ Follow manual label



1.6.3 OHTER LABELS (ONLY FOR CE)

⑤CE UL WEEE Label



1.7 SYMBOLS

The symbols used on the X-ray tube assembly are shown below:

Symbol	Location	Meaning
	On Identification label	Refer to the operation manual
	On warning and caution labels	Observe described items, or refer to the operation manual
	On Identification label	Refer to the operation manual
	On Identification label	Year and month of manufacture
	On Identification label	Manufacturer
	On Identification label	Serial number
	On warning label (High voltage)	Warning: High voltage
	On warning label (Electrical shock)	Warning: Electrical shock
	On Follow manual label	Follow the manual
	On packaging	Temperature limitation
	On packaging	No wet
	On packaging	Fragile-Handle with care
	On packaging	Do not turn over

1.8 STATEMENT OF COMPLIANCE [FOR EUROPE]

(a) Regulatory Information

The product complies with the requirement of the Medical Device Directive 93/42/EEC and RoHS Directive 2011/65/EU

Product Name : X-ray tube assembly
Model Name : 0.7/1.2JG326D-265
Parts Number : 582-24825
Manufacturer : SHIMADZU CORPORATION
Medical Systems Division
Address : 1, NISHINOKYO-KUWABARACHO,
NAKAGYO-KU, KYOTO, 604-8511, JAPAN
Authorized Representative in EU : SHIMADZU EUROPA GmbH
Address : Albert-Hahn-Strasse 6-10,
47269 Duisburg, Germany

(b) Company's Quality System

The company's quality management system complies with the requirements of Annex II, excluding Section 4 of the MDD 93/42/EEC, which is certified by TUV Rheinland LGA Products GmbH (Notified under No.0197)

(c) International Standards

- IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+A1:2013
- IEC 60601-1-2:2007 / EN 60601-1-2:2007
- IEC 60601-1-3:2008+A1:2013 / EN 60601-1-3:2008+A11:2016
- IEC 60601-2-28:2017 / EN 60601-2-28:2010
- IEC 60522:1999 / EN 60522:1999
- ISO 14971:2007, Corrected version 2007-10-01 / EN ISO 14971:2012
- ISO 15223-1:2016 Corrected version 2017-03 / EN ISO 15223-1:2016
- EN 1041:2008

1.9 STATEMENT OF COMPLIANCE WITH STANDARDS

- X-RAY TUBE ASSEMBLY 0.7/1.2JG326D-265), IEC 60601-2-28:2017
- X-RAY TUBE ASSEMBLY 0.7/1.2JG326D-265), EN 60601-2-28:2010

2 TECHNICAL DATA

2.1 TECHNICAL DATA LIST

Table 2 TECHNICAL DATA

Items		Rated value	
Nominal X-ray tube Voltage IEC 60613:2010	Fluoroscopy	125 kV	
	Radiography	150 kV	
X-ray tube Assembly	Max. heat content		1,600kJ {2,260kHU}
	Nominal continuous input power IEC 60613:2010		2,000W
X-ray Tube	Max. anode heat content		530kJ { 750kHU}
	Max. anode heat dissipation rate		2,500W
	Max. continuous load		950W
	Continuous anode input power IEC 60613:2010		950W (Continuous)
Nominal focal spot value IEC60336		0.7	1.2
Measuring method of focal spot size		Slit camera	Slit camera
Nominal anode input power (0.1sec)	180Hz	55kW	105kW
	120Hz ^{*1}	45kW	85kW
Nominal radiographic anode input power IEC 60613:2010	180Hz	55kW	105kW
	120Hz ^{*1}	45kW	85kW
Max. filament voltage		13.8V	18.4V
Max. filament current ^{*2}		5.6A	5.6A
Cut off voltage		-2,200V	N/A
Anode target	Material		Rhenium-tungsten faced molybdenum
	Angle/diameter		12°/125mm
Anode rotation ^{*3}		Direction of anode rotation is counterclockwise as viewed from the cathode side and R.P.M as follows. 9700 min. ⁻¹ {R.P.M.} at 180 Hz 6500 min. ⁻¹ {R.P.M.} at 120 Hz	
Minimum total filtration IEC 60601-2-28:2017		2.4 mm Al/75 kV (Including added filter ^{*4})	
Permanent filtration ^{*5}	IEC 60601-2-28:2017	1.1 mm Al/75 kV IEC 60522:1999 (without added filter)	
	JIS Z 4751-2-28:2008 (IEC 60601-2-28:1993)	Min. 1.5 mm Al at 70kV ^{*6} (Including added filter)	
Leakage radiation ^{*7} IEC 60601-1-3:2008+A1:2013		Leakage radiation in hour from the X-ray tube assembly and collimator is less than 1.0mGy at a distance of 1 meter from the focal spot. However, leakage radiation in an hour from the collimator is less than 0.35mGy.	
X-ray radiation field		350mm × 350mm (at distance of 1000mm from focal spot)	
IEC classification	IEC 60601-1:2005+A1:2012	CLASS I	
Mode of operation		Continuous operation with intermittent loading	
Mass		29 kg (main unit)	
High voltage connector		IEC 60526 type	

- *1 The rating under 120Hz rotation is determined automatically being combined with Shimadzu high voltage generator such as UD150B-40.
- *2 This value is the maximum value usable in tube current adjustment, and its limit in usual use is less than 5.2A.
- *3 This X-ray tube shall be combined with Shimadzu starter SA-61.
The recommended frequency of input power to the stator is less than once a minute.
- *4 Added filter
Added filter (1 piece of 1.2mm Al filter and 1 piece of 0.3mm Al filter, Min. 1.3mmAl equivalent considering the tolerance of thickness) is inserted in X-ray port. It should not be removed in any case to attain specified total filtration.
- *5 Inherent filtration of X-ray tube is min. 0.9 mm Al.
- *6 This value is including the added filter. Total filtration is stated as permanent filtration according to JIS Z 4751-2-28:2008 which is the IDT standard to IEC 60601-2-28:1993.
- *7 Leakage radiation dose measuring condition
125kV, 950W continuous

2.2 ROTATIONAL PERFORMANCE

Table 3 ROTATIONAL PERFORMANCE

Mode		Start conditions			Specified rotational speed holding conditions				Phase advancer capacitor
Basic rotational Speed	Specified Rotational speed	Time	Frequency	Voltage	On time	Off Time	Frequency	Voltage	
Stop	Triple rotation	3.5s	180Hz	500V	1s	25s	180Hz	500V	5μF
Stop	Double rotation	3.5s	120Hz	280V	0.28s	15s	120Hz	280V	10μF
Double Rotation	Triple rotation	0.8s	180Hz	500V	1s	25s	180Hz	500V	5μF

Mode		Damping conditions			Phase advancer capacitor
Basic rotational Speed	Specified Rotational speed	Time	Frequency	Voltage	
Triple rotation	Double rotation	3.5s	120Hz	280V	10μF
Double rotation	Normal rotation	2.0s	DC	260V	-----

2.3 SPECIFICATIONS OF HEAT EXCHANGER

Table 4 SPECIFICATION OF HEAT EXCHANGER

Heat exchanger		HE-12S	HE-05S
Maximum cooling rate	W {HU/s}	2,000 {2,800}	2,500 {3,500}
Line voltage	Vac	Single Phase 100	Three Phase 200~220
Line power	W	230	150
Mass	kg	13	63
Maximum oil flow rate	l/min	3.0	3.0
Maximum fan air flow	50/60Hz m ³ /min	4.6/5.0	14.4/17
Cooling liquid		Insulating oil (IEC60296)	Insulating oil (IEC60296)
Installation type	IEC60601-1:2005	Fixed	Stationary

2.4 HIGH VOLTAGE GENERATOR

This apparatus is recommended to be used in combination with Shimadzu's high voltage generator UD150B-30, UD150B-40 or D150BC-40S.

3 OPERATING PRINCIPLE

Operating principle is as follows.

- (a) The filament is heated by passing an electric current, and then thermoelectrons are emitted.
- (b) The anode is rotated by electromagnetic induction from a series of stator.
- (c) A high voltage is applied between the cathode and anode to accelerate the electrons.
- (d) The accelerated electrons strike the anode target and X-rays are generated.
- (e) The field size of X-ray beams are limited by the collimator.
- (f) Large amounts of heat which are generated with X-rays are removed by the heat exchanger.

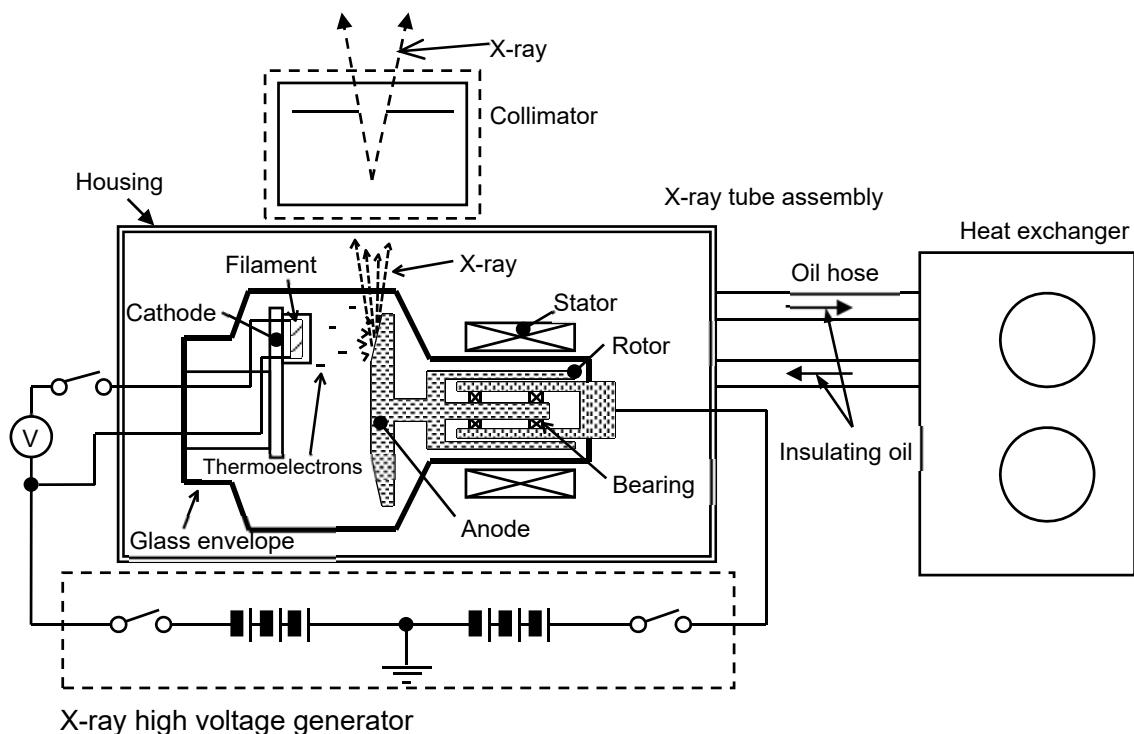


Fig. 7 OPERATING PRINCIPLE

4 THERMAL UNIT

Generated heat quantity in the anode of X-ray tube on loading is proportional to the product of tube voltage {kV}, tube current {mA} and loading time {s}.

When used in constant voltage, the relationship is as follows.

$$J = kV \times mA \times s \quad \{HU = kV \times mA \times s \times 1.41\}, \quad W = kV \times mA \quad \{HU/s = kV \times mA \times 1.41\}$$

$$\text{Remarks: } 1J = 1.41HU = 0.24\text{cal} \quad \{1HU = 0.71J = 0.17\text{cal}\}, \quad 1W = 1J/s = 1.41HU/s$$

5 OPERATION PROCEDURE

5.1 GENERAL OPERATION PROCEDURE

General operation procedure is as follows.

- (1) Turn on the X-ray diagnostic apparatus.
- (2) Carry out the daily seasoning described in subsection 6.3.2.
- (3) Prepare to diagnose a patient.
- (4) Fluoroscope the patient.
- (5) Limit the field size of X-ray beam by operating the collimator.
- (6) Operate ready switch for the X-ray tube to get ready ,and conduct radiography after "READY" sign is shown.
- (7) After operating ,keep running the heat exchanger about 40 minutes for cooling down the X-ray tube, and then turn off the X-ray diagnostic apparatus.

5.2 FLUOROSCOPY

In the case of long-time continuous fluoroscopy, operation is available on conditions up to the specified max. continuous load. It is, however, necessary to make the average long time continuous load lower than the specified one when radiography is combined therewith.

Accordingly, operation under average fluoroscopy load of 200W (100kV, 2mA) max. is recommendable to leave margin for radiography.

5.3 RAOGRAPHY

Refer to SINGLE LOAD RATING CHARTS. Rating Charts support to indicate the absolute maximum load of X-ray tube in a short time and are showing the relation between the X-ray tube current (in mA) and the loading time (in sec) for various voltages (in kV).

SINGLE LOAD RATING CHARTS is supposed to show the maximum permissible value. Never apply the load over ratings at any condition of operation including permissible error of the apparatus. So, it is recommendable to operate the tube under the condition of less than 90% of SINGLE LOAD RATING CHARTS.

5.3.1 SINGLE RADIOGRAPHY

- (a) The load of exposure must be less than 90% of SINGLE LOAD RATING CHARTS.
- (b) Take the rest time so that the average anode load will become 200W {280HU/s}.

The necessary rest time should be 10 minutes if the value obtained in the above expression exceeds 10 minutes.

5.3.2 SPOT FILMING

Radiography including fluoroscopy on gastro-intestinal examination.

- (a) The average load of fluoroscopy and radiography should be less than 460W {640HU/s}.
- (b) The radiographic load should be less than 80% of SINGLE LOAD RATING CHARTS, if the average load is less than 200W{280HU/s}, and less than 70% if exceeding 200W{280HU/s}.
By the way, the exposure interval may be optional.
- (c) The average load of X-ray tube assembly(fluoroscopy+radiography+stator load) is less than 2,000W{2,800HU/s}.

5.3.3 HIGH-SPEED SERIAL RADIOGRAPHY

- (a) The X-ray tube should be rested for more than 10 minutes before performing High-Speed serial radiography.
- (b) Find allowable load as following procedure.

Referring to HIGH-SPEED SERIAL LOAD RATING TABLE, find a block under "Number of exposures in series" which is greater than or equal to expected number of exposures in series. Select a block under "Tube load (kW) as a function of the exposure time (sec.) of the individual radiographs of the series" which is greater than or equal to expected exposure time. At the intersection of the two blocks, find maximum kW allowed for each exposure.

- (c) Example

0.7/1.2JG326D, 1.2mm focal spot, Determine kW allowed with following factors.

Maximum number of exposures: 100

Exposure time: 0.05 second

From the HIGH-SPEED SERIAL LOAD RATING TABLE, find 100 exposure block and 0.05 second block. At the intersection of the two blocks, find 30.0kW allowed for each exposure. Take rest time so that the average anode load becomes 950W, in case that X-ray tube is operated for more than 20 minutes.

* In case of high voltage generator being microcomputer type, allowable load and number of series are controlled automatically. In case of high voltage generator being non-micro computer type, determine load factor with referring this chapter.

6 CAUTION FOR USE

6.1 CAUTIONS FOR BEGINNING OF USE

Handling the X-ray tube assembly without qualification is prohibited by law, and do not execute installation and adjustment without our serviceman or designated serviceman.

WARNING

Be careful of exposure to X-ray.
Take measures for protection from X-ray.

- (a) To use this X-ray tube assembly for many years, it is recommended to take as much rest time between patients as possible.
- (b) In the event of an abnormally high sound of rotation, discharge or a situation such that high voltage can not be loaded, please contact your nearest service organ immediately.

6.2 GENERAL CAUTIONS

- (a) Do not use this apparatus in an atmosphere of inflammable or noxious gas.
- (b) The X-ray tube assembly is high voltage proof, but be sure to use ethanol anhydride for the disinfection.
- (c) If no radiography is conducted for a certain time in state with the trigger switch pulled, problems such as break in wiring to the filament due to evaporation of filament tungsten, improper withstand voltage, etc. are likely to occur. Do not conduct unnecessary ignition.
- (d) Do not turn off the power switch for at least 40 minutes after operating the X-ray tube assembly to cool it by the heat exchanger.
- (e) Do not tilte the HE-05S after installation to avoid overflowing the insulating oil.

WARNING

Take appropriate measures such as preparing alternative apparatus to prevent a patient from being in danger if the X-ray tube is broken. Because the X-ray tube could break down suddenly due to its product lifetime or unexpected failure.

6.3 SEASONING

6.3.1 INITIAL SEASONING

When using the X-ray tube assembly for the first time after its installation or after interruption of operation for longer than one month, initial seasoning shown as follows must be carried out.

- (a) With the X-ray tube current kept at 2.5 mA, raise the X-ray tube voltage gradually from 60kV to 120kV at the rate of 10kV/minute and keep the tube voltage 120kV for 5 minutes.
- (b) Take the rest time for 5 minutes
- (c) Raise the X-ray tube voltage with a large focus (1.2mm) as follows, and apply the following load at the rate of once in one minute per each voltage.
 - ① 70kV,250mA, 1sec ----- 1 exposure
 - ② 80kV,250mA, 1sec ----- 1 exposure
 - ③ 90kV,250mA, 1sec ----- 1 exposure
 - ④ 100kV,250mA, 1sec ----- 5 exposures
 - ⑤ 110kV,250mA,0.1sec ----- 1 exposure
 - ⑥ 120kV,250mA,0.1sec ----- 1 exposure
 - ⑦ 125kV,250mA,0.1sec ----- 1 exposure
 - ⑧ 130kV,250mA,0.1sec ----- 2 exposures
 - ⑨ 135kV,250mA,0.1sec ----- 2 exposures
 - ⑩ 140kV,250mA,0.1sec ----- 2 exposures
 - ⑪ 145kV,250mA,0.1sec ----- 2 exposures
 - ⑫ 150kV,250mA,0.1sec ----- 2 exposures
- (d) When there is such abnormality as unstable tube current during the seasoning, lower the tube voltage to where it becomes stable, keep the tube voltage for a while, and then raise the tube voltage again.
- (e) Take the rest time for 10 minutes.

6.3.2 DAILY SEASONING

Conduct daily seasoning in the following sequence.

- (a) Seasoning by fluoroscopy (0.7 mm focus)

- ① 80 ~ 120kV increase 2.5mA - 1min - 10kV/min
- ② 120kV keep 2.5mA - 5min

- (b) Seasoning by exposure (1.2mm focus)

Raise the X-ray tube voltage with a large focus as follows, and apply the following load at the rate of once in one minute per each voltage.

- ① 80kV, 250mA, 0.1sec ----- 1 exposure
- ② 90kV, 250mA, 0.1sec ----- 1 exposure
- ③ 100kV, 250mA, 0.1sec ----- 1 exposure
- ④ 110kV, 250mA, 0.1sec ----- 1 exposure
- ⑤ 120kV, 250mA, 0.1sec ----- 1 exposure
- ⑥ 125kV, 250mA, 0.1sec ----- 1 exposure

In the case of using over 130kV, continue the seasoning as follows.

- ⑦ 130kV, 250mA, 0.1sec ----- 1 exposure
- ⑧ 135kV, 250mA, 0.1sec ----- 1 exposure
- ⑨ 140kV, 250mA, 0.1sec ----- 1 exposure
- ⑩ 145kV, 250mA, 0.1sec ----- 1 exposure
- ⑪ 150kV, 250mA, 0.1sec ----- 1 exposure

(c) When there is such abnormality as unstable tube current during the seasoning, lower the tube voltage to where it becomes stable, keep the tube voltage for a while, and then raise the tube voltage again.

(d) Take the rest time for 10 minutes

6.4 SAFETY CIRCUIT

The thermal switch actuates to stop loading the high voltage when the temperature inside of the tube housing reaches 70 °C.

6.5 MAINTENANCE OF X-RAY TUBE ASSEMBLY

Periodical check of the X-ray tube assembly is necessary to maintain its stable performance and life for many years. The maintenance items and frequency are shown in the following Table 5 and 6. Also, in the following section, the detail of maintenance items and the others is shown.

Table 5 THE INSPECTION ITEMS FOR MAINTENANCE BY AN OPERATOR

Item	Frequency	Detail (Section No.)
Appearance	Before daily use	6.5.1
Safety circuit		-
Seasoning		6.3.2

Table 6 THE INSPECTION ITEMS FOR MAINTENANCE BY A MANUFACTURER

Item	Frequency	Detail (Section No.)
Appearance	Within a year	6.5.1
Safety circuit		6.5.2
Connection of high voltage cables		6.5.3
stator coils		6.5.4
Rotation of anode		10. TROUBLE SHOOTING
Oil level		6.5.6
Oil hose	Within five years	6.5.7
Insulating oil	Within two years	6.5.8

6.5.1 APPEARANCE

Check no oil leakage from the X-ray tube housing and heat exchanger.

Check no abnormal sound from pump and cooling fan of heat exchanger.

6.5.2 SAFETY CIRCUIT

Check function of this circuit, continuity of ground terminal wire, etc. Should there be the case where the thermal switch actuates, contact us or our agent because such a happening is abnormal.

6.5.3 CONNECTION OF CABLES

Replace the isolation packing with new one every year. Be sure to replace it whenever H.V. cable is disconnected from H.V. socket for repair or maintenance purpose. Replacement shall be done by our service person.

For connecting and disconnection, please refer to installation manual (section 6)

6.5.4 RESISTANCE OF STATOR COIL

Measure the resistance between X and Y, X and Z, and Y and Z on the terminal board of X-ray tube assembly and check the measured value within the following range.

X-Y : 14.0 - 18.0 Ω , X-Z : 45.0 - 55.0 Ω , Y-Z : 59.0 - 73.0 Ω

WARNING

Risk of electric shock. Be sure to measure the resistance after power has been turned off.

6.5.5 CLEANING

Use absolute ethanol to clean the X-ray tube assembly.

6.5.6 OIL LEVEL CHECK(FOR HE-05S ONLY)

An oil level indicator is mounted at the cap of an oil tank. Please take out the indicator from a tank and confirm that the position of oil surface level is at the knurling area of the indicator.

6.5.7 RENEWAL OF DETACHABLE HOSE

It is necessary to renew the oil hose every five years for the heat exchanger equipping detachable hose.

Please contact us or our agent for hose renewal.

6.5.8 RENEWAL OF INSULATING OIL (FOR HE-05S ONLY)

As for heat exchanger HE-05S, replacement of X-ray tube assembly does not always lead to replacement of heat exchanger. Using the heat exchanger for a long time, oil quality gets worse because of oxidation. So, insulating oil in HE-05S shall be changed to new one at the earlier period of following conditions.

- (a) Two years after newly installation or the last oil changing.
- (b) At the third replacement of X-ray tube assembly after newly installation or the last oil changing.

Please contact authorized Shimadzu Service Center to renew the insulating oil.

6.5.9 LABEL CHECK

Please check labels identified in section 1.5 and 1.6. If these labels are degraded or missing, please contact our service office or representative described on the back cover of the operation manual.

6.5.10 MANUAL CHECK

If any page of the manual is missing, please contact our service office or representative described on the back cover of the operation manual.

7 ENVIRONMENTAL CONDITIONS

7.1 TRANSPORTATION

In transportation of the X-ray tube assembly, be careful to handle it not to give excessive shock (vibration).

7.2 ENVIRONMENTAL CONDITIONS

7.2.1 TRANSPORTATION AND STORAGE

Transportation and storage environmental conditions are as follows.

X-ray tube assembly shall be transported and stored in the packing box.

Ambient temp. : -20 - 70 °C

Relative humidity : 10 - 95 % (No condensation)

Atmospheric pressure : 500 - 1,060 hPa {50 - 106kPa}

7.2.2 OPERATION

Operation environmental conditions are as follows.

Ambient temp. : 5 - 40 °C

Relative humidity : 30 - 90 % (No condensation)

Atmospheric pressure : 700 - 1,060 hPa {70 - 106kPa}

7.3 ELECTROMAGNETIC COMPATIBILITY (EMC) INFORMATION

X-ray tube assembly 0.7/1.2JG326D-265 satisfies the EMC (Electromagnetic Compatibility) standard IEC 60601-1-2:2007.

The 0.7/1.2JG326D-265 belongs to Group 1 and Class A equipment in accordance with EN/IEC 60601-1-2.

The equipment uses radio-frequency energy only for its internal function and is not intended to deliver energy to the patient. But little leakage radio-frequency energy does harm high sensitive equipment.

The system main power line in the clinical site should be connected to the domestic power sources which are separated from the public main network.

NOTE

All functions of “0.7/1.2JG326D-265” shall be considered essential performance.

All functions of “0.7/1.2JG326D-265” include generating preset X-ray radiation, monitoring the temperature of inside the housing, etc

CAUTION

Pay attention to the electromagnetic circumstances at the installation site.

The equipment may be affected by the electromagnetic environment at the installation site. Also, the installation of the equipment may affect other existing equipment.

X-ray tube assembly 0.7/1.2JG326D-265 is sensitive to electromagnetic environment under an installed room. It may be necessary to relocate the 0.7/1.2JG326D-265 because of affecting on other equipment functions.

Portable and mobile communication equipment can affect the 0.7/1.2JG326D-265, so that you need them to place far from it or turn them off. The 0.7/1.2JG326D-265 is in compliance with EMC requirements and Table 7 – Table 11 show detail EMC information. Refer to these tables when the equipment is installed and used.

Table 7

Guidance and manufacturer's declaration – electromagnetic emissions		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions EN55011/ CISPR11	Group 1	The 0.7/1.2JG326D-265 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions EN55011/ CISPR11	Class A	
Harmonic emissions EN61000-3-2/ IEC61000-3-2	Not Applicable (Combined total system's RATED input current exceeds 16A per phase)	The 0.7/1.2JG326D-265 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions EN61000-3-3 IEC61000-3-3	Not Applicable (Combined total system's RATED input current exceeds 16A per phase)	

Table 8

Guidance and manufacturer's declaration – electromagnetic immunity			
The 0.7/1.2JG326D-265 is intended for use in the electromagnetic environment specified below. The customer or the user of the 0.7/1.2JG326D-265 should assure that it is used in such an environment.			
Immunity test	EN/IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) EN61000-4-2/ IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst EN 61000-4-4/ IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5/ IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11/ IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Not Applicable (Combined total system is not LIFE SUPPORTING and it's RATED input current exceeds 16A per phase)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 0.7/1.2JG326D-265 requires continued operation during power mains interruptions, it is recommended that the 0.7/1.2JG326D-265 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field EN 61000-4-8/ IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 9

Guidance and manufacturer's declaration – electromagnetic immunity			
The 0.7/1.2JG326D-265 is intended for use in the electromagnetic environment specified below. The customer or the user of the 0.7/1.2JG326D-265 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the 0.7/1.2JG326D-265, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF EN 61000-4-6/ IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms 150kHz to 230MHz	Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF EN 61000-4-3/ IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m 351.2 MHz 800 MHz 1980 MHz 2412 MHz	$d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80MHz and 800MHz, the higher frequency range applies.			
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 0.7/1.2JG326D-265 is used exceeds the applicable RF compliance level above, the 0.7/1.2JG326D-265 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 0.7/1.2JG326D-265.			
^b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.			

WARNING

An exemption has been used and the 0.7/1.2JG326D-265 has not been tested for radiated RF IMMUNITY over the entire frequency range 80MHz to 2.5GHz. the 0.7/1.2JG326D-265 has been tested for radiated RF IMMUNITY only at selected frequencies.

Table 10

List of the transmitters or equipment used as RF test sources and the frequency and modulation characteristics of each source.				
Kind of equipment	Type	Manufacturer	Spot check frequencies	Modulation
For Radiated Immunity				
Digital Transceiver	IC-DPR5	ICOM	351.2MHz	FSK(frequency shift keying)
Cellular Telephone	F212i	Fujitsu	800MHz	PM(Phase modulation)
Cellular Telephone	812SH	Sharp	1980MHz	PM(Phase modulation)
Wireless LAN Station	WHR-HP-G	BUFFALO	2412MHz	OFDM(Orthogonal Frequency-Division Multiplexing)

Table 11

Recommended separation distances between portable and mobile RF communications equipment and the 0.7/1.2JG326D-265.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
 NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 12 CABLE LIST

Object	Part Name	Note
Low voltage cable *1	Low voltage cable, #20	Cable length: Max. 28m Shield : N Composition parts of X-ray tube assembly
Low voltage cable *1	Low voltage cable, #21	Cable length: Max. 28m Shield : Y Composition parts of X-ray tube assembly
HE power cable for HE-12S	Cable HE-12S	Cable Length : 12m Shield : Y Composition parts of the heat exchanger
HE power cable for HE-05S	Cable HE-05,A	Cable Length : 9m Shield : N Composition parts of the heat exchanger

*1 Low voltage cable for the X-ray tube assembly is alternative.

CAUTION

Do not use any cables other than the cables that provided or specified by us.

WARNING

All peripheral devices must satisfy the EMC standards regarding emission of electromagnetic waves and sensitivity to emitted electromagnetic waves. Devices that do not satisfy these standards may disturb the correct functioning of the system. In the worst case, this can cause serious injuries or clinical errors.

CAUTION

The 0.7/1.2JG326D-265 requires special precautions regarding EMC and needs to be installed and use according to the EMC information provided in this operation manual.

CAUTION

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Shimadzu as replacement parts for internal components, may result in increase emission or decreased immunity of the 0.7/1.2JG326D-265.

CAUTION

The 0.7/1.2JG326D-265 should not be used adjacent to or stacked use is necessary, 0.7/1.2JG326D-265 should be observed to verify normal operation in the configuration in which it will be used.

CAUTION

Anyone who connects additional equipment to the signal input / output parts, configuring a medical system, is responsible that the system complies with the requirements of EN/IEC 60601-1-2.

8 REMODELING

Remodeling of the apparatus shall be subject to agreement with our Engineering Section with actual remodeling done by our serviceman or those of a company so designed by us.

Do not remodel the apparatus without our agreement.

9 WASTE

On wasting X-ray tube assembly, contact our service department because it may be harmful to environment if the contents of X-ray tube assembly should come out.

Action for Environment

To all user of Shimadzu equipment in the European Union:

Equipment marked with this symbol indicates that it was sold on or after 13th August 2005, which means it should not be disposed of with general household waste. Note that our equipment is for industrial/professional use only.

Fig. 8 WEEE MARK



Contact Shimadzu service representative when the equipment has reached the end of its life. They will advise you regarding the equipment take-back.

With your co-operation we are aiming to reduce contamination from waste electronic and electrical equipment and preserve natural resource through re-use and recycling.

Do not hesitate to ask Shimadzu service representative, if you require further information.

10 TROUBLESHOOTING

If any troubles occur, contact your nearest service organ without disassembling the tube assembly by yourselves.

(a) In the following cases of anode rotation, you may continue using the X-ray tube.

- ① Rotating sound is high, but it is continuous sound and there is no abnormal sound like creak or scratch sound during rotation.
- ② Inertial rotation of the X-ray tube continues over 2 minutes after loading, and rotation does not stop quickly. (Check for this after DC brake works after fluoroscopy)

(b) There might be a case of a small flaw or stain-like trace on the target of the X-ray tube, but this is due to small discharge occurring in the course of seasoning. As far as steady operation is conducted at Nominal X-ray tube voltage attained at the end of seasoning described in Subsection 6.3.1 and 6.3.2, there is no hindrance to electrical performance.

11 MAINTENANCE PARTS

Our company service representative will exchange the maintenance parts of this product.

Refer to the Table 13 for a list of the maintenance parts.

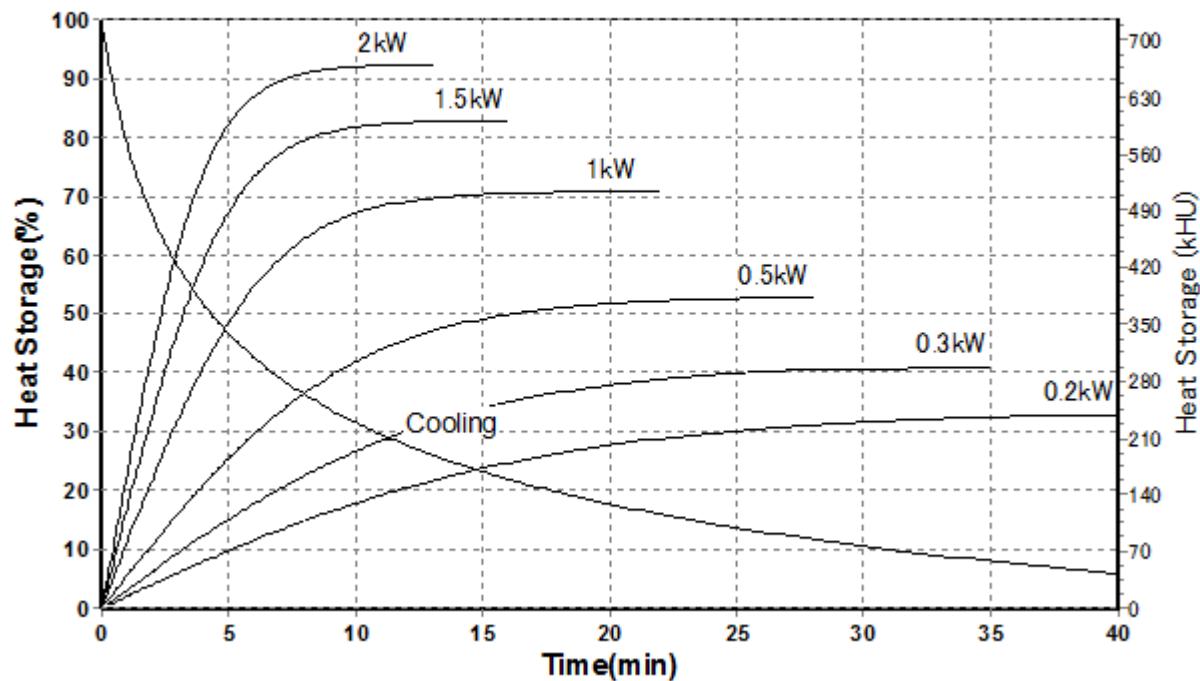
Table 13 LIST OF MAINTENANCE PARTS

	Parts name	Parts number	Necessary amount
X-ray tube main unit	Low voltage cable, #21L	582-24776-11	1pc
	Trunnion ring, B-22A	582-22966-01	1set
	Packing,#1	582-23029	1pc
	Packing,#5	582-24381	1pc
HE-12S	Cable HE-12S	582-24741	1pc
	Fuse, FGA0-2 4A *1	572-72000	1pc
	Fuse, FGA0-2 5A *1	572-72000-01	1pc
	Cable,HE-12S(D)	582-24902	1pc
	Relay Hose Assy	582-24900	2pcs
HE-05S	Cable HE-05, A	582-24008-01	1pc
	Cable HE-05, B	582-24008-02	1pc
	Hose assy, HE-05, A	582-24007-01	1pc
	Hose assy, HE-05, B	582-24007-02	1pc
	Fuse UL CSA FGA0-2	072-01678-07	2pcs
	Insulating oil, transformer S	582-24467	2Cans

*1 Refer to the indication label of fuse rating inside the HE-12S.

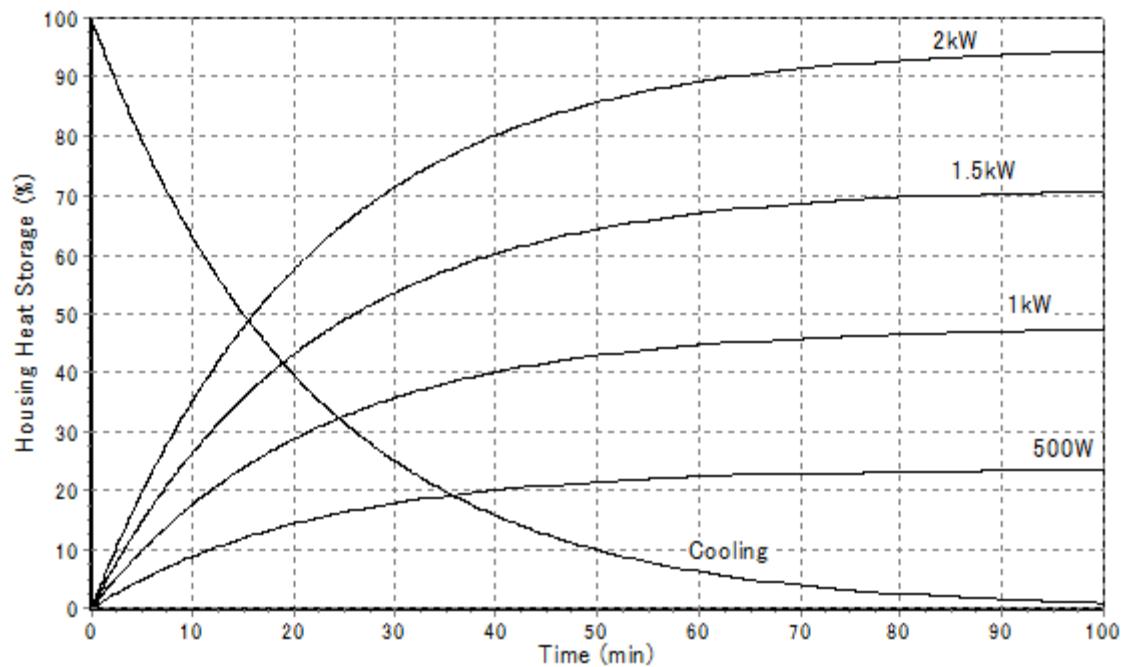
APPENDIX

Anode Heating and Cooling Characteristics

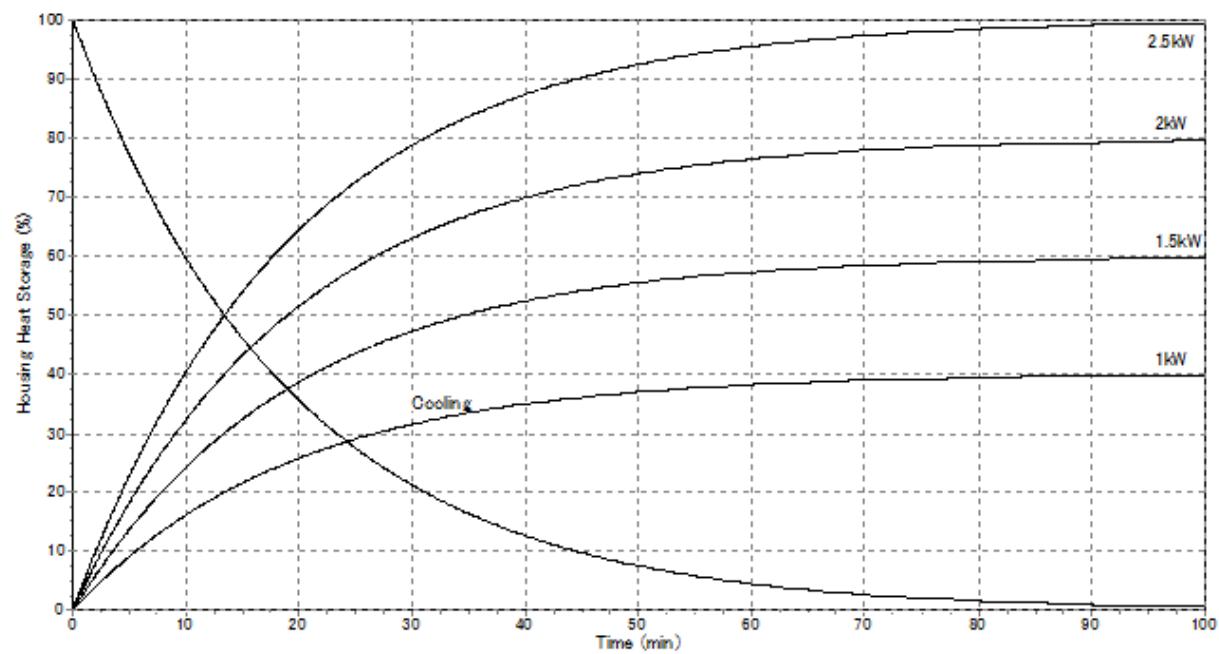


X-RAY TUBE ASSEMBLY HEATING AND COOLING CURVE (HE-12S)

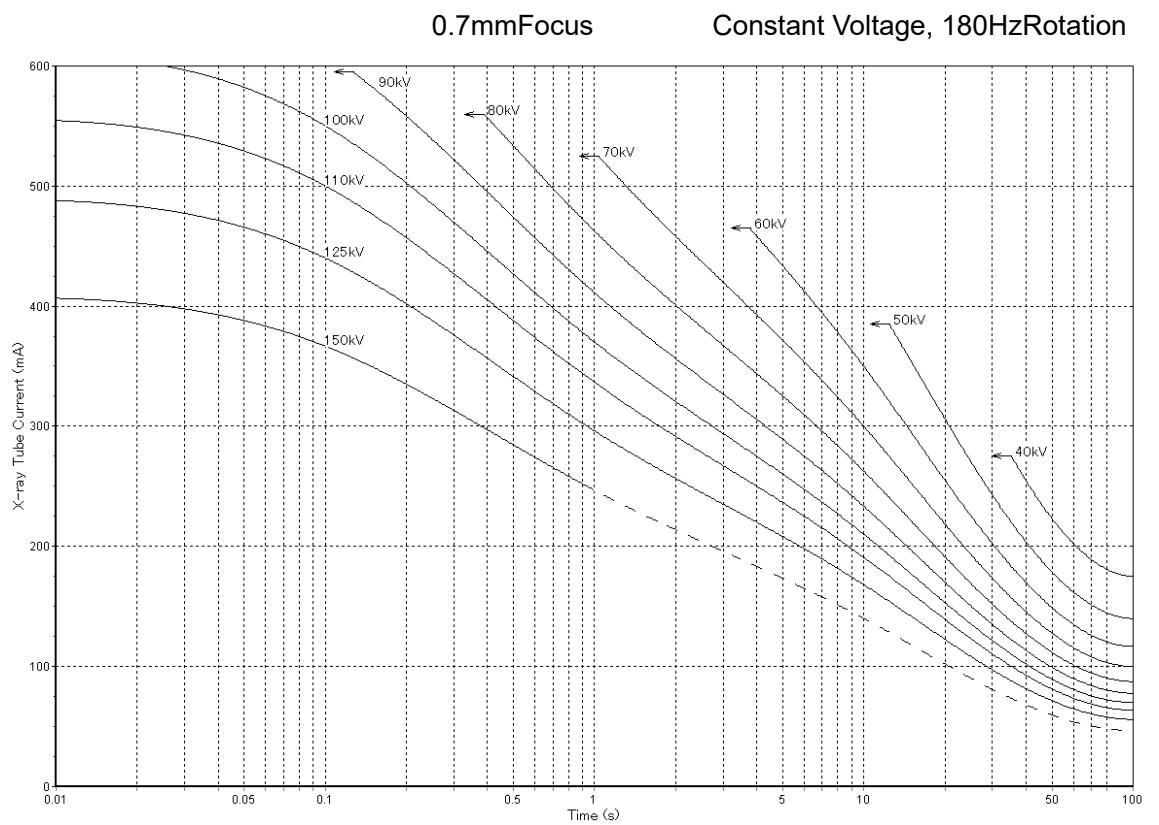
X-ray Tube Assembly Heating and Cooling Characteristics



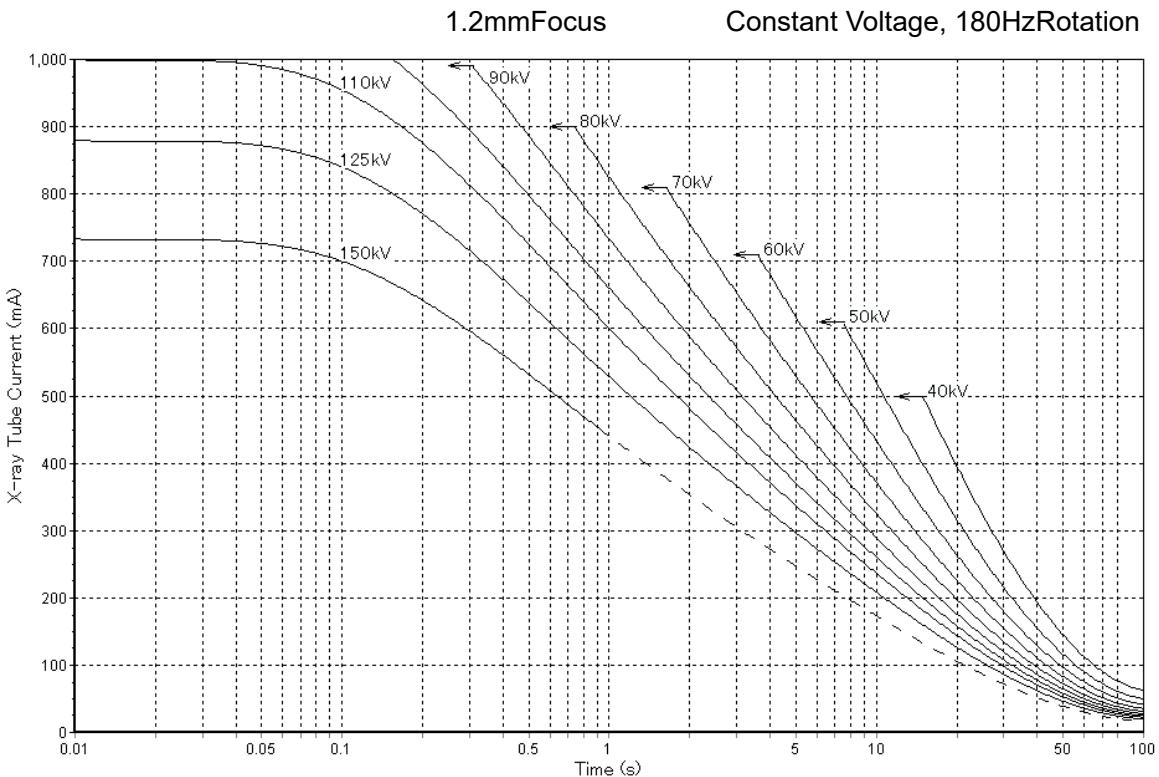
X-RAY TUBE ASSEMBLY HEATING AND COOLING CURVE (HE-05S)



SINGLE LOAD RATING CHARTS



Refer to IEC 60613:2010



Refer to IEC 60613:2010

HIGH-SPEED SERIAL LOAD RATING TABLE

"0.7"JG326D, 180Hz, Three Phase or Constant voltage

Number of exposure in series (exp)	Tube load (kW) as a function of the exposure time (seconds) of the individual radiographs of the series														
	0.01	0.02	0.03	0.04	0.05	0.06	0.08	0.1	0.12	0.14	0.16	0.18	0.2	0.225	0.25
10	43.8	40.0	37.2	35.2	33.5	32.4	31.2	29.8	28.6	27.6	26.8	26.1	25.6	25.0	24.4
20	40.0	35.2	32.4	31.2	29.8	28.6	26.8	25.6	24.7	23.9	23.2	22.6	22.0	21.1	20.4
40	35.2	31.2	28.6	26.8	25.6	24.7	23.2	22.0	20.7	20.0	19.4	18.7	18.0	17.3	16.8
60	32.4	28.6	26.1	24.7	23.4	22.7	20.7	19.6	18.7	17.8	17.0	16.2	15.4	14.7	14.0
80	31.2	26.8	24.7	23.2	22.0	20.7	19.4	18.0	17.0	15.9	15.0	14.2	13.4	12.7	12.0
100	29.8	25.6	23.4	22.0	20.4	19.6	18.0	16.8	15.4	14.4	13.4	12.3	11.2	10.3	9.6
150	27.2	23.4	21.1	19.6	18.4	17.3	15.4	14.0	12.3	11.0	10.0	9.3	8.4	7.7	7.0

Refer to IEC 60613:2010

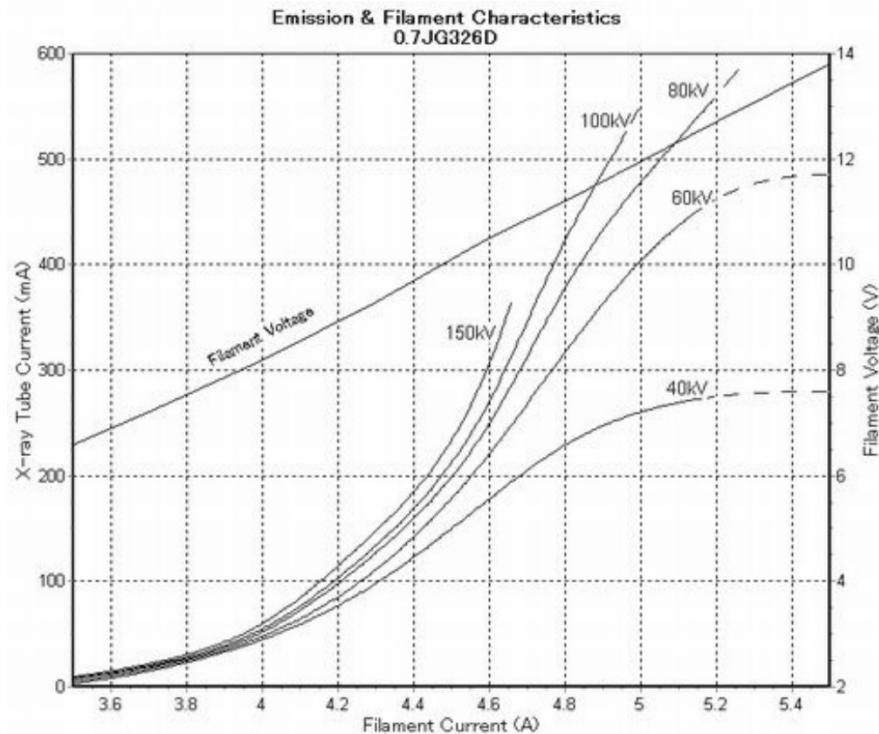
"1.2"JG326D, 180Hz, Three Phase or Constant voltage

Number of exposure in series (exp)	Tube load (kW) as a function of the exposure time (seconds) of the individual radiographs of the series														
	0.01	0.02	0.03	0.04	0.05	0.06	0.08	0.1	0.12	0.14	0.16	0.18	0.2	0.225	0.25
10	80.0	73.6	68.8	65.3	62.4	59.9	55.9	52.8	50.2	48.0	46.1	44.4	42.9	41.2	39.8
20	73.6	65.3	59.9	55.9	52.8	50.2	46.1	42.9	40.4	38.2	36.3	34.6	33.1	31.5	30.0
40	65.3	55.9	50.2	46.1	42.9	40.4	36.3	33.1	30.6	28.5	26.7	25.1	23.6	22.1	20.8
60	59.9	50.2	44.4	40.4	37.1	34.6	30.6	27.5	25.1	23.1	21.3	19.8	18.4	16.9	15.6
80	55.9	46.1	40.4	36.3	33.1	30.6	26.7	23.6	21.3	19.3	17.6	16.1	14.8	13.5	12.5
100	52.8	42.9	37.1	33.1	30.0	27.5	23.6	20.8	18.4	16.5	14.8	13.5	12.5	11.0	10.0
150	47.0	37.1	31.5	27.5	24.5	22.1	18.4	15.6	13.5	11.8	10.4	9.2	8.4	7.1	6.3

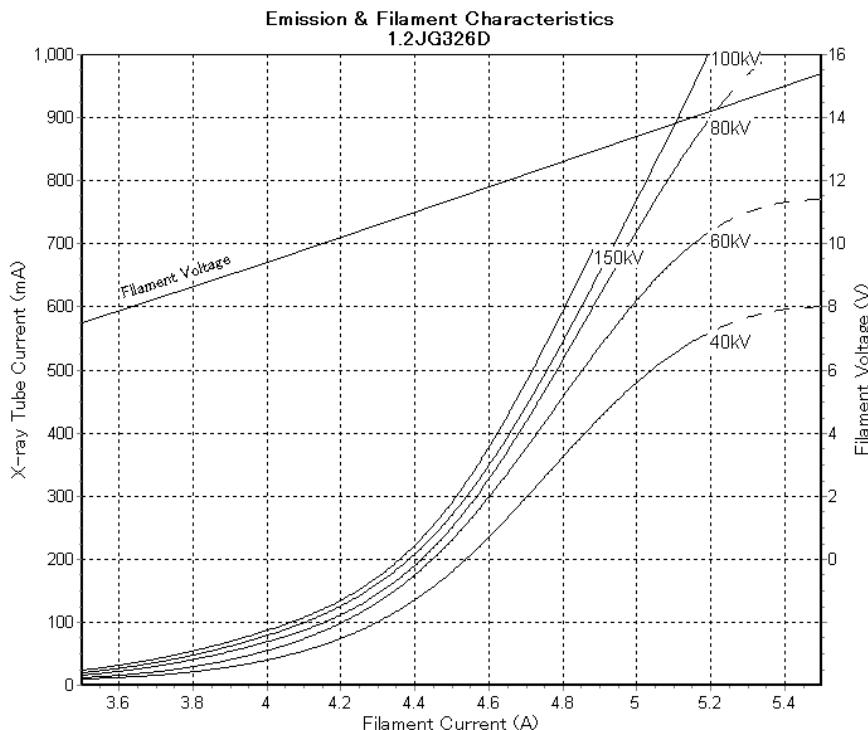
Refer to IEC 60613:2010

CATHODE EMISSION AND FILAMENT CHARACTERISTICS

The curves show the emission characteristic under constant wave and three phase full wave operation. In the case of single phase full wave operation, mA values are decreased by approximately 30% for same filament current.



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