CANON ELECTRON TUBES
& DEVICES CO., LTD.

CE
2797

Instructions For Use
X-ray Tube Assembly for Angiography

No. EEN-IFU015-10_Rev.0

0.Scope

This document is provided to meet the requirements in Section 23.4 of Annex I and the related sections of

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices,

amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

and its subsequent amendments.

Objective areas and countries of this document are EEA, Switzerland and Turkey.

1. Device category:

X-ray Tube Assembly

2. Manufacturer name:

Canon Electron Tubes & Devices Co., Ltd.

3. Model:

Refer to Table.1

4. Registered place of business:

1385, Shimoishigami, Otawara-shi, Tochigi 324-8550, Japan

5. About medicinal substance, including a human blood or plasma derivative, or tissues or cells of animal origin, or their derivatives:

There is neither inclusion nor combination of the substances.

6. About CMR substances and endocrine-disrupting substances:

The substance is not included in the part (contact part) that may affect the user and patient. Also, there is neither residual risk information nor preventive measures information.

7. Storage /handling condition:

Environmental Limits

・Operating Limits: Refer to Table.1

・Shipping and Storage Limits: Refer to Table.1

8. Sterilization:

This device is not intended to be sterilized.

9. Single use:

This device is not intended for single use.

10. The overall qualitative composition and quantitative information;

It is not a device that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body.

11.Intended purpose:

A component, rotating anode X-ray tube assembly that converts electric energy from the high voltage generator of the X-ray radiography and/or fluoroscopy system to X-ray beam with the expected beam profile and dose, is intended for diagnostic X-ray radiography and/or fluoroscopy system but is not intended for mammography. It shall be installed in the X-ray radiography and/or fluoroscopy system.

12. Indications

X-ray tube assembly is intended for the following purposes.

Intended for diagnostic radiography and/or fluoroscopy system.

13. Contra-indications:

No contra-indications

14. The patient target group or groups:

It is impossible to identify patients using with this device because the target patient group changes with the X-ray systems in which the device is installed**.**

15.Intended users:

Physicians, Radiographers, Radiological Technologists

16. Clinical benefits:

•Noninvasively and painlessly help to diagnose disease and monitor therapy;

•support medical and surgical treatment planning; and

•guide medical personnel as they insert catheters, stents, or other devices inside the body, treat tumors, or remove blood clots or other blockages.

17. Links to EUDAMED:

Not applicable since this device is not an implantable device or a class III device.

18. Performance characteristics;

Nominal Focus Spot Value: Refer to Table.1

19. Corresponding software and accessories:

This device has no corresponding software and accessories to be selected.

20. Residual risks, contra-indications and side-effects:

It is installed into X-ray system and radiates X-rays for diagnosis.

Therefore, the side effects of exposure occur.

Residual risks

- The performance of this device gradually deteriorates with frequent use, so if any malfunction occurs, contact the X-ray system manufacturer and ask the X-ray system manufacturer to replace it as necessary.
- This device might be broken with applying just one over rated shot.
- The leakage radiation from the X-ray source are regulated legally.
- The X-ray system manufacturer is required to check the conformity with the requirement of the local regulations.

21. About appropriate use of device:

This requirement is for X-ray system manufacturers.

22. Requirements for qualifications:

Physicians, Radiographers, Radiological technologists, Dentists

23. About safe use of device:

Reuse process is not required. Because this device is installed inside of the X-ray system.

24. Reuse processes:

No special processes are required for reuse.

25. About reusable or not:

This device is reusable.

26. Combination device:

Documents are provided to X-ray system manufacturers regarding the connection and installation with high voltage generator, anode drive power (in case of rotating anode type), starter (in case of rotating anode type), tube container (if not included), and heat exchanger (if you have a heat exchanger) in the X-ray system, and electrical / mechanical ratings.
The user is not involved in this part.

27. Radiation:

・Type of radiation : X-ray
・Nature : X-rays that can be acceptable through the human body.
・Intensity : High intensity X-ray for diagnostic purposes (not for treatment)
・Distribution : X-ray distribution covering the patient's body parts for diagnosis.
・Means of protecting : Protection against the radiation in accordance with IEC60601-1-3

28. Warnings, precautions, contra- indications:

28.1. Measures to be taken in the event of malfunction that may affect safety:

If any defect was found in the X-ray tube, stop using it immediately and according to the instructions for handling the defect and failure in the instruction for use of the X-ray system manufacturer.

28.2. External influences:

Use in accordance with “reasonably foreseeable external influences or environmental conditions,” described in the instruction for use of the X-ray system manufacturer.

28.3. Affecting other equipment:

Use in accordance with description in the instruction for use of X-ray system manufacturer to be taken as regards of the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or monitoring of therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment.

28.4. Substance to be delivered:

It is not a device intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances.

28.5. Medicinal substance or biological material:

The medicinal substances or biological materials are not incorporated into the device as an integral part of the device.

28.6. CMR substances and endocrine-disrupting substances:

The substances are not included in the part (contact part) that may affect the user and patient.

29. Interaction with other substances:

It is not a device which intended to be inserted into the human body and absorbed by the human body or composed of a substance or combination of substances that are localized in the human body.

30. Implantable device:

This device is not an implantable device.

31. Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it:

○Beryllium metal(Be);

Some of the X-ray radiation ports of X-ray Tube Assemblies are made of the Beryllium metal (Be). Beryllium is not toxic under normal conditions (metal), but it is very toxic in powder or vapor form. If the powder or vapor contacts the skin, it may produce eruptions, ulcers or interfere with wound healing. Furthermore, breathing the powder or vapor can result in serious personal injury or death. To prevent these toxic effects, it is strictly prohibited to cut, grind, or polish beryllium, to wipe it with chemicals, or to burn it which produce powder or vapor. If the X-ray radiation port is broken during handling, collect all the fragments of the Beryllium metal and the disposal of them should complies with all applicable laws and regulations. Dispose the scrapped products according to the requirement of local regulation.

○Lead Metal;

Lead metal is used inside some of the X-ray Tubes housing unit to protect against X-ray leakage. Lead powder and vapor are highly toxic. Disposal of X-ray Tube and X-ray Tube Assembly should comply with all applicable laws and regulations.

Dispose the scrapped products according to the requirement of local regulation.

○Insulation Oil

Insulation oil is used to ensure electric insulation in X-ray Tube Assembly. Insulation oil is toxic if ingested. If insulation oil leaks from the X-ray tube assembly, disposal of the oil should comply with all applicable laws and regulations. Dispose the scrapped products according to the requirement of local regulation. (Refer to Table.1)

○Liquid Metal;

Some of the Rotating X-ray Tubes and X-ray Tube Assembly are to be used liquid metal (gallium, indium, and tin alloy) for their rotation mechanism. These metals are toxic if ingested or absorbed through the skin. Never burn the X-ray tube because toxic vapors will be produced. Do not allow the liquid metal to come into contact with the skin. Disposal of them should comply with all applicable laws and regulations. Dispose the scrapped products according to the requirement of local regulation.

32. Use by lay persons:

This device is not intended for use by lay persons.

33. About Article 1(2) of MDR:

This device is not covered by this Regulation pursuant to Article 1(2).

34.Report any serious incident:

If a serious incident occurs in relation to the device, it should be reported to the manufacturer (X-ray system manufacturer) and the competent authority of the Member State in which the user / patient established.

35. IT security measures:

This is not a device that incorporates electronic programmable systems, including software, or software that are devices in themselves.

36. Implementation of seasoning, getter activation and tube current adjustment.

If the electric discharge phenomenon of the X-ray tube device has confirmed after long-term use, perform seasoning, getter activation, and tube current adjustment.

In addition, it should be done periodically once within 3 months according to the usage conditions to use the X-ray tube device for a long time without any failure.

Table. 1: List of model and reference data

#	Operating Limits			Shipping and Storage Limits			Nominal Focal Spot Value	Insulation Oil
								
LX-2011	18 ~ 40°C	30 ~ 85%	70 ~ 106kPa	-20 ~ 70°C	20 ~ 90%	50 ~ 106kPa	1.0 / 0.6	X
LX-3081	18 ~ 40°C	30 ~ 85%	70 ~ 106kPa	-20 ~ 70°C	20 ~ 90%	50 ~ 106kPa	0.8 / 0.5	X
LX-6308	18 ~ 40°C	30 ~ 85%	70 ~ 106kPa	-20 ~ 70°C	20 ~ 90%	50 ~ 106kPa	0.8 / 0.5	X
LX-6311	18 ~ 40°C	30 ~ 85%	70 ~ 106kPa	-20 ~ 70°C	20 ~ 90%	50 ~ 106kPa	0.8 / 0.5	X
E79039X	18 ~ 40°C	30 ~ 85%	70 ~ 106kPa	-20 ~ 70°C	20 ~ 90%	50 ~ 106kPa	1.0 / 0.6	X
XRV-T4941X	18 ~ 40°C	30 ~ 85%	70 ~ 106kPa	-20 ~ 70°C	20 ~ 90%	50 ~ 106kPa	1.0 / 0.6 / 0.4	X
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0	2024-03-01	Issued

EU IMPORTERS on EU Medical Device Regulation:

Multiple EU IMPORTERs are handling CETD products. For more information about the relations between the CETD products and EU IMPORTERs, please contact CETD.

- **CANON MEDICAL COMPONENTS EUROPE B.V. is the importer which deals CETD products sold via CANON MEDICAL COMPONENTS EUROPE B.V.**

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