CANON ELECTRON TUBES
& DEVICES CO., LTD.

CE

Instructions For Use

X-ray Flat Panel Imager

No. EEN-IFU018-02 2023-10-01 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. CETD Device Category:

X-ray Flat Panel Imager

*So-called X-ray Flat Panel Detector (FPD)

2. Manufacturer name:

Canon Electron Tubes & Devices Co., Ltd.

3. Name:

X-Ray FLAT PANEL IMAGER FDX3543RP

X-Ray FLAT PANEL IMAGER FDXA3543RP

X-Ray FLAT PANEL IMAGER FDXA3543RPS

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:

Not Applicable.

6. About CMR substances and endocrine-disrupting substances:

Not Applicable.

7. Storage /handling condition:

・Under Operating:

	FDX3543RP	FDXA3543RP	FDXA3543RPS
Temperature(℃)	10~35	10~35	10~35
Humidity(%)	10~85	10~85	10~85
Pressure(kPa)	70~106	70~106	70~106

・Under Shipping and Storage

	FDX3543RP	FDXA3543RP	FDXA3543RPS
Temperature(℃)	-15~55	-20~70	-20~70
Humidity(%)	10~90	10~90	10~90
Pressure(kPa)	50～106	50～106	50～106

8. Sterilisation:

Not Applicable.

9. Single use:

Not Applicable.

10. The overall qualitative composition and quantitative information;

Not Applicable.

11. Intended purpose:

A component, X-ray flat panel imager provides digital signals by detecting X-rays pattern which pass through a patient body and reach its surface. It is intended for radiography but is not intended for mammography and fluoroscopy applications. It is not intended for recording of diagnostic images because this device does not have recording function of diagnostic images. It shall be installed to an X-ray system.

It does not provide clinical image, nor function of controlling X-ray generator.

For medical diagnosis, it additionally requires image processing with application software to visualize digital image.

12. Indications:

This X-ray flat panel imager is intended for medical X-ray imaging, radiography.

13. Contra-indications:

Not Applicable.

14. The patient target group or groups:

Not Applicable.

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.

17. Links to EUDAMED:

Not Applicable

18. Performance characteristics;

	FDX3543RP	FDXA3543RP	FDXA3543RPS
Active Area	35(H)×43(V) cm	346(H)×426(V) mm	430(H)×439(V)
Pixel Matrix	2448(H)×2984(V)	2466(H)×3040(V)	3008(H)×3072(V)

19. Corresponding software and accessories:

Not Applicable.

20. Residual risks, contra-indications and side-effects:
***In accordance with MDR Annex I, Sec 23.4(g),**

Residual risks;
-If any malfunction occurs, contact the X-ray manufacturer and ask the X-ray manufacture to replace it as necessary.
-The performance of this device gradually deteriorates with frequent use, so if any malfunction occurs, contact the X-ray manufacturer, and ask the X-ray manufacture to replace it as necessary.
-Be sure to observe the precautions on this technical data (TD: Technical data) in order to maintain the EMC characteristics of this device. Also, please carry out inspection according to the contents indicated in this technical data.
- Do not spill a liquid (Blood, Body fluid, Cleaning liquid, etc) on the FPI. When spilled a liquid, please wipe it off with soft cloth promptly, and clean the surface.
When a large quantity of blood or body fluid might attach, please use sanitary cover from a sanitary point of view.
- Do not hold the FPI connector and sensor unit cable when lifting and/or moving the FPI. Please be careful not to drop the FPI. If dropped, check appearance and do not use FPI if it has abnormality. Position the main cable carefully so that nobody steps on or stumbles.
-This document describes the attention of equipment manufacturers and users to use safety X-Ray FLAT PANEL IMAGER (hereafter called FPI). Please find the technical data sheet of each product and this document “SAFETY PRECAUTIONS AND WARNING” and understand these contents before using FPI.

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 appropriate use of device:
This requirement is for X-ray system manufacturers.

24. Reuse processes:
Not Applicable.

25. About reusable or not:

Not Applicable.

26. Combination device:

Documents are provided to X-ray system manufacturers regarding the connection to X-ray Control Unit and PC.

The user is not involved in this part.

27. Radiation:

The device does not emit radiation for medical purposes.

28. Warnings, precautions, contra- indications:

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

The X-ray flat panel imager may stop operating suddenly due to its life or unexpected failure.

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

28.2 External influences:

To prevent device malfunction, do not use anything generates electromagnetic waves, which are not related to its operation, in the environment where the X-ray flat panel imager is installed.

28.3 Affecting other equipment:

Notifying the manufacturer of X-ray system to evaluate electromagnetic interference.

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 substance is not included in the part (contact part) that may affect the user and patient.

29. Interaction with other substances:

Not Applicable.

30. Implantable device:

Not Applicable.

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:

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

32. Use by lay persons:

Not Applicable.

33. About Article 1(2) of MDR:

Not Applicable.

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 device is controlled by X-ray system. Therefore, X-ray system side shall take appropriate actions to maintain necessary security level by consistent risk management such as system setting, network security and system management, etc.. Otherwise, it may cause security problems (illegal operation, hacking, data manipulation, information leaking, etc…)

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Revision History

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0	2023-10-01	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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