

# Effect of X-ray dose rates higher than 8 Gy/min on the functioning of cardiac implantable electronic devices

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## ABSTRACT

Direct irradiation may cause malfunctioning of cardiac implantable electronic devices (CIEDs). Therefore, a treatment plan that does not involve direct irradiation of CIEDs should be formulated. However, CIEDs may be directly exposed to radiation because of the sudden intrafractional movement of the patient. The probability of CIED malfunction reportedly depends on the dose rate; however, reports are only limited to dose rates  $\leq 8$  Gy/min. The purpose of this study was to investigate the effect of X-ray dose rates  $> 8$  Gy/min on CIED function. Four CIEDs were placed at the center of the radiation field and irradiated using 6 MV X-ray with flattening filter free (6 MV FFF) and 10 MV X-ray with flattening filter free (10 MV FFF). The dose rate was 4–14 Gy/min for the 6 MV FFF and 4–24 Gy/min for 10 MV FFF beams. CIED operation was evaluated with an electrocardiogram during each irradiation. Three CIEDs malfunctioned in the 6 MV FFF condition, and all four CIEDs malfunctioned in the 10 MV FFF condition, when the dose rate was  $> 8$  Gy/min. Pacing inhibition was the malfunction observed in all four CIEDs. Malfunction occurred simultaneously along with irradiation and simultaneously returned to normal function on stopping the irradiation. An X-ray dose rate  $> 8$  Gy/min caused a temporary malfunction due to interference. Therefore, clinicians should be aware of the risk of malfunction and manage patient movement when an X-ray dose rate  $> 8$  Gy/min is used for patients with CIEDs.

**Keywords:** cardiac implantable electronic devices; malfunction; radiotherapy; dose rate

## INTRODUCTION

Cardiac implantable electronic devices (CIEDs) are used for the non-pharmacological management of cardiac arrhythmias. CIEDs include pacemakers, implantable cardioverter-defibrillators, cardiac resynchronization therapy devices and cardiac resynchronization therapy with implantable cardioverter-defibrillators. A CIED consists of a main unit, which is composed of a control circuit, a semiconductor element and a battery, and a lead to send and receive electrical signals to the heart [1]. Several reports have stated that direct radiation exposure to CIEDs caused malfunctions (i.e. permanent device damage, power-on reset, pacing inhibition and inappropriate shock) [2–4]. These reports showed that radiation exposure to the control circuit caused the malfunction [5, 6]. Because radiation exposure to silicon dioxide (SiO<sub>2</sub>), which is used to fabricate the complementary metal oxide

semiconductor (CMOS) in the control circuit, leads to the formation of electron-hole pairs in SiO<sub>2</sub>, the electron hole creates transient or permanent aberrant electrical pathways [5, 6]. The overcurrent due to the aberrant electrical pathways is recognized as false cardiac activity, and CIED malfunctions are thought to occur. Since a CMOS that does not use SiO<sub>2</sub> has not been developed yet, it is impossible to prevent the generation of overcurrent that occurs when the control circuit is exposed to ionizing radiation. Although technical improvements have been made to reduce the influence of overcurrent on the control circuit by the use of protection software, the basic structure of CIEDs has remained unchanged [7]. Therefore, the issue of malfunctioning caused by irradiation to CIEDs still exists.

A report by Task Group 203 for management of radiotherapy patients with implanted cardiac pacemakers and defibrillators was

published by the American Association of Physicists in Medicine in 2019, it described the causes of radiation-induced malfunctions as cumulative dose, neutrons and dose rates [8]. Several studies on cumulative dose reported that implantable cardioverter-defibrillators failed at  $\leq 2.5$  Gy, and that pacemakers failed at  $\leq 5$  Gy [4, 5, 9–11]. Furthermore, the probability of CIED malfunction was 0% for non-neutron-producing radiation, indicating that neutrons are involved in the occurrence of malfunctions [12–15]. However, although there are some reports on cumulative doses and neutrons, there are few reports on dose rates. To the best of our knowledge, the only report on the relationship between CIED malfunction and dose rate is by Mouton *et al.* [10]. According to their report, malfunctions were observed in 0, 4, 14 and 68 out of 96 pacemakers, when dose rates were  $\leq 0.2$ ,  $\leq 1.0$ ,  $\leq 4.0$  and  $\leq 8.0$  Gy/min, respectively. On the other hand, even if the dose rate was 8 Gy/min, no malfunction was observed in 10 of 96 pacemakers. These results indicate that the probability of CIED malfunction depends on the dose rate. However, high-energy X-rays used in conventional radiotherapy have been equipped with a flattening filter (FF) in the treatment head of a medical accelerator to ensure a flat dose profile, so that the maximum dose rate is  $\leq 8$  Gy/min. Hence, the existing data only document the relationship between the probability of malfunction of CIEDs and high-energy X-ray dose rates  $\leq 8$  Gy/min and there is no evidence for dose rates  $> 8$  Gy/min [8, 10]. Flattening filter-free (FFF) beams, which can deliver high dose rates of radiation by removing the FF, have recently been used in clinical practice. Thus, the effect of X-ray dose rates  $> 8$  Gy/min on CIED operation has not been investigated. X-ray dose rates  $> 8$  Gy/min have been used for stereotactic radiotherapy to the head and neck, cervical spine and lung, which are in close proximity to the CIED [16]. Guidelines for the management of patients with CIEDs recommend placing the CIED outside the field of radiation [8, 17–20]. However, sudden intrafractional movement of the patient may lead to temporary direct irradiation to the CIED. Thus, it is necessary to report the relationship between dose rate  $> 8$  Gy/min and CIED malfunction. The purpose of this study was to investigate the effect of X-ray dose rates  $> 8$  Gy/min on CIEDs by evaluating CIED function.

## MATERIALS AND METHODS

### Models and settings of CIEDs

We used four CIEDs (two pacemakers and two cardiac resynchronization therapy devices). The CIEDs included Sensia (Medtronic, Minneapolis, MN, USA), INSYNC III (Medtronic, Minneapolis, MN, USA), Assurity Magnetic Resonance Imaging (MRI) (St. Jude Medical, Sylmar, CA, USA) and FRONTIER II (St. Jude Medical, Sylmar, CA, USA). Table 1 shows the manufacturer, model and type of CIED. Each CIED was set to the AAI mode, the atrial pulse amplitude was set at 7.5 V, the rate setting was 40 pulses/min, the sensitivity was set to the 'most sensitive' setting and the sensing polarity was bipolar. The CIED was connected to a Y-adapter (S866-38 M, Medtronic, Minneapolis, MN, USA) to pace the pulse output. The pacemaker (Sensia) with the pacing lead (Attain Bipolar OTW 4194, Medtronic, Minneapolis, MN, USA), was used as a pseudo beat generator with a rate setting of 70 pulses/min. The CIED function during each irradiation was evaluated with an electrocardiogram (ECG) with a patient monitoring system (BSM-2401, NIHON KOHDEN Corp., Tokyo, Japan).

**Table 1. Models of CIEDs**

Manufacturer	Model	Type <sup>a</sup>
Medtronic	Sensia	PM
Medtronic	INSYNC III	CRT
St. Jude Medical	Assurity MRI	PM
St. Jude Medical	FRONTIER II	CRT

<sup>a</sup>PM = pacemaker; CRT = cardiac resynchronization therapy device; MRI = magnetic resonance imaging.

### Installation of CIEDs

The CIED was placed on a 20-cm stack of tissue equivalent phantoms (Tough-Water, Kyoto Kagaku Co. Ltd, Kyoto, Japan) on a treatment couch top. The field size was  $10 \times 10$  cm<sup>2</sup> at the phantom surface, the source-to-surface distance was 100 cm, and the CIED was placed at the center of the radiation field. The tip of the Y-adapter for pacing pulse output was inserted in a water tank filled with 0.18 wt% saline, simulating the electrical conductivity of the human body, and the pseudo beat generator was placed at the bottom of the water tank. Furthermore, the electrodes installed in the water tank for recording the ECG were placed more than 2 m away from the center of the radiation field to prevent direct irradiation. The experimental scheme of the CIED is shown in Fig. 1.

### Irradiation conditions of CIEDs

Irradiation was performed with an FFF beam using a TrueBeamSTx (Varian Medical Systems, Palo Alto, CA, USA). The X-ray energy of the FFF beam was 6 MV FFF and 10 MV FFF. Dose rates of 4, 6, 8, 10, 12 and 14 Gy/min were used for the 6 MV FFF beam and 4, 8, 12, 16, 20 and 24 Gy/min for the 10 MV FFF beam.

### Test of CIED malfunction

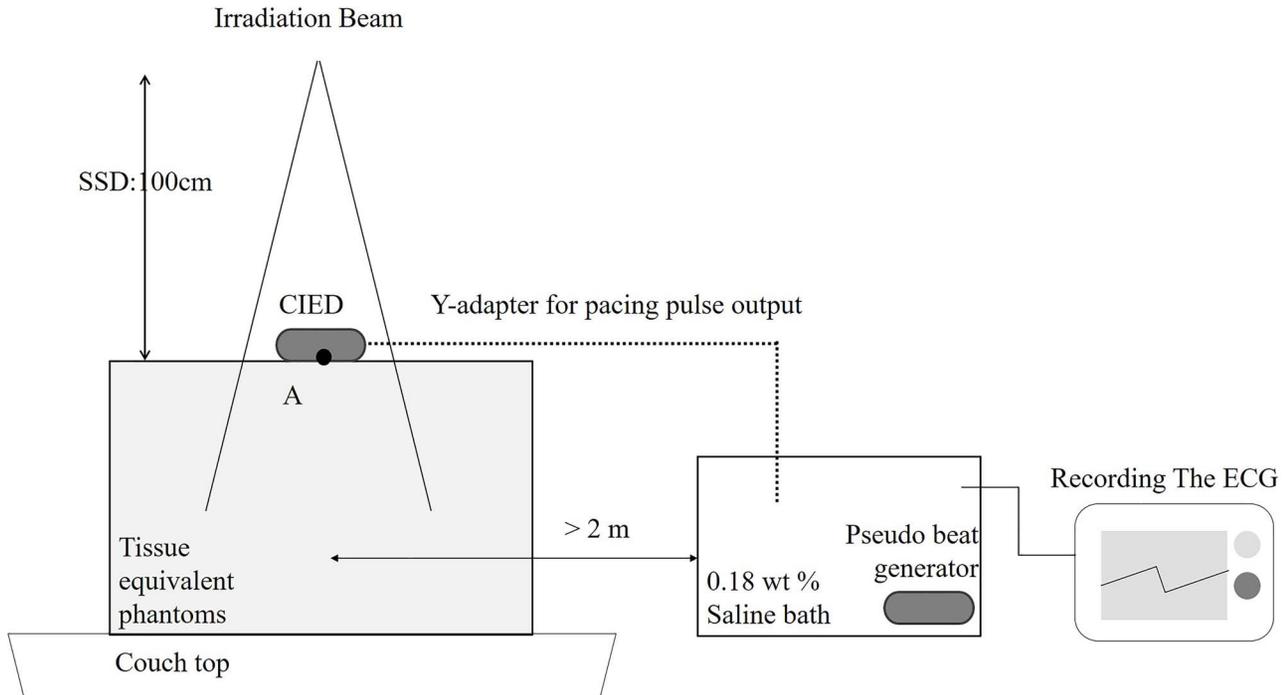
We evaluated transient CIED malfunctions in this study, since we assumed the condition of temporary direct X-ray exposure to the CIED. Transient malfunctions caused by radiation to the CIED have different effects, based on the patient's CIED-dependency. We performed the inhibition test for the condition of high CIED-dependency and the asynchronous test for the condition of low CIED-dependency.

#### Inhibition test

The inhibition test was performed without the input pulse of the pseudo beat generator described under Installation of CIEDs. The ECG was recorded when the CIED was irradiated by the FFF beam with the parameters described under Irradiation conditions of CIEDs. We evaluated the presence or absence of the pacing pulses in the CIEDs, i.e. the pacing inhibition.

#### Asynchronous test

The asynchronous test was performed with an input pulse obtained from the pseudo beat generator, as described under Installation of CIEDs. The ECG was recorded when the CIED was irradiated by the FFF beam with the parameters described under Irradiation conditions of CIEDs. We evaluated the presence or absence of pulses, unrelated to



**Fig. 1.** Experimental scheme of a CIED. A, The center of the radiation field at the beam isocenter of a  $10 \times 10 \text{ cm}^2$  field at the surface of tissue equivalent phantoms with a source-to-surface distance of 100 cm. The pacing pulse output for the Y adapter was recorded by the electrocardiogram via electrodes installed in the water tank.

the pacing pulses of the pseudo beat generator, i.e. the asynchronous pacing.

## RESULTS

### Inhibition test

The results of the inhibition tests of 6 MV FFF and 10 MV FFF are depicted in Tables 2 and 3, respectively. In the 6 MV FFF condition, pacing inhibition was observed in three of four CIEDs and in all four CIEDs, when the dose rates were 4–12 Gy/min and  $\geq 14$  Gy/min, respectively. In the 10 MV FFF condition, pacing inhibition was observed in three of four CIEDs and in all four CIEDs, when the dose rates were 4 Gy/min and 8–24 Gy/min, respectively. Fig. 2 shows an example of an ECG in normal function and pacing inhibition. Pacing inhibition occurred simultaneously with irradiation and returned to normal function simultaneously on stopping the irradiation.

### Asynchronous test

The results of the asynchronous tests of the 6 MV FFF and 10 MV FFF are depicted in Tables 4 and 5, respectively. In the 6 MV FFF condition, asynchronous pacing was observed in one of four CIEDs and two of four CIEDs, when the dose rate was 4–8 Gy/min and  $\geq 10$  Gy/min, respectively. In the 10 MV FFF condition, asynchronous pacing was observed in two of four CIEDs, when the dose rate was 4–24 Gy/min. Fig. 3 shows an example of an ECG in normal function and asynchronous pacing. The asynchronous pacing occurred simultaneously with irradiation and returned to the normal function simultaneously on stopping the irradiation.

## DISCUSSION

We investigated the effect of X-ray dose rate >8 Gy/min on CIED function based on the results of the inhibition test and asynchronous test in this study, while considering the possibility of direct temporary CIED irradiation due to sudden patient movement.

This study similarly demonstrated that the probability of malfunction depended on the dose rate at dose rates of 4–24 Gy/min. (Tables 2–5). Malfunction was observed in three of four CIEDs in the 6 MV FFF condition, and in all four CIEDs in the 10 MV FFF condition, for dose rates >8 Gy/min. Malfunction was observed simultaneously with irradiation, which returned to normal function simultaneously when irradiation was stopped. Thus, it was transient and reversible malfunction, which did not require the replacement of CIEDs. The malfunction is thought to be caused by interference. Interference occurs if an overcurrent generated by X-ray exposure to the CMOS circuit is erroneously recognized as spontaneous cardiac activity. Interference has been reported not only with high-energy X-ray exposure, but also with diagnostic X-ray exposure [21, 22]. In this study, malfunction was observed on both inhibition and asynchronous testing. Thus, a dose rate >8 Gy/min may cause interference regardless of the patient's CIED-dependency. However, a transient malfunction caused by interference can be eliminated by stopping irradiation. Moreover, dose rates  $\leq 24$  Gy/min did not cause significant malfunction, such as a power-on reset or loss of pacing.

It is suggested that radiation treatment plans should ensure that the CIED is outside the radiation field, in cases where the target area

**Table 2. Summary of inhibition test results in 6 MV FFF. A dose rate  $\geq 14$  Gy/min induced pacing inhibition in all CIEDs. Assurity MRI induced pacing inhibition dependent on the dose rate. I, Pacing inhibition; –, normal operation**

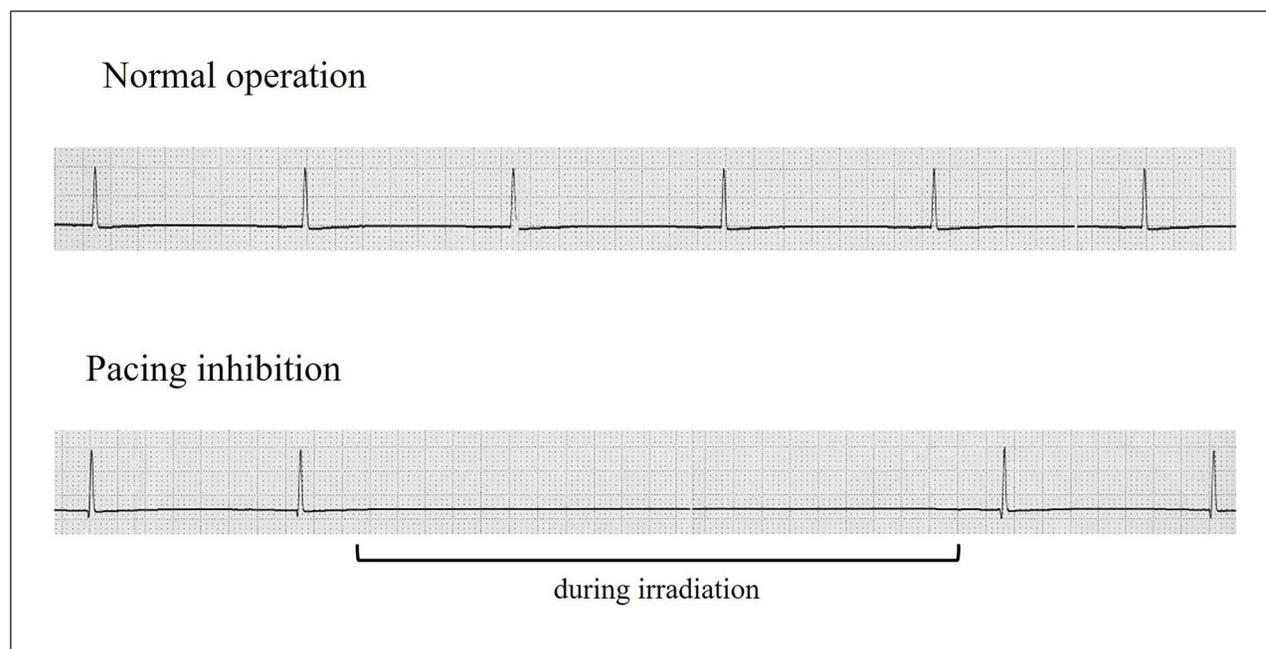
Dose rate (Gy/min)		4	6	8	10	12	14
Medtronic	Sensia	I	I	I	I	I	I
Medtronic	INSYNC III	I	I	I	I	I	I
St. Jude medical	Assurity MRI	–	–	–	–	–	I
St. Jude medical	FRONTIER II	I	I	I	I	I	I

**Table 3. Summary of inhibition test results for 10 MV FFF. A dose rate  $\geq 8$  Gy/min induced pacing inhibition in all CIEDs. Assurity MRI induced pacing inhibition dependent on the dose rate. I, Pacing inhibition; –, normal operation**

Dose rate (Gy/min)		4	8	12	16	20	24
Medtronic	Sensia	I	I	I	I	I	I
Medtronic	INSYNC III	I	I	I	I	I	I
St. Jude Medical	Assurity MRI	–	I	I	I	I	I
St. Jude Medical	FRONTIER II	I	I	I	I	I	I

is close to the CIED [8, 17, 19]. However, sudden intrafractional movement of the patient may cause direct radiation exposure to the CIED. Malfunction was observed simultaneously with irradiation in this study (Figs 2 and 3). Hence, even temporary exposure of the CIED to radiation due to a sudden intrafractional patient movement, may cause interference. Interference can cause pacing inhibition in patients with pacemakers and inappropriate shock in patients with implantable cardioverter defibrillators. These patients with CIED may experience palpitations, dizziness, loss of consciousness etc.,

although there have been few reports of clinical accidents caused by interference [23]. Interference occurred only with irradiation and returned to normal function immediately when radiation was stopped. The patient's movement is constantly monitored during radiotherapy, and irradiation should be suspended immediately if abnormal patient movement is detected, thus the possibility that the malfunction is permanent is low [24]. Therefore, CIED malfunction due to interference, as observed in this study, is considered to have a low impact on patients.

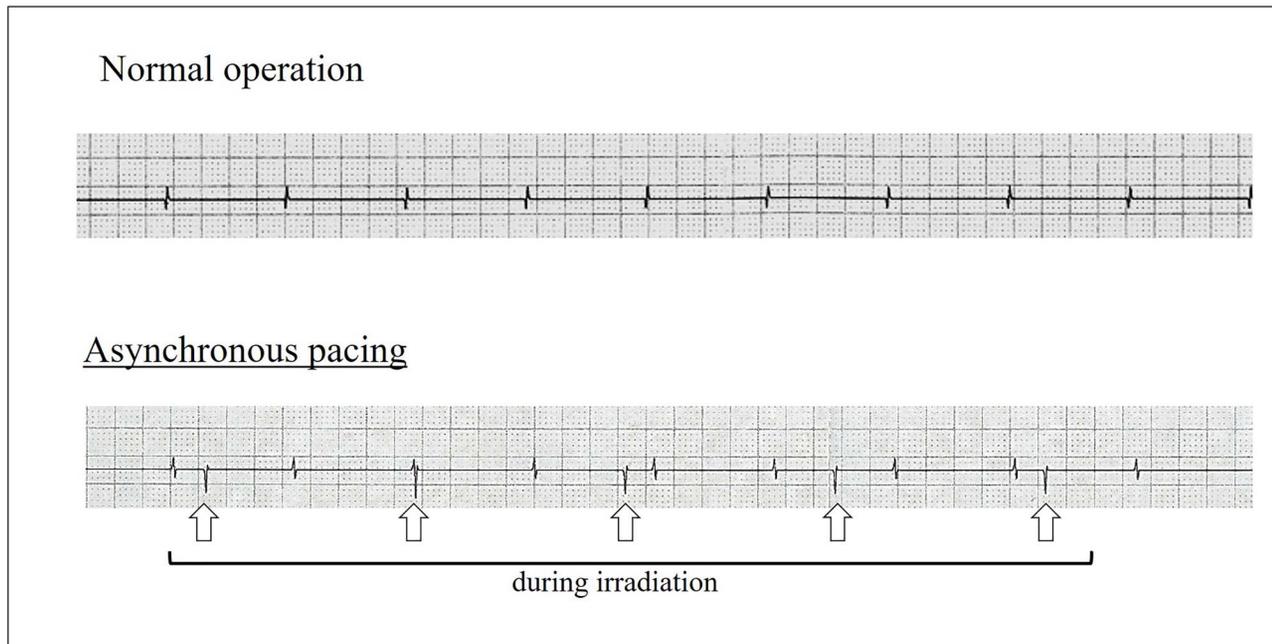
**Fig. 2. ECG output recording of CIEDs during irradiation in an inhibition test. In normal operation only the pacing pulse was recorded. If pacing inhibition occurred, pacing pulse was not recorded only during radiation exposure to the CIED.**

**Table 4.** Summary of asynchronous test results for 6 MV FFF. A dose rate  $\geq 10$  Gy/min induced asynchronous pacing in two of four CIEDs, but not in the other CIEDs. Sensia induced asynchronous pacing dependent on the dose rate. A, Asynchronous pacing; –, normal operation

Dose rate (Gy/min)		4	6	8	10	12	14
Medtronic	Sensia	–	–	–	A	A	A
Medtronic	INSYNC III	A	A	A	A	A	A
St. Jude Medical	Assurity MRI	–	–	–	–	–	–
St. Jude Medical	FRONTIER II	–	–	–	–	–	–

**Table 5.** Summary of asynchronous test results for 10 MV FFF. A dose rate  $\geq 4$  Gy/min induced asynchronous pacing in two of four CIEDs, but not in the other CIEDs. A, Asynchronous pacing; –, normal operation

Dose rate (Gy/min)		4	8	12	16	20	24
Medtronic	Sensia	A	A	A	A	A	A
Medtronic	INSYNC III	A	A	A	A	A	A
St. Jude medical	Assurity MRI	–	–	–	–	–	–
St. Jude Medical	FRONTIER II	–	–	–	–	–	–



**Fig. 3.** ECG output recording of CIEDs during irradiation during asynchronous testing. In normal operation, only the pseudo beat was recorded. If asynchronous pacing occurred, the pacing that was unrelated to the pseudo beat was recorded only during radiation exposure to the CIED.

On the other hand, the conditions of malfunctioning differed for each model of CIED (Tables 2–5). This could be attributed to the software that prevents malfunction and the material of the CMOS circuit, which differs for each CIED model and manufacturer. As the effects of X-ray dose rates > 8 Gy/min on CIEDs differ, depending on the model and the manufacturer of the CIED, it is necessary to determine clinical management based on the patient's CIED-dependency.

Furthermore, Mouton *et al.* reported that the probability of malfunctions increases with an increase in the dose rate for dose rates of 0.2–8 Gy/min [10]. However, in their report, it was possible that malfunctions occurred due to the effects of neutrons generated by an 18 MV photon or the effects of cumulative doses, and it was difficult to accurately evaluate the dose rate dependence of malfunctions [8]. Likewise, in this study, we could not determine whether malfunction

in some models depends on the dose rate. Thus, further verification is necessary to clarify the relationship between the dose rate and the probability of CIED malfunction.

X-ray dose rates  $>8$  Gy/min are frequently used in clinical practice, and there are several indications for stereotactic radiotherapy using X-ray dose rates  $>8$  Gy/min for patients with CIED. Therefore, it is essential that clinicians administering radiotherapy (radiation oncologists, medical physicists, radiation therapists, nurses, etc.) be aware of the risk of malfunction caused by direct exposure of the CIEDs to X-ray dose rates  $>8$  Gy/min and be able to adequately manage the patient's movement during treatment.

This study was conducted using only the FFF beam. FFF beams can irradiate with a higher dose rate than the flattening filtered beam, while, the characteristics of the FFF beam are different from those of the flattening filtered beam [25]. Therefore, the possibility cannot be denied that the malfunction was caused by not only the dose rate, but also by the characteristics of the FFF beam.

This study investigated the effects of X-ray dose rates of 4–24 Gy/min on CIED function. An X-ray dose rate  $>8$  Gy/min caused transient malfunction due to interference in three of four CIEDs. We confirmed that the probability of malfunction depended on the X-ray dose rate, even for dose rates  $>8$  Gy/min, like earlier studies. Therefore, when an X-ray dose rate  $>8$  Gy/min is used for patients with CIEDs, it is necessary to be aware of the risks of CIED malfunction and manage patient movement.

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#### CONFLICT OF INTEREST

None declared.

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