Received: 27 December 2022 | Revised: 20 March 2023 | Accepted: 2 April 2023

DOI: 10.1002/joa3.12853

Journal of Arrhythmia Open Access WILEY

ORIGINAL ARTICLE

Interference of cardiac implantable electronic devices and computed tomography imaging in the current era with a phantom model

Akihito Ideishi MD, PhD[1,2] | Kenichiro Yamagata MD, PhD[1] | Tatsuya Nishii MD, PhD[3] | Hideto Miyanooi[3] | Yuichiro Miyazaki MD[1] | Akinori Wakamiya MD[1] | Keiko Shimamoto MD, PhD[1] | Nobuhiko Ueda MD, PhD[1] | Kenzaburo Nakajima MD[1] | Mitsuru Wada MD[1] | Tsukasa Kamakura MD, PhD[1] | Kohei Ishibashi MD, PhD[1] | Yuko Inoue MD, PhD[1] | Koji Miyamoto MD, PhD[1] | Takashi Noda MD, PhD[1] | Satoshi Nagase MD, PhD[1,4] | Takeshi Aiba MD, PhD[1] | Kengo Kusano MD, PhD[1]

[1]Department of Cardiovascular Medicine, National Cerebral and Cardiovascular Center, Suita, Japan

[2]Department of Cardiology, Fukuoka University School of Medicine, Fukuoka, Japan

[3]Department of Radiology, National Cerebral and Cardiovascular Center, Suita, Japan

[4]Department of Advanced Arrhythmia and Translational Medical Science, National Cerebral and Cardiovascular Center, Suita, Japan

Correspondence
Kenichiro Yamagata, Department of Cardiovascular Medicine, National Cerebral and Cardiovascular Center, 6-1 Kishibe-Shimmachi, Suita, Osaka 564-8565, Japan.
Email: look.cardiology@gmail.com

Abstract

Introduction: Cardiac implantable electronic devices are used in patients with cardiac rhythm disorders. Computed tomography irradiation is not prohibited for patients with cardiac implantable electronic devices, despite adverse events being reported. Hence, appropriate preparation and knowledge are required before computed tomography irradiation can be carried out in these patients. Since there is limited knowledge or literature about the influence of computed tomography irradiation in cases with recent cardiac implantable electronic devices, we aimed to evaluate the adverse events and elucidate the necessary and sufficient safety measures associated with this therapy.

Methods and Results: We placed cardiac implantable electronic devices on an anthropomorphic phantom model and observed their electrical activity in electrograms, while various protocols of computed tomography irradiation were implemented and adverse events evaluated. Oversensing with pauses of up to 3.2 s was observed in standard computed tomography protocols, but ventricular tachyarrhythmia or other clinically significant events could not be confirmed. Oversensing with pauses of up to 8.0 s was observed and ventricular tachyarrhythmia was detected in the maximum-dose protocols. However, treatments such as antitachycardia pacing or shock therapy for ventricular tachyarrhythmia were not observed because of their absence.

Conclusion: Computed tomography irradiation for patients using cardiac implantable electronic devices is highly unlikely to cause clinically significant adverse events with the device settings and computed tomography protocols currently being used. Changing or monitoring the device settings routinely before computed tomography irradiation is not necessarily required for most patients.

KEYWORDS
cardiac implantable electronic device, computed tomography, oversensing

1 | INTRODUCTION

Cardiac implantable electronic devices (CIEDs), such as pacemakers, implantable cardioverter defibrillators (ICD), and cardiac resynchronization therapy (CRT), are treatment devices for patients with cardiac rhythm disorders or those having experienced heart failure. Various types of magnetic and electromagnetic interference (EMI) have been reported to influence CIED functions, and new hazards have been reported with the advent of new technology.[1]

Computed tomography (CT) is a widely used diagnostic tool for various diseases. Interactions between CIED and CT have been reported to inhibit proper pacing[2] and activate the partial electrical reset safety feature of CIEDs.[3] High-energy X-ray emitting CT has been commercially utilized to obtain high-resolution images for accurate diagnosis in the medical field. At present, there is limited knowledge about the interaction between recent high-energy CIEDs and high-energy X-ray emitting CT.

Therefore, this study aimed to evaluate adverse events in high-energy CIEDs currently available commercially, under various CT irradiation protocols and elucidate the necessary and sufficient countermeasures for such events.

2 | MATERIALS AND METHODS

2.1 | Devices and settings

Four ICDs from four manufacturers, and five CRT defibrillators (CRT-Ds) from five manufacturers (Abbott Laboratories, Chicago, United States; BIOTRONIK SE & Co. KG, Berlin, Germany; Boston Scientific Corporation, Marlborough, United States; Medtronic plc, Dublin, Ireland; MicroPort Inc., Shanghai, China), which are the newest commercially available devices in March 2022, were tested. The types of devices, product names, and specific settings are shown in Table 1. CIEDs were set to the dual-chamber pacing mode (DDD) with a lower/upper tracking rate of 60/110 pulses per minute. The sensitivities were measured with the RV tip-ring at the highest (i.e., lowest parameter) to detect as many artifacts as possible. The refractory period, blanking period, and ventricular tachycardia (VT)/ventricular fibrillation (VF) detection rate were set to the lowest to have the highest sensitivity to detect VT/VF in the minimum duration possible. For the CRT-Ds, the interventricular (VV) delay was set to 0 ms.

2.2 | CT imaging system and irradiation protocols

A 192-row dual-source CT scanner (SOMATOM Force, syngo CT VB20A, Siemens, Forchheim, Germany) was used for CT scanning. The irradiation protocols used are detailed in Table 2. We performed five CT scanning protocols: (1) normal-dose scan for body CT, (2) normal-dose scan for coronary CT angiography (CTA), (3) maximum-dose scan for coronary CTA, (4) maximum-dose scan for body CT, and (5) high-pitch dual helical scan for body CT. CT scanning was performed with a normal dose conforming to the Japan diagnostic reference levels (DRLs) 2020[4] (Table 2: protocol 1 and 2) and the experimental maximum-dose protocol achievable by the CT system, which is not used for patients because of its excessively high radiation (Table 2: protocol 3, 4, and 5). The ICD and CRT-D without leads were placed on the left precordium of the anthropomorphic phantom model (CT Whole Body Phantom PBU-60: Kyoto Kagaku Co., Ltd., Kyoto, Japan) (Figure 1).

The irradiation protocols were performed each of the five times while monitoring the devices in real time from outside the CT room using telemetry.

TABLE 1 Types of the devices and specific settings of the ICDs and the CRT-Ds.

Manufacturer	Type of the device	Product name	Mode	Lower/upper rate (ppm)	VV delay (ms)	Sensitivity of atrium (mV)	Sensitivity of ventricle (mV)	VT detection rate (bpm)	VF detection rate (bpm)
Medtronic plc	ICD	Cobalt XT DR	DDD	60/110	–	0.15	0.15	120	188
	CRT-D	Claria MRI quad	DDD	60/110	0	0.15	0.15	120	188
Boston Scientific Corporation	ICD	Resonate el	DDD	60/110	–	0.15	0.15	120	180
	CRT-D	Resonate X4	DDD	60/110	0	0.15	0.15	120	180
MicroPort Inc.	ICD	Platinium DR	DDD	60/110	–	0.2	0.4	120	200
	CRT-D	Platinium	DDD	60/110	0	0.2	0.4	120	200
Abbott Labortories	ICD	Ellipse DR	DDD	60/110	–	0.2	0.3	116	153
	CRT-D	Quadra Assura MP	DDD	60/110	0	0.2	0.3	116	153
Biotronik SE & Co. KG	CRT-D	Acticor 7 HF-T QP	DDD	60/110	0	0.2	0.5	120	188

Abbreviations: CRT, cardiac resynchronization therapy defibrillator; DDD, dual-chamber pacing mode; ICD, implantable cardioverter defibrillators; VF, ventricular fibrillation; VT, ventricular tachycardia; VV, interventricular.

TABLE 2 CT irradiation protocols.

Parameters	Protocol 1 Body CT	Protocol 2 Coronary CTA	Protocol 3 Coronary CTA	Protocol 4 Body CT	Protocol 5 Body CT
Radiation dose	Reference level based on Japan DRLs2020		Maximum level available with CT system		
Scan mode	Helical scan	Helical scan	Helical scan	Dual-power helical scan	High-pitch dual helical scan
Detector configuration (mm)	192×0.6	192×0.6	192×0.6	192×0.6	192×0.6
Tube voltage (kV)	120	120	150	150	150
Tube current (mA)	240	774	1304	822	1598
Tube current–time product (mAs)	240	186	326	2354	258
Pitch	0.5	0.15	0.15	0.35	1.55
Rotation speed (sec)	0.5	0.25	0.25	1	0.25
Scan length (cm)	10	10	10	10	10
Scan time (sec)	2.54	4.79	4.79	7.35	0.41
ECG gating	N/A	Retrospective	Retrospective	N/A	N/A
CT dose index (mGy)	15.91	66.25	201.26	268.34	23.76
Dose length products (mGy×cm)	159	663	2013	2683	238
Dose length products/time (mGy×cm/sec)	62.64	138.31	420.17	365.09	579.51

Abbreviations: CT, computed tomography; CTA, computed tomography angiography; DRL, diagnostic reference levels; ECG, electrocardiography.

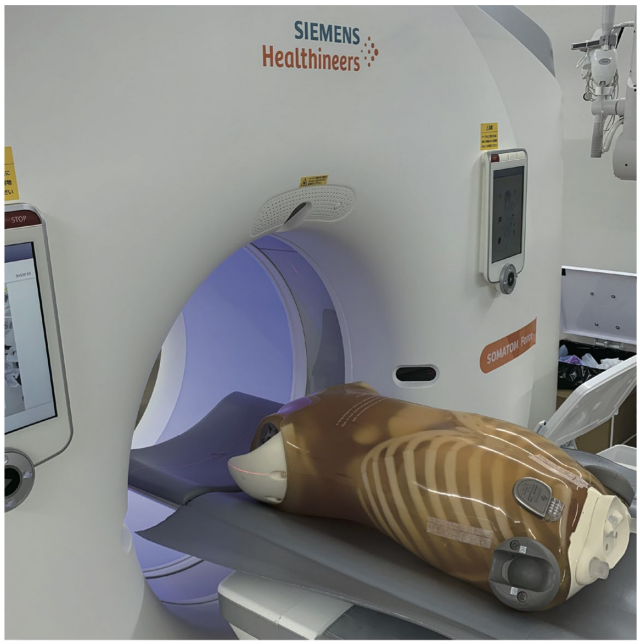

FIGURE 1 A transvenous defibrillator was placed on the left precordium.

2.3 | Evaluation and analysis of adverse events

The presence of ventricular oversensing, duration of pauses because of oversensing, VT/VF detection, treatments for VT/VF (antitachycardia pacing [ATP] or shock), and occurrence of partial electrical reset were studied. A pause was defined as a ventricular pacing inhibition of more than 2.5 seconds. The longest pause for each protocol was recorded.

3 | RESULTS

All devices were examined before CT irradiation and were confirmed to have no oversensing during the movement of the CT table in the absence of radiation. Events during CT irradiation are shown in Table 3. Representative examples of the pseudo-intracardiac electrogram during CT irradiation are shown in Figures 2A,B.

While assessing the protocols for Japan DRLs 2020, pauses were detected in the ICDs (Medtronic plc, Dublin, Ireland and Boston Scientific Corporation, Marlborough, United States) only during the CTA protocol. For CRT-Ds, pauses were also detected during a normal helical scan on plain CT. None of the devices detected VT/VF using this protocol.

When performing the experiment using a protocol for the maximum dose achievable by the CT system, oversensing was detected by devices from Medtronic plc and Boston Scientific Corporation for both ICDs and CRT-Ds, which resulted not only in a pause but also in VT/VF detection. VT/VF detection was confirmed in ICDs and CRT-Ds (Boston Scientific Corporation) in the maximum-dose protocols, but treatment was not given because the oversensing ended during the initial detection delay to confirm the persistence

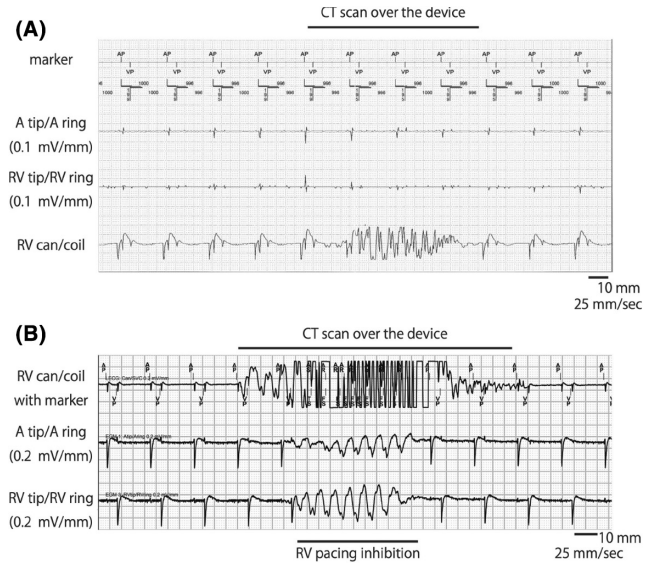

FIGURE 2 Representative examples of the pseudo-intracardiac electrogram during CT irradiation. (A) Oversensing was not observed during CT scan. (B) Oversensing was observed during CT scan.

of tachycardia. VT/VF detection and capacitor charging prior to shock were confirmed in CRT-Ds (Medtronic plc) in the maximum-dose protocols, but the shock was not observed as the oversensing ended during charge. In this device, other therapies such as ATP during charging were not administered because the oversensing was too frequent.

Oversensing without pauses was detected only in the maximum-dose protocol (protocol 5) of the CRT-D (MicroPort Inc.).

4 | DISCUSSION

This study assesses the correlation between high-energy CIEDs and CT radiation in the 2020s. We found that radiation from CT examinations produces artifacts, even in devices currently in use. The major findings are that artifacts causing oversensing in the CIEDs occurred mainly in a manufacturer-specific manner, pacing inhibition occurred even in the routine CT protocol, VT/ VF detection occurred only in the maximum-dose protocol even in the absence of therapy, and no malfunction occurred in any device after the irradiation protocol, including partial electrical reset.

For the experimental system, we used the standard CT protocols currently used in clinical practice and high-dose protocols that are not in clinical used. Adverse events in CIEDs because of CT imaging have previously been reported to be caused only by direct X-ray radiation on complementary metal oxide semiconductor (CMOS) transistors in the generator.[5,6] This study was conducted without a lead connected to the device and far-field potentials, such as the RV coil-CAN and LV lead, were not evaluated because they are not involved in pacing inhibition and VT/VF detection.

Oversensing because of artifacts that resulted in pacing inhibition of more than 2.5 s, even in the normal CT protocol, was observed only in devices from Medtronic plc and Boston Scientific Corporation. As the duration of the pauses caused by pacing inhibition depended on the CT radiation scan time, it is advisable to shorten the CT radiation time over the device or exclude the device from the imaging area. These results aligned with those of previous in vivo and in vitro reports on pacing inhibition.[3,7] Oversensing was caused mainly because of manufacturer-dependent factors, possibly like, difference in the CMOS transistor structures[2] or a higher sensitivity parameter set by these manufactures, resulting in the detection of more artifacts. The latter should be taken note of, as some devices are set to these parameters. CRT-D from MicroPort Inc. showed oversensing without causing malfunction in protocol 5 (Table 2). As this protocol had the highest dose per unit time, this may have contributed to oversensing even in the absence of artifacts.[3,8]

VT/VF detection was not confirmed in the normal CT protocol, but was confirmed in ICDs (Boston Scientific Corporation) and CRT-Ds (Medtronic plc and Boston Scientific Corporation) in the maximum-dose protocol. It is generally believed that X-rays irradiating the device enter the CMOS and generate excess current owing to the photoelectric effect, which is amplified by the transistor, causing oversensing. The dose-dependent difference may be because more photons are likely to contribute to the photoelectric effect and generate excess current when the radiation dose is large, and the scattered rays because of the Compton effect may generate additional current. However, even with the highest sensitivity and the shortest detection period, VT/VF detection was not observed in the daily CT protocol, and the maximum-dose protocol did not require treatment with ATP or shock. This charge was also reported in a case report, although therapy was not administered even in that case.[9] Furthermore, a study has identified no adverse events from diagnostic CT scans in approximately 2000 CIED patients.[10] Therefore, the possibility of inappropriate treatment with CT imaging seems to be rare in daily practice.

Chronic malfunction, including partial electrical reset safety features, after daily CT scans has not been reported thereafter InSync 8040 and Thera-I from Medtronic plc, which reset. This aligns with the current study which shows no device malfunction after CT radiation, even in experimental maximum-dose protocols.

The Japanese Pharmaceuticals and Medical Devices Agency provides following notification based on the previous data. "When performing tests that irradiate X-ray flux to the main body implantation site, the patient should be asked to 'raise both arms' and consider whether the defibrillator position can be shifted away from the irradiated area. If the X-ray flux is still irradiated at the implantation site, the tachycardia detection should be switched off during the examination, and the pulse should be monitored or temporary external pacing should be prepared and used."[11] On the other hand, the Heart Rhythm Society recommends that patients with a CIED should undergo clinical diagnostic CT without any additional device interrogation, programming, or monitoring.[12] We

TABLE 3 Events during CT irradiation.

		Japan DRLs 2020 protocol								Maximum-dose protocol
		Protocol 1				Protocol 2				Protocol 3
	Manufacturer	Oversensing	Frequency of oversensing	Max pause (sec)	VT/VF detection	Oversensing	Frequency of oversensing	Max pause (sec)	VT/VF detection	Oversensing
ICD	Medtronic plc	−	−	−	−	+	5/5	2.6	−	+
	Boston Scientific Corporation	+	4/5	−	−	+	5/5	3.2	−	+
	MicroPort Inc.	−	−	−	−	−	−	−	−	−
	Abbott Laboratories	−	−	−	−	−	−	−	−	−
	Biotronik SE & Co. KG	N.E.	N.E.	N.E.	N.E.	N.E.	N.E.	N.E.	N.E.	N.E.
CRT-D	Medtronic plc	+	5/5	2.5	−	+	5/5	3	−	+
	Boston Scientific Corporation	+	4/5	3	−	+	5/5	3	−	+
	MicroPort Inc.	−	−	−	−	−	−	−	−	−
	Abbott Laboratories	−	−	−	−	−	−	−	−	−
	Biotronik SE & Co. KG	−	−	−	−	−	−	−	−	−

Abbreviations: CRT, cardiac resynchronization therapy defibrillator; CT, computed tomography; ICD, implantable cardioverter defibrillators; N. E., not evaluated; VF, ventricular fibrillation; VT, ventricular tachycardia; VV, interventricular.

believe that our study will be applicable in clinical practice in this aspect. However, physicians should keep in mind that pacing inhibition causes pauses. This can be avoided by ensuring that the CT scanner does not scan the patient over the location of their device. In patients requiring CT scanning over a device that is pacing dependent, which may cause lethal arrhythmias because of bradycardia, changes in device settings to magnetic resonance imaging mode (fixed pacing mode) or rhythm monitoring may be considered.

4.1 | Limitations

This study has several limitations. First, this was an in vitro study, which may differ from the possible cardiac reactions in actual patients. Second, various old high-energy CIEDs are currently in use until they require generator exchange, which were not assessed in this study. They may react differently and not align with these results. Third, this study examined only existing CIEDs and may not apply to future CIEDs.

5 | CONCLUSIONS

CT irradiation in patients with CIED can only cause oversensing with pauses in the normal clinical setting of devices from specific manufacturers. Therefore, changing or monitoring the device settings routinely before CT irradiation is not necessary for most patients with CIED assessed in this study.

ACKNOWLEDGMENTS

The authors thank the CT technologists, Yuka Yamao, Ryogo Enoki, Susumu Morikawa, and Masaki Sakurai for the support in the image acquisition.

FUNDING INFORMATION

The study was not supported by any organization.

CONFLICT OF INTEREST STATEMENT

N.U. and K.I. received remuneration for lecture from Medtronic Japan Co., Ltd. S.N. belongs to an affiliation with endowed department from Medtronic Japan Co., Ltd. T. N. received honoraria for lectures by Medtronic Japan Co., Ltd and BIOTRONIK Japan, Inc., and belongs to a department endowed by BIOTRONIK Japan, Inc. which were not directly associated with this study. K.K. received speaker honoraria and research grant from BIOTRONIK Japan, Inc. and Medtronic Japan, Co., Ltd. All the other authors have no disclosures relevant to the contents of this paper to disclose.

DATA AVAILABILITY STATEMENT

The data underlying this article cannot be shared publicly because of intellectual rights concerns. The data will be shared on reasonable request to the corresponding author.

ORCID

Akihito Ideishi https://orcid.org/0000-0002-3754-6256
Kenichiro Yamagata https://orcid.org/0000-0002-9571-7017
Keiko Shimamoto https://orcid.org/0000-0001-6296-150X
Koji Miyamoto https://orcid.org/0000-0003-1728-0240

			Protocol 4				Protocol 5			
Frequency of oversensing	Max pause (sec)	VT/VF detection	Oversensing	Frequency of oversensing	Max pause (sec)	VT/VF detection	Oversensing	Frequency of oversensing	Max pause (sec)	VT/VF detection
5/5	3.2	–	+	4/5	2.8	–	+	4/5	–	–
5/5	3.6	–	+	5/5	4.5	+	+	4/5	–	–
–	–	–	–	–	–	–	–	–	–	–
–	–	–	–	–	–	–	–	–	–	–
N.E.	N.E.	N.E.	N.E.	N.E.	N.E.	N.E.	N.E.	N.E.	N.E.	N.E.
5/5	3.4	+	+	5/5	8	+	+	4/5	–	–
5/5	3.4	–	+	5/5	4.2	+	+	5/5	–	–
–	–	–	–	–	–	–	+	2/5	–	–
–	–	–	–	–	–	–	–	–	–	–
–	–	–	–	–	–	–	–	–	–	–

Takashi Noda https://orcid.org/0000-0001-9731-6842
Satoshi Nagase https://orcid.org/0000-0001-7894-0914

REFERENCES

1. Nadeem F, Nunez Garcia A, Thach Tran C, Wu M. Magnetic interference on cardiac implantable electronic devices from apple iPhone MagSafe technology. J Am Heart Assoc. 2021;10:e020818.
2. Yamaji S, Imai S, Saito F, Yagi H, Kushiro T, Uchiyama T. Does high-power computed tomography scanning equipment affect the operation of pacemakers? Circ J. 2006;70:190–7.
3. McCollough CH, Zhang J, Primak AN, Clement WJ, Buysman JR. Effects of CT irradiation on implantable cardiac rhythm management devices. Radiology. 2007;243:766–74.
4. Abe K, Hosono M, Igarashi T, Iimori T, Ishiguro M, Ito T, et al. The 2020 national diagnostic reference levels for nuclear medicine in Japan. Ann Nucl Med. 2020;34:799–806.
5. Blamires NG, Myatt J. X-ray effects on pacemaker type circuits. Pacing Clin Electrophysiol. 1982;5:151–5.
6. Uiterwaal GJ, Springorum BG, Scheepers E, de Ruiter GS, Hurkmans CW. Interference detection in implantable defibrillators induced by therapeutic radiation therapy. Neth Heart J. 2006;14:330–4.
7. Elagha AA, Weissman G. Pacemaker malfunction attributed to multidetector cardiac computed tomography. Circulation. 2016;133:342–3.
8. Mouton J, Haug R, Bridier A, Dodinot B, Eschwege F. Influence of high-energy photon beam irradiation on pacemaker operation. Phys Med Biol. 2002;47:2879–93.
9. Porres JM, Cerezuela JL, Luque O, Marco P. Computed tomography scan and ICD interaction. Case Rep Med. 2009;2009:189429.
10. Tsutsui K, Kato R, Mori H, Kawano D, Ikeda Y, Matsumoto K, et al. Chest computer tomography is safe without additional interrogation or monitoring for modern cardiac implantable electrical devices. J Cardiovasc Electrophysiol. 2022;33:1336–40. (Online; ahead of print).
11. Pharmaceuticals and Medical Devices Agency of Japan. Revised instructions for "precautions for use" relating to interactions between X-ray CT systems and cardiac implantable electronic devices. 2005 https://www.pmda.go.jp/safety/info-services/devices/0021.html
12. Indik JH, Gimbel JR, Abe H, Alkmim-Teixeira R, Birgersdotter-Green U, Clarke GD, et al. 2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices. Heart Rhythm. 2017;14:e97–e153.

How to cite this article: Ideishi A, Yamagata K, Nishii T, Miyanooi H, Miyazaki Y, Wakamiya A, et al. Interference of cardiac implantable electronic devices and computed tomography imaging in the current era with a phantom model. J Arrhythmia. 2023;39:580–585. https://doi.org/10.1002/joa3.12853