

Cardiac Rhythm Device Identification Algorithm using X-Rays: CaRDIA-X

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Introduction

A 75-year-old woman with a dual-chamber pacemaker was seen in the cardiology clinic for possible device malfunction. The patient's device identification card revealed that a pacemaker from "Manufacturer A" was implanted in 2001. However, device interrogation using the corresponding programmer failed to communicate with the device. Given the age of the device, complete depletion of the battery was suspected and the patient was thus referred for pacemaker generator change.

On the day of the surgery in the holding area, upon inspection of the pacemaker implantation site, existence of 2 healed scars side by side raised the suspicion of a previous generator change out or revision of leads. However, the patient did not recall any such procedures; therefore all of the 5 major manufacturers were contacted. Manufacturer A confirmed the information in the identification card, whereas the others showed no record of the patient. Nevertheless, the second scar at the device site still remained a question. Although the decision regarding the pacemaker generator change was acceptable, the possibility of a mistaken device manufacturer identity could not be completely ruled out. The patient's chest X-ray with the pacemaker image was compared with other patients' X-rays with known pacemakers for possible manufacturer identification. Similarities with one of the other manufacturer's ("Manufacturer B") X-ray pacemaker image prompted device in-

terrogation using the corresponding programmer, which recognized a functioning device from Manufacturer B. Further investigation with Manufacturer B revealed that the patient demographics had been erroneously documented at the time of implantation, thereby causing the dilemma.

Clinical problem

The number of pacemakers (PMs), implantable cardioverter-defibrillators (ICDs), and implantable loop recorders (ILRs), collectively called cardiac rhythm management devices (CRMD), implanted each year has increased exponentially,¹ and their management now extends across a continuum of clinical care settings and providers. Optimal care of such patients requires correct and timely identification of their implanted CRMD, especially when device interrogation is warranted.² This is performed using manufacturer-specific device programmers designed to communicate only with CRMDs from the corresponding manufacturer. The clinical vignette presented above exemplifies one of the many device management conundrums that physicians may face during care of patients with implanted CRMD.

We surveyed over 50 physicians from different medical specialties in an inner-city hospital to assess the frequency of patients with CRMDs encountered in their clinical practice. Approximately 80% of the physicians acknowledged frequent such patient encounters, difficulties in CRMD manufacturer recognition, and the need for a better CRMD identification method. Additionally, a second survey composed of a 5-item, self-administered questionnaire was conducted among 105 industry-employed allied professionals (IEAP). A high proportion (49.4%) of the 75 respondents indicated that they received ≥ 5 calls per month for device identification, more commonly from emergency rooms (32%) and operating rooms (20%). A number of those calls (up to 3 to 4 per month) were directed to the wrong manufacturer IEAP, resulting in significant time delays (>20 minutes per 35.3% of the respondents) because cross-checking with other manufacturers was needed. Additionally, an average of 1 to 2 times per month, a wrong device was discovered only after attempting CRMD interrogation at the

KEYWORDS Radiological identification; Pacemaker; Implantable cardioverter-defibrillator; Implantable loop recorder; Cardiac rhythm management devices

ABBREVIATIONS ANC = alphanumeric codes; CaRDIA-X = Cardiac Rhythm Device Identification Algorithm using X-rays; CRMD = cardiac rhythm management device; EMR = electronic medical records; ICD = implantable cardioverter-defibrillator; IEAP = industry-employed allied professionals; ILR = implantable loop recorder; PM = pacemaker (Heart Rhythm 2011;8:915-922)

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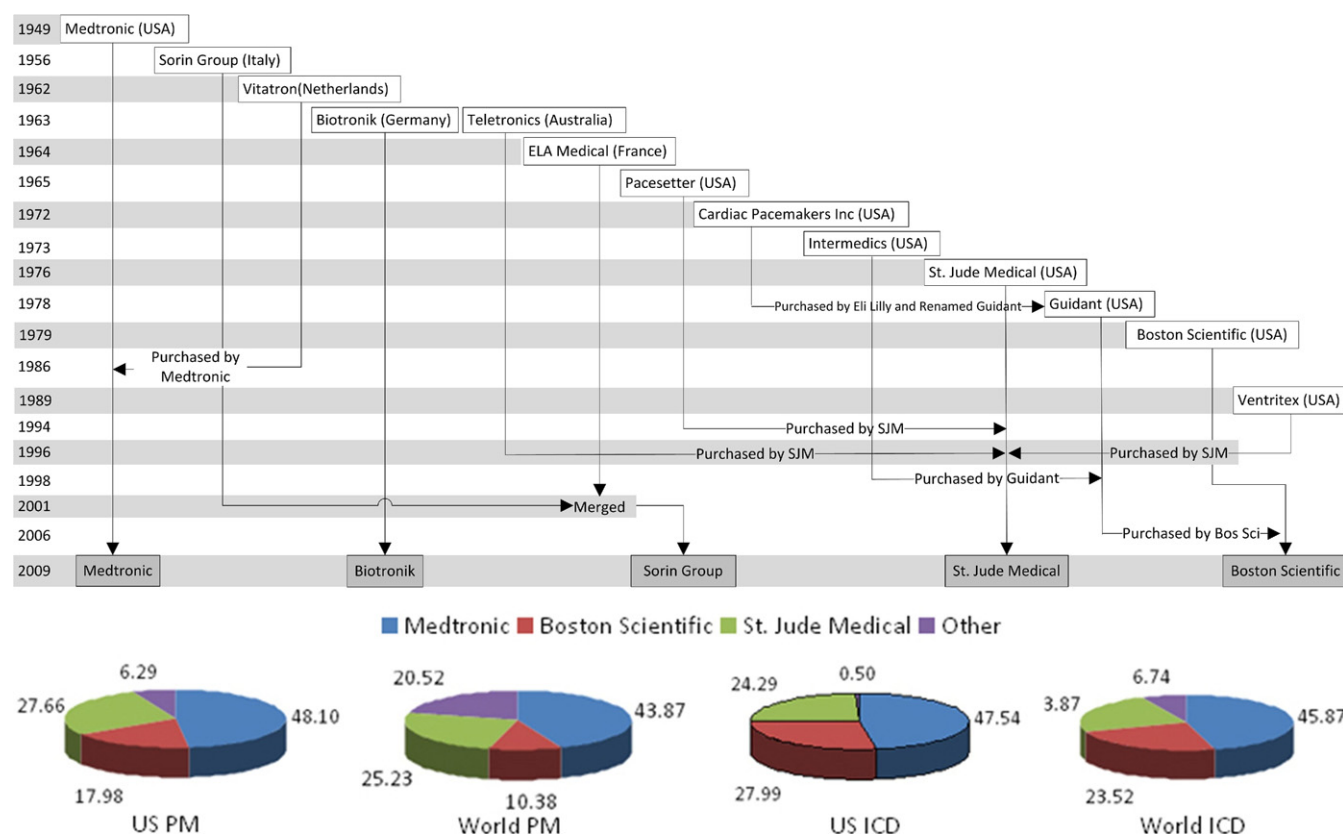


Figure 1 Current device manufacturers. A chronological history of mergers and acquisitions among CRMD manufacturers from 1949 leading to the formation of the current 5 major transnational manufacturers in the market today. Graphs represent their U.S. and worldwide market shares. CRMD = cardiac rhythm management device, PM = Pacemaker, ICD = Implantable Cardioverter Defibrillator.

patient bedside. All of these clearly indicate the magnitude of this clinical problem and perhaps the need for an easy-to-use CRMD identification tool.

Current CRMD identification techniques and limitations

Although several manufacturers were in the CRMD industry over the years, mergers and acquisitions evolved to the current 5 major manufacturers: Medtronic, St. Jude Medical, Boston Scientific, Biotronik, and Sorin (Figure 1). Techniques to identify the CRMD from the above manufacturers include using the patient's identification card, electronic medical records (EMR), manufacturers' patient registries, device-specific radiopaque alphanumeric codes (ANC), and other nonconventional methods. Patients are provided with a CRMD identification card at the time of device implantation, although they may not have it at their disposal all the time. CRMD manufacturers also maintain their own in-house registry of patients implanted with their devices and provide 24-hour telephone technical support.³ However, manufacturer maintained registries and hospital EMRs may sometimes be misleading, particularly if the patient information has been omitted or erroneously entered into the database, as seen in the clinical vignette above.

The radiopaque ANC marked into the device for identification⁴ is unique for each manufacturer. However, its

visibility is highly dependent on the X-ray image quality, and its clinical utility has not been substantiated by any published study. Three physicians at our institution, blinded to any relevant patient data, reviewed more than 1,000 X-rays of patients with implanted CRMDs using the standard-resolution hospital EMR system. The results revealed <20% accuracy with significant interobserver and intraobserver variation in device identification due to their inability to clearly visualize the ANC on the chest X-rays. The clinical value of ANC without high-resolution magnification is thus too low to justify its routine use in device identification.

Although the manufacturer-specified pacing mode and rate response upon magnet application might be used to identify the pacemaker manufacturer, the magnet response of different CRMDs is varied and complex to interpret. A trial-and-error method of interrogating a device using programmers from all of the manufacturers until one of them recognizes the CRMD is another unconventional approach. However, this not only is cumbersome, but also may fail when the CRMD battery is depleted. Furthermore, it may have unwanted effects, including switching off defibrillation therapy⁵ in certain ICD models.

Each of the previously described CRMD identification techniques is thus fraught with different problems. An extensive literature search did not identify any published tech-

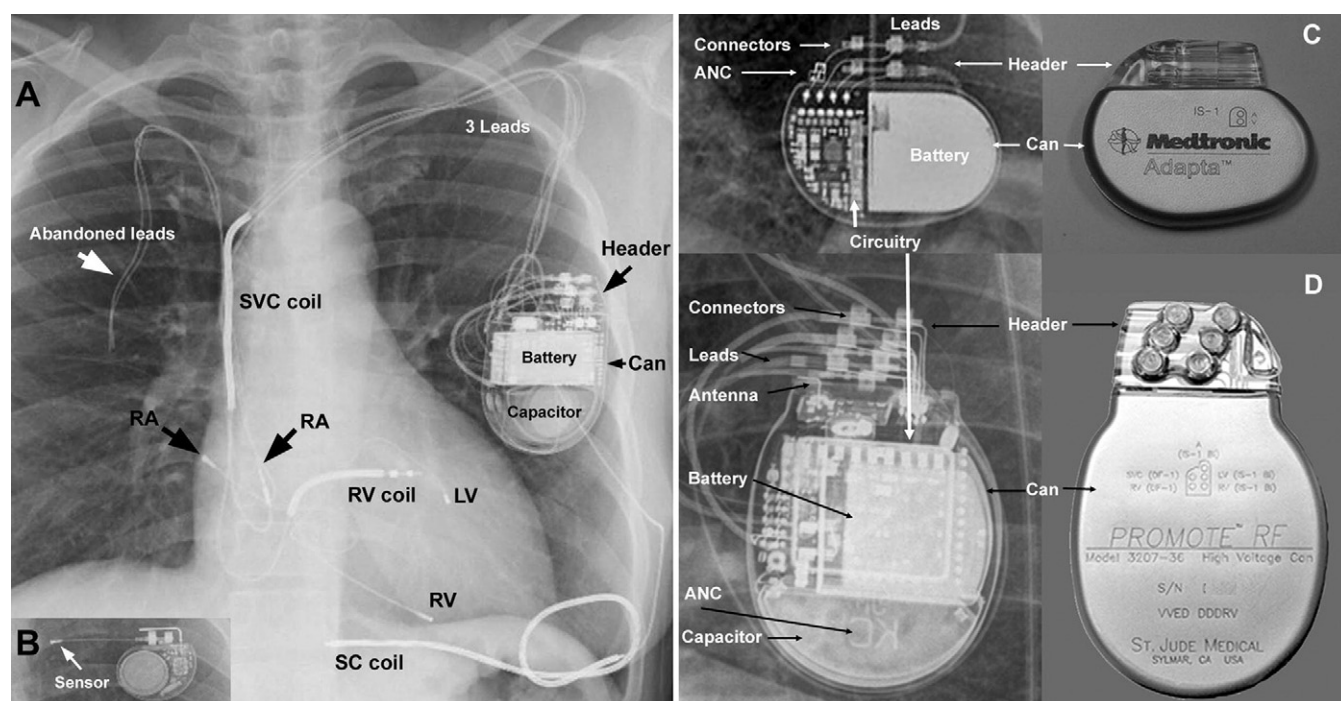


Figure 2 **A:** Chest X-ray of a patient with a biventricular implantable cardioverter-defibrillator (BiV ICD). Note the right atrium (RA), right ventricle (RV), and left ventricle (LV) leads connected to the header of the device. The RV lead has a combination of RV pace/sense lead, RV coil, and superior vena cava (SVC) coil. The subcutaneous (SC) coil is connected to the SVC port in this case. Another set of RA and RV abandoned pace sense leads can also be seen from the previous pacemaker implantation. **B:** Transoma Medical (Sleuth) implantable loop recorder (ILR). Note the flexible sensor (antenna) with no transvenous leads. **C, D:** Side-by-side images of radiological and gross appearance of a pacemaker (Medtronic Adapta™) and implantable cardioverter-defibrillators (St. Jude Medical Promote™).

nique or algorithm for comprehensive identification of the CRMD and/or their respective manufacturers. Delays or errors in device identification in various clinical situations may jeopardize timely patient care and may negatively impact health care costs. Hence, there is scope and need for a more reliable and easy to use CRMD identification technique to facilitate timely, efficient, and cost-effective management of patients implanted with CRMD.

Solution: Cardiac rhythm device identification algorithm using X-rays

Chest X-ray offers an untapped, easily available tool that can help reliable identification of the type and manufacturer of CRMD (Figure 2). Each CRMD has certain distinctive morphological features that make its radiological identification possible. This prompted us to develop and validate an algorithm, Cardiac Rhythm Device Identification Algorithm Using X-rays (CaRDIA-X), for radiological identification of CRMDs (Figure 3).

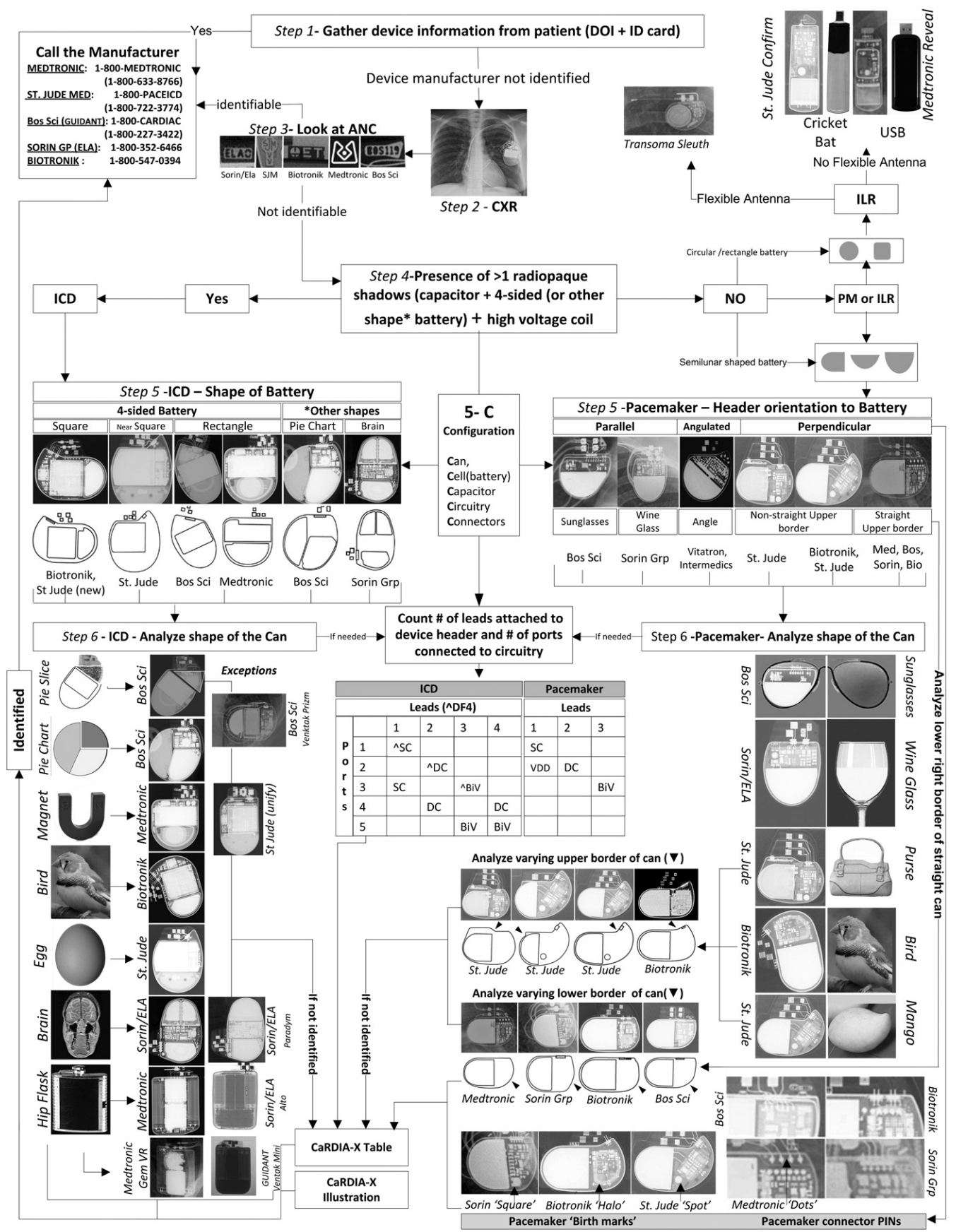
Development of the CaRDIA-X algorithm

We retrospectively analyzed over 2,200 chest X-rays of patients implanted with CRMDs from the 5 major manufacturers. The study protocol was approved by the institutional review board. While systematically reviewing each X-ray, unique morphological characteristics that help distinguish the type and manufacturer of each CRMD were identified. The information thus gathered was summarized

into tabular form, which was subsequently conceptualized into the CaRDIA-X algorithm.

Although it appears complex, CaRDIA-X is a simple yet comprehensive stepwise CRMD identification algorithm. The first step is to see whether the patient has a device identification card or knows the device manufacturer. If such information is not available, then access or obtain a chest X-ray (step 2). Step 3 involves identifying the radiopaque manufacturer-specific ANC; if not identifiable, then proceed to step 4.

This step is crucial for determining the type of the device implanted: ICD, pacemaker, or ILR. It involves the analysis of both the leads and the CRMD “can”. The tachytherapy leads that are unique to ICDs are distinguished from bradytherapy leads by the presence of single or dual endovascular or sometimes subcutaneous high-voltage defibrillation coils. These coils are characterized by thickened radiopaque portion of the lead body (Figure 2). However, caution must be used because rarely, a pace-sense component of a pre-existent tachytherapy lead from a previously implanted ICD may be connected to a new pacemaker when an ICD is no longer indicated. On the other hand, bradytherapy leads have a uniform radiopaque body and represent a pacemaker lead. The newer magnetic resonance imaging-compatible Medtronic bradytherapy leads have a characteristic radiopaque marking (Online Supplementary Figure 1 and Figure 2).



The CRMD casing (*can*) houses a battery (cell), capacitor, circuitry, and connector pins and forms a specific pattern radiographically. This *can*, cell, capacitor, circuitry, and connector configuration (5-C configuration) or pattern, which is unique for each manufacturer's device, supplements the ICD, PM or ILR identification pathways. The battery forms the main radiopaque shadow in any CRMD, whereas the capacitor, which is unique to an ICD, forms the second radiopaque shadow (Figure 2). Thus, a single radiopaque shadow is characteristic to PMs or ILRs. A single semilunar-shaped battery shadow confirms a PM, whereas a single circular or quadrangular shadow represents an ILR. The presence of more than 1 radiopaque shadow and a high-voltage coil always confirms the presence of an ICD. Once the type of the device has been identified, proceed to step 5 of the corresponding PM, ICD, or ILR pathway.

ILR pathway

The presence of a flexible antenna confirms a Sleuth ILR (Transoma Medical). The St. Jude Medical (*Confirm*) and Medtronic (*Reveal*) ILRs lack any flexible antennae and radiographically bear resemblance to a cricket bat and USB flash drive, respectively.

ICD pathway

Step 5 is to assess the shape of the ICD battery: square (Biotronik or St. Jude Medical [UnifyTM/FortifyTM]), near square with a curved side (St. Jude Medical), rectangle (Boston Scientific or Medtronic), pie-shaped (Boston Scientific) and other shapes (Sorin). In addition to the battery shape, step 6 includes finding similarity of the shape of the ICD *can* or portion of the device to common real-life objects. A pie-slice or pie-chart shape is characteristic of Boston Scientific ICDs, whereas a similarity to a U-shaped magnet confirms a Medtronic or the St. Jude Medical (UnifyTM/FortifyTM) ICDs. Other St. Jude Medical ICD models have an egg-shaped *can*. A similarity to a coronal section of a human brain may favor Sorin ICDs (Ovatio/Paradym), whereas Biotronik ICDs have similarity to a bird, as shown in the algorithm. A few older models of ICDs from Medtronic (Gem VR/DR), Guidant Ventak Mini and Sorin (Alto) resemble the shape of a hip flask.

Pacemaker pathway

Step 5 is to analyze the orientation of the header (Figures 2 and 3) to the straight side of the semilunar battery within the *can*. The header could either be parallel (Boston Scientific or Sorin) or perpendicular to the straight side of the battery (any manufacturer). In some other older Vitatron or Intermedics models, it may be angled. In the next step, the shape of the *can* could be compared with other common real-life

objects for easy identification as shown in the figure: sunglasses (Boston Scientific), wine glass (Sorin), purse or mango shapes (St. Jude Medical), and a bird shape (Biotronik).

Some models of PMs have a very similar radiopaque appearance, hence additional steps have been incorporated into the algorithm for when further discrimination between various PMs is difficult. When the header is perpendicular to the straight side of the battery, analyze the upper border of the *can*. A nonstraight upper border may imply a St. Jude Medical (purse or mango shape) or a Biotronik (bird shape) PM. Additionally, the angle at the top of the *can* is much more pronounced in St. Jude Medical PMs as opposed to Biotronik PMs. However, if the upper border of the *can* is straight, the subtle differences in the lower right border of the PM *can* should be carefully analyzed (refer to pictorial description in the algorithm). Furthermore, key distinctive features described by us as "birth marks" are found to be characteristic of PMs from different manufacturers in addition to quite distinctive connector pin configurations unique to each manufacturer. For example 'Medtronic Dots', 'St. Jude Spot', 'Biotronik Halo', and 'Sorin Square' (Figure 3). Online Supplementary Figure 1 and Figure 2 provide detailed template shapes and corresponding X-ray images of various CRMDs to help further discriminate the CRMDs.

Validation of the CaRDIA-X algorithm

Study design

Based on the results of our preliminary survey, the algorithm was validated among physicians who were most likely to encounter patients with CRMDs in their practices. Five specialty groups of 3 physicians each (emergency room, cardiology, internal medicine, anesthesiology, and radiology) with an additional 6th nonclinical group of 3 graduate students for comparative analyses constituted the study participants. The validation was conducted in a 2-step process: CaRDIA-X training with pretraining and posttraining assessment phases and the final testing phase. All study participants were initially assessed using 25 selected X-ray images (N = 12 ICDs, 12 PMs, and 1 ILR) to identify the CRMD type and manufacturer. Subsequently, each participant group was given repetitive training by a single instructor on how to use the CaRDIA-X algorithm to identify the CRMD. This was followed by posttraining assessment sessions until $\geq 85\%$ correct CRMD identification was achieved by all of the study participants in each group. This allowed for standardized measurement of training effectiveness and avoided a learning curve during final testing. In the final testing phase, participants were tested on another care-

Figure 3 CaRDIA-X algorithm. The algorithm showing different steps for easy device identification. ICD, PM, and ILR pathways are incorporated but not labeled. See text for detailed explanation. BiV = biventricular; CaRDIA-X = Cardiac Rhythm Device Identification Algorithm Using X-rays; DC = dual chamber; DOI = Date of implantation; DF4 = New type ICD DF4 lead connector pin standard; ICD = implantable cardioverter-defibrillator; ILR = implantable loop recorder; PM = pacemaker; SC = single chamber; USB = universal serial bus (flash drive).

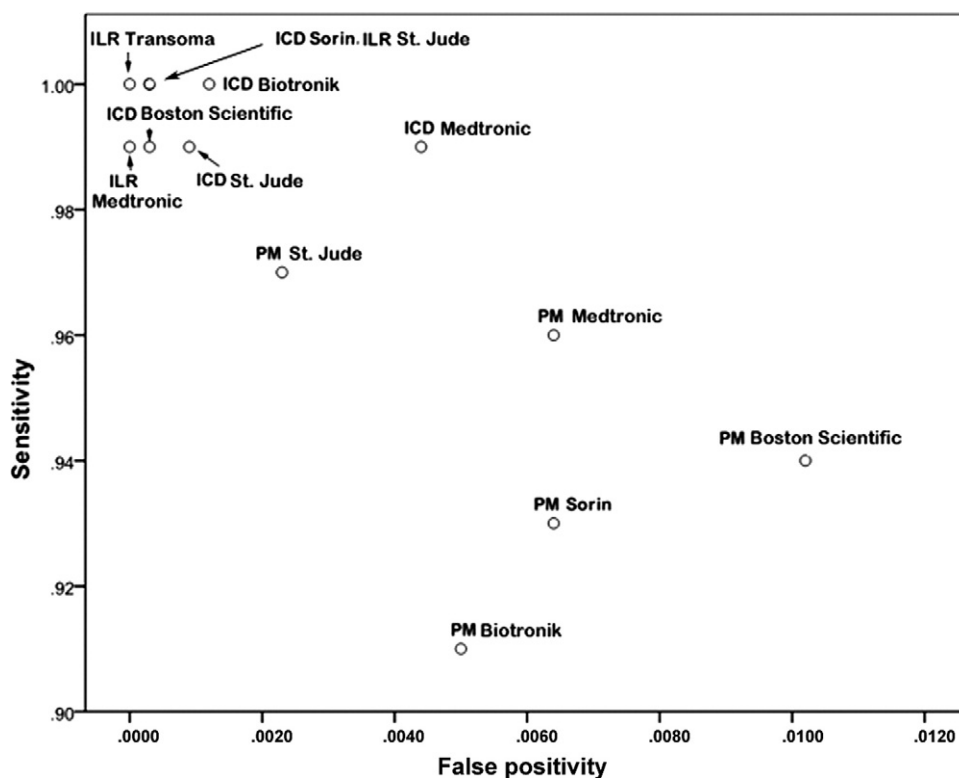


Figure 4 Scatterplot showing the CRMD identification test results using CaRDIA-X. The scatterplot of the sensitivity for device identification against the false positivity rates for each of the devices in the study: St. Jude Medical, Biotronik, Boston Scientific, Sorin Medical, Medtronic, and Transoma Medical. CaRDIA-X = Cardiac Rhythm Device Identification Algorithm Using X-rays; CRMD = cardiac rhythm management device, PM = Pacemaker, ICD = Implantable Cardioverter Defibrillator.

fully selected library of 208 X-rays, composed of ICD (N = 98), PM (N = 100), and ILR (N = 10) images.

Each X-ray was presented in a random sequence during pretraining and posttraining assessment sessions to all participants. All X-rays were DICOM (Digital Imaging and Communications in Medicine) images accessed using the hospital EMR with a standard screen resolution and viewing distance. The quality of the X-rays varied with each sample, during both training and testing sessions, to simulate a real-life clinical setting. Repeated images of various makes of the devices were presented to the readers, resulting in $N \times 3 \times 6$ exposures. This amplified the statistical power for measuring the effectiveness of our training protocol and also for detecting the effects of various device or reader parameters on CRMD identification during the final testing phase.

Statistical analysis

The study participants were expected to identify the CRMD type (ILRs, PMs, and ICDs) and manufacturer from the X-ray images. Only a correctly identified device type and manufacturer corresponded to a “correct identification” in this context, whereas an incorrect identification of either the device type or the manufacturer was a “false identification.” Sensitivity of detection of a specific device was calculated as the proportion of correct identifications of the manufacturer from the whole set of

X-rays for the corresponding device type category. False positivity rate was calculated as the proportion of instances in which a device/manufacturer was identified when a different device was presented. A scatterplot was prepared with sensitivity versus false positivity for each device/manufacturer.

Combined error rates or false negativity (proportion of cases in which the reader identified the device as belonging to another manufacturer or even belonging to another device type altogether) were additionally calculated for ICDs and PMs for each group of readers. The chi-square test was performed to find the differences between reader categories in terms of identification of various manufacturers’ devices. A *P* value of .05 was considered statistically significant. Statistical analysis was performed using SPSS version 17 (SPSS, Inc., Chicago, IL).

Results

There was significant improvement in the correct identifications between pretraining and posttraining assessment sessions using 25 X-rays among all of the readers. The scatterplot further compares the sensitivity and false positivity in identification of the devices in the final testing session (Figure 4). This directly indicates the strength of CaRDIA-X in training the study subjects to confidently differentiate the device type and manufacturer. Combined error rates of PMs and ICDs were compared sep-

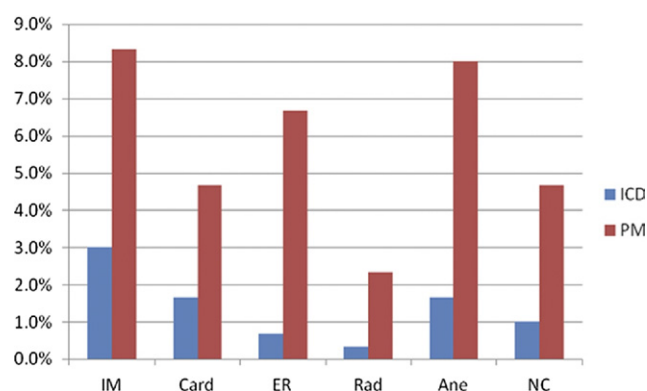


Figure 5 Combined error rates of CRMD identification using CaRDIA-X. The combined error rates (%) of different groups of readers are plotted for implantable cardioverter-defibrillators (ICDs) and pacemakers (PMs) separately. The internal medicine group was the furthest from the radiology group in terms of accuracy for differentiation of devices and/or manufacturers. Ane = anesthesiologists; Card = cardiologists; CaRDIA-X = Cardiac Rhythm Device Identification Algorithm using X-rays; CRMD = cardiac rhythm management device; ER = emergency medicine; IM = internal medicine; NC = nonclinical group; Rad = Radiologists.

arately among the 6 categories of readers. The internal medicine group was the furthest in terms of accuracy from the radiology group, which showed the maximum accuracy in identification (Figure 5). The difference in combined error rates among readers was significantly different ($P = .011$) with regard to the pacemakers. However, this was not so pronounced in the case of ICDs ($P = .077$). Finally, an overall accuracy (all groups pooled) of 96.9% was achieved using the CaRDIA-X algorithm.

Discussion

Identification of implanted CRMDs sometimes presents a significant clinical burden to the care providers and a challenge to currently stretched health care costs. Radiographic imaging promises reliable and accurate identification of implanted CRMDs because a majority of the patients with CRMDs have a chest X-ray performed at some point in time after the device implantation. Although X-ray images have been previously used to differentiate CRMDs,⁶ CaRDIA-X is the first comprehensive algorithm developed and tested. Radiological CRMD identification may lead to better patient care by avoiding any delay in interrogating the devices. This will also reduce hospital costs and other indirect patient expenditures in addition to service cost reduction for the device manufacturers, because unnecessary IEAP visits could be avoided. This is especially important in the current device market economics, which reflect a mismatch between the efforts to reduce CRMD prices and increasing service costs faced by manufacturers.

To assess the comprehensibility of CaRDIA-X, a post-validation survey of the participants was conducted. An anonymous, 4-item, self-administered questionnaire survey assessed on a 5-point Likert scale was used for this purpose; 50% of the 18 respondents agreed that the algorithm appeared complex initially, but during the training session a

high proportion (81.3%) of the respondents found it quite easy to understand and learn. All of the respondents agreed that they were extremely comfortable in applying CaRDIA-X for CRMD identification during testing.

An online version of CaRDIA-X, supplemented by a continually updated library of both illustrations and radiographic images of new CRMD models by their respective manufacturers, will provide up-to-date information about new and even future CRMD models in advance. The high-resolution downloadable CaRDIA-X algorithm, illustrations, and table would allow medical personnel to print large posters for easy viewing in any clinical setting.

Study limitations

Will we be able to identify all CRMDs with ease using CaRDIA-X? For most purposes, the answer is yes, but there are some considerations that should be borne in mind while applying the algorithm. Quality of the chest X-rays, rotation, position or tilt of the device, and underpenetration or overpenetration of the X-ray images could affect the CaRDIA-X interpretation. Likewise, unavoidable confounding factors such as stress, anxiety, and emergent situations encountered during real-life clinical practice may affect the accuracy of the algorithm. Additionally, use of CaRDIA-X entails a certain degree of preliminary training for appropriate understanding and application of the algorithm that might not interest some medical personnel.

Furthermore, CaRDIA-X is not designed to identify some of the older CRMD models. However, as comprehensively elaborated in Figure 1, the current CRMD manufacturers have been the only ones in the market for the last 13 years.⁷⁻¹¹ Although possible, given the average life of CRMDs, it is unlikely to see older device models. Other electronic implantable devices that resemble CRMDs, such as newer investigational heart failure monitoring devices, ST-segment monitoring devices, and other pacing or stimulating devices (e.g., devices for refractory hypertension, chronic pain, etc.) have not been incorporated into CaRDIA-X. Rarely, physicians might encounter patients implanted with CRMDs from smaller local manufacturers in other countries, e.g., CCC (Uruguay) and Medico (Italy), that are not included in our database.

Pacemakers were more frequently mistaken than ICDs in our study. It was plausibly due to analogous outlines of the device cans, header orientation, and similarities in the 5-C configuration. The most frequently mistaken devices in the study included some of the PM models from Biotronik and St. Jude Medical, which share similar shape and pattern. PMs from Biotronik, Boston Scientific, Sorin, and Medtronic with a straight upper border of the can were mistaken due to close resemblances both in can shape and 5-C configuration. Among ICDs, newer St. Jude Medical devices (UnifyTM and FortifyTM) were mistaken for Medtronic ICDs, which share a similar shape (U-shaped magnet). Despite these considerations, a high overall accuracy and discriminability of the CaRDIA-X achieved during validation of the algorithm promises precise identification of implanted CRMDs.

Future directions

Larger and easily visible radiopaque alphanumeric identifiers (e.g., SJI for St. Jude Medical ICDs or MP for Medtronic PMs) if incorporated during device manufacturing will be the simplest yet most logical innovation to identify CRMDs. However, during the interim, Automated CaRDIA-X (A-CaRDIA-X) utilizing edge-detection technology and pattern recognition algorithms permitting automated CRMD recognition from X-rays is a promising possibility. Mobile computing platforms supporting this technology could be developed for handheld devices.

Conclusion

Identification of CRMDs is a common problem frequently encountered by physicians in various clinical settings. Radiological identification opens a new avenue, with teleradiology specifically holding promise as a reliable and rational arbiter for precise, timely, and cost-effective CRMD recognition. It offers a readily available and more realistic approach over the existing diagnostic armamentarium, thereby minimizing any wrongful assumptions that could negatively impact patient care. Although the next-generation EMR would likely improve the situation, it would entail a concerted multidisciplinary approach from the industry, hospitals, and physicians to achieve this goal.

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Appendix

Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.hrthm.2011.01.012.

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