

FORENSIC SIGNIFICANCE OF CARDIAC IMPLANTABLE DEVICE (PACEMAKER)

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ABSTRACT

Pacemakers are automated electric medical devices that are imbibed in the pleural cavity near to heart so as to stimulate the heart with electrical inducement to maintain or restore a normal heartbeat. Pacemakers can be implanted temporarily to treat bradycardia after a heart attack, surgery or overdose of medication. They can also be implanted permanently to correct a slow heartbeat or, in some cases, to help treat heart failure. With increase in pacemaker indications and especially implantable cardioverter-defibrillators, the number of patients with implantable devices has been growing steadily. With the enhancement in the technology the design of pacemakers are being modified till date. Pacemakers being an electronic device also stores data of patient's heartrate, pulse rate and number of time it has paced in a day. Since, technology is killing our opportunity to falsify the information; the data stored in the pacemaker can either support or reject the alibi stated by the victim or assailant. The aim of this research paper is to study the concept and type of digital data stored in implantable cardiac device i.e. pacemaker. This study focuses on awareness about the application of pacemaker in solving forensic cases. Digital data provided by the pacemaker in any ongoing investigation will have a huge evidentiary potential, as it can be made admissible in the court of law under Section 65-B of the Indian Evidence Act, 1872. In this paper, we are recommending that pacemakers can be used as digital evidences since, they track the audit trails of the patient.

Keywords : Pacemaker, Digital Evidence, Forensic, Admissibility.

I. INTRODUCTION

Cardiac implantable medical devices are manufactured to replace damaged biological structure of heart and also to support the enhancements of the existing functions of heart .These devices are embedded into patients bodies to monitor their medical conditions by collecting a range of physiological values e.g. heart rate, blood glucose and neural activity and to provide specific therapies. These are configured to monitor patient's health status and equipped with wireless interfaces, which largely promotes patient's mobility and eliminating surgical procedures. Pacemaker is such a cardiac implantable electronic device which is surgically implanted into a patient's body, and wirelessly configured using externally programmed and primarily controlled by hardware. There are different type of pacemakers which are differentiated from each other by number of leads and its functions. A pacemaker has a pulse generator – a battery powered electronic circuit – and one or more electrode leads. There are three major types of pacemaker which are as follows:

- 1. Single-chamber pacemaker: In this pacemaker one of the heart chamber is connected to the pulse generator by one lead. Mostly depending on the symptoms and the type of pacing patients need, it is used to regulate heartbeat pacing by connecting lead to either of the lower chambers or upper chamber of heart.
- 2. Dual-chamber pacemaker: In this pacemaker, two leads are connected to both the cardiac chambers which are programmed by the doctors in order to monitor and improve the contractions of the chambers. It basically helps in synchronizing both the chambers making them work effectively with proper cardiac contraction and relaxation.
- 3. Biventricular pacemaker: These are used for the people with arrhythmias which are caused by advanced cardiac failure. In this type of pacemaker the three leads are connected to one of the atrium and both the ventricles.

We live in an era of technology, where digital information is being generated at unprecedented rates. Modern pacemakers are capable of storing large amount of diagnostic digital data in relation to the various arrhythmias. One of the most significant advantages of having such diagnostic digital data is that it is collected on 24*7 basis. This allows physicians to figure out the appropriate functioning of the device, the status and improvement of the patient's arrhythmias and the effects of pacing and pharmacological therapies by reviewing the device digital data. Hence it is possible to transfer data between the pacemaker and external devices, thereby enabling the physician to draw conclusions about the historical condition of the patients. The latest technological pacemaker is that it continuously analysis and stores the data periodically instead of discarding it, which is of potential use for future evaluation.

Since, pacemakers provide digital information they can be used in solving legal cases. This digital information is stored in the form of small sets of data with the cardiac arrhythmias, pulse rate and recurrence of electric stimulus generated along with the timeline. This data is not only limited to reveal time and cause of death in cases where autopsy fails, also it can be used during interrogation to support a person's alibi in legal investigations

II. AIM AND OBJECTIVES

In this paper, we have proposed that the pacemaker can be considered as electronic evidence in the court of law as it stores data in digital form. Our objective was to carry out a digital forensic investigation of the pacemaker as it tracks the audit rails of patient's activities. In India the electronic device is admissible under section 65B of the Indian Evidence Act 1872.

III. LITERATURE REVIEW

Sanders *et al.* (1984) studied the data storage and transmission capabilities of the microprocessor-controlled pacemaker to record, process and transmit data related patient, pacemaker and their interaction. Further the obtained data by these can be used in patient management system, follow-ups in the area of optimization of programming, monitoring of disease progression, evaluation of pharmacologic therapy and pacemaker trouble shooting.

Lindqvist (2005) studied a wide range of compression techniques and evaluated them to find a possible compression technique for pacemaker data. Also various database models, data mode, memory consumption, storage media, operating system platforms, real time properties and accessibility of pacemaker were studied. He concluded that Fan and Adaptive peak algorithm were the best compression technique used in the pacemaker and Berkeley DB and extreme databases were better for database solutions. Schuchert *et al.* (2005) analyzed the data collected from implanted pacemakers without any prior history of atrial arrhythmias. In his study of 239 patients, 31% of patients were detected with atrial arrhythmias. This work concluded that the data can be analyzed and used by the physicians for the detection of future technical issues and arrhythmias. Kirkpatrick *et al.* (2007) investigated management of pacemaker and defrillators and reviewed about the device investigation during the routine postmortem. As per the survey, the average number of devices annually explanted per mortician was 7±10.

Implantable pacemakers and defrillators were rarely analyzed after patient's death as they were disposed as medical waste. Many patients and morticians willingly accept and support systematic postmortem device evaluation.

Burri and Senouf (2009) stated details of the various existing remote monitoring cardiac implantable systems and its qualities in order to achieve the requirements of the doctors due to increase in use of the devices. They discussed the possible benefits of the wireless monitoring systems like reduction of inclinic visits and to improve patient safety. Issues relating patient's privacy, security and optimal overflow of data and its management capabilities were discussed.

Shi and Zhou (2011) studied the recent advances of sensors incorporated in modern pacemakers. Authors have compared the various sensors in a pacemaker with respect to their sense signals and providing more diagnostic data. They also have focused on limitations and applied conditions of various sensors. Bisset and Matin (2012) in their paper explained the process of storage of electrograms in pacemaker. They have explained various parameters that help in the understanding of the electrogram and have highlighted an important feature of arrhythmia monitoring and recording feature in the pacemakers. Hence, these pacemakers can serve as a silent witness to partial and ventricular arrhythmias which are continuously monitored and stored in permanent pacemakers.

Cusack *et al.* (2012) highlighted the threats or vulnerability caused by the wireless medical system at the user level. It tells basically that more sophisticated the device design is more it is vulnerable to attacks. This research also emphasis on the various types of wireless networks communication used in medical devices and emphasis on the detailed architecture of the forensically readymade medical systems.

Ellouze *et al.* (2014) stated that implantable medical devices are designed using a programmer which transmits wirelessly with IMDs which are insecure. A three step protocol was recommended together with a set of procedure for a digital investigation of cardiac IMDs which allows detecting and rebuilding possible attack that lead to a patient's death. Firstly cause of death was confirmed depending on medical observations from the IMDs, secondly the logs were gathered from the IMDs and lastly both technical and medical observations were correlated to confirm the attack or cause of death.

French (2017) in her article entitled as "Data from Suspect's Pacemaker Leads to Arson, Insurance Fraud Charges" has illustrated a case study how pacemaker can be beneficial to the enforcement agencies. The accused Ross Compton, 59, of Ohio, allegedly set his own house on fire in order to collect compensation for about \$400,000 worth of damage. Forensic investigation was carried out and points such as Fire originated from multiple locations, Traces of gasoline found on his shirt and Data from his pacemaker were taken into consideration. The alibi stated by Ross Comptom was that on the discovery of the flames, he somehow managed to pack his essential belongings, used a cane to break a window, tossed the bags out of the broken window and then went outside to his car. The data obtained from the Compton's pacemaker included his pulse rate, heart rhythms and device's demand level around the time when fire took placed. As per the analysis of the obtained data it was unlikely for him to perform all the activities in such a short time which he had mentioned in his statement. Basso et al. (2017) stated minimum standards that are required for the routine autopsy practice for adequate investigation of sudden cardiac deaths throughout Europe. In their research they have mentioned that during the collection of clinical history relevant for the autopsy there should be a check on family cardiac history as well. The protocol also specifies the check for pacemaker and proceeds with its safe removal and interrogation during external examination of the body.

Chi et al. (2018) pointed the raised risk of malicious access to IMDs and suggested the security measures for well equipped IMDs with wireless interfaces which facilitate monitoring and management. They proposed an idea of e-SAFE, which helps to enhance the security and safety, overcome the communication and enables IMD-access forensics. They have also given the protocol concerning the device communication, two-factor authentication and accountability-enabled access in which patients mobile phones are proxy and acts as a controller.

Me et al. (2018) introduced the advanced computerized cardiac pacemaker which analysis and stores the different cardiac parameters based on the mathematical algorithms used for calculating the cardiac parameters using waveforms and frequency. It also states that the advance pacemakers do not require any skilled or technically qualified personnel to manage or operate the device. Hence, it is easy for a medical practitioner to monitor and advice the patient's medical visit with the automated reports generated by the device by any personnel.

Lacour et al. (2018) determined that non selective postmortem CIED interrogations and data analysis are useful for the forensic pathologist for calculation of time of death and cause of death. In the research work they considered total 5368 autopsies over 5 years, out of which 151 cardiac implantable devices, 109 pacemakers, 35 defrillators and implantable loop recorders were recorded. Interrogation of these implantable devices helped to determine 70% of cases of cause of death and 60.8% cases of time of death.

IV. OBSERVATIONS

Modern day pacemakers are small computers which are programmed externally by means of software. This allows cardiologist to select a type of pacing depending upon the patient's condition. The entanglement and dependability of pacemakers have increased due to developments in the sensing techniques. Developments in the sensor technology help not only for pacing but also for other functions such as maintaining diagnostic data and provides continuous cardiac monitoring. There are various types of sensors, such as activity, metabolic and dual sensors used to detect body activity, and measure some consequences of a physiological change during exercise or facing environmental or emotional changes.

The data stored with the help of these sensors can be used to record, process, and transmit information the patient, pacemaker, regarding or patient/pacemaker interaction. Data such as the physiological changes like body accelerations which includes physical activities paced QRS waves, impedance and abnormal cardiac activity continuously which is stored in digital form and can be extracted through the process of Telemetry.

Telemetry word is derived from Greek roots: tele = remote, and metry = measure, which literally means an automated communications process by which measurements and other data are collected at remote or inaccessible points and transmitted to receiving equipment for monitoring. This data can be seen on Health Monitoring System or any electronic device such as tablets, mobiles, etc with which the software is compatible.

The following parameters are extracted through the process of Telemetry

- 1. Fluid Status such as fluid retention, pressure, content in various body cavities.
- 2. Atrial tachycardia and *atrial fibrillation* (*AT/AF*) total hours per day.
- 3. Ventricular rate during AT/AF
- 4. Patient Activity
- 5. Average Day and Night heart-rate
- 6. Heart-rate variability
- 7. Percent pacing per day.

Before the data can be made visible on the output devices / monitors it needs to be synchronized with the compatible health monitoring software. The data is stored as long as the device is implanted in the living human body. The pervious data of the patient can be retrieved from the same or different device (if the device is changed) using the health monitoring software. Various pacemaker manufacturing companies have their own proprietary software for data extraction. In almost all the pacemakers the telemetry wand is placed on the individual's body where the pacemaker is implanted. This wand facilitates the communications between the pacemaker transmitter and the health monitoring software. Telemetry wand can be wireless, wired or combination of both. The extracted data from the health monitoring software which is visible on the output device/ monitor is then transferred to the individual's physician. This data can be further used for diagnosis, detection of any strokes and heart activity.

FORENSIC APPLICATIONS

All the mentioned applications are based on the data logs maintained during the use of pacemaker.

- The physiological changes, cardiac activities and the physical activities which are continuously recorded and stored in the pacemaker can help in the determination of cause of death in cases where the autopsy fails to do so.
- Diagnostic data from the pacemaker can be used for determination of time since death and cause of death during the autopsy or medical emergencies.
- Proves/disproves one's alibi in an ongoing legal investigation as it tracks patients audit trails which helps in knowing the everyday routine of any patient.

ADMISSIBILITY OF PACEMAKER AS DIGITAL EVIDENCE IN INDIA

Pacemaker stores and processes the data in electronic form. It also transmits the data over a network in electronic form. The following reasons comply the conditions under Section 2 (i), (o) and (t) of the Information Technology Act, 2010. Since pacemaker also falls under the criteria and satisfies the definition of Digital Evidence it can be admissible in the Indian Court of Law under Section 65 B of the Indian Evidence Act, 1872.

V. CONCLUSION

Based on the forensic applications and the admissibility of pacemakers as digital evidence in Indian Courts, the digital data stored in pacemaker can be of potential evidentiary value for solving forensic cases and investigations.

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