EFFECT OF APEX LOCATOR AND ELECTRONIC PULP TESTER ON PACEMAKER FUNCTION – AN IN VITRO STUDY.

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CERTIFICATE

This is to certify that this dissertation titled "**EFFECT OF APEX LOCATOR AND ELECTRONIC PULP TESTER ON PACEMAKER FUNCTION– AN IN VITRO STUDY"** is a bonafide record of work done by **Dr. A.S. Sriman Narayanan** under my guidance and to my satisfaction during his postgraduate study period between 2009 – 2012. This dissertation is submitted to THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY, in partial fulfillment for the award of the degree of Master of Dental Surgery in Conservative Dentistry and Endodontics, Branch IV. It has not been submitted (partial or full) for the award of any other degree or diploma.

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CONTENTS

INTRODUCTION

Diagnosis is arguably the most critical component in endodontics. Stedman's medical dictionary describes clinical diagnosis as "The determination of the nature of a disease made from study of the signs & symptoms of a disease"[63]. A thorough clinical examination and objective testing are mandatory prior to initiating treatment. The diagnostic process therefore is an essential part of treatment planning.

Endodontists routinely rely on electrical devices to aid in the diagnosis and treatment of endodontically involved teeth. In case of patients with cardiac pacemaker, electrical devices such as vitality testers and apex locators can create a treatment dilemma for the clinician because they may interfere with the function of the pacemaker and place the patient in a life-threatening situation [3].This leads to an unsure treatment planning, inconsistent measures leading to incomplete diagnosis and speculations that modify treatment modalities.

In dentistry, the electric pulp tester (EPT) and electronic apex locator (EAL), which are approved by the Food and Drug Administration, are routinely used in providing endodontic treatment. Both of these devices apply an electric current directly to the patient's oral tissues. It is likely that patients with ICP needing endodontic care will be encountered frequently. Use of implanted cardiac pacemakers (ICP) raises concern regarding electrical interference that might cause device dysfunction or patient harm No current recommendations from the manufacturers exist for their use in patients with ICPs [1, 48, 66]. Certain electronic equipments in the dental office

may have the potential for interference and therefore such patients should be approached with care. However, because of the variety and sophistication of systems available and lack of current research, there is confusion over which dental equipment should be a cause for concern.

The implanted cardiac pacemaker is a transmitter that generates pulses to regulate the heart rate. Pacemakers are used extensively for the treatment of cardiac rhythm disturbances, especially atrioventricular conduction defects and symptomatic sinus node disease. They consist of a pulse generator which may be planted subcutaneously in the pectoral, axillary or abdominal regions. The pulses generated pass through either epicardial or pervenous leads to either one (unipolar) or two (bipolar) electrodes which are implanted in the myocardium[24].

There are about 3 million people worldwide with pacemakers and each year 600000 pacemakers are implanted. In India an average of 20,000 patients get pacemaker implants every year [10] .With rare exceptions, implantation of a pacemaker does not change the recipient's activities or lifestyle. Although most people who receive pacemakers are aged 60 years or older, people of any age, even children, may need pacemakers [67]. Thus, the average dental practice that provides care to adults, including elderly people, is expected to have patients who have a permanently implanted cardiac device. An approximate calculation made from data presented in the **Meskin and colleagues**'[37] article suggests that about 17 percent of patient expenditures in the 65-years-and-older age group were for endodontic care.

Studies have been done to determine the potential of various devices that can interfere with implanted cardiac pacemakers. These include a wide array starting from cellular phones[19],

iPods[48] to instruments used in the dental office such as EALs, EPT, amalgamator, composite curing light, ultrasonic scalers, dental hand piece, electric toothbrush, electro surgery units, etc. Some devices such as ultrasonic scalers and cleaners, electrosurgical instruments, dental induction-casting machines, electric pulp testers, and microwave ovens have earlier been proved to cause interference with ICP function [38].

There have been dramatic improvements in pacemaker technology over the last few decades. Pacemakers manufactured before 1975 used discrete electronic components encapsulated in a clear epoxy case, this casing was not effective in shielding the cardiac pacemaker from electro magnetic interference [58]. The principle by which the primitive apex locator functioned used electrical resistance (direct current) to measure the canal length [60]. An artificial electrical stimulus may interfere with the function of these cardiac devices in several ways [5]. Interpretation of an extraneous electrical signal as a cardiac signal in origin may temporarily inhibit pacing of an ICP[4]. The electrical signal may be interpreted as noise and temporarily cause reversion of an ICP to an asynchronous pacing mode or the signal may inappropriately reprogram the cardiac device [15] and hence EALs were not recommended in patients with ICPs.

The present decade apex locators are of single or multiple frequency impedance type which use impedance measurements instead of resistance to measure location within the canal. Further, improved metal shielding and increased filtering circuits of pacemakers from 1977 have caused pacemaker manufacturers to discontinue their warnings of interference caused by these

devices. Modern pacemaker electronics are shielded in a hermetically sealed titanium case with capacitors that effectively filter out EMI signals [38, 24].

The available literature evaluating interference between EAL/EPTs and ICPs is limited, and conclusions are difficult to draw. There is only one study evaluating the effects of EALs on pacemakers. In 2002, an in vitro study reported that four out of five EALs tested with a single pacemaker showed normal pacing and only one produced an irregular pace recording on an oscilloscope [15].

Currently, manufacturers of EPTs and EALs warn against using these devices in patients with ICPs [1, 41]. Such warnings are based on speculation of potential risk of electromagnetic interference (EMI) rather than on scientific evidence. Although **Beach et al** [3] published a case report in 1996 showing the use of an EAL in a pacemaker patient without clinical incident, the dental literature lacks research in this area. No studies have been published so far to prove or disprove interference caused by EALs and EPTs on cardiac pacemaker function. The purpose of this study was to assess the effects of electronic apex locators and electric pulp tester on pacemaker function in vitro.

AIMS AND OBJECTIVES

The purpose of this study was to assess the effects of electronic apex locators and electric pulp tester on pacemaker function in vitro.

REVIEW OF LITERATURE

Sunada(1962) [60] constructed a simple device that used direct current to measure the canal length. He used a simple d.c. ohmmeter, the electrical resistance between the periodontium and the oral mucous membrane was measured in 124 teeth. The following results were obtained. When the tip of the reamer reached the apex through the canal, the resistance value was 6.5 KΩ (current 40 μA). Therefore, he concluded that the electrical resistance between them registered consistent values in any portion of the periodontium, regardless of the age of patients or the shape and type of teeth.

Mumford et al (1967) [42] in his review paper regarding "Thermal and Electrical Stimulation of Teeth in the Diagnosis of Pulpal and Periapical Disease" concluded that the electric pulp testing should be by means of a current-measuring instrument which allows control of the stimulus in shape, duration, frequency and direction. The method is valuable for determining which teeth have vital pulps and which do not, which facilitates the diagnosis of periapical disease; there does not appear to be a correlation between the threshold value and the histological appearance of the pulp.

Sowton, Gray, and Preston(1970) [57] investigated into the behavior of different types of implanted non-competitive pacemakers(Devices Demand 2980,Medtronic Demand 5841 Cordis Ectocor, Cordis Atricor, Cordis Stanicor, Elema EMI53, Elema EMI39, Cordis Ventricor II , Cordis Ventricor III or EctocorAmerican Optical Demand) when exposed to different electrical fields. Their report showed that the Implantable non-competitive pacemakers are sensitive to interference from physiotherapy diathermy apparatus, and patients with pacemakers should not

be treated with medical diathermy. Elema and Cordis pacemakers (both Atricor and Ectocor) were sensitive to interference from small electric motors but responded with irregular intermittent tachycardia or bradycardia, which was unlikely to be dangerous. The Devices demand 2980 and the Medtronic demand 584I were not affected by the domestic appliances tested.

Blank et al (1975) [4] clinically evaluated two types of commercial devices (Endometer and Sono explorer) for electronically locating the apical foramen of a root canal as an aid in determining canal length. Their results showed that both the devices performed within acceptable limits in approximately 87% of the canals tested and more consistent readings were obtained with the Endometer.

Simon et al (1975) [57] performed a systematic examination of the potential hazards of electromagnetic interference with pacemakers in patients in the dental environment with the use of several pulse generators of three manufacturers. Only one model was affected by the dental operatory equipment tested. In two of three patients 2-second periods of a systole were noted: this was accompanied by symptoms in one. Permanent pacemakers implanted in three dogs were unaffected by short or sustained stimulation with pulp vitality testers. A permanent pacemaker implanted in one dog was unaffected by short or sustained stimulation with an ultrasonic cleaner. Reliance on severe symptoms alone is a poor method of assessing interference in the clinical situation. Guidelines for protection of the patient wearing a pacemaker in the dental environment are given.

Kleier et al(1982) [29] in their study described the electronic output characteristics of three pulp testing devices(Analytic Technology Pulp Tester, Analytic Technology Corp., Richmond, VA Dentotest, Parkell, Farmingdale, NY).and compared pain responses reported by patients during a clinical trial of the three devices. The three devices varied in wave-form and rate of voltage rise. There were statistically significant differences in relative patient comfort when the three devices were compared against each other through the use of a clinical trial.

Jane Luker (1982) [24] studied the interference of Diathermy A) Siemens D30689-Cutting mode B) Electracise Model 411K , Ultrasonic scaler A) Siemens Siroson-Piezoelectric, B) DRM Automatic Scaler-Ferromagnetic, Handpieces A) Siemens Sirona-Motor S, B) Castellini Micro-Mega Model 40E, Dental chair A) SiemensSL3/S, B) Castellini PM4, Electric pulp tester 4.05 Battery-operated Malgic Dentotest with pacemaker function, the pacing system used viz Edwards, Cordis, Medtronic, Telectronic. His results showed that the only instrument that caused pacing interference was the surgical diathermy.

Rahn et al (1989) [52] tested two rate-responsive pacemakers (Activitrax and Sensolog) in order to determine to what extent their function can be affected by dental treatment. The test results showed that the inhibition of the pacemaker occurred by switching the electrical dental appliance on and off, or by moving it back and forth. In most cases, inhibition was only evident when the distance between the pacemaker and the electrical appliance was less than 10 cm. The electrotom proved to be the most potent source of disturbance, as the function of the pacemaker was totally inhibited when it was switched on and off with a frequency of l-2 Hz, even at a distance of 2.8 m. During dental treatment-especially osteotomies-vibrations are transferred to the patient which can cause an increase in the rate of the pacemaker.

Zappa et al (1991) [69] did an in vivo evaluation of possible interactions between electrically powered dental instruments and the function of artificial pacemakers in humans. In 26 patients with artificial pacemakers, different dental instruments were applied, including air scaler, ultrasonic curets, electric pulp tester and electrotome. These devices were applied at highest intensity. Their results showed that none of the dental devices caused an irregularity in the pacemaker function. The air scaler, Piezon ultrasonic curet and the electric pulp tester caused no measurable magnetic fields. The Sonus 2 ultrasonic curet and the electrotome magnetic fields were measured up to 60 and 50 cm, respectively. All dental devices caused induction tension. The highest value was produced by the electrotome. They concluded that cardiac pacemaker function is not affected by electrically powered dental devices.

Kaye et al (1993) [27] studied the effects of injected 50 Hz alternating current on the function of cardiac pacemakers has been observed in 18 patients with implanted unipolar VVI units. Current, in the range 0–600 μA was applied via electrodes attached to the patients' upper body and feet and fed from a specially designed current injection unit at the bedside. Their results showed that the current injection has proved to be a safe, controllable and reproducible method of testing the sensitivity of implanted pacemakers to 50 Hz external interference.

Kobayashi and Suda (1994) [30] reported a new method in which both in vitro and in vivo data relies on measuring the impedances to two frequencies and then calculating the ratio of these two impedances. They showed that this ratio represents the location of a file tip in the root canal and the ratio has a definite value determined by the frequencies used and that the ratio indicates the location of the file tip in the canal.

Beach et al (1996) [3] published a case report on a patient with a fixed-rate pacemaker requiring root-canal treatment. Under consultation with the patient's cardiologist, an resistance-type electronic apex locator (Neosono-MC, Amadent, Cherry Hill, NC) was used. The patient experienced no adverse effects immediately or with follow-up.

Lauper et al (1996) [31] evaluated the accuracy in vivo of two electronic apex locators based on the absolute (Odontometer) and gradient impedance (Apit) principles. Their results showed 93% and 73% of the findings for the Apit and the Odontometer, respectively, fell within the range -0.5 mm to +0.5 mm. Further, 100% and 86% of the findings for the Apit and Odontometer, respectively, fell within the range - 1.0 mm to + 1.0 mm. Finally, 33% of the results for the Apit and 43% for the Odontometer were 1.0 mm or less coronal to the apical foramen. They concluded that those devices based on the gradient impedance principles can locate the narrowest part within a root canal.

Hayes et al (1997) [19] assessed the prevalence of interference and the potential for a serious clinical risk resulting from the exposure of permanently implanted pacemakers to cellular telephones. They concluded that the use of telephones in the normal position at the ear was associated with the lowest incidence of interference of any position tested and did not result in any clinically significant interference.

Dunlap et al (1997) [10] determined the accuracy of canal length determinations in both vital and necrotic canals as provided by an electronic apex locator. Their results showed that there was no statistical difference in the ability of the Root ZX to accurately determine the apical

constriction in teeth with vital or necrotic canals. The Root ZX was 82.3% accurate to within 0.5mm of the apical constriction.

Miller et al (1998) [38] determined whether electromagnetic interference with cardiac pacemakers occurs during the operation of contemporary electrical dental equipment. Fourteen electrical dental devices (amalgamator, electric pulp tester, composite curing light, dental headpieces, electric toothbrush, portable radiography unit, microwave, electrosurgery units, ultrasonic baths, magnetorestrictive ultrasonic scalers, dental drills, ENAC, and sonic scalers) were tested in vitro for their ability to interfere with the function of two Medtronics cardiac pacemakers (one a dual-chamber, bipolar Thera 7942 pacemaker, the other a single-chamber, unipolar Minix 8340 pacemaker). Their results suggest that certain electrosurgical and ultrasonic instruments may produce deleterious effects in medically fragile patients with cardiac pacemakers.

Pagavino et al (1998) [46] assessed the accuracy in root canal length measuring of the Root ZX in the presence of vital tissue by means of scanning electrone microscopy and specifically evaluated the effects of the variation in the position of the foramen (apical versus lateral). Their results shows a clinical accuracy rate of 82.75% recorded in the total sample and with a ± 1.0-mm tolerance level, an *accu*racy of 100% was found. The error in locating the apex was significantly smaller in cases with a normal apical foramen than in cases with a lateral foramen.

Aranda (1999) [14] determined the reliability of different electronic apex locators to establish the working length. Apex Finder / Analytic Technology, Justy II / Yoshida, Locapex 3000 / Ionyx and Root ZX / J. Morita were used to determine the position of the physiological

foramen of the root canals. Their results showed that the localization of the physiological foramen with the electronic apex locators investigated in this study is reliable.

Madigan et al (1999) [33] reviewed the sources of electromagnetic interference (EMI) that may alter the performance of implanted cardiac devices (ICDs). They suggested that if electrocautery is to be used, pacemakers should be placed in a triggered or asynchronous mode; ICDs should have arrhythmia detection suspended before surgery. If defibrillation is to be used, the current flow between the paddles should be kept as far away from and perpendicular to the lead system as possible. Both pacemakers and ICDs should be properly shielded if magnetic resonance imaging, positron emission tomography, or radiation therapy is to be used. The effect of EMI on ventricular assist devices (VADs) depends on the model. Magnetic resonance imaging adversely affects all VADs except the Abiomed VAD, and therefore its use should be avoided in this population of patients. They concluded that patient with an implanted cardiac device can safely undergo surgery as long as certain precautions are taken.

Fouad and Reid (2000) [13] determined the value of EALs in reducing the number of working radiographs in patients treated by supervised undergraduate dental student and to determine the effect of using EALs versus a preoperative radiograph to estimate the WL, on the adequacy of length of the final endodontic obturation; and to compare the closeness of the electronic and radiographic estimates of the working length with the final working length used. Their study showed that using an electronic estimate before radiographic verification enhances length control throughout the treatment, improves the length of obturation from the apex, and reduces the number of radiographs in anterior or premolar teeth.

Pinski and Trohman (2000) [49] wrote a paper reviewing interference in implanted cardiac devices. They explained the general concepts and specific sources of EMI in everyday life and the workplace, medical sources of EMI, highlighting preventive measures. They stated that electromagnetic fields decrease with the inverse square of the distance from the source.

Jenkins et al (2001) [25] examined the accuracy of the Root ZX in the presence of various intracanal irrigants viz., 2% lidocaine with 1:100,000 epinephrine, 5.25% sodium hypochlorite, RC Prep, liquid EDTA, 3% hydrogen peroxide, and Peridex used in nonsurgical endodontic therapy, in an in vitro model. Their results indicate that the Root ZX electronic apex locator reliably measured canal lengths to within 0.31 mm and that there was virtually no difference in the length determination as a function of the seven irrigants used. These results strongly support the concept that the Root ZX is a useful, versatile, and accurate device for the determination of canal lengths over a wide range of irrigants commonly used in the practice of endodontics.

Tınaz et al (2002) [61] examined the effect of the various concentrations of NaOCl viz., 5.25%, 2.65%,1.00%, and 0.50% that were present in the canal on the accuracy of the Root ZX and on the determination of the working length. Their results showed that there were no statistically significant differences among all the groups when evaluating the distance of the file tips and apical constriction or for the distance from file tip to apical foramen. They concluded that the Root ZX can successfully be used in endodontic therapies in the presence of various concentrations of sodium hypochlorite.

Oishi et al (2002) [44] investigated the possibility of detecting root canal constrictions by using an apex locator. They concluded that the Root ZX is not only effective for accurately detecting the location of the apical foramen but also useful for detecting root canal constrictions.

Meares and Steiman (2002) [36] conducted an in vitro investigation to determine whether the presence of sodium hypochlorite influences the accuracy of the Root ZX electronic apex locator. The results of their study suggest the Root ZX is not adversely affected by the presence of sodium hypochlorite and the method of canal length determination used by the Root ZX apparently overcomes the limitations encountered by earlier electronic apex locators.

Pommer et al (2002) [51] conducted in vivo investigations to compare the root canal length determined by the Apex Finder Model 7005 in vital and necrotic canals and after retrieval of root canal filling material. Their results showed that the Apex Finder showed higher accuracy for determining the apical constriction in vital canals (93.9%) than in necrotic canals (76.6%). The Apex Finder indicated the point -1mm ±0.5 mm in canals with retrieval of root canal filling materials in 68.4% of the cases.The authors concluded that the Apex Finder is highly accurate in vital canals.

Garofalo et al (2002) [15] assessed the effects of five electronic apex locators Root ZX , Justwo (Toei Electric Co., Kanagawa, Japan), EIE (Analytic Endodontics, Orange, CA, U.S.A.), Neosono (Amadent, Cherry Hill, NJ, U.S.A.), and Bingo-1020 (Dent Corp, White Plains, NY, U.S.A.) on pacemaker function (Biotronik, Berlin, Germany) in vitro. They concluded that, four of five electronic apex locators tested showed no effect on cardiac pacemaker function in vitro except Bingo-1020 device which produced an irregular pace recording and oscilloscope pattern.

The results of this study suggest that EALs can be used safely in patients with pacemakers. Nevertheless, further studies in humans are required to confirm our findings.

Kaufman et al (2002) [28] conducted an in vitro study to test the accuracy of a Bingo 1020 electronic apex locator and to compare the results to those of a well known apex locator, Root ZX, as well as to those of the radiographic method of tooth length determination. Their results showed that the Bingo 1020 proved to be as reliable as Root ZX and was user friendly. Under the experimental conditions, electronic measurements were more reliable than radiographs in the process of root length determination.

Elayouti et al (2002) [11] conducted an in vitro study evaluating the use of Root ZX to reduce the frequency of working length overestimation in the root canals of premolars that demonstrated radiographically an acceptable working length (i.e. the tip of the measuring file is located 0- to 2-mm short of the radiographic apex). They concluded that complementing radiographic working length determination with electronic apex locator measurements may help to avoid overestimation beyond the apical foramen in premolars.

Roberts H W (2002) [54] conducted a study to investigate any potential interaction of commonly used electrical dental devices Cavitron SPS Ultrasonic Scaler (Dentsply Professional Division,York, Pa.), Cascade delivery unit with Model 6330 light (A-dec, Newberg, Ore), Automix amalgamator (Kerr Dentistry,Orange, Calif.), Analytic pulp tester (Sybron Dental Specialties Inc.,Orange, Calif.), Optilux 501 High Output Curing Light (Kerr Dentistry), Versalux LED Light Curing Unit (Centrix Inc., Maple Valley, Wash), Ellman Surgitron electrosurgical unit (Ellman International Inc., Hewlett, N.Y.) on the function of the

Neurocybernectic prosthesis Pulse Generator (Model 54645A, Hewlett-Packard, Palo Alto,Calif.). None of those dental devices produced electrical interference sufficient to alter the proper operation of the pulse generator.

Roberts et al (2002) [55] investigated whether electromagnetic interference with the Cochlear Implants occurs during the operation of the electric pulp tester, apex locator, electrocautery unit, electrosurgery unit, or panoramic radiograph machine. Their study results suggest that the electronic pulp tester, the electrocautery unit, and the panoramic radiograph machine are safe to use, but the electrosurgery unit, a monopolar device, is unsafe above level 5.

Welk et al (2003) [64] compared the accuracy in detecting the minor diameter of a two-frequency (Root ZX) and a five-frequency (Endo Analyzer Model 8005) EAL under clinical conditions. Their results showed that the Root ZX was able to predictably locate the minor diameter (± 0.5 mm) (90.7% accuracy) more frequently than the Apex Finder AFA Model 8005 (34.4% accuracy).

Lucena-Martın et al (2004) [32] conducted an in vitro evaluation of the accuracy of three electronic apex locators (EALs): the Justy II, Root ZX, and Neosono Ultima and to quantify the concordance of the measurements obtained by two different operators. Their results show that no statistically significant differences were observed among the three EALs or between the measurements made by the two operators.

Patel D et al (2005) [47] tested the in vivo effects of 7 dental instruments viz.,(1) Kavo Sonicflex 2000N Airscaler, (2) Dentsply model 3000 Ultrasonic Scaler, (3) Whaledent Perfect

TCS model S-7115 Electrosurgery Unit, (4) Root ZX Apex Locator, (5) Digitest D626D Electric Pulp Tester, (6) Demetron Optilux 400 Curing Light, and (7) Kavo Diagnodent Caries Detection Device on various pacemaker models implanted in patients, using realtime intracardiac telemetry (R-ICEG) and surface ECG monitoring. Their result showed that the 7 commonly used dental devices tested had no effect on pacemaker function, as determined from continuous-surface ECG recordings. The ultrasonic scaler did cause interference with real-time telemetry by interfering with wand function at close distance to the patient. They concluded that the use of these 7 instruments appears to be safe in this population.

Goldberg et al (2005) [16] conducted an in vitro study to evaluate the accuracy of three apex locators viz.,ProPex, NovApex and Root ZX in determining the working length during the retreatment process. Their study results showed that the ProPex, NovApex, and Root ZX were accurate within 0.5 mm 80, 85, and 95% of the time, and within 1 mm 95, 95, and 100%, respectively. No significant differences were detected between the three apex locators.

Tsenilk et al (2005) [62] compared the accuracy of the Root ZX and the Elements-Diagnostic EALs in detecting the minor constriction in vivo under clinical conditions. Their results showed no significant difference between Root ZX and Elements Diagnostic EALs in their ability to accurately identify the minor constriction.

Moshonov (2005) [40] tested the in vivo reliability of Apex NRG, and compared the results to those obtained using Root ZX, its accuracy recognized under clinical conditions. Their results show that the apex locator readings were compatible (within ±1 mm) in more than 84% of the

root canals. No significant differences were found between readings obtained by Apex NRG and Root ZX.

Wilson B L et al (2006) [66] in their invivo study determined whether, electronic apex locators (Root ZX) or electric pulp tester (Analyzer Model 8005) interfere with the function of implanted cardiac pacemakers or cardioverter/defibrillators. Their study results showed no evidence of any interference when the Electronic apex locators/ Electronic pulp testers were used as described in patients with working implanted cardiac devices.

Williams et al (2006) [65] compared the difference between the in vivo working length established by viewing a periapical radiograph and the in vitro measurement from the file tip to the apical foramen of the extracted tooth. Their findings suggest that radiographs are a useful adjunct in establishing appropriate working length; however, two trends should be considered. When a file is long radiographically it is actually longer than it appears by an average of 1.2 mm. When a file is short radiographically it is closer to the apical foramen than it appears by an average of 0.46 mm.

Cunha D'Assunçao et al (2006) [8] conducted an in vitro evaluation to compare the accuracy in detecting the apical foramen of two electronic apex locators: the Root-ZX and Novapex. Their results suggest that there were no statistically significant differences related between the two devices. Consequently, the Root-ZX and the Novapex were able to determine the position of the apical foramen accurately.

Plotino et al (2006) [50] tested in an ex vivo model the accuracy of two new EALs, the Elements Diagnostic Unit and Apex Locator and the Propex and to compare them ex vivo with the Root ZX, that has been studied widely and considered of great accuracy. The results of their study confirmed that electronic apex locators can accurately determine the root canal length within ±0.5 mm from the apical constriction in the majority of propex readings were long (positive)

Herrera et al (2007) [20] assessed the influence of apical constriction diameter on the precision of the Root ZX apex locator by using files of varying diameter on teeth with varying degrees of apical width. Their results showed that at apical constriction width of 0.37 and 0.62 mm, there was no significant difference between initial working lengths as determined by a Kerr #10 file and final working lengths after widening with files of up to #60. In those teeth whose apical width had been increased to 1.02 mm, there was no statistically significant difference between initial and final working lengths as measured by files from #10–#25; however, significant differences were apparent between #10 and #30, #35, or #40 and the degree of significance increased considerably for files #45 or greater. These results suggest that Root ZX apex locator precision varies as a function of apical constriction diameter.

Ozsezer et al (2007) [45] evaluated the performance of ProPex apex locator after extirpation and in presence of different irrigation solutions: 2.5% NaOCl, 0.9% NaCl, and 0.2% chlorhexidine gluconate solutions in ex vivo conditions. They concluded the following: ProPex is the most clinically suitable apex locator. In the majority of cases, ProPex determined the apical constriction with a high accuracy, the smallest distance to the actual length was obtained after

extirpation, representing that it is the most accurate. Among the irrigation solutions, chlorhexidine group showed the smallest distance to actual length, whereas saline had the greatest distance.

Baldi et al (2007) [2] compared the effectiveness of different embedding media viz., 1% agar, gelatin, alginate, saline, and flower sponge soaked in saline for in vitro assessment of electronic apex locators. Despite the lack of statistically significant difference among the media, the best result was obtained with alginate: The flower sponge was the only medium in which the file surpassed the apex in some measurements.

Patel M et al (2007) [58] evaluated the possible electromagnetic interaction caused by an iPod with pacemaker function. He concluded that the function of an iPod interfered with the pacemaker function by showing high atrial rates.

Goldberg et al (2008) [17] evaluated the ability of four frequency-based electronic apex locators viz., ProPex, the NovApex, the Root ZX, and the Elements Apex Locator to determine, in vitro, the coronal location of a 65° simulated horizontal root fracture. They concluded that the investigated electronic apex locators are capable of determining the working length of the coronal root canal segment in teeth with oblique horizontal root fractures.

Briseno-Marroquin et al (2008) [5] in an in vitro study investigated the accuracy of 4 different electronic apex locators(Elements Apex Locator, Justy II, Raypex 5, and ProPex II) with 3 different instrument sizes (K-type files sizes 08, 10, and 15.). Their results showed that

instrument sizes 08, 10, and 15 have no influence on the accuracy during working length determination with any of the investigated electronic apex locators. They also noted a nonsignificant higher number of unstable measurements were observed in all electronic apex locators with instrument size 15.

Robert et al (2009) [56] investigated the effects of electromagnetic interference on a Neurostimulator (Medtronic) implanted into the epidural space of a human cadaver which generates pulsed electrical signals that stimulate, the underlying dorsal columns of the spinal cord resulting in the perception of parathesia, during the operation of the Electronic pulp tester (Model 2001; Analytic Technology Corporation), apex locator (Root ZX II, Model DP-ZX), and electrocautery unit (Electrocautery Change-A-Tip; Aaron Medical Industries, Petersburg, FL). They concluded that the probability of damage to the neurostimulator by any of the devices was negligible.

Elayouti et al (2009) [12] evaluated the consistency of apex locators by determining the dysfunction frequency and investigated the clinical conditions (tooth vitality, presence of obliteration, and metallic restoration) that may influence the performance of apex locators. Two apex locators were used (Root ZX and Raypex5). Their results showed that the function of apex locators was consistent in 85% of the patients. The inconsistent measurements were strongly associated with partially or totally obliterated root canals. Radiographically, 97% of consistent measurements were "acceptable."

Chen E and Abbott P V (2009) [7] wrote a paper reviewing literature on dental pulp testing. According to their paper, Pulp sensibility tests include thermal and electric tests, which

extrapolate pulp health from sensory response. They concluded that pulp sensibility testing, even with its limitations, have been and still remain a very helpful aid in endodontic diagnosis.

Ding et al (2010) [9] investigated the ability of three electronic apexlocators, Root ZX, Raypex 5, and Elements Apex Locator, to detect the minor foramen and related morphological influencing factors during working length determination. Under the conditions of this ex vivo study, the authors concluded that the ability of three electronic apexlocators to detect the minor foramen was found to be significantly different. When the ‘‘minor foramen’’ reading was given, the file tips determined by the Root ZX were much closer to the major foramen than when the Raypex 5 and Elements Apex Locator were used and the minor foramen’s morphology and the major foramen’s location were both important influencing factors on the performance of electronic apex locators.

Ravanshad et al (2010) [53] compared the effect of working length determination using electronic apex locator (Raypex5) or working length radiograph on the length adequacy of final working length as well as the final obturation. Their results of endodontic treatment using electronic apex locator showed comparable if not superior to radiographic length measurement regarding the rates of acceptable and short cases. Furthermore, they concluded in addition to reducing radiographic exposure, electronic apex locator can reduce the rate of overestimation of root canal length.

Guise et al (2010) [18] compared the accuracy of the Root ZX II Apex Locator, the Elements Apex Locator, and the Precision Apex Locator. Their results showed that the Root ZX II Apex Locator was the most accurate at locating the apical foramen compared with the

Elements Apex Locator and the Precision Apex Locator. They further added that when using a clinical acceptability range of 0.5 mm from actual canal lengths, the Root ZX II also had the highest in-zone proportion of acceptable measurements at 97.5%.

Mancini et al (2011) [34] compared (1) the accuracy of Endex, Root ZX, and Propex II in detecting the apical foramen ex vivo under clinical conditions and (2) the accuracy of digital radiography in determining the WL, compared with visible control under a microscope in anterior teeth, bicuspids, and molars. On the basis of their results they concluded that the, electronic apex locators accuracy depends on the dental groups, and it is greater in bicuspids than in both molars and anterior teeth. To prevent overestimation of the root canal length by the 3 different electronic apex locators tested, 1 mm should be subtracted from the measurement on the APEX mark. The radiographic method is not reliable for determining the working length in both radiographic planes in any dental group.

Jung et al (2011) [26] compared the reliability of the measurements obtained by the ‘‘0.5’’ and ‘‘APEX’’ marks in vitro by using 2 impedance quotient-based electronic apexlocators (Root ZX and i-Root). They concluded, that the ‘‘APEX’’ mark of the EALs used in their study represents the major foramen consistently, whereas the ‘‘0.5’’ mark by Root ZX and i-Root was 0.26 and 0.29 mm short of the major foramen, respectively. When the bias in the ‘‘0.5’’ mark measurements was calculated, there was no difference in the reliability of the ‘‘0.5’’ and ‘‘APEX’’ marks for locating the minor foramen.

Stober E K et al (2011) [59] compared the accuracy of the Root ZX and iPex electronic apex locator in vivo in establishing the actual working length. Under the conditions of this in

vivo study, the Root ZX and iPex electronic apex locators performed equally well when determining a position 0.5 mm short of the major foramen.

MATERIALS AND METHODOLOGY

Dental Instruments used

Apex locators

1. Root ZX (J Morita Corp., Japan)

2. Propex (Dentsply Maillefer, Ballaigues, Switzerland)

3. Mini Apex locator (SybronEndo, Anaheim, CA, USA)

Pulp tester

1. Parkell pulp vitality tester (Farmingdale, NY, USA)

Diathermy

1. Neomed 250 B

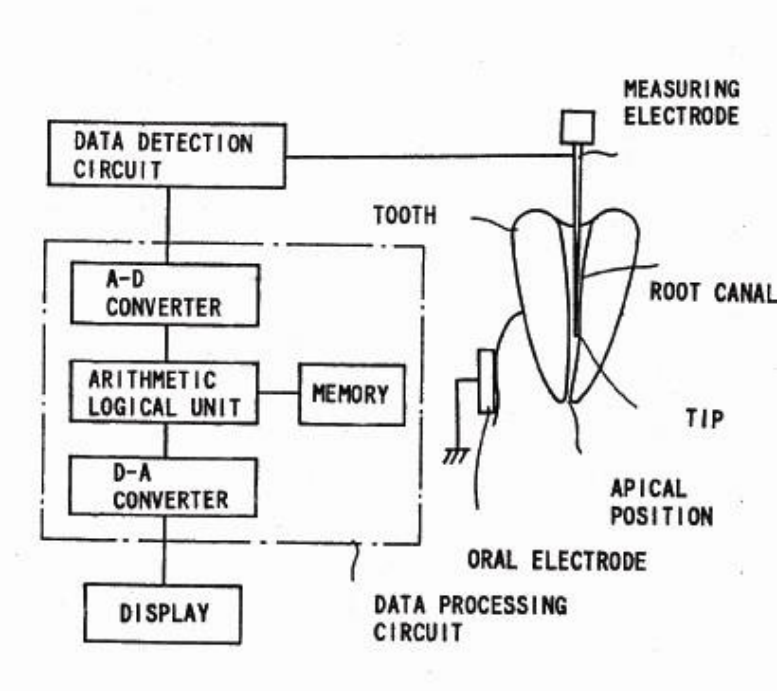
Pacing system used

1. Medtronic (KVDD901)

Other Instruments used

1. Tektronix TDS 220 2-channel digital real-time oscilloscope (Tektronix, Inc., Beaverton, OR, U.S.A.)
2. Pacemaker programmer Medtronic carelink/vitataron
3. Bread board
4. 150 ohms Resistor
5. Crocodile clips

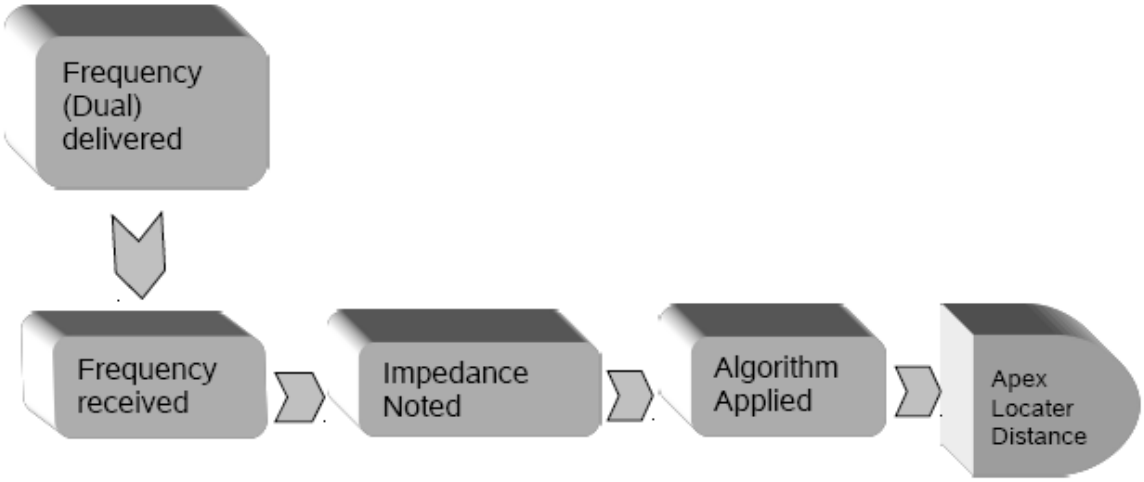
Principle of Third Generation Electronic Apex Locators:



The principle on which "third-generation" apex locators are based requires a short introduction. In biologic settings, the reactive component facilitates the flow of alternating current, more for higher than for lower frequencies. Thus, a tissue through which two alternating currents of differing frequencies are flowing will impede the lower- frequency current more than the higher-frequency current. The reactive component of the circuit may change, for example, as the position of a file changes in a canal. When this occurs, the impedances offered by the circuit to currents of differing frequencies will change relative to each other. This is the principle on which the operation of the third generation apex locators is based [22].

Since the impedance of a given circuit may be substantially influenced by the frequency of the current flow, these devices have been called "**frequency dependent**". Since it is impedance, not frequency that is measured by these devices, and since the relative magnitudes of the impedances are converted into "length" information, the term "**comparative impedance"** may be more appropriate.

The Root ZX (J. Morita Co., Kyoto, Japan), a third generation apex locator that uses dual-frequency and comparative impedance principles, was described by **Kobayashi & Suda** [30]. The electronic method employed was the "ratio method." The Root ZX simultaneously measures two impedances at two frequencies (8 and 0.4 kHz) inside the canal. A microprocessor in the device calculates the ratio of the two impedances. The device then determines a quotient value by dividing the 8 kHz impedance value by the 0.4 kHz impedance value. The minor diameter is located when the quotient equals 0.67. Different types of fluids in the canal will give different impedance values. By using two frequencies, the Root ZX can be used in all types of fluids because the quotient (0.67) is always the same. The quotient of the impedances is displayed on a liquid crystal display meter panel and represents the position of the instrument tip inside the canal. The quotient was hardly influenced by the electrical conditions of the canal but changed considerably near the apical foramen [30]. The Root ZX mainly detects the change in electrical capacitance that occurs near the apical constriction. Some of the advantages of the Root ZX are that it requires no adjustment or calibration and can be used when the canal is filled with strong electrolyte or when the canal is "empty" and moist [30].



Propex (Dentsply Maillefer, Ballaigues, Switzerland) is a multi-frequency based apex locator which is based on the same principle of the other modern devices which use multiple frequencies to determine root canal length. One important characteristic of ProPex is that the calculation is based on the energy of the signal where the other apex locators usually use the amplitude of signal. The manufacturer claims that energy measurement is more precise [50]. The manufacturer does not specify any other technical characteristics and no studies are present in current literature on the ex vivo or in vivo accuracy of this EAL.

Mini Apex Locator (SybronEndo, Anaheim, CA, USA) According to the manufacturers, despite its compact size, the Mini is rugged and durable. It uses a sophisticated, multi-frequency measurement system, an all-digital signal and an 80% shorter cable than other apex locators. The manufacturer claims that this all adds up to increased signal integrity, easy operation and consistently reliable measurements [39]. However, there is a lack of information in the literature about the accuracy of Mini Apex Locator in determining the correct electronic working length.

Parkell pulp vitality tester (Farmingdale, NY, USA) works on the premise that electrical stimuli cause an ionic change across the neural membrane, thereby inducing an action potential with a rapid hopping action at the nodes of Ranvier in myelinated nerves [7]. The pathway for the electric current is thought to be from the probe tip of the test device to the tooth, along the lines of the enamel prisms and dentine tubules and then through the pulp tissue [42]. The "circuit" is completed via the patient wearing a lip clip or by touching the probe handles with his/her hand; alternatively, the operator can have one "gloveless" hand that touches the patient's skin. A "tingling" sensation [29] will be felt by the patient once the increasing voltage reaches the pain threshold, but this threshold level varies between patients and teeth and is affected by factors such as individual age, pain perception, tooth surface conduction and resistance [7].

Electrosurgical unit (Neomed 250 B) was used to facilitate haemostasis and/or the cutting of tissue during surgical procedures. This is achieved by passing normal electrical current via the diathermy machine and converting it into a high frequency alternating current (HFAC). This HFAC produces heat within body tissues to coagulate bleeding vessels and cut through tissue.

Cardiac pacemaker is a transmitter that generates pulses to regulate the heart rate. They are used extensively for the treatment of cardiac rhythm disturbances, especially atrio-ventricular conduction defects and symptomatic sinus node disease. They consist of a pulse generator which may be planted subcutaneously in the pectoral, axillary or abdominal regions. The pulses generated pass through either epicardial or pervenous leads to either one (unipolar) or two (bipolar) electrodes which are implanted in the myocardium [24].

There are two main types of cardiac pacemakers:

1. The competitive pacing system, which discharges continuously at a fixed rate.

2. The non-competitive pacing system, which is active only in the absence of an intrinsic heart beat.

The latter are the more commonly used and they can be divided into groups depending on which part of the normal cycle they monitor or influence.

Non-competitive pulse generators are available as either unipolar or bipolar systems. Bipolar devices are less susceptible to conducted electromagnetic interference (EMI), such as those produced by dental equipment, due to the smaller area enclosed by the close apposition of the positive and negative electrodes. The unipolar system encloses a wider area as it has only one electrode close to the heart, the opposite pole being the generator itself and it is an established fact that EMI increases with increasing distance between electrodes. The most commonly implanted pacemaker at present is the ventricular-inhibited demand pacing system [24].

The pulse generator possesses a sensing circuit which detects electrical activity within the heart above a threshold of approximately l-2 mV, and registers it as an R-wave inhibiting discharge of the system. Any interference that reaches the pulse generator above threshold susceptibility is likely to be detected by the monitoring system and registered as either an R-wave or electrical ‘noise’ (multiple pulses or pulses not resembling an R-wave). The effect of interference on the pacemaker also depends on its occurrence within the time cycle of the generator. Interference registered as an R-wave may cause inhibition of the pacemaker. Interference registered as electrical noise may cause reversion to the fixed rate of the pacemaker.

Very high intensity electrical interference may cause damage to the myocardium and/or pacing system. A competitive pacing system is only subjected to high intensity electrical interference as it discharges continuously at a fixed rate. The source of interference may be either extrinsic, e.g. electrical equipment, or intrinsic, e.g. myopotentials [24].

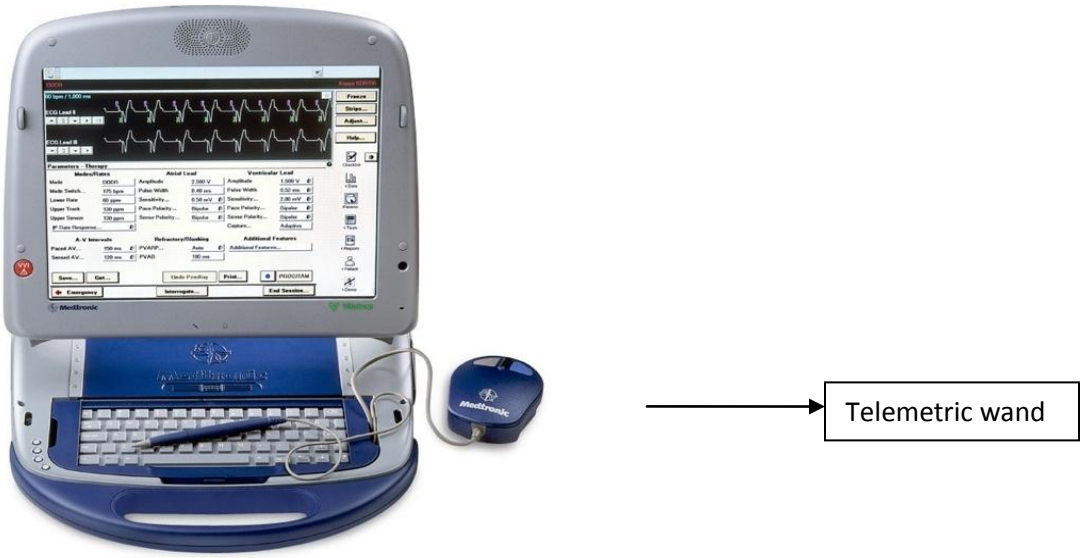
Pulsatile interference is the most hazardous type of interference. It is less likely to occur where the power source is either a direct (battery-operated) or a fully rectified alternating current. Alternating current itself is pulsatile, as is the interference produced by switching on or off the power sources. Magnetic fields may be used advantageously in some situations to convert a pulse generator to its fixed rate by positioning a magnet over the area of the implanted pacing system (due to the generator registering electrical noise from the magnetic interference). Inhibition or reversion may go unnoticed by the patient, as long as the generator is not subjected to the interference for a prolonged period and will not be hazardous. As a rule, bipolar systems will only be affected by currents perceptible to the patients and action taken to remove the interference can be instigated. This is not so with unipolar systems which are sensitive to lower levels of interference [24].

PACEMAKER PROGRAMMER

Pacemaker programmer is a laptop computer with specialized software and a telemetry wand that communicates with and if needed, changes the manner in which a pacemaker functions. Communication may be established via, telemetry when the pacemaker programmers 'head' is placed over the area, where the pacemaker generator lies. Once telemetry is established, all the functions of the pacemakers may be determined through a process called interrogation and

displayed for review both on the screen of the programmer and on the paper by having the programmer print the information. The programmer may also be used to perform certain test that allows the performance of the pacemaker system to be evaluated [21].

FIG 1: PACEMAKER PROGRAMMER



PROGRAMMER TELEMETRY

After the pacemaker generator has been interrogated, all of its current programmed parameters are transmitted to the programmer via telemetry, where they are available to be printed and reviewed [21].

EVENTS

An ECG rhythm strip may also be printed with the signal called an electro gram (EGM) that is recorded by the pacemaker and transmitted to the programmer by telemetry. An EGM represents the local electrical activity as recorded by a pacemaker lead tip in the heart [21].

OSCILLOSCOPE

The oscilloscope helps to see what is going on inside an electronic circuit by giving a visual display on its screen. The oscilloscope can be used to measure voltage, time period/frequency, phase shift, rise of a fail time, pulse duration, pulse delay, time and repetition rate. Oscilloscope plots a two dimensional graph with time on the x-axis and voltage on the y-axis, and therefore gives the exact wave shape of the measured signal. The proper name for an oscilloscope is cathode ray oscilloscope which forms the main component of oscilloscope [35].

PACING MODE

Pacemaker function is described by a universally accepted code devised by the North American and British pacing societies. The code provides for a description of a pacemaker pacing and sensing function using a five letter sequence. It is this sequence that is referred to as the "pacemaker mode". In practice only first 2 or 4 letter positions are commonly used to describe bradycardia pacing function. In the current study the pacemaker activity were recorded in VVI mode [21].

CODE DESCRIPTION

1st letter describes PACING CAPABILITIES:

A - Paces atrium

V - Paces ventricle

D - Dual (paces atrium & ventricle)

O - None

2nd letter describes SENSING CAPABILITIES:

A – Senses atrium

V – Senses ventricle

D – Dual (senses atrium & ventricle)

O – None

3rd letter describes RESPONSE TO SENSING**:**

I – Inhibits pacing (i.e. don't want to pace into a chamber where a sensed event is occuring)

T – Triggers pacing (i.e. want to pace into a chamber where a sensed event is occuring)

D – Inhibits and triggers pacing

O – None

METHODOLOGY

This study evaluated the potential for interference of electronic pulp tester, electronic apex locators and diathermy with pacemaker function. Dental devices were tested for pacemaker interference, including the Root ZX (J. Morita Co., Tustin, CA, U.S.A.), Propex (Dentsply), Mini Apex locator (SybronEndo, Anaheim, CA, USA), Diathermy (Neomed 250 B). A medtronic kappa KVDD901 (serial number: PLE734632S) pacemaker was set to 50 pulses/min and evaluated at maximum sensitivity (bipolar: VVI mode, 0.1 mV) on a flat bench top. Pace monitoring was carried out with a Medtronic carelink/vitataron programmer and a Tektronix TDS 220 2-channel digital real-time oscilloscope (Tektronix, Inc., Beaverton, OR, U.S.A.)

The study design consisted of directly connecting the pacemaker lead, EAL, and oscilloscope across a 150-ohm resistor (Fig. 1). With the electronic apex locator/ electronic pulp tester/ diathermy operating on a flat bench top, the telemetry wand was held directly over the pacemaker to monitor the pacing pattern for a period of 30 s. A negative control was conducted with the pacemaker alone. Pacemaker activity was continuously recorded on the EGM printout of the telemetric programmer. These recordings were then examined for pacer inhibition, noise reversion or inappropriate pacemaker pulses.

CIRCUIT DESIGN

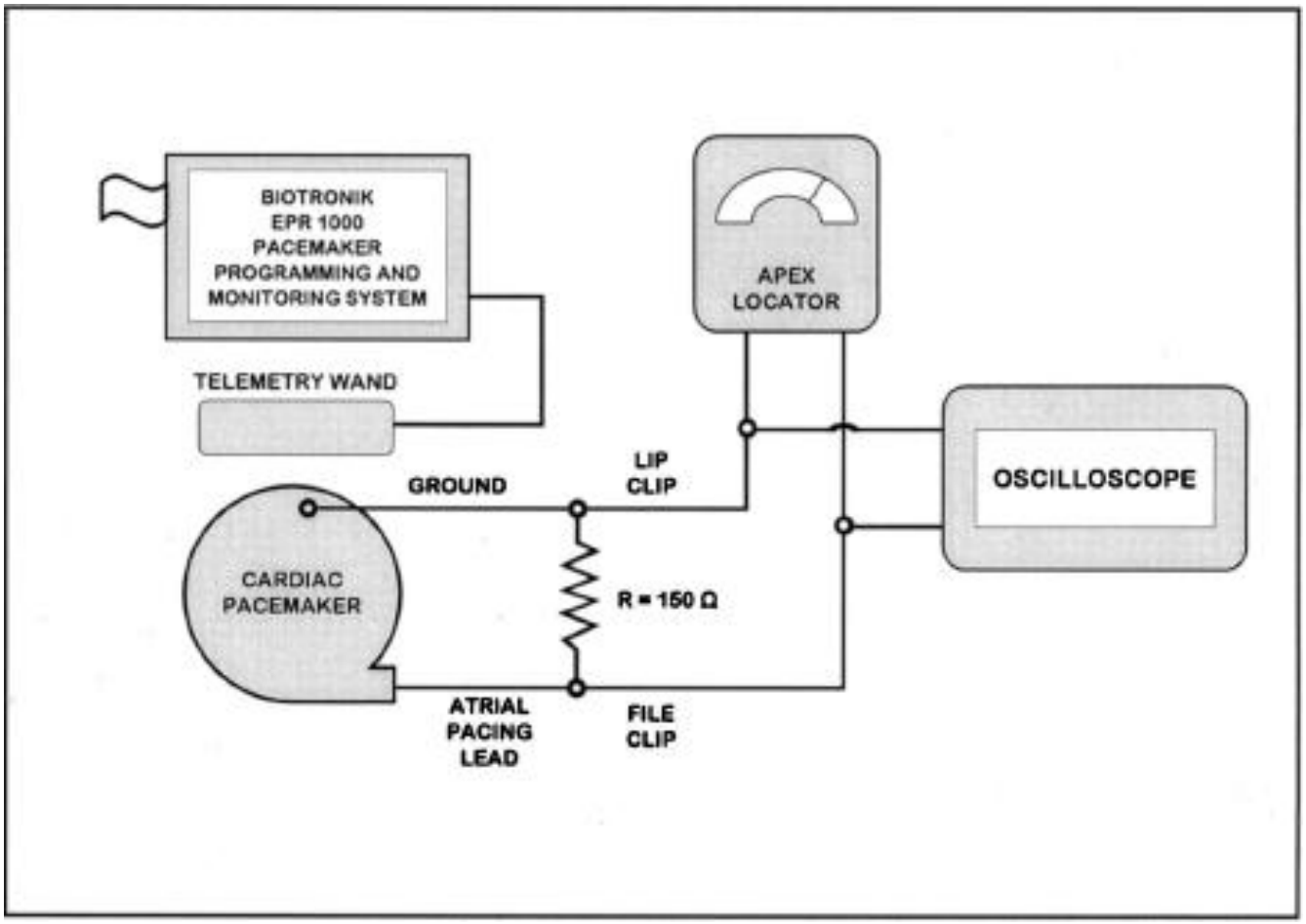


FIG 2: Digramatic representation of the protocol used to evaluate the effect of electronic apex locators on cardiac pacemaker function.

The Circuit Design

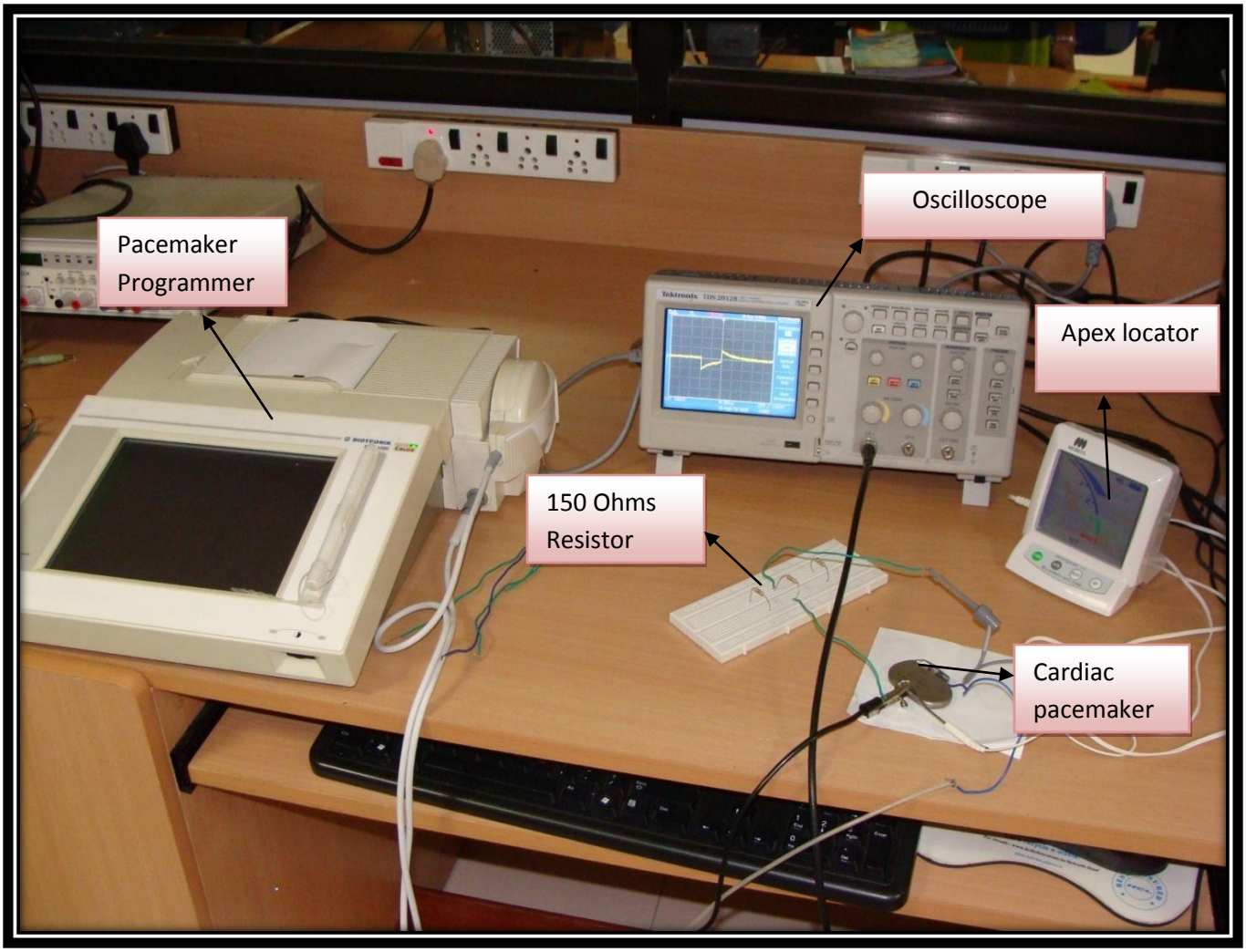


FIG 3 : Protocol used to evaluate the effect of electronic apex locators on cardiac pacemaker function.

STIMULATION PROTOCOL

With the telemetry wand in place, the surface and intracardiac electrocardiogram were continuously printed during testing, which consisted of ten phases each lasting 30 s.

Phase 1 (Rest 1) was recorded at rest, to serve as a baseline of normal device function.

Phase 2, was recorded during stimulation with the Root ZX, and followed by

Phase 3 without stimulation (rest 2).

Phase 4 was during stimulation with the Propex, followed by

Phase 5 without stimulation (rest 3).

Phase 6 was during stimulation with the Sybron endo mini apex locator, followed by

Phase 7 without stimulation (rest 4).

Phase 8 was during stimulation with Parkel electric pulp tester at level 4,

Phase 9 was during stimulation with Parkel electric pulp tester at level 10 followed by,

Phase 10 without stimulation (rest 5).

Phase 11 during stimulation with Diathermy (Neomed 250 B), followed by

Phase 12 without stimulation (rest 6)

The study design consisted of directly connecting the pacemaker lead, EAL and oscilloscopes across a 150 – ohm Resistor (Fig 1). The dental devices were operated on a flat bench top, the telemetry wand was held directly over the pacemaker to monitor the pacing pattern for a period of 30 seconds during stimulation and rest.

Initially pacemaker readings were recorded at rest, to serve as a baseline for normal device function. This was recorded as Phase 1. Root ZX was then connected to the circuit with lead wires and switched on and Phase 2 recorded readings during stimulation of Root ZX and Phase 3 recorded the readings at rest (That is, on removal of stimulation) As a next step, Propex replaced Root ZX in the circuit. Phase 4 recorded telemetry readings during stimulation with propex, and Phase 5 recorded readings at rest. Now mini-apex locator replaced Propex in the circuit, Phase 6 and 7 readings were recorded during stimulation and rest respectively.

Electric pulp tester was placed in the circuit in the position where mini- Apex locator was placed and stimulated at 2 levels: At level 4, 10 of EPT: followed by rest. These recorded Phases 8, 9, and 10 respectively on the EGM.

Finally Diathermy was applied in the circuit design and Phase11 readings were recorded during stimulation followed by Phase 12 at rest.

Pacemaker activity was continuously recorded by Telemetric programmer and printouts taken during various phases were then examined for Pacer inhibition, noise reversion or inappropriate pacemaker pulses.

EFFECT OF DENTAL ELECTRIC DEVICES ON PACEMAKER FUNCTION

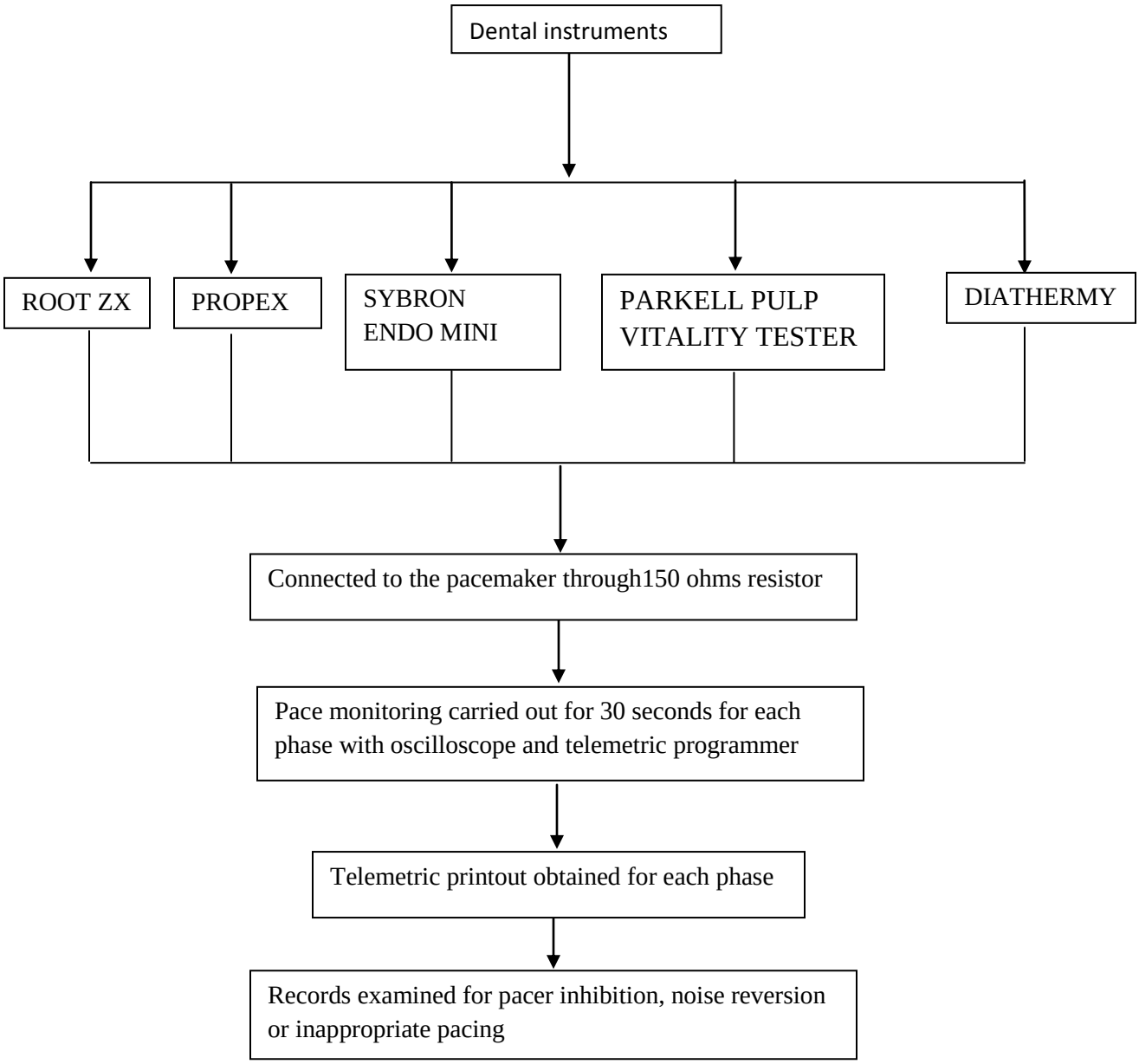


FIG 4 : Root ZX

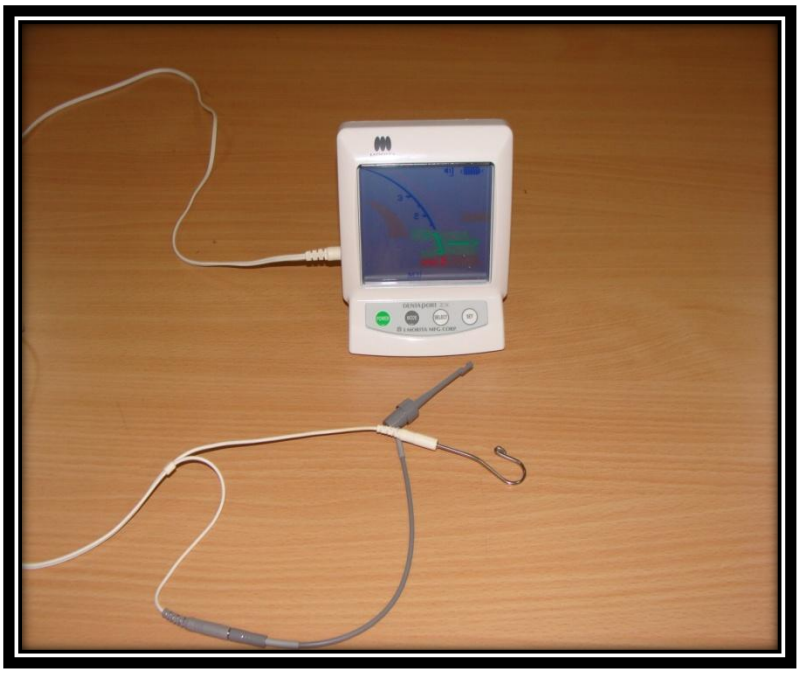


FIG 5 : Propex

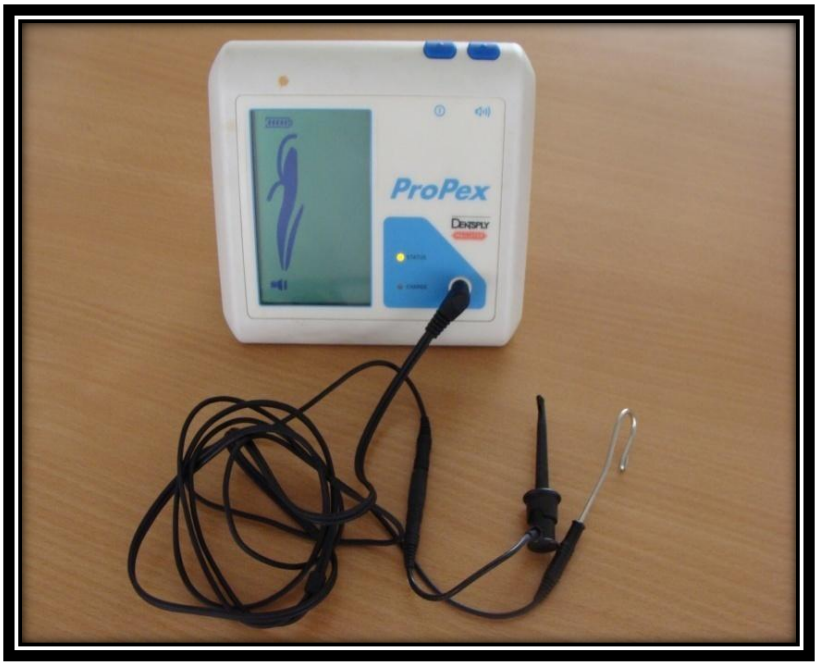


FIG 6 : Sybron Endo Mini

FIG 7 : Parkell pulp vitality tester

FIG 8 : Diathermy

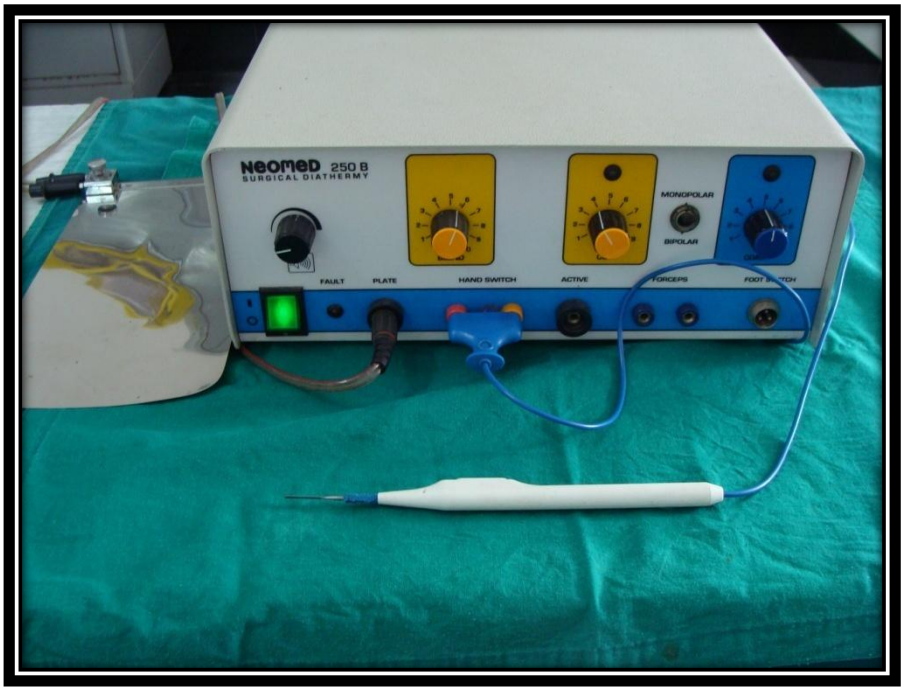
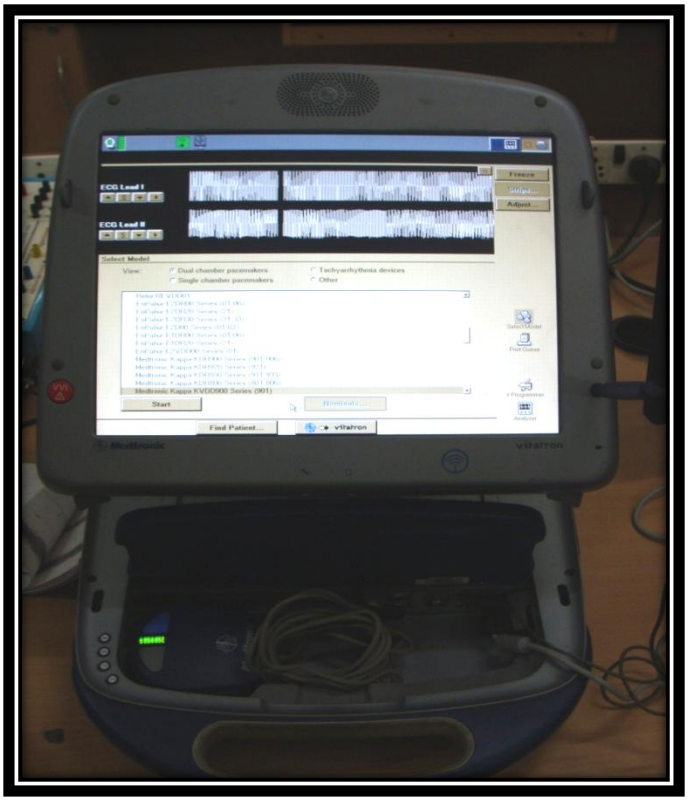


FIG 9 : Tektronix TDS 220 2-channel digital real-time oscilloscope

Pacing system

FIG 10 : Pacemaker – Medtronic

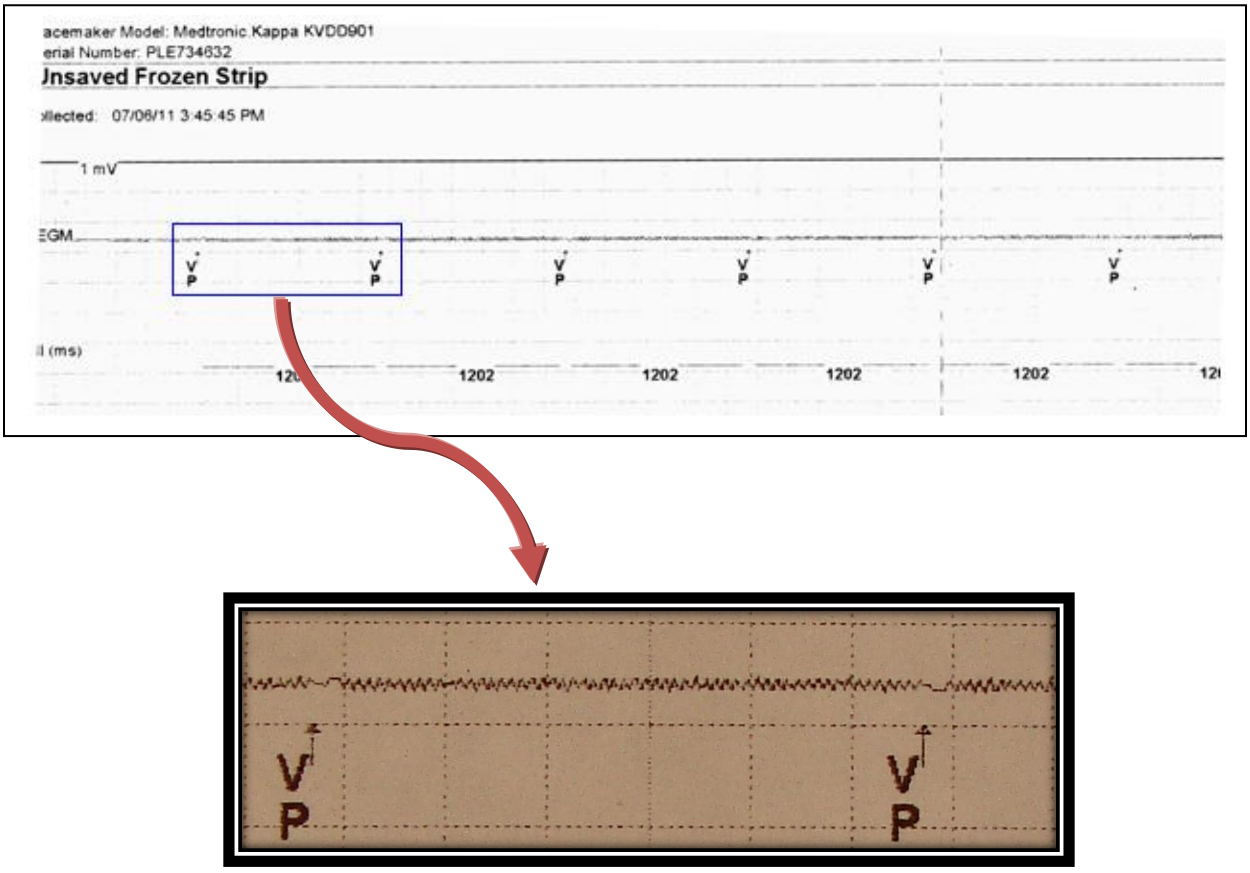
FIG 11 : Pacemaker Programmer



RESULTS

It was found that the pacemaker exhibited a normal pacing pattern during 30 seconds before each trial (phase I). The telemetric recordings of the pacemakers with all of the dental devices except for the diathermy were consistent in all three trials.

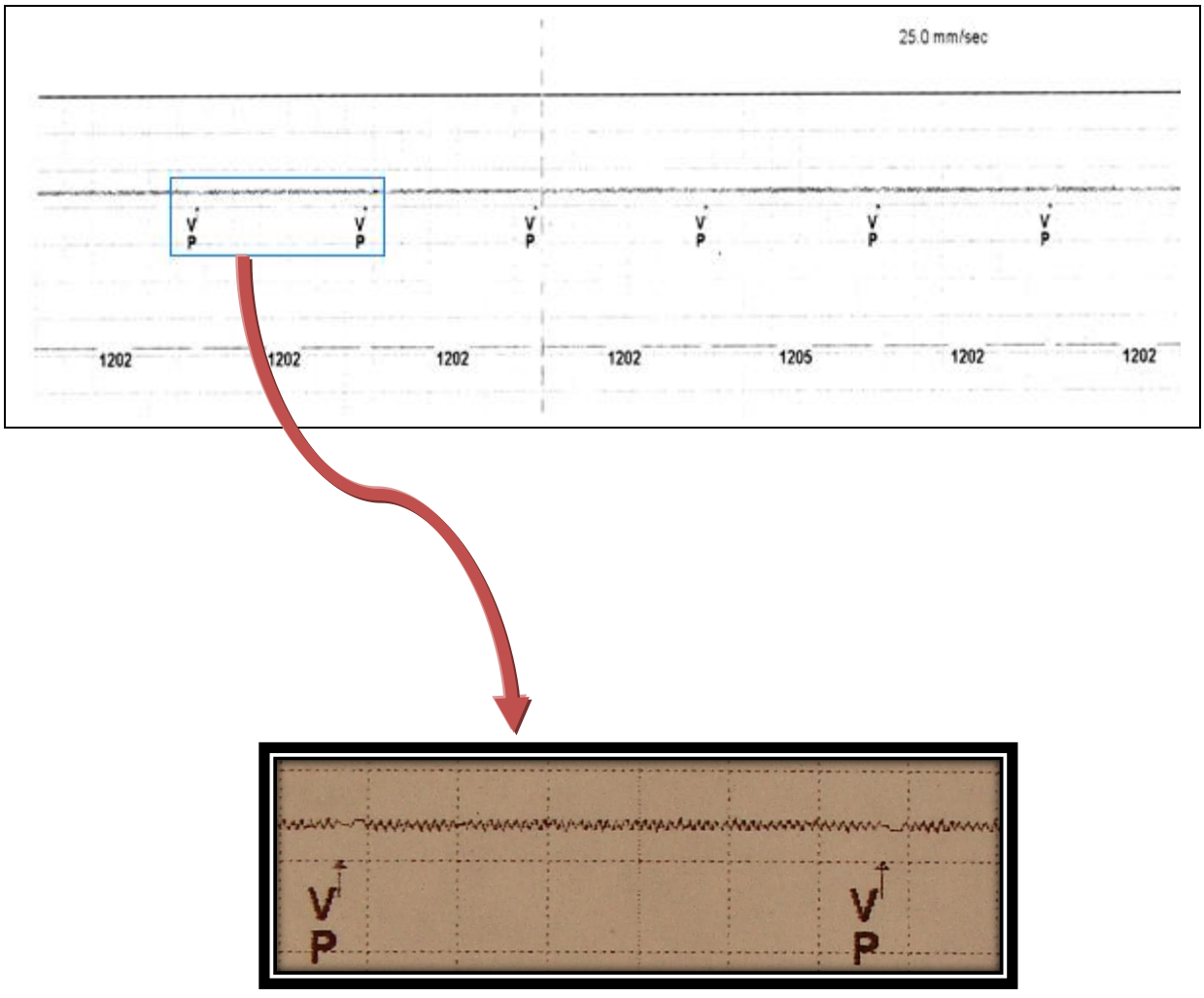
FIG 12: PHASE I – AT REST



NORMAL PACING PATTERN

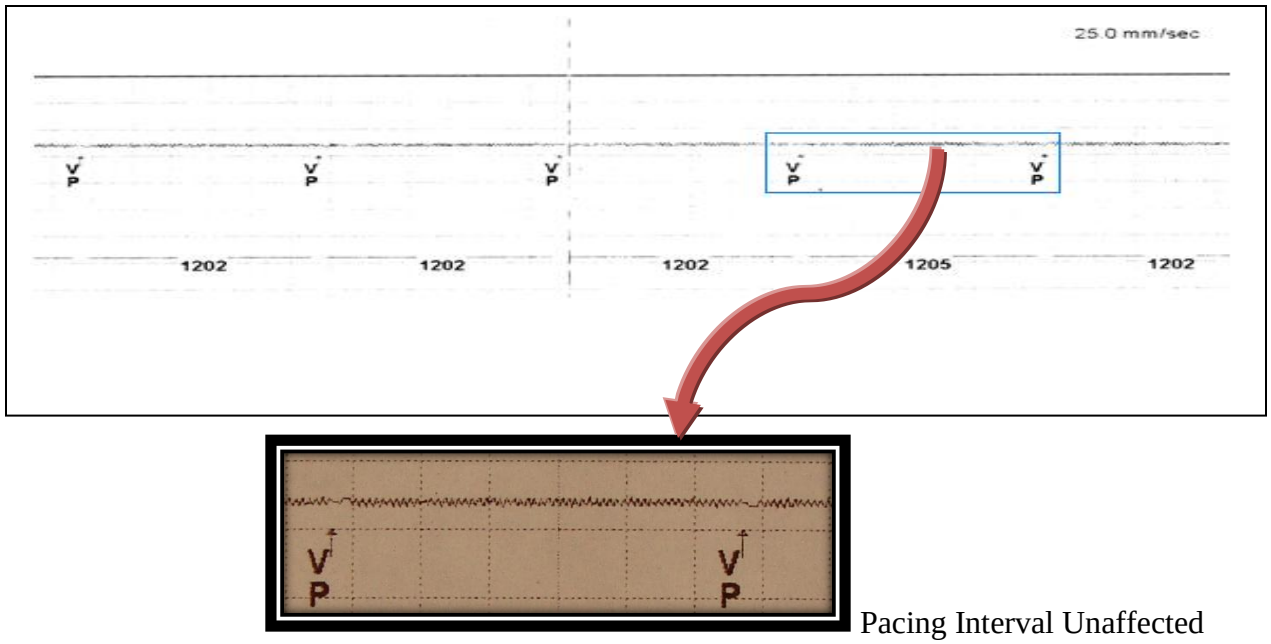
The telemetric recordings of the pacemaker with all the three apex locators were consistent in all three trials during stimulation (phase 3,5,7) and at rest(phase 2,4,6). No pacing interference or background noise was recorded during its function or at rest. Pacing interval remained constant.

FIG 13: PHASE II – GROUP I (ROOT ZX)



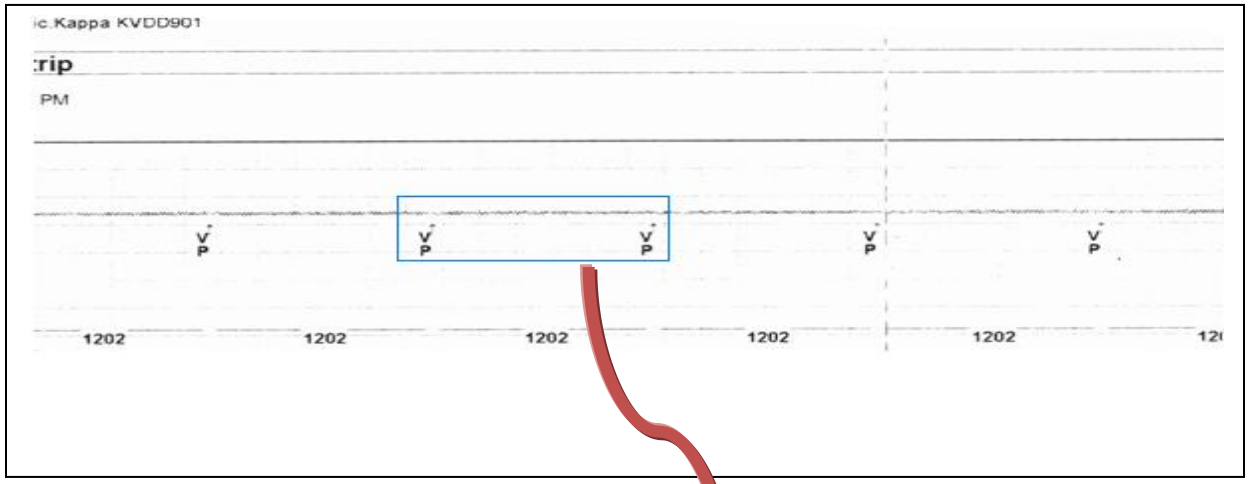
Pacing Interval Unaffected

FIG 14: PHASE 4 - GROUP 2 (PROPEX)



Pacing Interval Unaffected

FIG 15: PHASE 6 – GROUP 3 (SYBRON ENDO MINI)



Pacing Interval Unaffected

When electronic pulp tester is applied to the circuit and operated at different power levels (i.e. gradually increasing the power level from 0 to 10). Telemetric readings were recorded at power levels 4 (phase 8) and 10 (phase 9). The EGM readings showed varying levels of background noise in between pacing. However this did not affect the normal pacing pattern and the pacing interval remained constant.

FIG 16: PHASE 8 – GROUP 4 (ELECTRIC PULP TESTER AT POWER LEVEL 4)

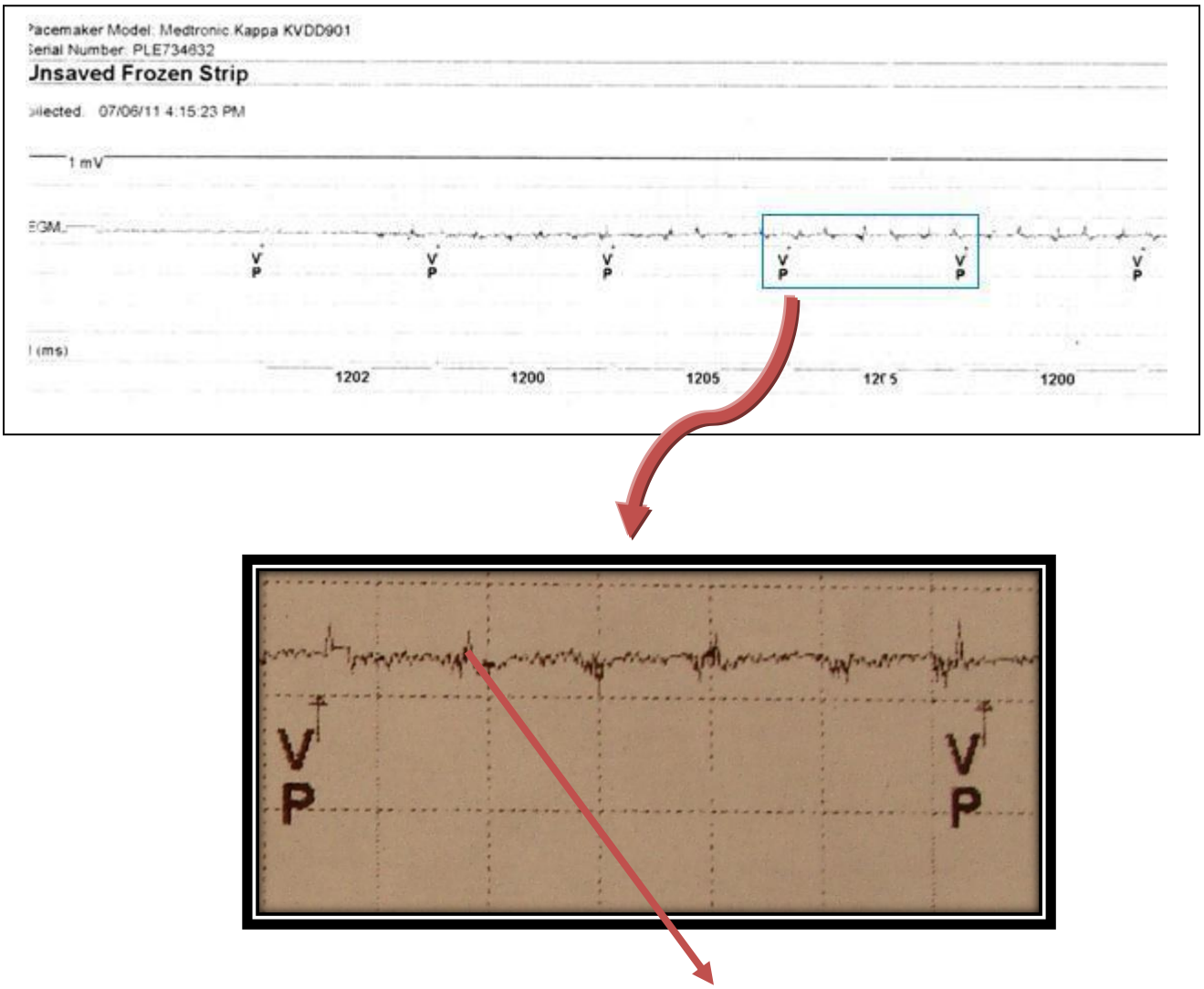
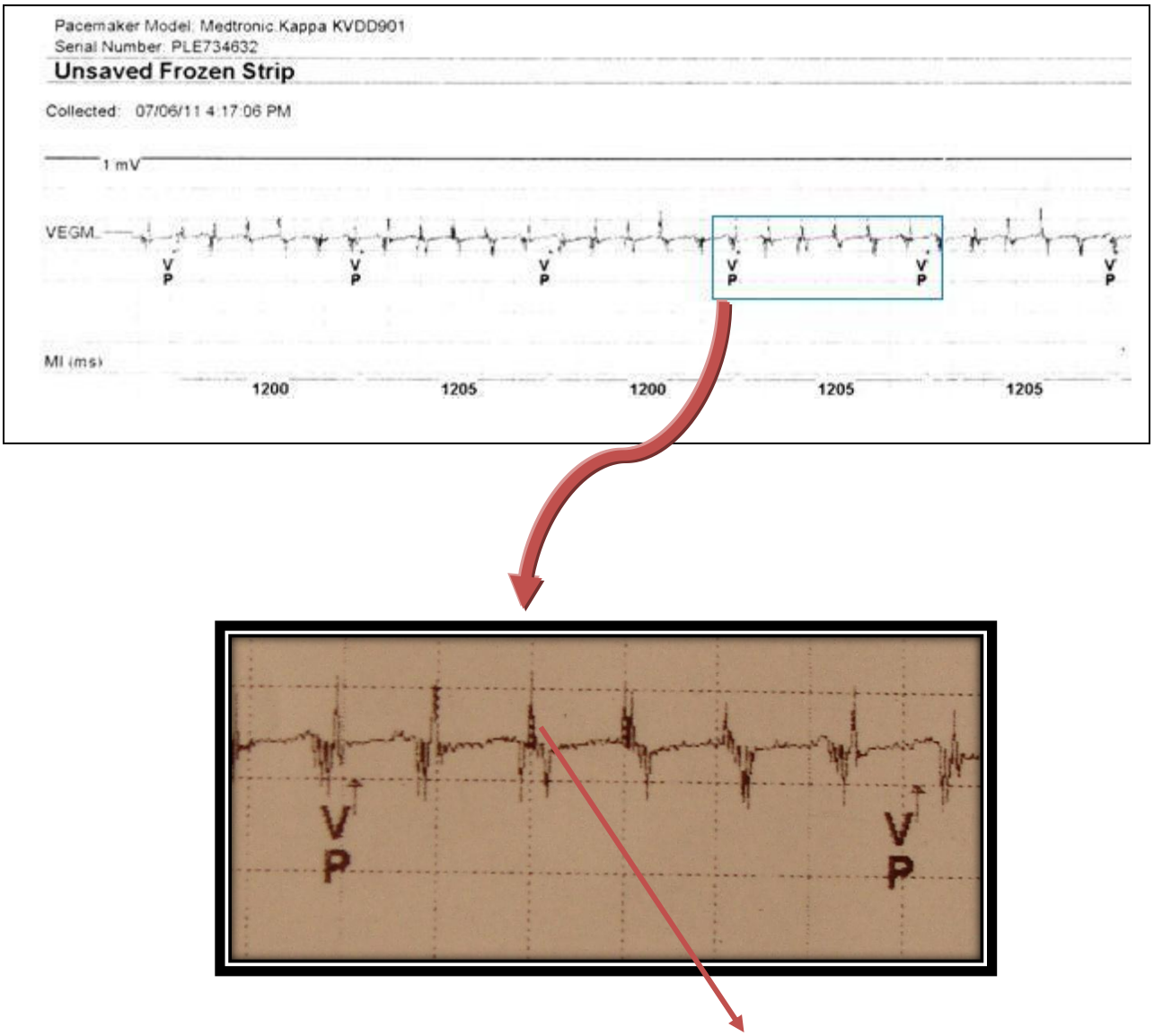


FIG 17: PHASE 9 – GROUP 4 (ELECTRIC PULP TESTER AT POWER LEVEL 10)



Varying levels of background noise are recorded

The only instrument shown to cause interference of pacing was the surgical diathermy. On the EGM from the telemetric programmer this was initially seen as increase in the pacing interval (irregular pacing pattern) followed by complete inhibition of the pacing system (Phase 11). After the diathermy was switched off the pacemaker resumed its normal pacing pattern as it was seen in phase I.

FIG 18: PHASE 11- GROUP 5 (DIATHERMY)

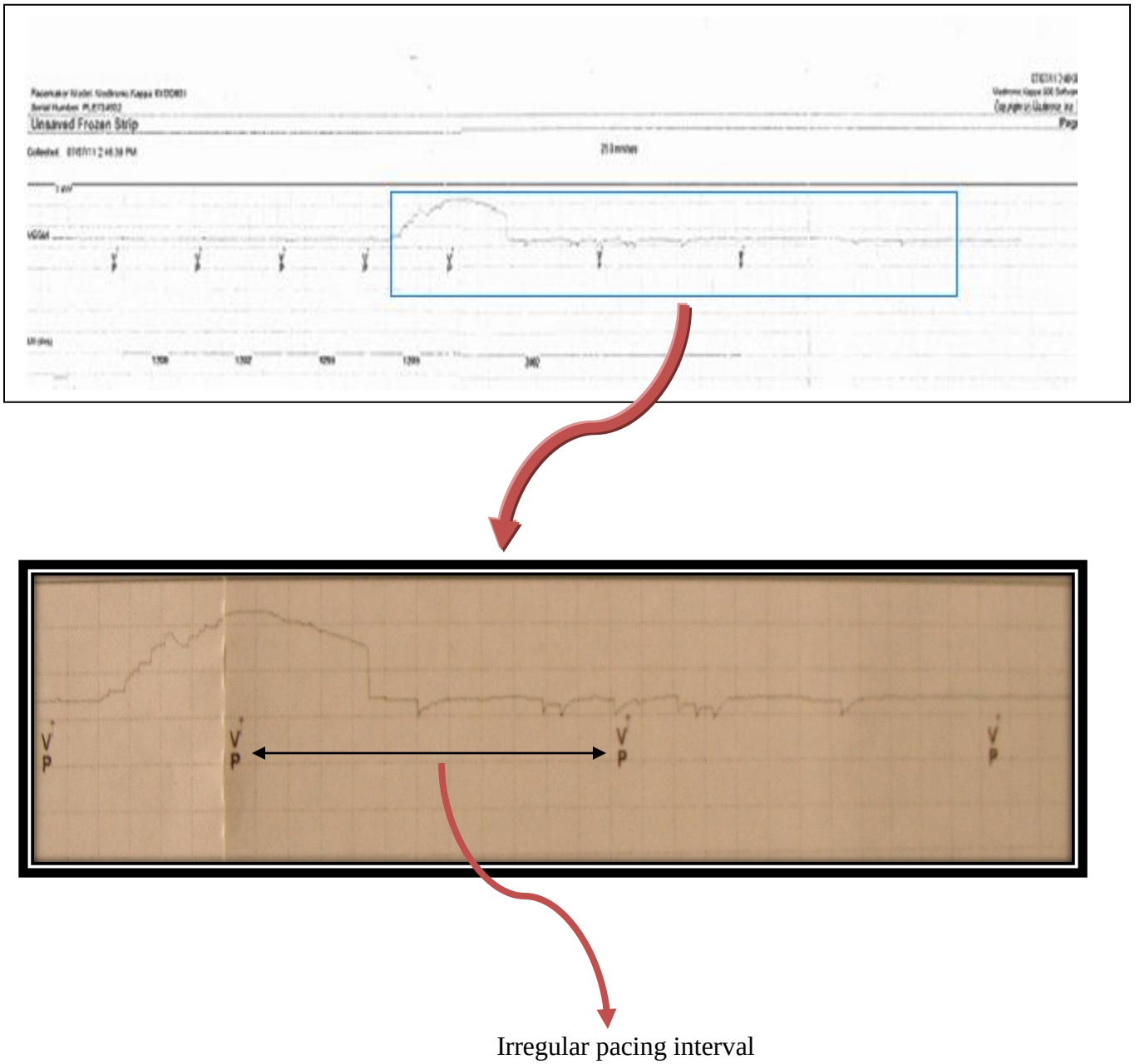


Fig 19: PACEMAKER PROGRAMMER SCREEN

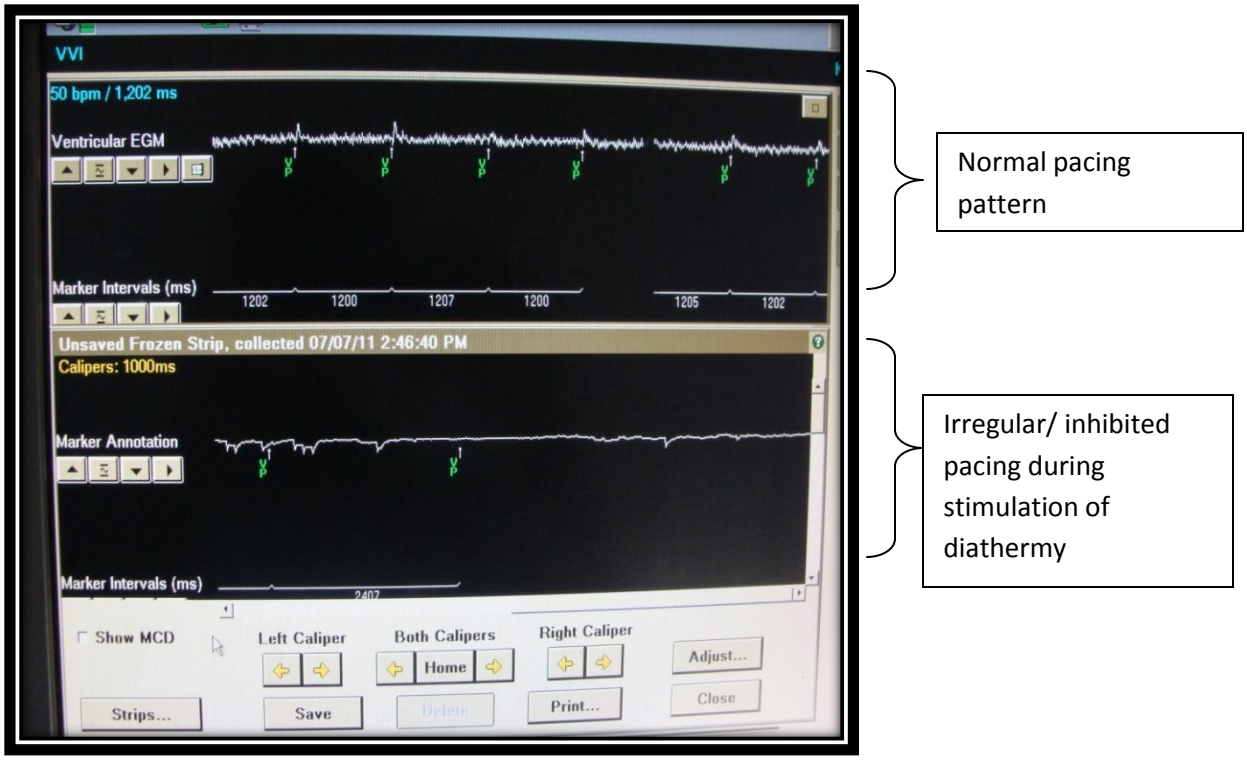


TABLE - 1

PHASE		PACING PATTERN	BACKGROUND NOISE
1	BASE LINE RECORD	UNCHANGED	ABSENT
2	ROOT ZX – ON	UNCHANGED	ABSENT
3	ROOT ZX – OFF	UNCHANGED	ABSENT
4	PROPEX – ON	UNCHANGED	ABSENT
5	PROPEX – OFF	UNCHANGED	ABSENT
6	MINI SYBRON ENDO – ON	UNCHANGED	ABSENT
7	MINI SYBRON ENDO – OFF	UNCHANGED	ABSENT
8	EPT AT POWER LEVEL – 4	UNCHANGED	PRESENT
9	EPT AT POWER LEVEL – 10	UNCHANGED	PRESENT
10	EPT – OFF	UNCHANGED	ABSENT
11	DIATHERMY – ON	PACING INHIBITED	PRESENT
12	DIATHERMY – OFF	UNCHANGED	ABSENT

The data collected in the present study were not in the quantitative form and hence no specific statistical tool can be applied.

Heuristic evaluation, a usability inspection method commonly used for software usability evaluation, was modified and extended for medical devices[70] was applied in this study. The modified method was used to evaluate and compare the patient safety of those devices through the identification and assessment of usability problems.

HEURISTIC EVALUATION

A usability engineering technique called heuristic evaluation for the evaluation of usability problems in medical devices has been used in this study. Heuristic evaluation is an evaluation technique that identifies major usability problems of a product. This technique typically requires three or more expert usability evaluators to independently apply a set of usability heuristics to a product, identify violations of the heuristics, and assess the severity of each violation. In general, evaluators can conduct the evaluation in a few hours with minimal training. Evaluators should already possess this knowledge or can obtain it through training at a level that is sufficient for the understanding and use of the device. Ideally, double experts trained in both usability and the target clinical domain should be the evaluators[70].

In the present study three evaluators, two endodontists and a cardiologist were selected. They were provided with a severity rating scale tool to rate the heuristic violation of the dental devices used in this study, by interpretation of the EGM printout derived from the pacemaker programmer.

Severity Rating Scale

The heuristics are used to check the interface of the device design. If a heuristic is violated, it is given a severity rating based on the following scales[43]:

0 - not a usability problem at all;

1 - Cosmetic problem only. Need not be fixed unless extra time is available;

2 - Minor usability problem. Fixing this should be given low priority;

3 - Major usability problem. Important to fix. Should be given high priority;

4 - Usability catastrophe. Imperative to fix this before product can be released.

TABLE II - SEVERITY RATING SCALE

S.No	Dental Instrument	Severity Rating Scale		
		Evaluator I	Evaluator II	Evaluator III
1	Root ZX	0	0	0
2	Propex	0	0	0
3	Sybron Endo Mini	0	0	0
4	Parkell Pulp Tester	1	1	1
5	Diathermy	4	4	4

HEURISTIC EVALUATION INTERFERENCES

Using severity rating scale all the three evaluators selected scale 0 for all three apex locators used in this study. This shows that Root ZX, Propex, Sybron endo mini do not cause any interference on pacemaker function.

Parkell pulp tester was graded as 1 using severity rating scale by all the three evaluators denoting a change in the reading of the EGM. This means that there is a change in the reading shown in the EGM report and it does not affect the normal function of pacemaker.

In case of diathermy alone, severity rating scale number 4 was marked by all three evaluators which represent usability catastrophe, indicating a direct effect on pacemaker function.

DISCUSSION

Successful root canal therapy depends on the true assessment of the working length. The ability to determine the working length accurately is a challenging task in endodontic therapy [64]. Traditionally, manual and radiographic methods were used to determine working length but their accuracy was questionable as they depended on the position of the apical constriction and radiographic apex. The advent of apex locators gave a novel approach for locating the actual apical foramen by measuring the change in the resistance from the root canal to the periapical tissues which helped working length determination with more accuracy

The idea of using the electrical method for root canal length determination was first put forth by **Custer**[4] in 1918. Suzuki stated that the electrical resistances between periodontal ligament and the oral mucosa registered a constant value of 6.5 kΩ [4]. The pivotal demonstration by **Sunada**[60] in 1962 that the root canal length can be measured using an electronic apex locator, has led to the development of different generations of electronic root canal length measurement devices [4]. Development of impedance type apex locators was another improvement over the resistance type apex locators which could be used only in dry canals and were affected by electro conductive irrigants.

Currently used third-generation apex locators are based on the principle that there is a maximum difference of impedance between electrodes depending on the frequencies used. The principle behind multiple frequency electronic apex locators is based on the change in impedance of the probing electrode (or file) to tissue fluids. When a file tip is located away from the minor diameter, the impedance in the canal is negligible, but when the file reaches the immediate vicinity of the minor diameter, the magnitude of the impedance of the canal suddenly increases.

As the file tip contacts the periapical tissue (tissue fluids), such as the periodontal ligament, the impedance value rapidly decreases, indicating that the file is beyond the minor diameter. Since the impedance of a given circuit may be substantially influenced by the frequency of the current flow, these devices have been called “frequency dependent” apex locators [23].

The Root ZX and Propex apex locators are based on dual frequency (frequency dependent) and Sybron Endo mini apex locator is based on multiple frequencies. These apex locators claim to be able to locate the point of maximum root canal narrowing with high accuracy [53].

Cardiac pacemakers were introduced over 30 years ago primarily for the treatment of bradycardia. The early devices were relatively simple, electrical timers that provided the heart with a timed stimulus to maintain a minimum heart rate [3]. Many pacemakers are now commercially available and are currently used to treat an array of arrhythmias, including bradycardia. Basically, a pacemaker consists of a pulse generator, lead wires and electrodes, and functions by firing its electrodes that are the uninsulated portions of the lead wires that come in direct electrical contact with the tissue to be stimulated [66].

A pacemaker is typically inserted into the patient through a simple surgery using either local anesthetic or a general anesthetic. In most cases the pacemaker is inserted in the left shoulder area where an incision is made below the collar bone creating a small pocket where the pacemaker is actually housed in the patient's body. The lead or leads (the number of leads varies depending on the type of pacemaker) are fed into the heart through a large vein using a fluoroscope to monitor the progress of lead insertion. The Right Ventricular lead would be

positioned away from the apex (tip) of the right ventricle and up on the inter ventricular septum, below the outflow tract, to prevent deterioration of the strength of the heart. The actual surgery may take about 30 to 90 minutes.

Pacemakers differ in several parameters, including the area of stimulation (atria, ventricle, etc.) and the mode of function (fixed rate vs. demand) [3]. Fixed rate (asynchronous) pacemakers stimulate the heart regularly and continually irrespective of the heart own rhythm. These devices are rarely used now and interference with their action is unlikely with any apparatus used in dentistry today. Demand pacemakers stimulate the heart when needed. They do not interfere with or compete with the patient's inherent rhythm [66].

An artificial electrical stimulus, delivered during the vulnerable period following a heart beat, can induce ventricular arrhythmias and even lethal ventricular fibrillation. The patient's life can also be threatened if a demand pacemaker malfunctions and delivers a stimulus during the vulnerable period--the period following a heart beat during the repolarization phase [3]. In addition to current leaks from electrical equipment, the application of electrical stimuli to pacemaker patients through the use of pulp testers, electrosurgical instruments and desensitizing equipment can interfere with pacemaker function [68].

There have been dramatic improvements in pacemaker technology over the last few decades. Pacemakers manufactured before 1975 used discrete electronic components encapsulated in a clear epoxy case. Electromagnetic interference (EMI) could easily penetrate the pacer and affect the electronic circuits. Modern pacemaker electronics are shielded in a hermetically sealed metal case with capacitors that effectively filter out EMI signals [49]. Because

newer pacers are less susceptible to interference, results of studies conducted in the past may no longer be applicable [15].

Safe dental treatment requires elimination of electrical interferences that could affect the cardiac health of patients fitted with pacemakers. However, guidelines for use of electrical dental equipment around pacemakers have not been updated for more than 20 years [27]. The aim of this study was to assess the effects of electronic apex locators and electric pulp tester on pacemaker function in vitro.

In this study Medtronic KAPPA, KVDD901, SN- PLE734632S pacemaker was evaluated for interference with Root ZX, Propex, Sybron endo mini electronic apex locators, Parkell electric pulp vitality tester and diathermy, with the use of telemetry, which permitted continuous monitoring of pacemaker behavior in vitro. Medtronic pacemakers have been shown to be more reliable than other models [27, 15] and are commonly used by cardiologists in India. The setting of the medtronic pacemaker in the VVI pacing mode provided the greatest sensitivity setting of any pacemaker products currently available. Therefore, testing in other modes such as dual modes, as well as including other pacemaker models, was deemed unnecessary and omitted from the study[38]. The selected resistance was determined from the previous study done by **Garofalo et al**[15] to simulate the resistance offered by the human body. Five hundred ohms were used initially, but the EALs displayed no activity [15]. When the devices were connected across 150 ohms resistance, the EAL read-outs approached the “apex” mark, confirming that the EALs were operating properly. The saline bath used by **Miller et al** [38] was omitted. Instead, in an attempt to

simulate the most rigorous conditions possible, the apex locator was connected directly to the pacemaker across 150 ohms resistance.

Cardiac pacemaker interference is not a time-dependent phenomenon. A given stimulus either does or does not inhibit normal pacing. Therefore, a testing interval of 25 to 30 s was deemed satisfactory for the purposes of this study [38].

The results obtained (Phases 2, 3, 4, 5, 6, 7) by evaluating three apex locators (Root Zx, Propex, Sybron Endo Mini) showed that they do not cause any interference with the pacemaker function. These findings support the case report published by **Beach et al** [3] showing the use of an electronic apex locator in a pacemaker patient without clinical incident. In 1991, **ZappaU**[69] studied EPT use in 26 patients with ICPs. Their report found no interference from EPT use on pacemaker rate or electrocardiogram morphology. EALs were not included in their study. Currently no other in vitro/in vivo data is available on interactions of EALs with ICPs. The Root ZX device caused no interference with pacemaker activity; this finding was similar to the findings of **Garofalo et al** [15]**.** However the finding of this study that even Propex and Sybron Endo mini do not cause interference with pacemaker function is a new one.

Findings with electric pulp tester (Phases 8, 9, 10) showed varying degree of background noise, however normal pacing was not affected, and no change in pacing interval was noted. Pacing interval remained constant. These findings were similar to the findings of **Simon et al** [57] they used vitality testers in both a continuous and intermittent manner on patients with implanted cardiac pacing systems, and found that there was no effect on the pulse generator of any interference produced and suggest that this device is probably safe to use in the dental office

during the treatment of pacemaker patients. It may however, be wise to use battery-operated EPT in preference to mains devices.

The fact that electric pulp tester does not cause interference is in contrast to the findings of **Woolley et al** [68] who found that electric pulp testers interfered with implanted pacemakers in dogs. This study is commonly cited as a rationale for not using EPTs in patients with ICPs. In 1974 ICPs were relatively immature in the evolution of pacemaker sophistication. Further, the type of interference that was reported would not be problematic to patients, since functional pacing continued. **Rahn et al** [52] found interference with Activitrax and Sensolog pacemaker activity during operation of an electric pulp tester. These discrepancies can most likely be explained by the improved titanium shielding and increased filtering circuits of pacemakers since 1977 that have caused pacemaker manufacturers to discontinue their warnings of interference caused by these devices [38].

Interference with pacemaker activity during operation of the electrosurgical unit occurred in this study (Phase 11). It was noted as an increase in pacing interval initially, followed by complete inhibition of the pacing system. Diathermy, although not absolutely contraindicated, generates high-intensity conducted interference which has been shown to be capable of interfering with pacing systems; it is unlikely that dental treatment using the diathermy justified the risks involved. The probability of the diathermy causing interference has been shown by **Simon et al** [57] and **Sowton et al** [58]. If sufficient energy is coupled into the pacing system from diathermy apparatus the myocardium may be burnt or ventricular fibrillation initiated. The pacing system itself may also be damaged. Radiated interference from a diathermy has been shown to be insignificant at a distance of 30 cm from the cutting point [24]. Interference by

electrosurgical units has been consistently reported [68, 31, 59] suggesting that these units produce deleterious effects on pacemaker function.

Electrical leakage is current flowing in a direction other than its intended path, e.g. through the operator holding an electrical instrument down through the patient. Any electrical system can have a current leakage which may be large enough to cause electric shock. Electrical shock of a much lower voltage may be lethal to a paced patient. The presence of pacemaker leads decreases the resistance to electrical flow through the body to the heart. A shock of 120 V (mains voltage) will cause a current of approximately 50 mA if pacemaker leads are present which is sufficient to cause ventricular fibrillation and death. It is therefore imperative that all electrical equipment be well maintained, guarded by insulation and earthed [24].

The medical history should reveal the fact that the patient has a pacemaker and appropriate precautions may be taken. Prophylactic antibiotic cover for prevention of sub acute bacterial endocarditis is not required unless otherwise indicated. The patient should be treated in the supine position and all electrical instruments should be kept at least 30cm from the patient. It is of use to know where the pacing system is implanted. Repetitive switching of electrical instruments should be avoided and where ever possible battery-operated devices should be used. If the pacing system shut off happens, then all possible sources of electrical interference should be switched off and cardio respiratory resuscitation should be administered if necessary [24].

Although it is well known that in vitro results cannot be directly transferred to clinical practice, several factors lead the authors to believe that pacemaker interference by EALs is highly unlikely. First, EALs would never be directly connected to the pacemaker leads in a clinical setting. Instead, the circuit produced by EALs is confined to the head region, roughly 10 to 12 inches from the heart, and does not cross the chest. **Pinski and Trohman** [49] stated that electromagnetic fields decrease with the inverse square of the distance from the source. Second, the titanium or stainless steel case of the pacemaker will serve as an EMI shield, reducing the effects of EMI on the device [52]. Third, the body tissues surrounding the pacemaker may serve as insulation, thus further shielding the device from EMI [21]. Finally, most EALs operate on a 7 to 9 V battery, resulting in low-level signals. For the reasons stated above, interference with cardiac pacing demonstrated in vitro may not occur in vivo.

Modern pacemakers represent a complex and heterogeneous group of devices. Electronic apex locator, electronic pulp tester, diathermy was tested despite manufacturer's warning to the contrary. There are no strict guidelines covering the use of electrical devices on pacemaker patients. Most electrical equipment can be used safely. At a minimum, a patient's cardiologist must be consulted before beginning any treatment that will involve the use of electrical equipment. This will help the dentist determine the patient's overall risk status and what treatment precautions need to be followed. These factors may depend on the specific pacemaker placed and if the patient is totally pacemaker dependent. The dentist should also make sure that all electronic equipment used during the procedure is properly grounded and not placed in close proximity to the pacemaker leads [66].

The results of this study show that electronic apex locators and electric pulp tester can be used safely in patients with pacemaker. However there is a need to corroborate the findings of the in vitro study by in-vivo testing before EALs and EPTs can be recommended for clinical use in patients with cardiac pacemakers.

SUMMARY

This study evaluated the potential for interference of electronic pulp tester, electronic apex locators and diathermy with pacemaker function.

Dental Instruments used

Apex locators

1. Root ZX (J Morita Corp., Japan)

2. Propex (Dentsply Maillefer, Ballaigues, Switzerland)

3. Mini Apex locator (SybronEndo, Anaheim, CA, USA)

Pulp tester

1. Parkell pulp vitality tester (Farmingdale, NY, USA)

Diathermy

1. Neomed 250 B

Pacing system used

1. Medtronic (KVDD901)

The study design consisted of directly connecting the pacemaker lead, EAL, and oscilloscope across a 150-ohm resistor (Fig. 1). With the electronic apex locator/ electronic pulp tester/ diathermy operating on a flat bench top, the telemetry wand was held directly over the pacemaker to monitor the pacing pattern for a period of 30 s. A negative control was conducted with the pacemaker alone. Pacemaker activity was continuously recorded on the EGM printout of the telemetric programmer. These recordings were then examined for pacer inhibition, noise reversion or inappropriate pacemaker pulses.

CONCLUSION

From the results of the present study, it may be concluded,

1. The tested Electronic Apex Locators Root ZX (J Morita Corp., Japan), Propex (Dentsply Maillefer, Ballaigues, Switzerland), Sybron Endo mini (SybronEndo, Anaheim, CA, USA) do not interfere with cardiac pacemaker function.

2. The tested Electric pulp tester, Parkell pulp vitality tester (Farmingdale, NY, USA) does not interfere with cardiac pacemaker function.

3. The results show that the use of Diathermy (Neomed 250 B) interfered with the normal pacing, leading to complete inhibition of the pacing system.

Manufacturers of EALs continue to warn against the use of their devices in patients with cardiac pacemakers despite the absence of evidence to support such claims. Although they may possess bench test data similar to those shown above, the lack of clinical data would make it difficult to obtain FDA approval for the devices without such warnings. Human trials are needed to clarify this issue.

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