

# PACEMAKERS AND IMPLANTABLE PACEMAKERS

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**Abstract**— A Pacemaker is a medical device that uses electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart. The primary purpose of a pacemaker is to maintain an adequate heart rate, either because the heart's native pacemaker is not fast enough, or there is a block in the heart's electrical conduction system. In this paper a review on the existing implantable pacemakers has been done along with the outline about the various other pacemakers in use. This provides a comparison between the products as well and thus gives a review of a suitable implantable pacemaker for the Indian market.

**Keywords**— Intrinsic depolarisation, Magnetic Resonance Imaging (MRI), Sinus, Bradycardia, Pectoral implantation.

## I. INTRODUCTION

An internal pacemaker is one in which the electrodes into the heart, the electronic circuitry and the power supply are implanted (internally) within the body. There are different types of pacemakers, all are designed to treat bradycardia, (a heart rate that is too slow). Pacemakers may function continuously and stimulate the heart at a fixed rate or at an increased rate during exercise. A pacemaker can also be programmed to detect too long a pause between heartbeats and then stimulate the heart.

## II. TYPES OF IMPLANTABLE PACEMAKERS

The implanted pacemakers, along with its electrodes, are designed to be entirely implanted beneath the skin. The different types of implantable pacemakers are as following:

[1] Fixed Rate Pacemaker: This type of pacemakers is intended for patients with permanent heart blocks.

[2] Demand Pacemaker: these pacemakers have gradually replaced the fixed rate pacemakers because they avoid the competition between the heart's natural rhythm and the pacemaker rhythm.

[3] R wave Triggered Pacemaker: This type of pacemaker is meant for patients who generally have heart block with occasional heart sinus rhythm.

[4] Ventricular Inhibited or R wave Blocked Pacemaker: This type of pacemaker is meant for patients who generally have sinus rhythm with occasional heart block.

[5] Atrial Triggered Pacemaker: This is a type of pacemaker that detects the atrial de-polarisation and starts the pulse forming circuits after a delay so that the impulse to the ventricles is delivered after a suitable PR interval.

[6] Dual Chamber Pacemaker: These devices are commonly capable of treating the majority of those patients who suffer from diseases of the sino-atrial node by providing atrial stimulation whenever needed.

Given in figure 1 below is the first ever pacemaker which was manufactured by Siemens-Elema.



Figure. 1 First implantable pacemakers by Siemens-Elema

## **DESIGN FEATURES OF AN IMPLANTABLE PACEMAKER**

Pacing systems in an implantable pacemaker consist of a pulse generator and pacing leads. The pulse generator contains a battery, as well as sensing, timing, and output circuits. The lifespan of the battery (most commonly lithium-iodide) is 5-10 years.

Pulse generators can be set to fixed-rate (asynchronous) or demand (synchronous) modes. In the asynchronous mode, impulses are produced at a set rate independent of intrinsic cardiac activity. In the synchronous mode, the sensing circuit searches for an intrinsic depolarization potential. If this is absent, a pacing response is generated. Hence the synchronous mode closely mimics intrinsic myocardial electrical activity.

## **III. INDICATIONS FOR PACEMAKER PLACEMENT**

Absolute indications for pacemaker placement include the following:

- 1) Sinus node dysfunction (sick sinus syndrome).
- 2) Third-degree atrioventricular blocks (complete heart block).
- 3) Symptomatic sinus bradycardia.
- 4) Atrial fibrillation with sinus node dysfunction.
- 5) Chronotropic incompetence (inability to increase the heart rate to match a level of exercise).
- 6) Long QT syndrome.

Relative indications for pacemaker placement include the following:

- 1) Dilated cardiomyopathy.
- 2) Severe refractory neurocardiogenic syncope.

## **IV. CLINICAL IMPLEMENTATION OF AN IMPLANTABLE PACEMAKER**

Pacemaker endocardial leads are inserted transvenously and advanced to the right ventricle, the right atrium, or both, where they are implanted into the myocardial tissue or, in the case of biventricular pacing, to the coronary sinus, from which point the lead is advanced to a terminal vein adjacent to the posterior surface of the left ventricle. The pulse generator is placed subcutaneously or sub muscularly in the chest wall.

During pacemaker placement, the amplitude and width of the electrical impulse are set high enough to reliably achieve myocardial capture but low enough to maximize battery life. Subsequent pacemaker programming can be performed noninvasively by an electrophysiology technician or cardiologist.

## **V. IMPLEMENTATION OF MRI-SAFE PACEMAKER**

A dedicated programming care pathway was developed for the MRI-safe pacemaker (i.e., the Revo MRI Sure Scan Pacing System) to facilitate the choice between asynchronous and non stimulation modes, to increase the pacing output to 5.0 V/1.0 ms during MRI, to prevent programming of the MRI mode if the device has failed any of the seven system integrity checks (listed further), and to facilitate restoration of pre scan program states and values.

Pacing system integrity checks are as follows:

- 1) Pacemaker and both leads implanted for more than 6 weeks.
- 2) Pectoral implantation.
- 3) No other active pacemakers, implantable cardioverter-defibrillators (ICDs), or leads.
- 4) No abandoned leads, lead extenders, or adapters.
- 5) Leads electrically intact, with stable and normal function.
- 6) Lead impedance between 200 and 1500 W.
- 7) Capture threshold less than 2.0 V at 0.4 ms.

## **VI. PACING WITH MRI**

Magnetic resonance imaging (MRI) is generally contraindicated in patients with pacemakers and American Heart Association (AHA) guidelines recommend consideration of MRI only in exceptional circumstances excluding the vast majority of pacemaker patients who might benefit from MRI examination. However, in February 2011, the US Food and Drug



Administration (FDA) approved the Revo MRI Sure Scan Pacing System, the first cardiac pacemaker designed to be used safely during MRI examinations [6].

The primary concern of using the technology of MRI scanning in patients with implantable pacemakers is overheating of implanted lead wires due to currents induced from the powerful RF fields of the MRI scanner.[8]

An experimental result shows that when a total of 26 leads were tested (23 PM leads, 3 ICD leads) and the rise in temperature induced by the RF field ranged from 2.1°C to 15.0°C. Significant heating was observed not only at the lead tip, but also at the ring (as high as 4.2°C), even if not in all the bipolar leads tested. Active-fix leads showed higher temperature increases than passive-fix ones (4.7°C versus 7.4°C). This clearly poses danger to the patient [9].

In order to reduce the heating of the lead tips during the MRI various design techniques were used. One such effort in this direction was to design and validate through experimental measurements, an accurate numerical model, which was able to reproduce the thermal effects induced by a birdcage coil on human tissues containing a metal implant (pacemaker in this case). The model was then used to compare the right versus left pectoral implantation of a pacemaker, in terms of power deposited at the lead tip. This numerical model may also be used as reference for validating simpler models in terms of computational effort [10].

## **VII. MANUFACTURERS OF IMPLANTABLE PACEMAKERS**

Permanent pacemakers are implantable devices that sense intrinsic cardiac electric potentials and, if these are too infrequent or absent, transmit electrical impulses to the heart to stimulate myocardial contraction. Magnetic resonance imaging (MRI) is generally contraindicated in patients with pacemakers.

A review on the products of Biotronik and St.Jude medical pacemaker devices, available in the Indian market is as listed below:

### *A. Biotronik Pacemaker devices*

- 1) Cylos DR-T/DR/VR
- 2) Evia
- 3) Philos DR/SR
- 4) Philos II DR-T/DR/SR

### *B. Biotronik CRT (cardiac resynchronization therapy) devices*

- 1) Lumax 540 HF-T
- 2) Lumax 340 HF-T
- 3) Stratos LV

### *C. ST. JUDE MEDICAL PACEMAKER DEVICES*

- 1) Accent®
- 2) Affinity®
- 3) AutoCapture™
- 4) Entity™
- 5) Identity® ADx
- 6) Identity®
- 7) Integrity® ADx
- 8) Integrity®
- 9) Microny™
- 10) Regency®
- 11) Verity® ADx
- 12) Victory®
- 13) Zephyr™

### *D. St. Jude Medical CRT devices*

- 1) Anthem® CRT-P
- 2) Atlas® + HF CRT-D
- 3) Atlas® II HF CRT-D
- 4) Epic® HF CRT-D

- 5) Epic™ II HF CRT-D
- 6) Frontier® II CRT-P
- 7) Promote ACE® CRT-D
- 8) Promote® Plus CRT-D
- 9) Promote® RF CRT-D
- 10) Unify™ RF CRT-D

### **VIII.COMPARISON BETWEEN ST.JUDE AND BIOTRONIC PACEMAKER DEVICES**

Given below in table1 is the comparison of two different pacemaker devices manufactured by two of the leading manufacturers of implantable pacemakers.

COMPANY NAME	St. JUDE MEDICALS (SJM)	BIOTRONIC
MODEL NAME	PHOTO ACCENT	EVIA SERIES
TYPES OF PACING LEADS	talos active type	siello active and passive type
NUMBER OF PACING CHAMBERS	dual (2)	three (3)
PROGRAMMABILITY	yes (inbuilt audio alerts programmed by default)	yes
LONGITIVITY	9 years	beyond 13 years
TYPE OF STIMULATION	automated closed loop system	closed loop stimulation
REMOTE PATIENT MONITORING	Present	present

Table1. Table showing comparisons between two different models of implantable pacemakers.

Shown below are the figures of biotronik's evia series pacemaker and also St. Jude medical's photo accent device



Fig 2. Evia DR-T pacemaker by Biotronik



Fig 3. Accent SR RF pacemaker by St. Jude Medicals

## IX.COMPLICATIONS INVOLVED IN IMPLANTING A PACEMAKER

Treatment of pacemaker complications depends on the etiology. Common complications include the following:

Pneumothoraces may necessitate medical observation, needle aspiration, or even chest tube placement.

Erosion of the pacer through the skin, though rare, necessitates replacement of the device and administration of systemic antibiotics.

Hematomas may be treated with direct pressure and observation; surgical drainage is rarely required.

Device-associated venous thrombosis is rare but generally presents as unilateral arm edema; treatment includes extremity elevation and anticoagulation.

Lead dislodgment generally occurs within 2 days of device implantation pacer and may be seen on chest radiography; free-floating ventricular leads may trigger malignant arrhythmias.

The majority of malfunctions, in fact, are due to normal programmed pacemaker function. Airport metal detector gates and hand-held metal detectors are safe for patients with pacemakers.

Major pacemaker malfunctions include the following:

- 1) Failure to output.
- 2) Failure to capture.
- 3) Failure to sense.
- 4) Pacemaker-mediated tachycardia.
- 5) Runaway pacemaker.
- 6) Pacemaker syndrome (loss of atrioventricular synchrony, retrograde ventriculoatrial conduction, absence of rate response to physiologic need).
- 7) Twiddler syndrome (patient manipulation of the pulse generator within the pocket, resulting in lead displacement or fracture).

## X.CONCLUSION

The technology of implantable pacemakers has brought an advent in the field of bio medical instrumentation. With its common usage in the present era its growing advantages have become clearer. The present day's pacemakers are long lived, efficient and the research for charging the battery using the body energy is also under progress. In this regard further developments of using a fuel cell in order to increase the longevity of the implanted device are being undertaken.

From the review its clear that the products of both the companies offers its own advantages.

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1. Vidya.M.J, Sorum Arunjith Singh presented a paper on "*Skin-line detection in mammograms: a more efficient approach to mammography diagnosis*" National Conference on Emerging trends in Bio Medical Signal Processing, Feb' 2011, page 91-95.
2. Presented a Paper titled "*Electromagnetic Surgical Device*" at the International Conference on ICSE-2010, held from 21<sup>st</sup>-23<sup>rd</sup> Apr' 2010 at Dayananda Sagar Institutions, Bangalore.
3. Presented a Paper titled "*Surgical Forceps for Extraction of Foreign Body*" at the National Conference on Emerging Trends in Biomedical Signal Processing, held on 26<sup>th</sup> Apr'2008 at RV College of Engineering, Bangalore.
4. Presented a Paper titled "*Cost Effective Electromagnetic Surgical Device for Removal of Ferromagnetic objects from the Endobronchial and Endoesophageal Passage*" at the International Conference on Emerging Technologies and Applications, held from 13th-14<sup>th</sup> Jan'2008 at the Saurashtra University, Rajkot, Gujarat.
5. Published a technical review paper entitled "*Analysis of EEG using 10:20 Electrode System*" in the online International Journal of Innovative Research in Science, Engineering and Technology on 15<sup>th</sup> Dec'2012.

Her areas of interest include Biomedical Signal processing, Biomedical Instrumentation and Communication.