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Electromagnetic Compatibility Issues in Medical Devices

Ting-Wei Wang and Ting-Tse Lin

Abstract

Electromagnetic compatibility (EMC) in biomedical applications is a significant issue related to the user's life safety, especially in implantable medical devices. Cardiovascular diseases and neurodegenerative disorders are the main chronic disease worldwide that rely on implantable treatment devices such as cardiac pacemakers and vagus nerve stimulators. Both devices must have high EMC to avoid electromagnetic interference-induced health risks, even death during the treatment. Thus, it is important to understand how EMI can affect implantable devices and proactively protect devices from electromagnetic interference, providing reliable and safe implantable device therapy. To this end, this chapter comprehensively introduces the clinical issues and provides EMC requirements for the implantable device such as a cardiac pacemaker and vagus nerve stimulator. The significance of this chapter is to present the EMC important issues in medical engineering that can help to evolve reliable and secure implantable device development in the future.

Keywords: Cardiac pacemaker, Cardiovascular disease, Electromagnetic compatibility, Implantable device, Medical device, Neuroscience, Vagus nerve stimulator

1. Introduction - Physiological background for implantable medical device

1.1 Cardiac pacemaker

Cardiovascular diseases (CVDs) are the major cause of death globally, which takes an estimated 17.9 million lives per year based on the World Health Organization (WHO) statistics. Especially, arrhythmia has a strong clinical correlation with sudden cardiac death (SCD) [1]. The irregular heart rhythm called arrhythmia can mainly be divided into two main types: tachycardia arrhythmia and bradycardia arrhythmia. As shown in **Figure 1**, the tachycardia and bradycardia arrhythmia represent the heart beats too fast and slow, respectively. The physical treatment for tachycardia and bradycardia syndrome required a regulator to suppress the abnormal heart rhythm. The implantable cardiac pacemaker is commonly applied in the cardiac modulation that generates the electrical stimulation pulse to regulate the heart's sinoatrial node, thus obtaining the normal rhythm.

As shown in **Figure 2**, the cardiac pacemaker would be activated once the heart detector measures the abnormal cardiac rhythm. Thus, the stable operation of a cardiac pacemaker is important for adverse patients, thus providing prompt treatment in arrhythmia.

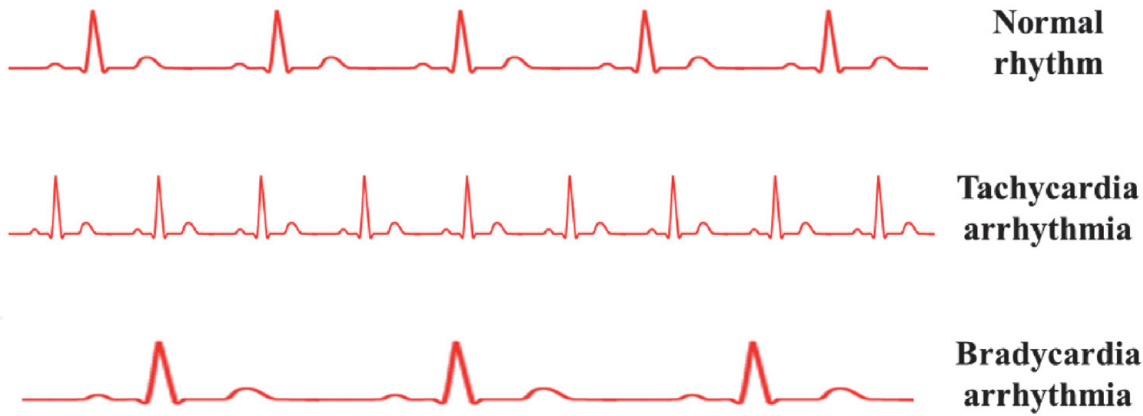


Figure 1.
Heart rhythm is divided into normal rhythm, tachycardia arrhythmia, and bradycardia arrhythmia.

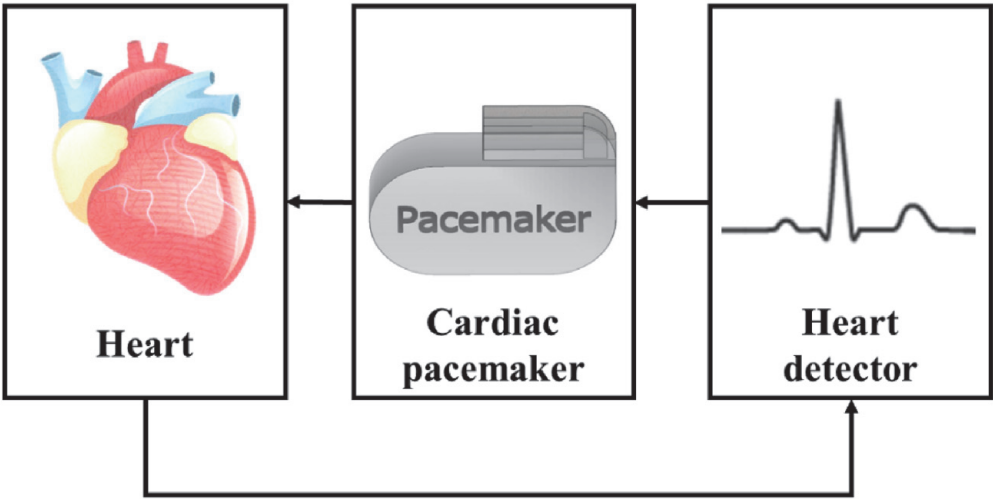


Figure 2.
Schematic of the detection and treatment system for cardiac arrhythmia.

1.2 Vagus nerve stimulator

Epilepsy is a neurological disorder that can induce the brain activities abnormal, causing seizures and further loss of awareness suddenly [2–4]. According to WHO statistics, epilepsy is a chronic non-communicable brain disease that affects humans of all ages, around 50 million globally, becoming one of the most common neurological diseases worldwide. The risk in the death probability of epilepsy patients is up to three times higher than healthy people. In epilepsy diagnosis, Electroencephalogram (EEG) is the most common non-invasive approach to record the brain's electrical activity and identify the measured signals, whether it is epilepsy or not [5]. In addition, the imaging-based diagnosis of computed tomography (CT) [6], positron emission tomography (PET) [7], and MRI [8] can help further examining brain-tumor-induced epilepsy. In epilepsy treatment, an vagus nerve stimulator is the common physical approach implanted near the left chest area, as shown in **Figure 3**. The electrode is attached around the vagus nerve in the neck to generates the electrical pulses to the brain via the vagus nerve. The delay time more than 10 minutes from seizure onset would increase mortality, which emphasizes the importance of timely treatment and time and medical emergency [9]. Therefore, high reliability is crucial for vagus nerve stimulation (VNS) during incidental neurological disease. Moreover, VNS is also widely applied in significant disease treatment, including cardiac function [10], depression [11], anxiety [12], Parkinson's disease [13], and Alzheimer's disease [14].

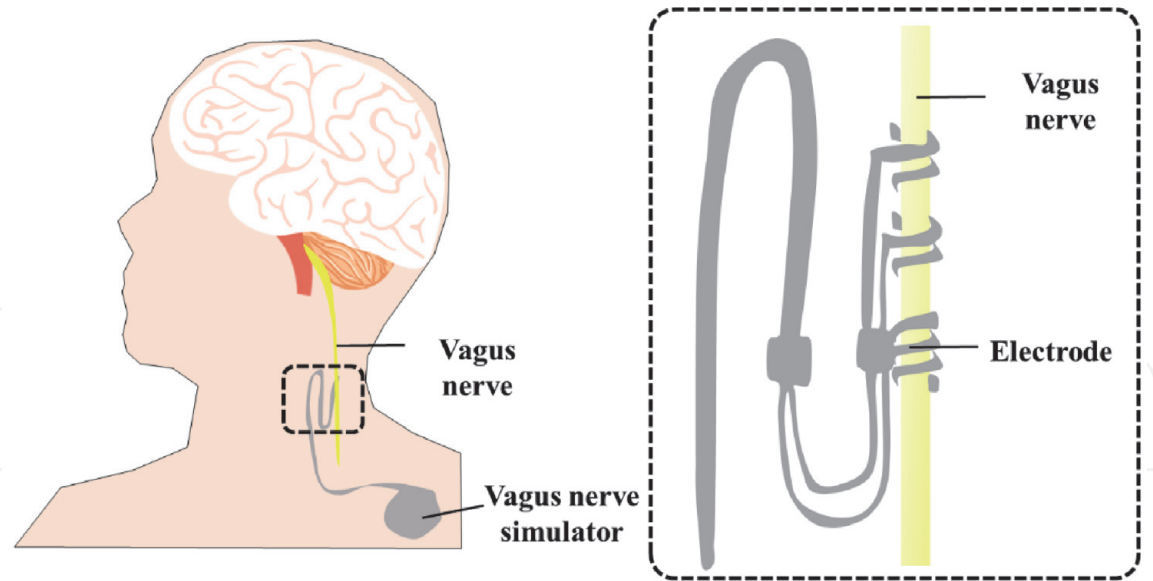


Figure 3.
Schematic of vagus nerve stimulation and its installations.

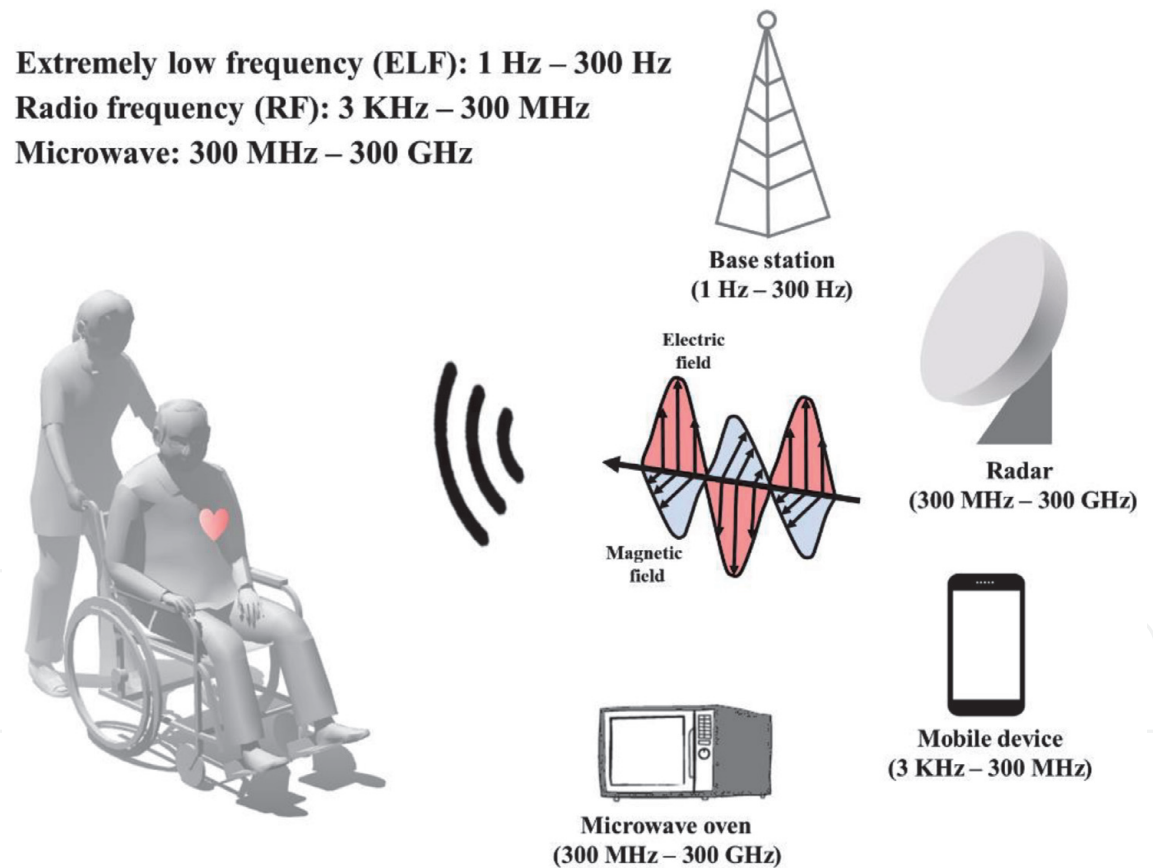


Figure 4.
EMI in medical devices from external sources with time-varying electrical and magnetic fields such as base station, radar, mobile device, and microwave oven [16].

2. Electromagnetic interference for implantable medical device

The electromagnetic interference (EMI) in the implantable medical device can be produced by the external source with the combined electric and magnetic fields [10, 15], as shown in **Figure 4**. EMI is due to radiation that can be through the air from many possible sources (**Table 1**) in our daily life [17–20], including the

Home environment
Mobile phone (RF)
Microwave oven (Microwave)
Remote controller (RF)
Refrigerator (ELF)
Electric razor (ELF)
Outdoor environment
Radar (Microwave)
Base station (Microwave)
High voltage power lines (ELF)
Medical environment
Magnetic resonance image machine (RF)
Radio-based therapy (RF)
Ionizing-based radiation therapy (X-ray)
Defibrillation (ELF)
Lithotripsy (ELF)
Industrial environment
Transformer (ELF)
High voltage power lines (ELF)
Electric motor (ELF)
Radiofrequency identification (RF)

Table 1.
EMI sources from home, outdoor, medical, and industrial environments.

common consumer device such as mobile phones, radio frequency identification (RFID) based systems, and microwaves. Moreover, the medical procedure-induced EMI is a critical concern. For example, dental equipment and magnetic resonance imaging (MRI) can generate EMI. In particular, the MRI equipment can cause a strong EMI that is very hard to guard against. The MRI machine can produce an intense magnetic field of about two or three teslas that are dangerous to any electronic device. The electromagnetic susceptibility (EMS) is frequently used to define immunity for EMI, which implies the degree of electronic system malfunctions under varying levels of EMI. Therefore, electromagnetic compatibility (EMC) in implantable medical devices such as cardiac pacemakers and vagus nerve stimulators is important to sustain the stable and normal function to treat accidental cardiac issues because humans are always surrounded by electrical equipment [21, 22].

3. Electromagnetic compatibility for implantable medical device

3.1 EMI shield

The EMI shield is designed to decrease the electromagnetic (EM) wave transmission using a shield to increase the reflection or absorption of EM wave incident at the interfaces between different mediums. As shown in **Figure 5**, the electric and magnetic fields of EM waves are perpendicular to each component and the EM

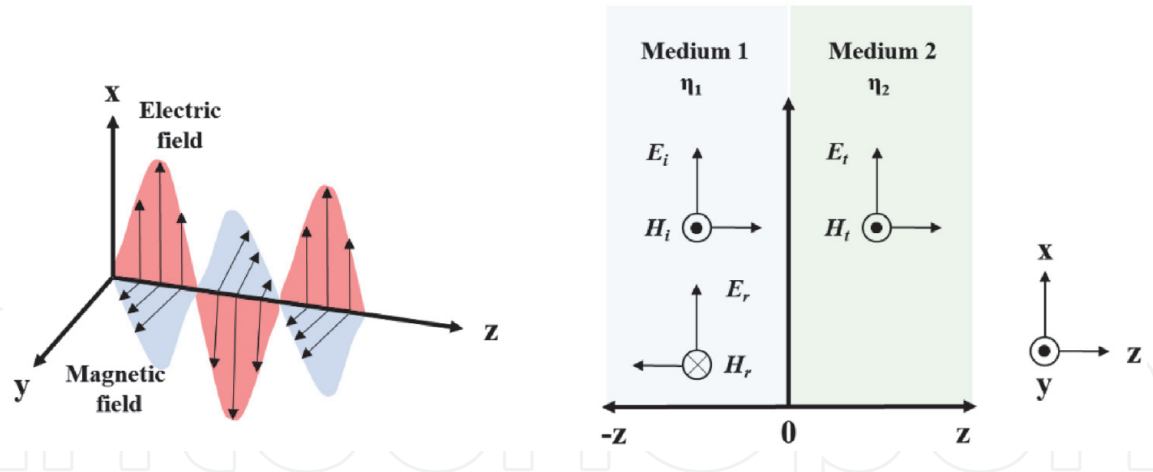


Figure 5.
Time-varying EM waves and the propagation, transmission, and reflection of the EM waves in different mediums.

propagation direction, which can be expressed as phasor form [23], according to Eqs. (1) and (2). Where γ , α , β are the propagation, attenuation, phase constants of the medium, respectively; E_0 and H_0 are the amplitude of the electric and magnetic fields.

$$\mathbf{E} = \hat{a}_y E_0 e^{-\gamma z} = \hat{a}_y E_0 e^{-\alpha z} e^{-j\beta z} \quad (1)$$

$$\mathbf{H} = \hat{a}_y H_0 e^{-\gamma z} = \hat{a}_y H_0 e^{-\alpha z} e^{-j\beta z} \quad (2)$$

The EM wave propagates at the interface of two different mediums that induce reflection due to impedance mismatching. The reflection coefficient (R_{12}) and transmission coefficient (T_{12}) at the interface between two mediums can be determined, according to Eqs. (3) and (4). E_i , E_r , η_1 , η_2 represent incident, reflected electric fields, impedances in Medium 1 and Medium 2, respectively. The impedance in the medium can be defined by a ratio of electric field and magnetic field, which is related to the permittivity (ϵ), permeability (μ), and conductivity (σ), according to Eq. (5).

$$R_{12} = \frac{E_r}{E_i} = \frac{\eta_2 - \eta_1}{\eta_2 + \eta_1} \quad (3)$$

$$T_{12} = \frac{E_t}{E_i} = \frac{2\eta_2}{\eta_2 + \eta_1} \quad (4)$$

$$\eta = \frac{|\mathbf{E}|}{|\mathbf{H}|} = \sqrt{\frac{j\omega\mu}{\sigma + j\omega\epsilon}} \quad (5)$$

The time-domain electric field can be rewritten as Eq. (6), according to Eq. (1).

$$\mathbf{E} = \hat{a}_y E_0 e^{-\gamma z} = \hat{a}_y E_0 e^{-\alpha z} \cos(\omega t - \beta z) \quad (6)$$

When the EM wave propagates in the conductive shield (loss medium) at a time of zero, the expression between the distance and amplitude of the electric field can be obtained, according to (7).

$$\mathbf{E} = \hat{a}_y E_0 e^{-\alpha z} \cos(\beta z) \quad (7)$$

Figure 6 demonstrates the EM wave propagation in the conductive shield. The skin depth (δ) can be defined as that penetration distance at which the intensity of

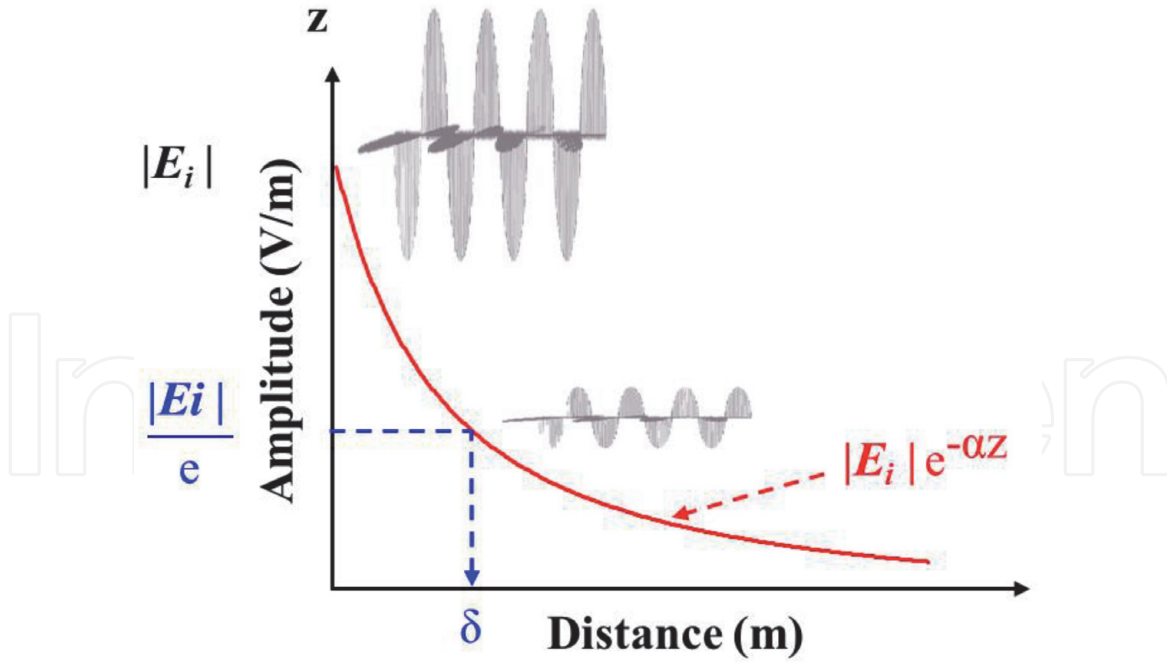


Figure 6.
Schematic of skin depth of EM waves using the shield.

the electric field attenuates to $1/e$ of the original incident wave intensity. According to the Eqs. (8) and (9), the skin depth (δ) is the reciprocal of attenuation constant (α), which is related to the EM operating frequency, permeability (μ), and conductivity (σ) in the medium [10].

$$\frac{E_0}{e} = E_0 e^{-\alpha \delta} \quad (8)$$

$$\delta = \frac{1}{\alpha} = \frac{1}{\sqrt{\pi f \mu \sigma}} \quad (9)$$

Thus, conductivity and permeability in shielding design play an important role in EM wave absorption enhancement, thus increasing the overall EMI shielding effectiveness.

However, the implantable medical device is not a fully closed system that must require the openings of the shield to interact with external equipment such as body sensing devices for signal transmit or receive. In some cases, the external controlled magnetic fields or electrical signals can be utilized to externally modulate the stimulation protocol of implantable medical devices according to patients' clinical requirements. So, the selective filtering of EMI waves is important for implantable medical devices to classify the noise and external signals. Thus, the EMI filter was provided in the following subsection to promote the EMC applications in implantable medical devices.

3.2 EMI filter

The filter implementation is also a strategy for EMI elimination in medical devices [24–27]. For example, the typical ranges of P, R, T waves in ECG are 20 to 40 Hz, 18 to 50 Hz, and 0 to 10 Hz [28], as shown in **Table 2**.

Filtering can be divided into active and passive modes. Active filters consist of several operational amplifiers and passive elements such as capacitors and resistors. [29–32]. The active filters are applied in wide applications owing to excellent filter performance. However, the active filters need a power source to sustain the

	Frequency (Hz)	Signal amplitude (mV)
T-waves	0–10	3.5
R-waves	18–50	30
P-waves	20–40	4.5
Muscle signals	30–200	3.5

Table 2.
Significant frequency bandwidth of ECG waveform [28].

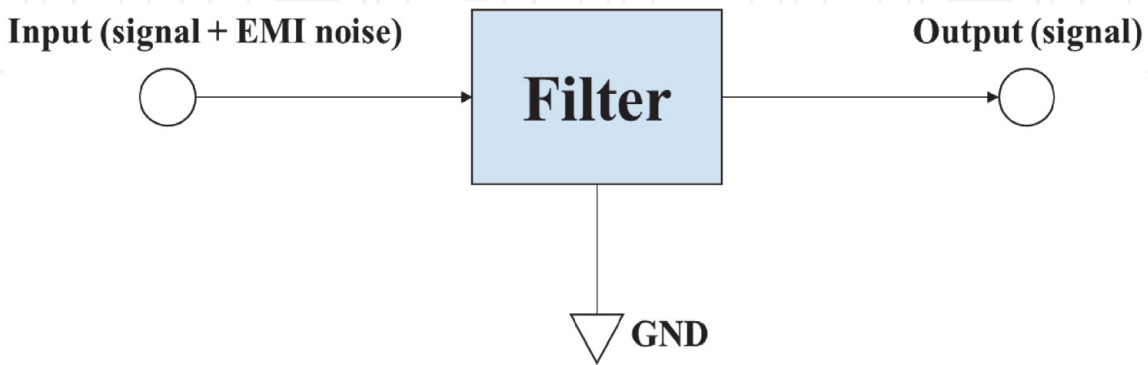


Figure 7.
Filter implementation for removing the time-varying electric and magnetic fields.

operations. Moreover, the upper frequency of active filters may be limited. Thus, the active filter is not suitable for EMI filtering in implantable medical devices. The active filter can perform programmatical filtering for the received signals, thus separating the signal from noise. However, programmatical computation requires a high-cost and complex circuit with larger power consumption to sustain the processing functions. Because the implantable devices aim to sustain life, such devices are not expected to remove or insert frequently because of extremely high costs for device failure.

Moreover, it is not easy to replace it if the devices fail due to the high risk of surgery. The concern regarding the surgery risk, which makes battery life issues more important. Owing to the battery requirements of implantable medical devices, the minimization of filters' power is crucial to prolong the implantable device lifespan.

The capacitor-based passive filter is frequently used for most high-frequency noise in the surrounding ambient for the filter design regarding implantable medical devices. Capacitors can filter EMI noise utilizing absorption and smoothing of electromagnetic noise. The high-frequency noise attenuates as quickly as charging and discharging the capacitor-based filter. Absorbing such EMI noise to the ground will neutralize or prevent specific frequencies from passing through the circuit, as shown in **Figure 7**.

The discoidal capacitor and feedthrough capacitor array were commonly utilized in the practical applications of medical devices, which deliver high-density performance with low-volume packaging [33–35], as shown in **Figure 8**.

The circular-shaped discoidal capacitor is one of the most common constructions for feed-through-style EMI filters. Circular capacitors outside and inside diameters serve as connection points for the case and the lead and serve as the capacitor poles. Moreover, several discoidal capacitors can be assembled to integrate as a capacitor array on a single piece of ceramic [36]. Such assembly offers the highest filter performance within the limited physical dimension. Thus, the feedthrough

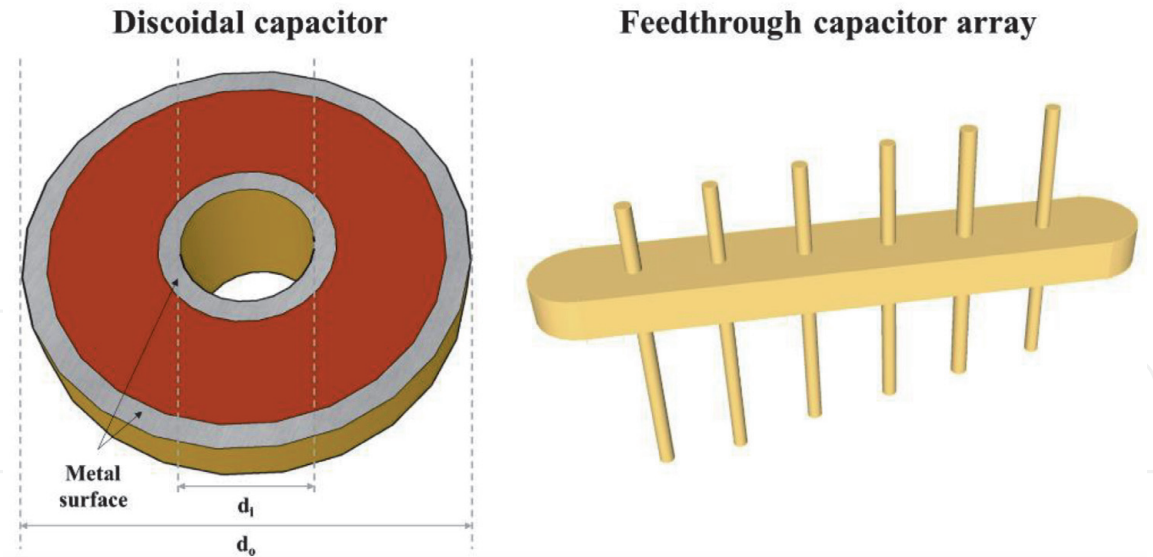


Figure 8.
The feedthrough capacitor array and discoidal capacitor for the implantable medical device.

capacitor array provides the merits of the miniature dimension and lightweight within a high-density implantable device [37].

However, a feedthrough filter will have a double impact on battery life. First, a minimal amount of current always flows between the plates of the charging capacitor. Since one capacitor is processing the signal and the other capacitor is grounded, the leakage current will drain the battery over time. A strong dielectric with an appropriate thickness can resist this current flow, thereby significantly reducing battery consumption. Besides, filter design in implantable medical devices is to minimize the loss of expected signals. The filter's insertion loss implies how much a signal will be lost or reduced for each frequency. An excellent filter requires a lower insertion loss for signal frequencies and a higher insertion loss for noise frequencies. Some energy in the expected signal will attenuate in internal resistance and inductance of the filter, which implies that the implantable battery needs optimize in the power design. Thus, an optimized design can suppress the energy loss. The less power dissipated in the battery, which extends battery life and improves effectiveness.

4. Conclusion

This chapter has demonstrated the EMC methodology for implantable medical devices. A common effective EMI removal approach was provided by EMI shielding and filtering. Such EMC design in implantable medical devices can resist EMI day-to-day exposure to ensure the stable and reliable operation in implantable medical devices such as cardiac pacemakers and vagus nerve stimulators.

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