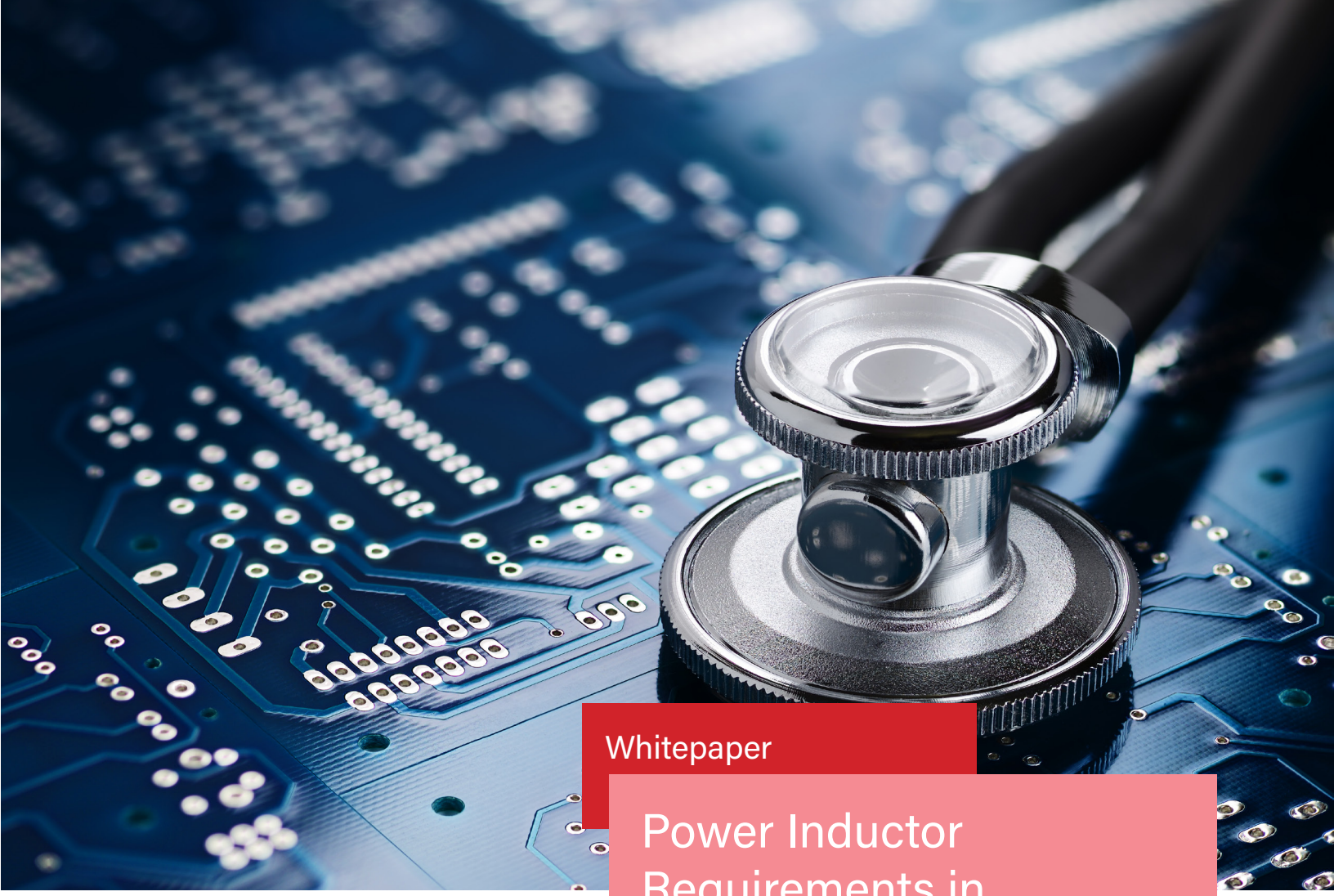

Whitepaper

# Power Inductor Requirements in Next-Generation Medical Devices

Medical devices ranging from in vitro diagnostic devices to wearable sensors/analyzers/aids are equipped with an ever-growing number of power management ICs, energy management units, and respective power supply circuits.

In order to qualify for use in medical devices, inductors must both meet the evolving demands as well as basic medical standards.

TAIYO YUDEN

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Medical devices ranging from in vitro diagnostic devices to wearable sensors/analyzers/aids are equipped with an ever-growing number of power management ICs, energy management units, and respective power supply circuits. This boosts the demand for power inductors used in those power supply circuits. Additionally, these various medical diagnostic systems and devices are routinely upgraded with more functionality and performance in a smaller package, furthering the need for high-current electronics components capable of driving high-performance ICs. In order to qualify for use in medical devices, these inductors must both meet these evolving demands as well as basic medical standards. This article dives into the applications and requirements of power inductors in medical applications.

# The Various Uses of Power Inductors

An inductor is a passive component that stores energy in the form of a magnetic field as current is passed through it. This is typically in the form of a coil wrapped around a magnetic core often consisting of a ferrite material. These ferrites are typically non-conductive ceramics fabricated from oxides of nickel, zinc, manganese, etc. These components are fundamental in a wide array of power and signal conditioning applications in power supplies and converters.

Possibly the most common use case for power inductors are as DC filter chokes in power supplies. These chokes are typically used to reduce both the ripple voltage and current at the output of the switching power supply (Figure 1). Inductors induce a voltage directly proportional to the rate of change of current (E= L di/dt). This resists any instantaneous changes in current (or alternating current) but will easily pass a steady-state DC current, and the quality of reactance to AC causes these components to smooth out any ripples caused by high frequency AC components superimposed on the DC in the output rectified voltage waveform of the power supply. These are typically more desirable than resistors, as they generally have a low DC resistance (DCR) and therefore exhibit a lower power consumption.

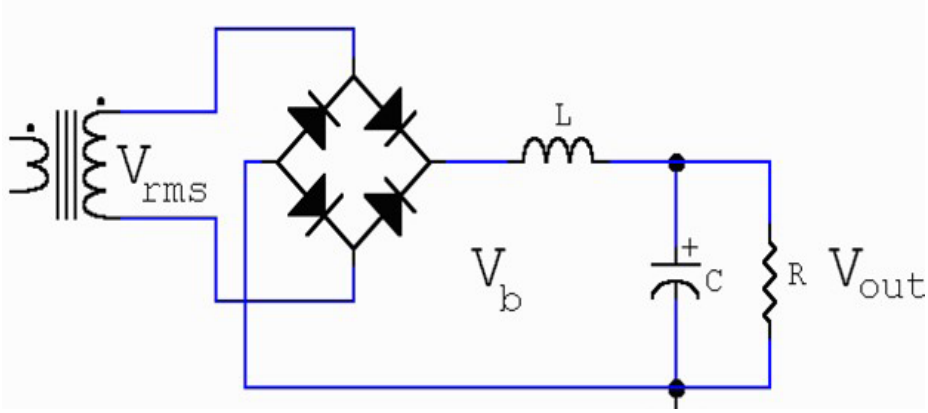


*Figure 1: Basic schematic of a power supply with the inductor/choke is placed at the output of the rectifier circuit before the shunt capacitor.*

# Types of Power Inductors: Wire-Wound or Multilayer

Inductors can come in different constructions with different winding configurations and cores. These can be through-hole or surface mount, depending upon the available space of the inductor and the circuit it will be used in. Cores can be air core, solid ferrite core, iron powder core, toroid core, or ferrite toroid cores. Air core inductors will not have a metallic core and generally exhibit the most linearity and the least distortion; however, a large coil is needed to create a large inductance value making these components relatively large. Solid ferrite core inductors will generally have a higher inductance and quality (Q) factor.

Surface mount configurations are typically either multilayer inductor or wire-wound. Wire-wound inductors are formed by winding copper wire into a spiral shape around a ceramic core while the multilayer inductor is created by layering a ferrite material and a coil conductor to generate a multilayer inductor (Figure 2). This multilayer chip mimics the effect of a toroidal coil with the coil wound in multiple layers with insulation between each layer, forming a very high inductance value in a small package size.

TAIYO YUDEN's L□CN series of multilayer inductors has case sizes as small as 0603 (1.6 mm x 0.8 mm) with inductance values from 0.24 µH to 0.47 µH. The series also contains 0805 (2 mm x 1.2 mm) with inductance values ranging from 0.24 µH to 1.0 µH. The L□CN multilayer inductors utilize silver screen-printed internal conductors, silver external conductors, and TAIYO YUDEN's original metallic material. This unique metal enables a much lower temperature coefficient so that the inductors perform well regardless of temperature variations or maximum DC current. These inductors operate at a temperature range from -55℃t o 150℃.

The L□EN series of wire-wound inductors include the large 0806 (2 mm x 1.6 mm) and 1008 (2.5 mm x 2 mm) form factors. However, inductance values for the 0806 SMT package run from 0.24 µH to 4.7 µH--the same inductance values as the L□EN but in a slightly larger package. The inductance values for the 1008 models go from 0.15 µH to 4.7 µH. These inductors feature a metal resin composite iron alloy with a higher heat resistance. The iron-based amorphous alloy features a mixed system of three particles and is coated with thermally stable oxides to balance inductor performance and insulation reliability. The inherently high insulation resistance of these inductors allows them to be implemented in high reliability applications as opposed to standard consumer applications. The L□EN features a low DCR when compared to other thin film and wire-wound inductors. The five-sided electrode configuration allows for greater conductive heat transfer between the internal and external electrodes, this effectively suppresses self-heating. TAIYO YUDEN's wire-wound inductor has a higher self-resonant frequency (SRF), a lower DCR, a higher Q factor, and a higher current rating than the multilayer. Both of these configurations can be used as power inductors; however, the multilayer chip inductors are most often used for matching, decoupling, and minimizing crosstalk in high frequency circuits.

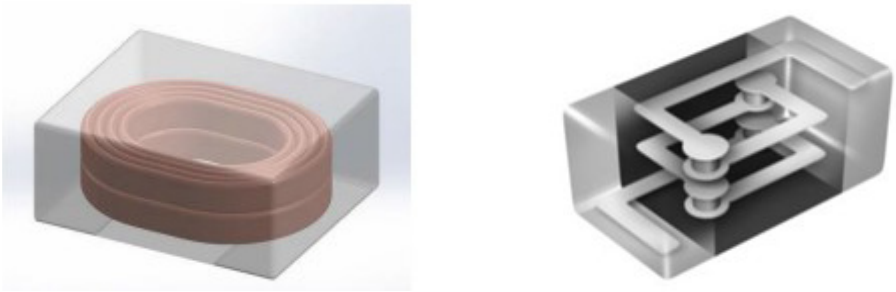

*Figure 2: Basic construction of wire-wound chip inductor (left) and multilayer chip inductor (right).*

# The Tightening Requirements of Medical Devices

## Electrical Performance, Reliability and Miniaturization

The applications for inductors also move into the realm of medical devices where power supplies used in medical devices are pushing for more miniaturization, tight tolerances, and a high reliability. This means that while through-hole inductors may offer a higher current rating and better DCR, the amount of board space that they require limits their utility in many medical applications. In these cases, smaller surface mount power inductors would be most applicable. In use cases where space and cost are heavily limited but an inductor is required, a multilayer chip may be sufficient. However, a wire-wound chip inductor may function best as a choke in medical power supply due to their superior electrical characteristics (e.g., higher inductance, lower DCR, and higher current rating).

## The Importance of Standards / Certifications

The major differentiating factor between any industrial, automotive, or medical equipment and standard commercial equipment is the requirement for a high reliability. Medical equipment is considered mission critical, so everything from the amount of down-time equipment is allowed to have in the event of a blackout/brownout to the spacing between the electrodes of the electrical component is highly regulated.

In the United States, the FDA-recognized standard is IEC 60601-1 that defines requirements for basic safety and essential performance of medical electrical equipment spanning from electrocardiographs to electron accelerators [1]. This standard has been adopted by many countries on the international level: the Global Harmonization Task Force (GHTF), established by the United States, Canada, Australia, Japan, and the European Union, helps to converge these various regulatory systems for medical devices in order to "facilitate trade whilst preserving the right of participating members to address the protection of public health by those regulatory means considered the most suitable [2]." The GHTF regulatory body does recognize the popular IEC 60601-1 standard as a model for compliance in medical devices as well. For this reason, most countries are following the GHTF model.

| Risk Level | | Low → High | | | |
|---|---|---|---|---|---|
| Japan | Classification according to the PMD Act of Japan (based on the GHTF Rules) | **Class I** General Medical Devices (GHTF Class A) | **Class II** Controlled Medical Devices (GHTF Class B) | **Class III** Specially-controlled Medical Devices (GHTF Class C) | **Class IV** Specially-controlled Medical Devices (GHTF Class D) |
| | | Medical devices with extremely low risk to the human body in case of problems | Medical devices with relatively low risk to the human body in case of problems | Medical devices with relatively high risk to the human body in case of problems | Medical devices highly invasive to patients and with life-threatening risk in case of problems |
| | | [Ex.]<br>·In Vitro Diagnostic Devices<br>·Nebulizer<br>·Blood Gas Analyzer<br>·Plethysmographs<br>·Breathing Sensor<br>·AC-powered Operating Table<br>·Surgical Light<br>·Cholesterol Analysis Device<br>·Blood Type Analysis Device, etc. | [Ex.]<br>·Electronic Thermometer<br>·Electronic Blood Pressure Gauge<br>·Electronic Endoscope<br>·Hearing Aid<br>·Electrocardiograph<br>·MRI<br>·Ultrasonic Diagnostic System<br>·Diagnostic Imaging Equipment<br>·X-ray Diagnostic Equipment<br>·Central Monitor<br>·Pulse Oximeter, etc. | [Ex.]<br>·Dialysis Machine<br>·Radiation Therapy Equipment<br>·Infusion Pump<br>·Respirator<br>·Glucose Monitoring System<br>·AED (Automated External Defibrillator)<br>·Skin Laser Scanner<br>·Electric Surgical Unit<br>·Insulin Pump, etc. | [Ex.]<br>·Cardiac Pacemaker<br>·Video Flexible Angioscope<br>·Implantable Infusion Pump<br>·Cardiac Electrosurgical Unit<br>·Inspection Device with Cardiac Catheter<br>·Defibrillator, etc. |
| U.S.A. | FDA Classification | **Class I** General Controls | **Class II** General Controls and Special Controls | **Class III** General Controls and Premarket Approval | |
| | | Medical devices without the possibility of causing serious injury or harm to the patient or user even if there is a defect or malfunction in such medical devices | Medical devices with the possibility of causing injury or harm to the patient or user if there is a defect or malfunction in such medical devices | Medical devices with the possibility of causing serious injury, disability or death to the patient or user if a defect or malfunction occurs in such medical devices | |

*Figure 3: FDA classification V.S. Japan PMD Act (based on GHTF Rules)*

# Meeting Requirements for Medical Applications

The GHTF defines classes of medical devices, and these classifications are assigned by the level of risk that the medical device presents to the patient. This ultimately corresponds to the level of regulatory control that is required to market the device legally. Class A (class I) devices are generally regarded as low risk while class B (class II) controlled devices are still relatively low risk to the human body. Examples of GHTF class A devices include nebulizers, surgical light, and blood gas analyzers. Class B devices include electronic thermometers, hearing aids, electronic endoscopes, and x-diagnostic equipment. Class C (class III) specially-controlled devices are relatively high risk to the human body and finally, class D (class IV) specially-controlled devices are highly invasive to patients and have life-threatening risks in case the device malfunctions. Class C devices include dialysis machines, glucose monitoring systems, and insulin pumps, while class D devices could be a cardiac pacemaker, an implantable medical device (IMD), and a cardiac electrosurgical unit.

These indirectly correspond to the three FDA classifications for US medical devices: Class I, Class II and Class III, where the level of risk to the patient increases as the class level rises. In this case, the FDA determines the device classification based upon the device's intended use. This is determine whether or not the device requires a premarket notification (i.e., FDA review of a 510(k) clearance-to-market submission) and must comply with special controls (e.g., labeling requirements, performance requirements, postmarket surveillance, guidance).

# A Look at TAIYO YUDEN's Power Inductors and Their Benefits

TAIYO YUDEN has power inductors available to meet class A, B, and C GHTF requirements. Class C rated power inductors have LM□□ part numbers, while the class A/B power inductors have LL□□ part numbers. Wire-wound chip inductors (LMEN) use wound enameled flat copper wire and metal resin composite for the core (Figure 3). The metal resin component uses iron-based amorphous alloys coated with thermally stable oxides to strike a balance between high performance and insula-tion reliability. Five-sided silver-nickel-tin (Ag-Ni-Sn) electrodes are leveraged for an improved bonding strength to the PCB, making it suitable for high reliability applications that require the device to perform continually despite any potential tem-perature fluctuations and mechanical instabilities (e.g., shock and vibration). This construction allows the enameled copper wire to be connected to the bottom face of the inner electrode rather than the side face of the inner electrode. The increase in surface area allows for more heat transfer and is effective in suppressing the negative effects of self-heating. The con-ductor and core materials used in the construction allow for better magnetic performance, higher insulation reliability, and better high temperature durability as well as a lower DCR and high current rating.

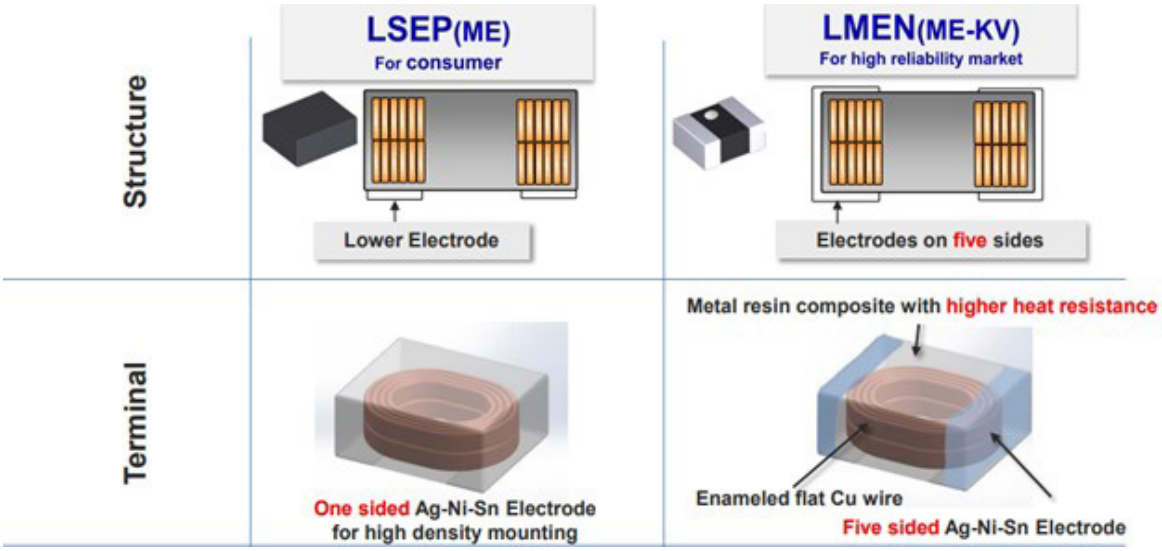


*Figure 4: Wire-wound chip inductor for GHTF Class A/B (left) and wire-wound chip inductor for GHTF Class C (right). The superior materials and construction of the high reliability power inductors allow this unit to exhibit better electrical and thermal performance.*

TAIYO YUDEN also offers class C multilayer chip inductors that leverage a unique insulating material and a screen printed silver multi-layer process to achieve better temperature performance and a highly stable inductance regardless of current change when compared to traditional Nickel-Zinc (Ni-Zn) ferrite solutions. This allows for a higher current in a relatively small package size.

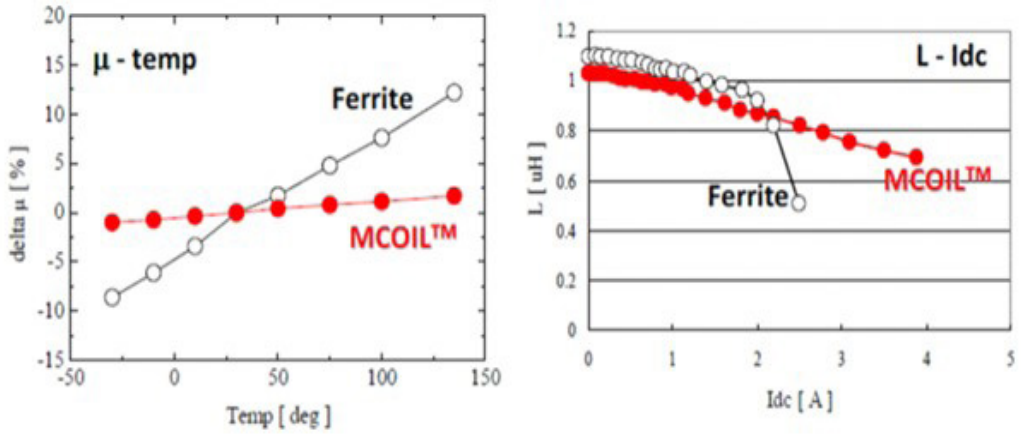


*Figure 5: Temperature performance of MCOIL™ and Ni-Zn ferrite for multilayer inductor (left) and Inductance over maximum DC current (IDC) of MCOIL™ and Ni-Zn ferrite for multilayer inductor (right).*

# Conclusion

Power inductors used in medical applications will often be applied in circuits that are limited in space and yet demand good, reliable electrical performance despite the potentially harsh environment it may be used in. Next, it is important to assess the viability of the component based upon the electrical requirements of the circuit/system. High reliability components will generally have better thermal performance and therefore better withstand thermal shock and mechanical shock/vibration without failure.

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TAIYO YUDEN (U.S.A.) INC.
2077 Gateway Place, Suite 350
San Jose, CA 95110
United States
www.t-yuden.com


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