Improving Medical Isolation Transformers with Segmented Core Cap Technology

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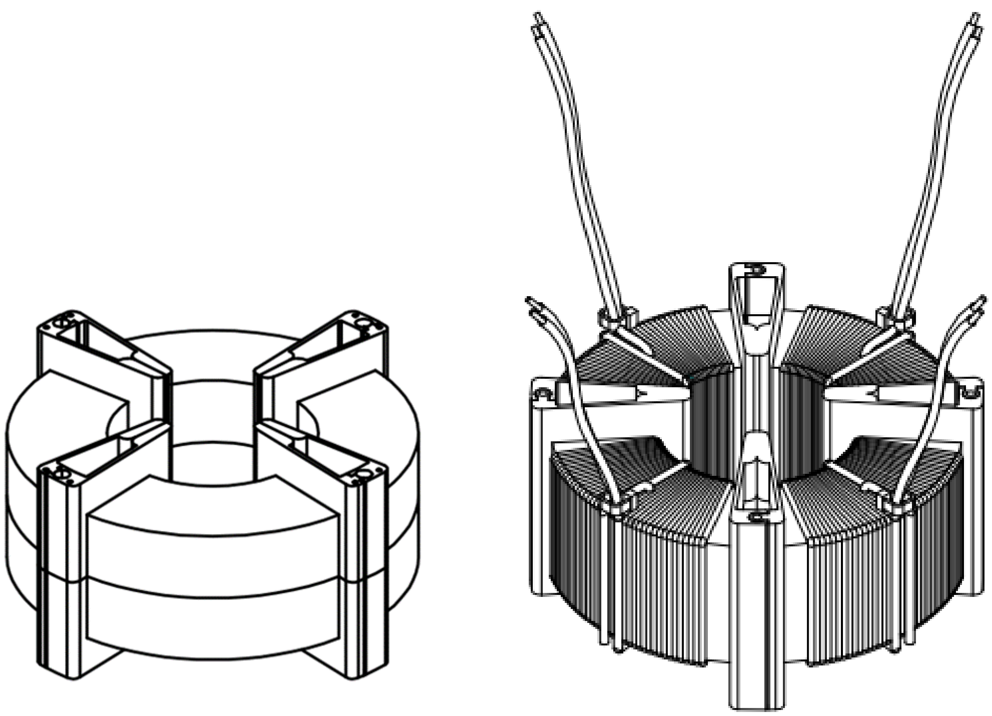

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INTRODUCTION

Medical Devices Overview

A **medical device** may be defined as any appliance, instrument, material, apparatus or other article, either used in a singular form in combination with other equipment/devices, including the software essential for its intended purpose by the manufacturer to be used for human beings for the following purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Medical Devices form an important component of patient care. From tongue depressors to dialysis machines, medical devices encompass a very broad and complex variety of technologies. The complexities are coupled with presence of power factors in most medical devices. Thus, in addition to the device performance, the crucial aspect of patient safety and the health provider's safety gets incorporated. In order to comply with all safety requirements, sets of universal standards and norms have been prescribed, compliance to which ensures delivery of the right technology in the right way. A means to verify the devices against this desired compliance is testing. Thus, product testing brings into existence the first level of assessment of appropriateness and safety of a device.

With developing economies and increasing awareness, people are becoming more conscious about their health. Regardless the cost factor, people are willing to opt for advanced technologies and solutions to improve their health. Hence medical devices have seen significant growth in the healthcare industry. Further, the medical device industry has its sub-industries like diagnostics, imaging, cardiovascular devices, surgical devices, and orthopedic devices.

Medical Device Types

Active medical device — any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

Active implantable medical device — any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

In vitro diagnostic medical device — any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

Medical Device Classification

Class	Characterization / Device type	Example
Class I	Low risk level	Thermometers, Tongue depressors
Class IIA	Low to Moderate risk level	Hypodermic needles
Class IIB	Moderate to High risk level	Lung ventilators and bone fixation plates
Class III	High risk level	Heart valves and implantable defibrillators

Environment, destination and intended use are determinant for the classification of a medical device.

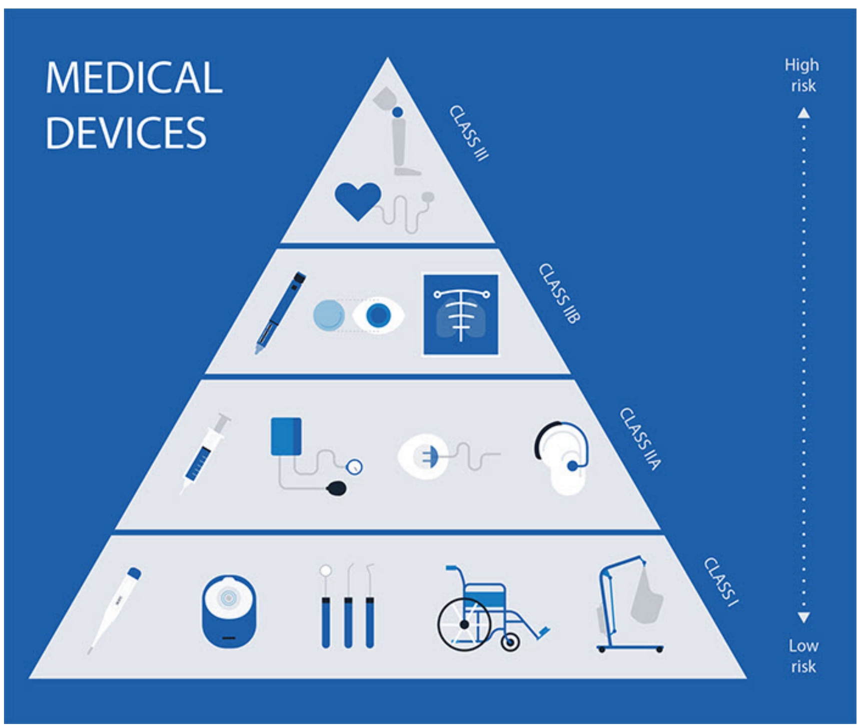


Image source: https://towardsdatascience.com/how-to-get-clinical-ai-tech-approved-by-regulators-fa16dfa1983b

Examples of Medical Devices

Image source: http://higportfolio.com/ace/www/medical_springs.html

Medical Electrical Equipment

Medical electrical equipment is provided with no more than one connection to a particular mains supply and is intended to:

- diagnose the patient
- treat the patient
- monitor the patient under medical supervision
- make physical or electrical contact with the patient
- transfer energy to or from the patient and/or detect such energy transfer to or from the patient

The equipment includes those accessories as defined by the manufacturer which are necessary to enable the normal use of the equipment.

During normal operation and in the event of a malfunction, it is imperative that the equipment does not pose any danger to patients or medical staff. A piece of equipment that causes a short circuit or residual current can trigger a protective system upstream and in doing so shut down other, possibly life-sustaining, equipment. Thus, it is necessary to pay special attention to how each unit is supplied with power.

The use of electricity for medical diagnostic, measurement and therapy equipment potentially exposes patients and even care givers to the risk of electrical shock, burns, internal-organ damage and cardiac arrhythmias directly due to **leakage current** resulting from improper grounding and electrical isolation. The electrical conductivity of body fluids and the presence of various conductive solutions and gels in the patient care system make this environment even more vulnerable.

Several techniques commonly provide isolation when designing electronic equipment. Careful component placement and printed-circuit-board layout can provide adequate room for creepage and clearance of components in close proximity of high voltages. Meeting these two specifications can be a tedious, time-consuming task, and each component subject to them must meet the requirements called out in the applicable standards.

Medical Equipment Regulation

Most major world markets regulate medical equipment. In the United States, the Federal Food, Drug and Cosmetic Act (and succeeding acts) requires that all medical devices be "safe and effective," and FDA recognizes consensus standards as a means to support a declaration of conformity (new 510(k) paradigm, "abbreviated 510(k)"). FDA lists IEC 60601 + national deviations (UL 2601-1) as a recognized consensus standard.

In Europe, the Medical Devices Directive (93/42/EEC, Article 3) requires medical devices to meet the "essential requirements." Compliance is presumed by conformity to the harmonized standards in the Official Journal of the EC (93/42/EEC, Article 5). IEC 60601 + regional deviations (EN 60601) is a harmonized standard. Similarly, IEC 60601 forms the basis for national medical equipment safety standards in many countries, including Japan, Canada, Brazil, Australia, and South Korea.

IEC 60601-1 Overview

IEC 60601 is a series of technical standards for the safety and effectiveness of medical electrical equipment.

The primary standard governing medical device design is formally known as IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. More simply it is referred to as IEC 60601-1 or just "60601," and compliance with this standard has become a de facto requirement for bringing new medical devices to market in many countries. We will look at the global adoption of the standard in more detail later, but it is worth noting that there are European (EN 60601-1) and Canadian (CSA 60601-1) versions of the standard that are identical to the IEC standard. There are also deviations from the standard that relate to country-specific requirements.

Within IEC 60601-1, there are "collateral" standards that are denoted as IEC 60601-1-x; for example, IEC 60601-1-2 is the EMC collateral standard mentioned above. Other collateral standards include 60601-1-3, covering radiation protection for diagnostic x-ray systems, 60601-1-9 relating to environmental design, and 60601-1-11 recently introduced for home healthcare equipment.

As well as collateral standards, there are also many "particular" standards, denoted as IEC 60601-2-x that define specific requirements related to particular types of products, e.g. 60601-2-16 covers blood dialysis and filtration equipment.

Medical Electrical Equipment Classification

Applied parts (AP) is a part of medical electrical equipment that in normal use necessarily comes into physical contact with the patient for medical electrical equipment or a medical electrical system to perform its function.

There are three classification types of applied parts:

- **Type B (Body)** – No electrical contact with patient and maybe earthed
- **Type BF (Body Floating)** – Electrically connected to patient but not directly to heart
- **Type CF (Cardiac floating)** – Electrically connected to the heart of the patient

Parameters	Type B	Type BF	Type CF
Symbol as per IEC/EN 60601-1			
Examples	LED operating lighting, medical lasers, MRI body scanners, hospital beds and phototherapy equipment	Blood pressure monitors, incubators and ultrasound equipment	Dialysis machines

The purpose of safety testing medical electronic equipment is to ensure that a device is safe from electrical hazards to patients, maintenance personnel's and users.

Electric shock is caused by electricity flowing through the body after touching a damaged electrical device and results muscle spasms, burns, cardiac and respiratory arrest and ventricular fibrillation.

Electrical Safety

Electrical safety in a hospital is a shared responsibility between several parties including:

- physicians
- nurses
- engineers (electrical, biomedical, facility, etc)
- manufacturers

The increasing number of medical devices being used in hospitals creates several basic concerns, one of which is patient safety. An important electrical safety requirement is to measure the leakage current.

Safety Classifications in Medical Standards

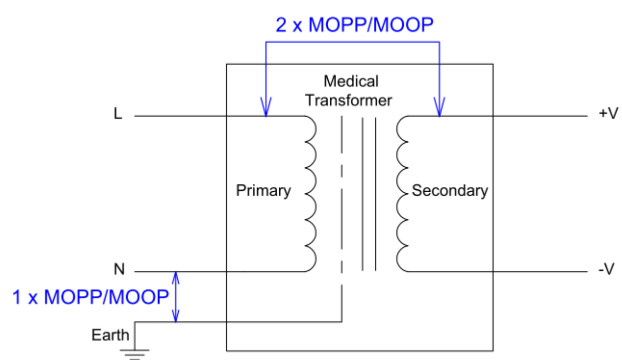
MOPP (Means of Patient Protection) — Electrical equipment with direct patient contact must fulfill the highest safety requirements.

MOOP (Means of Operator Protection) — Electrical equipment without direct patient contact must fulfill high safety requirements.

It is the responsibility of the medical product manufacturer to determine the likelihood of a patient coming into contact with the product, and decide whether to use patient protection (MOPP) or operator protection (MOOP).

In either case, the insulation between primary to secondary must meet at least 2 × MOP under and at least 1 × MOP between primary to protective earth (FG) at normal conditions.

The isolation, creepage and insulation requirement for MOPP and MOOP are different and provided in the table below.



Classifications	Isolation	Creepage / Clearance	Insulation
1 × MOOP	1500 VAC	2.5 mm / 2 mm	Basic
2 × MOOP	3000 VAC	5 mm / 4 mm	Double
1 × MOPP	1500 VAC	4 mm / 2.5 mm	Basic
2 × MOPP	4000 VAC	8 mm / 5 mm	Double

Leakage Current

Electric equipment operating in the patient vicinity, even though operating perfectly, may still be hazardous to the patient. This is because every piece of electrical equipment produces a **leakage current**. The leakage consists of any current, including capacitively coupled current, not intended to be applied to a patient, but which may pass from exposed metal parts of an appliance to ground or to other accessible parts of an appliance.

Normally, this current is shunted around the patient via the ground conductor in the power cord. However, as this current increases, it can become a hazard to the patient.

Isolated systems are now commonly used to protect against electrical shock in many areas, among them:

- intensive care units (ICUs)
- coronary care units (CCUs)
- emergency departments
- special procedure rooms
- cardiovascular laboratories
- dialysis units
- various wet locations

Without proper use of grounding, leakage currents could reach values of 1,000 µA before the problem is perceived. A patient can be injured by a leakage current of as little as 10 to 180 µA. Ventricular fibrillation can also occur from exposure to this leakage current.

Leakage current is the current that flows from either AC or DC circuit in an equipment to the chassis, or to the ground, and can be either from the input or the output. If the equipment is not properly grounded, the current flows through other paths such as the human body. This may also happen if the ground is inefficient or is interrupted intentionally or unintentionally.

Leakage currents are involuntary currents which flow when a resource or electrical medical device is operating in normal, faultless state. Therefore, leakage currents are not fault currents. Fault currents only occur in the event of a fault (e.g., defective insulation). Leakage current can flow from live parts through the intact insulation to protective earth or from a live part via the insulation to another live part.

Leakage currents are always present because there is no such insulation which insulates to 100% efficiency. Leakage currents are composed of ohmic and capacitive leakage currents. Ohmic leakage current is produced by the loss resistance of the insulation materials. Capacitive leakage current is inevitably produced where two electrically conductive surfaces or conductors are separated by insulation.

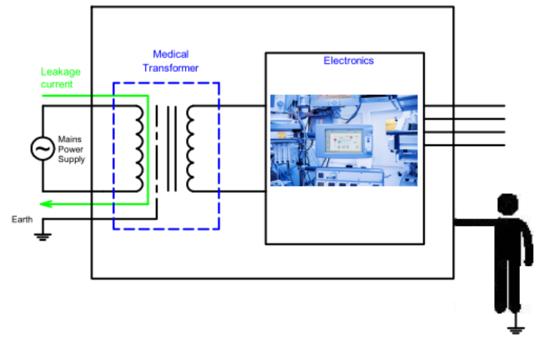
In practice, the ohmic shares can normally be ignored due to their minimal size. However, the capacitive leakage current plays an important part in the electrical safety test of resources and medical devices.

The amount of current that flows depends on :

- the voltage on the conductor
- the capacitive reactance between the conductor and earth
- the resistance between the conductor and earth

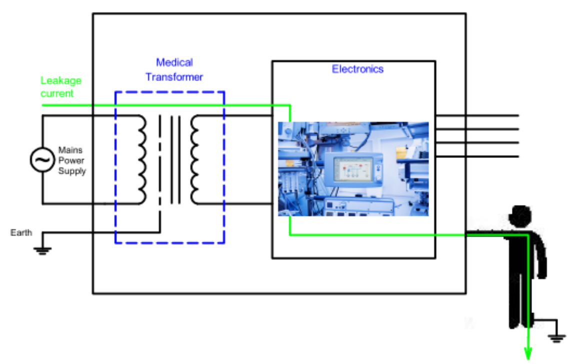
For medical electrical equipment, several different leakage currents are defined according to the paths that the currents take.

Leakage Current Classifications



Earth leakage current — Earth leakage current flows in the earth conductor of a protectively grounded piece of equipment. As long as the connection to earth remains closed, a person coming into contact with the metal enclosure of the equipment would be safe. But if the connection to earth opens, the impedance to earth through the person becomes much lower, thus creating a shock hazard.

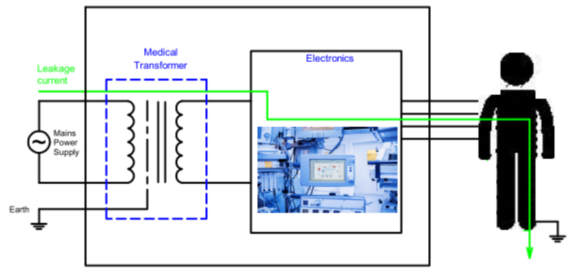
Because of this potential hazard, the impedance between the mains part of the transformer and the enclosure must be very high so that the potential for electric shock is minimized, even in the event of a fault in the earth circuit.



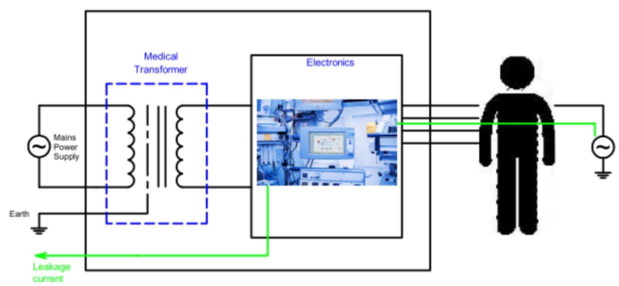
Enclosure Leakage current — Enclosure leakage current flows from an exposed conductive part of the enclosure to earth through a conductor other than the normal ground conductor.

Great lengths are usually taken to protectively ground any conductive point in the enclosure. For this reason, testing is usually conducted on points of the enclosure that are not intended to be protectively grounded to cover the unlikely possibility that a fault may exist.

Patient Leakage Current — Patient leakage current is the leakage current that flows through a patient connected to an applied part or parts. It can either flow from the applied parts via the patient to earth or from an external source of high potential via the patient and the applied parts to earth. The below figures illustrate the two scenarios.

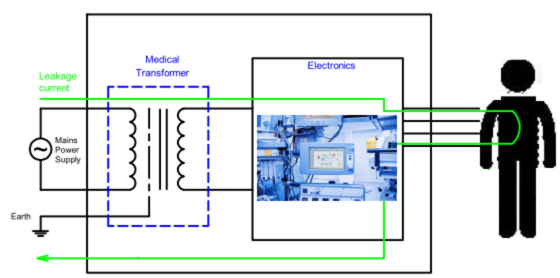


A). Patient leakage current path from equipment



B). Patient leakage current path to equipment

Patient Auxiliary Current — Patient auxiliary current is the current that normally flows between parts of the applied part through the patient, which is not intended produce a physiological effect.



Medical equipment that has direct physical contact with patients must limit its leakage current to the lowest prescribed levels. According to IEC 60601-1, the leakage current limits are provided in the table below.

Leakage Current	Type B		Type BF		Type CF	
	NC	SFC	NC	SFC	NC	SFC
Earth Leakage Current	500 µA	1 mA	500 µA	1 mA	500 µA	1 mA
Enclosure Leakage Current	100 µA	500 µA	100 µA	500 µA	100 µA	500 µA
Patient Leakage Current	100 µA	500 µA	100 µA	500 µA	10 µA	50 µA

NC = Normal Conditions SFC : Single Fault Conditions

Leakage Current Standards

Today, the International Electrotechnical Commission (IEC) and Underwriters Laboratories (UL) are the two main regulatory bodies that determine and publish minimum safety standards for electronics products, including medical transformers.

UL is the official regulatory body for the United States, as it was appointed by the Occupational Safety and Health Administration (OSHA) to both test and certify all electronic equipment. The IEC is the standards body in Europe, working closely with each nation's own national laboratory. UL 60601-1 is a standard that has been harmonized with IEC 60601-1.

The UL 60601-1 standard, which replaced the original UL 544 standard, specifies the maximum allowable leakage current values, which differ depending on equipment class and whether the equipment is located in a patient care area, such as an exam, overnight, or operating room. The largest allowable leakage current is 500 microamps (μA) for Class I non-patient care area equipment; as the equipment classes progress, this number steadily decreases. IEC 60601 follows very similar guidelines. Please note that these standards specify the performance of the completed medical device; they do not specify limitations of the transformer. However, having a low leakage transformer can greatly simplify the ease in which a completed device will meet leakage requirements.

Creepage and Clearance Requirements

Creepage distance — the shortest distance along the surface of the insulating material between two conductive parts.

Clearance — Shortest path in air between two conductive parts.

Minimum spacings, as indicated below, shall be provided through air and over surface between uninsulated live primary parts of different potential, uninsulated live primary parts and dead-metal parts, uninsulated live secondary parts and dead-metal parts, and uninsulated live primary parts and uninsulated secondary parts. The spacings apply to coils, crossover leads, splices, uninsulated lead wires, and any turn of the primary winding to any turn of the secondary winding. The spacings do not apply to the turn-to-turn spacings of a coil.

	AC Voltage (V)											
	12	30	60	125	250	400	500	660	750	1000	1250	
*Basic of Opposite Polarity (1MOP)	0.4	0.5	0.7	1	1.6	2.4	3	4	4.5	6	-	Air **Clearances**
	0.8	1	1.3	2	3	4	5.5	7	8	11	-	Creepage Distances
*Basic Insulation or Supplementary Insulation (1MOPP)	0.8	1	1.2	1.6	2.5	3.5	4.5	6	6.5	9	11.4	Air **Clearances**
	1.7	2	2.3	3	4	6	8	10.5	12	16	20	Creepage Distances
*Double Insulation or Reinforced Insulation (2MOPP)	1.6	2	2.4	3.2	5	7	9	12	13	18	22.8	Air **Clearances**
	3.4	4	4.6	6	8	12	16	21	24	32	40	Creepage Distances

Electrical Isolation in Medical Devices

Isolation physically and electrically separates two parts of a circuit that may interact. The isolation is achieved by using electromagnetic field coupling between the two circuits. The three most commonly used methods are optocouplers (light), transformers (magnetic flux), and capacitive couplers (electric field). Isolation provides several advantages:

- it breaks ground loops
- it improves common-mode voltage rejection
- it permits the two parts of the circuit to be at different voltage levels, which means one can be safe while the other side is at hazardous voltage levels.

For isolation to be safe, it needs to have two things: high-integrity isolation components (optocouplers, transformers, capacitive couplers) and a safe insulator barrier. For example, an insulator can be a piece of plastic, a keep-out space in a PWB, or an air gap.

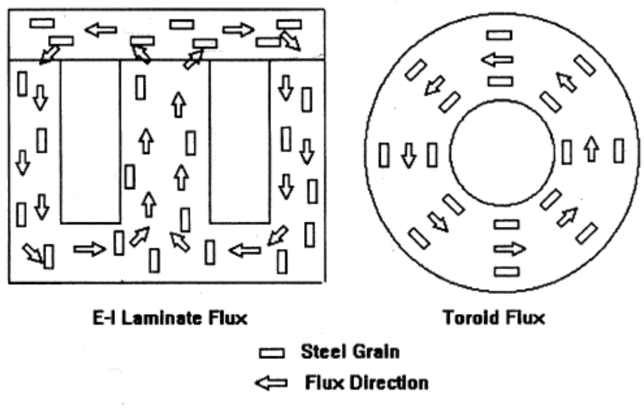
For the purposes of this discussion, we will focus on using **transformers** as a method of electrically isolating medical equipment.

Transformer Overview

A **transformer** is an electrical device that transfers energy between two or more circuits through electromagnetic induction. Commonly, transformers are used to increase or decrease the voltages of alternating current in electric power applications.

This is accomplished by passing a varying current through the primary winding to generate a magnetic flux in the transformer's core. This flux then induces a voltage in the transformer's secondary winding. Depending on the ratio of the primary windings to the secondary windings, the transformer's output voltage can be increased or decreased.

For most transformers designed for use within homes or offices, one of two styles of transformers is used. They can be made with either an EI laminate or a toroidal core.



(source for image : https://www.semanticscholar.org/paper/Optimizing-linear-power-supply-performance-with-Taggart-Goff/d71687f36e6ace5c8d14cc40862f5bf1455681b0)

EI Transformer Construction

In an E-I structure, the matching "E" and "I" components are stamped from sheets of thin grain oriented electrical steel that are later stacked to create the core. The primary and secondary windings are wound on bobbins. Multiple bobbins are placed on spindles and spun in order to apply the windings. This method of using bobbins allows for automation that reduces the manufacturing times and also provides insulation between the windings and the core. The EI core laminations are stacked inside the bobbins to complete the transformer.

Toroidal Transformer Construction

A toroidal core is made from a continuous strip of silicon steel, which is wound like a tight clock spring. The ends are tacked into place with small spot welds, to prevent the coiled steel from unwinding. The core is insulated with an epoxy coating or a set of caps or multiple wraps of insulating film (Mylar/Nomex). The transformer's windings are applied directly onto the core itself. Additional insulation is required to isolate the windings. Since the windings must be wound through the center hole of the core and the core is one piece, bobbins can't be used on toroidal transformers.

Since a toroidal transformer is more labor intensive and does not lend itself to automation, why are they used? The continuous strip of steel used in the core allows the transformer to be smaller, lighter, more efficient, and quieter than an EI laminate. These qualities are highly desirable in many applications and justify the additional expense.

Toroidal transformers are also ideal for use in a medical environment because they are compact, can be completely encapsulated when necessary, have low stray-fields and are therefore less likely to cause radiated electromagnetic disturbances.

Medical Grade Isolation Transformers

For the safety of the patient in hospitals, all diagnostic or therapeutic medical equipment (medical electrical devices and non-medical electrical devices in the patient's environment and/or areas for medical use) should be completely isolated from the supply line using strengthened isolation. Complete patient/operator safety is assured by medical grade isolation transformers with very low leakage current (IEC 60601-1 medical electrical equipment).

Medical grade transformers are designed to isolate the patient and/or the operator from an electric shock, and to protect the equipment from power surges or faulty components.

Medical grade transformers also maintain strict adherence to the following:

- maximums on earth, patient or enclosure leakage current
- compliance to the harmonized IEC 60601 standard
- minimums on creepage distance and air clearance
- maximum temperature rise

Benefits of Medical Grade Transformers

- reduced safety testing time allowing for faster to-market time
- low leakage current
- guaranteed compliance with international safety agency standards
- compact size
- reduced weight
- low power losses
- built-in thermal protection

A secure galvanic separation is provided from the public power supply, within the leakage current limits of connected devices. The low stray magnetic fields and faulttolerant design makes these transformers suitable for use near monitors. They are not only an ideal solution for medical diagnosis or medical electronic devices, but they can also be used in IT equipment and video systems in the patient environment.

Isolation Design Methods

Medical grade isolation transformers use two design options to achieve isolation: safety ground, and reinforced insulation.

Safety Ground — Safety ground transformers utilize standard transformer isolation. A safety shield between the primary and secondary coils, with insulation between the shield and each coil, maintains leakage current maximums. The safety shield has to be thick to be able to meet required tests in the safety standard. If the isolation breaks, the electrical path goes directly to ground, providing safety.

Double/Reinforced Insulation — For a transformer that relies on double or reinforced insulation there is no “safety” shield, but the insulation, as indicated by the name, is much thicker. It is designed so that all layers of the insulation can pass the thickness and high potential voltage tests required by the standard. If one insulation layer breaks, the next layer will be able to provide the required safety.

In both the design options, the construction design must still meet the required creepage and clearance requirements. If the transformer includes a static shield for noise reduction, it is important to note that this shield does not provide the transformer with safety ground but rather works as a functional earth. When the shield is grounded, it attenuates the common mode noise and can reduce the leakage current from the primary to the secondary winding (please note that this leakage reduction is not the same as when measured primary to ground).

Normally, without extra mechanical barriers between the primary and shield and secondary, a transformer with double/reinforced insulation has lower leakage current than the one with a safety shield.

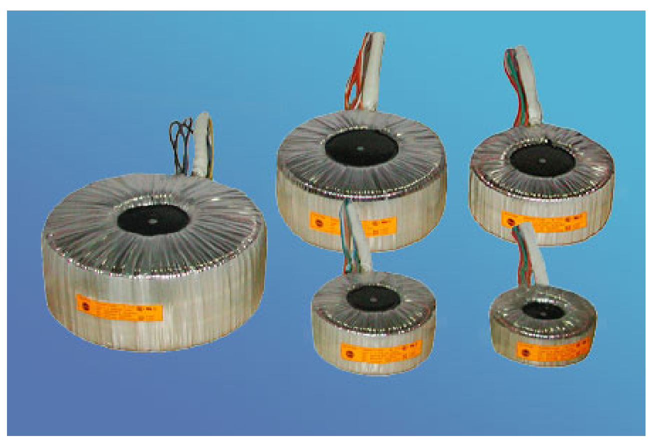
A safety shield wire should be connected to the protective earth terminal in the equipment while the static shield, if included, should be connected to the functional earth terminal.

Medical Grade Isolation transformers are mostly used in a 1:1 ratio (the primary voltage rating equals the rated secondary voltage value). The two windings will have the same number of turns. There might be a slight difference in the number of turns to compensate for voltage drops; otherwise, the secondary voltage would be slightly less than the primary voltage.

By using isolation tape and a screen winding between the primary and secondary windings the required dielectric strength of ≥ 4 kV for reinforced and double insulation is achieved, plus the required "general earth leakage current" of < 100 µA is also achieved.

Talema Medical Grade Isolation Transformers

Talema designs and manufactures medical grade isolation transformers for 240/120/100 V and 240/120 V rated for up to 3000 VA (standard range) and up to 15 kVA (custom designs). Talema isolation transformers offer reinforced safety for use in medical electronic devices. Our safety specifications are well within the recommended standards and adhere to the compliance guidelines as stipulated by IEC and UL safety standards.



See the following page on the Talema website for more information:
https://talema.com/medical-isolation-transformers-md

Improving Medical Grade Transformer Design

As previously discussed, standard toroidal transformers are more labor intensive than standard EI transformers as the construction does not lend itself to automation. Also, they employ a thicker mid insulation construction to meet the leakage current requirements specified by the safety standards. Thus, there is a need for a toroidal transformer to be designed overcoming these drawbacks.

Segmented core cap technology addresses these needs. By using specially designed core caps that provide the insulation benefits of a bobbin (linear construction), manufacturing costs can be reduced and other advantages of leakage current, temperature rise and weight reduction can be achieved.

Segmented Core Cap Technology for Toroidal Transformers

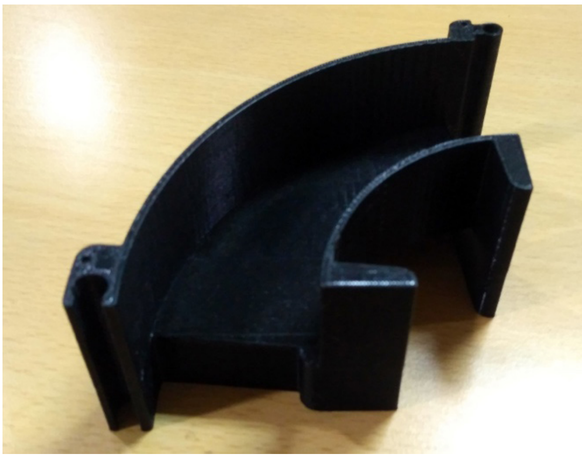
US patent 10056184; EPO application number 3365901;
Indian patent application number 201817019014.

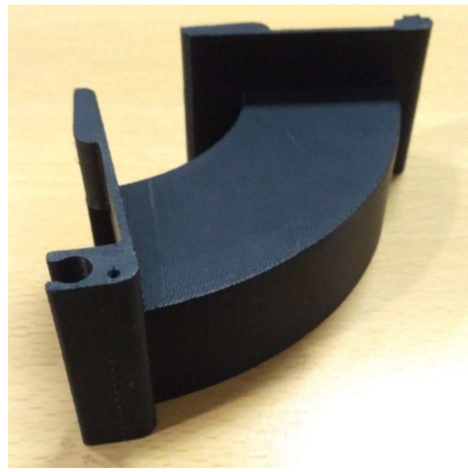
The typical method of manufacturing a toroidal transformer entails creating a steel core, insulating the core, winding magnet wire around the core to create a primary winding, insulate the primary, winding magnet wire over the insulation to create a secondary winding and insulating the secondary to complete the transformer. To mount the transformer, either a mounting washer and bolt are used or the center of the transformer is filled with an epoxy with a hole for a bolt. Between each step of manufacturing, the transformer is handled and moves from one operation to the next.

Design & Construction of Segmented Core Caps

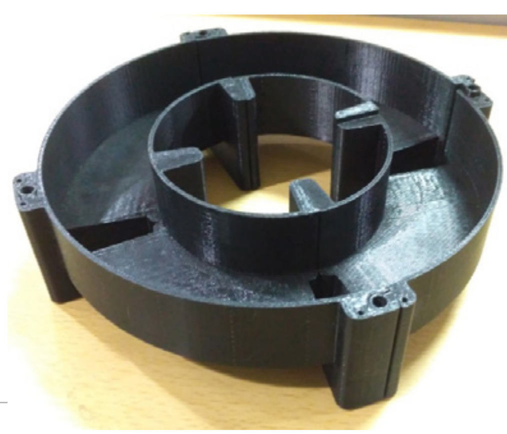
Segmented core caps support primary and secondary windings in alternate sectors to reduce leakage current. Several modular electrically insulating segments typically snap or otherwise join together to form annular or semi-annular core caps for covering or partially covering a ring-type toroidal transformer core. The segments or modules are typically made from Zytel® FR50, Rynite® FR530, or Zytel® E103HSL.

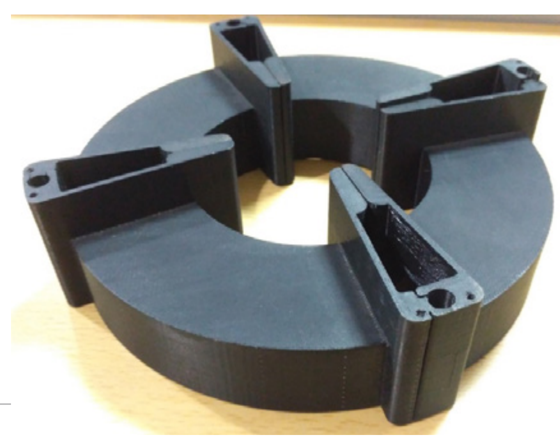
The core cap modules insulate windings from the core over the full range of the windings, and allow for double wall insulation between adjacent windings, significantly reducing leakage current compared to conventional toroidal transformers. The core cap modules also provide for direct cooling of the core by ambient or forced air without intervening insulation. The core cap may also be assembled from component modules over a completed wound toroidal core.





The segments of each module include a pair of spaced, typically electrically insulating, walls between which a core-covering panel portion is connected. The walls are disposed at a predetermined angle relative to each other, typically 30 degrees, 45 degrees, 60 degrees, or the like so that each modular segment spans an arc of about 30 degrees, 45 degrees, 60 degrees, etc. The respective spaced walls include engageable, typically male and female, connector portions, such that adjacently disposed segments may be repeatedly engaged with one another, with sufficient connected segment portions defining an annular core cap.





The number of segments required to complete a core cap is predetermined and is typically a function of the predetermined angle between the walls; for example, if the angle is 45 degrees, eight segments will be required to be connected together to define a ring shape. If the angle is 60 degrees, only six segments will be required to define a ring shape. While core caps are typically built from identical core cap modules, core caps may alternately include combinations of core cap modules spanning different arcs, such as four core cap modules spanning 45 degrees each and six core cap modules spanning 30 degrees each.

While identically sized and shaped modules are typically more convenient, there are no practical restrictions on the combinations of core cap module sizes and shapes that may be combined to yield a custom core cap having desired properties and characteristics.

Separating Walls

Typically, the walls engage the panel to define a relatively flat or flush core-engaging side or surface (defining the bottom or underside of the segment and ring) and disposed opposite the barriers established by two joined or locked together walls (defining the wire-segmenting or top side of the ring). The barriers define the parameters between which alternating wire windings are restricted, typically alternating primary and secondary windings.

The segments include one or more separation or wall positioned to partially or completely extend across the topside of the panel to further define parameters between which wire windings are directed. The one or more separations are typically positioned equidistantly between the walls and/or each other, respectively. The separations are typically oriented to extend radially outwardly from the center of the core and/or the annulus defined by the joined segments; in other words, each respective separation typically lies on a radius of the annulus, although the separation walls may have other convenient shapes and contours as desired.

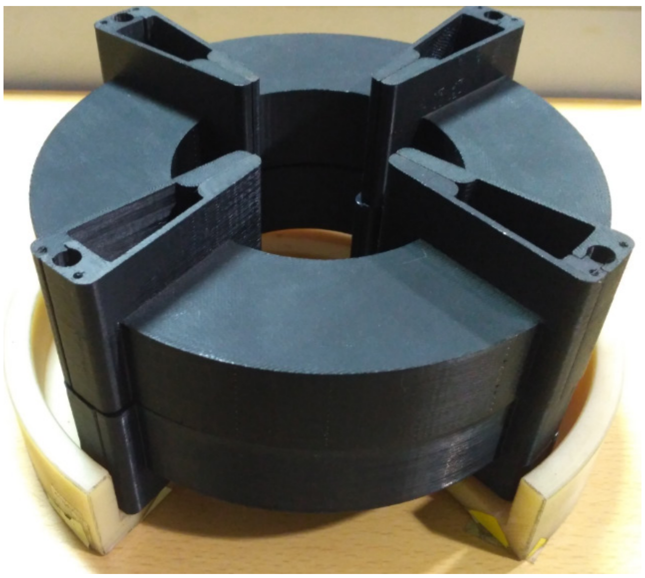
The segments further include a core outer diameter or OD cover panel and/or a core inner diameter or ID cover panel, both extending downwardly so as to at least partially cover the OD and ID, respectively, of a toroidal core ring placed against the core cover panels of a partially or completely formed annulus. These panels may be flat for covering a core ring having flat outer and inner diameter sides or curved to follow a core ring having a rounded or curved inner and outer diameter portions.

The walls are truncated and do not extend across the panels. In some of these, lower walls are positioned opposite the panel from the respective wall. The lower wall may likewise include matable connectors for co-joining. Some of the segments include ribs positioned on the upper side of the panels, so as to generate an air gap between wire windings and the topside of the ring. The production of an air gap facilitates air cooling of windings by allowing air to circulate between windings and the topside of the cap.

Segmented Core Cap Winding Tool

A winding tool is used to facilitate the winding of a capped core from a single bobbin. The winding tool is typically a flat ring having a projecting rim or flange extending from the outer diameter. The ring typically includes a slot, giving it a C-shape. The ring is sized to accept a segment, with the slot sized to pass wire onto the segment. The winding tool also typically includes an elongated arced wire lock member having multiple partial slots and one or more locking apertures for connecting the wire lock to one or more segments during the wire winding process.

In operation, multiple segments may be connected to one another to define a ring. The ring includes an annular core top cover portion defined by the panels of the individual segments. In most embodiments, the ring also includes (typically) equidistantly spaced radial protrusions, defined by mutually engaged connectors, extending outwardly from the ring. Each radial protrusion is typically part of an elongated wall positioned on the topside of the ring and extending radially inwardly partway or completely across the topside surface. Some of the walls terminate in radial protrusions extending inwardly from the ring. These radial protrusions are typically formed from the joinder of two lower walls, although they may be formed separately.



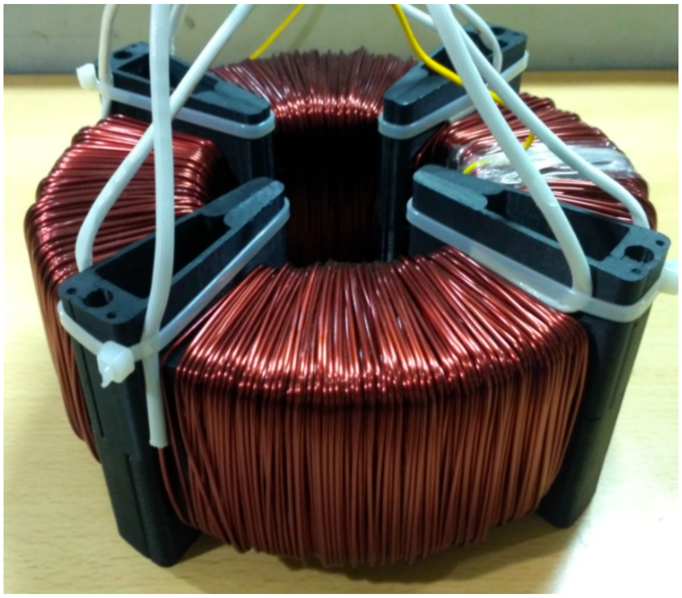
The ring may also include an annular core, outer diameter cover and/or an annular core inner diameter cover, each cover positioned generally perpendicular to the core top cover portion and extending downwardly away.

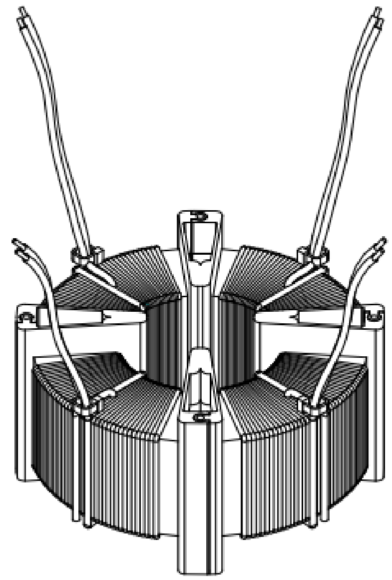
The respective covers are typically composed of adjacent cover panels when the segments are connected to define the ring.

Typically, a pair of cap rings are constructed from connected segments and positioned on opposite sides of a toroidal core with outward protrusions aligned. Typically, an even number of segments are connected to make each ring. Wire is wound contiguously around alternating segments to define the primary windings, with N windings per segment. Wire is wound contiguously around the remaining segments, in multiples of N windings per segment, to define the secondary windings. Typically, all of the windings may be accomplished from a single bobbin or shuttle in one contiguous bobbin winding operation, with wire guided from one segment to the next through the groove or gap between the two opposite core caps. The wire is typically cut or severed to isolate the primary windings from the secondary windings, and the wound core may then be wrapped in insulation to define a toroidal transformer. In some of the winding tool may be utilized to facilitate core winding. Coils so wound retain the advantages of toroidal transformers while enjoying the benefits of being lighter, Smaller, more efficient and quieter than E-I laminate cores. Cores so wound exhibit reduced interwinding leakage current when compared with standard wound toroidal transformer cores.

Typically, the primary windings will occupy the odd numbered segments, starting with the first segment wound, and the secondary windings will occupy the even numbered segments. In some designs, each ring may contain multiples of three segments, such as six, nine, or twelve, and the core may be wound with primary, secondary and tertiary (not shown) windings as above to yield a three-phase transformer. In others, the ring may contain segments having different configurations

In some of them, an insulating material, such as a MYLAR strip, is positioned to cover the portion of the core exposed by the gap. In other the core is partially or completely wrapped in an insulating material prior to the positioning of the cap(s) thereupon. In still other embodiments, walls are spaced and oriented relative each other to define an annulus but are not physically connected to each other. All leads are double insulated/ sleeved & attached with cable ties.





Summary: Segmeted Core Cap Advantages

If a segment core cap can be designed that meets safety agencies specifications for creepage and clearance, then manufacturing time is reduced because:

- There is no need for ground and inter-winding insulation and also outer wrap
- The primary and secondary windings can both be wound on one machine reducing handling time
- Provided the cap includes mounting holes, the time to fill the center of the transformer with epoxy is not required.

If a segment core cap can be designed that is made of repeatable sections that "snap-together", then the cost to tool and assemble the caps would be less because:

- The cost to tool a smaller part for injection-molding is less than the cost of tooling a larger part
- Assembling "snap-together" parts require less skill levels than other core insulation techniques

If an inexpensive tool can be designed to hold the segment core cap in place during primary and secondary winding, then the manufacturing costs will be less as existing manufacturing equipment can be used.

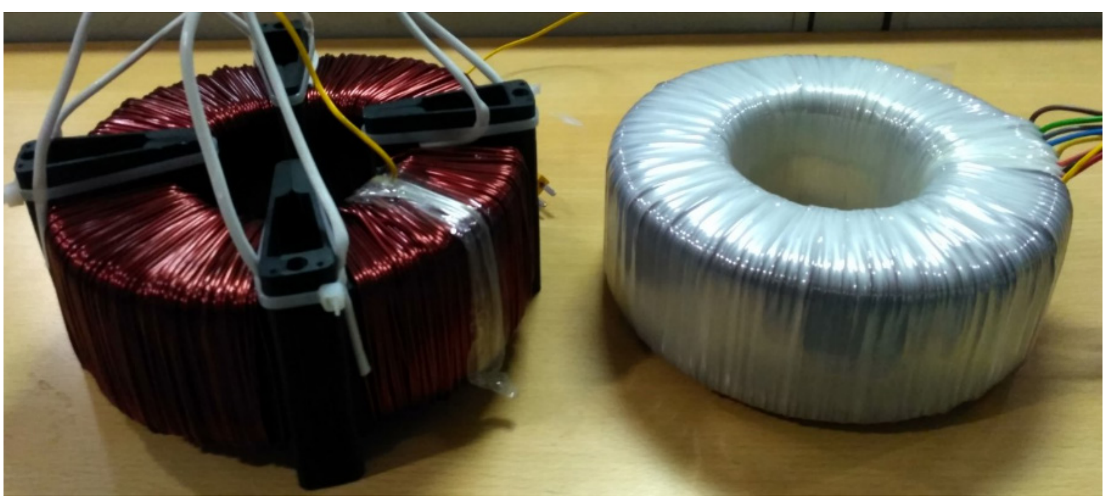
If a segment core cap transformer can be designed that meets safety agencies specifications for creepage and clearance and allows airflow around the core and windings, then the temperature rise will be less because:

- There is a direct path for heat to escape from the un-insulated core into the environment
- There is no inter-winding insulation and outer wrap that traps heat
- All windings have direct path for heat to transfer from them to the environment

If a segment core cap can be designed that includes mounting holes, then the weight of the transformer will be less because:

- No center epoxy will be necessary
- No mounting washer will be necessary

Segment Core Cap Transformer vs. Standard Toroidal Transformer



Segment Cap transformers offer significant reduction in leakage current and heat rise in comparison to standard toroidal transformers. Heat exchange is comparatively better on segment cap transformer since the design of the caps itself bestow all necessary insulations in place. It has been found in our experiment transformer of simple schematic (1:1 isolation txmrs) pose an advantage of 13~17°C over temperature rise.

Test Comparison / Power rating : 1500VA

Test Parameters	Standard Toroidal construction	Segment Core Cap Construction
No load voltage @ 240 V	239.64 V	239.60 V
No load current @ 240 V	36 mA	48 mA
Core loss @ 240 V	7.9 W	8.8 W
No load current @ 264 V	85 mA	85 mA
Core loss @ 264 V	12.0 W	11.9 W
Max leakage current @ 264 V	81 µA	14 µA
Leakage @ Hi-pot 5 kV, 50 Hz, 2 sec	1030 µA	210 µA
Primary DCR @ 28°C	0.719	0.779
Secondary DCR @ 28°C	0.784	0.781
Output power @ thermal equilibrium	1440 VA	1425 VA
Input power @ thermal equilibrium	1524 VA	1519 VA
Efficiency	94.49%	93.81%
Surface Temperature	111.5°C	98.6°C

Test Parameters	Standard Toroidal construction	Segment Core Cap Construction
Ambient Temperature	29.4°C	30°C
Temperature rise	82.1°C	68.6°C
Mechanical Size	Ø200 × 90mm	Ø200 × 90 mm

Weight Comparison

Weight	Standard Toroidal construction	Segment core cap construction
Core	7.80 KG	7.80 KG
Caps	400.0 Grams (Mylar)	360.0 Grams
Copper	1.90 KG	1.95 KG
Center potting	0.60 KG	-
Total	10.7 KG	10.1 KG

Temperature rise comparison

Power Rating	Temperature Rise (°C)		
	Standard Toroidal construction	Segment core cap construction	Difference
1500VA (Nominal)	82.1	68.6	13.5
1800VA (Extended)	108.3	91.5	16.8

Labor time comparison (1500VA)

Standard Toroidal construction	Segment core cap construction	Difference
100%	66%	34%

Segment core cap transformer construction itself lend for better heat dissipation so they can be rated for extended power for the same volume which is the primary advantage. So, they are relatively smaller in size and lighter in weight compared to transformer of standard method of construction for the same power levels. Less leakage current, less manufacturing cost and cost effective mounting design are the other advantageous.

For example, the below is a comparison of the 1500 VA segment cap transformer (Extended power 1800 VA) to our standard 1800 VA medical transformer of standard method of toroidal construction 1800MD-1-003.

Test Comparison

Test Parameters	Standard Toroidal construction (1800MD-1-003)	Segment Core Cap Construction (Extended power – 1800 VA)
No load voltage @ 240 V	247.35 V	239.60 V
No load current @ 240 V	55 mA	48 mA
Max leakage current @ 264 V	86 µA	14 µA
Leakage @ Hi-pot 5 KV, 50 Hz, 2 sec	1100 µA	210 µA
Primary DCR @ 28°C	0.414	0.779
Secondary DCR @ 28°C	0.480	0.781
Efficiency	94.50%	93.50%

Test Parameters	Standard Toroidal construction (1800MD-1-003)	Segment Core Cap Construction (Extended power – 1800 VA)
Surface Temperature	120°C	121.5°C
Ambient Temperature	30°C	30°C
Temperature rise	90°C	91.5°C
Mechanical Size	Ø210 × 100 mm	Ø200x90 mm

Weight Comparison

Weight	Standard Toroidal construction (1800MD-1-003)	Segment core cap construction (Extended power – 1800VA)
Core	11.3 kg	7.80 kg
Caps	500.0 g (Mylar)	360.0 g
Copper	2.70 kg	1.95 kg
Center potting	0.50 kg	-
Total	15.0 kg	10.1 kg

Labor time comparison

Standard Toroidal construction (1800MD-1-003)	Segment core cap construction (Extended power – 1800VA)	Difference
100%	66%	34%

UL Approval for Segment wound construction

UL investigated the Segment wound construction transformer as per standards UL60601-1 1st Edition, ANSI/AAMI ES60601-1 1st Edition, CAN/CSA C22.2 No 601.1 M90 and CSA C22.2 NO. 60601-1 2nd Edition Construction and determined that segment wound transformer comply with the applicable requirements.

Talema UL file number : E251176

Conclusion

Although toroidal transformer designs are fairly mature in general, this white paper shows there is still room for innovation and improved efficiencies through the use of segmented core cap technology. We hope this piece of work is helpful for the medical device manufacturers, magnetic designers, and anyone who may be interested.

For more information regarding segmented core cap technology or other medical grade magnetics from Talema, please contact us at sales@talema.com or visit talema.com/contact-us.

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