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Designing for High-Voltage Isolation, Creepage and Clearance Requirements in Medical Devices

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Abstract: As electrification accelerates across the automotive, industrial, and medical domains, ensuring electrical safety and system reliability in high-voltage environments has become a critical design challenge. The integration of high-voltage circuits within the compact, complex housings of medical electromechanical devices presents critical safety challenges. This paper explores the design considerations for ensuring proper high-voltage isolation, with an emphasis on creepage and clearance distances, insulation coordination, and material selection within electromechanical housings. Special focus is given to patient and operator protection as defined by MOPP (Means of Patient Protection) and MOOP (Means of Operator Protection) under IEC 60601-1, alongside practical guidance on structural design, risk mitigation, and validation testing.

The integration of high-voltage electrical systems into compact electromechanical housing has introduced new complexities in insulation coordination and safety design. Medical devices such as infusion pumps, imaging systems, surgical robots, and dialysis machines increasingly integrate electromechanical systems that operate at potentially hazardous voltages. Their housings must safely contain and isolate these electrical components while often remaining compact and lightweight.

Distances are governed by strict international safety standards such as **IEC 60664-1**, which provides insulation coordination rules, and domain-specific regulations like **IEC 60601-1** for medical devices. The required distances vary based on several factors: working voltage, pollution degree, material tracking resistance (CTI), altitude, and insulation type (functional, basic, and reinforced).

Keywords: Creepage clearance, Medical domain, Electromechanical devices, CTI, Housing

I. INTRODUCTION

A. The Importance of High-Voltage Isolation in Medical Devices

High-voltage systems are integral to many advanced medical devices used for diagnostics, treatment, and patient monitoring. Devices such as CT scanners, MRI machines, X-ray systems, defibrillators, and electrosurgical units often operate with voltages that exceed conventional safety thresholds. These voltages, while essential for device functionality, pose significant safety risks if not properly controlled and isolated. High-voltage isolation serves as a critical safety barrier, preventing unintended current flow between the conductive components and ensuring that dangerous voltages are kept away from patient contact areas. Without effective isolation, there is a potential for electrical shock, thermal damage, equipment malfunction, and even life-threatening situations. Additionally, isolation helps in maintaining signal integrity, reducing noise, and protecting sensitive electronic circuits from voltage spikes and transient disturbances. In medical environments, where both patient safety and operator protection are paramount, achieving the highest levels of electrical isolation is not optional it is a regulatory and ethical requirement. Isolation systems must be capable of withstanding mechanical stress, environmental influences such as humidity and temperature fluctuations, and the possibility of long-term material degradation.

B. Role of Electromechanical Housings

Electromechanical housing in medical devices serves as the primary physical and dielectric barrier that separates high-voltage circuits from accessible parts and other low-voltage systems. These housings are typically made of insulating materials like high-grade plastics, ceramics, or composite structures, specifically selected for their dielectric strength, environmental resistance, and long-term reliability. The geometry and layout of the housing directly determine the available creepage and clearance paths. If these distances are insufficient or poorly managed, risks such as surface tracking, arching, and dielectric breakdown may occur, especially under conditions of condensation, dust accumulation, or pollution ingress. Electromechanical housing must also accommodate:

- Heat management without compromising insulation.
- Sealing solutions to prevent moisture and contaminants.
- Compact design requirements without sacrificing safety margins. Well-designed housing not only meets regulatory requirements but also enhances device reliability, serviceability, and product longevity.

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C. Regulatory Importance: Patient and Operator Safety

The safety of medical devices is governed by stringent international regulations that dictate how high-voltage isolation must be implemented and validated. The **IEC 60601-1** standard explicitly defines the requirements for:

- **Means of Patient Protection (MOPP)**: Isolation strategies aimed at protecting patients.
- **Means of Operator Protection (MOOP)**: Isolation strategies aimed at protecting healthcare personnel and device operators.

The standard mandates specific creepage and clearance distances based on working voltage, pollution degree, and material insulation classes. It also defines testing procedures such as dielectric withstand testing, leakage current measurement, and fault condition simulation to ensure that the device remains safe under all foreseeable conditions.
Additional standards like **IEC 61010-1** (Safety requirements for electrical equipment for measurement, control, and laboratory use) further reinforce these design criteria for test and diagnostic devices.
Compliance with these standards is not just a regulatory formality, it is essential to:

- Prevent catastrophic device failures.
- Protect human life during intended and unintended use conditions.
- Achieve global market access and certification.
- Build trust in the reliability and safety of medical technologies.

Regulatory Landscape

Table 1. IEC 60601-1 Key Highlights

Category	**Details**
Scope	Applies to all active medical devices intended to diagnose, monitor, or treat patients.
Electrical Isolation Requirements	- Specifies creepage and clearance distances based on: • Working voltage • Pollution degree • Insulation category - Requires multiple layers of protection: • Reinforced insulation • Double insulation • Especially in patient-connected circuits
Means of Protection (MOPP vs. MOOP)	- Introduces MOPP and MOOP concepts - Differentiates protection for: • Patients (MOPP) • Operators (MOOP)
Testing Requirements	- Dielectrics withstand test - Leakage current measurement - Fault condition simulation
Environmental Conditions	- Device must remain safe under: • Humidity • Temperature fluctuations • Varying pollution degrees

The Significance: IEC 60601-1 compliance is mandatory for all electrical medical equipment and is essential for international market access.

Table 2. IEC 61010-1 Key Highlights

Category	**Details**
Scope	Applies to laboratory equipment, control systems, and testing devices used in medical settings.
Creepage and Clearance	- Defines minimum distance requirements. - Specifies insulation classes and test voltages.
Insulation Categories	- Functional - Basic - Supplementary - Double-reinforced
Pollution Degree and Overvoltage Categories	- Critical parameters for determining creepage and clearance distances. - Influences the required insulation strength and safety margins.
Risk-Based Approach	- Focuses on identifying potential hazards under both normal operation and fault conditions. - Emphasizes risk assessment and mitigation at the design stage.

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The Significance: Essential for laboratory diagnostic equipment and complementary to IEC 60601-1 for devices not directly involved in patient treatment.

II. FUNDAMENTALS OF CREEPAGE AND CLEARANCE IN HIGH-VOLTAGE DESIGN

A. Definitions

A-1. Creepage Distance

Creepage refers to the shortest path between two conductive components measured along the surface of a solid insulating material, as illustrated in Figure 1. This distance is defined based on the pollution degree, material group, and working voltage — the maximum root-mean-square (RMS) voltage the insulating material is expected to withstand. It is specified to prevent flashover or insulation breakdown from occurring. Beyond the working voltage, creepage distance is significantly impacted by environmental conditions such as pollution, humidity, and condensation. (1)

A-2. Clearance Distance

Clearance refers to the shortest path through air separating two conductive components, as shown in Figure 1. This spacing helps avoid arcing or ionization of air when sudden voltage spikes occur. Clearance is primarily influenced by environmental factors such as air pressure (determined by altitude) and pollution levels.

While creepage pertains to continuous steady-state voltages, clearance is intended to manage brief transient overvoltage occurring over milliseconds or less. Although there is no direct physical relationship between creepage and clearance, the creepage distance must always be equal to or greater than the clearance distance. It is essential to optimize creepage and clearance distances wherever possible, considering the associated trade-offs in size and cost.

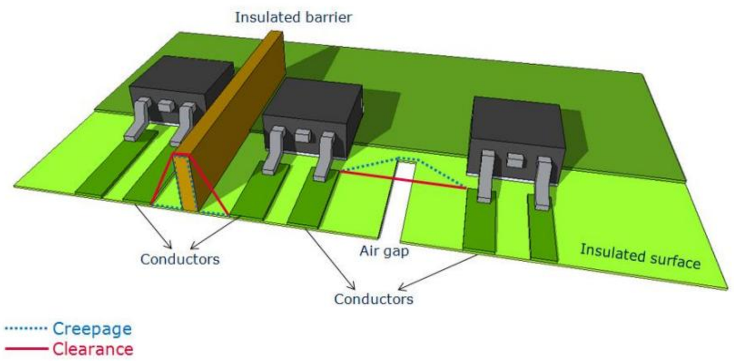

Figure 1: Definition of Creepage and Clearance

Ref: Electrical saft and isolation in high voltage discrete component applications and design hints by Infineon Technologies Austria AG

In some scenarios, particularly when corner pins are located near the package edge, the minimum creepage distance may occur along the side surface instead of the top or bottom, as illustrated in Figure 2. (1)

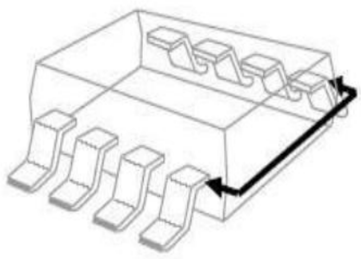

Figure 2: Example where the shortest creepage distance is across the side rather than the top.

Ref: Demystifying Clearance and Creepage Distance for High-Voltage End

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Impact of Material, Pollution Degree, and Working Voltage

B-1 Comparative Tracking Index (CTI) and Material Group

CTI is used to categorize insulating materials based on the voltage at which they experience electrical breakdown caused by surface tracking. CTI is measured by applying a specified voltage to the material as it is subjected to fifty drops of a contaminant solution containing 0.1% ammonium chloride. The CTI rating represents the highest voltage a material can withstand during the test without allowing a tracking current of 0.5 A or more. Table 1 shows the categories of insulating materials based on the CTI. Material group classifications provide guidance in selecting the appropriate creepage distance based on insulation requirements.

Material Group	CTI Range (Volts)	Material Examples	Required Creepage Distance (Higher CTI = Less Required)
Group I	CTI ≥ 600	Polycarbonate (PC), Epoxy Resin, High-grade Polyamide	Minimum creepage required (most compact designs possible)
Group II	400 ≤ CTI < 600	Polyamide (PA), Polypropylene (PP), Glass-filled nylon	Moderate creepage required
Group IIIa	175 ≤ CTI < 400	ABS, PVC, Low-grade thermoplastics	Larger creepage required
Group IIIb	1 00 ≤ CTI < 175	Some flame-retardant plastics, materials with fillers	Maximum creepage required

Table 3: Material groups based on the CTI.

Material has an influence on design choices, as material with high CTI enables compact design, reduced creepage distance, therefore often preferred in tightly packed medical devices. On the other hand, material with low CTI forces large creepage distance increasing overall size of component. It also requires careful environmental sealings. Below table 2 illustrates the materials that are commonly used in medical devices.

Material	CTI Rating	Typical Application	Advantages
Polycarbonate (PC)	600+	Medical housing, covers	High CTI, good impact strength
Polyamide (PA)	400-600	Connectors, structural supports	Good thermal and chemical resistance
Polypropylene (PP)	400-600	Insulation barriers, panels	Chemically resistant, light weight
Epoxy Resins	600+	Encapsulation, PCB insulation	Excellent dielectric properties
ABS	<400	Non-critical covers	Cost-effective but limited CTI

Table 4: Insulating Materials with CTI ratings and application

B-2 Pollution Degree

Pollution degree is another key factor in defining the appropriate creepage and clearance distances. Pollution degree environments are classified into four categories.

Pollution degree 1: No pollution or only dry. Pollution has no influence (example: sealed or potted products) (2)

Pollution degree 2: Normally only non-conductive pollution occurs. Occasionally, temporary conductivity due to condensation must be considered, for example, in products used in standard office environments. (2)

Pollution degree 3: In some environments, conductive pollution is present, or dry, non-conductive contaminants may become conductive when exposed to condensation, as seen in heavy industrial settings typically affected by dust and similar pollutants. (2)

Typical usage: Industrial environment.

Pollution degree 4: Persistent conductivity may result from pollution sources such as conductive dust, or environmental conditions like rain or snow. (2)

Steps can be taken to control the pollution degree by design features or the consideration of the operating characteristics of the product.

Pollution degree 1 can be achieved by encapsulation or hermetic sealing of the product.

Achieving Pollution Degree 2 conditions requires reducing the likelihood of condensation or elevated humidity. This can be accomplished by implementing adequate ventilation or applying continuous heating either through dedicated heating elements or by keeping the equipment energized continuously. Continuous energizing implies either uninterrupted

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operation or interruptions so brief that they prevent the system from cooling to the point where condensation could develop.
Pollution degree 3 can be achieved using appropriate enclosures which act to exclude or reduce environmental influences, particularly moisture in the form of water droplets. (1)

B-3 Transient Overvoltage Category
Another factor used in determining the required clearance is the transient overvoltage category, which categorizes equipment based on where it is connected relative to the mains voltage. This voltage level is not set by calculation, but by estimating the chance of overvoltage based on where the equipment is used.

Category	Definition	Examples of Equipment
OVC I	Equipment with extremely low transient exposure; overvoltage is highly controlled or internally generated.	Battery-powered devices protected electronic circuits.
OVC II	Equipment connected to local distribution (plug-in devices) that can see limited transients.	Household appliances, portable medical devices, diagnostic instruments.
OVC III	Equipment that is part of a building installation, subject to higher transients from fixed wiring.	Industrial machinery, equipment connected to fixed installations (hospital CT scanners, large imaging equipment).
OVC IV	Equipment directly connected to the origin of installation, where the highest transients can occur.	Utility-level equipment, electric meters, building service panels.

Table 5: Overvoltage category

OVC I: Minimal Exposure
- Devices are isolated from the main power.
- Typically powered via low-voltage DC sources or batteries.
  Example: Handheld ECG machines.

OVC II: Controlled Environment
- Standard for most medical devices used in hospitals or clinics.
- Connected via standard wall outlets.
- Overvoltage transient typically limited to 2500V to 4000V surge.
  Example: Patient monitors, portable imaging devices.

OVC III: Installation Level
- Connected directly to building wiring, subject to higher surge levels.
- Typically rated for transients up to 4000V to 6000V.
- Requires larger clearance distance.
  Example: Fixed diagnostic equipment, hospital X-ray systems.

OVC IV: Utility Level
I. Direct connection to outdoor lines or upstream building-level protection.
II. Transients can exceed 6000V to 8000V.

Example: Incoming service panels, industrial power meters.

B. Protection with isolation
According to general safety requirements, a single layer of insulation is sufficient when the circuit is inaccessible. In contrast, accessible components must be safeguarded from hazardous voltages through a double-insulation scheme, where each layer complies with the relevant insulation standards for the application. (3)
Five categories of insulation can be defined as below:
1. **Functional insulation (F)** is that which is only necessary for circuit operation. It is assumed to provide no safety protection. (3)
2. **Basic insulation (B)** provides fundamental protection against electric shock through a single layer of insulation but does not specify a minimum thickness for solid insulation and assumes potential vulnerability to pinholes. An additional layer of safety is achieved by incorporating either supplementary insulation or a protective earthing system. (3)

3. **Supplementary insulation (S)** This type of insulation is applied in conjunction with basic insulation, serving as a secondary safeguard should the primary insulation fail. A single layer must have a minimum thickness of 0.4 mm to be classified as supplementary insulation. (3)
4. **Double insulation (D)** This refers to a dual-layer insulation system, consisting of both basic and supplementary insulation. (3)
5. **Reinforced insulation (R)** This type offers protection comparable to that of a double-insulation system, despite consisting of only a single layer. In accordance with UL 60950/EN 60950, a minimum thickness of 0.4 mm is required for such applications. (3)

III. DESIGN CONSIDERATIONS FOR ISOLATION AND CREEPAGE/CLEARANCE

A. Determining Appropriate Creepage and Clearance Distances

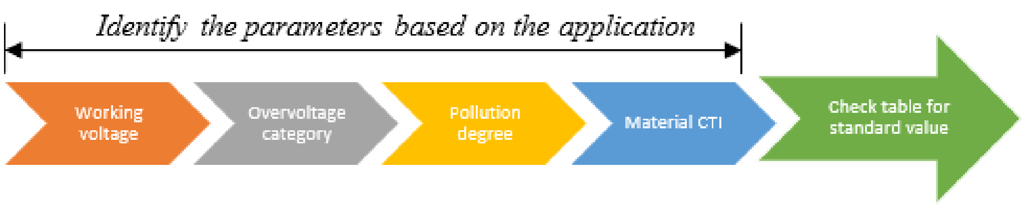
Key Factors:

- Working Voltage
  Higher voltages require larger creepage and clearance.
- Overvoltage Category (OVC)
  OVC II or OVC III typically applies to medical devices, influencing minimum clearance.
- Pollution Degree
  - *Pollution Degree 2*: Normal hospital environment (most medical devices).
  - *Pollution Degree 3*: Harsh environments, humid storage areas.
- CTI of Material
  Higher CTI allows reduced creepage distances.
- Altitude Consideration
  Devices used at higher altitudes require increased clearance to prevent flashover.

Design Approach

- Use IEC 60601-1 Tables to determine minimum creepage/clearance based on:

- Apply a safety margin to account for manufacturing tolerances and material aging.
- Referring to the IEC 60601-1 for creepage and clearance values.



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Creepage distances to avoid failure due to tracking. (4)

Voltage r.m.s.	Minimum creepage distance (in mm)								
	Printed wiring material								
	1	2	1	2			3		
	Pollution degree								
	All material groups	All material groups, expect IIIb	All material groups	Material group I	Material group II	Material group III	Material group I	Material group II	Material group III
10	0.025	0.04	0.08	0.4	0.4	0.4	1	1	1
12.5	0.025	0.04	0.09	0.42	0.42	0.42	1.05	1.05	1.05
16	0.025	0.04	0.1	0.45	0.45	0.45	1.1	1.1	1.1
20	0.025	0.04	0.11	0.48	0.48	0.48	1.2	1.2	1.2
25	0.025	0.04	0.125	0.5	0.5	0.5	1.25	1.25	1.25
32	0.025	0.04	0.16	0.53	0.53	0.53	1.3	1.3	1.3
40	0.04	0.063	0.18	0.6	0.85	1.2	1.5	1.7	1.9
50	0.04	0.063	0.2	0.63	0.9	1.25	1.6	1.8	2
63	0.04	0.063	0.22	0.67	0.95	1.3	1.6	1.9	2.2
80	0.04	0.1	0.25	0.71	1	1.4	1.8	2	2.2
100	0.1	0.16	0.25	0.71	1	1.4	1.8	2	2.2
125	0.16	0.25	0.28	0.75	1.05	1.5	1.9	2.1	2.4
160	0.25	0.4	0.32	0.8	1.1	1.6	2	2.2	2.5
200	0.4	0.63	0.42	1	1.4	2	2.5	3.2	3.2
250	0.56	1	0.56	1.25	1.8	2.2	3.2	4	3.2
320	0.75	1.6	0.75	1.6	2.2	3.2	4	5	5
400	1	2	1	2	2.8	4	5	6.3	7.9
500	1.3	2.5	1.3	2.5	3.6	5	6.3	8	8
630	1.8	3.2	1.8	3.2	4.5	6.3	8	9	10
800	2.4	4	2.4	4	5.6	8	11	9.6	12.5
1000	3.2	5	3.2	5	7.1	10	12.5	11.2	12.5
1250			4.2	6.3	9	12.5	16	14.4	20
1600			5.6	8	11	16	22	17.6	25
2000			7.5	10	14	20	25	20	32
2500			10	12.5	18	25	32	25.6	40
3200			12.5	16	22	32	40	36	50

Table 6: Creepage distances to avoid failure due to tracking.

Clearances to Withstand Voltages.

- *Clearances to withstand steady-state voltages, temporary over-voltages or recurring peak voltages (Table 7).*
- *Clearances to withstand transient over-voltages (Table 8).*

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Voltage (peak value) kV	Minimum clearance in air up to 2000m above sea level: Case A Homogeneous field conditions (sea level) mm See (3.15)	Minimum clearance in air up to 2000m above sea level: Case B non-homogeneous field conditions (sea level) mm See (3.14)
0.04	0.001	0.001
0.06	0.002	0.002
0.1	0.003	0.003
0.12	0.004	0.004
0.15	0.005	0.005
0.2	0.006	0.006
0.25	0.008	0.008
0.33	0.01	0.01
0.4	0.02	0.02
0.5	0.04	0.04
0.6	0.06	0.06
0.8	0.13	0.1
1	0.26	0.15
1.2	0.42	0.2
1.5	0.76	0.3
2	1.27	0.45
2.5	1.8	0.6
3	2.4	0.8
4	3.8	1.2
5	5.7	1.5
6	7.9	2
8	11	3
10	15	3.5
12	19	4.5
15	25	5.5
20	34	8
25	44	10
30	55	12.5
40	77	17
50	100	22
60	-	27
80	-	35
100	-	45

Table 7

Required Impulse withstand voltage 1) 5) KV	Minimum Clearances in air up to 2000m m above sea level: Case A Inhomogeneous Field See (3.15)			Case B Inhomogeneous Field See (3.14)		
	Pollution Degree [6)]			Pollution Degree [6)]		
	1 mm	2 mm	3 mm	1 mm	2 mm	3 mm
0.33 [2)]	0.01	0.2 [3)] [4)]	0.8 [4)]	0.01	0.2 [3)] [4)]	0.8 [4)]
0.4	0.02			0.02		
0.5 [2)]	0.04			0.04		
0.6	0.06			0.06		
0.8 [2)]	0.1			0.1		
1	0.15			0.15		
1.2	0.25	0.25		0.2		
1.5 [2)]	0.5	0.5		0.3	0.3	
2	1	1	1	0.45	0.45	
2.5 [2)]	1.5	1.5	1.5	0.6	0.6	
3	2	2	2	0.8	0.8	
4 [2)]	3	3	3	1.2	1.2	1.2
5	4	4	4	1.5	1.5	1.5
6 [2)]	5.5	5.5	5.5	2	2	2
8 [2)]	8	8	8	3	3	3
10	11	11	11	3.5	3.5	3.5
12 [2)]	14	14	14	4.5	4.5	4.5
15	18	18	18	5.5	5.5	5.5
20	25	25	25	8	8	8
25	33	33	33	10	10	10
30	40	40	40	12.5	12.5	12.5
40	60	60	60	17	17	17
50	75	75	75	22	22	22
60	90	90	90	27	27	27
80	130	130	130	35	35	35
100	170	170	170	45	45	45

Table 8

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In medical device design, the required insulation distances must be determined with consideration of both Means of Operator Protection (MOOP) and Means of Patient Protection (MOPP). These factors are critical in maintaining safe distances between conductive parts to prevent electrical hazards such as arcing, tracking, or dielectric breakdown.

Type of Protection: MOOP vs. MOPP

1) **Means of Operator Protection (MOOP)** focuses on protecting the device operator from electrical hazards. The distance requirements for MOOP are less stringent and can be aligned with IEC 61010-1 (safety for measurement and control equipment).
2) **Means of Patient Protection (MOPP)** is much stricter because patients may have direct or indirect contact with device circuits, often in vulnerable physical conditions. MOPP demands greater creepage and clearance distances and more robust insulation barriers.

- **Single vs. Double Protection:**
  - **1 x MOOP or 1 x MOPP:** One layer of protection.
  - **2 x MOOP or 2 x MOPP:** Two independent layers of protection, usually achieved through physical separation, redundant insulation, or reinforced barriers.

Considering distances based on MOPP and MOOP (4)

Working Voltage V.d.c. up to and including	Working Voltage V.r.m.s. up to and including	Spacing providing one Means of Patient protection		Spacing providing two Means of Patient protection	
		Cripage Distance mm	Air Clearance mm	Cripage Distance mm	Air Clearance mm
17	12	1.7	0.8	3.4	1.6
43	30	2	1	4	2
85	60	2.3	1.2	4.6	2.4
177	125	3	1.6	6	3.2
354	250	4	2.5	8	5
566	400	6	3.5	12	7
707	500	8	4.5	16	9
934	660	10.5	6	21	12
1061	750	12	6.5	24	13
1414	1000	16	9	32	18
1768	1250	20	11.4	40	22.8
2263	1600	25	14.3	50	28.6
2828	2000	32	18.3	64	36.6
3535	2500	40	22.9	80	45.8
4525	3200	50	28.6	100	75.2
5656	4000	63	36	126	72
7070	5000	80	45.7	160	91.4
8909	6300	100	57.1	200	114.2
11312	8000	125	71.4	250	142.8
14140	10000	160	91.4	320	182.8

Table 9: Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF PATIENT PROTECTION (MOPP)

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Working Voltage V r.m.s or d.c.	Spacing for one means of operator Protection						
	Pollution Degree 1	Pollution Degree 2			Pollution Degree 3		
	Material Group	Material Group			Material Group		
	I, II, IIIa, IIII b	I	II	IIIa or IIII b	I	II	IIIa or IIII b
50	Use the CLEARANCE from appropriate table	0.6	0.9	1.2	1.5	1.7	1.9
100		0.7	1	1.4	1.8	2	2.2
125		0.8	1.1	1.5	1.9	2.1	2.4
150		0.8	1.1	1.6	2	2.2	2.5
200		1	1.4	2	2.5	2.8	3.2
250		1.3	1.8	2.5	3.2	3.6	4
300		1.6	2.2	3.2	4	4.5	5
400		2	2.8	4	5	5.6	6.3
600		3.2	4.5	6.3	8	9.6	10
800		4	5.6	8	10	11	12.5
1000		5	7.1	10	12.5	14	16
NOTE: Minimum Creepage distances for two means of operator protection are obtained by doubling the values in this table							
Creepage distance within this table applies to all situations							

Table 10: Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION (MOOP)

Working Voltage up to and including		Nominal mains Voltage <=150V (Mains transient voltage 1500V)				150V< Nominal mains voltage <=300V (Mains transient voltage 2500V)		300V< Nominal mains voltage <=600V (Mains transient voltage 4000V)	
Voltage peak or d.c	Voltage r.m.s (sinusoidal)	Pollution degree 1 & 2		Pollution degree 3		Pollution degree 1,2 & 3		Pollution degree 1,2 & 3	
		One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP
210	150	1	2	1.3	2.6	2	4	3.2	6.4
420	300	1 MOOP 2, 0 2 MOOP 4,0						3.2	6.4
840	600	1 MOOP 3,2 2 MOOP 6,4							
1400	1000	1 MOOP 4,2 2 MOOP 6,4							
2800	2000	1 OR 2 MOOP 8,4							
7000	5000	1 OR 2 MOOP 17,5							
9800	7000	1 OR 2 MOOP 25							
14000	10000	1 OR 2 MOOP 37							
28000	20000	1 OR 2 MOOP 80							
AIR CLEARANCES for WORKING VOLTAGES above 20kV r.m.s. or 28kV d.c. Can be prescribed by standards if necessary									
NOTE: AIR CLEARANCES are a function of peak voltage in the circuit. The r.m.s. voltage column is provided for the special case where the voltage has a sinusoidal waveform									

Table 11: Minimum CLEARANCE DISTANCES providing MEANS OF OPERATOR PROTECTION (MOOP from the MAINS PART

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Working Voltage V d.c. up to and including	Working Voltage V.r.m.s up to and including	Creepage Distance mm	Air Clearance mm
17	12	0.8	0.4
43	30	1	0.5
85	60	1.3	0.7
177	125	2	1
354	250	3	1.6
566	400	4	2.4
707	500	5.5	3
934	660	7	4
1061	750	8	4.5
1414	1000	11	6

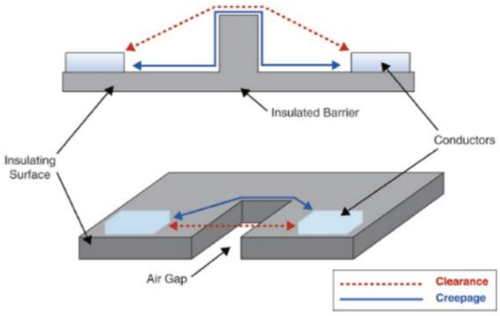
Table 12: Minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART

Note: Refer Table 12 When calculating distances within the mains circuit (before the transformer or isolation barrier.

B. Influence of Housing Geometry

B-1. Ribbing, Slots, and Barriers

Ribs and physical barriers are used to increase the *creepage distance* (the path along an insulating surface) without increasing the overall footprint of the device.
By adding ribs or walls to the insulating surfaces (either in the PCB or in the housing), the creepage path is forced to travel over, around, or along additional surfaces. This mechanically extends the distance that a potential tracking arc would need to cover.
Ribs effectively increase creepage without changing the horizontal dimensions, which is highly valuable in compact medical devices.
IEC 60601-1 and IEC 60664-1 both recognize ribs as valid creepage-increasing features if they meet certain geometric criteria.



Ref: Selecting Power Supplies for Medical Equipment Designs - Medical Design

Design Guidelines:
For Ribs and Barriers

- Rib-height should be at least equal to or greater than the required creepage addition.
- The spacing between ribs should prevent electric field concentration.
- Proper venting is essential near ribs to avoid condensation or dirt accumulation that could lower the insulation strength.

For Slots

- The slot must pass entirely through the insulating material to be considered.

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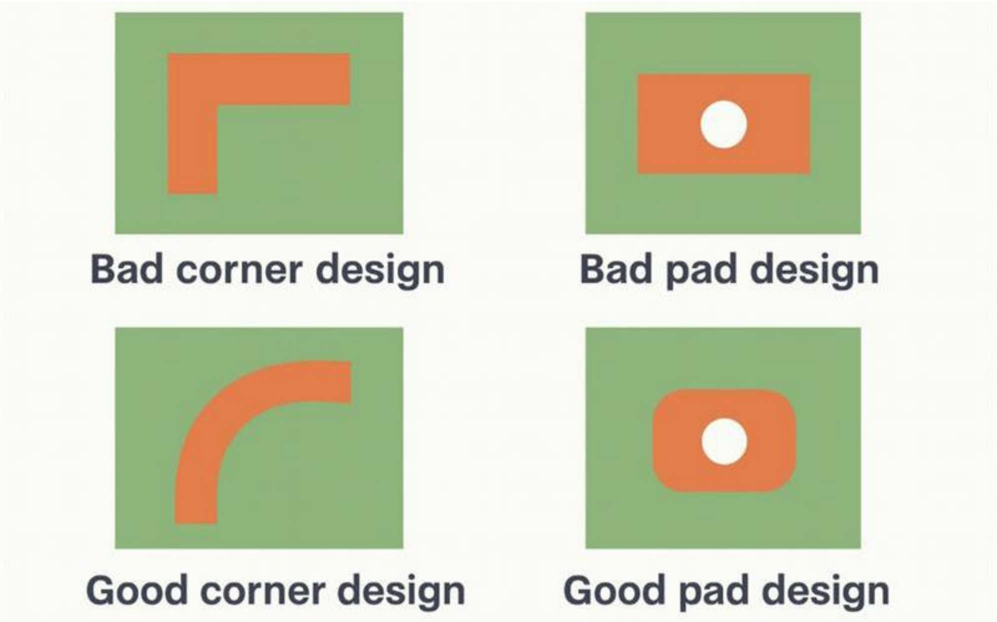
- The slot must be wide enough (typically >1 mm) to prevent moisture bridging.
- Slots must be free of sharp edges, burs, or residues that could degrade insulation.
- If the slot is in a PCB, no conductive layers should remain in the slot area.

B-2. Sharp Edges and Corners

Sharp edges concentrate electric fields and can cause premature dielectric breakdown.
Electrical field strength is intensified at sharp corners, which lowers the local breakdown voltage of air or insulating materials. This phenomenon is particularly problematic in high-voltage applications where even slight field intensifications can cause flashover or corona discharge.
Rounded geometries help distribute the electric field more uniformly, raising the effective breakdown voltage.

Design Guidelines:

- Avoid right-angle corners on conductive tracks or housing cutouts near high-voltage areas.
- Use rounded edges (fillets or chamfers) on housings and metal parts.
- Ensure that no pointed metal protrusions (like solder spikes or improperly trimmed leads) are present near high-voltage areas.



Ref: 4 Common PDN Design Challenges | Sierra Circuits

B-3. Surface Finish

Surface finishes play a critical role in insulation performance, tracking resistance, and long-term reliability. Surface quality directly impacts the likelihood of tracking, contamination retention, and dielectric breakdown. Rough or porous surfaces can trap contaminants and create micro-paths for electrical leakage.
PCB surface finishes (such as HASL, ENIG, and OSP) and housing surface textures can either reduce or increase the risk of electrical tracking, depending on their properties and application.

Design Guidelines:

Use smooth, non-porous materials for insulating housing and barriers.
Select PCB finishes that minimize surface irregularities – ENIG (Electroless Nickel Immersion Gold) is superior to HASL (Hot Air Solder Leveling) in this regard.
Avoid uncoated or exposed rough plastic near high-voltage areas.
Proper cleaning during manufacturing is crucial – residual flux can drastically reduce surface insulation resistance.

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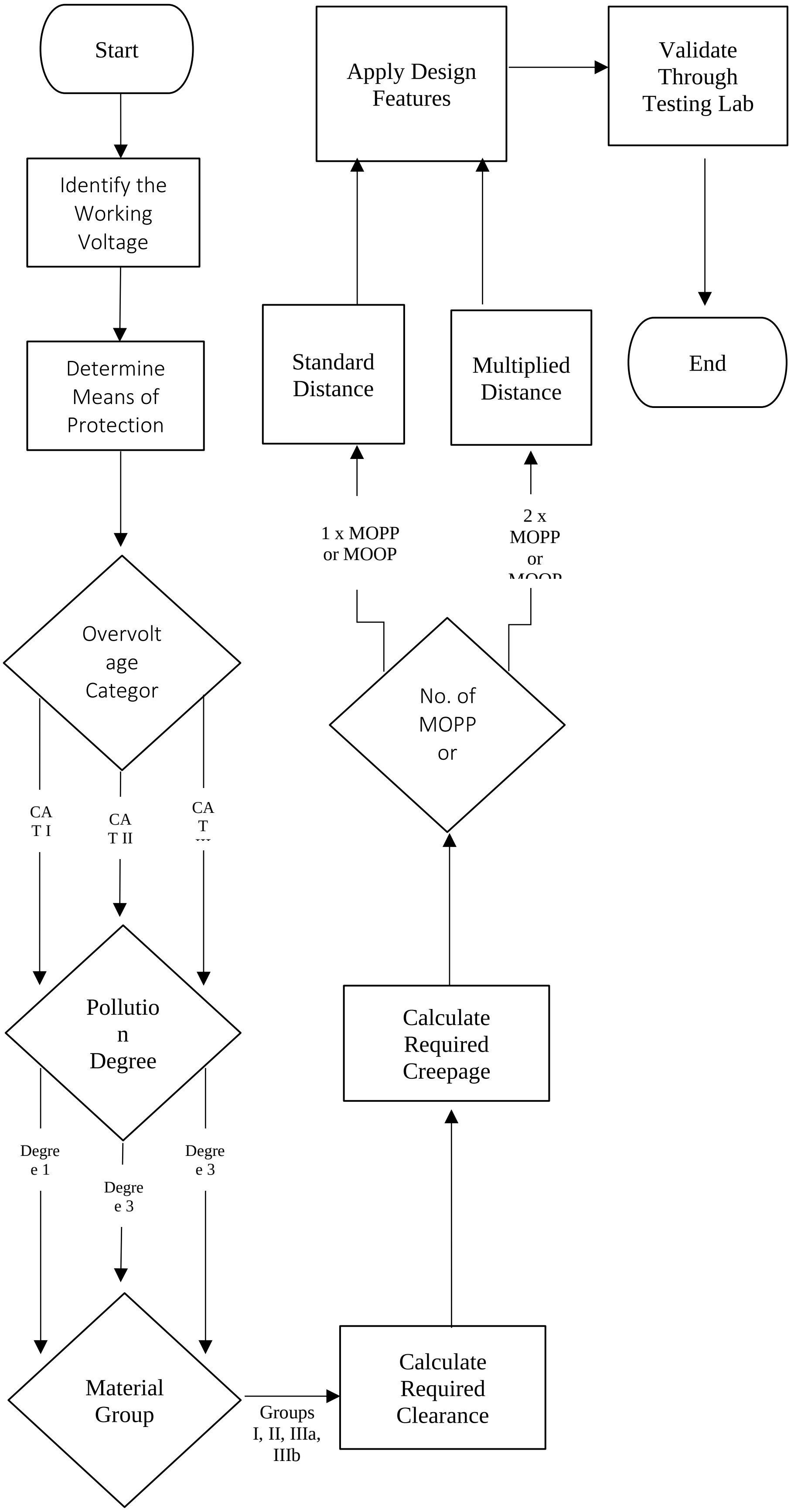
C. Flowchart to guide the selection of creepage and clearance distances.



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IV. CONCLUSION

High-voltage isolation and the precise selection of creepage and clearance distances are essential for ensuring the safety and long-term reliability of medical devices. This white paper has outlined the critical role of international standards such as **IEC 60601-1** and **IEC 61010-1** in guiding design practices that protect both patients and operators from electrical hazards.

The selection of creepage and clearance distances is not arbitrary but must be based on a combination of standardized parameters, including:

- **Working voltage** (either main or secondary circuit, depending on the insulation barrier)
- **Overvoltage category**
- **Pollution degree** of the operating environment
- **Material group**, classified by Comparative Tracking Index (CTI)
- The required level of protection (**MOOP or MOPP**)

Design features like ribbing and barriers allow designers to increase the effective creepage distance without increasing the overall device size. The surface finish of insulating materials must also be optimized to reduce the risk of tracking and surface degradation over time.

The use of protective coatings and surface treatments compatible with IEC standards further enhances insulation performance, especially for plastic and cast components in housing.

In conclusion, the systematic calculation and careful selection of creepage and clearance distances are not merely compliance steps but essential design activities that directly impact the safety, reliability, and regulatory success of medical devices. A methodical, standards-driven approach supported by smart material choices, detailed geometry planning, and adherence to IEC requirements ensures safe, efficient, and durable device performance throughout the product lifecycle.

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BIOGRAPHY

Mahendra Ingale is a Mechanical Technical Lead at eInfochips, with over 15 years of experience in R&D focused on electromechanical product design and development, particularly in medical devices. He holds a bachelor's degree in mechanical engineering from Pune University. Mahendra's work emphasizes the development of safe, reliable, and high-performance products, with deep expertise in high-voltage isolation, and compliance with creepage and clearance standards. His research and project experience demonstrate a strong commitment to addressing electrical safety challenges and advancing innovation in medical device design.