

# IEC standards - IEC 60601

## Safety Class II

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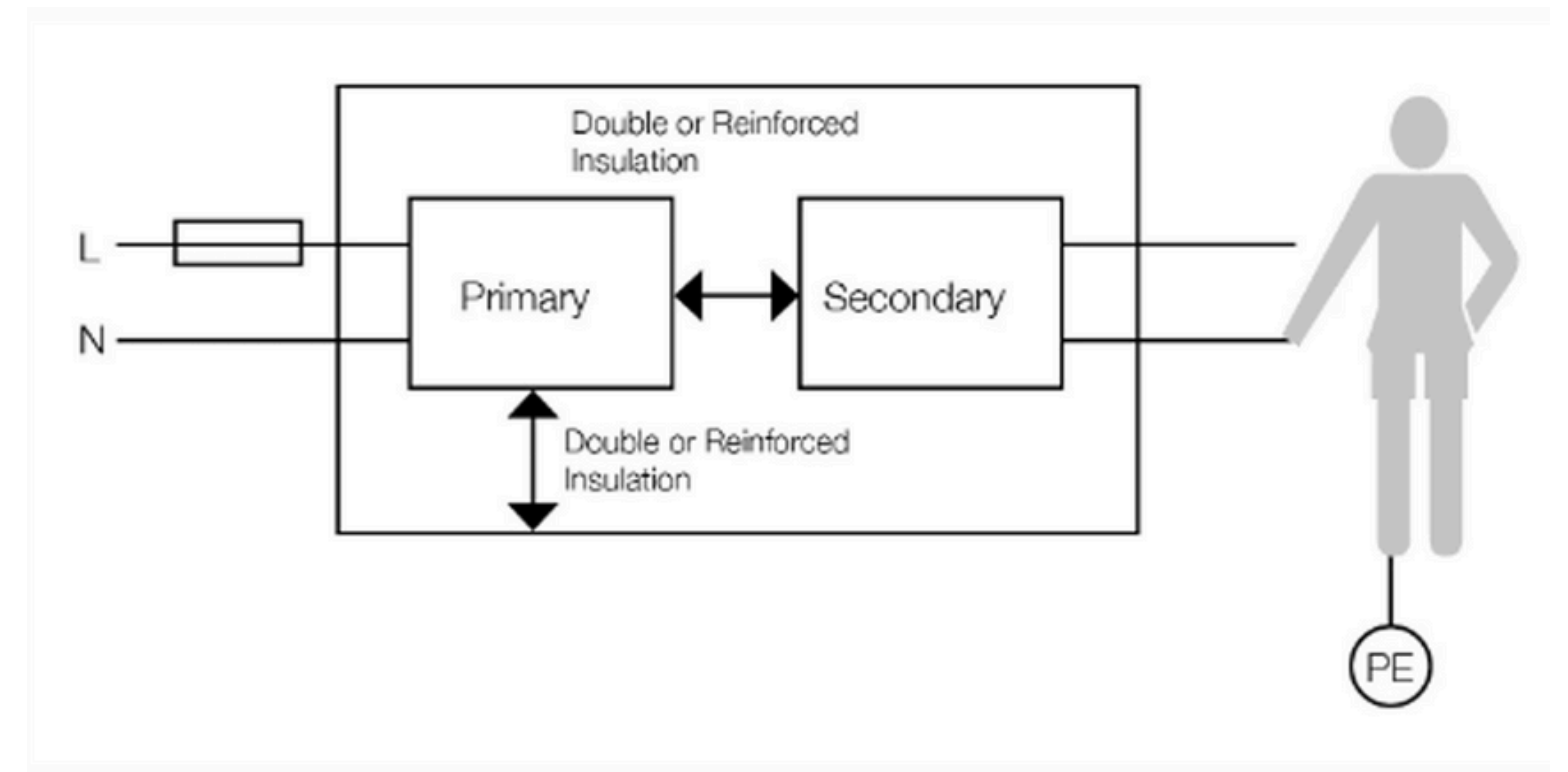


# Definition of Class II Equipment

“Electrical equipment in which protection against electric shock does not rely on basic insulation only; additional precautions such as double or reinforced insulation are provided, with no provision for protective earthing.”

## Key idea:

Safety is achieved through insulation integrity, not earthing.



# Concept of Double Insulation and Reinforced Insulation

## Basic insulation:

- Primary barrier between live conductors and accessible parts.
- Prevents electric shock in normal operating conditions.

## Supplementary insulation:

- Independent second barrier added in case the basic insulation fails.
- Maintains safety under single-fault condition.

## Double Insulation

- Combination of **basic + supplementary** insulation.
- Provides two Means of Protection (MOP) against electric shock.
- Common in plastic-housed portable devices (e.g., monitors, pumps).

## Reinforced Insulation

- A **single insulation system** designed and tested to provide **the same protection as double insulation**.
- Saves space while offering **two MOP in one layer** (used in transformers, cables, PCB layouts).

## Safety Outcome

Even if one barrier breaks down, current cannot reach the patient or metal enclosure. Ensures continuous protection in both normal and fault conditions.

# Construction Features of Class II Equipment

## 1 No Protective-Earth Conductor

- Class II equipment does not rely on an earth connection for safety.
- The design ensures protection through insulation barriers instead.

## 2 Double / Reinforced Insulation

- All accessible conductive parts are completely isolated from live circuits.
- Even under a single-fault condition, the user or patient cannot touch a live surface.

## 3 Creepage & Clearance

- Both must comply with IEC 60601-1 Tables 7–12, ensuring adequate spacing to prevent arcing or tracking.

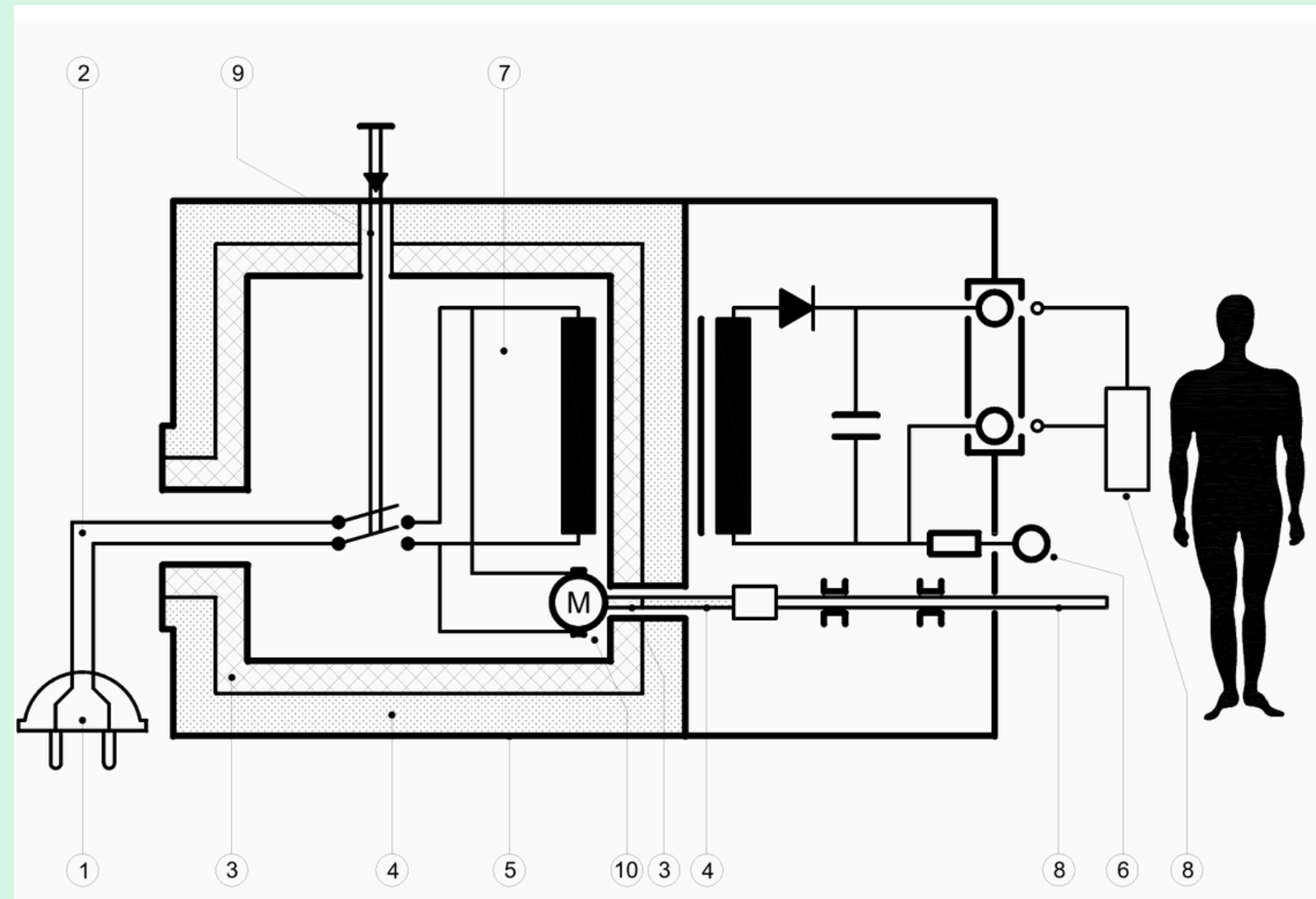
## 4 Design Integrity

- Layouts and materials selected to maintain insulation over device lifetime. resisting heat, humidity, and mechanical stress.

## 5 Enclosure Material

- Plastic or composite housings are preferred. lightweight, durable, and inherently insulating.
- If metal chassis is used, it must be fully encapsulated or double-insulated to prevent accidental contact.

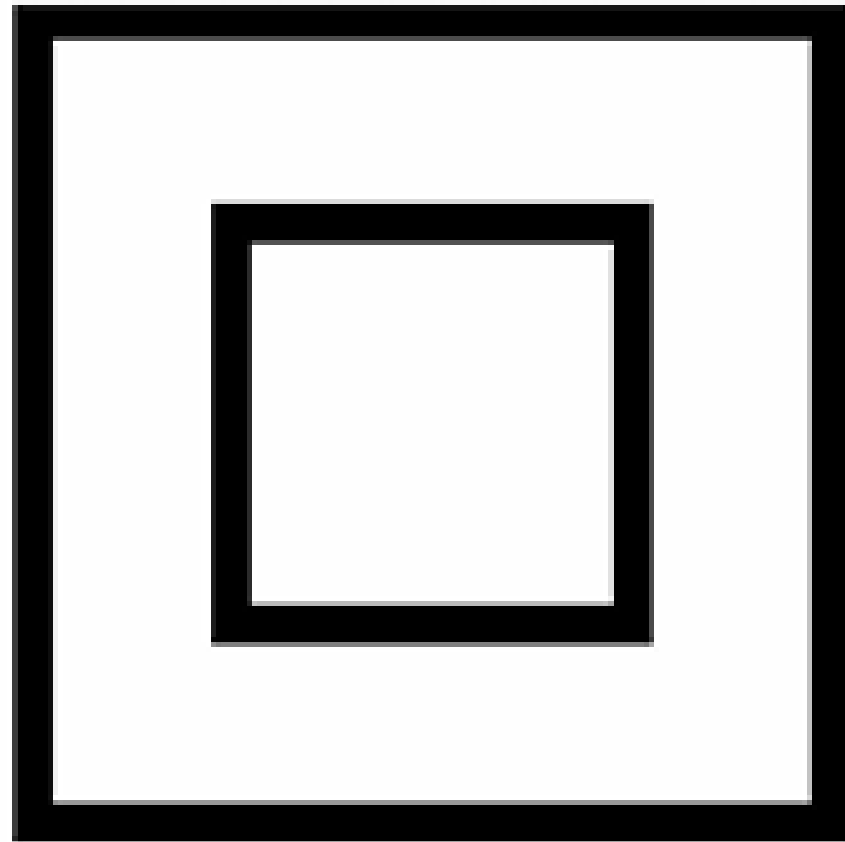
# Internal Design Elements of Class II Devices



- |   |                           |
|---|---------------------------|
| ① | MAINS PLUG                |
| ② | POWER SUPPLY CORD         |
| ③ | BASIC INSULATION          |
| ④ | SUPPLEMENTARY INSULATION  |
| ⑤ | ENCLOSURE                 |
| ⑥ | FUNCTIONAL EARTH TERMINAL |
| ⑦ | MAINS PART                |
| ⑧ | APPLIED PART              |
| ⑨ | REINFORCED INSULATION     |
| ⑩ | Motor                     |

- Every conductive path from the mains to the patient or operator passes through two independent insulation barriers.
- The functional earth exists only for electromagnetic compatibility, not protection.
- Even in a single-fault condition, no current can reach the patient.

# Marking and Identification



The symbol for class II equipment is 2 concentric squares indicating double insulation as shown in the image.

- Must appear on:
  - Equipment enclosure
  - Rating plate and accompanying documents
- Warns users that no earth connection should be made

# Testing Requirements for Class II Equipment

Test	Purpose	Typical Standard / Limit
<b>Dielectric Strength Test</b>	Ensures insulation can safely withstand high voltages between live parts and accessible surfaces.	4–5 kV AC for 1 minute
<b>Insulation Resistance Test</b>	Checks insulation material quality and verifies no moisture or contamination.	$\geq 50 \text{ M}\Omega$ at 500 V DC
<b>Leakage Current Test</b>	Confirms that touch and patient currents remain within safe levels during operation.	$\leq 0.1 \text{ mA}$ (touch); $\leq 0.01 \text{ mA}$ (patient)
<b>Creepage &amp; Clearance Verification</b>	Measures spacing between conductive parts to prevent arcing and tracking.	$\geq 8 \text{ mm}$ (mains to accessible parts)
<b>Single Fault Condition Test</b>	Simulates failure of one insulation barrier to confirm continued protection.	No electric shock hazard allowed