# Medical Approval Introducation

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## A. Medical General Introducation

The new IEC60601-1 3rd edition standard is standard for medical electrical equipment that has been adopted globally, and published as the following versions:

USA: ANSI/AAMI ES 60601-1:2005
EU: EN60601-1:2005
Canada: CSA-C22.2 No. 60601-1:08

The major impact of 3rd edition is made between **operator** and **patient**.

As result ：

**Means of Protection (MOP)**
**Means of Patient Protection (MOPP)**
**Means of Operator Protection (MOOP)**

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

In either case, the insulation between **PRIMARY** to **SECONDARY** must meet at least 2 x MOP（MOOP/MOPP）under and at least 1 x MOP （MOOP/MOPP）between PRIMARY to FG at normal conditions. It is shown as below:

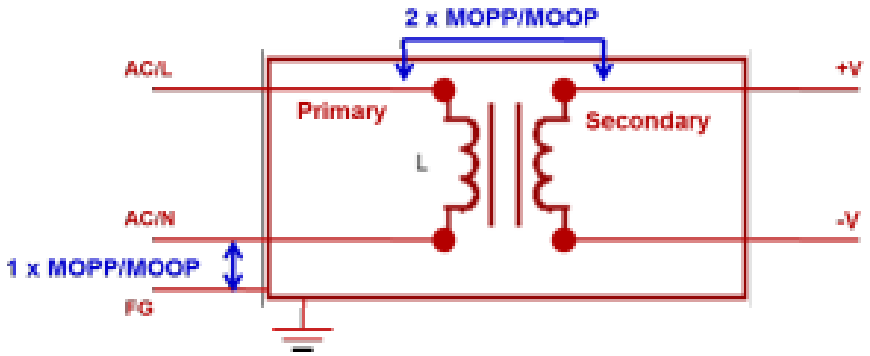


Figure 1.

# B. Terms and Classification of MOP (MOOP/MOPP) of 3rd Edition

## B.1 Terms

Creepage : the shortest path between two conductive parts measured along the surface of the insulation.
Clearance : the shortest distance through air between two conductive parts.

## B.2 Classification

| 3rd EDITION REQUIREMENTS BY CLASSIFICATION | | | | |
|---|---|---|---|---|
| CLASSIFICATIONS | ISOLATION | CREEPAGE | CLEARANCE | INSULATION |
| 1 x MOOP | 1500 Vac | 2.5mm | 2mm | Baisc |
| 2 x MOOP | 3000 Vac | 5mm | 4mm | Double |
| 1 x MOPP | 1500 Vac | 4mm | 2.5mm | Baisc |
| 2 x MOPP | 4000 Vac | 8mm | 5mm | Double |

# C. Terms and Classification of 2nd Edition

## C1. Terms

B type : "B" (body) equipment operates within the vicinity, but without patient contact
BF type : "BF" (body floating) equipment makes physical contact with the patient
CF Type : "CF" (cardiac floating) makes physical contact with the heart.

## C2. Classification

| 2nd EDITION REQUIREMENTS BY CLASSIFICATION | | | | | | |
|---|---|---|---|---|---|---|
| CLASSIFICATIONS | Type B | | Type BF | | Type CF | |
| ISOLATION | Input-Output: 4000 Vac<br>Input-GND : 1500 Vac<br>Output-GND : 500 Vac | | Input-Output: 4000 Vac<br>Input-GND : 1500 Vac<br>Output-GND : 1500 Vac | | Input-Output: 4000 Vac<br>Input-GND : 1500 Vac<br>Output-GND : 1500 Vac | |
| Description | No electrical contact with Patient and maybe earthed | | Electrically connected to Patient but not directly to heart | | Electrically connected to the heart of the Patient | |
| Leakage Current | NC | SFC | NC | SFC | NC | SFC |
| Earth Leakage current | 500uA | 1mA | 500uA | 1mA | 500uA | 1mA |
| Enclosure Leakage current | 100uA | 500uA | 100uA | 500uA | 100uA | 500uA |
| Patient Leakage current | 100uA | 500uA | 100uA | 500uA | 10uA | 50uA |

NC=Normal Conditions SFC=Single Fault Conditions

# D. COSEL Medical Power Supply

## D.1 COSEL Medical Power supply List

| COSEL Medical Power Supply Classification | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| No. | Series | Isolation | Isolation Voltage | Measured Creepage (mm) | Measured Clearance (mm) | Isolation Type | Safety Approval Status | | | |
| | | | | | | | Approval | | Report Availability | |
| | | | | | | | 2nd | 3rd | 2nd | 3rd |
| 1 | PMA | Pri-Sec | AC4KV | 8.4 | 7.2 | 2*MOOP | √ | √ | √ | √ |
| | | Pri-GND | AC2KV | 3.3 | 3.3 | 1*MOOP | | | | |
| 2 | LMA | Pri-Sec | AC4KV | 6.4 | 5.9 | 2*MOOP | | √ | | √ |
| | | Pri-GND | AC2KV | 4.8 | 4.3 | 1*MOOP | | | | |
| 3 | GHA | Pri-Sec | AC4KV | 8 | 8 | 2*MOPP | | √ | √ | √ |
| | | Pri-GND | AC2KV | 6 | 6 | 1*MOPP | | | | |
| 4 | GMA | Pri-Sec | AC4KV | 8.1 | 7 | 2*MOPP | | √ | | √ |
| | | Pri-GND | AC2KV | 5.5 | 4.7 | 1*MOPP | | | | |
| 5 | PCA | Pri-Sec | AC4KV | 8 | 8 | 2*MOPP | | √ | | √ |
| | | Pri-GND | AC2KV | 4 | 4 | 1*MOPP | | | | |
| 6 | ACE-H (output) | Pri-Sec | AC4KV | 8 | 8 | 2*MOOP | √ | √ | √ | √ |
| | | Pri-GND | AC2KV | 5 | 5 | 1*MOOP | | | | |

For equipment used within laboratory environment without contacting patients, a power supplies that meet 2 x MOOP standard.

A power supplies that meet 2 x MOPP standards provide the highest level of protection. It can be advantageous to specify a 2 x MOPP power supply because it can cover most of medical applications.

D.2 Medical Approval Request Fuse in COSEL Medical Power Supply.

Medical Standard requires fuse for Line and Nuetral line both, as below table.

| Model | Fuse |
|---|---|
| PMA | Dual |
| LMA | Dual |
| GHA | Dual |
| GMA | Dual |
| PCA | Dual |
| ACE-H | Single (Live line) *1 |

When using ACE as medical PSU, please put fuse in nuetral line as shown in instruction manual.