Introduction to Applied Part (AP)
Type B, BF & C

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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 3 classification types of Applied Parts:

- **Type B** – No electrical contact with Patient and maybe earthed
- **Type BF** – Electrically connected to Patient but not directly to hear
- **Type CF** – Electrically connected to the heart of the Patient

Power supplies are not medical devices or applied parts, and the outputs of power supplies should never be connected directly to a patient. Many medical devices contain medical-rated power supplies. However, only the part of these "medical devices" that may come in contact with a patient during normal operation is classified as an "Applied Part."

It is the responsibility of the medical product manufacturer to determine the classification of AP types (B/BF/CF) in the final product with proper evaluation.

In order for ended medical electrical system to apply for desired AP types, Power Supplies must meet these 2 requirements which are (1) leakage current and (2) insulation between Secondary output to protective earth (FG).

In AC-connected power supply there will be leakage current caused by capacitive coupling across power transformers and by the Y-class filter capacitors that are necessary to maintain EMC performance. 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 Table 1.

Table 1.

Leakage Current	Type B		Type BF		Type CF	
	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

In addition to leakage current requirement, power supply also needs to meet the isolation level provided in Table 2.

Table 2.

Type	Input to Output Isolation	Input to Ground Isolation	Output to Ground Isolation
B rated	4000VAC (2 x MOPP)	1500VAC (1 x MOPP)	500VAC
BF/CF rated	4000VAC (2 x MOPP)	1500VAC (1 x MOPP)	1500VAC (1 x MOPP)

Again, power supplies are not medical devices or applied parts. Although the power supply meets both leakage-current and isolation, the ended system is still required to further evaluate and confirm the compliance of AP types (B/BF/CF).

MEAN WELL has a board range of power supplies which is suited for BF applications. Please contact MEAN WELL authorized distributors or sale representatives for more information.