



RIGEL MEDICAL
GMC-INSTRUMENTS GROUP

What are the definitions and symbols commonly used in IEC 60601 and IEC 62353?

Equipment Under Test - The equipment (EUT) which is the subject of testing.

Device Under Test - The device (DUT) which is the subject of testing.

Applied Part - Part of the medical equipment, which is designed to come into physical contact with the patient, or parts that are likely to be brought into contact with the patient.

Patient Connection - Individual physical connections and / or metal parts intended for connection with the patient, which form (part of) an Applied Part.

Patient Environment - Volumetric area in which a patient can come into contact with medical equipment or contact can occur between other persons touching medical equipment and the patient, both intentional and unintentional. (see Appendix E)

F-Type Applied Part - Applied Part which is electrically isolated from Earth and other parts of the medical equipment. i.e. floating. F-type Applied Parts are either type BF or type CF Applied Parts.

Type B Applied Part - Applied Part complying with specified requirements for protection against electric shock. Type B Applied Parts are those parts, which are usually Earth referenced. Type B are those parts not suitable for direct cardiac application.

Type BF Applied Part - F Type Applied Part complying with a higher degree

of protection against electric shock than type B Applied Parts. Type BF Applied Parts are those parts not suitable for direct cardiac application.

Type CF Applied Part - F Type Applied Part complying with the highest degree of protection against electric shock. Type CF Applied Parts are those parts suitable for direct cardiac application.

Medical Electrical Equipment - Electrical equipment, designed for treatment, monitoring or diagnoses of patients, powered from not more than one connection to mains supply and which are necessarily in physical or electrical contact with the patient or transfers energy to or from the patient or detects such energy transfer to or from the patient.

Medical Electrical System - Combination of equipment of which at least one is classed as medical electrical equipment and as such specified by the manufacturer to be connected by functional connection or use of a multiple portable socket-outlet.

Class I - Equipment protection against electric shock by (earthed) additional protection to basic insulation through means of connecting exposed conductive parts to the protective Earth in the fixed wiring of the installation.

Class II - Also referred to as Double Insulated. Equipment protection against electric shock by additional protection to basic insulation through means of supplementary insulation are provided, there being no provision for the connection of exposed metalwork of the equipment to a protective conductor and no reliance upon precautions to be taken in the fixed wiring of the installation.

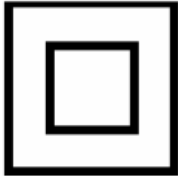
Commonly used symbols and markings in IEC 60601 and IEC 62353:



Class I



Earth
Reference
point



Class II



i.e.
"Conformité
Européenne"



Type B
Applied
Part



Defibrillation
proof type B
Applied Part



Type
BF
Applied
Part



Defibrillation
proof type
BF Applied
Part



Type
CF
Applied
Part



Defibrillation
proof type
CF Applied
Part

Figure 1: Commonly used symbols and markings

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