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SYNOPSIS

Doc: MHD 15 (12816) IS 13450 (Part 1/Sec 8): 2019/ IEC 60601-1-8 : 2006 - Medical Electrical Equipment Part 1 General Requirements for the Basic Safety and Essential Performance Section 8 Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

a) Scope:

This Indian Standard applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems, hereafter referred to as ME equipment and ME systems.

This collateral standard specifies requirements for alarm systems and alarm signals in ME equipment and ME systems.

b) Salient features of content:

The objective of this collateral standard is to specify basic safety and essential performance requirements and tests for alarm systems in ME equipment and ME systems and to provide guidance for their application. This is accomplished by defining alarm categories (priorities) by degree of urgency, consistent alarm signals and consistent control states and their marking for all alarm systems.

This collateral standard does not specify:

- a) whether any particular ME equipment and ME system is required to be provided with alarm systems
- b) the particular circumstances which initiate an alarm condition
- c) the allocation of priorities to a particular alarm condition
- d) the means of generating alarm signals

c) Type/grades/classes, if any covered in the standard: Nil.

d) Disclaimer (to be automatically provided by the program/ software)

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