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SYNOPSIS

Doc: MHD 15 (12817) IS 13450 (Part 1/Sec 10) : 2019/ IEC 60601-1-10 : 2007 - Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 10 Collateral standard: Requirements for the development of physiologic closed-loop controllers

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 the development (analysis, design, verification and validation) of a Physiologic Closed Loop Controller (PCLC) as part of a Physiologic Closed Loop Controller System (PCLCS) in ME Equipment's and ME Systems to control a Physiologic Variable.

b) Salient features of content:

This collateral standard applies to various types of PCLC, e.g. linear and non-linear, adaptive, fuzzy, neural networks.

This collateral standard does not specify:

- a) Additional mechanical requirements
- b) Additional electrical requirements.

This collateral standard applies to a closed-loop controller that sets the Controller Output Variable in order to adjust (i.e., change or maintain) the measured Physiologic Variable by relating it to the Reference Variable.

A closed-loop controller that maintains a physical or chemical Variable, using feedback that is not measured from a Patient, is outside the scope of this standard

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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