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The number of continuously measuring non-invasive automated

sphygmomanometers has increased significantly in the last 10

years. This standard is intended to provide the necessary

requirements for clinical investigation to ensure that the essential

performance of these sphygmomanometers is at an adequate level,

similar to those standards on intermittent automated non-invasive

sphygmomanometer .

ISO/DIS 81060-3(en). Non-invasive sphygmomanometers ? Part ...

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The standard ISO 81060-2 "Non-invasive sphygmomanometers" Part2: Clinical validation of the automated measurement type (ISO in preparation). All three standards are expected to become European harmonized standards in the near future. The ISO 81060-1 addresses requirements for the alternative non-automated sphygmomanometers. Because these requirements are identical for all possible manometers, they include requirements for accuracy of the cuff pressure measurement and for the resistance to ...

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by means of an inflatable cuff, are used for non continuous indirect estimation of the blood pressure without ...

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IEC 80601-2-30:2018 applies to the basic safety and essential performance of automated sphygmomanometers, hereafter referred to as ME equipment, which by means of an inflatable cuff, are used for non continuous indirect estimation of the blood pressure without arterial puncture. This document specifies requirements for the basic safety and essential performance for this ME equipment and its accessories, including the requirements for the accuracy of a determination.

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me equipment used for the intermittent non-invasive automated estimation of the arterial blood pressure by utilizing a cuff. This document is applicable to all sphygmomanometers that sense or display pulsations, flow or sounds for the estimation, display or recording of blood pressure. These sphygmomanometers need not have automatic cuff inflation.

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## Recognized Consensus Standards

IEC 80601-2-30:2009 Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers; ISO 80601-2-55:2011 Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

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This part of the 80601 International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of AUTOMATED SPHYGMOMANOMETERS, hereafter referred to as ME EQUIPMENT, which by means of an inflatable CUFF, are used for non-continuous indirect estimation of the BLOOD PRESSURE without arterial puncture.

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