

IEC 80601-2-71:2015-06 (E)

Medical electrical equipment - Part 2-71: Particular requirements for the basic safety and essential performance of functional Near-Infrared Spectroscopy (NIRS) equipment

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
201.1 Scope, object and related standards.....	7
201.2 Normative references.....	9
201.3 Terms and definitions.....	9
201.4 General requirements.....	12
201.5 General requirements for testing ME EQUIPMENT.....	12
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	12
201.7 ME EQUIPMENT identification, marking and documents.....	12
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	12
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	13
201.10 Protection against unwanted and excessive radiation HAZARDS.....	13
201.11 Protection against excessive temperatures and other hazards.....	13
201.12 ACCURACY of controls and instruments and protection against hazardous outputs.....	13
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT.....	21
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	21
201.15 Construction of ME EQUIPMENT.....	21
201.16 ME SYSTEMS.....	21
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	21
Annexes.....	22
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	22
Annex AA (informative) Particular guidance and rationale.....	23
Annex BB (normative) Evaluating ME EQUIPMENT performance using the FUNCTIONAL NIRS PHANTOM.....	25
Annex CC (informative) Reference to the essential principles.....	34
Bibliography.....	36
Index of defined terms.....	37

Figure 201.101 – FULL WIDTH AT HALF MAXIMUM of spectral power distribution	10
Figure 201.102 – Measurement of AVERAGE OPTICAL POWER	14
Figure 201.103 – Measurement of PEAK WAVELENGTH and FWHM	15
Figure 201.104 – Measurement of signal stability	16
Figure 201.105 – Measurement of RESPONSE TIME.....	17
Figure 201.106 – Rise time and fall time in RESPONSE TIME.....	18
Figure 201.107 – Measurement of signal-to-noise ratio	19
Figure 201.108 – Measurement of SIGNAL CROSS-TALK.....	21
Figure 201.BB.1 – The FUNCTIONAL NIRS PHANTOM in two states with different detected light intensities	28
Figure BB.2 – FUNCTIONAL NIRS PHANTOM measurement using the reference system	29
Figure BB.3 – FUNCTIONAL NIRS PHANTOM measurement using the ME EQUIPMENT to be evaluated	29
Figure BB.4 – Schematic for measurement of OPTICAL LOSS	32
Table 201.101 – Performance tests employing the FUNCTIONAL NIRS PHANTOM or attenuator and the required OPTICAL LOSS	13
Table 201.C.101 – Marking on the outside of FUNCTIONAL NIRS EQUIPMENT or their parts.....	22
Table 201.C.102 – ACCOMPANYING DOCUMENTS, instructions for use of FUNCTIONAL NIRS EQUIPMENT	22
Table CC.1 – Correspondence between this particular standard and the essential principles.....	34