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TECHNICAL SPECIFICATION



Medical electrical equipment – Part 4-6: Guidance and interpretation – Voluntary guidance to help achieve basic safety and essential performance with regard to the possible effects of electromagnetic disturbances

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CONTENTS

FOREWORD 5
INTRODUCTION 7
1 Scope 8
2 Normative references 8
3 Terms, definitions and abbreviated terms 8
3.1 Terms and definitions 8
3.2 Abbreviated terms 9
4 How to use this document 9
5 General 10
5.1 Mitigation of effects caused by EM DISTURBANCES 10
5.2 Implementing well-proven techniques and measures for mitigating the effects that can be caused by EM DISTURBANCES 10
5.2.1 General principles 10
5.2.2 Choosing design techniques and measures from Annex A 10
5.3 Documenting the well-proven techniques and measures used for mitigating the effects that can be caused by EM DISTURBANCES 13
5.3.1 ME EQUIPMENT or ME SYSTEM 13
5.3.2 Non-ME EQUIPMENT 14
Annex A (informative) Detailed guidance on the techniques and measures for mitigating the effects that can be caused by EM DISTURBANCES 15
A.1 Techniques and measures that might be helpful in project management, planning and specification 15
A.1.1 Techniques and measures for project management and planning 15
A.1.2 Techniques and measures for use when creating a design specification 15
A.1.3 Specifying EMC test standards to help ensure availability 16
A.1.4 Protecting against high impact, unusual and malicious EM DISTURBANCES 19
A.2 Techniques and measures that might be helpful in system design 20
A.2.1 General 20
A.2.2 Separating system parts necessary for achieving BASIC SAFETY or ESSENTIAL PERFORMANCE from system parts that are not important for BASIC SAFETY or ESSENTIAL PERFORMANCE 20
A.2.3 Recording how the design specifications are achieved through design choices 21
A.2.4 Co-design electromagnetically diverse hardware/software in redundant channels 21
A.2.5 System integration, installation, and commissioning 24
A.2.6 Fault detection and event data recording for later diagnosis 25
A.2.7 Improving mitigation of the effects that can be caused by EM DISTURBANCES in communication links 26
A.2.8 Synchronization and resynchronization techniques 28
A.2.9 Protection from persistent interference by monitoring retry counts 28
A.2.10 Independent detection of EM DISTURBANCES and/or EMI 29
A.2.11 Protection of systems from tampering via communication links to external systems 30
A.2.12 Robust, high-specification electromagnetic mitigation 31
A.2.13 Techniques and measures to prevent RISKS being increased by virtualization of memory and PROCESS resources (e.g. a "digital twin") 31
A.2.14 Usability Engineering (Human Factors) 32
A.3 Techniques and measures that might be helpful in operational design 32

A.3.1 General 32
A.3.2 Developing appropriate operation and maintenance instructions 33
A.3.3 Designing appropriate maintenance techniques 33
A.3.4 Limiting the possibilities for operation and hence mis-operation 34
A.3.5 Protecting against operation errors 34
A.3.6 Protecting against hardware or software modifications or manipulations 35
A.3.7 Defensive programming techniques 35
A.3.8 Limited use of interrupts 38
A.3.9 Limited use of memory address pointer variables 39
A.3.10 Avoiding recursion 39
A.3.11 Error detection and correction for invariable memory 40
A.3.12 Error detection and correction techniques in redundant designs 41
A.3.13 Time-based error detection/correction in buses and interfaces 42
A.3.14 Error detection and correction for variable memory 43
A.3.15 Error detecting/correcting coding for ROM, RAM, buses, and interfaces 45
A.3.16 Error detection and correction for logic and data processing 45
A.3.17 Error detection and correction for electrical and electromechanical components 47
A.3.18 Caution when using hardware or software libraries 48
A.3.19 Error detection and correction for electronic components 48
A.3.20 Error detection/correction by monitoring program sequence (i.e. watchdogs) 51
A.3.21 Error detection and correction using multi-channel input/output interfaces 53
A.3.22 Using test patterns: static and dynamic 53
A.3.23 Using fiber-optic cables for signals and data communications 54
A.3.24 Techniques and measures for AC and DC power supplies/power converters 54
A.3.25 Monitoring of ventilation, cooling, and heating 56
A.3.26 Careful use of wireless (radio) data communications 57
A.3.27 Good electromagnetic engineering at every level of design 58
A.3.28 Design to comply with EMC test specifications as set out in A.1.3 and A.1.4 58
A.3.29 De-rating of hardware components, where appropriate 59
A.3.30 Improve robustness of interrupts 59
A.4 Techniques and measures that might be helpful in implementation, integration, installation, and commissioning 60
A.4.1 Providing information on constraints and additional measures 60
A.4.2 Procuring materials, components, and products 61
A.4.3 Assemble/integrate according to the design for adequate mitigation of the effects that can be caused by EM DISTURBANCES 62
A.4.4 Install/commission according to the design for achieving adequate mitigation of the effects that can be caused by EM DISTURBANCES 62
A.5 Techniques and measures that might be helpful in VERIFICATION and validation (including testing) 62
A.5.1 Applying VERIFICATION and/or validation techniques and measures 62
A.5.2 VERIFICATION testing to the EMC test plan from A.1.3 and A.1.4 64
A.5.3 Using non-standardized ad hoc checks or tests 65
A.5.4 Verifying correct installation and commissioning 66
A.5.5 EMC tests before and after accelerated life tests 67

A.6 Techniques and measures that might be helpful in operation, maintenance, repair, overhaul, refurbishment, and upgrade 67
A.6.1 Assessment of changes in the ELECTROMAGNETIC ENVIRONMENT 67
A.6.2 Assessment of continuing correct installation 68
A.6.3 Maintaining adequate mitigation of the effects that can be caused by EM DISTURBANCES, despite modifications or changes 69
A.6.4 Batch (lot) traceability 70
A.6.5 Component changes, new supplier, dual / alternate source 70
A.7 Techniques and measures that might be helpful in decommissioning 71
A.8 Integrating third-party items into ME EQUIPMENT or ME SYSTEMS 71
A.8.1 The general iterative approach 71
A.8.2 Suppliers' certifications and electromagnetic assessments 73
A.8.3 Custom-manufactured component parts 73
Annex B (informative) Checklist of techniques and measures recommended for helping to achieve adequate mitigation of the effects that can be caused by EM DISTURBANCES 75
Bibliography 89
Index of defined terms 126

Figure 1 – General principles for achieving mitigation of effects that can be caused by EM DISTURBANCES 13
Figure A.1 – Choosing standard volume-manufactured subsystems and component parts 73

Table B.1 – Checklist of techniques and measures recommended for adequate mitigation of the effects that can be caused by EM DISTURBANCES throughout the EXPECTED SERVICE LIFE 76

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 4-6: Guidance and interpretation – Voluntary guidance to help achieve basic safety and essential performance with regard to the possible effects of electromagnetic disturbances

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IEC TS 60601-4-6 has been prepared by subcommittee 62A: Common aspects of medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is a Technical Specification.

The text of this Technical Specification is based on the following documents:

Draft	Report on voting
62A/1538/DTS	62A/1589/RVDTS

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Technical Specification is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, the following print types are used:

– recommendations and definitions: roman type.

– *test instructions: italic type.*

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THIS TECHNICAL SPECIFICATION OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 1 includes 1.1, 1.2, etc.);

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References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

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INTRODUCTION

In 2017 it was decided to remove Annex F of IEC 60601-1-2:2014 [1][1] into a separate document and provide guidance to help achieve basic safety and essential performance with regard to the possible effects of ELECTROMAGNETIC DISTURBANCE by a technical specification under the IEC 60601 series of standards.

This IEC document provides voluntary guidance on the assessment and application of techniques and measures that can help reduce the risks associated with the interfering effects of ELECTROMAGNETIC DISTURBANCES on medical equipment and medical systems.

1 Numbers in square brackets refer to the Bibliography.

MEDICAL ELECTRICAL EQUIPMENT –

Part 4-6: Guidance and interpretation – Voluntary guidance to help achieve basic safety and essential performance with regard to the possible effects of electromagnetic disturbances

1 Scope

This document provides practical methods to help achieve BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to the possible effects of EM DISTURBANCES throughout the EXPECTED SERVICE LIFE of ME EQUIPMENT or an ME SYSTEM.

These practical methods attempt to address all of the different types of errors, malfunctions or failures that can be caused by EM DISTURBANCES in ME EQUIPMENT or ME SYSTEMS.

The purpose of this document is to provide recommendations for the techniques and measures used in the design, VERIFICATION, and validation of systems, hardware, software, and firmware used in ME EQUIPMENT or ME SYSTEMS to help achieve BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to the EM DISTURBANCES that could occur throughout the EXPECTED SERVICE LIFE.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*