

# IEC/TR 60601-4-1:2017-05 (E)

## Medical electrical equipment - Part 4-1: Guidance and interpretation - Medical electrical equipment and medical electrical systems employing a degree of autonomy

Contents	Page
FOREWORD.....	5
INTRODUCTION.....	7
1 Scope.....	9
2 Normative references .....	9
3 Terms and definitions .....	10
4 DEGREE OF AUTONOMY (DOA).....	17
4.1 Introduction to DEGREE OF AUTONOMY.....	17
4.2 Methodology to determine DEGREE OF AUTONOMY.....	17
4.3 Relationship between DOA and RISK .....	18
5 PROCESS STANDARDS supporting DOA.....	18
5.1 General.....	18
5.2 RISK MANAGEMENT PROCESS .....	19
5.2.1 Defining INTENDED USE .....	19
5.2.2 INTENDED USE and characteristics related to SAFETY .....	19
5.3 RISK CONTROL.....	20
5.3.1 General .....	20
5.3.2 RISK CONTROL hierarchy .....	21
5.4 USABILITY engineering considerations for MEE or MES having a higher DOA.....	22
5.4.1 General .....	22
5.4.2 OPERATOR situation awareness .....	22
5.4.3 OPERATOR reaction time.....	23
5.4.4 OPERATOR sensory input and response .....	23
5.4.5 Detectability by OPERATOR of malfunction or errors of MEE or MES with a higher DOA.....	23
5.5 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) and software development LIFE CYCLE (IEC 62304) .....	23
5.6 Application of RISK MANAGEMENT for IT-networks incorporating medical devices .....	24
6 BASIC SAFETY and ESSENTIAL PERFORMANCE related to DOA .....	25
6.1 GENERAL .....	25
6.2 BASIC SAFETY related to DOA .....	25
6.3 ESSENTIAL PERFORMANCE related to DOA.....	26
Annex A (informative) Rationale for defining the AUTOMATIC, AUTONOMY and DOA framework and the distinction between a MEDICAL ROBOT and other MEE or MES.....	28
A.1 General.....	28
A.2 Existing definitions and limitations .....	28
A.3 New approaches .....	29
A.4 Definition of MONITOR – GENERATE – SELECT – EXECUTE .....	30
A.5 Approaches to define ROBOT and MEDICAL ROBOT.....	31
A.6 Conclusions .....	31
Annex B (informative) DOA and relevant terms used in MEE standards.....	32
B.1 General.....	32
B.2 Procedure .....	32
B.3 Results .....	32

B.3.1	Summary .....	32
B.3.2	Tables .....	33
Annex C (informative)	Exemplar methods for classifying DEGREE OF AUTONOMY .....	42
C.1	Descriptive method .....	42
C.2	Binary method.....	43
C.3	Weighted method .....	44
Annex D (informative)	Examples of introducing DOA to MEE/MES .....	50
D.1	General.....	50
D.2	Example 1 – Lower extremity exoskeleton.....	50
D.2.1	Description of the medical procedures .....	50
D.2.2	DOA classification method.....	50
D.2.3	Effect of DOA on the RISK MANAGEMENT PROCESS.....	52
D.3	Example 2 – Orthopaedic MEE/MES/MEDICAL ROBOT for reshaping bone.....	54
D.3.1	Description of the medical procedures .....	54
D.3.2	DOA classification method.....	54
D.3.3	Effect of DOA on the RISK MANAGEMENT PROCESS.....	55
D.3.4	Summary and conclusions .....	55
D.4	Example 3 – Instrument exchange on robotically-assisted surgical equipment .....	55
D.4.1	Description of the medical procedures .....	55
D.4.2	DOA classification method.....	56
D.4.3	Effect of DOA on the RISK MANAGEMENT PROCESS.....	56
D.4.4	Summary and conclusions .....	57
D.5	Example 4 – Master–slave robotically-assisted surgical equipment.....	57
D.5.1	Description of the medical procedures .....	57
D.5.2	DOA classification method.....	58
D.5.3	Effect of DOA on RISK MANAGEMENT PROCESS.....	58
D.5.4	Summary and conclusions .....	58
D.6	Example 5 – Image-guided radiotherapy equipment.....	58
D.6.1	Description of the medical procedures .....	58
D.6.2	DOA classification method.....	59
D.6.3	RISK ANALYSIS for each level of DOA .....	61
D.6.4	Effect of DOA on the RISK MANAGEMENT PROCESS .....	61
D.6.5	Summary and conclusions .....	61
D.7	Example 6 – Automated external defibrillator (AED).....	62
D.7.1	Description of the medical procedures .....	62
D.7.2	DOA classification method.....	63
D.7.3	Effect of DOA on the RISK MANAGEMENT PROCESS.....	64
D.7.4	Summary and conclusions .....	64
Annex E (informative)	PATIENT SAFETY characteristics to be taken into account during RISK MANAGEMENT for MEE or MES employing DOA.....	65
E.1	Types of PATIENTS .....	65
E.2	Additional attention for child (PATIENT) SAFETY.....	65
E.3	PATIENT abilities and variability of physiological signals .....	66
E.3.1	ISO/IEC Guide 71 .....	66
E.3.2	Changing need and abilities of PATIENTS .....	66
E.3.3	PATIENT’S sensory abilities.....	66
E.3.4	PATIENT’S PHYSICAL ABILITIES .....	67
E.3.5	PATIENT’S COGNITIVE ABILITIES.....	67
E.3.6	PATIENT ALLERGIES .....	67
ANNEX F (informative)	PHYSIOLOGIC CLOSED-LOOP CONTROL SYSTEM AND DOA .....	69
Annex G (informative)	Examples of distributed ESSENTIAL PERFORMANCE .....	72
Bibliography.....		75

Figure 1 – Basic model of interoperability of MEE in an MES (Order of execution: 1 to 3) .....	25
Figure A.1 – ALFUS approach applied to MEE or MES applications .....	30
Figure C.1 – Application of weighted method to the “MONITOR” TASK .....	45
Figure C.2 – Application of weighted method to “GENERATE OPTIONS” .....	46
Figure C.3 – Application of weighted method to “SELECT OPTION” TASK .....	47
Figure C.4 – Application of weighted method to the “EXECUTE” TASK .....	48
Figure F.1 – Functional diagram indicating typical components of a PHYSIOLOGIC CLOSED-LOOP CONTROL SYSTEM (PCLCS) utilizing a PCLC .....	69
Figure F.2 – Examples of introducing DOA into the MONITORING TASK via PCLCS .....	70
Figure F.3 – Examples of introducing DOA into the GENERATING TASK via PCLCS .....	70
Figure F.4 – Examples of introducing DOA into the SELECTION TASK via PCLCS .....	70
Figure F.5 – Examples of introducing DOA into the EXECUTION TASK via PCLCS .....	71
Table 1 – Examples of ESSENTIAL PERFORMANCE of MEE or MES with a DOA .....	27
Table B.1 – List of terms that indicate the use of AUTONOMY .....	33
Table B.2 – List of reviewed standards – sorted by standard number (1 of 4) .....	34
Table B.3 – List of identified inconsistencies in reviewed standards (1 of 2) .....	40
Table C.1 – Descriptive classification of DOA .....	43
Table C.2 – Binary classification of DOA .....	44
Table D.1 – Example 1 – Effect of DOA on the RISK MANAGEMENT PROCESS .....	52
Table D.2 – Example 1 – Physical and cognitive capability of individual and CLINICAL FUNCTION needed .....	52
Table D.3 – Example 1 – Sub-function TASK example .....	53
Table D.4 – Example 2 – Effect of DOA on the RISK MANAGEMENT PROCESS .....	55
Table D.5 – Example 3 – Comparison of instrument exchange design implementations .....	57
Table D.6 – Example 3 – Effect of DOA on the RISK MANAGEMENT PROCESS .....	57
Table D.7 – Example 4 – Effect of DOA on the RISK MANAGEMENT PROCESS .....	58
Table D.8 – Example 5 – Descriptive classification of DOA for IGRT MEE .....	60
Table D.9 – Example 5 – Binary classification of DOA for IGRT MEE .....	60
Table D.10 – Example 5 – Effect of DOA on the RISK MANAGEMENT PROCESS .....	62
Table D.11 – Example 6 – Descriptive method classification of DOA in external defibrillators .....	63
Table D.12 – Example 6 – Effect of DOA on the RISK MANAGEMENT PROCESS .....	64
Table G.1 – Examples of distributed ESSENTIAL PERFORMANCE (1 of 3) .....	72