

IEC/TS 81001-2-2:2025-09 (E)

Health software and health IT systems safety, effectiveness and security - Part 2-2: Guidance for the implementation, disclosure and communication of security needs, risks and controls

Contents	Page
FOREWORD	3
INTRODUCTION	5
1 Scope.....	7
2 Normative references.....	8
3 Terms and definitions.....	8
4 Use of security capabilities	9
4.1 Structure of a <i>security capability</i> entry	9
4.2 Guidance on the communication of <i>security capabilities</i> and shared responsibility	9
4.3 Guidance for use of <i>security capabilities</i> in the <i>risk management process</i>	9
4.4 Guidance on the application of <i>risk management processes</i>	9
5 Security capabilities	10
5.1 General	10
5.2 Automatic logoff (ALOF)	11
5.3 Audit controls (AUDT)	11
5.4 Authorization (AUTH).....	12
5.5 Cybersecurity product upgrades (CSUP).....	13
5.6 Health data de-identification (DIDT).....	14
5.7 Data backup and disaster recovery (DTBK)	15
5.8 Emergency access (EMRG).....	15
5.9 Health data integrity and authenticity (IGAU).....	16
5.10 Malware detection/protection (MLDP)	16
5.11 Node authentication (NAUT)	17
5.12 Person authentication (PAUT).....	18
5.13 Physical locks on product (PLOCK).....	19
5.14 Third-party components in product life cycle roadmaps (RDMP)	19
5.15 System and application hardening (SAHD)	20
5.16 Health data storage confidentiality (STCF)	20
5.17 Transmission confidentiality (TXCF)	21
5.18 Transmission integrity and authenticity (TXIG).....	21
6 Additional supporting information	21
6.1 General	21
6.2 Connectivity capabilities (CONN).....	22
6.3 Management of personally identifiable information (MPII)	22
6.4 Remote services (RMOT)	23
6.5 Software Bill of Materials (SBOM)	24
6.6 <i>Security guides</i> (SGUD)	25
7 Examples of some <i>security capabilities</i>	25
7.1 Example of detailed specification under <i>security capability</i> : Person authentication (PAUT).....	25

7.2	Example for Software Bill of Materials (SBOM)	26
8	References and other resources	27
8.1	General	27
8.2	Manufacturer disclosure statement for <i>medical device security</i> (MDS2)	28
8.3	Application <i>security</i> questionnaire (ASQ)	28
8.4	HL7 Functional Electronic Health Record (EHR)	28
8.5	Standards and frameworks	28
Annex A (informative)	Sample scenario showing the exchange of security information	31
A.1	Introduction to the <i>security</i> characteristics scenario	31
A.2	Manufacturer Disclosure Statement for Medical device Security (MDS2)	32
Annex B (informative)	Examples of regional specification on a few <i>security</i> capabilities	46
Annex C (informative)	Guidance for selecting <i>security controls</i> to satisfy the <i>security</i> capabilities	49
C.1	General	49
C.2	Automatic logoff (ALOF)	52
C.3	Audit controls (AUDT)	53
C.4	Authorization (AUTH)	55
C.5	Cybersecurity product upgrades (CSUP)	58
C.6	Health data de-identification (DIDT)	59
C.7	Data backup and disaster recovery (DTBK)	61
C.8	Emergency access (EMRG)	63
C.9	Health data integrity and authenticity (IGAU)	64
C.10	Malware detection/protection (MLDP)	66
C.11	Node authentication (NAUT)	69
C.12	Person authentication (PAUT)	72
C.13	Physical locks on product (PLOK)	74
C.14	Third-party components in product life cycle roadmaps (RDMP)	76
C.15	System and application hardening (SAHD)	78
C.16	Health data storage confidentiality (STCF)	82
C.17	Transmission confidentiality (TXCF)	84
C.18	Transmission integrity and authenticity (TXIG)	86
C.19	Connectivity capabilities (CONN)	87
C.20	Management of personally identifiable information (MPII)	89
C.21	Remote services (RMOT)	90
C.22	Software Bill of Materials (SBOM)	92
C.23	Security guides (SGUD)	93
Annex D (informative)	<i>Security capability</i> and additional <i>security</i> information mapping to C-I-A-A-A	97
	Bibliography	99
	Alphabetized index of defined terms	103
	Figure 1 – <i>Health software</i> Field of Application as shown in IEC 81001-5-1 [3]	7
	Figure 2 – Sample Structure for “ <i>Medical device2</i> ”	26
	Table 1 – Example SBOM for “ <i>Medical device2</i> ”	27
	Table D.1 – Sample mapping by a hypothetical <i>HDO</i>	97