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Interested committees:

Title: BS EN IEC 60050-880 International Electrotechnical Vocabulary (IEV)

Part 880: Electrical equipment, electrical systems and software used in healthcare

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

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- iii) requires additional national guidance or information

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62/458/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:
IEC 60050-880 ED1

DATE OF CIRCULATION:
2023-05-19

CLOSING DATE FOR COMMENTS:
2023-08-11

SUPERSEDES DOCUMENTS:
62/393/NP, 62/410A/RVN

IEC TC 62 : MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS

SECRETARIAT:
Germany

SECRETARY:
Ms Regina Geierhofer

OF INTEREST TO THE FOLLOWING COMMITTEES:
TC 1,TC 65,TC 66,TC 76,TC 87,SyC AAL

PROPOSED HORIZONTAL STANDARD:



Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☒ EMC

☒ ENVIRONMENT

☒ QUALITY ASSURANCE

☒ SAFETY

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TITLE:

International Electrotechnical Vocabulary (IEV) – Part 880: Electrical equipment, electrical systems and software used in healthcare

NOTE FROM TC/SC OFFICERS:

Previous documents: 62/393/NP and 62/410A/RVN, 62/423/DC and 62/442/INF, 62/443/DC and 62/459/INF.

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1 Notice to the readers of this Committee Draft:

2 This document contains all proposed sections of the International Electrotechnical Vocabulary
3 (IEV) or IEC 60050-880 for the terms used in IEC TC 62. The document is circulated for
4 comments to the national committees of TC 62 in the English language only. In the CDV stage,
5 the document will be bilingual, English and French. Selected sections were circulated previously
6 in two Documents for Comments. Those sections have been updated following comments
7 received from the national committees and are included in the Committee Draft together with
8 the remaining IEV sections.

9 Sections included in DC1 (see 62/423/DC and 62/442/INF) were:

- 10 • Section 880-01 “Alarm systems”;
- 11 • Section 880-03 “Classifications”;
- 12 • Section 880-04 “Cleaning”;
- 13 • Section 880-07 “Electrical”;
- 14 • Section 880-09 “Environment”;
- 15 • Section 880-13 “Information”;
- 16 • Section 880-16 “Organizations, people and roles”.

17 Sections included in DC2 (see 62/443/DC) were:

- 18 • Section 880-08 “EMC”;
- 19 • Section 880-14 “Protection against hazards”;
- 20 • Section 880-15 “Mechanical”;
- 21 • Section 880-18 “Processes”;
- 22 • Section 880-19 “Quality”;
- 23 • Section 880-20 “Risk management”;
- 24 • Section 880-21 “Signals”;
- 25 • Section 880-23 “Usability”.

26
27 New sections in this CD are:

- 28
- 29 • Section 880-02 “Circular economy”;
- 30 • Section 880-05 “Connections”;
- 31 • Section 880-06 “Security”;
- 32 • Section 880-10 “Equipment and its parts and accessories”;
- 33 • Section 880-11 “General (Generic)”;
- 34 • Section 880-12 “Health information technology systems”;
- 35 • Section 880-17 “Physiological closed-loop control”;
- 36 • Section 880-22 “Software/PEMS”.
- 37

38 Links to figures and tables.

39 Several figures and tables are included to explain the relationships between different related
40 terms. Each figure and each table is included only once, but when searching for a term in the
41 (electronic) IEV database, the figure or table is shown for each related term by means of a
42 dynamic link. This is shown in this document as “Link to figure” or “Link to table”. In this CD,
43 the figures and tables are numbered by section.

44
45

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

INTERNATIONAL ELECTROTECHNICAL VOCABULARY –

**Part 880: Electrical equipment, electrical systems
and software used in healthcare**

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 60050-880 has been prepared by IEC technical committee 62: Medical equipment, software, and systems, under the responsibility of IEC technical committee 1: Terminology.

It has the status of a horizontal standard in accordance with IEC Guide 108.

The text of this standard is based on the following documents:

FDIS	Report on voting
1/####/FDIS	1/####/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

128 In this part of the IEV, the terms and definitions are provided in French and English; in addition,
129 the terms are given in Arabic (ar), Czech (cs), German (de), Spanish (es), Finnish (fi), Italian
130 (it), Japanese (ja), Norwegian [Bokmål (nb) and Nynorsk (nn)], Polish (pl), Portuguese (pt),
131 Slovenian (sl), Serbian (sr), Swedish (sv) and Chinese (zh).

132 A list of all parts of the IEC 60050 series, published under the general title *International*
133 *Electrotechnical Vocabulary*, can be found on the IEC website and is available at
134 www.electropedia.org.

135

INTERNATIONAL ELECTROTECHNICAL VOCABULARY –**Part 880: Electrical equipment, electrical systems
and software used in healthcare****1 Scope**

This part of IEC 60050 gives the general terminology used for electrical equipment, electrical systems and software used in healthcare, as well as general terms pertaining to specific applications and associated technologies.

It has the status of a horizontal standard in accordance with IEC Guide 108, *Guidelines for ensuring the coherency of IEC publications – Application of horizontal standards*.

This terminology is consistent with the terminology developed in the other specialized parts of the IEV.

This horizontal standard is primarily intended for use by technical committees in the preparation of standards in accordance with the principles laid down in IEC Guide 108.

One of the responsibilities of a technical committee is, wherever applicable, to make use of horizontal standards in the preparation of its publications.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

Section 880-01 – Alarm systems

880-01-01

acknowledged, <alarm system>

state of an **alarm system** initiated by **user** action, where the auditory **alarm signal** associated with a currently active **alarm condition** is inactivated until the **alarm condition** no longer exists or until a predetermined time interval has elapsed

Note 1 to entry: **Acknowledged** only affects **alarm signals** that are active at the time of the **user** action.

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.37, modified — replaced “operator” with “user”.]

880-01-02

alarm condition

state of an **alarm system** when it has determined that a potential or actual **hazardous situation** exists for which **user** awareness or response is required

Note 1 to entry: An **alarm condition** can be invalid (i.e. a **false positive alarm condition**).

Note 2 to entry: An **alarm condition** can be missed (i.e. a **false negative alarm condition**).

[SOURCE: IEC 60601-1-8:2006, 3.1, modified — replaced “the” with “an” and “operator” with “user”.]

880-01-03

alarm condition delay

time from the occurrence of a triggering **event** either in the **patient** or in the equipment to the moment when an **alarm system** determines that an **alarm condition** exists

Note 1 to entry: The triggering **event** can occur in the **patient** for **physiological alarm conditions** or in the equipment for **technical alarm conditions**.

[SOURCE: IEC 60601-1-8:2006, 3.2, modified — moved “for physiological alarm conditions” and “for technical alarm conditions” to a new note.]

880-01-04

alarm de-escalation

process by which an **alarm system** decreases the priority of an **alarm condition** or decreases the sense of urgency of an **alarm signal**

Note 1 to entry: **Alarm de-escalation** may include a transition from a **low priority alarm condition** and its **alarm signal** to an **information signal**.

[SOURCE: IEC 60601-1-8:2006, 3.15, modified — added “alarm” to the term and note.]

880-01-05

alarm escalation

process by which an **alarm system** increases the priority of an **alarm condition** or increases the sense of urgency of an **alarm signal**

[SOURCE: IEC 60601-1-8:2006, 3.18, modified — added “alarm” to the term.]

880-01-06

alarm fatigue

situation wherein the presence of frequent **alarm signals** desensitizes a **user** to an **alarm signal**

Note 1 to entry: A desensitized **user** can fail to perceive, recognize or act on an **alarm signal**.

Note 2 to entry: The response of a desensitized **user** can be inadequate, delayed or non-existent.

Note 3 to entry: **Alarm flood** can cause **alarm fatigue**.

207 [SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.39, modified — replaced “operator” with “user”.]
208

209 **880-01-07**

210 **alarm flood**

211 situation wherein **users** receive more **alarm signals** in a time period than they can manage
212 appropriately

213 [SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.40, modified — replaced “operator” with “user”
214 and deleted note.]

215
216 **880-01-08**

217 **alarm limit**

218 threshold used by an **alarm system** to determine an **alarm condition**

219 [SOURCE: IEC 60601-1-8:2006, 3.3]

220
221 **880-01-09**

222 **alarm off**

223 state of indefinite duration in which an **alarm system** or part of an **alarm system** does not
224 generate **alarm signals**

225 [SOURCE: IEC 60601-1-8:2006, 3.4]

226
227 **880-01-10**

228 **alarm paused**

229 state of limited duration in which an **alarm system** or part of an **alarm system** does not generate
230 **alarm signals**

231 [SOURCE: IEC 60601-1-8:2006, 3.5, modified — replaced “the” with “an”.]

232
233 **880-01-11**

234 **alarm preset**

235 set of stored **alarm settings**

236 [SOURCE: IEC 60601-1-8:2006, 3.6, modified — replaced “configuration parameters, including
237 selection of algorithms and initial values for use by algorithms, which affect or modify the
238 performance of the **alarm system**” with “**alarm settings**”.]

239
240 **880-01-12**

241 **alarm reset**

242 **user** action that causes the cessation of an **alarm signal** for which no associated **alarm condition**
243 currently exists

244 [SOURCE: IEC 60601-1-8:2006, 3.7, modified — replaced “operator” with “user”.]

245
246 **880-01-13**

247 **alarm settings**

248 **alarm system** configuration that affects or modifies the performance of an **alarm system**,
249 including but not limited to:

- 250 – **alarm limits**;
- 251 – the characteristics of any **alarm signal** inactivation states; and
- 252 – the values of variables or parameters that determine the function of an **alarm system**

253 Note 1 to entry: Some algorithmically determined **alarm settings** can require time to be determined or redetermined.

254 Note 2 to entry: **Alarm settings** can include selection of algorithms and initial values for use by algorithms.

255 [SOURCE: IEC 60601-1-8:2006, 3.8, modified — added “that affects or modifies the
256 performance of an **alarm system**” and note 2.]

- 257
258 **880-01-14**
- 259 **alarm signal**
- 260 auditory, visual, electronic or other signal generated by a [communicator](#) to indicate the
261 presence (or occurrence) of an [alarm condition](#)
- 262 Note 1 to entry: Other [alarm signals](#) can include haptic or tactile signals.
- 263 [SOURCE: IEC 60601-1-8:2006, 3.9, modified — replaced “type of” with “auditory, visual,
264 electronic or other” and added note.]
- 265
266 **880-01-15**
- 267 **alarm signal generation delay**
- 268 time from the onset of an [alarm condition](#) to the generation of its [alarm signal\(s\)](#)
- 269 [SOURCE: IEC 60601-1-8:2006, 3.10]
- 270
271 **880-01-16**
- 272 **alarm system**
- 273 parts of [MEE](#) or [MES](#) that detect [alarm conditions](#) and, as appropriate, generate [alarm signals](#)
- 274 [SOURCE: IEC 60601-1-8:2006, 3.11]
- 275
276 **880-01-17**
- 277 **audio off**, <auditory [alarm signal](#)>
- 278 state of indefinite duration in which an [alarm system](#) or part of an [alarm system](#) does not
279 generate an auditory [alarm signal](#)
- 280 [SOURCE: IEC 60601-1-8:2006, 3.12]
- 281
282 **880-01-18**
- 283 **audio paused**, <auditory [alarm signal](#)>
- 284 state of limited duration in which an [alarm system](#) or part of an [alarm system](#) does not generate
285 an auditory [alarm signal](#)
- 286 [SOURCE: IEC 60601-1-8:2006, 3.13]
- 287
288 **880-01-19**
- 289 **auditory icon**, <auditory [alarm signal](#)>
- 290 sound that creates a strong semantic link to the category it represents
- 291 Note 1 to entry: An [auditory icon](#) is typically a real-world sound or mimics a real-world sound.
- 292 Note 2 to entry: An [auditory icon](#) can aid in locating the [communicator](#) and the [source](#) type.
- 293 [SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.42]
- 294
295 **880-01-20**
- 296 **auditory pointer**, <auditory [alarm signal](#)>
- 297 sound that attracts attention, denotes the priority and aids in localization of the [communicator](#)
- 298 [SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.43]
- 299

880-01-21**clinically actionable**, adj <alarm condition>

type of **alarm condition** for which a panel of experts would agree that **user** action is necessary to prevent **harm** within the timeframe implied by the priority communicated by an **alarm system**

Note 1 to entry: A **user** action can include assessment of a **patient** or the changing of **alarm limits** when they are inappropriately set for the state of the **patient**.

Note 2 to entry: A **low priority alarm condition**, which requires action within the timeframe of a **medium priority** or **high priority** timeframe, is considered **clinically actionable**. A **high priority alarm condition**, which requires action within the timeframe of a **low priority** or **medium priority** timeframe, is considered **clinically nonactionable**. In both cases, the **alarm condition** priority was improperly assigned.

Note 3 to entry: A **false positive alarm condition** is never considered **clinically actionable** even though an unrelated **user** action might be required to prevent a future **false positive alarm condition**.

Note 4 to entry: A **clinically actionable alarm condition** is generally considered useful by the **user**.

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.44, modified — replaced “operator” with “user”.]

880-01-22**clinically nonactionable**, adj <alarm condition>

type of **alarm condition** for which a panel of experts would agree that **user** action is not expected within a timeframe equal to or shorter than the timeframe implied by its priority

Note 1 to entry: A **low priority alarm condition**, which requires action within the timeframe of a **medium priority** or **high priority** timeframe, is considered **clinically actionable**. A **high priority alarm condition**, which requires action within the timeframe of a **low priority** or **medium priority** timeframe, is considered **clinically nonactionable**. In both cases, the **alarm condition** priority was improperly assigned.

Note 2 to entry: A **clinically nonactionable alarm condition** is considered detrimental to **user** performance and **patient safety**.

Note 3 to entry: **Alarm signals** for an **alarm condition** of which the **user** is already aware are considered **clinically nonactionable**.

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.45, modified — replaced “operator” with “user”.]

880-01-23
communicator, <alarm system>
COM
annunciator
function or part of an **alarm system** that generates **alarm signals** to notify a **user** (e.g. of the presence of an **alarm condition**)

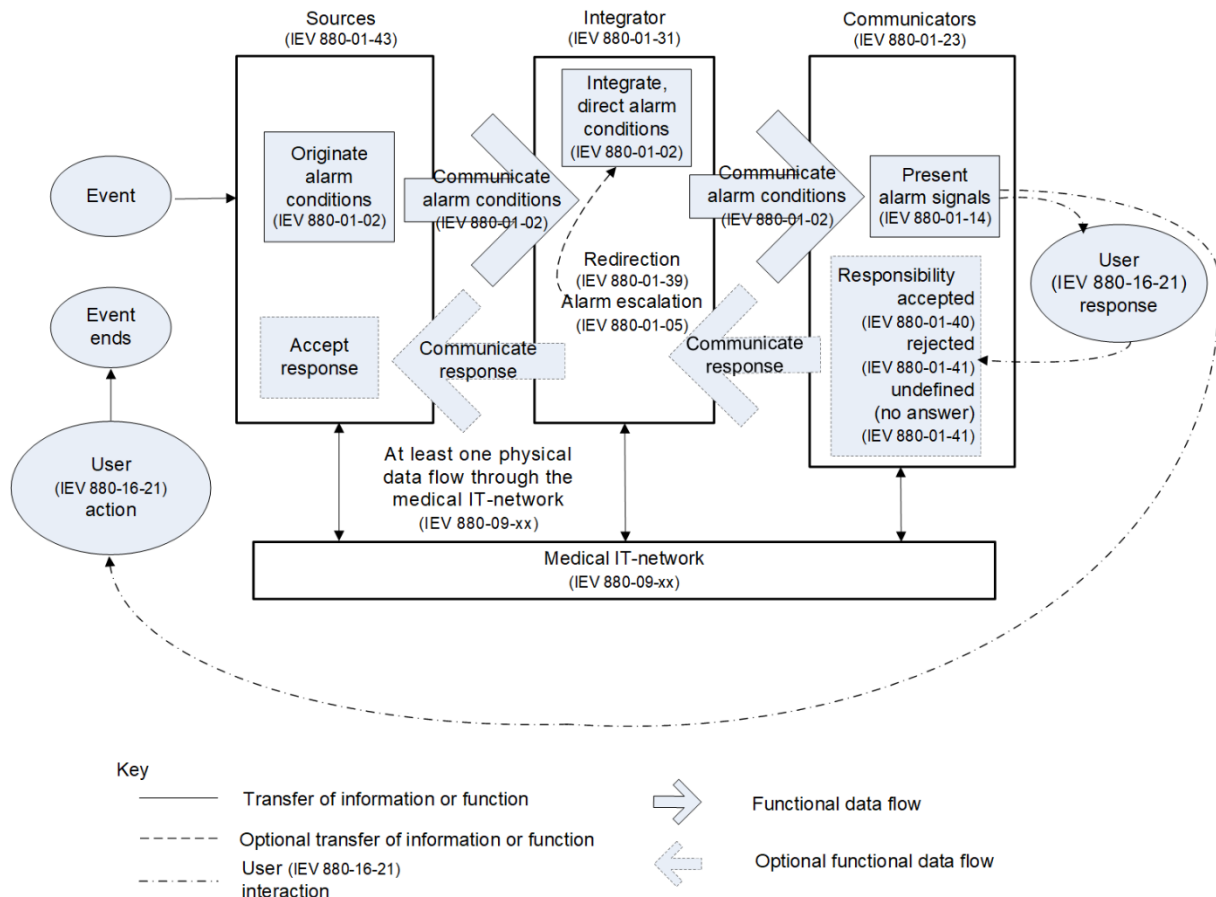


Figure 1.1 — Alarm system (IEV 880-01-16) relationships

Note 1 to entry: A **communicator** can receive a **user** response.

Note 2 to entry: A **user** response is not limited to direct **user** action.

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.46, modified — replaced “operator” with “user”.]

880-01-24

default alarm preset

alarm preset that can be activated by an **alarm system** without **user** action

EXAMPLE **Default alarm preset** configured by the **manufacturer** or the **responsible organization**.

[SOURCE: IEC 60601-1-8:2006, 3.16, modified — replaced “operator” with “user”.]

880-01-25

distributed alarm system

DAS

alarm system that involves more than one item of equipment in a **MES** intended for delivery of **alarm conditions** with technical confirmation

Note 1 to entry: The parts of a **distributed alarm system** can be widely separated in distance.

353 Note 2 to entry: A **distributed alarm system** is intended to notify **users** of the existence of an **alarm condition**.

354 Note 3 to entry: Technical confirmation means that each element of a **distributed alarm system** confirms or
355 guarantees the successful delivery of an **alarm condition** to the next element or the appropriate creation of **technical**
356 **alarm conditions**.

357 [SOURCE: IEC 60601-1:2005/AMD2:2020, 3.17, modified — replaced “operators” with “**users**”.]

358

359 **880-01-26**

360 **distributed alarm system with user confirmation**

361 **CDAS**

362 **distributed alarm system** that includes the capability to receive a **user** response

363 [SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.47, modified — replaced “operator” with “**user**”.]

364

365 **880-01-27**

366 **distributed information system about alarm conditions**

367 **DIS**

368 system that involves more than one item of equipment in a **MES** intended to provide information
369 about **alarm conditions** but does not guarantee delivery of that information

370 Note 1 to entry: A **distributed information system about alarm conditions** is not intended to notify **users** of the
371 existence of an **alarm condition** as a **risk control** measure. A **distributed information system about alarm conditions**
372 is intended to provide information about an **alarm condition** while the **user** is aware of the existence of the **alarm**
373 **condition** by an **alarm system**.

374 Note 2 to entry: A **distributed information system about alarm conditions** is not intended for confirmed delivery of
375 **alarm conditions**.

376 [SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.48, modified — replaced “operator” with “**user**”.]

377

378 **880-01-28**

379 **false negative alarm condition**

380 absence of an **alarm condition** when a valid triggering **event** has occurred in the **patient**, the
381 equipment or an **alarm system**

382 Note 1 to entry: An **alarm condition** can be rejected or missed because of spurious information produced by the
383 **patient**, the **patient**-equipment interface, other equipment or an **alarm system** itself.

384 [SOURCE: IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.20]

385

386 **880-01-29**

387 **false positive alarm condition**

388 presence of an **alarm condition** when no valid triggering **event** has occurred in the **patient**, the
389 equipment or an **alarm system**

390 Note 1 to entry: A **false positive alarm condition** can be caused by spurious information produced by the **patient**, the
391 **patient**-equipment interface, other equipment or an **alarm system** itself.

392 [SOURCE: IEC 60601-1:2005, 3.21]

393

880-01-30

high priority

indicating that immediate **user** response is required

Potential result of failure to respond to the cause of alarm condition (IEV 880-01-02)	Onset of potential harm ^a (IEV 880-20-06)		
	Immediate ^b	Prompt ^c	Delayed ^d
Death or irreversible injury	high priority (IEV 880-01-30) ^e	high priority (IEV 880-01-30)	medium priority (IEV 880-01-351)
Reversible injury	high priority (IEV 880-01-30)	medium priority (IEV 880-01-35)	low priority (IEV 880-01-34)
Discomfort or reversible minor injury	medium priority (IEV 880-01-35)	low priority (IEV 880-01-34)	low priority (IEV 880-01-34), no alarm condition (IEV 880-01-02) or information signal (IEV 880-21-05)
^a Onset of potential harm (IEV 880-20-06) refers to when an injury occurs and not to when it is manifested. ^b Having the potential for the event (880-06-03) to develop within a period of time not usually sufficient for manual intervention. ^c Having the potential for the event (880-06-03) to develop within a period of time usually sufficient for manual intervention. ^d Having the potential for the event (880-06-03) to develop within an unspecified time greater than that given under “prompt”. ^e Where practicable, MEE (IEV 880-10-26) with a therapeutic function incorporates automatic safety (IEV 880-20-21) mechanisms to prevent immediate death or irreversible injury caused by the MEE.			

Figure 1.2 — Assignment of priorities to an alarm condition (IEV 880-01-02)

Note 1 to entry: The priority is assigned through **risk analysis**.

Note 2 to entry: Immediate implies the interruption of current workflow is expected.

[SOURCE: IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.22, modified — replaced “operator” with “**user**” and added figure.]

880-01-31

integrator, <**alarm system**>

INT

alarm manager

function or part of an **alarm system** that distributes **alarm conditions**, combines **alarm conditions** from **sources** or handles the communication between those **sources** and **communicators**

Link to figure

Figure 1.1 — Alarm system (IEV 880-01-16) relationships

Note 1 to entry: An **integrator** can direct or redirect an **alarm condition** to another **communicator** and hence **user**.

Note 2 to entry: An **integrator** can send the acceptance of responsibility from a **communicator** to a **source**.

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.49, modified — replaced “operator” with “**user**”.]

880-01-32

intelligent alarm system

alarm system that makes logical decisions based on monitored information without **user** intervention

EXAMPLE 1 An **alarm system** that changes priority based on the rate of change of a monitored variable

421 EXAMPLE 2 An **alarm system** that suppresses an **alarm condition** when a related **alarm condition** of higher priority
422 has recently generated an **alarm signal**.

423 [SOURCE: IEC 60601-1-8:2006, 3.24, modified — replaced “operator” with “user”.]
424

425 **880-01-33**

426 **latching alarm signal**

427 **alarm signal** that continues to be generated after its associated triggering **event** no longer exists
428 until stopped by deliberate **user** action

429 [SOURCE: IEC 60601-1-8:2006, 3.26, modified — replaced “operator” with “user”.]
430

431 **880-01-34**

432 **low priority**

433 indicating that **user** awareness is required, and that future action might be needed

434 [Link to figure](#)

435 **Figure 1.2 — Alarm conditions (IEV 880-01-02) and assignment of priorities**

436 Note 1 to entry: The priority is assigned through **risk analysis**.

437 Note 2 to entry: Awareness implies the planning of future workflow is expected.

438 [SOURCE: IEC 60601-1:2005/AMD2:2020, 3.27, modified — replaced “operator” with “user”
439 and added figure.]
440

441 **880-01-35**

442 **medium priority**

443 indicating that prompt **user** response is required

444 [Link to figure](#)

445 **Figure 1.2 — Alarm conditions (IEV 880-01-02) and assignment of priorities**

446 Note 1 to entry: The priority is assigned through **risk analysis**.

447 Note 2 to entry: Prompt implies the re-planning of current workflow is expected.

448 [SOURCE: IEC 60601-1:2005/AMD2:2020, 3.28, modified — replaced “operator” with “user”
449 and added figure.]
450

451 **880-01-36**

452 **non-latching alarm signal**

453 **alarm signal** that automatically stops being generated when its associated triggering **event** no
454 longer exists

455 [SOURCE: IEC 60601-1-8:2006, 3.29]
456

457 **880-01-37**

458 **nuisance alarm signal**

459 **alarm signal** for which a panel of experts would agree that the **harm** associated with the **alarm**
460 **signal** is greater than the **benefit** associated with action resulting from the **alarm signal**

461 Note 1 to entry: A **nuisance alarm signal** contributes to **alarm fatigue**.

462 Note 2 to entry: A **nuisance alarm signal** can arise from a **false positive alarm condition**.

463 Note 3 to entry: A **nuisance alarm signal** can arise from a **clinically nonactionable alarm condition**.

464 Note 4 to entry: A **nuisance alarm signal** can cause an inappropriate **user** action.

465 EXAMPLE Causing the **user** to set **alarm limits** to inappropriate settings.

Note 5 to entry: An **alarm signal** that unnecessarily irritates or startles the **patient** or **user** can be a **nuisance alarm signal**.

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.50, modified — replaced “operator” with “user”.]

880-01-38

physiological alarm condition

alarm condition arising from a monitored **patient**-related variable

EXAMPLE 1 High exhaled anaesthetic agent concentration.

EXAMPLE 2 Low exhaled tidal volume.

EXAMPLE 3 Low oxygen saturation measured by pulse oximetry.

EXAMPLE 4 High arterial pressure.

EXAMPLE 5 High heart rate.

[SOURCE: IEC 60601-1-8:2006, 3.31]

880-01-39

redirection, <alarm system>

means by which an **integrator** provides a response hierarchy for directing an **alarm condition** to a **communicator** or redirects an **alarm condition** to another **communicator**

[Link to figure](#)

Figure 1.1 — Alarm system (IEV 880-01-16) relationships

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.51]

880-01-40

responsibility accepted, <alarm condition>

state created by a **user** response accepting ownership for addressing an **alarm condition**

[Link to figure](#)

Figure 1.1 — Alarm system (IEV 880-01-16) relationships

Note 1 to entry: A **responsibility accepted** can be used to initiate an **alarm signal** inactivation state.

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.52, modified — replaced “operator” with “user”.]

880-01-41

responsibility rejected, <alarm condition>

state created by a **user** response rejecting ownership for addressing an **alarm condition**

[Link to figure](#)

Figure 1.1 — Alarm system (IEV 880-01-16) relationships

Note 1 to entry: A **responsibility rejected** can be used to initiate an **alarm escalation** or **redirection**.

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.53, modified — replaced “operator” with “user”.]

880-01-42

responsibility undefined, <alarm condition>

state, automatically initiated when neither a [responsibility accepted](#) nor [responsibility rejected](#) is received within a specified period, which indicates that a [user](#) is not responding

Link to figure

Figure 1.1 — Alarm system (IEV 880-01-16) relationships

Note 1 to entry: A [responsibility undefined](#) is not used as an indication that the [communicator](#) and [integrator](#) cannot communicate.

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.54, modified — replaced “operator” with “[user](#)”.]

880-01-43

source, <alarm system>

SRC

function or part of an [alarm system](#) that has the capability to initiate an [alarm condition](#)

Link to figure

Figure 1.1 — Alarm system (IEV 880-01-16) relationships

Note 1 to entry: The [source](#) transfers the [alarm condition](#) to the [integrator](#).

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.55]

880-01-44

technical alarm condition

[alarm condition](#) arising from a monitored equipment-related or [alarm system](#)-related variable

EXAMPLE 1 An electrical, mechanical or other failure.

EXAMPLE 2 A failure of a sensor or component (unsafe voltage, high impedance, signal impedance, artifact, noisy signal, disconnection, calibration error, tubing obstruction, etc.).

EXAMPLE 3 An algorithm that cannot classify or resolve the available data.

[SOURCE: IEC 60601-1-8:2006, 3.36]

880-01-45

true negative alarm condition

absence of an [alarm condition](#) when no valid triggering [event](#) has occurred in the [patient](#), the equipment or an [alarm system](#)

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.56]

880-01-46

true positive alarm condition

presence of an [alarm condition](#) when a valid triggering [event](#) has occurred in the [patient](#), the equipment or an [alarm system](#)

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.57]

Section 880-02 – Circular economy

Box Note:

IEV Part 193 is under development for circular economy and material efficiency.
This section of Part 880 will be revisited as Part 193 progresses.

880-02-01

end of life

stage of the **life-cycle** of a **product** starting when it is removed from its use stage

880-02-02

environment

See IEV 901-07-01.

880-02-03

environmental aspect

element of an **organization's activities** or **products** that interacts or can interact with the **environment**

Note 1 to entry: An **environmental aspect** can cause **environmental impact**. A significant **environmental aspect** is one that has or can have a significant **environmental impact**.

Note 2 to entry: Significant **environmental aspects** are determined by the **organization**.

[SOURCE: ISO 14001:2015, 3.2.2, modified — deleted “or services” and “applying one or more criteria”.]

880-02-04

environmental impact

change to the **environment**, whether adverse or beneficial, wholly or partially resulting from an **organization's activities**

[SOURCE: ISO 14001:2015, 3.2.4, modified — replaced “environmental aspects” with “activities”.]

880-02-05

hazardous substance

substance that has the potential for an immediate or delayed effect that adversely impacts human **health** or the **environment**

880-02-06

life-cycle

series of all stages in the life of a **product**, from the initial conception to final decommissioning and disposal

[SOURCE: ISO/IEC Guide 63:2019, 3.5, modified — replaced “medical device” with “**product**” and “phases” with “stages”.]

589 **880-02-07**

590 **maintenance**

591 See IEV 192-06-01.

592

593 **880-02-08**

594 **post-production**

595 stage of the **life-cycle** of the **product** after the design has been completed and the **product** has
596 been manufactured

597 EXAMPLE Transportation, storage, installation, **product** use, **maintenance**, **repair**, **product** changes,
598 decommissioning and disposal.

599 [SOURCE: ISO 14971: 2019, 3.12, modified — replaced “part” with “stage” and “medical device”
600 with “**product**”.]

601

602 **880-02-09**

603 **recycling**

604 See IEV 901-07-10.

605

606 **880-02-10**

607 **refurbisher**

608 **organization** that conducts **refurbishment** of a **medical device** or **accessory**

609 Note 1 to entry: Some **authorities having jurisdiction** consider the responsible **refurbisher** a **manufacturer**.

610

611 **880-02-11**

612 **refurbishment**

613 **process** or combination of **processes** applied during the **expected lifetime** to restore a **medical**
614 **device** or **accessory**, which has been put into service, to a condition of **safety** and performance
615 according to the specification of the **manufacturer**

616 Note 1 to entry: **Refurbishment** can include activities such as **repair**, **rework**, replacement of worn components, and
617 update of software/hardware but does not change the specifications of the **medical device** or **accessory**.

618 Note 2 to entry: **Refurbishment** does not include restoration after the **expected service life**.

619

620 **880-02-12**

621 **repair**

622 **process** for fixing a **medical device** or **accessory**, which has been put into service, to a safe and
623 functional state

624 Note 1 to entry: **Repair** includes fault localization, fault diagnosis, fault correction and function checkout.

625

626 **880-02-13**

627 **rework**

628 action on a nonconforming **product** to make it conform to its **requirements**

629 Note 1 to entry: **Rework** can affect or change parts of the nonconforming **product**.

630 [SOURCE: ISO 9000:2015, 3.12.8, modified — deleted “or service”.]

880-02-14

shelf-life

period during which a **medical device** or **accessory** in its original **packaging** maintains its **stability** under the conditions specified in the **information supplied by the manufacturer**

[SOURCE: ISO 20417:2021, 3.24, modified — deleted “of time until the expiry date”.]

Section 880-03 – Classifications

880-03-01

body-worn, adj

portable whose **intended use** includes operation while being worn by a **patient** or attached to a **patient's** clothing

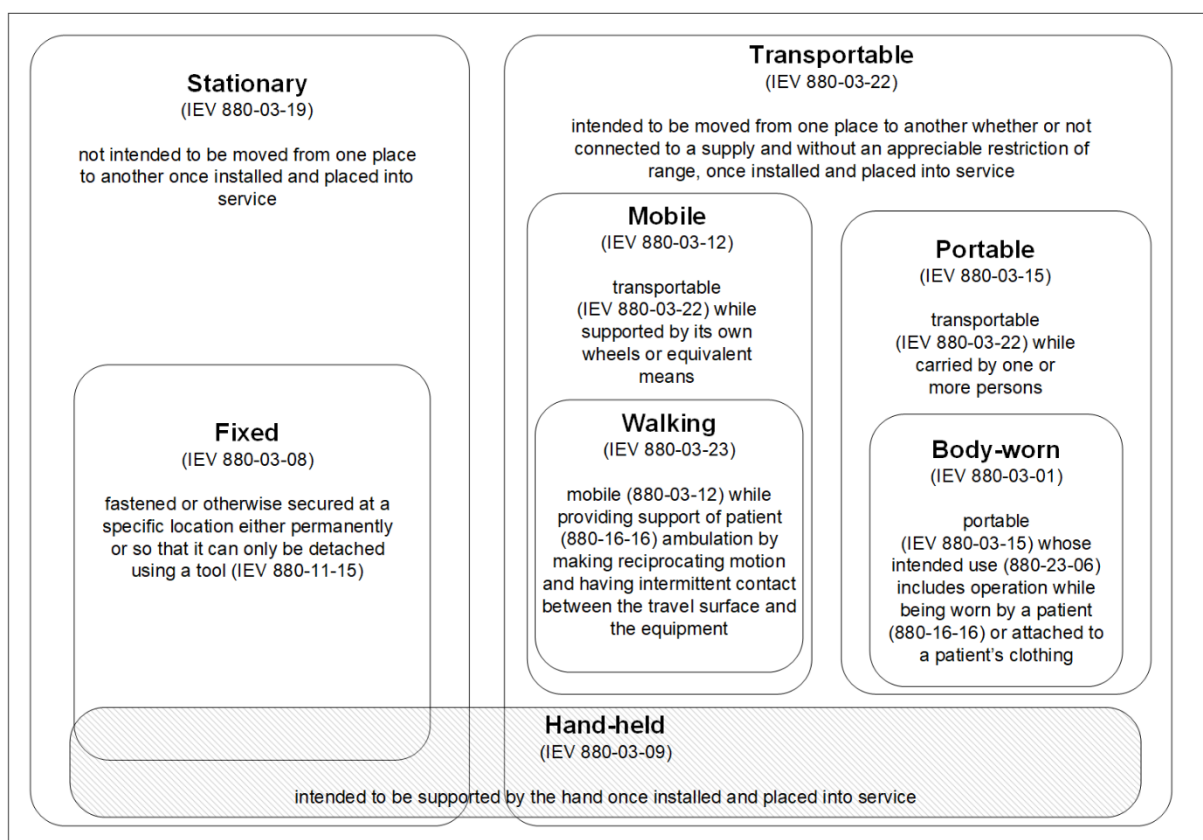


Figure 3.1 —Relationship of the terms used to describe equipment, accessories or equipment parts

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.144, modified — replaced “term referring to transportable equipment” with “**portable**” and deleted note.]

880-03-02

Class I, adj <electrical equipment>

having protection against electric shock that does not rely on **basic insulation** only, but which includes a supplementary safeguard that provides means for conductive **accessible parts** or conductive internal parts to be **protectively earthed**

Note 1 to entry: **Class I** equipment may be provided with **Class II** construction such as **double insulation** or **reinforced insulation**.

[SOURCE: IEC 60601-1:2005, 3.13, modified — replaced “term referring to electrical equipment in which” with “having” and “an additional safety precaution in that means are provided for” with “a supplementary safeguard that provides means for conductive” and changed the note.]

880-03-03

Class II, adj <electrical equipment>

having protection against electric shock that does not rely on [basic insulation](#) only, but which includes a supplementary safeguard, there being no provision for protective earthing or reliance upon installation conditions

Note 1 to entry: Supplementary safeguards include [double insulation](#) and [reinforced insulation](#).

Note 2 to entry: [Class II](#) equipment may be provided with a [functional earth terminal](#) or a [functional earth conductor](#).

[SOURCE: IEC 60601-1:2005, 3.14, modified — replaced “term referring to electrical equipment in which” with “having”, “in which additional safety precautions such as double insulation or reinforced insulation are provided” with “which includes a supplementary safeguard”, “can” with “may” and replaced note 1.]

880-03-04

continuous operation

operation in [normal use](#) for an unlimited period without the specified limits of temperature being exceeded

[SOURCE: IEC 60601-1:2005, 3.18]

880-03-05

detachable

part, component or [accessory](#), which can be installed and removed by the [user](#) without the use of a [tool](#)

880-03-06

direct cardiac application

use of an [applied part](#) that can come in direct contact with the [patient's](#) heart

[SOURCE: IEC 60601-1:2005, 3.22]

880-03-07

duty cycle

maximum activation (on) time followed by minimum deactivation (off) time necessary for safe operation

Note 1 to entry: The [duty cycle](#) may be expressed as a ratio of the activation (on) time divided by the total time.

[SOURCE: IEC 60601-1:2005, 3.24, modified — deleted “of the ME equipment” and added note.]

880-03-08

fixed, adj

fastened or otherwise secured at a specific location either permanently or so that it can only be detached using a [tool](#)

EXAMPLE 1 Permanently affixed by welding, etc.

EXAMPLE 2 Affixed by means of fasteners (screws, nuts, etc.) making removal/opening impossible without using a [tool](#).

705 [Link to figure](#)

706 **Figure 3.1 —Relationship of the terms used to describe equipment, [accessories](#) or**
707 **equipment parts**

708 [SOURCE: IEC 60601-1:2005, 3.30, modified — deleted “term meaning”.]

709
710 **880-03-09**

711 **hand-held**, adj

712 intended to be supported by the hand once installed and placed into service

713 Note 1 to entry: [Accessories](#) or equipment parts may be [hand-held](#).

714 [Link to figure](#)

715 **Figure 3.1 —Relationship of the terms used to describe equipment, [accessories](#) or**
716 **equipment parts**

717
718 **880-03-10**

719 **internally powered**, adj <electrical equipment>

720 able to operate from an [internal electrical power source](#)

721 [SOURCE: IEC 60601-1:2005, 3.46, modified — deleted “term referring to electrical equipment
722 that is”.]

723
724 **880-03-11**

725 **large**, adj

726 having a size that does not fit within a 2 m x 2 m x 2,5 m volume, excluding cables

727
728 **880-03-12**

729 **mobile**, adj

730 [transportable](#) while supported by its own wheels or equivalent means

731 [Link to figure](#)

732 **Figure 3.1 —Relationship of the terms used to describe equipment, [accessories](#) or**
733 **equipment parts**

734 [SOURCE: IEC 60601-1:2005/AMD2:2020, 3.65, modified — replaced “term referring to
735 TRANSPORTABLE equipment that, once installed and placed into service, is intended to be
736 moved from one location to another” with “transportable”.]

737
738 **880-03-13**

739 **multiple patient multiple use**

740 intended by the [manufacturer](#) to be reused on multiple [patients](#) for multiple uses

741 Note 1 to entry: A [multiple patient multiple use medical device](#) or [accessory](#) typically requires [processing](#) between
742 [patients](#).

743 Note 2 to entry: A [multiple patient multiple use medical device](#) or [accessory](#) may require [processing](#) between uses
744 on a single [patient](#).

745 [SOURCE: ISO 20417:2021, 3.18]

746

747 **880-03-14**748 **permanently installed**, adj749 electrically connected to the **mains** by means of a permanent connection that can only be
750 detached using a **tool**751 [SOURCE: IEC 60601-1:2005, 3.84, modified — deleted “term meaning” and “supply”, replaced
752 “by the use of” with “using”.]
753754 **880-03-15**755 **portable**, adj756 **transportable** while carried by one or more persons757 [Link to figure](#)758 **Figure 3.1 —Relationship of the terms used to describe equipment, accessories or**
759 **equipment parts**760 [SOURCE: IEC 60601-1:2005/AMD2:2020, 3.85, modified — replaced “term referring to
761 transportable equipment that, once installed and placed into service, is intended to be moved
762 from one location to another” with “**transportable**” and deleted notes.]
763764 **880-03-16**765 **protectively earthed**, adj766 connected to the **protective earth terminal** for reliable protective purposes767 Note 1 to entry: Standards that use this term shall specify the **requirements** for reliable protective purposes.768 [SOURCE: IEC 60601-1:2005, 3.96, modified — deleted “by means complying with the
769 requirements of this standard”.]
770771 **880-03-17**772 **single patient multiple use**773 intended by the **manufacturer** to be reused on an individual **patient** for multiple uses774 Note 1 to entry: A **single patient multiple use medical device** or **accessory** may require **processing** between uses.775 Note 2 to entry: For an **implantable medical device**, the duration of a **single use** is from implanting to explanting the
776 **medical device**.777 [SOURCE: ISO 20417:2021, 3.25]
778779 **880-03-18**780 **single use**, <**medical device**, **accessory**>

781 do not re-use

782 use only once

783 intended by the **manufacturer** to be used on an individual **patient** or specimen during a single
784 **procedure** and then disposed of785 Note 1 to entry: A **single use medical device** or **accessory** is not intended by its **manufacturer** to be further **processed**
786 and used again.787 [SOURCE: ISO 20417:2021, 3.26]
788789 **880-03-19**790 **stationary**, adj

791 not intended to be moved from one place to another, once installed and placed into service

792 [Link to figure](#)793 **Figure 3.1 —Relationship of the terms used to describe equipment, accessories or**
794 **equipment parts**

795 [SOURCE: IEC 60601-1:2005/AMD1:2012, 3.118, modified — deleted “term referring to
796 equipment that”, moved “once installed and placed into service” and deleted the note.]

797
798 **880-03-20**

799 **sterile**

800 free from viable microorganisms

801 [SOURCE: ISO 20417:2021, 3.28]

802
803 **880-03-21**

804 **transit-operable**, adj

805 having an **intended use** that includes operation while being moved

806 Note 1 to entry: **Transit-operable** equipment can be used indoors, outdoors and in vehicles.

807 [SOURCE: IEC 60601-1-11:2015, 3.4, modified — replaced “term referring to transportable
808 equipment whose” with “having an”, changed note and deleted example.]

809
810 **880-03-22**

811 **transportable**, adj

812 intended to be moved from one place to another whether or not connected to a supply and
813 without an appreciable restriction of range, once installed and placed into service

814 EXAMPLE **Mobile** equipment, **portable** equipment and **body-worn** equipment.

815 Note 1 to entry: **Transportable** equipment can be both **body-worn** and **hand-held**.

816 Link to figure

817 **Figure 3.1 —Relationship of the terms used to describe equipment, accessories or**
818 **equipment parts**

819 [SOURCE: IEC 60601-1:2005/AMD1:2012, 3.130, modified — deleted “term referring to
820 equipment that”, moved “once installed and placed into service” and changed the note.]

821
822 **880-03-23**

823 **walking**, adj

824 **mobile** while providing support of **patient** ambulation by making reciprocating motion and having
825 intermittent contact between the travel surface and the equipment

826 Link to figure

827 **Figure 3.1 —Relationship of the terms used to describe equipment, accessories or**
828 **equipment parts**

829 [SOURCE: IEC 80601-2-78:2019, 201.3.215, modified — replaced “equipment that, once
830 installed and placed into service, is intended to move from one location to another” with “while
831 providing support of **patient** ambulation”, “contact with” with “contact between”, “RACA robot”
832 with “equipment” and deleted examples and note.]

833
834

835 **Section 880-04 – Cleaning, disinfection and sterilization**

836 **880-04-01**

837 **cleaning**

838 **process** to remove contaminants to the extent necessary for further **processing** or for **intended**
839 **use**

840 Note 1 to entry: **Cleaning** consists of the removal of adherent soil (e.g. blood, protein substances and other debris)
841 from the surfaces, crevices, serrations, joints and lumens of a **medical device** by a manual or automated **process**
842 that prepares the items for safe handling or further **processing**.

[SOURCE: ISO 17664-2:2021, 3.1, modified — replaced “removal of” with “**process** to remove” and “and/or” with “or”.]

880-04-02

disinfection

process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 17664-2:2021, 3.5]

880-04-03

processing

activity to prepare a new or used healthcare **product** for its **intended use**

Note 1 to entry: **Processing** includes **cleaning**, **disinfection** and **sterilization**.

Note 2 to entry: Healthcare **products** include **medical devices** and **accessories**.

[SOURCE: ISO 17664-2:2021, 3.10, modified — deleted “(if necessary and applicable)” and added note 2.]

880-04-04

sterilization

process to render **product** free from viable microorganisms

Note 1 to entry: In a **sterilization process**, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

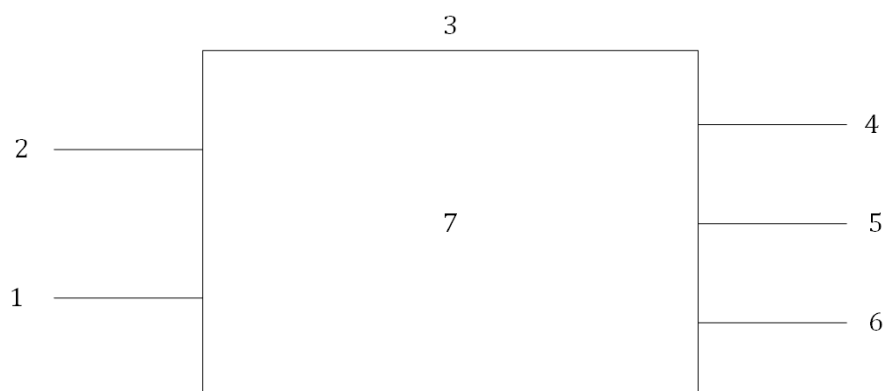
[SOURCE: ISO 17664-1:2021, 3.17, modified — deleted “used”.]

Section 880-05 – Connections

880-05-01

EMC port, <**electromagnetic compatibility**>

particular interface of equipment which couples this equipment with the external **electromagnetic environment** and through which the equipment is influenced by this **environment**



Key

- 877 1 DC power
- 878 2 AC power
- 879 3 Enclosure (880-10-12)
- 880 4 Patient coupling point (880-05-06)
- 881 5 Network/data coupling (880-05-04)
- 882 6 SIP/SOP (880-05-08)
- 883 7 MEE (880-10-26)

884 **Figure 5.1 — Examples of EMC ports (880-05-01)**

885 Note 1 to entry: Examples of **EMC ports** of interest are shown in Figure 5.1. The **enclosure EMC port** is the physical
 886 boundary of the equipment (e.g. **enclosure**). The **enclosure** and **patient coupling point EMC ports** provide for radiated
 887 and **electrostatic discharge** energy transfer, whereas the other **EMC ports** provide for conducted energy transfer.

888 [SOURCE: IEC 60050-161:1990/AMD4:2014, 161-01-27, modified — added “EMC” to the term
 889 and “**patient coupling point**” to the figure and replaced the example with a note.]

890 **880-05-02**

891 **fluid port**

892 opening for the passage of a fluid through a specified interface

893 Note 1 to entry: A **fluid port** can be in the form of a specific **connector** or designed to not allow connection with any
 894 **connector**.

895 Note 2 to entry: Both gases and liquids are fluids.

896 [SOURCE: ISO 4135:2022, 3.1.4.10, modified — added “fluid” to the term and added note 2.]

897 **880-05-03**

898 **functional connection**

899 intentional connection to equipment, electrical, mechanical, wireless or otherwise, including
 900 those transferring signals, data, power or substances

901 Note 1 to entry: A connection to the **mains** is not considered to result in a **functional connection**.

902 Note 2 to entry: A connection to a **mains socket-outlet** is considered a **functional connection**.

903 Note 3 to entry: A **patient connection** is not considered a **functional connection**.

904 [SOURCE: IEC 60601-1:2005, 3.33, modified — replaced “connection, electrical or otherwise,
 905 including those intended to transfer” with “intentional connection to equipment, electrical,
 906 mechanical, wireless or otherwise, including those transferring” and replaced note 1 with notes
 907 1 to 3.]

908 **880-05-04**

909 **network/data coupling**

910 **functional connection** used to transmit or receive information to or from other equipment in
 911 accordance with the specifications

912 [SOURCE: IEC 60601-1:2005, 3.68, modified — replaced “any means” with “**functional**
 913 **connection** used” and deleted “**manufacturer’s**”.]

914 **880-05-05**

915 **patient connection**

916 individual point on the **applied part** through which current can flow between the **patient** and the
 917 **MEE** in **normal condition** or **single fault condition**

918 Note 1 to entry: A **patient connection** is not considered a **functional connection**.

919 [SOURCE: IEC 60601-1:2005, 3.78, modified — added note.]

921

Box Note 1:

Input from the National Committees is requested whether the definition should be broadened to other energy sources (e.g. thermal, acoustic) by deleting electromagnetic and whether thermal and acoustic should be added to the examples in Note 1 to entry.

880-05-06**patient coupling point**

sensing or treatment point of MEE that is necessary to achieve the intended use of the MEE and that provides a path for transfer of energy to or from the patient, whether intended or unintended

Note 1 to entry: Examples of types of coupling include conductive, capacitive, inductive and optical.

Note 2 to entry: A patient coupling point is not considered a functional connection.

[SOURCE: IEC 60601-1-2:2022, 3.16, modified — deleted “or an ME system” and “electromagnetic” and added note 2.]

Box Note 2:

Input from the National Committees is requested whether the definition should be broadened to other energy sources (e.g. thermal, acoustic) by deleting electromagnetic and whether thermal and acoustic should be added to the examples in Note 1 to entry.

880-05-07**patient-coupled**

presence of a path for the transfer of energy to or from the patient, whether intended or unintended

Note 1 to entry: Examples of types of coupling include conductive, capacitive, inductive and optical.

[SOURCE: IEC 60601-1-2:2022, 3.15, modified — deleted “term referring to the” and “electromagnetic”.]

880-05-08**signal input/output part****SIP/SOP**

functional connection intended to transmit or receive signals by direct electrical connection to or from other electrical equipment

EXAMPLE Connections for display, recording or data processing.

[SOURCE: IEC 60601-1:2005, 3.115, modified — replaced “part of ME equipment, not being an applied part,” with “functional connection” and “deliver” with “transmit”, moved “display, recording or data processing” to the example and deleted the note.]

Section 880-06 – Security

NOTE Following the CD, this section will be renumbered and moved to become 880-21.

Box note 3:

Input from the NC is requested regarding the definitions of both security (see IEC 880-06-05) and cybersecurity where cybersecurity is defined as a subset of security that is focused on the protection of information and systems.

880-06-01

cybersecurity

state where information and **systems** are protected from unauthorized **activities** to a degree that the **risks** related to violation of confidentiality, integrity and availability are maintained at an acceptable level throughout the **life-cycle**

Note 1 to entry: Unauthorized **activities** include access, use, disclosure, disruption, modification or destruction.

Note 2 to entry: **Cybersecurity** is a subset of **security** focused on the protection of information and **systems**.

[SOURCE: ISO 81001-1:2021 3.2.13, modified — deleted “such as access, use, disclosure, disruption, modification, or destruction”, deleted alternate term security and added notes.]

880-06-02

cybersecurity capability

broad category of technical, administrative or organizational controls to manage **risks** to confidentiality, integrity, availability and accountability of data and **systems**

[SOURCE: ISO 81001-1:2021, 3.2.14, modified — added “cyber” to the term.]

880-06-03

event

occurrence or change of a particular set of circumstances

Note 1 to entry: An **event** can be one or more occurrences and can have several causes.

Note 2 to entry: An **event** can consist of something not happening.

Note 3 to entry: An **event** can sometimes be referred to as an “incident” or “accident”.

[SOURCE: ISO Guide 73:2009 3.5.1.3, modified — deleted note 4.]

880-06-04

exploit, noun

defined way to breach the **cybersecurity** of **systems** through **vulnerability**

[SOURCE: ISO 81001-1:2021, 3.4.3, modified — replaced “security” with “**cybersecurity**”.]

Box note 4:

Input from the National Committees is requested whether exposure should also address **product** and **health IT infrastructure**.

880-06-05

exposure, <security>

extent to which an **organization** or stakeholder is subject to an **event**

[SOURCE: ISO Guide 73:2009 3.6.1.2, modified — replaced “and/or” with “or”.]