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Title: Draft BS EN IEC 60050-880. International Electrotechnical Vocabulary (IEV)
Part 880. Electrical equipment, electrical systems and software used in healthcare

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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 Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.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

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Template for comments and secretariat observations

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



62/495/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:
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2023-12-15

CLOSING DATE FOR COMMENTS:
2024-03-08

SUPERSEDES DOCUMENTS:
62/458/CD, 62/477A/CC

IEC TC 62 : MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS	
SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES: TC 1, SC 62A, SC 62B, SC 62C, SC 62D, 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

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Notice to the readers of this Committee Draft

This document contains all proposed sections of the International Electrotechnical Vocabulary (IEV) or IEC 60050-880 for the terms used in IEC TC 62. The document is circulated for comments to the national committees of TC 62 in the English language only. In the CDV stage, the document will be bilingual, English and French.

Based on the comments from the national committees on the first Committee Draft (see 62/458/CD and 62/477A/INF), the following major changes have been made in this second Committee Draft.

- The section on “Health IT systems” is merged with the section on “Software”.
- The section on “Signals” is merged with the section on “Alarm systems”.
- Definitions for “maintenance interval”, “remanufacturer” and “remanufacturing” are added to Section 880-02 on circular economy.
- Definitions for “MR conditional”, “MR safe” and “MR unsafe” are added to Section 880-03 on classifications and a definition for “MR environment” to Section 880-08 on environment.
- Definitions for “basic/intermediate/critical care area”, “patient care area” and “wet procedure location” are added to Section 880-08 on environment.
- A definition for “shield/shielding” is added to Section 880-12 on protection against hazards.
- Definitions for “software as a medical device (SaMD)” and “software in a medical device (SiMD)” are added to Section 880-20 on software.
- Modifications to the definitions for “software of unknown provenance (SOUP)” and “user interface of unknown provenance (UOUP)” are proposed. Input from the national committees is requested for the related definition of “legacy”.
- The terms “critical component”, “configuration item” and “exposure” are deleted.
- The term “means of operator protection” is changed to “means of others protection” since it is not only related to operators (users) but also to by-standers, i.e., persons other than the patient. The abbreviation “MOOP” is retained for consistency.

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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.

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

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

88

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 IEC.

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

IEV 880-01-01

acknowledged, <alarm system>

state of an *alarm system* (IEV 880-01-17) initiated by *user* (IEV 880-14-21) action, where the auditory *alarm signal* (IEV 880-01-15) associated with a currently active *alarm condition* (IEV 880-01-03) 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*”.]

IEV 880-01-02

advisory signal

DEPRECATED: advisory

information signal (IEV 880-01-35) notifying the *user* (IEV 880-14-21) of a condition of the *patient* (IEV 880-14-16) or *MEE* (IEV 880-09-26) providing contextual awareness that is intended to improve the clinical workflow or understanding of the *patient* (IEV 880-14-16) condition, but the awareness is not intended as a means of *risk control* (IEV 880-18-17)

EXAMPLE 1 A notification that it is time to draw the next blood sample.

EXAMPLE 2 A battery status notification that replacement will be needed in a day.

EXAMPLE 3 A notification that it is time to bathe the *patient*.

EXAMPLE 4 A notification that lab result is available, where the lab results are normal.

Note 1 to entry: A notification that lab result is available, where the lab result requires immediate clinical action is not an *advisory signal*. It is an *alarm signal* from an *alarm condition*.

Note 2 to entry: An *advisory signal*, which is an *information signal*, shall be designed so that a *user* does not confuse it with an *alarm signal*.

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.38, modified — replaced “operator” with “*user*” and deprecated the term “advisory”.]

IEV 880-01-03

alarm condition

state of an *alarm system* (IEV 880-01-17) when it has determined that a potential or actual *hazardous situation* (IEV 880-18-09) exists for which *user* (IEV 880-14-21) 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/AMD1:2012, 3.1, modified — replaced “the” with “an” and “operator” with “*user*”.]

IEV 880-01-04

alarm condition delay

time from the occurrence of a triggering *event* (IEV 880-18-05) either in the *patient* (IEV 880-14-16) or in the equipment to the moment when an *alarm system* (IEV 880-01-17) determines that an *alarm condition* (IEV 880-01-03) 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.]

IEV 880-01-05**alarm de-escalation**

process (IEV 880-16-16) by which an *alarm system* (IEV 880-01-17) decreases the priority of an *alarm condition* (IEV 880-01-03) or decreases the sense of urgency of an *alarm signal* (IEV 880-01-15)

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

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

IEV 880-01-06**alarm escalation**

process (IEV 880-16-16) by which an *alarm system* (IEV 880-01-17) increases the priority of an *alarm condition* (IEV 880-01-03) or increases the sense of urgency of an *alarm signal* (IEV 880-01-15)

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

IEV 880-01-07**alarm fatigue**

situation wherein the presence of frequent *alarm signals* (IEV 880-01-15) desensitizes a *user* (IEV 880-14-21) 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*.

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

IEV 880-01-08**alarm flood**

situation wherein a *user* (IEV 880-14-21) receives more *alarm signals* (IEV 880-01-15) in a period than can be managed appropriately

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.40, modified — replaced “operators receive” with “a *user* receives” and deleted “time”, “they” and the note.]

IEV 880-01-09**alarm limit**

threshold used by an *alarm system* (IEV 880-01-17) to determine an *alarm condition* (IEV 880-01-03)

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

IEV 880-01-10**alarm off**

state of indefinite duration in which an *alarm system* (IEV 880-01-17) or part of an *alarm system* does not generate *alarm signals* (IEV 880-01-15)

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

IEV 880-01-11**alarm paused**

state of limited duration in which an *alarm system* (IEV 880-01-17) or part of an *alarm system* does not generate *alarm signals* (IEV 880-01-15)

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

IEV 880-01-12**alarm preset**

set of stored *alarm settings* (IEV 880-01-14)

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

IEV 880-01-13**alarm reset**

user (IEV 880-14-21) action that causes the cessation of an *alarm signal* (IEV 880-01-15) for which no associated *alarm condition* (IEV 880-01-03) currently exists

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

IEV 880-01-14**alarm settings**

alarm system (IEV 880-01-17) configuration that affects or modifies the performance of an *alarm system*, including but not limited to:

- *alarm limits* (IEV 880-01-09);
- the characteristics of any *alarm signal* (IEV 880-01-15) inactivation states; and
- the values of *variables* (IEV 880-15-29) or parameters that determine the function of an *alarm system*

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

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

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

IEV 880-01-15**alarm signal**

auditory, visual, electronic or other signal generated by a *communicator* (IEV 880-01-26) to indicate the presence (or occurrence) of an *alarm condition* (IEV 880-01-03)

Note 1 to entry: Other *alarm signals* can include haptic or tactile signals.

[SOURCE: IEC 60601-1-8:2006, 3.9, modified — replaced “type of” with “auditory, visual, electronic or other” and added note.]

IEV 880-01-16**alarm signal generation delay**

time from the onset of an *alarm condition* (IEV 880-01-03) to the generation of its *alarm signal(s)* (IEV 880-01-15)

[SOURCE: IEC 60601-1-8:2006, 3.10]

IEV 880-01-17**alarm system**

parts of *MEE* (IEV 880-09-26) or *MES* (IEV 880-09-27) that detect *alarm conditions* (IEV 880-01-03) and, as appropriate, generate *alarm signals* (IEV 880-01-15)

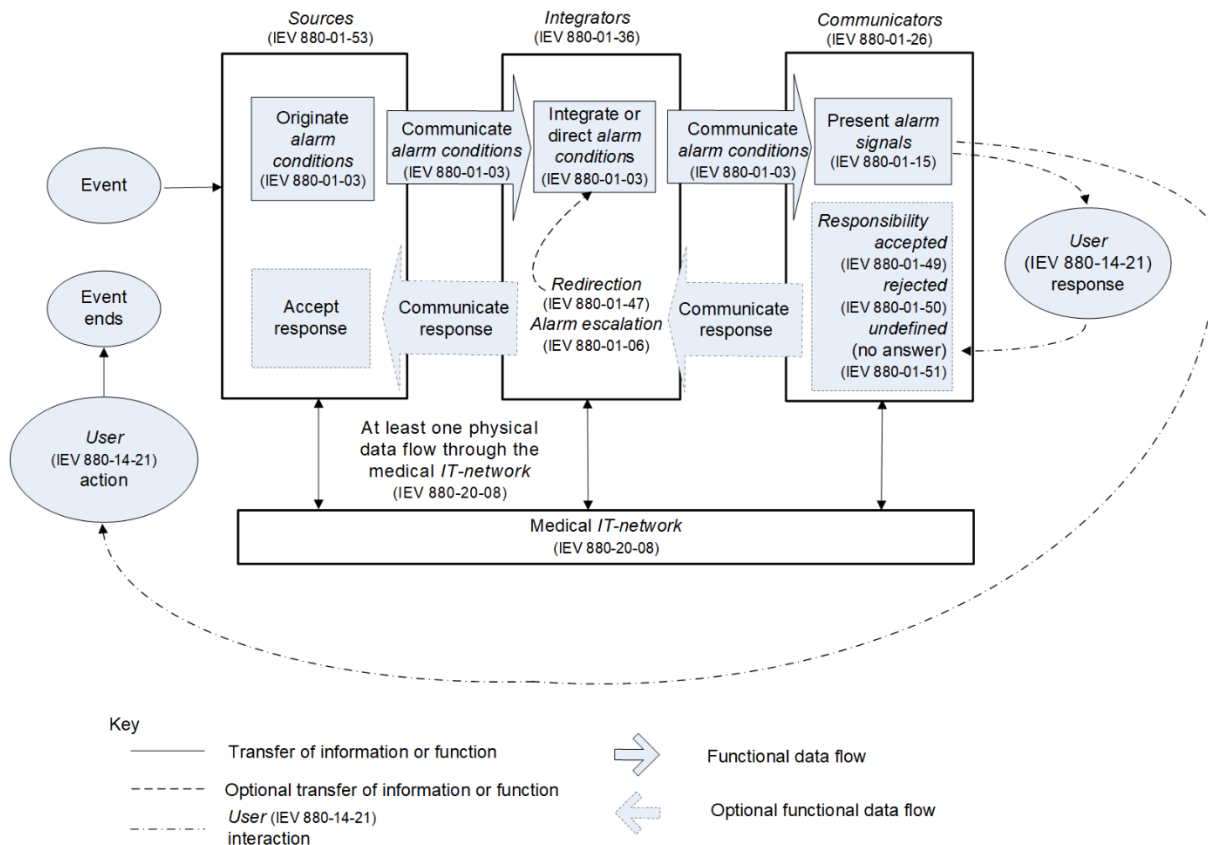


Figure 1.1 — Relationship of the terms used to describe an *alarm system* (IEV 880-01-17)

[SOURCE: IEC 60601-1-8:2006, 3.11]

IEV 880-01-18**alert**

state where a *physiological alarm condition* (IEV 880-01-44), a *technical alarm condition* (IEV 880-01-54) or an *advisory signal* (IEV 880-01-02) is present

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.41, modified — replaced “synonym for the combination of” with “state where a” and replaced “advisories” with “an *advisory signal* is present”.]

IEV 880-01-19**audio off, <auditory *alarm signal*>**

state of indefinite duration in which an *alarm system* (IEV 880-01-17) or part of an *alarm system* does not generate an auditory *alarm signal* (IEV 880-01-15)

[SOURCE: IEC 60601-1-8:2006, 3.12]

273 **IEV 880-01-20**

274 **audio paused, <auditory *alarm signal*>**

275 state of limited duration in which an *alarm system* (IEV 880-01-17) or part of an *alarm system*
276 does not generate an auditory *alarm signal* (IEV 880-01-15)

277 [SOURCE: IEC 60601-1-8:2006, 3.13]

278

279 **IEV 880-01-21**

280 **auditory icon, <auditory *alarm signal*>**

281 sound that creates a strong semantic link to the category it represents

282 Note 1 to entry: An *auditory icon* is typically a real-world sound or mimics a real-world sound.

283 Note 2 to entry: An *auditory icon* can aid in locating the *communicator* and the *source* type.

284 [SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.42]

285

286 **IEV 880-01-22**

287 **auditory pointer, <auditory *alarm signal*>**

288 sound that attracts attention, denotes the priority and aids in localization of the *communicator*
289 (IEV 880-01-26)

290 [SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.43]

291

292 **IEV 880-01-23**

293 **burst, <auditory *alarm signal*>**

294 group of *pulses* (IEV 880-01-45) with a distinctive rhythm or pattern

295 [SOURCE: IEC 60601-1-8:2006, 3.14]

296

297 **IEV 880-01-24**

298 **clinically actionable, adj. <*alarm condition*>**

299 type of *alarm condition* (IEV 880-01-03) for which a panel of experts would agree that *user*
300 (IEV 880-14-21) action is necessary to prevent *harm* (IEV 880-18-07) within the timeframe
301 implied by the priority communicated by an *alarm system* (IEV 880-01-17)

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

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

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

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

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

312

313 **IEV 880-01-25**

314 **clinically nonactionable, adj. <*alarm condition*>**

315 type of *alarm condition* (IEV 880-01-03) for which a panel of experts would agree that *user*
316 (IEV 880-14-21) action is not expected within a timeframe equal to or shorter than the timeframe
317 implied by its priority

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

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

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

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

327
 328 **IEV 880-01-26**

329 **communicator, <alarm system>**
 330 **COM**
 331 **annunciator**

332 function or part of an *alarm system* (IEV 880-01-17) that generates *alarm signals*
 333 (IEV 880-01-15) to notify a *user* (IEV 880-14-21) [e.g., of the presence of an *alarm condition*
 334 (IEV 880-01-03)]

335 Link to figure

336 **Figure 1.1 — Relationship of the terms used to describe an *alarm***
 337 ***system* (IEV 880-01-17)**

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

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

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

341
 342 **IEV 880-01-27**

343 **default alarm preset**

344 *alarm preset* (IEV 880-01-12) that can be activated by an *alarm system* (IEV 880-01-17) without
 345 *user* (IEV 880-14-21) action

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

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

348
 349 **IEV 880-01-28**

350 **distributed alarm system**
 351 **DAS**

352 *alarm system* (IEV 880-01-17) that involves more than one item of equipment in a *MES*
 353 (IEV 880-09-27) intended for delivery of *alarm conditions* (IEV 880-01-03) with technical
 354 confirmation

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

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

357 Note 3 to entry: Technical confirmation means that each element of a *distributed alarm system* confirms or
 358 guarantees either the successful delivery of an *alarm condition* to the next element or the appropriate creation of
 359 *technical alarm conditions* if reliable delivery of the *alarm conditions* is not confirmed.

360 [SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.17, modified — replaced “operators” with
 361 “*users*” and added “either” and “if *reliable* delivery of the *alarm conditions* is not confirmed”.]

362
 363 **IEV 880-01-29**

364 **distributed alarm system with user confirmation**
 365 **CDAS**

366 *distributed alarm system* (IEV 880-01-28) that includes the capability to receive a *user*
 367 (IEV 880-14-21) response

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

369

IEV 880-01-30

**distributed information system about alarm conditions
DIS**

system (IEV 880-10-14) that involves more than one item of equipment in a *MES* (IEV 880-09-27) intended to provide information about *alarm conditions* (IEV 880-01-03) but does not guarantee delivery of that information

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

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

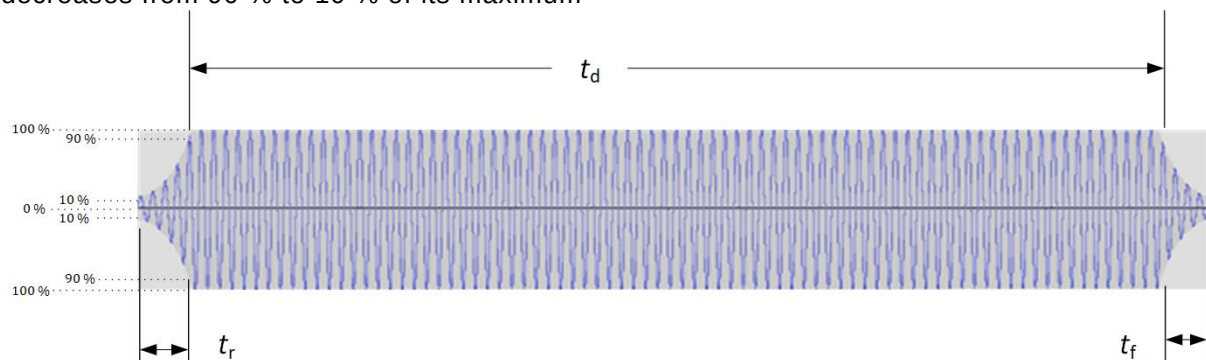
[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.48, modified — replaced “operator” with “user”.]

IEV 880-01-31

t_f

fall time, <auditory *alarm signal*>

interval over which the *pulse* (IEV 880-01-45) amplitude of the *auditory pointer* (IEV 880-01-22) decreases from 90 % to 10 % of its maximum



Key

t_d *auditory pointer* (IEV 880-01-22) *pulse* (IEV 880-01-45) duration

t_r *auditory pointer* (IEV 880-01-22) *rise time* (IEV 880-01-52)

t_f *auditory pointer* (IEV 880-01-22) *fall time* (IEV 880-01-31)

**Figure 1.2 — Illustration of temporal characteristics of an
auditory pointer (IEV 880-01-22) *pulse* (IEV 880-01-45)**

[SOURCE: IEC 60601-1-8:2006, 3.19]

IEV 880-01-32

false negative alarm condition

absence of an *alarm condition* (IEV 880-01-03) when a valid triggering *event* (IEV 880-18-05) has occurred in the *patient* (IEV 880-14-16), the equipment or an *alarm system* (IEV 880-01-17)

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

[SOURCE: IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, 3.20]

IEV 880-01-33**false positive alarm condition**

presence of an *alarm condition* (IEV 880-01-03) when no valid triggering *event* (IEV 880-18-05) has occurred in the *patient* (IEV 880-14-16), the equipment or an *alarm system* (IEV 880-01-17)

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

[SOURCE: IEC 60601-1-8:2006, 3.21]

IEV 880-01-34**high priority, <alarm condition, alarm signal>**

indicating that immediate *user* (IEV 880-14-21) response is required

Potential result of failure to respond to the cause of <i>alarm condition</i> (IEV 880-01-03)	Onset of potential <i>harm</i> ^a (IEV 880-18-07)		
	Immediate ^b	Prompt ^c	Delayed ^d
Death or irreversible injury	<i>high priority</i> (IEV 880-01-34) ^e	<i>high priority</i> (IEV 880-01-34)	<i>medium priority</i> (IEV 880-01-41)
Reversible injury	<i>high priority</i> (IEV 880-01-34)	<i>medium priority</i> (IEV 880-01-41)	<i>low priority</i> (IEV 880-01-40)
Discomfort or reversible minor injury	<i>medium priority</i> (IEV 880-01-41)	<i>low priority</i> (IEV 880-01-40)	<i>low priority</i> (IEV 880-01-40), no <i>alarm condition</i> (IEV 880-01-03) or <i>information signal</i> (IEV 880-01-35)

^a Onset of potential *harm* (IEV 880-18-07) refers to when an injury occurs and not to when it is manifested.

^b Having the potential for the *event* (IEV 880-18-05) to develop within a period of time not usually sufficient for manual intervention.

^c Having the potential for the *event* (IEV 880-18-05) to develop within a period of time usually sufficient for manual intervention.

^d Having the potential for the *event* (IEV 880-18-05) to develop within an unspecified time greater than that given under “prompt”.

^e Where practicable, *MEE* (IEV 880-09-26) with a therapeutic function incorporates automatic *safety* (IEV 880-18-22) mechanisms to prevent immediate death or irreversible injury caused by the *MEE*.

Figure 1.3 — Assignment of priorities to an *alarm condition* (IEV 880-01-03)

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 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, 3.22, modified — replaced “operator” with “*user*” and added figure.]

IEV 880-01-35**information signal**

any signal that is not an *alarm signal* (IEV 880-01-15) or a *reminder signal* (IEV 880-01-48)

EXAMPLE ECG waveform, SpO₂ tone, fluoroscopy beam-on indication

Note 1 to entry: An *advisory signal* is a type of *information signal*.

[SOURCE: IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, 3.23]

431 **IEV 880-01-36**

432 **integrator, <alarm system>**

433 **INT**

434 **alarm manager**

435 function or part of an *alarm system* (IEV 880-01-17) that distributes *alarm conditions*
436 (IEV 880-01-03), combines *alarm conditions* from *sources* (IEV 880-01-53) or handles the
437 communication between those *sources* and *communicators* (IEV 880-01-26)

438 [Link to figure](#)

439 **Figure 1.1 — Relationship of the terms used to describe an *alarm***
440 ***system* (IEV 880-01-17)**

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

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

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

444

445 **IEV 880-01-37**

446 **intelligent alarm system**

447 *alarm system* (IEV 880-01-17) that makes logical decisions based on monitored information
448 without *user* (IEV 880-14-21) intervention

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

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

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

453

454 **IEV 880-01-38**

455 t_b

456 **interburst interval, <auditory *alarm signal*>**

457 time between the end of the last *pulse* (IEV 880-01-45) of a *burst* (IEV 880-01-23) and the start
458 of the first *pulse* of the next *burst* of the same *alarm signal* (IEV 880-01-15)

459 Note 1 to entry: When an *auditory icon* is used, the *interburst interval* begins at the end of the *auditory icon*.

460 [SOURCE: IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, 3.25]

461

462 **IEV 880-01-39**

463 **latching alarm signal**

464 *alarm signal* (IEV 880-01-15) that continues to be generated after its associated triggering *event*
465 (IEV 880-18-05) no longer exists until stopped by deliberate *user* (IEV 880-14-21) action

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

467

468 **IEV 880-01-40**

469 **low priority, <alarm condition, *alarm signal*>**

470 indicating that *user* (IEV 880-14-21) awareness is required, and that future action might be
471 needed

472 [Link to figure](#)

473 **Figure 1.3 — Assignment of priorities to an *alarm condition* (IEV 880-01-03)**

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

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

476 [SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.27, modified — replaced “operator” with “*user*”
477 and added figure.]

478
479 **IEV 880-01-41**

480 **medium priority, <*alarm condition*, *alarm signal*>**

481 indicating that prompt *user* (IEV 880-14-21) response is required

482 Link to figure

483 **Figure 1.3 — Assignment of priorities to an *alarm condition* (IEV 880-01-03)**

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

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

486 [SOURCE: IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, 3.28, modified —
487 replaced “operator” with “*user*” and added figure.]

488
489 **IEV 880-01-42**

490 **non-latching alarm signal**

491 *alarm signal* (IEV 880-01-15) that automatically stops being generated when its associated
492 triggering *event* (IEV 880-18-05) no longer exists

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

494
495 **IEV 880-01-43**

496 **nuisance alarm signal**

497 *alarm signal* (IEV 880-01-15) for which a panel of experts would agree that the *harm*
498 (IEV 880-18-07) associated with the *alarm signal* is greater than the *benefit* (IEV 880-18-03)
499 associated with action resulting from the *alarm signal*

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

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

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

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

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

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

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

508
509 **IEV 880-01-44**

510 **physiological alarm condition**

511 *alarm condition* (IEV 880-01-03) arising from a monitored *patient*-related (IEV 880-14-16)
512 *variable* (IEV 880-15-29)

513 EXAMPLE 1 High exhaled anaesthetic agent concentration.

514 EXAMPLE 2 Low exhaled tidal volume.

515 EXAMPLE 3 Low oxygen saturation measured by pulse oximetry.

516 EXAMPLE 4 High arterial pressure.

517 EXAMPLE 5 High heart rate.

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

519

520 **IEV 880-01-45**

521 **pulse, <auditory *alarm signal*>**

522 brief continuous sound having a specific spectral content

523 [Link to figure](#)

524 **Figure 1.2 — Illustration of temporal characteristics of an**
 525 ***auditory pointer* (IEV 880-01-22) *pulse* (IEV 880-01-45)**

526 [SOURCE: IEC 60601-1-8:2006, 3.32]

527

528 **IEV 880-01-46**

529 f_0

530 **pulse frequency, <auditory *alarm signal*>**

531 fundamental frequency (largest spectral component) of a *pulse* (IEV 880-01-45)

532 [SOURCE: IEC 60601-1-8:2006, 3.33, modified — replaced “first harmonic” with “largest
 533 spectral component”.]

534

535 **IEV 880-01-47**

536 **redirection, <*alarm system*>**

537 means by which an *integrator* (IEV 880-01-36) provides a response hierarchy for directing an
 538 *alarm condition* (IEV 880-01-03) to a *communicator* (IEV 880-01-26) or transfers an *alarm*
 539 *condition* to another *communicator*

540 [Link to figure](#)

541 **Figure 1.1 — Relationship of the terms used to describe an *alarm***
 542 ***system* (IEV 880-01-17) relationships**

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

544

545 **IEV 880-01-48**

546 **reminder signal**

547 periodic signal that reminds the *user* (IEV 880-14-21) that an *alarm system* (IEV 880-01-17) is
 548 in an *alarm signal*-inactivation (IEV 880-01-15) state

549 [SOURCE: IEC 60601-1-8:2006, 3.34, modified — replaced “operator” with “*user*”.]

550

551 **IEV 880-01-49**

552 **responsibility accepted, <*alarm condition*>**

553 state created by a *user* (IEV 880-14-21) response accepting ownership for addressing an *alarm*
 554 *condition* (IEV 880-01-03)

555 [Link to figure](#)

556 **Figure 1.1 — Relationship of the terms used to describe an *alarm***
 557 ***system* (IEV 880-01-17)**

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

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

560

IEV 880-01-50**responsibility rejected, <alarm condition>**

state created by a *user* (IEV 880-14-21) response rejecting ownership for addressing an *alarm condition* (IEV 880-01-03)

Link to figure

Figure 1.1 — Relationship of the terms used to describe an *alarm system* (IEV 880-01-17)

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*”.]

IEV 880-01-51**responsibility undefined, <alarm condition>**

state, automatically initiated when neither a *responsibility accepted* (IEV 880-01-49) nor *responsibility rejected* (IEV 880-01-50) is received within a specified period, which indicates that a *user* (IEV 880-14-21) is not responding

Link to figure

Figure 1.1 — Relationship of the terms used to describe an *alarm system* (IEV 880-01-17)

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*”.]

IEV 880-01-52 t_r **rise time, <auditory alarm signal>**

interval over which the *pulse* (IEV 880-01-45) amplitude of the *auditory pointer* (IEV 880-01-22) increases from 10 % to 90 % of its maximum

Link to figure

Figure 1.2 — Illustration of temporal characteristics of an *auditory pointer* (IEV 880-01-22) *pulse* (IEV 880-01-45)

[SOURCE: IEC 60601-1-8:2006, 3.35]

IEV 880-01-53**source, <alarm system>
SRC**

function or part of an *alarm system* (IEV 880-01-17) that has the capability to initiate an *alarm condition* (IEV 880-01-03)

Link to figure

Figure 1.1 — Relationship of the terms used to describe an *alarm system* (IEV 880-01-17)

Note 1 to entry: The *source* transfers the *alarm condition* to one or more *integrators*.

[SOURCE: IEC 60601-1-8:2006/AMD2:2020, 3.55, modified — replaced “the *integrator*” with “one or more *integrators*”.]

605 **IEV 880-01-54**

606 **technical alarm condition**

607 *alarm condition* (IEV 880-01-03) arising from a monitored equipment-related or *alarm system*-
608 related (IEV 880-01-17) *variable* (IEV 880-15-29)

609 EXAMPLE 1 An electrical, mechanical or other failure.

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

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

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

614

615 **IEV 880-01-55**

616 **true negative alarm condition**

617 absence of an *alarm condition* (IEV 880-01-03) when no valid triggering *event* (IEV 880-18-05)
618 has occurred in the *patient* (IEV 880-14-16), the equipment or an *alarm system* (IEV 880-01-17)

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

620

621 **IEV 880-01-56**

622 **true positive alarm condition**

623 presence of an *alarm condition* (IEV 880-01-03) when a valid triggering *event* (IEV 880-18-05)
624 has occurred in the *patient* (IEV 880-14-16), the equipment or an *alarm system* (IEV 880-01-17)

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

626

627

Section 880-02 – Circular economy**Box Note 1:**

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

IEV 880-02-01**end of life**

See IEV 904-01-17.

IEV 880-02-02**environment**

See IEV 904-01-01.

IEV 880-02-03**environmental aspect**

See IEV 904-01-02.

IEV 880-02-04**environmental impact**

See IEV 904-01-03.

IEV 880-02-05**hazardous substance**

substance that has the potential for an immediate or delayed effect that adversely impacts *health* (IEV 880-10-05) or the *environment* (IEV 880-02-02)

IEV 880-02-06**life cycle**

series of all stages in the life of a *product* (IEV 880-10-10), 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”.]

IEV 880-02-07**maintenance**

See IEV 192-06-01.

IEV 880-02-08**maintenance interval**

period between two *maintenance* (IEV 880-02-07) *activities* (IEV 880-16-01)



671 **IEV 880-02-09**

672 **post-production**

673 stage of the *life cycle* (IEV 880-02-06) of the *product* (IEV 880-10-10) after the design has been
674 completed and the *product* has been manufactured

675 EXAMPLE Transportation, storage, installation, *product* use, *maintenance*, *repair*, *product* changes,
676 decommissioning and disposal.

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

679
680 **IEV 880-02-10**

681 **recycling**

682 See IEC 901-07-10.

683
684 **IEV 880-02-11**

685 **refurbisher, <*medical device*, *accessory*>**

686 *organization* (IEV 880-14-15) that conducts *refurbishment* (IEV 880-02-12)

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

688
689 **IEV 880-02-12**

690 **refurbishment, <*medical device*, *accessory*>**

691 *process* (IEV 880-16-16) applied during the *expected lifetime* (IEV 880-18-06) to restore a
692 *product* (IEV 880-10-10), which has been put into service, to a condition according to the
693 original specifications

694 Note 1 to entry: *Refurbishment* can include *activities* such as *repair*, *rework*, replacement of worn components, and
695 update of software/hardware but does not change the specifications or *intended use*.

696 Note 2 to entry: *Refurbishment* does not include restoring after the *expected lifetime*.

697 Note 3 to entry: Specifications include form, fit, function, performance and *safety* aspects.

698
699 **IEV 880-02-13**

700 **remanufacturer, <*medical device*, *accessory*>**

701 *organization* (IEV 880-14-15) that performs *remanufacturing* (IEV 880-02-14)

702 Note 1 to entry: Some *authorities having jurisdiction* consider *remanufacturers* as *manufacturers*.

703
704 **IEV 880-02-14**

705 **remanufacturing, <*medical device*, *accessory*>**

706 *process* (IEV 880-16-16) applied to a *product* (IEV 880-10-10) that changes the specifications
707 or *intended use* (IEV 880-21-06)

708 Note 1 to entry: *Remanufacturing* can include restoring before or after the *expected lifetime*.

709 Note 2 to entry: Specifications include form, fit, function, *expected lifetime*, performance and *safety* aspects.

710

711 **IEV 880-02-15**712 **repair, <medical device, accessory>**713 *process* (IEV 880-16-16) for fixing a *product* (IEV 880-10-10), which has been put into service,
714 to a safe and functional state715 Note 1 to entry: *Repair* includes fault localization, fault diagnosis, fault correction and function checkout.716
717 **IEV 880-02-16**718 **rework**719 action on a nonconforming *product* (IEV 880-10-10) to make it conform to its *requirements*
720 (IEV 880-16-19)721 Note 1 to entry: *Rework* can affect or change parts of the nonconforming *product*.

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

723
724 **IEV 880-02-17**725 **shelf-life**726 period during which a *medical device* (IEV 880-09-24) or *accessory* (IEV 880-09-04) in its
727 original *packaging* (IEV 880-09-29) maintains its *stability* (IEV 880-10-12) under the conditions
728 specified in the *information supplied by the manufacturer* (IEV 880-11-05)

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

730
731

Section 880-03 – Classifications

IEV 880-03-01

body-worn, adj.

portable (IEV 880-03-18) whose *intended use* (IEV 880-21-06) includes operation while being worn by a *patient* (IEV 880-14-16) or attached to a *patient's* clothing or body

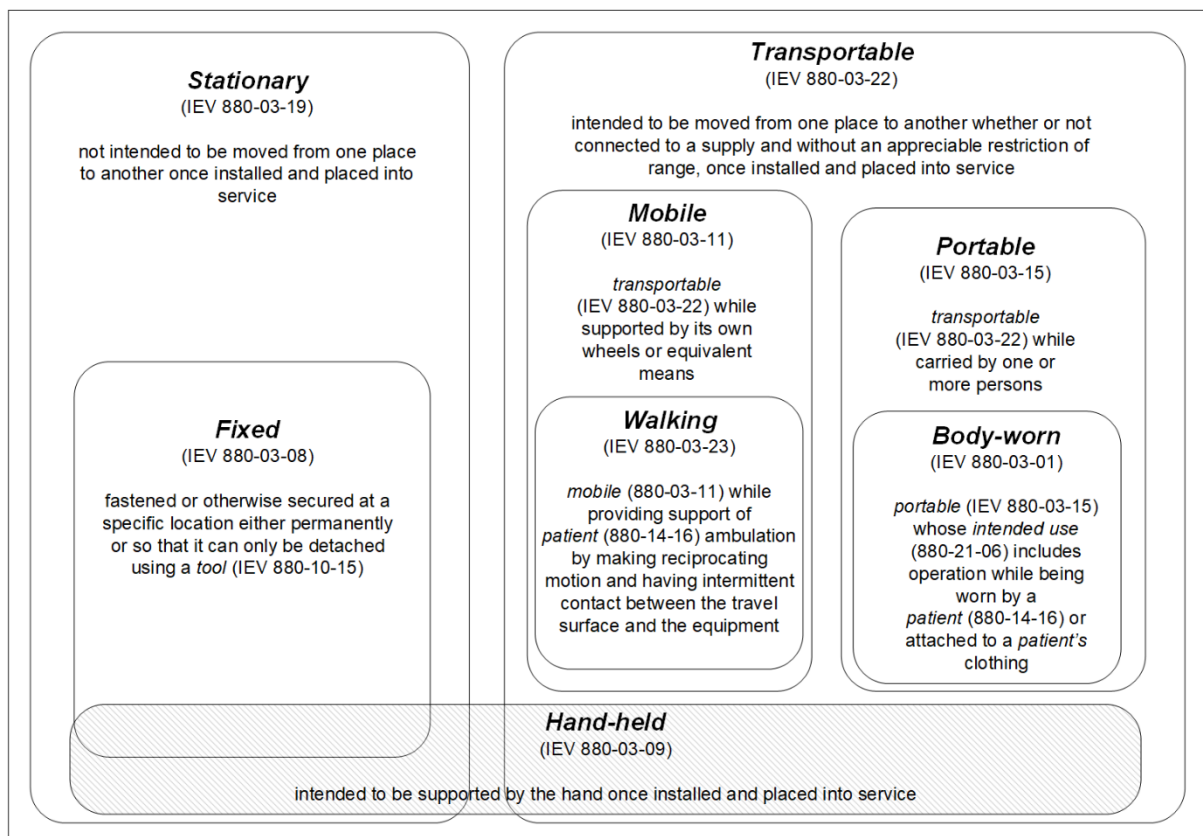


Figure 3.1 —Relationship of the terms used to describe equipment, accessories (IEV 880-09-04) or equipment parts

Note 1 to entry: *Body-worn* can include use without being *transit-operable* (e.g., a bed ridden *patient*).

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

IEV 880-03-02

Class I, adj. <electrical equipment>

having protection against electric shock that does not rely on *basic insulation* (IEV 880-06-01) only, but which includes a supplementary safeguard that provides means for conductive *accessible parts* (IEV 880-09-02) or conductive internal parts to be *protectively earthed* (IEV 880-03-19)

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.]

IEV 880-03-03**Class II, adj. <electrical equipment>**

having protection against electric shock that does not rely on *basic insulation* (IEV 880-06-01) 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.]

IEV 880-03-04**continuous operation, <medical device, accessory>**

operation in *normal use* (IEV 880-21-07) without interruption for an unlimited period without leading to a *hazardous situation* (IEV 880-18-09)

Note 1 to entry: *Continuous operation* can apply to a *medical device*, *accessory* or their parts.

[SOURCE: IEC 60601-1:2005, 3.18, modified — replaced “the specified limits of temperature being exceeded” with “leading to a *hazardous situation*”, deleted “of time” and added “without interruption” and note.]

IEV 880-03-05**detachable, adj.**

intended to be installed and removed by the *user* (IEV 880-14-21) without the use of a *tool* (IEV 880-10-15)

IEV 880-03-06**direct cardiac application**

use of an *applied part* (IEV 880-09-07) that can come in direct contact with the *patient's* (IEV 880-14-16) heart

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

IEV 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.]

IEV 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* (IEV 880-10-15)

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*.

Link to figure

**Figure 3.1 —Relationship of the terms used to describe equipment,
accessories (IEV 880-09-04) or equipment parts**

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

IEV 880-03-09

hand-held, adj.

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

Note 1 to entry: *Accessories* or equipment parts may be *hand-held*.

Link to figure

**Figure 3.1 —Relationship of the terms used to describe equipment,
accessories (IEV 880-09-04) or equipment parts**

IEV 880-03-10

internally powered, adj. <electrical equipment>

able to operate from an *internal electrical power source* (IEV 880-09-19)

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

IEV 880-03-11

mobile, adj.

transportable (IEV 880-03-25) while supported by its own wheels or equivalent means

Link to figure

**Figure 3.1 —Relationship of the terms used to describe equipment,
accessories (IEV 880-09-04) or equipment parts**

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

Box Note 2:

New terms “MR safe”, “MR unsafe” and “MR conditional” are proposed for inclusion in this Section 880-03 on classifications. The terms are derived from IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*, which is an identical copy of ASTM F2503-13. It is noted that a new edition of IEC 62570 will be prepared after the recent revision of the ASTM document in 2023.

IEV 880-03-12

MR conditional, adj.

having demonstrated *safety* (IEV 880-18-22) in the *MR environment* (IEV 880-08-03) within defined conditions, including conditions for the static magnetic field, the time-varying gradient magnetic fields and the time-varying radiofrequency fields

Note 1 to entry: Additional conditions, including specific configurations of the *MR conditional* item, may be required.

[SOURCE: IEC 62570:20xx (ASTM F2503-23), 3.1.9, modified — Replaced “an item with” with “having” and inserted second occurrence of “time-varying”.]

IEV 880-03-13**MR safe, adj.**

posing no known *hazards* (IEV 880-18-08) resulting from exposure to any *MR environment* (IEV 880-08-03)

Note 1 to entry: *MR safe* items are composed of materials that are electrically nonconductive, non-metallic and nonmagnetic.

Note 2 to entry: An item composed entirely of electrically nonconductive, non-metallic and nonmagnetic materials may be determined to be *MR safe* by providing a scientifically based rationale rather than test data.

Note 3 to entry: *Hazards* include those related to *essential performance* of the MR equipment and the *MR safe* item with regards to the static magnetic field, the time-varying gradient magnetic fields and the time-varying radiofrequency fields.

[SOURCE: IEC 62570:2014 (ASTM F2503-13), 3.1.13, modified — Replaced “an item that poses” with “posing” and added note 3.]

IEV 880-03-14**MR unsafe, adj.**

posing unacceptable *risks* (IEV 880-18-14) to the *patient* (IEV 880-14-16), medical staff or other persons within the *MR environment* (IEV 880-08-03)

EXAMPLE Pair of ferromagnetic scissors, steel oxygen cylinder

[SOURCE: IEC 62570:2014 (ASTM F2503-13), 3.1.14, modified — Replaced “an item which poses” with “posing”.]

IEV 880-03-15**multiple patient multiple use**

intended by the *manufacturer* (IEV 880-14-14) to be reused on multiple *patients* (IEV 880-14-16) for multiple uses

Note 1 to entry: A *multiple patient multiple use medical device* or *accessory* typically requires *processing* between *patients*.

Note 2 to entry: A *multiple patient multiple use medical device* or *accessory* may require *processing* between uses on a single *patient*.

[SOURCE: ISO 20417:2021, 3.18]

IEV 880-03-16**non-continuous operation**

operation in *normal use* (IEV 880-21-07), while continuously powered, requiring intermittent use to avoid a *hazardous situation* (IEV 880-18-09)

Note 1 to entry: *Non-continuous operation* can apply to a *medical device*, *accessory* or their parts.

IEV 880-03-17**permanently installed, adj.**

electrically connected to the *mains* (IEV 880-06-10) by means of a permanent connection that can only be detached using a *tool* (IEV 880-10-15)

[SOURCE: IEC 60601-1:2005, 3.84, modified — deleted “term meaning” and “supply”, replaced “by the use of” with “using”.]

896 **IEV 880-03-18**

897 **portable, adj.**

898 *transportable* (IEV 880-03-25) while carried by one or more persons

899 Link to figure

900 **Figure 3.1 —Relationship of the terms used to describe equipment,**
901 *accessories* (IEV 880-09-04) or equipment parts

902 [SOURCE: IEC 60601-1:2005/AMD2:2020, 3.85, modified — replaced “term referring to
903 transportable equipment that, once installed and placed into service, is intended to be moved
904 from one location to another” with “*transportable*” and deleted notes.]

905
906 **IEV 880-03-19**

907 **protectively earthed, adj.**

908 connected to the *protective earth terminal* (IEV 880-09-36) for reliable protective purposes

909 Note 1 to entry: Standards that use this term shall specify the *requirements* for reliable protective purposes.

910 [SOURCE: IEC 60601-1:2005, 3.96, modified — deleted “by means complying with the
911 requirements of this standard”.]

912
913 **IEV 880-03-20**

914 **single patient multiple use**

915 intended by the *manufacturer* (IEV 880-14-14) to be reused on an individual *patient*
916 (IEV 880-14-16) for multiple uses

917 Note 1 to entry: A *single patient multiple use medical device* or *accessory* may require *processing* between uses.

918 Note 2 to entry: For an *implantable medical device*, the duration of a *single use* is from implanting to explanting the
919 *medical device*.

920 [SOURCE: ISO 20417:2021, 3.25]

921
922 **IEV 880-03-21**

923 **single use, <*medical device*, *accessory*>**

924 do not re-use

925 use only once

926 intended by the *manufacturer* (IEV 880-14-14) to be used on an individual *patient*
927 (IEV 880-14-16) or specimen during a single *procedure* (IEV 880-16-15) and then disposed of

928 Note 1 to entry: A *single use medical device* or *accessory* is not intended by its *manufacturer* to be further *processed*
929 and used again.

930 [SOURCE: ISO 20417:2021, 3.26]

931
932 **IEV 880-03-22**

933 **stationary, adj.**

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

935 Link to figure

936 **Figure 3.1 —Relationship of the terms used to describe equipment,**
937 *accessories* (IEV 880-09-04) or equipment parts

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

940

941 **IEV 880-03-23**942 **sterile**

943 free from viable microorganisms

944 [SOURCE: ISO 20417:2021, 3.28]

945

946 **IEV 880-03-24**947 **transit-operable, adj.**948 having an *intended use* (IEV 880-21-06) that includes operation while being moved949 Note 1 to entry: *Transit-operable* equipment can be used indoors, outdoors and in vehicles.950 [SOURCE: IEC 60601-1-11:2015, 3.4, modified — replaced “term referring to transportable
951 equipment whose” with “having an”, changed note and deleted example.]

952

953 **IEV 880-03-25**954 **transportable, adj.**955 intended to be moved from one place to another whether or not connected to a supply and
956 without an appreciable restriction of range, once installed and placed into service957 EXAMPLE *Mobile* equipment, *portable* equipment and *body-worn* equipment.958 Note 1 to entry: *Transportable* equipment can be *hand-held*.

959

Link to figure

960 **Figure 3.1 —Relationship of the terms used to describe equipment,**
961 ***accessories* (IEV 880-09-04) or equipment parts**962 [SOURCE: IEC 60601-1:2005/AMD1:2012, 3.130, modified — deleted “term referring to
963 equipment that”, moved “once installed and placed into service” and replaced the note.]

964

965 **IEV 880-03-26**966 **walking, adj.**967 *mobile* (IEV 880-03-11) while providing support of *patient* (IEV 880-14-16) ambulation by
968 making reciprocating motion and having intermittent contact between the travel surface and the
969 equipment

970

Link to figure

971 **Figure 3.1 —Relationship of the terms used to describe equipment,**
972 ***accessories* (IEV 880-09-04) or equipment parts**973 [SOURCE: IEC 80601-2-78:2019, 201.3.215, modified — replaced “equipment that, once
974 installed and placed into service, is intended to move from one location to another” with “while
975 providing support of *patient* ambulation”, “contact with” with “contact between”, “RACA robot”
976 with “equipment” and deleted examples and note.]

977

Section 880-04 – Cleaning, disinfection and sterilization

IEV 880-04-01

cleaning

process (IEV 880-16-16) to remove contaminants to the extent necessary for further *processing* (IEV 880-04-03) or for *intended use* (IEV 880-21-06)

Note 1 to entry: *Cleaning* consists of the removal of adherent soil (e.g., blood, protein substances and other debris) from the surfaces, crevices, serrations, joints and lumens of a *medical device* by a manual or automated *process* 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”.]

IEV 880-04-02

disinfection

process (IEV 880-16-16) to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

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

IEV 880-04-03

processing

processes (IEV 880-16-16) to prepare a new or used healthcare *product* (IEV 880-10-10) for its *intended use* (IEV 880-21-06)

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

Note 2 to entry: A healthcare *product* includes *medical devices* and *accessories*.

[SOURCE: ISO 17664-2:2021, 3.10, modified — added note 1 and replaced “refers to a medical device” with “includes *medical devices* and *accessories*” and replaced “activity” with “*process*”.]

IEV 880-04-04

sterilization

process (IEV 880-16-16) to render *product* (IEV 880-10-10) 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.

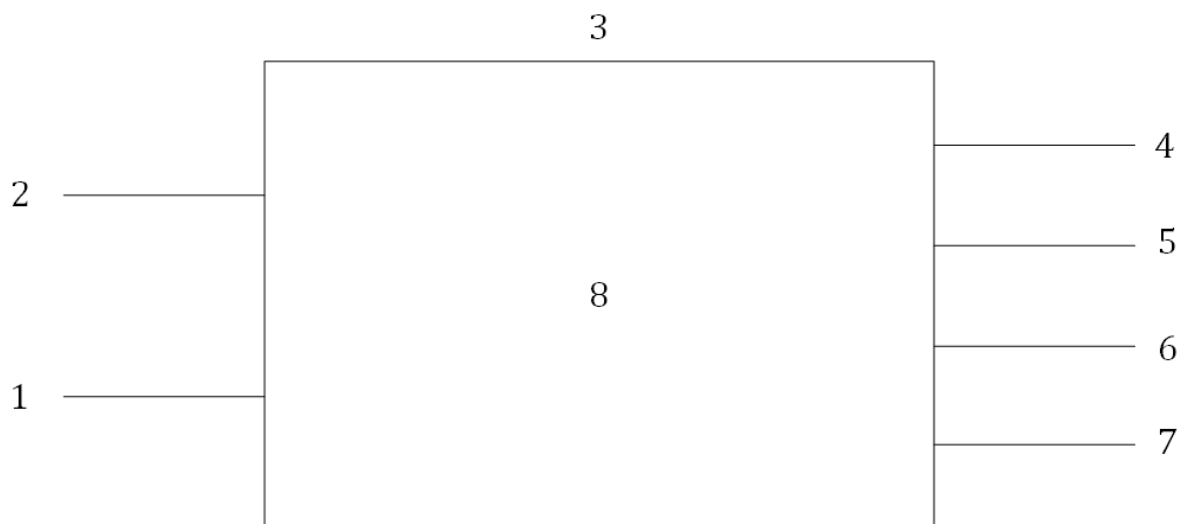
[SOURCE: ISO 17664-1:2021, 3.17, modified — deleted “used”.]

Section 880-05 – Connections

IEV 880-05-01

EMC port, <electromagnetic compatibility>

particular interface of equipment which couples this equipment with the external *electromagnetic environment* (IEV 880-07-05) and through which the equipment is influenced by this *electromagnetic environment*



Key

- 1 DC power
- 2 AC power
- 3 *Enclosure* (IEV 880-09-11)
- 4 *Patient coupling point* (IEV 880-05-06)
- 5 *Network/data coupling* (IEV 880-05-04)
- 6 *SIP/SOP* (IEV 880-05-08)
- 7 Antenna coupling
- 8 *MEE* (IEV 880-09-26)

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

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

[SOURCE: IEC 60050-161:2014-06, 161-01-27, modified — added “EMC” to the term and “*patient coupling point*” to the figure and replaced the example with a note.]

IEV 880-05-02

fluid port

opening for the passage of a fluid through a specified interface

Note 1 to entry: A *fluid port* can be in the form of a specific *connector* or designed to allow connection only to a limited type of *connector*.

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

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

IEV 880-05-03

functional connection

connection by electrical, mechanical, wireless or other means, including those intended to transfer signals, data, power or substances

Note 1 to entry: A connection to the *fixed mains socket-outlet*, whether single or multiple, is not considered to result in a *functional connection*.

- 1050 Note 2 to entry: *Permanently installed* equipment is not considered to have a *functional connection* to *mains*.
- 1051 Note 3 to entry: A *patient connection* is not considered a *functional connection*.
- 1052 Note 4 to entry: Power can be electrical, gas, mechanical, etc.
- 1053 [SOURCE: IEC 60601-1:2005, 3.33, modified — replaced “electrical or otherwise” with “by
1054 electrical, mechanical, wireless or other means” and replaced note 1 with notes 1 to 4.]
- 1055
- 1056 **IEV 880-05-04**
- 1057 **network/data coupling**
- 1058 *functional connection* (IEV 880-05-03) used to transmit or receive information to or from other
1059 equipment in accordance with the specifications
- 1060 [SOURCE: IEC 60601-1:2005, 3.68, modified — replaced “any means” with “*functional*
1061 *connection* used” and deleted “*manufacturer’s*”.]
- 1062
- 1063 **IEV 880-05-05**
- 1064 **patient connection**
- 1065 individual point on the *applied part* (IEV 880-09-07) through which current can flow between the
1066 *patient* (IEV 880-14-16) and the *MEE* (IEV 880-09-26) in *normal condition* (IEV 880-18-10) or
1067 *single fault condition* (IEV 880-18-24)
- 1068 Note 1 to entry: A *patient connection* is not considered a *functional connection*.
- 1069 [SOURCE: IEC 60601-1:2005, 3.78, modified — added note.]
- 1070
- 1071 **IEV 880-05-06**
- 1072 **patient coupling point**
- 1073 *patient-coupled* (IEV 880-05-07) sensing or treatment point of *MEE* (IEV 880-09-26) that is
1074 necessary to achieve the *intended use* (IEV 880-21-06) of the *MEE*
- 1075 Note 1 to entry: Examples of types of coupling include conductive, capacitive, inductive, thermal, acoustic and optical.
- 1076 Note 2 to entry: A *patient coupling point* is not considered to result in a *functional connection*.
- 1077 [SOURCE: IEC 60601-1-2:2022, 3.16, modified — deleted “or an ME system and that provides
1078 a path for transfer of electromagnetic energy to or from the patient, whether intended or
1079 unintended”, replaced “a” with “*patient-coupled*” and added note 2.]
- 1080
- 1081 **IEV 880-05-07**
- 1082 **patient-coupled, adj.**
- 1083 having a path for the transfer of energy to or from the *patient* (IEV 880-14-16), whether intended
1084 or unintended
- 1085 Note 1 to entry: Examples of types of coupling include conductive, capacitive, inductive, thermal, acoustic and optical.
- 1086 [SOURCE: IEC 60601-1-2:2022, 3.15, modified — replaced “term referring to the presence of”
1087 with “having” and deleted “electromagnetic”.]
- 1088
- 1089 **IEV 880-05-08**
- 1090 **signal input/output part**
- 1091 **SIP/SOP**
- 1092 *functional connection* (IEV 880-05-03) intended to transmit or receive signals by direct electrical
1093 connection to or from other electrical equipment
- 1094 EXAMPLE Connections for display, recording or data processing.
- 1095 [SOURCE: IEC 60601-1:2005, 3.115, modified — replaced “part of ME equipment, not being an
1096 *applied part*,” with “*functional connection*” and “deliver” with “transmit”, moved “display,
1097 recording or data processing” to the example and deleted the note.]

Section 880-06 – Electrical hazards

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IEV 880-06-01**basic insulation**

insulation providing basic protection against electric shock

Note 1 to entry: *Basic insulation* provides one *means of protection*.

Note 2 to entry: This concept does not apply to insulation used exclusively for functional purposes.

[SOURCE: IEC 60601-1:2005, 3.9, modified — added note 2 to entry.]

IEV 880-06-02**clearance****air clearance**

See IEV 581-27-76.

IEV 880-06-03**creepage distance**

shortest distance along the surface of an insulating material between two conductive parts

[SOURCE: IEC 60050-151:2001-07, 151-15-50, modified — replaced “a solid” with “an”.]

IEV 880-06-04**double insulation**

insulation comprising both *basic insulation* (IEV 880-06-01) and *supplementary insulation* (IEV 880-06-19)

Note 1 to entry: *Double insulation* provides two *means of protection*.

[SOURCE: IEC 60050-195:2021-06, 195-06-08, modified — added note 1 to entry.]

IEV 880-06-05**earth leakage current**

current flowing from the *mains part* (IEV 880-09-21) through or across the insulation into the *protective earth conductor* (IEV 880-09-34) of *Class I* (IEV 880-03-02) equipment or into the functional earth conductor of *Class II* (IEV 880-03-03) equipment

[SOURCE: IEC 60601-1:2005, 3.25, modified — replaced “or a functional earthed connection according to 8.6.9” with “of *Class I* equipment or into the functional earth conductor of *Class II* equipment”.]

IEV 880-06-06**high voltage****HV**

See IEV 195-05-26.

IEV 880-06-07**insulation coordination**

mutual correlation of insulation characteristics of electrical equipment considering the expected micro-*environment* (IEV 880-02-02) and other influencing stresses

Note 1 to entry: *Insulation coordination* includes insulation types, *creepage distances*, *clearances*, distance through insulation, coatings, encapsulation, *environmental aspects*, etc.

[SOURCE: IEC 60050-442:2014-11, 442-09-01, modified — replaced “taking into account” with “considering” and added note 1 to entry.]