

SYSTEMS REFERENCE DELIVERABLE



Active assisted living (AAL) use case standards inventory and mapping

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SYSTEMS REFERENCE DELIVERABLE



Active assisted living (AAL) use case standards inventory and mapping

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The text of this Systems Reference Deliverable is based on the following documents:

Draft SRD	Report on voting
SyCAAL/332/DTS	SyCAAL/338/RVDTS

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

The language used for the development of this Systems Reference Deliverable is English.

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

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INTRODUCTION

IEC systems committee Active Assisted Living (SyC AAL) was formed to develop solutions to help AAL users of any age to live independently for as long as possible. AAL International Standards provide guidance for systems to be developed to ensure independent living. AAL develops systems based on the criteria of individual use cases. AAL systems are compilations of components, systems, and services from multiple vendors and service providers and contain a large variety of hardware and software systems, including medical devices, wellness devices, network hubs, IT systems, home monitoring devices, smart home technology, etc.

The task of AAL is to develop standards considering products, services, systems, safety, security, privacy, usability, accessibility, performance, and interoperability.

This document describes the process of identifying, compiling, and maintaining an inventory of international standards applicable to AAL systems. This document also describes the process of mapping international standards to individual use cases and identifying any gaps in the coverage of these international standards.

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ACTIVE ASSISTED LIVING (AAL) USE CASE STANDARDS INVENTORY AND MAPPING

1 Scope

The purpose of this document is to describe the process of building an inventory of international standards based on use cases, mapping these international standards to individual use cases, and providing a visual representation in the IEC mapping platform.

This document identifies the main categories of international standards applicable to AAL systems and applies these international standards to AAL components and the complete AAL system.

Although there are national and regional standards that can address parts of AAL systems, this document will focus only on standards developed at the international level (e.g., IEC, ISO, ITU-T).

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1

AAL

active assisted living

DEPRECATED: ambient assisted living concepts, products, services, and systems combining technologies and social environment with the aim of improving the quality of people's lives

[SOURCE: IEC 60050-871:2018, 871-01-02]

3.2

AAL application

AAL application and services

program or application that interacts with the AAL users or within the network infrastructure to transmit or exchange data and information in the network

[SOURCE: IEC 63240-1:2020, 3.1.4]

3.3

AAL architecture model

view of the AAL reference architecture with the main purpose of allowing for use case mapping and for conducting standards gap analysis

[SOURCE: IEC 60050-871:2023, 871-07-05]

3.4

AAL care recipient

person who receives and consumes AAL care services

Note 1 to entry: The concept denoted by the term "AAL user" (IEV 871-02-05) includes a wider range of people, including people who do not necessarily require AAL care services.

[SOURCE: IEC 60050-871:2018, 871-02-08]

3.5

AAL component

active assisted living component

object that, individually or in combination with accessories or software, contributes to the proper functioning of a manufacturer-defined application of an AAL system for the assisted compensation for persons with health problems

Note 1 to entry: All AAL components contribute to

- detection, prevention, monitoring, treatment or amelioration of diseases, illnesses and injuries,
- examination, replacement or alteration of anatomical structure or a physiological movement,
- facilitation of daily-life activities, improvement of facilities and enhancement of opportunities for self-determination.

[SOURCE: IEC 60050-871:2018, 871-04-02]

3.6

AAL device

device (IEV 151-11-20) used in an AAL system

EXAMPLE Examples are sensors and actuators that contain one or more components (functionality).

Note 1 to entry: External conditions and events include measurements of temperature, motion, and electrical conditions.

Note 2 to entry: There are 1) medical devices (IEV 871-06-06), as defined by regulatory agencies, 2) personal health devices and sensors (IEV 871-04-29) for fitness, wellbeing, personal comfort, and personal security and 3) devices that can serve as aggregators of personal data produced by the user of the device.

[SOURCE: IEC 60050-871:2018, 871-07-01, modified – IEV references for the terms "device" and "medical device" added.]

3.7

AAL gateway

gateway functional unit that connects two computer networks with different network architectures and protocols

Note 1 to entry: The computer networks may be local area networks, wide area networks, or other types of networks.

Note 2 to entry: Examples of gateways are a LAN gateway, a mail gateway.

[SOURCE: IEC 60050-732:2010, 732-01-17]

3.8

AAL information system

collection of technical and human resources that provide the storage, computing, distribution, and communication for the information required by an AAL service (871-01-04)

[SOURCE: IEC 60050-871:2023, 871-07-02, modified – Note to entry omitted.]

3.9

AAL level of assistance

designation indicating the degree of assistance needed by an AAL care recipient

Note 1 to entry: There are four AAL levels of assistance:

Level 0 – Independent: able to live independently with minimal assistance.

Level 1 – Some assistance: able to live independently but some assistance is needed occasionally (not on a permanent basis).

Level 2 – Assistance with IADL: level of assistance that involves physical/social/cognitive skills related to independent living in addition to ADL. This may include transportation, communication (i.e. use of telephone, e-mails), shopping, meal preparation, housekeeping, managing medications and managing personal finances.

Level 3 – Assistance with ADL: level of assistance that includes basic human activities like walking and moving around, going up a few steps, bathing (plus eating, clothing, continence, grooming).

[SOURCE: IEC 60050-871:2023, 871-07-03]

3.10

AAL platform backend system

AAL backend system

system that houses a number of components (and functionalities) in order to collect the data from AAL gateways or AAL devices directly over a wide area network connection, and that can also implement components for the remote management of the AAL gateways or AAL devices (e.g. firmware update) and components for interfacing with AAL information systems or other-information systems

[SOURCE: IEC 60050-871:2023, 871-07-04]

3.11

AAL reference architecture

model that defines concepts and provides generic rules for designers of AAL systems and services with the aim to facilitate system design and enable interoperability between components

[SOURCE: IEC 60050-871:2023, 871-07-09]

3.12

AAL service

active assisted living service

action or function of an AAL system creating an added value for customers

EXAMPLE An AAL service could comprise, for example configuration and maintenance of AAL systems, assistant systems to support the home environment.

Note 1 to entry: An AAL service can consist of several individual services.

[SOURCE: IEC 60050-871:2018, 871-01-04]

3.13**AAL use case****active assisted living use case**

description of a typical situation or series of events in which active assisted living can be realized

Note 1 to entry: The aim of an AAL use case is to describe a problem scenario in such a way that AAL approaches to solutions are made evident in their temporal, spatial as well as technical dimension.

[SOURCE: IEC 60050-871:2018, 871-01-07]

3.14**AAL use case category**

group of AAL use cases for which the AAL system is similar

Note 1 to entry: The AAL use case categories are the following:

- 1) prevention and management of chronic long-term conditions
- 2) social interaction
- 3) mobility
- 4) health and wellness
- 5) (self-) management of daily life activities at home

[SOURCE: IEC 60050-871:2023, 871-01-09]

3.15**AAL user****active assisted living user**

person who uses or benefits from, or uses and benefits from, AAL devices, systems, or services.

[SOURCE: IEC 60050-871:2018, 871-02-05]

3.16**ADL****activity of daily living**

basic human action that involves physical self-maintenance ability

Note 1 to entry: ADL comprises the following six areas: transferring; bathing; eating; dressing; continence; grooming and toileting.

[SOURCE: IEC 60050-871:2023, 871-01-10]

3.17**IADL****instrumental activity of daily living**

human action that involves physical/social/cognitive skills related to instruments for independent living in addition to ADL

Note 1 to entry: IADL includes various actions: transportation; communication (i.e. use of telephone, e-mails); shopping; meal preparation; housekeeping; managing medications; managing personal finances.

[SOURCE: IEC 60050-871:2023, 871-01-12]

3.18**other information system**

collection of technical and human resources that provide the storage, computing, distribution, and communication for the information not specific to AAL services

[SOURCE: IEC 63240-1:2020, 3.1.12, modified – notes have been deleted.]

4 Systems approach to developing international standards inventory and use case mapping

Systems Committees take a top-down approach to standardization starting at the systems level rather than at the product level.

This document will describe the process used by the Systems Committee for Active Assisted Living to develop the international standards inventory and systems mapping tools:

- Use case analysis – to gain a better and more detailed understanding of stakeholder needs;
- Standards analysis – to analyse relevant standards and map them to the system model;
- Gap analysis – to identify any gaps in which new standardization work is needed.

A brief description of the architecture and modelling used to develop system models and architecture views, will also be shown.

5 Domain and stakeholder analysis

The vision of SyC AAL is to foster standardization of Active Assisted Living (AAL) products, services, and systems to enhance the quality of life and to enable independent living for AAL users of all ages. The IEC Systems Committee for Active Assisted Living (SycAAL) was formed to develop solutions for AAL users to live independently as long as possible. AAL supports the development of systems to meet these goals based on use cases. These systems are compilations of components, systems, and services from multiple vendors and service providers and contain a large variety hardware and software systems, including medical devices, wellness devices, network hubs, IT systems, home monitoring devices, smart home technology, etc.

SyC AAL is comprised of six working groups, each developing processes to align with a specific section of the systems approach process. SyC AAL also maintains liaisons internally with various IEC technical committees, system committees and ISO/IEC joint technical committees (JTCs), and externally with ISO technical committees, ETSI and ITU-T.

6 Use case analysis

6.1 General

IEC TS 63134 describes the use case development process for IEC SyC AAL. In SYC AAL, use cases characterize user needs which in turn provide input into the development of AAL systems and services required to meet these needs. Use cases categorize products and services within AAL system technology to assist system developers and service providers to implement solutions that address AAL user needs.

Use cases provide a description of the user and the user needs that include:

- Level of assistance required by the user;
- Level of criticality to the user caused by a system failure or use error;
- Category of the use case

6.2 Use case level of assistance

Use cases determine the level of assistance required by the AAL care recipient as shown in the x-axis of Figure 1:

- Level 0: independent. AAL users are not dependent on AAL technology;
- Level 1: some assistance. Some assistance is necessary from AAL technology;
- Level 2: IADL (instrumental activities of daily living). Assistance required for needs such as managing transportation, housekeeping, meal preparation, etc.;
- Level 3: ADL (activities of daily living). Assistance required with basic activities such as bathing, feeding, walking, grooming, etc.

6.3 Use case level of criticality

The level of criticality refers to the level of severity that a system failure or use error can cause to the AAL user:

- Major: failure or error can cause death or serious injury to a user or operator;
- Moderate: failure or error can cause minor injury to a user or operator;
- Minor: failure or error is unlikely to cause injury to a user or operator.

6.4 Use case categories

AAL use cases are grouped into five categories based on use case analysis. Multiple categories can be applicable to a single use case.

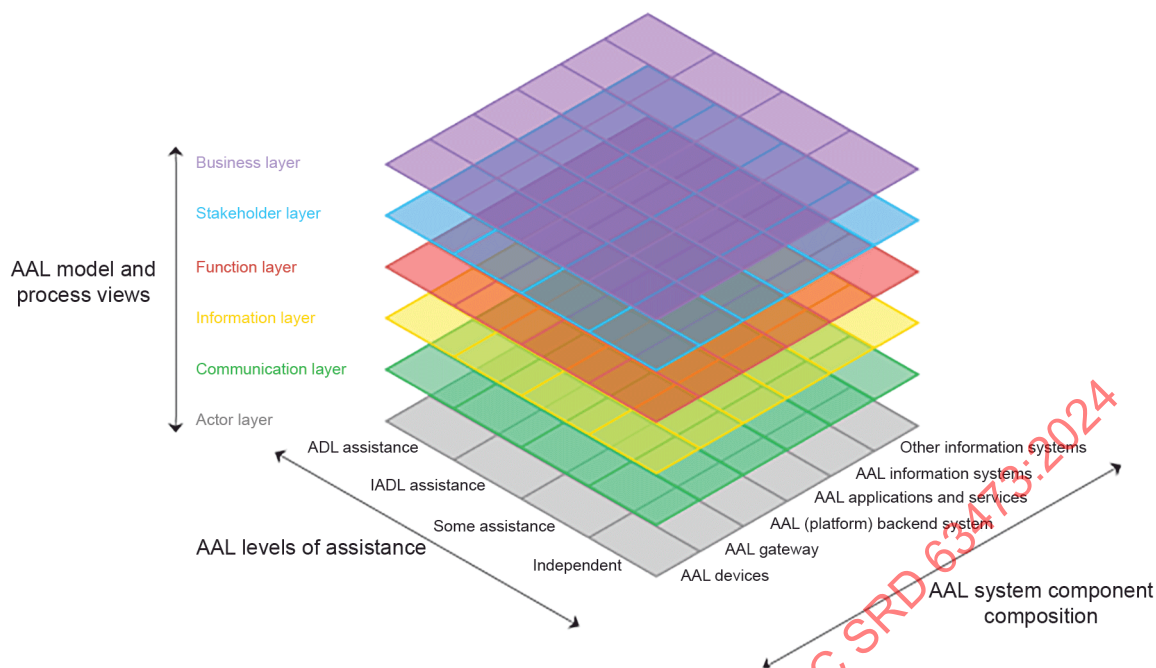
- 1) Prevention and management of chronic long-term conditions,
- 2) Social interaction (social connections and networking),
- 3) Mobility (mobility inside and outside the home; transportation needs),
- 4) Health and wellness management,
- 5) (Self-)management of daily life activities at home.

6.5 AAL use cases

AAL use cases will be added periodically as SyC AAL progresses with its work. The current list and titles of use cases are available in IEC TS 63134.

7 Architecting and modelling

IEC 63240-1 defines the concepts and terminology of the reference architecture. IEC 63240-2 describes the AAL architecture model and its relationship to the use case structure. As shown in Figure 1, the AAL system is represented in the three-dimensional view of the AAL architecture. The AAL architecture model consists of the x-axis that describes the levels of assistance, the y-axis that describes AAL system component composition, and the z-axis that describes the AAL model and process views.



IEC

Figure 1 – Conceptual AAL Architecture Model (per IEC 63240-2)

8 Standards analysis

8.1 Approach to developing the international standards inventory

The AAL international standards inventory is developed and maintained based on identifying international standards that are applicable to the AAL system structure as developed per use cases. Standards are also linked to the developing technical committee and to internal and external AAL liaison organizations or to international regulatory requirements, if applicable.

8.2 AAL standards evaluation

AAL systems are designed and developed based on the individual use cases. International standards applicable to the separate AAL components and to the overall AAL system are identified and included in the standards inventory. The international standards are categorized as described in 8.3 and Table 2 and linked to the technical committee responsible for its development. Technical committees are further identified as being internal and external AAL liaison organizations or other. Standards are also linked to the relevant international regulatory requirements, if applicable. There is some commonality in each AAL system, but each system shall be evaluated individually to determine the applicable standards.

The criteria for international standards evaluation are:

- 1) Standards applicable to AAL components;
- 2) Standards applicable to the complete AAL system;
- 3) Standards developed on the international level: IEC, ISO, ITU international standards;
- 4) Standards required to fulfil regulatory requirements.

8.3 AAL standards categories

Within these systems, the main categories of standards to be evaluated are in the areas of:

- 1) Accessibility
 - Includes standards identified for active and non-active accessibility and assistance devices;
- 2) AI ethics
 - Includes standards and guidance to consider the ethical considerations to the AAL user;
- 3) Battery management
 - Includes standards for the safety and performance of primary and secondary batteries;
- 4) Biocompatibility
 - Includes standards to ensure the safety of materials touched or inhaled by the AAL user;
- 5) Design guidance
 - Design criteria for AAL components and systems (e.g., ISO Guides, IEC SyC AAL publications);
- 6) Energy efficiency
 - Energy efficiency targets;
- 7) Electrical safety
 - Protection of the AAL user (basic safety – shock, fire, mechanical);
- 8) Electromagnetic compatibility
 - Includes standards to ensure compliance to device and system EMC levels based on the AAL environment of use; these include standards harmonized to the European Union's Electromagnetic Compatibility (EMC) Directive;
- 9) Environmental (temperature/humidity/mechanical strength)
 - Includes standards to evaluate the robustness of devices in the AAL home and domestic environments;
- 10) Functional safety
 - Includes standards developed by IEC SyC AAL to evaluate the functional safety of AAL safety related systems;
- 11) Interoperability
 - Includes standards to evaluate the exchange of data and information between AAL components made by different manufacturers;
- 12) Medical equipment
 - Provides monitoring, therapy, or assistance to the AAL user (includes active and non-active devices);
- 13) Privacy and security
 - Includes standards to evaluate the level of protection of the AAL user's identity and personal information;
- 14) Risk management
 - Includes standards and guidance to evaluate the AAL system in terms of the level of risk to the AAL user;
- 15) Robotics
 - Includes standards for robotic SyC AAL user assistance and companionship;
- 16) Specific absorption rate
 - Includes standards to evaluate human exposure to RF fields;

17) SyC AAL

- Requirements unique to SyC AAL (can also fall under the design guidance category);

18) Usability (human factors)

- Includes standards and guidance to assess the user's ability to understand and operate within an AAL system;

19) Use cases

- Use case analysis according to IEC TS 63124 is the basis for developing AAL systems and services.

Other standards to be evaluated are those that include requirements or normative references in any of the standard types above.

As described in IEC SRD 63219:2022, the purpose of standards evaluation is to ensure that AAL systems are designed as intended and to ensure that the AAL system meets the needs of the AAL user.

8.4 AAL international standards inventory

The AAL international standards inventory is available in a spreadsheet at <https://www.iec.ch/sycaal/supportingdocuments/> and is planned to be visually represented on the IEC mapping platform <https://mapping.iec.ch/#/maps/97>.

The AAL international standards inventory is formatted by designation, title, category, technical committee, regulation, if applicable, and use case. Examples are shown in Table 1.

Table 1 – AAL international standards inventory format

Designation	Title	Category	TC	Regulation
Standard designation number e.g., IEC 62368-1	Title of international standard	Category of standard according to 8.1.2	Identification of the Technical Committee responsible for developing the standard	If pertinent, the applicable regulation

8.5 AAL use case international standards analysis

During use case analysis, standards are further categorized as those being applicable to the individual AAL components, those being applicable to the complete system, and those being applicable to both.

An overview is shown in Table 2.

Table 2 – Standards categorization

Category	Description	AAL component	AAL System
Accessibility	Assistive products	X	X
AI ethics	Specific to the AAL user		X
Battery management	Battery safety and performance	X	
Biocompatibility	Material evaluation	X	
Design guidance	Design criteria for AAL components and systems	X	X
Energy efficiency	Energy efficiency targets	X	X
Electrical safety	Protection of the AAL user	X	
Electromagnetic compatibility	Evaluate performance in the AAL home environment	X	X
Environmental	Robustness	X	X
Functional safety	Design and maintenance of cooperative multiple systems in the connected home environment		X
Interoperability	Exchange of data and information		X
Medical equipment	Provide monitoring, therapy, or assistance to the AAL user	X	X
Privacy and security	Protection of identity and personal information	X	X
Risk Management	Evaluate the residual risk based on AAL user capabilities	X	X
Robotics	AAL user assistant	X	
Specific absorption rate	Evaluate human exposure to RF fields	X	
SyC AAL	Requirements unique to SyC AAL	X	X
Usability	Evaluate effectiveness to the AAL user	X	X
Use case	Use case analysis	X	X

8.6 AAL use case analysis

An example of use case analysis is shown below by analysing use case 1 from IEC TS 63134 shown in Figure 2.

Standards for individual AAL components are listed followed by standards that are applicable to the complete system.

The information shown below is preliminary, the final analysis will be found in the IEC mapping platform <https://mapping.iec.ch/#/maps/66> currently under development.

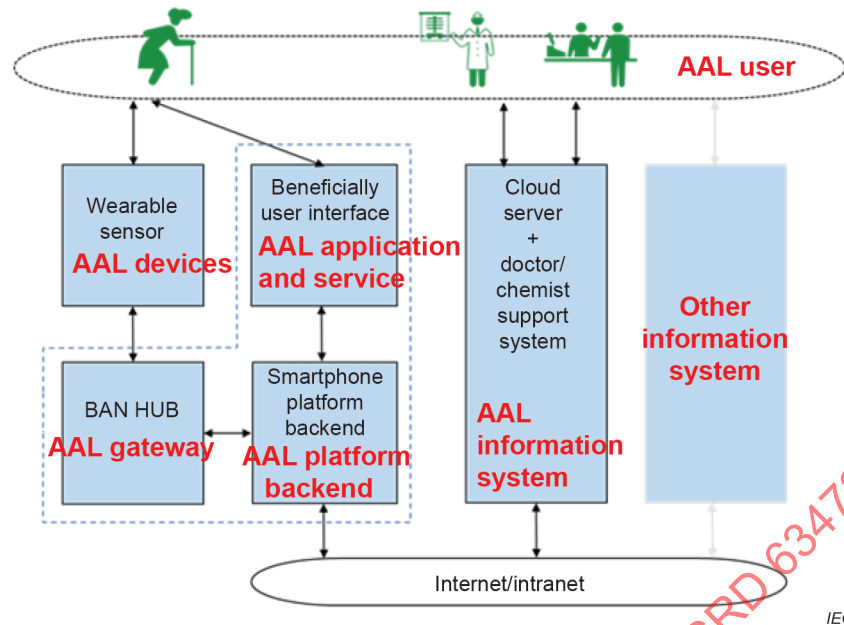


Figure 2 – Use case 1 from IEC TS 63134

Use case 1 is analysed as follows.

AAL components (devices):

- Vital signs monitoring devices for the AAL user are medical devices within the scope of the IEC 60601-1 series:
 - IEC 60601-1
 - IEC 60601-1-2
 - IEC 60601-1-8
 - IEC 60601-1-11
 - IEC 60601-2-47
 - ISO 80601-2-56
 - ISO 80601-2-61
 - IEC 62304
 - ISO 10993 series
 - IEC 62133-2
 - IEC 63203-801 series

- Gateway to transmit data to the cloud server can be body worn, a mobile (smart phone) device or a dedicated hub
 - IEC 62368-1
 - IEC 62311
 - IEC/IEEE 62209-1528
 - IEC 62232
 - ITU-T H.820-H.850 series
 - IEC 63203-801-1
 - IEC 63203-801-2
 - IEC 63430¹

Examples of applicable standards for the complete AAL system for use case 1:

- Usability
 - IEC 62366-1
 - ISO 9241-210
- Risk assessment:
 - ISO 14971
 - ISO 31000
- Privacy and security:
 - ISO/IEC 29184
 - ISO/IEC 29100
- Functional safety:
 - IEC 63168

NOTE IEC 63168 is currently under development within IEC SyC AAL.

- EMC
 - Applicable harmonized standards to the European Union's Electromagnetic Compatibility (EMC) Directive

8.7 Visual representation – Device

An example visual representation of the use case analysis for the electrocardiogram (ECG) device is shown in Figure 3. Selecting ECG for use case 1 will display the applicable standards designations, titles with a link to the IEC webstore. Also displayed are the designated technical committees, links to the Technical Committee websites, and a listing of the use cases where ECG devices are utilized.

¹ Under preparation. Stage at the time of publication IEC CDV 63430:2024.

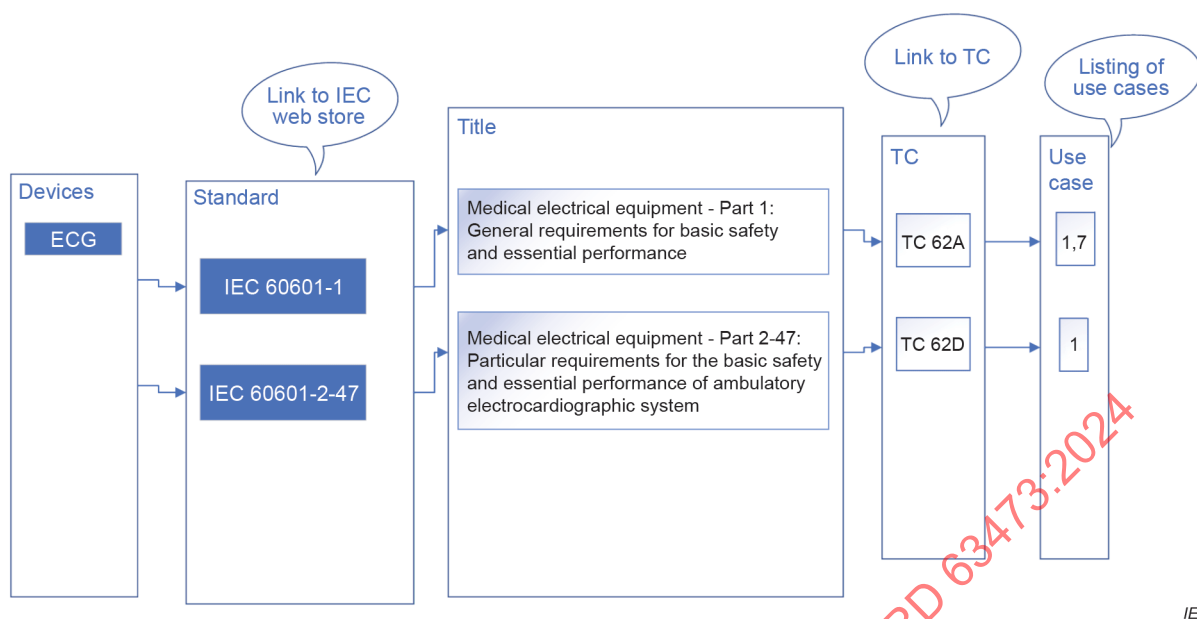


Figure 3 – Example visual representation – Device

8.8 Visual representation – System

An example visual representation of the use case analysis for the AAL system is shown in Figure 4. Selecting system for use case will display the applicable standards categories, standards designations, standard titles with links to the designated technical committees and listings of the use cases where these standards are applied.

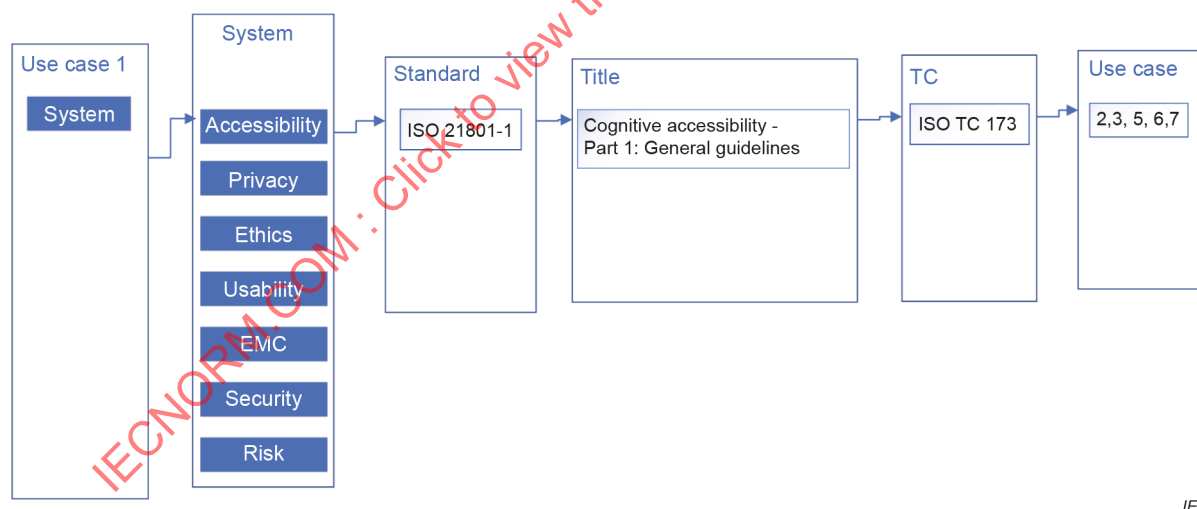


Figure 4 – Example visual representation – System

8.9 Visual representation – Regulations

Regulations applied to use cases will also be mapped. An example visual representation of the regulations use case analysis for the AAL system is shown in Figure 5. Selecting system for use case will display the applicable standards categories, standards designation, standard titles with links to the designated technical committees, and listings of the use cases where these standards are applied.