INBOTS

Inclusive Robotics for a better Society

WHITE PAPER

STANDARDISATION AND INTERACTIVE ROBOTS

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

www.inbots.eu

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Table of Contents

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Executive summary

The White Paper is dedicated to future interactive robotic and robotic device standardisation activities. The focus lies on interactive robots in the manufacturing, healthcare and consumer domain.

This document gives an overview of general information, such as the international and European standardisation system and legal issues connected to standardisation. The White Paper is supposed to point out the state-of-the-art in robotic standardisation and standardisation potentials, which were identified by the INBOTS consortium, the literature and the INBOTS survey. In addition, it is described how the identified standardisation potentials can be taken up by the standardisation system. The overall aim of the INBOTS project is to aid standardisation activities across the robotics community.

In general, the robotics community seems to be satisfied with the robotic standards quantity; but they demand specific standards and the advancement of existing standards. The INBOTS standardisation survey provides a perspective on these future standardisation topics, but it has to be acknowledged that the amount of answers received is not sufficient. Currently, there are approximately 30 standards directly related to robotics, which are mainly developed on an international level with European technical committees mirroring the work. Standardisation on European level is not sought after by the robotics community because of the internationality of the robotic market. The robotics community faces problems in identifying standards that are applicable for their devices. They face problems with affixing the CE mark and ask for a user-friendly categorisation of standards, so that they know for each of their products which standards they can follow to affix the CE mark to ensure that their products are aligned with the basic safety requirements of the European directives.

This is a challenging task for the standardisation system due to the increasing modularity of robots and their fast-changing nature. The INBOTS project gives recommendation on how to solve the identified challenges and shows a potential path for the standardisation of exoskeletons in the manufacturing domain and for surgical teleoperated robots in the healthcare domain. An initial set of key performance indicators for both domains is provided. General recommendations are for example the creation of an open access benchmarking database on a European level, the provision of subsidized advisory services on how to identify and apply standards, and European research projects to elaborate further and initiate standardisation activities on key performance indicators and test methods for interactive robots and robotic devices.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Preface

The aim of this White Paper is to disseminate knowledge about current and future standardisation topics within the scope of interactive robots. The target group of this White Paper are stakeholders engaged in the development, manufacturing and employment of interactive robots as well as the European Commission (EC). The document is particularly relevant for standardisation bodies and organisations that take part in standardisation activities and research projects. The document is structured in eight sections, which build up on one another. INBOTS conducted a standardisation survey and the results are incorporated throughout the document.

Since not all readers are familiar with standardisation, an introduction into the general system is included in the 1st section. The standardisation organisations are introduced as well as the relevant Technical Committees (TC) on European and International level and the European directives. The meaning of the term "Presumption of conformity" with a European directive and the legal background of standards is also explained.

The domains that the document focuses on are described in Section 2. Each domain describes the devices usually employed and the technologies behind them. The categorisation focuses on where the interactive robots are primarily used. This is only one option to assess interactive robots and it is closely related to the structure of European directives. The section also shows the connections between the domains and that service robots are applicable in each domain.

In order to acquire an overview of the standardisation landscape a standards research was conducted, which is explained in Section 3. The different types of standards, the search methodology as well as the TCs and robotic standards are introduced. The findings of the INBOTS standardisation survey on the usage of standards are included here.

Standardisation potentials that were identified after the conduction of the standards research are described in Section 4. This section does not only focus on the identified INBOTS potentials, but also on the standardisation potentials from the INBOTS standardisation survey and literature.

The 5th section describes a portfolio of tools to initiate or contribute to standardisation activities. It is described when a particular tool should be used and who can use it. In addition, recommendations are given on what to do with the identified potentials for standardisation and how European research projects and the general public benefit from standardisation.

Section 6 shows challenges in standardising robotics and provides recommendations for addressing these challenges. In Section 7, two detailed paths are described on how to proceed with two standardisation potentials. The first is dedicated to exoskeletons in the manufacturing domain and the second is dedicated to surgical teleoperated robots. Section 8 focuses on the key finding of the overall White Paper.

To sum it up, this document provides the reader with an overview of the relevant interactive robotic standards, the TCs who develop them, standardisation potentials and challenges and solutions regarding standardisation and the regulatory framework as well as how the standardisation potentials can become standardisation activities.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

1. Introduction to standardisation

This section introduces the structure of the standardisation system and the entities involved in the development of robotic standards as well as their connection to one another. The legal background of standard is explained as well as relevant EU directives are introduced.

1.1 Standardisation system

Standards are documents that set technical information with regards to various kinds of products, materials, services and processes. A *standard* is a document, established by consensus and approved by a recognised body, which provides common rules, guidelines or characteristics for activities or their results having the purpose of achieving an optimal degree of order in a given context[1]. In this definition a "recognised body" refers to the official National Standardisation Body (NSB) of a country.

In Germany, DIN has been contractually the responsible standards organisation of the Federal Republic of Germany since 1975 and represents German interests as a member of CEN in European standardisation and of ISO international standardisation. Today almost 90 percent of DIN's standards work is European and/or international in nature.

At national level in Germany, standardisation work on robotics is carried out within the DIN Standards Committee Mechanical Engineering (NA 060-38-01 AA Robotics). This technical committee elaborates the German position in robotics standardisation and mirrors the work done at international and European level. Various German technical experts contribute their know-how to the development of standards, while DIN is the independent platform for standardisation in Germany and worldwide.

European standardisation organisations

The European standardisation organisations (CEN and CENLEC) are umbrella organisations that consist of National Standardisation Bodies (NSB) like DIN, including the European Union member states and other countries that are part of the European single market. European standards are developed by teams of experts who possess particular knowledge of the specific sector or topic that is being addressed. The work is structured in technical committees (TC). The experts who develop standards in these TCs are nominated by the NSBs and they represent their country on European level (see Figure 1). NSBs are obliged to adopt European standards as national standards and to make them available in their country. They also have to withdraw any existing national standard that conflicts with the new European standard. Therefore, a given European standard becomes a national standard in all 34 member states (EU member states, EFTA countries, and future EU or EFTA countries). The main goal of the European standardisation system is to unify all standards that apply within Europe[2].

International standardisation organisations

International standardisation organisations are also umbrella organisations. The members are foremost standards organisations in their countries and there is only one member per country

[1] EN 45020 Standardisation and related activities - General vocabulary.
[2] CEN/CENELEC Internal Regulations Part 2 - Common rules for standardisation work (2017).

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

(see Figure 1). The adoption of international standards at national level by the NSBs is voluntary except for if an international standard is adopted as a European standard. It must then be adopted as a national standard. In addition, a standard that has been developed at international level can be simultaneously adopted as a European standard by means of parallel voting procedures in accordance with the Vienna Agreement[3]. Such standards are to be automatically adopted by the NSBs. As with European standardisation, national mirror committees decide whether to take part in international standardisation work. These committees develop the national standpoint, send experts to represent this standpoint, and often lead project work by taking on the secretariat of the relevant international technical committee (see Figure 1). The mirror committees also decide whether an international standard should be adopted as a national standard[4].

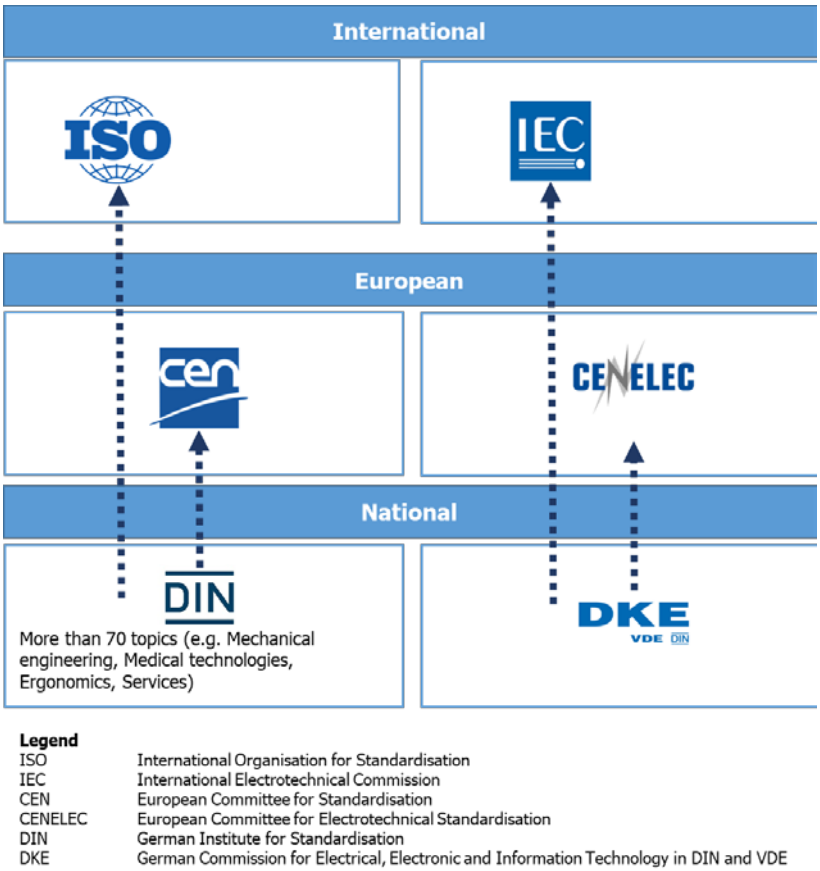

Figure 1: Standardisation system

1.2 Entities in standardisation

The following international and European technical committees develop standards that are relevant for interactive robots. They develop standards that are specifically dedicated to interactive robots or could be applied to interactive robots. The focus is on the international level, because the major standardisation work in robotics is conducted on the international level. Figure 2 gives an overview of Liaisons between international technical committees.

[3] Agreement on technical co-operation between ISO and CEN (Vienna Agreement, 1991).
[4] ISO/IEC Directives Part 1 - Procedures for the technical work (2019).

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

ISO/TC 299 Robotics / CEN/TC 310 Advanced Manufacturing Technologies

ISO/TC 299 is active in the field of robotics in the manufacturing, healthcare and consumer domain, excluding toys and military applications and they consider robots as machines. ISO/TC 299 develops standards on for example personal care robots (physical assistant robots, mobile servant robots, and person carrier robots), service robots, industrial robots, mobile robots, and collaborative robots. There is an agreement between the CEN and ISO to avoid duplication of work and parallel development (Vienna Agreement). CEN/TC 310 on Advanced Manufacturing Technologies is the counterpart of ISO/TC 299 on European level. The following working groups (WG), study group (SG) and joint working group (JWG) are of interest for interactive robots:

- *ISO/ TC 299/ SG 1 Study group on gaps and structure,*
- *ISO/ TC 299/ WG 1 Vocabulary and characteristics,*
- *ISO/ TC 299/ WG 2 Service robot safety (e.g. ISO 13482, ISO/ TR 23482-1)*
- *ISO/ TC 299/ WG 3 Industrial safety (e.g. ISO/ TS 15066),*
- *ISO/ TC 299/ WG 4 Service robot performance (e.g. ISO 18646-1),*
- *ISO/ TC 299/ WG 6 Modularity for service robots,*
- *ISO/ TC 299/ WG 7 Management system for service robots,*
- *ISO/ TC 299/ JWG 5 Medical robot safety (e.g. IEC/ TR 606001-4-1, IEC 80601-77, IEC 80601-78).*

ISO/TC 199 Safety of machinery / CEN/TC 114 Safety of machinery

ISO/TC 199 standardises basic concepts and general principles for safety of machinery. The TC focuses for example on integrated manufacturing systems, emergency stop functions, two-hand control devices, minimum gaps to avoid harm, safeguards, safety distances, pressure-sensitive protective devices, and the reduction of risks. CEN/TC 114 standardises general principles for safety of machinery on European level (harmonised standards type A, B and C of the machinery directive). Directive 2006/42/EC gives the political and legal environment for CEN/TC 114.

Machinery is an "assembly, fitted with or intended to be fitted with a drive system consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application"[5].

The following working groups (WG) are of interest for interactive robots:

- *ISO/ TC 199/ WG 3 Safety of integrated manufacturing systems,*
- *ISO/ TC 199/ WG 5 General principles for the design of machinery and risk assessment,*
- *ISO/ TC 199/ WG 6 Safety distances and ergonomic aspects,*
- *ISO/ TC 199/ WG 12 Human-machine-interactions.*

IEC/TC 62 Electrical equipment in medical practice / CLC/TC 62 Electrical equipment in medical practice

IEC/TC 62 prepares international standards and other publications concerning electrical equipment, electrical systems and software used in healthcare and their effects on patients,

[5] EN ISO 12100 Safety of machinery - General principles for design - Risk assessment and risk reduction.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

operators, other persons and the environment. While ISO considers robots as machines, IEC considers robots as medical electrical equipment.

Two subcommittees (SC) of IEC/TC 62 are of particular interest for interactive robot:

- *SC 62A Common aspects of electrical equipment used in medical practice, and*
- *SC 62D Electromedical equipment.*

IEC/ SC 62A JWG 9 Medical electrical equipment & systems using robotic technology develops general requirements and guidance related to the safety of medical electrical equipment and systems that utilise robotic technology (e.g. IEC/TR 60601-4-1[6]). The work encompasses medical applications (including aids for the disabled) covering invasive and non-invasive procedures such as surgery, rehabilitation therapy, imaging and other robots for medical diagnosis and treatment. ISO/TC JWG 5 and IEC/SC 62A JWG 9 are the same committees, however, ISO and IEC use different names for the same group. JWG indicates that it is a joint working group among ISO and IEC, as the scope of the work is at an overlap of their domains, e.g. Medical Electrical Equipment (IEC) and Robotics (ISO).

IEC/ SC 62D JWG 35 Medical robots for surgery is also linked to ISO/TC 299/JWG 5 and has the main focus of maintaining IEC 80601-2-77 "Medical Electrical Equipment – Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment". *IEC/ SC 62D JWG 36 Medical robots for rehabilitation* is also linked to ISO/TC 299/JWG 5 (e.g. IEC 80601-2-78 "Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation").

CLC/TC 62 also develops standard and takes over the work of IEC/TC 62 and its subcommittees, because of an agreement between IEC and CENELEC (Frankfurt Agreement).

ISO/TC 173 Assistive products / CEN/TC 293 Assistive products and accessibility

ISO/TC 173 is active in the field of assistive products and related services to assist a person in compensating for reduced abilities. ISO/TC 173 focuses on assistive products like wheelchairs, assistive products for walking, personal hygiene, hoists for the transfer of persons and assistive products for people with cognitive disability. On European level CEN/TC 293 is active in the field of assistive products and related services.

The following subcommittees (SC) and working groups (WG) are of interest for interactive robots:

- *ISO/ TC 173/ SC 1 Wheelchairs,*
- *ISO/ TC 173/ SC 7 Assistive products for persons with impaired sensory functions,*
- *ISO/ TC 173/ WG 1 Assistive products for walking,*
- *ISO/ TC 173/ WG 10 Assistive products for cognitive disabilities.*

ISO/IEC JTC 1/SC 35 User interfaces

ISO/TC JTC 1/SC 35 is active in the field of user-system interfaces in information and communication technology (ICT) environments and support for these interfaces to serve all users,

[6] IEC/TR 60601-4-1 Medical electrical equipment - Part 4-1: Guidance and interpretation - Medical electrical equipment and medical electrical systems employing a degree of autonomy.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

including people having accessibility or other specific needs. The following working groups (WG) are of interest for interactive robots:

- *ISO/ IEC JTC 1/ SC 35/ WG 2 Graphical user interface and interaction,*
- *ISO/ IEC JTC 1/ SC 35/ WG 4 User interfaces for mobile devices,*
- *ISO/ IEC JTC 1/ SC 35/ WG 5 Cultural and linguistic adaptability,*
- *ISO/ IEC JTC 1/ SC 35/ WG 6 User interfaces accessibility.*

ISO/TC 159/SC 4 Ergonomics of human-system interaction / CEN/TC 122 Ergonomics

ISO/TC 159 is active in the field of ergonomics, in particular, general ergonomics principles, anthropometry and biomechanics, ergonomics of human system interaction and ergonomics of the physical environment, addressing human characteristics and performance, and methods for specifying, designing and evaluating products, systems, services, environments and facilities. ISO/TC 159/SC 4 focuses on computer-based interaction, visual display requirements, human-centred design processes for interactive systems, tactile and haptic interaction, accessible design for consumer products and image safety. On European level CEN/TC 122 is active in the field of ergonomic principles and requirements. The following working groups (WG) are of interest for interactive robots:

- *ISO/ TC 159/ SC 4/ WG 2 Visual display requirements,*
- *ISO/ TC 159/ SC 4/ WG 3 Controls, workplace and environmental requirements,*
- *ISO/ TC 159/ SC 4/ WG 5 Software ergonomics of human-computer interaction,*
- *ISO/ TC 159/ SC 4/ WG 6 Human-centred design processes for interactive systems,*
- *ISO/ TC 159/ SC 4/ WG 9 Tactile and haptic interaction.*

ISO/TC 168 Prosthetics and orthotics

ISO/TC 168 is active in the field of prosthetics and orthotics, covering such aspects as performance, safety, environmental factors, and interchangeability. Temporary and permanent procedures and devices are included. Priority is given to standards on prostheses (artificial limbs and auxiliary equipment). Prosthesis is an externally applied device used to replace wholly, or in part, an absent or deficient limb segment. Orthosis is an externally applied device used to modify the structural and functional characteristics of the neuro-muscular and skeletal system to assist a person with a limb issue[7] (e.g. exoskeleton). Both, prosthesis and orthosis, are wearable devices. A wearable device is mechanical or mechatronic device attached to the human body for supplementing and augmenting of motor functions. The following working groups (WG) are of interest for interactive robots:

- *ISO/ TC 168/ WG 1 Nomenclature and classification,*
- *ISO/ TC 168/ WG 3 Testing.*

Other standardisation organisations and connections

Apart from formal standardisation, there are a number of professional associations and consortia that publish corresponding specifications or recommendations on robotics (e.g. ASTM, IEEE). The IEEE Standard Association has for example a couple of working groups on ethically aligned

[7] ISO 8549-1 Prosthetics and orthotics – Vocabulary – Part 1: General terms for external limb prostheses and external orthoses.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

autonomous and intelligent systems[8]. A cooperation agreement between ISO and the IEEE Standard Association does not exist for robotic topics. A PSDO cooperation agreement (Partner Standards Development Organisation) does exist for example for health informatics and information technology.

The ASTM International committee F48 on exoskeletons and exosuits was formed in 2017 to develop voluntary consensus standards that address safety, quality, performance, ergonomics and terminology for systems and components during the full life cycle of the product – from before usage, to maintenance, to disposal – including, security and information technology considerations. There is also no cooperation agreement between ISO and ASTM International (American Society for Testing and Materials) for robotic topics. The only PSDO cooperation agreement currently existing is on additive manufacturing. On European level, CEN and ASTM have signed a technical cooperation agreement with the aim to facilitate global dialogue and coordination in specific standardisation areas of mutual interest.

A Memorandum of understanding (MoU) between the European Patent Office (EPO) and CEN/CENELEC was signed in 2019 to enhance the support they provide to industry and stakeholders in Europe and beyond in the field of standard-essential patents.

Liaisons between International technical committees

Originally, standards were developed for specific objects, devices or services like for example screws. Nowadays, the situation is different for complex and converging topics like interactive robots. Here, the usage of standards has changed: a cross-sectoral approach leaving the silo specific view. The creation of Liaisons between technical committees (TCs) is one way to exchange information on the current work programme (see Figure 2).

[8] https://ethicsinaction.ieee.org/p7000/

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

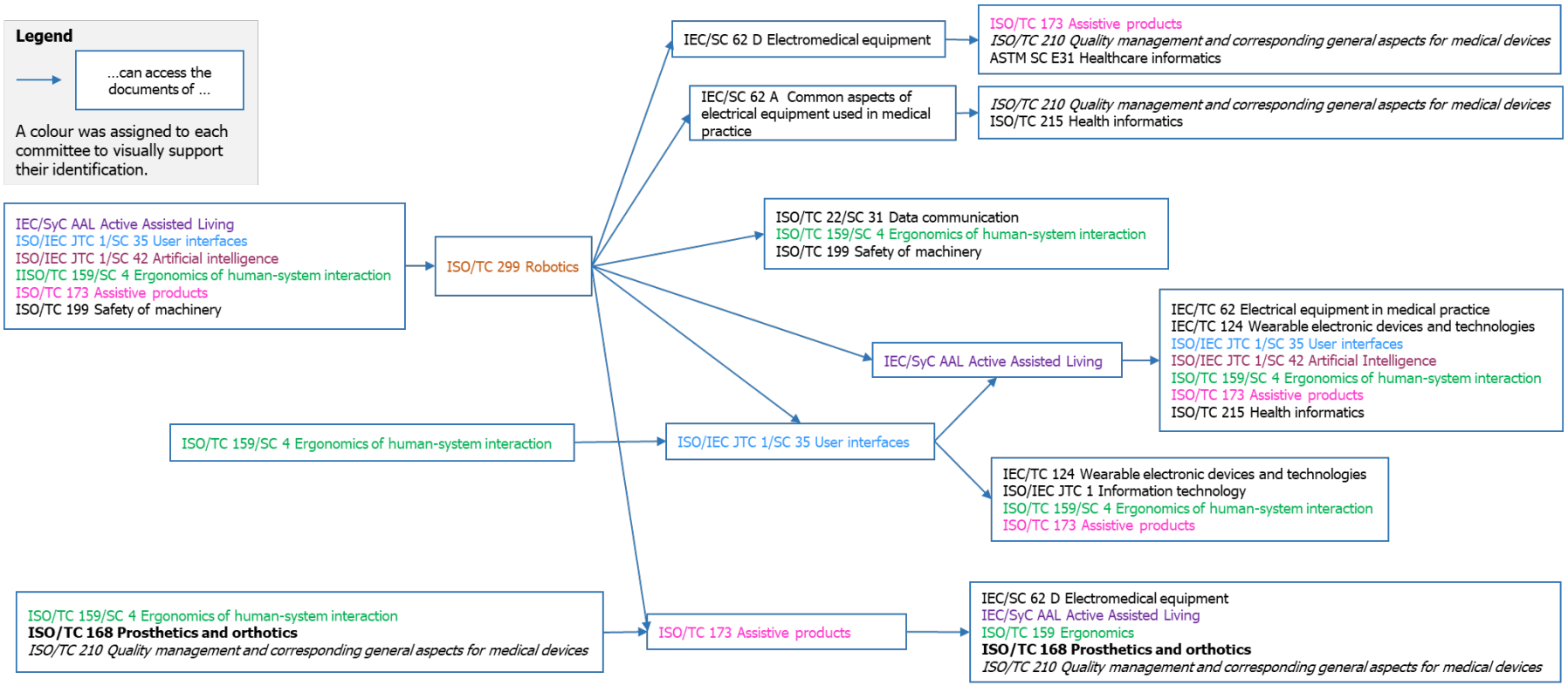

Figure 2: Overview of Liaisons between International technical committees

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

1.3 Legal significance of (safety) standards in Europe

The European standards published by CEN or CENELEC are developed by experts, established by consensus and adopted by the NSBs. It is important to note that the use of standards is voluntary, and therefore there is no legal obligation to apply them. This section gives a short overview of the legal significance of standards, more information can be found in the INBOTS White Paper on the regulatory and risk assessment framework of interactive robots.

Standards not only benefit the private sector and consumers, but also relieve the State of its responsibility for drawing up detailed technical requirements. They also protect the citizens from overly rigid laws. In its laws and regulations, the State refers to standards for the technical details necessary to comply with essential requirements.

National laws lay down the legal framework and set protection targets, while consensus-based standards describe the means of achieving those targets in detail. Standards reflect the state-of-the-art, because they are regularly reviewed by experts to adjust for new developments. Thus, technical regulation is delegated to those most suited: Experts from industry and other stakeholder groups. In this way, standardisation contributes to much-desired deregulation.

The aim of the European Union's New Approach is to harmonise technical standardisation within Europe. It is a central pillar of the internal market and applies to over 30 European directives. According to the New Approach, European directives specify essential safety and health requirements, which are then given more technical detail in the harmonised European standards mandated by the EC. These European standards are implemented at national level. Users of a harmonised standard can presume that they meet the essential requirements of the respective European directive (presumption of conformity).

The use of standards is voluntary. They only become mandatory if they are referred to in contracts, laws or regulations. In addition, contract partners may choose to make use of a standard binding. Standards are also used to settle legal disputes, especially in product liability cases. Courts use standards to help decide whether the manufacturer has followed the acknowledged rules of technology and thus has exercised due diligence. Standards are thus recommendations which, when followed, provide legal certainty.

Although the use of standards which are referred to in legislation does not absolve anyone of liability, the presumption of conformity principle applies. This means that when a manufacturer complies with legal provisions laid down in a directive or law by applying the relevant standards, it can be presumed that the product is in conformance with these provisions and can thus be placed on the market. The presumption of conformity that results from applying harmonised European standards refers to conformity with European legislation, such as European directives or European regulations that specify essential safety and health requirements for products. Products that meet these requirements bear the CE mark. CE marking demonstrates conformity with the essential safety requirements laid down in EU legislation (such as directives). The CE mark is to be applied by the manufacturer or exporter, or their representative. It should be noted that the CE mark is not a quality mark, nor does it indicate that the product was made in Europe. As such, it is not intended for the end consumer.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Partly completed machinery and assemblies of machinery

Partly completed machinery is almost machinery, but cannot in itself perform a specific application e.g. a drive system. Industrial robots and manipulators are usually partly completed machinery. They are partly completed machinery, because the mechanisms usually consist of a series of segments. Completed machinery consists of a system that is fully defined and integrated to realize a safe system. Partly completed machinery is mostly intended to be incorporated into or assembled with other machinery or other partly completed machinery and must thus undergo further construction in order to become final machinery that can perform its specific application.

Partly completed machinery alone cannot comply fully with the essential health and safety requirements, since certain risks may result from the fact that the machinery is not complete or from the interface between the partly completed machinery and the rest of the machinery or assembly of machinery into which it is to be incorporated. However, the manufacturer of partly completed machinery must state, in a Declaration of Incorporation, which of the essential health and safety requirements were fulfilled.

Similarly, assemblies of machinery (with or without partly completed machinery) are subject to the 2006/42/EC Machinery Directive as machinery itself, because their safety depends not just on the safe design and construction of their constituent units, but also on the suitability of the units and the interfaces between them.

If the new unit (machinery or assembly of machinery) is constituted by partly completed machinery accompanied by a Declaration of Incorporation and assembly instructions, the person incorporating the partly completed machinery into the assembly is to be considered as the manufacturer of the new unit. The manufacturer must therefore assess any risks arising from the interface between the partly completed machinery, other equipment and the assembly of machinery fulfil any relevant essential health and safety requirements that have not been applied by the manufacturer of partly completed machinery, apply the assembly instructions, draw up an EC Declaration of Conformity and affix the CE mark to the new unit as assembled. Regarding the assembly of machinery, the CE marking will thus be applied only to the whole assembly[9].

1.4 European directives and harmonised standards

Harmonised European standards are those drawn up on the basis of a standardisation request (formerly called mandate) by the EC (or EFTA). These standards give more detail to the more general essential safety and health requirements laid down in European legislation such as the directives. Lists of harmonised standards are published in the Official Journal of the European Union (OJEU). In each harmonised standard, the relationship between it and the relevant directive is described in an Annex. Compliance with a harmonised European standard means that it can be assumed that the essential requirements of the respective directive(s) have been met. Although products and services in accordance with harmonised European standards must be accepted in all EU member countries, the use of such standards remains voluntary.

[9] Directive 2006/42/EC of the European Parliament and of the Council on machinery, May 17, 2006.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

However, manufacturers who do not comply with these standards must provide another form of proof that the essential requirements of the directive have been met[10, 11].

Around 30% of the European standards published by CEN have been developed in response to specific requests (standardisation mandates) issued by the EC. Many of these standards are known as harmonised standards. They enable businesses to ensure that their products or services comply with essential requirements that have been set out in European legislation (European directives).

Manufacturers that conform to harmonised standards which have been published in the Official Journal of the European Union (OJEU) can presume to comply with the essential safety requirements of the concerned directive. In each directive, there is a paragraph on the presumption of conformity, e.g. "Machinery manufactured in conformity with a harmonised standard, the references to which have been published in the OJEU shall be presumed to comply with the essential health and safety requirements covered by such a harmonised standard".

A list of harmonised standards applicable to interactive robots can be found on the INBOTS website (www.inbots.eu).

Directive 2006/42/EC on Machinery[12]

Machinery in this directive refers to an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application. There are different types of harmonised standards under the machinery directive:

- *A-type: Specify basic concepts, terminology and design principles applicable to all categories of machinery,*
- *B-type: Deal with specific aspects of machinery safety or specific types of safeguard that can be used across a wide range of categories of machinery,*
- *C-type: Provide specifications for a given category of machinery.*

A guideline to apply the machinery directive was published in 2017 - Guide to application of the Machinery Directive 2006/42/EC (Edition 2.1). Harmonised standards are for example:

- *EN ISO 13482 Robots and robotic devices - Safety requirements for personal care robots (ISO 13482:2014) (C-type),*
- *EN ISO 10218-1 Robots and robotic devices - Safety requirements for industrial robots - Part 1: Robots (ISO 10218-1:2011)(C-type),*
- *EN ISO 10218-2 Robots and robotic devices - Safety requirements for industrial robots - Part 2: Robot systems and integration (ISO 10218-2:2011) (C-type).*

[10] German Institute for Standardisation, "An introduction to standardisation – a practical guide for small businesses".
[11] Regulation (EU) No 1025/2012 of the European Parliament and the Council on European Standardisation.
[12] Directive 2006/42/EC of the European Parliament and of the Council on machinery.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Regulation (EU) 2017/745 on Medical Devices[13]

Medical devices in this directive refer to "any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of a disease;*
- *diagnosis, monitoring, treatment, alleviation of, or compensation for, any injury or disability;*
- *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;*
- *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donation;*

and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means". Harmonised standards are for example:

- *EN 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005),*
- *EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016),*
- *EN ISO 22523 External limb prostheses and external orthoses - Requirements and test methods (ISO 22523:2006).*

The Regulation (EU) 2017/745 on Medical Devices (MDR) replaced the Medical Directive 93/42/EEC (MDD) in 2020. The main changes are listed below[14]:

- *Any existing products with the CE marking under previous regulations/ directives must be recertified and a Unique Device Identification (UI) is required to help track devices throughout the supply chain.*
- *Broadened definitions of regulated devices, now including new devices which can be related to the use of interactive robots, e.g. medical purpose devices and cleaning products.*
- *Heightened safety measures and risk managements will have a direct effect on interactive robots. This implies that more clinical data is necessary to ensure safety and performance, a faster reporting of all incidents, injuries and deaths, redefinition of quality assurance, risk-management and post-market expectations, reclassification of medical devices as higher risk.*

[13] Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, May 17, 2017.
[14] Factsheet for manufacturers of medical devices: https://ec.europa.eu/health/md_newregulations/publications_en.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Directive 2014/30/EU on Electromagnetic Compatibility [15]

The directive ensures that electrical and electronic equipment does not generate or is not affected by electromagnetic disturbance. All electric devices or installations influence each other when interconnected or close to each other, e.g. interference between TV sets, radios or electrical power lines. The purpose of electromagnetic compatibility (EMC) is to keep all those side effects under reasonable control. EMC designates all the existing and future techniques and technologies for reducing disturbance and enhancing immunity. Equipment in this directive refers to any apparatus or fixed installation. Apparatus means any finished appliance or combination thereof made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance. Fixed installation means a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location.

2. Domains of interactive robots

This section introduces three application areas in which interactive robots can be used: manufacturing, healthcare and the consumer domain. It shows the devices that this White Paper focused on and the technologies behind them.

2.1 Manufacturing domain

In industrial manufacturing, as in many high-intensity mass production systems, there is a widespread use of industrial robots and automation (e.g. welding, painting, and internal logistics). Industrial robots are defined as automatically controlled, reprogrammable multipurpose manipulators, programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications[16].

A prerequisite for the success of modern manufacturing companies is the ability to produce mass-customized products with many variants as effectively as possible. This demands a high degree of flexibility and re-configurability of the production system that so far only human operators can achieve.

To improve the workers' capabilities and to support the working activities, a strong trend toward hybrid systems has been observed in the last years, in which the automation is more and more interacting with the operators.

The use of these interactive robotics solutions is linked to enabling technologies, as[17]:

- *accurate indoor positioning systems for mobile manipulators, particular in dynamic environments,*
- *sensor based safety systems to enhance human-robot interaction,*

[15] Directive 2014/30/EU of the European Parliament and of the Council on electromagnetic compatibility, March 29, 2014.
[16] ISO 8373:2012 Robots and robotic devices – Vocabulary.
[17] EU-Robotics, "Strategic Research Agenda – For Robotics in Europe 2014 – 2020", accessed July 2, 2019, https://www.eu-robotics.net/cms/upload/topic_groups/SRA2020_SPARC.pdf.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

- *higher level of realism in system modelling, and*
- *reactive planning and control able to operate an interactive robot safety in real industrial environments.*

In the context of the continuously increasing use of automation, interactive robots are expected to increase the manufacturing process performances significantly.

Three main categories of interactive robots in the manufacturing domain are considered in this White Paper: exoskeletons and wearable robots, human-robot collaborative (HRC), and automatic guided vehicles (AGV) as well as autonomous mobile robots (AMR).

Exoskeletons and wearable devices

Exoskeletons are wearable, external mechanical or mechatronic devices that help or enhance the abilities of a person[18]. Exoskeletons give support to, or enhance, certain body functions (e.g. upper limbs, lower limbs, back, hands). They are classified as passive or active, depending on the actuation system. The first ones use passive materials, springs or dampers with the ability to store energy harvested by human motion and to use it as required. Active exoskeletons use actuators as electric motors, hydraulic actuators, pneumatic muscles or other types[19]. They include sensors and control systems that assist human capabilities and create a close interaction with the wearer. In this context, we will refer to active exoskeletons. The purpose of these technologies is the prevention of work-related injuries, so called work related musculoskeletal disorders (MSD), and the extension of the workers' working life.

MSDs are injuries and disorders that affect the human body's movement or musculoskeletal system (e.g. muscles, tendons, ligaments, nerves, discs, blood vessels)[20]. Their onset, in working conditions, is linked to ergonomic factors such as force, repetition and postures. In Europe, the incidence of work related MSDs constitutes around 38.1 %[21] and the impact on the gross domestic product of the related countries (up to 3.3 %) increases the focus on the phenomenon[22]. Hence, the exoskeletons that address the industrial world are mainly oriented to assist the worker with targets of postural assistance (when the worker assumes unhealthy working postures for a long period of time), force multipliers, supporting tools (e.g. screwdrivers, sanders) and manual material handling (for loads higher than 3 kg), reducing the biomechanical loads on the human joints and thus preventing the onset of work related MSDs.

[18] De Looze, M. P., Bosch, T., Krause, F., Stadler, K. S., & O'Sullivan, L. W. (2016). Exoskeletons for industrial application and their potential effects on physical work load. *Ergonomics*, *59*(5), 671-681.
[19] Gopura, R. A. R. C., & Kiguchi, K. (2009, June). Mechanical designs of active upper-limb exoskeleton robots: State-of-the-art and design difficulties. In *2009 IEEE International Conference on Rehabilitation Robotics* (pp. 178-187). IEEE.
[20] ErgoPlus, "The Definition and Causes of Musculoskeletal Disorders", accessed March 4, 2021, https://ergo-plus.com/musculoskeletal-disorders-msd/.
[21] European Agency for Safety and Health at Work, "OSH in figures: Work-related musculoskeletal disorders in the EU – Facts and figures", accessed March 4, 2021, https://osha.europa.eu/en/tools-and-publications/publications/reports/TERO09009ENC/view.
[22] European Agency for Safety and Health at Work, "Work-related accidents and injuries cost EU €476 billion a year according to new global estimates", accessed March 4, 2021, https://www.eurofound.europa.eu/news/news-articles/eu-osha-work-related-accidents-and-injuries-cost-eu-eu476-billion-a-year-according-to-new-global.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

The use of exoskeletons in these working contexts has been proposed for those activities in the production process that are difficult to automate or where the use of manipulators is not effective due to the low flexibility (not standard working activities) or the unsuitability for the workplace (bulkiness, costs). The identification of the workstations that could benefit from the introduction of the exoskeletons is fundamental to increase its acceptability and use. The effectiveness of human machine interaction together with the equipment compatibility of the workstations must be guaranteed and respected.

Possible applications in which exoskeletons could be applied in the manufacturing domain, that contain manual load handling, static awkward postures and tooling support, refer to:

- *handling of heavy/cumbersome goods,*
- *dismantling operations including handling, moving, cutting,*
- *on site system maintenance,*
- *parts assembly (small, medium, large components), and*
- *manual screwing, welding, sanding, and sealing.*

Human-Robot Collaboration (HRC)

HRC is a new work approach whose implementation and use is allowed by a newly available technology (collaborative robots, often named COBOTS) and new international standards for the safety in industrial environment like ISO 10218-1:2011[23], 10218-2:2011[24] and ISO/TS 15066[25]. HRC in manufacturing impacts on aspects related to human performance (ergonomics), productivity, inherent quality and is increasingly used worldwide.

According to ISO 8373:2012, collaborative robots are robots designed for direct interaction with a human, while the definition in ISO 10218-2:2011 comprises an important detail: "Robot designed for direct interaction with a human within a defined collaborative workspace. The collaborative workspace is within the safeguarded space, where the robot and the human can perform tasks simultaneously during production operations".

The benefits expected from the HRC technology derive from the possibility to exploit the physical abilities of the robot such as precision, repeatability and force, the simple connectivity of the robots with the ICT layers (in reading, sharing data, use of tools, objectivities of operations) and the human operator cognitive (intelligence, problem solving, immediate vision, critical thinking or on-the-spot decisions) and physical (manipulation, dexterity) capabilities.

When used to improve ergonomics of specific applications, it allows to carry out heavy operations and gives support to elderly or reduced work capacity operators and reintroduce them in the workforce.

The ideal applications for collaborative robots are repetitive, manual processes nearby human workers that do not require specific human abilities, e.g. machine tending or pick-and-place operations. HRC fits especially to those jobs that can cause ergonomic injuries or require human workers to interact with dangerous machinery.

[23] ISO 10218-1:2011 Robots and robotic devices – Safety requirements for industrial robots – Part 1: Robots.
[24] ISO 10218-2:2011 Robots and robotic devices – Safety requirements for industrial robots – Part 1: Robot systems and integration.
[25] ISO/TS 15066:2016 Robots and robotic devices – Collaborative robots.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

With the current regulatory framework, most of the automated systems directly interacting with humans respond to this set of standards. Amongst them are automatic manipulators (manipulators capable to perform parts of their activity, like part pick-up or transport in proximity of the assembly zone, in autonomous mode) and self-reconfiguring workplaces, when the reconfiguration is active and dynamic during the operator's activities.

Automatic Guided Vehicles (AGV) and Autonomous Mobile Robots (AMR)

Automatic Guided Vehicles (AGVs) are a solution for the autonomous transport of goods and loads. The term AGV covers a wide scope of wheeled, mobile, and industrial materials handling solutions. In their simplest and most traditional form, they are automated vehicles autonomously guided from one point to another. Guiding occurs by following a fixed track (magnetic, electric wires or colour path) on the pavement. Their definition is: "mobile platform following a predetermined path indicated by markers or external guidance commands, typically in the factory"[26].

They are equipped with collision preventing safety systems to stop in case an operator crosses their path. From the standardisation point of view there is only one American standard (ANSI/ITSDF B56.5:2019[27]), while AGVs in Europe follow Directive 2006/42/EC on Machinery.

This technology has limited interaction with humans; nevertheless, the introduction of collaborative robots and natural navigation technologies enables a trend towards more interactive systems. Natural navigation is the capability to navigate in the environment using a preregistered map and inheriting the capability to adapt to changes in the predefined path. This level is achieved through proper sensors and allows a major degree of improvisation capabilities. These AGVs with increased autonomy capability are often referred to as Autonomous Mobile Robots (AMR).

The use of collaborative robots pushes the use of AMRs with collaborative robots mounted on top. In this shape, the whole system can fall both in the category of AMRs and in the category of HRC. Robotised AMRs can act blocked with a movable robotic arm, or in movement with a blocked or moving robot arm (e.g. the AMR follows a vehicle moving along the manufacturing line while the robot performs screwing actions in a collaborative environment shared with human operators).

An important professional development of this trend is the use of AMRs capable to follow the operator autonomously through RFID wearable tags. In particular in logistics, there is the opportunity to support material kitting delivery or preparation by the operator (e.g. Amazon warehouses, DHL goods delivery services, and innovative warehouses).

Description of workers and technicians - end users of the interactive robots

Workers able to use interactive robots in industry are generally healthy skilled workers appointed to the manufacturing activity and workers addressed to the maintenance operations. As the range of workers age in the European manufacturing domain is quite wide (from about 20 to about 60 years old), interactive robots should be able to interface with different needs.

[26] ISO 8373:2012 Robots and robotic devices – Vocabulary.
[27] Safety Standard for Driverless, Automatic Guided Industrial Vehicles and Automated Functions of Manned Industrial Vehicles.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

For example, younger people, that are usually physically stronger, could need less physical help deriving from the interactive robots (even if a support is still useful for the prevention of long-term operational diseases), while they can easily interact with innovative cognitive interfaces. On the other hand, elderly people prefer to have physical support with an easy human-robot interface. The workers could be able to use the interactive robots for many hours per day and in different environmental conditions without feeling annoyed, but instead perceiving the benefit derived from their use. The same general considerations on the professional workers and listed technologies should be extended to other fields as agriculture and constructions.

2.2 Healthcare domain

Robotic technologies can address numerous societal drivers for improved healthcare. Medical procedures can be less invasive and with fewer side effects, this results in faster recovery, improved cost-benefit ratios and worker productivity. In addition, healthcare costs are lowered due to improved quality (fewer complications, shorter hospital stays and increased efficiency).

Population factors play an important role in economics. There is a growing need for improved access and quality of health related services. Demographic studies show an increase of population ageing over the next decades (50% in Europe, 40% in US, 100% in Japan by 2030 for people over 65 years old). This trend implies an increased prevalence of injuries, disorders, diseases and life-long conditions (diabetes, autism, obesity and cancer). On the other side, the aim is to increase life-long independence: the ability to age at home, improving mobility, reducing isolation and depression, improving working conditions for caregivers[28].

In addition, there is a decrease in available social security and retirement funding, with the result that people have to work longer. Robotic technologies should help people with disabilities to stay in the workforce (and contribute to social security).

Robots in healthcare are used because they are capable of executing tasks more efficiently than a human. Robots in healthcare are used from the operating room to the family room, from the young to the very old and different physical and cognitive deficits. Interactive robotics for healthcare plays an important role in solving this challenge, by supporting personal assistance, professional care, cognitive support, etc., and integrating appliances, sensors and Internet of Things[29].

Improved teleoperation and physical interaction as well as miniaturised mechanical systems and sensing made technologies in the healthcare domain possible. The improvements in the monitoring of patient conditions and improved data interpretation during procedures as well as inherently safety were also important[30].

[28] Tiwari, P., Warren, J., Day, K. J., & MacDonald, B. (2010). Some non-technology implications for wider application of robots to assist older people. *Health Care and Informatics Review Online*.
[29] BCC-Research-Staff, "Robotics: Technologies and Global Markets", BCC Research Report, 2010.
[30] EU-Robotics, "Strategic Research Agenda – For Robotics in Europe 2014 – 2020", accessed March 4, 2021, https://www.eu-robotics.net/cms/upload/topic_groups/SRA2020_SPARC.pdf.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Main applicable standards and regulations for interactive robotics in the healthcare domain are summarised in Section 1 and 3. In this document, healthcare robots are structured into three categories: clinical, rehabilitation and assistive robots.

Clinical robots

Robotic systems that support care and cure processes fall under the sub-category clinical robots, primarily in diagnosis, treatment, surgical intervention and medication, but also emergency healthcare (see Figure 3). These robots are operated by clinical staff or other trained care personnel. Clinical robots are divided into interactive robots for precision surgery (e.g. laparoscopic surgery, spine surgery, and arthroscopy) and interactive robots for diagnostic or therapeutically treatment (e.g. accurate introduction of catheter through the body).

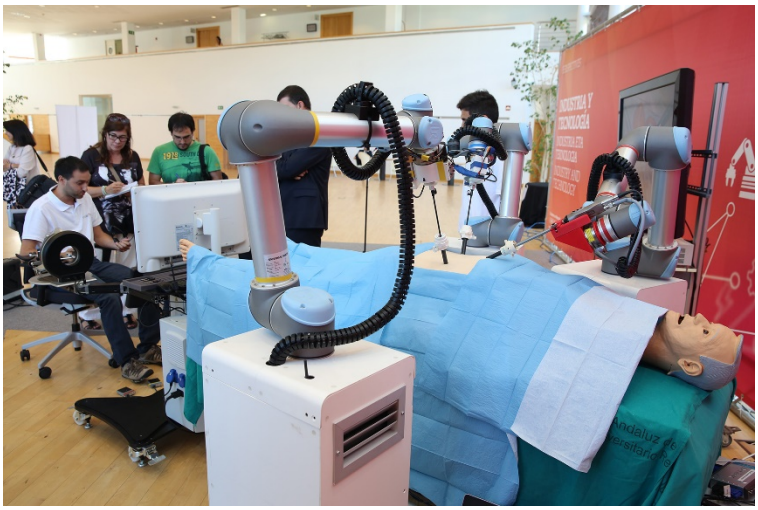

Figure 3: Example of tele operated robotic system for laparoscopic surgery (Source: Tecnalia)

Rehabilitation robots

Cover post-operative or post injury care where direct physical interaction with a robot system will either enhance recovery or act as a replacement for lost function. Orthotic and prosthetic devices increase functionality by physically assisting a limb with limited movement or control, or by replacing an amputated limb. The sub-category covers interactive robots for rehabilitation purposes and support for walking, where end users are elderly, disabled, and injured persons/patients (see Figure 4).

Walking supporters and rehabilitation devices for patients suffering from neuromuscular injuries or diseases fall under this section. Sensory motor therapy is time-consuming and labour-intensive, thus the use of robots can provide consistent, personalised treatment.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Figure 4: Example of a robot for rehabilitation of upper limb in patients who have suffered stroke (Source: Tecnalia)

Assistive robots

This covers other aspects of robotics within the healthcare process where the primary function of the robotic system is to provide assistive help either to carers or directly to patients either in hospital or in a specialist care facility (see Figure 5). Robots are designed to help with routine functions, which may cover the convalescence and management of life-long cognitive social disorders. Assistive robots are for example interactive robots for repetitive tasks like blood sampling robots.

Figure 5: Example of an assistive robot to give support to elderly (Source: Tecnalia)

2.3 Consumer domain

Consumer robots are operated by, or interact with, untrained, or minimally trained people in everyday environments. Typically, these robots will be bought or leased and used to provide services to individuals. Domestic applications such as floor or pool cleaners are already well established. Other application areas are at a lower level of maturity, for example window cleaning

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

or security robots. The domain also covers education and entertainment robots. Robotic technologies are also developed for assisted living. Early applications are likely to focus on mobility assistance within the home and later extend to other function.

An improved sensing and interpretation of the surrounding environment as well as enhanced energy efficient systems made the new application possible. Additionally, low-cost sensing technologies increase the application usages[31].

The consumer domain can be divided into domestic appliances, entertainment robot, education robot, and assisted living robots. The latter one focuses on non-medical applications and on an ageing society such as for example social robots. Social robots are used for elderly or people with cognitive disabilities (autism, etc.) and improve the quality of life of humans that need care like elderly, disabled, and injured persons/patient.

Consumer domain robots are also covered by ISO 13482:2014, since the standard covers mobile servant robots, physical assistant robots and person carrier robots.

2.4 Service robots

A service robot performs useful tasks for humans or equipment excluding industrial automation[32]. Service robots can be from partially autonomic to fully autonomic without the need of active human intervention. The application areas of service robots are very heterogeneous, which makes it difficult to derive a general statement concerning their economic implication. Besides service robots for personal or professional use, service robots have many forms and structures as well as areas of application. Personal service robots are for example frequently used by lay people for domestic purposes - typical examples being home and family servants, pet companions, and mobility assistants.

Professional robots are for example often managed by qualified operators and perform commercial tasks such as cleaning and patrolling public places, helping in surgical and fire-fighting operations, serving customers in retail stores, and entertaining people in amusement parks and museums.

ISO 13482:2014 focuses on *personal care robots*, which are "service robot that perform actions contributing directly towards improvement on the quality of life of humans, excluding medical applications". ISO 13482:2014 also covers mobile servant robots, physical assistant robots and person carrier robots.

A *mobile servant robot* is a "personal care robot that is capable of travelling to perform serving tasks in interaction with humans, such as handling objects or exchanging information". A *personal carrier robot* is a "personal care robot with the purpose of transporting humans to an intended destination". A *physical assistant robot is* a "personal care robot that physically assist a user to perform required tasks by providing supplementation or augmentation of personal capabilities".

[31] EU-Robotics, "Strategic Research Agenda - For Robotics in Europe 2014 - 2020", accessed March 4, 2021, https://www.eu-robotics.net/cms/upload/topic_groups/SRA2020_SPARC.pdf.
[32] ISO 8373 Robots and robotic devices - Vocabulary.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

2.5 Connection between robotic domains

The users of interactive robots apply the devices to their organisation background and therefore to the manufacturing, healthcare or consumer domain. Researchers, developers or robot manufacturers focus either on a specific or more than one domain. European directives are basically related to the domains e.g. Machinery Directive and Medical Device Regulation[33]. Categorising interactive robots therefore depends on the point of view. Technologies can be adjusted and then the field of use changes. For example, service robots can be used in the manufacturing, healthcare and consumer domain depending on their functions/capabilities. Other technologies are simply used in a single domain. Thus, the technologies set the capabilities and the domains set the requirements[34].

Manufacturing domain exoskeletons vs. healthcare domain exoskeletons

Exoskeletons are mechanical structures, active or passive, that support the wearer in specific tasks. There are different requirements for such devices, depending on the application domain. In manufacturing, exoskeletons are used to prevent injuries caused by repetitive work or non-ergonomic gestures at workplace e.g. lifting of heavy loads or working in overhead positions. Industrial exoskeletons usually support the upper part of a worker's body. In the healthcare domain, exoskeletons are usually applied to the lower limbs to support walking, but also to upper limbs for rehabilitation or support.

Interactive robots in the healthcare domain vs. consumer domain

Consumer robot's distribution increases due to their price and size. Differences between healthcare and consumer domain robots are mainly related to the type of end-user and technology as well as managed data. Consumer robots are for the domestic use while healthcare robots are typically handled by professional staff.

AGV in the manufacturing domain vs. service robots

AGVs in the manufacturing domain and service robots can be differentiated through their degree of autonomy. AGVs in the manufacturing domain are mostly fully autonomous, whereas service robots are generally characterised by varying the levels of autonomy, which can even be dynamically adjusted to switch from full autonomy to tele-operation. Generally referred to as adjustable autonomy, this possibility is one of the factors that make the set of application scenarios envisioned for service robotics extremely wide and heterogeneous.

3. State of the art – standardisation landscape

With this section the readers gain an overview of potentially relevant standards for their interactive robots. In order for the reader to understand the identification process of standards, the search methodology is shortly described as well as the search categories. The standards that are directly connected to interactive robots are then introduced and the total overview of identified standards can be found on the INBOTS website. The research gives an indication of

[33] The European Union Medical Device Regulation of 2017, accessed March 4, 2021, https://eumdr.com/.
[34] EU-Robotics, "Strategic Research Agenda – For Robotics in Europe 2014 – 2020", accessed March 4, 2021, https://www.eu-robotics.net/cms/upload/topic_groups/SRA2020_SPARC.pdf.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

potentially relevant standards from different TCs and supports the identification of missing topics, so called gaps, in the current standardisation landscape. Furthermore, it is useful for certification organisations to gain insights into potentially relevant standards for interactive robots. In the end, the outcome of the survey on standardisation in terms of the usage of standards is evaluated.

3.1 Types of standards

A standard is a consensus-based document that is approved by a recognised body. It provides rules, guidelines or characteristics for activities or their results, reflecting the state-of-the-art. It should be based on the consolidated results of science, technology and experience, aiming at the promotion of the optimum community benefits.

International (ISO, IEC) or European Standard (EN, CLC)

An *International (ISO, IEC) or European Standard (EN, CLC)* is a document that consists mainly of requirements that reflect the current state of technology and knowledge of a product or service. International or European standards are developed by committees by consensus decisions and involvement of all interested groups. While developing a European standard, the standstill policy applies. This means that during work on a European standard and after its publication, CEN/CENELEC members agree not to publish national standards which are not in line with it. This is done to prevent any situation occurring during the preparation or after publication of a standard which could impair or undermine harmonisation. National standards which are in conflict or duplicate European standards have to be withdrawn. On International level the standstill policy does not apply and they do not have to be adopted at national level.

One special type of European standard is the mandated European standard (harmonised EN), which is applied in the context of the New Legislative Framework (also known as New Approach) and developed on the basis of a mandate from the EC to set out the essential requirements for the product or service that are specified in an EC directive. These essential requirements deal in particular with the health and safety of users and other fundamental matters like performance.

International/European Technical Specification

Other products of standardisation is the *International/European Technical Specification* (ISO/TS, IEC/TS, CEN/TS, CLC/TS), this type of document aims to aid market development and growth for products or methods that are still in the development and/or trial phase.

International/European Technical Report

An *International/European Technical Report* (ISO/TR, IEC/TR, CEN/TR, CLC/TR) provides specifications of a recommendatory and explanatory nature.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

International/ European Workshop Agreement (IWA, CWA)

While the afore mentioned documents can only be developed by experts working in technical committees, an *International/ European Workshop Agreement (IWA, CWA)* is open for participation of experts that are not a member of a permanent committee in standardisation. Innovative topics are described in Specifications and Agreements, because they offer a fast development process and they do not have to be fully consensus based, e.g. draft documents do not have to be published for commenting. Research results from projects that are for example funded by the EU's Research and Innovation programme Horizon2020 can be transferred into a Workshop Agreement. This way the research results are distributed even after the project has finished. The standardisation system envisages transferring these documents at a later point into for example a European Standard[35, 36].

Industry standards

Standards that are not developed by recognised standardisation organisations are Industry Standards. Industry standards are developed by an organisation and used by the organisation itself or cooperating organisations. The present document focuses on standards developed by recognised standardisation organisations, official members of the International or European standardisation system.

Standards cannot only be categorised into different degrees of consensus, but also into the content they describe. Table 1 shows four types of standards from a content related perspective.

Table 1: Content related structure of standard in the standardisation system of CEN/CENELEC and ISO/IEC

Type of standard	Definition
Basic standard	Wide-ranging coverage or contains general provisions for one particular field, e.g. terminology.
Test standard	Concerned with test methods, sometimes supplemented with other provisions related to testing.
Particular standard	Defines the characteristics of a product (product standard), service (service standard) or process (process standard) and their performance thresholds such as fitness for use, interface and interchangeability, health and safety, environmental protection.
Supplementary standard	Document that refers to other standards for example as a guideline of use of these standards.

[35] CEN/CENELEC Internal Regulations Part 2 – Common Rules for Standardisation Work (2017).
[36] ISO/IEC Directives Part 1 – Procedures specific to ISO (2019).

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

3.2 Search methodology

With the support of search terms, the identification of existing standards and ongoing standardisation activities led to a list of interactive robot related standards. The results can be downloaded from the INBOTS website[37]. The search for standards and harmonised standards was not performed for a specific robotic device, but rather for interactive robots in general. The standards were categorised into ten groups (see Table 2).

Table 2: Categories and search terms of the standards research

Categories	Search terms
Ergonomic	Human-system interaction, tactile/haptic interaction, ergonomic design, working posture, health risk, repetitive movement, repetitive work, handling at high frequency, limits for whole body, manual handling, manual limit
Safety	Unexpected start-up, safe human intervention, safe design, safety-related control systems, tolerable risk, risk assessment, risk management, safe design, hazard zone, safety requirements, hazard, unexpected movement
General	Terminology, vocabulary, guidance, classification, categorization, characteristics, graphical symbols, labelling, considered factors, environmental conscious design
Test	Key performance indicators, parameter, test equipment, test condition, test method, test forces, method, performance criteria, measurement, determination
Information and Communication Technology (ICT)	Industrial communication, fieldbus, network, taxonomy, user interface, gesture-based interfaces, voice command, interaction, security, software, life-cycle, data confidentiality
Acoustic	Sound power level, noise, sound energy level, sound source, acoustical measurement, sound intensity, noise emission
Ethics	Ethical design, ethical harm
Surrounding	Navigation, coordinate system, dimension, sensor integration, data fusion
Electromagnetic-Compatibility	Electromagnetic emission, electromagnetic immunity, electronic apparatus, radio-frequency disturbance
Others	Mechanical interface, smart device

The categorisation revealed that the majority of the identified standards belong to the safety category. The category is followed by standards on general issues and ICT as well as testing. The complete overview is shown in Figure 6.

[37] INBOTS, "Standardisation", accessed March 4, 2021, http://inbots.eu/contributing-to-inbots/standardisation/.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

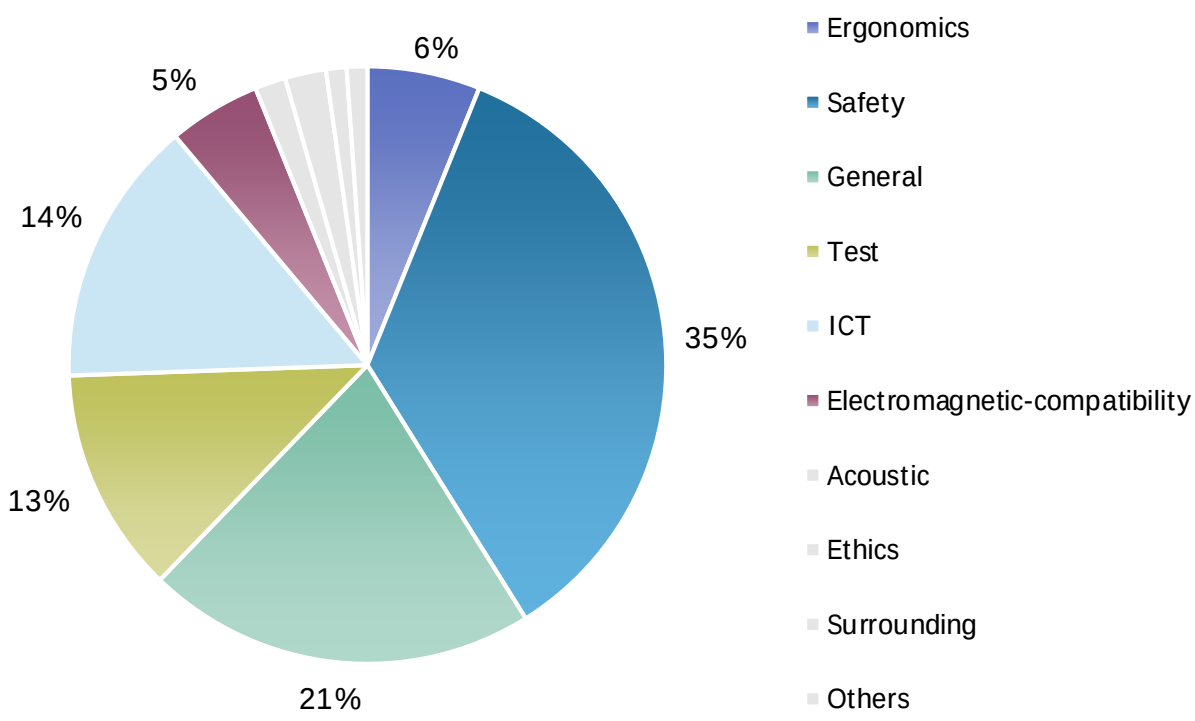

Figure 6: Standardisation landscape - percentage distribution per category

3.3 Interactive robotic standards

The identified standards are not always directly connected to interactive robots. The list of standards was evaluated by the INBOTS consortium. Only the standards that for example help to conform to regulations, to fulfil a customer requirement, to ensure technical compatibility, and/or improve the quality were taken into account. From the total amount of standards, only 29 standards are directly related to robots. The remaining standards are beneficial for interactive robots, but have to be adapted to specific needs. These standards are relevant, but the impact is limited, since some of the standards might not apply completely.

Standardisation activities of interactive robots only take place on international level and European technical committees transfer the international standards to the European level. Currently, there is no CEN/TC working on robotics. Companies prefer the international standardisation level rather than the European standardisation level, because of the following reasons (see Annex A):

- *reduction of market barriers,*
- *foster of globalisation and the access to larger markets,*
- *higher acceptance of goods and services,*
- *better markets access,*
- *market is global thus EN and ISO standards should be aligned, and it is*
- *economically and technically efficient (same product sold worldwide).*

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

The identified robotic standards are managed by ISO/TC 299 on Robotics. Robots can be categorised in numerous different ways. The standards of ISO/TC 299 are categorised into documents that focus on the application area of the interactive robot (e.g. industrial robot, personal care robots, medical robots and medical electrical equipment). The standards for each of these application areas are introduced below.

Industrial robots – Manufacturing domain

Standards on industrial robots focus on vocabulary, performance criteria, test methods, characteristics, interfaces, collaboration, and safety requirements. An industrial robot is an "automatically controlled, reprogrammable multipurpose manipulator, programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications"[38]. Table 3 gives an overview of industrial robot standards.

Table 3: Overview of industrial robot standards

No.	Title
ISO 14539	Manipulating industrial robots - Object handling with grasp-type grippers - Vocabulary and presentation of characteristics
ISO 11593	Manipulating industrial robots - Automatic end effector exchange systems - Vocabulary and presentation of characteristics
ISO 19649	Mobile robots - Vocabulary Note: This standard applies to industrial and service robots.
ISO 9283	Manipulating industrial robots - Performance criteria and related test methods
ISO/TR 13309	Manipulating industrial robots - Informative guide on test equipment and metrology methods of operation for robot performance evaluation in accordance with ISO 9283
ISO 9946	Manipulating industrial robots - Presentation of characteristics
ISO 9409-1	Manipulating industrial robots - Mechanical interfaces - Part 1: Plates
ISO 9409-2	Manipulating industrial robots - Mechanical interfaces - Part 2: Shafts
ISO/TR 20218-1	Robotics - Safety design for industrial robot systems - Part 1: End effectors
ISO/TR 20218-2	Robotics - Safety design for industrial robot systems - Part 2: Manual load/unload stations

[38] ISO 8373 Robots and robotic devices - Vocabulary.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

ISO 10218-1	Robots and robotic devices - Safety requirements for industrial robots - Part 1: Robots
ISO 10218-2	Robots and robotic devices - Safety requirements for industrial robots - Part 2: Robot systems and integration
ISO/TS 15066	Robots and robotic devices - Collaborative robots

Service robots – Healthcare and consumer domain

Service robot standards focus on performance criteria and test methods as shown in Table 4. ISO 18646-1 for example describes methods for specifying and evaluating the locomotion performance of wheeled robots in indoor environments. Standards concerning navigation, manipulation and lower-back support robots are currently under development.

Table 4: Overview of service robot standards

No.	Title
ISO 19649	Mobile robots - Vocabulary Note: This standard applies to industrial and service robots.
ISO 18646-1	Robotics - Performance criteria and related test methods for service robots - Part 1: Locomotion for wheeled robots
ISO 18646-2	Robotics - Performance criteria and related test methods for service robots - Part 2: Navigation
ISO 22166-1	Robotics - Modularity for service robots - Part 1: General requirements
ISO/FDIS 18646-3	Robotics - Performance criteria and related test methods for service robots - Part 3: Manipulation
ISO/DIS 18646-4	Robotics - Performance criteria and related test methods for service robots - Part 4: Lower-back support robots
ISO/AWI 31101	Robotics - Services provided by service robots - Safety management systems requirements

Standards on personal care robots also belong to the category of service robots and they focus on safety requirements and test methods (see Table 5). ISO 13482 focuses on mobile servant robots, physical assistant robots, and person carrier robots (see Subsection 2.2). The standard describes hazards associated with the use of these robots, and provides requirements to eliminate, or reduce,

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

the risks associated with these hazards to an acceptable level. ISO/TR 23482-1 supports the application of ISO 13482.

Table 5: Overview of personal care robot standards

No.	Title
EN ISO 13482	Robots and robotic devices - Safety requirements for personal care robots (ISO 13482:2014)
ISO/TR 23482-1	Robotics - Application of ISO 13482 - Part 1: Safety-related test methods
ISO/TR 23482-2	Robotics - Application of ISO 13482 - Part 2: Application guide
ISO/AWI 5363	Robotics - Test methods for Walking RACA Robot

Standards on medical electrical equipment focus on steps to be taken to perform a detailed risk management for systems employing a degree of autonomy (see Table 6). IEC 60601 is a standards series for the basic safety and essential performance of medical electrical equipment.

Table 6: Overview of medical robots and medical electrical equipment standards

No.	Title
IEC/TR 60601-4-1	Medical electrical equipment - Part 4-1: Guidance and interpretation - Medical electrical equipment and medical electrical systems employing a degree of autonomy
IEC 80601-2-77	Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of medical robots for surgery
IEC 80601-2-78	Medical electrical equipment - Part 2-78: Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, compensation or alleviation of disease, injury or disability

ISO 8373 defines general robotic terms for industrial and non-industrial environments (see Table 7) and ISO 9787 describes robot coordinate systems for such devices.

Table 7: Overview of general robotic standards

No.	Title
ISO 8373	Robots and robotic devices - Vocabulary
ISO 9787	Robots and robotic devices - Coordinate systems and motion nomenclatures

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

3.4 Usage of standards

Organisations use formal standards to (see Annex A):

1. *conform to regulations,*
2. *improve quality,*
3. *fulfil customer requirements, and*
4. *get additional marketing advantages.*

Organisations that answered the INBOTS survey neither:

- *consider standards as legal protection from litigation,*
- *nor as good guidance's.*

The decisive reason for organisations not to use formal standards is that they have interpretation problems. Organisations also stated in the INBOTS survey that they do not use formal standards, because they do not know which standards they should follow. The access to standards also seems to be an issue. Fewer organisations stated that the inconsistency between standards and the inaccuracy of standards are reasons for not using standards. It also seems to be less of an issue that topics are not covered by standards.

At conferences participants stated the following issues:

- *access to standardisation system is challenging,*
- *standards are not detailed enough,*
- *standards are no code books,*
- *standards are too expensive.*

4. Potentials for future standards

This section connects the state-of-the-art of standardisation for interactive robots with newly identified standardisation potentials. First, the potentials identified by the INBOTS consortium are described. Next, the results of a survey and a literature review are explained in detail.

4.1 INBOTS consortium potentials

The following ideas were identified as future standardisation potentials. For each idea, a title and an application area (scope) was drafted in the form of a real standard. Additionally, the domains that the ideas relate to were added.

a) *Draft standard title: Robots and robotic devices – Measurement of autonomy*

Draft scope: Interactive robots will integrate artificial intelligence in the distant future. In certain circumstances it might no longer be the human who makes the decisions, but the robot. This could change the mostly positive attitude towards the growing presence of robots in every sector. A standardised way to measure the autonomy of an interactive robot in terms of the capacity to take own decisions based on artificial intelligence technologies is needed.

Affected domains: Manufacturing, healthcare, and consumer domain.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

b) *Draft standard title: Lower-limb wearable devices – Performance test method for walking on uneven terrain*

Draft scope: This standard defines a methodology to obtain performance indicators of lower-limb wearable devices during locomotion on uneven terrain, which enables a quantitative comparison of those performance indicators between systems. This document includes:

- *a morphological description of a test bed composed of different combinations of inclined uneven step, soft and unstructured terrain;*
- *a set of required and recommended performance indicators;*
- *the experimental procedure needed to collect the performance indicators;*
- *the structure of a unified test report.*

This document is intended to be used by developers, manufacturers, researchers, and end-users of any type of lower-limb orthoses, exoskeleton or prostheses, independently from the structural properties (hard or soft), actuation typology (powered or unpowered), body coverage (trunk, spine, hip, knee, ankle, full leg), and application domain (industrial, healthcare, consumer). This document may be applied to other types of bipedal systems, including humanoids, autonomous or teleoperated robots. In these cases, this CWA represents a basis that may be extended by including other aspects specifically related to these bipedal systems (e.g. autonomy decision, perception, or cognitive abilities).

Affected domains: Manufacturing and healthcare domain.

c) *Draft standard title: Robots and robotic devices – Device categories for wearable robots*

Draft scope: This standard defines classes of wearable robots with respect to their primary function in an application context and performance characteristics. It describes mutually exclusive categories that are based on one or several device characteristics and presents decision trees that allow systematic classification of devices. This standard does not address the wearable robot as a whole. Features and functionality of devices within a single category might differ substantially if these features and functions are not part of the classification criteria.

This standard does not apply to robots that are not body-worn, or are not worn by human users, or are not primarily body-worn by nature, e.g. if only a control interface is worn and the remainder robot is not connected to the human user.

Affected domains: Manufacturing and healthcare domain.

d) *Draft standard title: Robots and robotic devices – Contact surfaces in human-robot systems – General requirements*

Draft scope: This standard defines mechanical, thermal, and electrical requirements for surfaces of wearable robots that are in contact with or in close proximity of human body parts during device operation. The current standards available are not detailed enough (e.g. EN ISO 13482). EN ISO 13482 only mentions that personal care robot users shall be protected from emission of any poisonous or noxious material, or from solvents from the robot body surface and that no material that causes allergies should be used.

The standard describes lower and upper limits for the defined requirements over various exposure durations relevant to device use. This standard does not address general electrical or mechanical device safety if not directly related to contact interfaces between the wearable robot and the human user. It also does not explicitly address the requirements on surfaces that are only in contact with the human user in a case of device malfunctioning or failure.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

This standard does not apply to robots that are not body-worn, or are not worn by human users, or are not primarily body-worn by nature, e.g. if only a control interface is worn and the remainder robot is not connected to the human user.

Affected domains: Manufacturing and healthcare domain.

e) *Draft standard title: Robots and robotic devices – Test methods for devices used by non-professionals*

Draft scope: This standard specifies a test method for interactive robots used by non-professionals. Tests in laboratories are not enough to predict the ethical implications of use in human environments. Technologies regulated by Regulation (EU) 2017/745 on Medical Devices, are based on tests of products used in healthcare organisations with healthcare professionals taking care of patients. Today, healthcare products, including artificial intelligence and robots, are moving out of the hospitals into the patient's homes. This development shows the importance of testing having to include private and public environments. Hence, testing in laboratories is no longer sufficient in order to address ethical aspects of robotics in human environments.

Affected domains: Healthcare and consumer domain.

f) *Draft standard title: Robots and robotic devices – Data confidentiality of vulnerable groups – Children, elderly and disabled people*

Draft scope: This standard specifies requirements and recommendations for the administration of personal data when using interactive robots directly with children, elderly and disabled people. Interactive robots accompany these vulnerable groups and therefore a standardised way to access the collected data is needed. This standard does not apply for interactive robots that do not manage personal data.

Affected domains: Healthcare and consumer domain.

g) *Draft standard title: Robots and robotic devices – Human-robot interaction – End-user requirements*

Draft scope: This standard specifies technical knowledge of end-users that is needed in order to cooperate with an interactive robot that works directly with humans. The standard is applicable for cooperation where the end-user needs to support the interactive robot with inputs/commands. This standard does not apply for interactive robots with enough autonomy to make decisions by themselves.

Affected domains: Manufacturing, healthcare and consumer domain.

h) *Draft standard title: Robots and robotic devices – Privacy – Impact assessment*

Draft scope: The standard specifies measures to what extent the activity of an interactive robot has an impact on the privacy of a human being. Direct cooperation between humans and robots can lead to a lack of privacy by the user. The standard is applicable for interactive robots that accompany and/or assists people at home or at work. This standard is not applicable for robots that do not interact with humans.

Affected domains: Healthcare and consumer domain.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

i) Draft standard title: Robots and robotic devices – Performance criteria and related test methods – Evaluation of active exoskeletons as wearable devices in manufacturing

Draft scope: This standard defines a test method for active exoskeletons as a wearable robot in the manufacturing context. It describes which variables, in specific application contexts, should be considered for the evaluation of the performance of an active exoskeleton. It shows how to detect variables of specific work cases addressing a specific industry sector to detect the effects and quantifiable benefits of active exoskeletons. The standard also defines ergonomic variables to show the efficiency of the device's application. Use-cases as well as a functional analysis of the technological device are included. This standard does not apply to robots that are not body-worn, or are not worn by human users. This standard does not apply for safety investigation. This standard does not apply outside the manufacturing domain.

Affected domains: Manufacturing domain.

j) Draft standard title: Medical electrical equipment – Performance criteria and indicators to be measured for teleoperated surgical robots

Draft scope: This document defines variables, in specific application contexts, that should be considered for the evaluation of the performance of a teleoperated surgical robot. The standard defines which performance indicators should be considered, but information on the performance level is not envisaged to be included.

Affected domains: Healthcare domain.

4.2 Potentials from the INBOTS standardisation survey

The INBOTS standardisation survey gave organisations outside of the INBOTS consortium the opportunity to elaborate their level of satisfaction with the current standard quantity. The participants were asked which types of standards would increase their satisfaction (see Annex A). The number of answers is insufficient and therefore the results show only directions that need to be checked before further pursuit.

The survey showed that there is a need for action in terms of data security. *Guidelines*, *benchmarks* or *characteristics* would increase the satisfaction of the robotics community. This might be related to the General Data Protection Regulation from 2018 and the overall uncertainty in terms of online data security that the Regulation has triggered in organisations.

Furthermore, there is a need for action in human-robot interaction safety and performance. *Test methods, metrics* and *guidelines* would increase the satisfaction of the robotics community. Guidelines are also important for ergonomic design and ethical behaviour. In Subsection 3.3, very few people answered that they use standards as a good guidance. The request for guidelines indicates that people generally would like to use standards as guidance documents, but only a few currently use them in that way.

In general, organisations ask for test standards, particular standards and supplementary standards, which have been described in Subsection 3.1.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

4.3 Potentials from external sources other than the survey

The Robotics 2020 Multi Annual Roadmap (MAR) stated that there is a need for standardisation to define the boundaries between robotics domains. The INBOTS standardisation survey relates to this; since organisations answered that they do not know which standards they should apply. Categorizing standards by domain can help organisations identify useful standards for their products, services, or processes. Human-robot interaction and environmental impact issues were also considered as standardisation potentials in the MAR[39].

Fosch-Villaronga stated that ISO 13482:2014[40] focuses on physical safeguards and that this might not be sufficient to provide comprehensive protection to the user, because the standard disregards cognitive aspects. He also pointed out that current harmonised standards do not cover areas such as automated vehicles or collaborative robots/systems in sufficient detail[41]. Harmonised standards mainly focus on industrial robots and personal care robots. ISO 13482:2014 also does not provide any specific testing approaches or protocols that relate to their safety in a space shared by humans and robots, e.g. regarding stability of the robot under different conditions, or the potential hazards of interaction (e.g. a collision) with a human. This need has already been noticed and countermeasures were taken with the initiation of ISO TR 23482-1:2020[42].

ISO 13482:2014 defines amongst others safety aspects of wearable robots, which are called restraint physical assistant robots in ISO 13482:2014. Although a general approach for safety is provided, no specific testing approaches or protocols are provided to evaluate the potential physical risk to the individual. Non-safety related performance testing will be described in ISO/DIS 18646-4[43].

Fosch-Villaronga has also stated that NSBs do not adequately address non-technical, for example ethical issues, and that the industry dominates standardisation. In principle, everybody has the opportunity to comment on draft standards as they are publicly available. However, only a few use this opportunity and therefore INBOTS recommends associations to represent the society. The German Institute for Standardisation together with the German Federal Ministry for Economic Affairs and Energy initiated a research project on artificial intelligence and ethical design that developed a standardisation roadmap for Germany. In 2017, a joint initiative of ISO and IEC on artificial intelligence (ISO/IEC JTC 1/SC 42) was introduced. Together they developed ISO/IEC TR 24028:2020 on trustworthiness in artificial intelligence. Thus, on national and international level the importance of ethical issues is being addressed increasingly.

[39] EU-Robotics, "Robotics 2020 - Multi Annual Roadmap", accessed March 4, 2021, https://www.eu-robotics.net/cms/upload/downloads/ppp-documents/Multi-Annual_Roadmap2020_ICT-24_Rev_B_full.pdf.
[40] ISO 13482 Robots and robotic devices – Safety requirements for personal care robots focuses.
[41] Villaronga, E. F. (2019). Robots, standards and the law: Rivalries between private standards and public policymaking for robot governance. *Computer Law & Security Review*, *35*(2), 129-144.
[42] ISO TR 23482-1 Robotics – Application of ISO 13482 – Part 1: Safety-related test methods.
[43] ISO/DIS 18646-4 Robotics – Performance criteria and related test methods for service robots – Part 4: Wearable robots.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Xu and Borson argued that when developing regulations for autonomous robotics, users and regulators should consider evolving the current specific framework for existing (non-autonomous) devices, rather than focusing on developing a novel set of rules[44].

Veneman reports the need for safety standards in wearable robotics, specifically that standardised testing methods for safety that do not require human subject testing could facilitate the road to the market while also reducing the costs[45].

Also, Bostelman et al. report the need for performance standards for these systems and describe the possible benefit of relating to existing standards for manufacturing robots and rescue robots[46].

The following issues have been raised several times in the INBOTS community:

- *hazards and risks not clearly defined with parameters and limits,*
- *lack of performance measurement standards,*
- *modularity standards are missing,*
- *active exoskeleton safety testing,*
- *evaluation of industrial exoskeletons,*
- *ethics of autonomous robots.*

4.4 Assessment of standardisation potentials

In order to ensure that standardisation potentials have a positive impact on all affected stakeholders, they need to be assessed in greater detail. To pursue these standardisation potentials the standardisation body dealing with the potential should take the following aspects into account:

- *impact on end-user of the potential standard (e.g. improvement of safety, cost savings for end-user organisation, improvement of robot capability),*
- *impact on industry and research (e.g. increase of business opportunities, improvement of business quality management, Innovation progress, improvement of business functions),*
- *impact on ethical, societal and legal issues (e.g. consideration of potential effects of the proposed standard – dignity, avoidance of harm, non-discrimination, privacy etc.),*
- *feasibility (e.g. expected support by standardisation member bodies, clear scope, clear work plan, properly balanced development team).*

[44] Xu, H., & Borson, J. E. (2018, October). The Future of Legal and Ethical Regulations for Autonomous Robotics. In *2018 IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS)* (pp. 2362-2366). IEEE.
[45] Veneman, J. F. (2017). Safety standardization of wearable robots - The need for testing methods. In *Wearable Robotics: Challenges and Trends* (pp. 189-193). Springer, Cham.
[46] Roger Bostelman, Elena Messina, and Sebti Foufou, "Cross-industry standard test method developments: from manufacturing to wearable robots", Frontiers of Information Technology & Electronic Engineering 18, no. 10 (2017): 1447-1457.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

5. Standardisation tools for future activities

This section introduces standardisation tools to transfer standardisation potentials into standardisation activities.

5.1 Specifications and agreements

One way to proceed and push a standardisation potential to the next level is the initiation and development of a specification or agreement. As introduced in Section 3, there is the possibility to initiate a technical report, technical specification or agreement. Technical reports and specifications are developed within set technical committees (TC) by experts who are members of a CEN/TC or ISO/TC. Thus, they are not instruments for consortia that are not active in standardisation (e.g. research projects).

CEN Workshop Agreement (CWA)

CEN Workshop Agreements (CWA) can be initiated and developed by consortia that are not members of TCs. If there are for example precise standardisation potentials and ideas that have been derived from the results and/or deliverables of a research project (i.e. H2020 Innovation Action (IA)), the development of a standardisation document is a way to spread the outcomes and to share knowledge with the community. Horizon 2020 Coordination and Support Actions (CSA) can gather information on standardisation potentials and hand it over to the TCs or find IAs that can develop CWAs on the missing topics. Therefore, the EC should support standardisation activities in IAs that match the standardisation needs of the robotics community.

The development group of a CWA does not have to be constituted by stakeholders from all areas (e.g. industry, research, and consumer side), but can be a consortium of partners agreeing to develop a document together. Ideally, all interested parties are represented. Such a document does not have the same character as a European or International Standard, due to the partly consensus-based process. The draft documents do not have to be published for commenting and thus the consortium does not have to take into account the feedback of the general public, but they can, if they want to. Anyhow, publication of the draft document is recommended to increase the acceptance of the document. A CWA has a life-span of six years and has a "pre-standard" character.

The nature and the procedure of a CWA is described in the CEN-CENELEC Guide 29. The guide details the characteristics and the development process of a CWA. A CWA is basically a working platform that is open to the participation of all interested parties to elaborate the CWA. The proposal of a new CWA leads to the creation of a new Workshop. The proposer of a CWA shall prepare a draft project plan and a self-assessment. Furthermore, the proposer has to undertake an analysis of the degree of interest in the subject across different European countries and amongst different stakeholders. In case of a CWA development out of a research project, this is usually done by including the different project partners from all over Europe.

A CWA's project plan contains the CEN Workshop motivation, a description of the scope, the objectives, the development schedule and the contact persons. After one month of publication of the Project Plan on the CEN website, a Kick-off Meeting needs to be organized. During the Kick-off Meeting of the CEN Workshop the project plan is confirmed and the chairperson and the secretariat are elected. The next step is the development phase during which the role of the

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Workshop participants is to provide input and comments on draft documents. In order to finalise the CWA, the Workshop participants need to agree on the final document (organisations approving the CWA will be listed in the European Foreword). If the CWA deals with safety aspects public consultation is mandatory; therefore the CWA will be posted on the CEN website for a minimum of 60 days. For any other workshop it is recommended, but not mandatory[47].

5.2 New work item proposal (NWIP)

CEN New Work Item

New documents (EN, CEN/TS, CEN/TR) that are developed within CEN Technical Committees (CEN/TC) at the European level are usually initiated by a New Work Item Proposal (NWIP), which is commonly proposed by a CEN TC or a corresponding Working Group (WG). The experts within the WG recommend the NWIP to the TC for balloting, and the TC then decides on how to proceed. The Committee Internal Balloting (CIB) is subsequently started; it constitutes an enquiry with all CEN member states. Each member state has one vote on whether to proceed with the NWIP or not, and they vote according to the outcome of their respective national enquiry. The national experts can leave comments and information about deviating national regulations that should be taken into account and they can volunteer to participate in the work on the European Level if the NWIP is accepted. The TC then determines the outcome of the CIB. For the New Work Item (NWI) to be adopted, at least 5 members have to confirm their commitment to actively participate in the work of the new Technical Body; and in addition the following two criteria have to be met:

- *Number of consents must be ≥ 55 %*
- *Population of the affirmative countries must be ≥ 65 % of the total population*

When the conditions for the adoption of a New Work Item are fulfilled, the TC takes a decision in order to include a New Work Item in its programme of work. Other entities that can propose a NWI are the EC or EFTA Secretariat, international organisations or European trade, professional, technical or scientific organisations or national standardisation bodies of CEN member states. An example could be a NWIP resulting from a standardisation request by the EC.

A common misinterpretation is that any person or organisation can propose a NWI at European level. The usual way is to propose the work envisaged at national level to the national standardisation body which then considers whether this work should possibly be carried out at the European level.

If the new work does not fall within the scope of an existing CEN/TC, the proposal has to be submitted directly to the CEN/CENELEC Management Centre (CCMC). Usually, however, the NWIP is submitted directly to the CEN/TC concerned.

When proposing a new work item, it is highly advisable to deliver a first draft of the envisaged document in order to convince fellow members of a working group to actively collaborate on the topic as well. Once the NWIP is accepted, there is a rather strict time frame to be followed, and the time to the next steps, such as the enquiry, is limited. If only a rough idea is proposed, it is harder for the TC to estimate the time needed for the development and assess the feasibility, keeping in mind that work may also need to be done on other projects. A tool available but used

[47] CEN/CENELEC Internal Regulations Part 2 – Common rules for standardisation work (2017).

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

very rarely is the feasibility study through which the TC can determine, in the absence of a first draft, whether it is possible to deliver a first draft from a "blank sheet of paper" within the timeframe required for a CEN deliverable.

Besides a comprehensive manuscript, factors to help the adoption of a NWIP are the presentation of the proposed work at an early stage and the personal attendance of TC and/or WG meetings to explain the background of the idea and the plan to implement it. The nomination of a project leader in charge of coordination and answering questions is also advisable.

Within European research projects, a NWIP could be a potential deliverable to start new standardisation work that uses the results of the project. Because a first draft is needed, the NWIP is usually scheduled for the end of the project, when deliverables of the partners, which can be used as drafts, exist and can be handed in. Before this, it is advisable to inform the TC that a NWIP is envisaged and to attend a meeting to present the research project and its aims in order to avoid handing in a NWIP to an unknown group of people[48].

ISO New Work Item

A similar approach to the CEN New Work Item Proposal is the NWIP on the international level (ISO). This first step is to confirm that a new International Standard in the subject area is really needed. Then a NWIP is submitted to the technical committee for vote, using an electronic balloting portal. The NWIP is adopted if more than four or five countries (depending on the number of members) volunteer to participate in the work and if a 2/3 majority of the P-members (actively participating member) of the technical committees or subcommittees vote to approve the work item.

Similar to a CEN NWIP, an ISO New Work Item Proposal within the scope of an existing technical committee or subcommittee may be made in the respective organisation by a National Standardisation Body (NSB); the secretariat of that technical committee or subcommittee; another technical committee or subcommittee; an organisation in category A liaison; the technical management board or one of its advisory groups or the Chief Executive Officer[49,50].

National New Work Item

The usual case for a single person or a company based within a certain country to start standardisation activities is to request a NWI at a national level. This can be done by anyone as the proposer does not have to be an active member of a committee within the NSB. A form including a title and a scope (and possibly more information) has to be filled out and sent to the NSB. The delivery of a draft manuscript is not obligatory but highly recommended for the success of the NWI adoption. The vast majority of NWIs originate from the committee itself, not from people outside of the standardisation committee. The NSB, or more precisely the committee in charge of the standardisation project, can then investigate whether a development of the standard on the European or International level might be appropriate and can initiate the standardisation activities.

[48] CEN/CENELEC Internal Regulations Part 2 – Common rules for standardisation work (2017).
[49] International Organisation for Standardisation, "Developing ISO standards", accessed March 4, 2021, https://www.iso.org/developing-standards.html.
[50] ISO/IEC Directives Part 1 – Procedures specific to ISO (2019).

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

5.3 Contribution to existing standards

There is also the possibility to contribute to ongoing standardisation activities. A contribution to existing activities and standards should especially be made, if:

- *an existing standard or draft standard is inaccurate,*
- *a standard is hindering innovation, and/ or*
- *standards contradict each other.*

The responsible TC has to be contacted immediately, if a standard hinders innovation or if standards contradict each other. In case of an inaccurate standard, a research project or organisation could improve the standard by taking part in the public commenting phase of the document, e.g. ISO/DIS (Draft International Standard). An organisation or research project has to fill out the commenting form and send it to an NSB that can forward it to the respective TC before the end of deadline.

For the INBOTS standardisation potentials no European or International standard is currently under development or revision and could be commented. The project partners will keep on working on interactive robotics standards even after the project has finished. DIN will keep the robotics community informed about publicly available draft standards through social media.

5.4 STAIR Platform

A STAIR (STAIR = STAndards, Innovation and Research) platform aims to bring together standardisers, researchers and innovators in order to discuss and identify standardisation needs and opportunities for a specific area of concern. The platform is not intended to develop standard-like documents but recommendations for future action. The starting initiative typically comes from one or more European-financed research and/or innovation projects. The functioning of a STAIR platform follows principles similar to the CEN/CENELEC Workshop:

- *an NSB is committed to take the secretariat,*
- *direct participation of the stakeholders (open to all with an interest),*
- *duration is limited in time*
- *mixture of physical meetings and electronic exchanges between registered participants.*

For a STAIR platform to be created it requires approval of its Terms of Reference by the CEN and/or CENELEC Technical Board, upon recommendation by STAIR[51]. A STAIR platform for interactive robots is currently not advised, because the EU Robotics topic group on standardisation[52] has a similar focus, but without a NSB as the secretariat. However, this could be an option in the future to continue the work of INBOTS or other future interactive robotics research projects.

[51] https://www.cencenelec.eu/research/tools/projects/STAIRplatform/Pages/default.aspx
[52] https://www.eu-robotics.net/eurobotics/topic-groups-/topic-groups-overview.html

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

5.5 Liaison

Another tool that can help transfer a CWA to a standard or initiate the adoption of a NWIP is the prior formation of a liaison with a technical committee. In exchange for an annual fee for a TC and its corresponding Working Groups (WG), a liaison on European level (CEN) can be established. A liaison on International level (ISO) is free of charge. Organisations then have access to all of the committee's documents that have been circulated via a document exchange system, can attend meetings but cannot vote on work items. Forming a liaison can provide an insight into the TC's work programme and the standardisation landscape of a certain topic. It can also help to identify gaps and be a platform for networking with other experts working in the field[53].

As already mentioned in Section 1 liaisons can also be set up between different TCs. Liaisons between for example ISO/TCs include the exchange of basic documents, including new work item proposals and working drafts. A TC may designate a liaison representative, to follow the work of another TC with which a liaison has been established. Liaison representatives have the right to participate in the discussions of the other TC whose work they have been designated to follow, and may submit written comments; they do not have the right to vote[54].

5.6 Paths for the INBOTS standardisation potentials

Possible ways to further process the identified INBOTS standardisation potentials from Section 4 are presented below. INBOTS is a Horizon 2020 "Coordination and Support Action" (CSA) and focuses on developing strategic solutions for future activities. The project exceeded the expectations and developed a CWA (see item b).

a) Robots and robotic devices – Measurement of autonomy

This standardisation potential could be further developed in a joint working group (JWG) between ISO/TC 299 on Robotics and ISO/IEC JTC 1/SC 42 on Artificial Intelligence. At the moment the latter can access documents form ISO/TC 299, but not vice versa (see Figure 2). In the future robots will integrate more and more artificial intelligence and therefore an early cooperation between the TCs is advised.

b) Lower-limb wearable devices – Performance test method for walking on uneven terrain

Over a period of 7 month (plus 2 month public commenting phase) and in the course of 8 meetings the INBOTS project plus 17 organisations form 10 countries (Germany, Italy, Iceland, Spain, Sweden, Switzerland, The Netherlands, France, Belgium, and South Korea) and the Horizon 2020 research project EUROBENCH jointly developed the CWA 17664:2021 on lower-limb wearable devices. The EUROBENCH coordinator Diego Torricelli (CSIC) was the chairperson and Roberto Conti (IUVO) from INBOTS the vice-chairperson. The development of the CWA was announced in May 2020 through the website of the European Committee for Standardisation (CEN). The Kick-off Meeting took place on the 29th of June 2020 following a one month public call for participation. The final text of CWA 17664 was submitted to CEN for publication on 2021-03-26.

[53] CEN/CENELEC Guide 25 – The concept of Partnership with European Organizations and other stakeholders (2017).
[54] ISO/IEC Directive, Part 1 Procedures for the technical work.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

The following TCs were informed and invited to take part in the development of the CWA:

- *ISO/ TC 168 Prosthetics and orthotics,*
- *CEN/ TC 293 Assistive products and accessibility,*
- *CEN/ TC 293/ WG 5 Prostheses and orthoses,*
- *NA 027-06-03 AA Orthopaedic technology,*
- *ISO/ TC 299 Robotics,*
- *ISO/ TC 299/ WG 4 Service robot performance,*
- *CEN/ TC 310 Advanced automation technologies and their applications, and*
- *NA 60 Mechanical Engineering.*

Members of ISO/TC 168 and ISO/TC 299 actively participated in the development of the CWA and the ASTM International and other organisations provided input during the public commenting phase of the draft CWA from December 2020 to January 2021. The feedback received was incorporated in the document to make it even more user-friendly and to increase the usage probability.

c) Robots and robotic devices – Device categories for wearable robots

ISO/TC 299 on Robotics is currently very active in developing standards for service robots. A device categorisation based on the functions of wearable robots could be included in the approved new work item "ISO/AWI 31101 Robotics - Services provided by service robots - Safety management systems requirements". Future Europe robotics research projects could offer their support in developing this new standard. Another option could be that a Horizon Europe robotics research project develops a CWA, if a categorisation for wearable robots cannot be added to ISO/AWI 31101.

d) Robots and robotic devices – Contact surfaces in human-robot systems – General requirements

Safety matters like the definition of the human machine contact surface should not be developed via any fast track standardisation deliverable. The full consensus process and the involvement of every affected entity should be envisaged. Robotic safety standards should therefore be developed by ISO/TC 299 on Robotics or its European counterpart CEN/TC 310 Advanced Manufacturing Technologies. Therefore, a new work item proposal could be handed in on European or International level.

e) Robots and robotic devices – Test methods for devices used by non-professionals

Robots and robotic devices are increasingly used by lay people, which is why traditional laboratory tests may no longer be sufficient. Developing a test method for equipment used by lay people could be a task for a future Europe research project. The project could initiate the development of a standardisation document such as a CWA or could hand in an ISO or CEN new work item proposal through an NSB.

f) Robots and robotic devices – Data confidentiality of vulnerable groups – Children, elderly and disabled people

This standardisation potential could be further developed by a joint working group (JWG) of ISO/TC 299 on Robotics and ISO/IEC JTC 1/SC 27 Information security, cybersecurity and privacy protection. In addition, consumer protection institutes and European legislation should be consulted. This topic might not just be relevant for interactive robots, but also for other devices.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

g) Robots and robotic devices – Human-robot interaction – End-user requirements

On this standardisation potential a CWA in the format of a guideline could be developed. It could be described how the end-user of an interactive robot has to be trained to use a robot or robotic device. This could be a task for a Europe research project. The project could initiate the development of a standardisation document such as a CWA or could hand in an ISO or CEN new work item proposal through a NSB.

h) Robots and robotic devices – Privacy – Impact assessment

Privacy is weighted differently between ethnic groups and therefore it seems unlikely to develop a standard on international level on this topic. A research project could develop a CWA in the format of a technical report to clarify the state-of-the-art and make a first suggestion on what a privacy impact assessment of robots and robotic devices could look like.

i) Robots and robotic devices – Performance criteria and related test methods – Evaluation of active exoskeletons as wearable devices in manufacturing

The INBOTS project analysed the state-of-the-art and developed a process on how to transfer this standardisation potential into a future standard (see Section 7.1). Section 7.1 focuses on performance indicators that were identified through a literature review. The future standard needs to define the overall test method, the performance indicators and their thresholds. The collection of what a future standard on active exoskeletons should cover can be the basis for a new standardisation work item. A “Research and Innovation Action” under Horizon Europe, for example, could pick up the work and initiate the development of a standard or CWA.

j) Medical electrical equipment – Performance criteria and indicators to be measured for teleoperated surgical robots

The INBOTS project analysed the state-of-the-art and developed a process on how to transfer this standardisation potential into a future standard (see Section 7.2). Section 7.2 focuses on performance indicators that were identified through a literature review. The collection of what a future standard on surgical robots should cover can be the basis for a new standardisation work item. A “Research and Innovation Action” under Horizon Europe, for example, could pick up the work and initiate the joint development of a standard with ISO/TC299 JWG/5.

5.7 European research projects and standardisation

Figure 7 shows the different standardisation documents (see Section 3.1) in connection to the variables time and impact as well as the areas of application of a European research project. The development of a standard with the greatest impact supposes a greater dedication of time and therefore of effort. That means in case of the greatest impact (EN and ISO), whose coverage is international, the effort required to achieve it is highest.

This project has received funding from the European Union’s Horizon 2020 research and innovation program under grant agreement No. 780073.

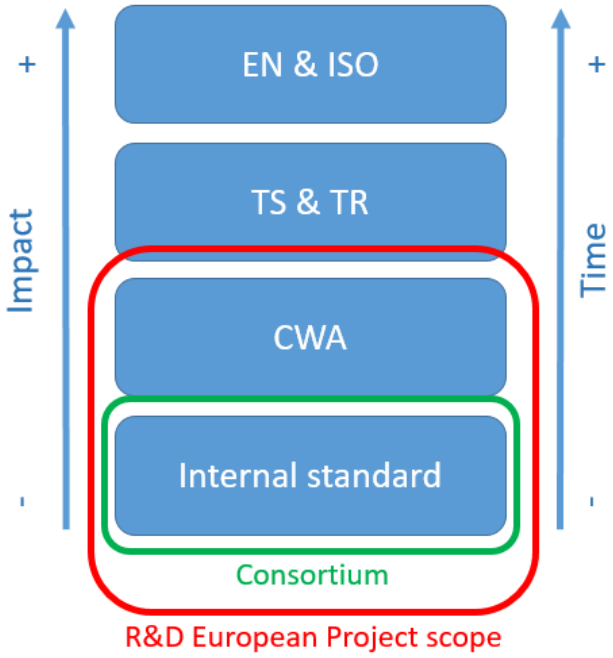

Figure 7: Relation among time, impact, areas of application and type of standards

European research projects normally have a duration of 2 to 4 years, the majority of them being 3 years. Usually, in these types of projects, products or services are developed based on existing standards. However, in some cases an innovative product or service is developed without an existing standard in this particular field. This situation then becomes a great opportunity to initiate standardization activities as the project's results advance. Experience shows that within the scope of a European project, a reasonable target may be the development of an internal standard, valid for the consortium itself, or the creation of a CWA (see Section 5.1) defining a consensual work methodology for all stakeholders.

The aim of European research projects is the promotion and development of results in science and technology that have a positive impact on the society. This is done in public-private collaboration between different entities across Europe. Standardisation focuses on the development of technical standards that are developed by all stakeholders and approved by a nationally or internationally recognised organisation. The use of standards is not mandatory but advisable. Therefore, the standardisation process is a sum of several elements:

- *knowledge of what is standardised from a technical, legal, ethical, business, production, market and financial point of view,*
- *an agreement among all the involved stakeholders,*
- *standardisation process will be done by a generally recognised organisation,*
- *a set of requirements and recommendations is created in a transparent process and everyone can voluntarily join to work on them and use them.*

In this context, the following questions arise:

- *Are standardisation and European research projects related?*
- *Can standardisation be used as a tool for a European research project?*
- *Does it make sense to use standardisation and does the project have advantages from it?*

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

The answer to all these questions is yes.

First of all, using a standard for a particular technology or product/service development enables the use of a set of requirements that have been established as "good" by mutual agreement among key market stakeholders. This means that a development based on this standard will have greater compatibility and dissemination to future customers and will facilitate collaboration with technology partners. Nevertheless, standardisation is much more. It allows generating new standards and modifying existing ones. A technology, a product or a service that has been developed in a European research project can be a starting point to generate a new framework of agreed requirements (a new standard) for future projects that work on new developments in the same field or it can modify standards that have already been developed or have become obsolete.

Standardisation as an impact tool[55]

- *Standardisation is a powerful tool because it improves the results of the investigative and innovative process through a series of characteristics.*
- *From the point of view of building trust between the product developer and the customer, a standard establishes the premises on which this product will be developed and the customer is clear at all times of what to expect due to the fact that the manufacturer brings to the market a product based on a certain standard. Both parties can consult this standard with transparency. This transparency between entities facilitates the creation of international communities and networks that develop and work under the principles of transparency and openness.*
- *From the point of view of collaborative development, the process of co-creation of standards favours innovation between different industries in an open way, ensuring comparability, compatibility, and interoperability of all processes and procedures.*
- *From an economic point of view, any company can benefit from both using existing standards when developing products and writing a new standard when working on an innovation. At macroeconomic level, standardisation allows access to new international markets that work with products and developments based on the same language and framework (standard), which directly impacts economic growth in all participating countries.*

Putting the focus of attention specifically on researchers, the impact of standardisation for this group generates a series of aids and benefits in their research project.

- *Already published standards provide researchers with information on advanced technologies in the industry, in the same way that information about new standards under development or existing standards in the process of modification keep the researcher updated on technological, political and market changes.*
- *From a more practical point of view, the great variety of stakeholders that have participated in a standardisation process increases the possibilities of meeting new and interesting partners from different fields. On the other hand, the granting of European financial aid to research values the creation of standards and promotes those proposals that have a strong standardisation plan. Once the proposal is approved and during the project's lifetime and beyond, it can have a greater impact in terms of recognition of the project outcome by project externals, if standardisation is included.*

[55] Standards plus Innovation, accessed March 4, 2021, https://www.standardsplusinnovation.eu/.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Those entities that are dedicated to innovation will be able to benefit from an improvement in the impact of their results thanks to standardisation, for reasons very similar to the previous ones.

- *It will be easier to have access to the latest technologies that are already incorporated into standards. Innovative results will reach a greater public interest and their acceptance and dissemination will be wider. The network of contacts is expanded by the fact that standards are developed with very diverse entities, many of which, because they are public, facilitate close coordination of standards and support regulation. Finally, and as previously mentioned, public funds value the development of standards in innovation projects by granting aid. Furthermore, the professional recognition of the people who work and develop standards is important and is reflected in documents such as CWAs.*
- *Related to the previous point and the 'extra effort' involved in drafting a standard, it is observed that many researchers prefer to dedicate additional efforts to carrying out a scientific/ technological paper instead of a standard, thinking that this action will have much more impact at the level of dissemination and even professional recognition. However, it is important to emphasize that both tools (the publication of a scientific paper and the creation of standards) are equally important and complementary.*
- *The specific target of scientific publications is the scientific community, while standards, being developed by many stakeholders from various fields, have great impact in many areas: business, public, legal, social, etc. Talking about professional promotion, scientific publications generate prestige for those who have carried them out, but it is important to indicate that standards also generate this prestige, since both, the organisations and the authors who have participated in their development, are stated in the document, which confers professional recognition to all parties.*

TRLs and why it is important to standardise from TRL > 6

Figure 8 shows the description of the Technology Readiness Levels (TRL). This acronym is widely used in research projects to define the scope and level of maturity to be reached within a project. A basic classification of this table, generally accepted by all researchers, indicates that the first three levels (TRL 1 - 3) usually collect the contributions of basic science. The next three levels (TRL 4 - 6) are focused on laboratory tests, reaching the verified prototype level. Finally, the last levels (TRL 7 - 9) are those that transform a prototype to a practically commercial level.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

	Technology Readiness Level Definition
TRL 1	**Basic Research:** Initial scientific research has been conducted. Principles are qualitatively postulated and observed. Focus is on new discovery rather than applications.
TRL 2	**Applied Research:** Initial practical applications are identified. Potential of material or process to solve a problem, satisfy a need, or find application is confirmed.
TRL 3	**Critical Function or Proof of Concept Established:** Applied research advances and early stage development begins. Studies and laboratory measurements validate analytical predictions of separate elements of the technology.
TRL 4	**Lab Testing/Validation of Alpha Prototype Component/Process:** Design, development and lab testing of components/processes. Results provide evidence that performance targets may be attainable based on projected or modeled systems.
TRL 5	**Laboratory Testing of Integrated/Semi-Integrated System:** System Component and/or process validation is achieved in a relevant environment.
TRL 6	**Prototype System Verified:** System/process prototype demonstration in an operational environment (beta prototype system level).
TRL 7	**Integrated Pilot System Demonstrated:** System/process prototype demonstration in an operational environment (integrated pilot system level).
TRL 8	**System Incorporated in Commercial Design:** Actual system/process completed and qualified through test and demonstration (pre-commercial demonstration).
TRL 9	**System Proven and Ready for Full Commercial Deployment:** Actual system proven through successful operations in operating environment, and ready for full commercial deployment.

Figure 8: Technology Readiness Level[56]

A project that reaches TRL 6 has already had to perform a real demonstration in the operational environment. This means that something has already been developed. A tangible product, for example, works and can be shown to future customers as proof that a certain development works in reality. It is a prototype that can begin to take its first steps towards a commercialisation phase. No matter if extra financing is needed to continue development or if it will be commercialised with its own funds, it is not only advantageous but often necessary to develop this system within a common standardisation framework, so that the product will have greater interoperability, viability, dissemination and acceptance by future customers. In fact, a greater viability is based on:

- *Standards make the preparation of documentation for the transfer and exploitation of IP easier.*
- *Different regulations and bidding processes refer to and value the use of certain standards by bidders.*
- *Standards lay the foundation for future development in an orderly and scalable manner.*
- *Carrying out a development based on a standard or creating a new standard offers, once finished, a better access to international markets due to the compatibility with other products / developments that are based on the same standard.*

[56] European Commission, accessed March 4, 2021, https://ec.europa.eu/research/industrial_technologies/pdf/workshop-innovation-report_en.pdf.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

- *Starting from a TRL 6 and having made a standard allows a product or development to maintain its consistency and robustness as its development and implementation is scaled to new levels of TRL and finally to different markets. On the other hand, having clearly defined the standard, potential clients can anticipate its characteristics and have a precise idea of what properties to expect from this product.*

Working on European research projects starting from a TRL 6, is a very good opportunity to create a standard, as these types of projects facilitate one of the most important elements: bringing together various specialist stakeholders working together over several years, each in their own field, in a common project and in a common dialogue.
From this point on, the only thing left to do is to apply that standard. In fact, it would be advisable to consider this condition already in the first laboratory tests (TRL 4), since the ultimate goal in research projects should be to deliver these results to citizens and therefore have a positive impact on their improvement of the quality of life, health, work, leisure, etc.; in an orderly way and with projects that have a greater probability of reaching technological and market consensus.
The standardisation process and standardisation bodies can be involved in a European research project from the very beginning. These bodies, along with the other partners, can assess from the beginning what standards currently exist and which ones a project can use to achieve its objectives. They can evaluate which aspects are not covered by standardisation (gaps), but would make a good standardisation potential, and by linking the results of this evaluation with the existing tools of standardisation they can give advice which standardisation potential may constitute an opportunity of expanding an existing standard or even develop a new one.

The main benefits of including standardisation aspects in a project are, on the one hand, experts from standardisation organisations can contribute their knowledge to the project, providing additional reliability to the developed document and increasing its impact. On the other hand, standardisation facilitates the widespread dissemination of the project's results making them accessible to everyone. Therefore, the standardisation process acts as a link between researchers and the market.

Standardisation of European research project outcomes

Once the decision is made to carry out standardisation activities in a European project, a National Standardisation Body (NSB) has to be included. An NSB as a project partner can help with the process of standardisation. NSBs represent the member countries of the International (ISO or IEC) and European standardisation organisations (CEN or CENELEC) for example DIN in Germany, UNE in Spain, NEN in the Netherlands. NSBs can help with:

- *determining if developments of a research project have the potential to be standardised and, if this is the case, establishing contact with relevant organisations and partners in this field,*
- *assisting in the search for existing standards to identify technologies that are interesting for research as well as coordinating and working jointly and continuously on the standardisation strategy of the project,*
- *providing guidelines and supporting the development of a CWA within the scope of the project,*
- *promoting the dissemination of research results so that they have a greater impact.*

Specific tasks and envisaged deliverables need to be designed with a defined budget for the standardisation task. In the end, the process of modifying an existing standard or creating a new standard and even just following one, means an additional effort for developers and companies,

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

which will boost and improve the market acceptance of an innovation. For this reason, it is important to include this process from the very beginning in the business plan as well as in the exploitation and IP plan of the innovative project result.

Examples of robotics standardisation in European research projects

- *The COVR project focuses on being safe around collaborative and versatile robots in shared spaces. COVR (2018 - 2021) compiles existing safety regulations relating to collaborative robots in several fields and fills in regulatory gaps for newer fields of collaborative robots to present detailed safety assessment instructions to manufacturers and developers.*
- *The EUROBENCH project focuses on a EUropean ROBotic framework for bipedal locomotion bENCHmarking. EUROBENCH (2018 - 2021) aims at creating a benchmarking framework for robotic systems, allowing companies and researchers to test the performance of robots at any stage of development.*
- *The ROSSINI project (2018 - 2022) develops a secure hardware and software platform to generate applications between humans and robots collaborating for manufacturing.*

6. Challenges and recommendations

This section gives an overview of the identified standardisation challenges, their background and recommendations how to solve the challenges (see tables below). INBOTS has analysed, if certain challenges are only for specific domains (manufacturing, healthcare and/or consumer). The consortium came to the conclusion that the challenges refer to all domains.

Table 9: Product safety & performance challenges: requirements on the design of the robot system itself

#	Challenge	Background	Recommendation
1	Difficulty to identify potential sources of harm (hazards).	Companies face the challenge that they cannot foresee or identify all hazards that might arise from their interactive robot. Not all situations and human behaviour can be foreseen and be taken into account before actually using the interactive robot in a real application. The impact on the users can appear after long-term usage of the interactive robot.	Develop an open access benchmark database that covers many situations in real scenarios for different applications and tracks the effects of different interactive robots in the long term. The open access benchmark database could also show typical hazards of interactive robots that companies reported for their robotic devices. Additionally the applied standards could be highlighted.
2	Difficulties to identify and apply standards.	Companies face the challenge that when they identified potential hazards they do not know which standards they can apply to limit those hazards. Standards are possibly not reflecting the “state-of-the-art”. There is insufficient information on where to find harmonized standards, what they are and how to use them.	Intensify communication on where to find information on standardisation and risk management on European level. For example, companies in Germany can access standards for free at certain access points, typically in universities. The German Standardisation Organisation offers also seminars like "Successful implementation of a risk management system for medical devices according to DIN EN ISO 14971: 2020-07".

This project has received funding from the European Union’s Horizon 2020 research and innovation program under grant agreement No. 780073.

		There may also be different national standards depending on the target markets.	More guidelines with practical examples on how standards can be applied could also be developed (e.g. ISO/TR 23482 Robotics – Application of ISO 13482 – Part 2: Application guidelines). The open access benchmark database (see number 1) could also show how standards have been applied for different robotic devices. The EU should provide subsidized advisory services on standards by eligible companies.
3	Unclear boundaries between robot domains.	Companies face the challenge that they can hardly grasp what it means, if they classify their exoskeleton as, for example, a medical device or personal care robot. As a flexible machine, a robot can be used in several domains/applications. There is a potential for misuse of a robotic device that manufacturers have to address this in their risk assessment. For example a medical robot will most likely not be used as a personal care robot. However, the use of a personal care robot as a medical robot seems more likely.	It is important to include clarification of the application domain and the capabilities of a system, when developing a standard. It should also be stated for which domains the standard is not applicable.

Table 10: Occupational safety & performance challenges: validation of the robot as a work/daily life equipment

#	Challenge	Background	Recommendation
4	Difficulties when certifying safety in wearable devices.	The need to involve humans in testing wearable devices can be hazardous. The certification process is long, not always self-explaining and expensive for SMEs.	Development of procedures on how to conduct a certification process and execution of a risk analysis for wearable devices. Establishing guidelines, metrics and test methods, not involving humans (e.g. simulation of use for primary testing). Introducing a mandatory public reporting requirement on human subject tests for device certification, even if results are negative, to broaden available knowledge before designing future tests (see number 1).
5	Lack of guidelines for an ergonomic design of robotic applications.	Details on ergonomic needs are not fully known for different robot domains. Also long-term follow-ups may not be available at the time guidelines are created, so only short-	Increase efforts to transfer available knowledge about ergonomic design from other fields to robotics.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

		term ergonomics are considered. In addition, operational situations are not always predictable.	
6	Lack of ethical guidelines for autonomous robots.	Ethics are often subject to cultural differences and cannot easily be standardised globally.	Define basic guidelines that are universally applicable (e.g. dignity, avoidance of harm, non-discrimination). Extend standardisation working groups beyond collaborators from industry and the technical field.
7	Lack of performance index for a robot used in a certain application.	Information on how to link performance and functional benefits is missing (e.g. wearable device). The definition of the performance index is be controversial as it could give an advantage to one device/manufacturer over the other. A trade-off between clarity of the performance index and its completeness needs to be found.	Funding of research projects to identify performance index and initiation of standardisation activities on the identified measures and test methods (e.g. EUROBENCH).

Table 11: Process safety & performance challenges

	Challenge	Background	Recommendation
8	Unknown impact of the robots' activity on the industrial manufacturing process. Sometimes the impact arises after medium/long term.	It is difficult to measure parameters related to the impact on human factors. Sometimes it is not clear if the use of a certain type of robot has a real impact on the production or on the improvement of a task or service.	Measurement of the impact using objective metrics and benchmarks. Change the way of measuring parameters of exoskeletons, because the standard ergonomic indexes to evaluate its ergonomic impact on the process are not valid. Standardisation of a benefit analysis for interactive robots affecting humans.
9	Lack of standards for software reliability.	Increasing complexity of software and importance of cloud computing. Reliability of software often depends on the data input, which may not be consistent. There is also an insufficient understanding of functional principles of certain types of software (e.g. "We use machine learning to control the robot").	Introducing guidelines and a standardised procedure for testing of software reliability in an emulation environment, to discover hidden failures.
10	Lack of standardised way to manage personal data/privacy.	Up to now, the existing robots and robotic devices have not managed personal data.	Development of guidelines and benchmarks. Introduction of substantial fines, if personal data is mistreated.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

11	No sufficient coverage of new applications by existing standards.	There is a general difficulty of keeping a standard, which is the result of discussion and review, up-to-date with the latest technical development.	Standards on new applications should be initiated and developed. The recording of information by different users and their applications may be a flexible way to help cover as many applications as possible with new standards.
12	Shortage of Notified Bodies accredited under the new Medical Device Regulation.	There is insufficient monetary incentive to set up such a body or obtain accreditation.	Increase incentives to boost accreditation of more Notified Bodies under the new Medical Device Regulation.

Table 12: General challenges

#	Challenge	Background	Recommendation
13	Design and content of standards, e.g. interpretation problems and uncertainty which standard to follow.	Sometimes standards leave room for interpretation – sometimes on purpose and sometimes not. Terminology is also an issue. The vocabulary can evolve rapidly after a standard is written, reducing the comprehensibility of the published standard. In some cases the lack of communication between technical committees could also be a reason.	Provide a database of examples where and how standards have been used (see number 1). Funding of projects like COVR[57]. The COVR project tries to clarify, which standards should be followed for different devices.
14	Resource issues, e.g. limited access to standards and lack of resources to utilize standards.	Standards are not freely available. Insufficient information on where to buy standards.	Financial support from EU / Governments – make suggestions on what the EC could finance e.g. more access to standards via official reading points all over Europe.
15	Lack of resources to take part in standardisation working groups, e.g. membership costs of standardisation bodies, smaller companies are not sufficiently represented in the development of standards, cost of time for participation and follow-up.	Members have to pay a fee and developing a standard is a long and time consuming process.	Financial support from EU through research projects (Innovation Actions) for research partners to take part in standardisation, e.g. development of a CEN Workshop Agreement out of a research project.
16	Development process of standards is time-consuming and complex.	Standards are written on the basis of consensus, which	On national level different standardisation bodies already started initiatives to reduce the development time.

[57] COVR, accessed March 4, 2021, https://www.safearoundrobots.com/home.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

		makes the process complex but inclusive.	Inform the robotics community that there are different types of standardisation documents – including a fast track standard (CEN Workshop Agreement).
17	Participation raises intellectual property issues	Companies are afraid to give up confidential information. However, it is not the design of the products that is envisaged to be standardised, but the requirements for the product.	Inform organisations what knowledge can be transferred into a standard without harming their intellectual property rights.

7. Strategy for new standards

The development process of standards is well defined (e.g. ISO/IEC Directive – Part 1[58] and Part 2[59], CEN Regulations Part 2[60] and Part 3[61]. It usually follows six-steps as shown in Figure 9.

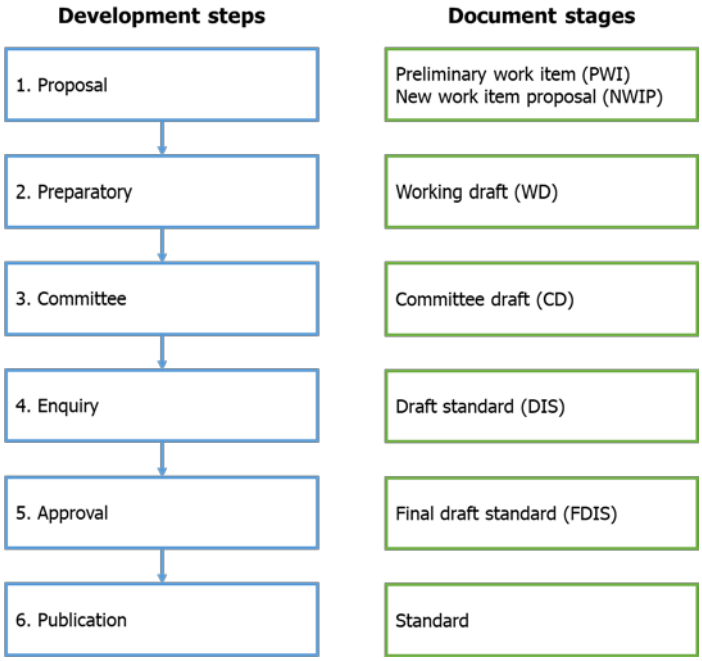

Figure 9: Development process of a standard

[58] ISO/IEC Directive – Part 1 Procedures for the technical work
[59] ISO/IEC Directive – Part 2 Principles and rules for structure and drafting of ISO and OEC documents
[60] CEN/CENELEC Regulation – Part 2: Common Rules for Standards Work
[61] CEN/CENELEC Regulation – Part 3: Principles and rules for the structure and drafting of CEN and CENELEC documents

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

1) Proposal stage

The first step in the development of a standard is to confirm that a particular standard is needed. A New Work Item Proposal (NWIP) is submitted to the members of the relevant technical committee (TC) or sub-committee (SC) for a vote to determine whether to include the work item in the work programme. At this stage, a project leader is usually appointed to be responsible for the work item.

2) Preparatory stage

Usually, a working group of experts, whose chairperson (convener) is the project leader, is appointed by the TC/SC to prepare a working draft. Successive working drafts may be considered until the working group is satisfied that it has developed the best technical solution to the problem being addressed. At this stage, the draft is forwarded to the working group's parent committee for the consensus-building phase.

3) Committee stage

As soon as a first committee draft is available, it is registered by the secretariat and circulated for commenting. Successive committee drafts may be considered until consensus is reached on the technical content. Once consensus is attained, the text is finalised for submission as a draft standard (DIS).

4) Enquiry stage

The draft standard (DIS) is circulated to all member bodies by the secretariat for voting and commenting. If the approval criteria are not met, the text is returned to the originating TC/SC for further editing and a revised document is circulated as a draft standard for voting and comment.

5) Approval stage

The final draft standard (FDIS) is circulated to all member bodies by the secretariat for a final vote. If technical comments are received during this period, they are no longer considered at this stage, but registered for consideration during a future revision of the standard. If the approval criteria are not met, the standard is referred back to the originating TC/SC for reconsideration taking into account the technical reasons submitted in support of the negative votes received.

6) Publication stage

Once a final draft standard has been approved, only minor editorial changes, if and where necessary, are inserted into the final text. The final text is sent to the secretariat which publishes the standard.

The trigger of the above standardisation process is the need for a new standard. This need may arise, for example, from the lack of a standard that regulates a new technology or when an existing technology is used in a different field that has certain peculiarities not covered by existing standards.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

7.1 Exoskeletons in the manufacturing domain

Before proposing a new standard, a research into the subject matter has to be conducted and the field of application of the future standard has to be defined. The definition of the field of application is essential to circumscribe the scope of the standard to be developed. This is useful not only for those who will develop the standard, but ultimately also for those who will use the standard. INBOTS identified the below standardisation potential (see Section 4) and conducted further investigation into the topic. A potential path on how to transfer this into standardisation activities is described.

Example Title: Robots and robotic devices – Performance criteria and related test methods – Evaluation of active exoskeletons as wearable devices in manufacturing
Example Scope: This standard defines a test method for active exoskeletons as a wearable robot in the manufacturing context. It describes which variables, in specific application contexts, should be considered for the evaluation of the performance of an active exoskeleton. It shows how to detect variables of specific work cases addressing a specific industry sector to detect the effects and quantifiable benefits of active exoskeletons. The standard also defines ergonomic variables to show the efficiency of the device's application. Use-cases as well as a functional analysis of the technological device are included. This standard does not apply to robots that are not body-worn, or are not worn by human users. This standard does not apply for safety investigation. This standard does not apply outside the manufacturing domain.

Collection of knowledge on what the envisaged standard should cover

The collection of fundamental information relating to the subject matter of the new standard represents a solid basis for its development. In fact, understanding what the scientific community is doing on the subject is an excellent starting point for defining the indications of the new standards. In particular, when talking about industrial exoskeletons, since there is no universally accepted evaluation procedure, it is essential to gather and analyse information to understand how the scientific community approaches the problem and what the most common methods of evaluation are. The activity of collecting and managing information has been conducted by INBOTS through the following steps.

1) *Benchmarking of exoskeleton analysis methodologies*
2) *Extraction of main parameters for exoskeleton evaluation*
3) *Definition of the exoskeleton environment and its categorisation*
4) *Description of Key performance indicators (KPI) from the parameters*

1) Benchmarking of exoskeleton analysis methodologies

Benchmarking is a key aspect of information gathering. In the case described in the White Paper, a research was conducted collecting information from scientific papers (starting from 2018), seminars, European publicly funded projects, and the INBOTS consortium experience. The main keywords used were: industrial exoskeleton, evaluation methodology, standard, ergonomic, and human factor. From the research, about 30 most promising articles (see Annex B) have been selected that relate to the methods of exoskeleton performance analysis in both laboratory and real-life environment.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

2) Extraction of the main parameters for exoskeleton evaluation

The analysis of the collected information (see Annex B) has enabled the extraction of the main industrial exoskeletons parameters investigated (PI) by the stakeholders. Twenty-two parameters were identified, each of which has been categorised into the following categories based on its nature: efficacy, efficiency, usability satisfaction, and comfort. The definition of "usability" is based on the ISO 9241-11[62]. An effective product allows the users to achieve specific goals in a complete and accurate way. Instead, an efficient product allows the users to minimise the expenditure of resources to achieve specific goals. Finally, a product is satisfactory if users reach their goal without any inconvenience and have a positive impression of it. An overview of the industrial exoskeletons parameters investigated is given in Figure 10.

Figure 10: Exoskeleton parameters classified according to efficacy, efficiency, usability satisfaction and comfort

3) Definition of the exoskeleton environment and its categorisation

The exoskeleton evaluation is divided in three main steps. Each step must have specific protocols to evaluate the exoskeleton parameters investigated (PI).

- *Step 0: Conceptual analysis and benchmarking*
- *Step 1: Functional analysis (lab environment)*
- *Step 2: Usability evaluation (lab environment)*
- *Step 3: Workplace and task analysis (factory)*

Step 0 includes the market research of exoskeleton solutions that can be potentially integrated in an industrial environment according to certain characteristics deriving from the reality in which they would be used. Alternatively, if the exoskeleton is under development, this step collects the first developments of prototypes, which will then be tested to continuously improve the product.

[62] ISO 98241-11 Ergonomics of human-system interaction - Part 11: Usability: Definitions and concepts

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Step 1 represents the first testing of the exoskeleton functionalities in the laboratory. In this phase, the proper characteristics of the exoskeleton are evaluated, such as weight, geometry of the components, and kinematics. All those aspects of the device that are the starting point for its usability are examined. In this phase, no user tests are performed, but measuring devices are used to objectively determine the characteristics of the exoskeleton. If these characteristics are unsuitable, testing of the exoskeleton would stop and improvements could be requested to the supplier or developers, before proceeding with further steps.

Step 2 represents the usability and comfort testing of the device in a laboratory environment. Once the characteristics of the exoskeleton are considered suitable for the industrial environment (Step 1), the next step is to evaluate its use by a sample of users in simulated work tasks (from simple to real-life). In this phase, all aspects of the interaction between the device and the person are evaluated both objectively and subjectively.

Step 3 foresees the testing in real industrial environment, during work activity and in respect to work organisation. The objective, in this case, is to understand if and how the use of the exoskeleton influences the industrial process and to validate its usability and comfort evaluation in an unstructured environment. At this stage, subjective and objective non-invasive measures are preferred in order to avoid hindering the work activity. To obtain good results from this step, the right assignment of exoskeleton and workstation is fundamental.

Steps 2 and 3, as they involve testing with people, on tasks and in specific environments, are very delicate in defining the testing conditions because they could affect the results obtained. It is therefore very important to pay attention to different aspects related to the definition of test protocols.

With regard to the usability tests protocols conducted in steps 2 and 3, while performance evaluation groups/institutions may have their own requirements for writing a research protocol, most protocols will include the following:

- *User sample*
- *Methods for evaluation (incl. tasks, system conditions, test environment)*
- *Metrics used to quantify human and/ or system performance*
- *Resources and user training*
- *Safety and risk mitigation*

User sample: The number and type of participants needed for an evaluation generally depends on the function of the intended user group for the system, the technical maturity of the system, the goals for the evaluation, and whether or not statistical significance in the findings is required. The first decision to be made is whether it is essential to recruit within a specific population. For evaluations early in the development cycle that are assessing basic functions with and without the system, recruitment from the general population is appropriate. As the system becomes more mature and the protocol tasks become more specific, it may be necessary to recruit subjects with particular skills or qualifications. Furthermore, in early system evaluations, when expectations for system performance are uncertain, it may be unrealistic to seek statistical significance in the results.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Often, early evaluations are exploratory and sufficient to provide data for further development of the system and generate trends for anticipated performance changes in future evaluations. For more mature systems, a greater number of subjects is typically desired.

Methods for evaluation – including tasks, system conditions, test environment:

Task definition: Understanding the intended use of the system is fundamental to selecting appropriate tasks. Tasks used to evaluate the system should simulate as closely as possible the task that the system has been designed to support. The task should be scaled, however, for the system's current level of technical maturity. In early evaluations, it is good practice to evaluate the system first using a modified, low-difficulty version of the task and gradually increasing the difficulty to identify changes in system performance.

System conditions: In order to understand the effect of the exoskeletons, evaluations are typically conducted by comparing the user experience with the exoskeleton ("ON" condition) to the performance without the exoskeleton (No Device condition, "ND"), or with the exoskeleton in OFF condition.

Test environment: Exoskeleton evaluations should be conducted in a laboratory environment (Step 2), in a real-world environment (Step 3), or include a combination of the two. Laboratory evaluations permit highly controlled, high-fidelity data collection with minimal abuse to the system. The disadvantage, however, is that they do not effectively quantify system performance in an operational scenario and there are limitations to the tasks that may be performed. Real-environment assessments are more operationally relevant and indicative of overall system efficacy, but the types of metrics that may be used to quantify performance are more restricted due to measurement equipment portability constraints.

Metrics used to quantify human and/or system performance: Appropriate metrics will be chosen to quantify the elements of performance that are of interest during the selected tasks. If the goal of the assessment is to conduct a formal evaluation to quantify specific changes in physical performance, biomechanical or physiological metrics would be most appropriate. If, instead, the evaluation is intended to be an assessment of real-world system performance, operational metrics would be most useful. For evaluations whose primary purpose is to collect user feedback regarding human/system interface, the human factor metrics would be appropriate. Certain performance metrics, due to the invasiveness and complexity of the measurement instruments, cannot be easily collected in a field environment.

Resources and user training: In order to be sure that all the aspects related to the parameter investigated are detected, it is very important to define the evaluation team, also depending on the testing environment. For example, in the Step 1 a small size team consisting of engineers that focuses on the product could be sufficient. In Step 2, due to the complexity of the evaluation, it is important to involve other persons, like ergonomists, psychologists, physiotherapists and physicians. In step 3, people from the industrial environment must be involved, as safety managers, production engineers, medics, and user's colleagues.

The appropriate duration of training varies by system and its specific application. This may initially be unknown, particularly in the case of early prototypes and novel technologies. Additionally, training requirements for a particular technology may change over time as the TRL increases.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Initial criteria for determining when participants are sufficiently trained is when they can demonstrate familiarity with the operation of the system and when they report that they were comfortable using the system to perform the evaluation tasks.

Safety and risk mitigation: Some measures are important in order to be able to conduct the tests safely. The evaluation team must be sure that the subject has deeply understood the test operations. The evaluation team can collect basic information such as height and weight to know what size individuals the system is suitable for. In addition, the exoskeleton developer should share results of any electrical or thermal safety, flammability, biocompatibility, durability, mechanical, and software testing. Referring to the test management, protocols using human subjects should be reviewed by an ethics committee and appropriate documentations regarding the data management and privacy must be shared with the users.

For each of the 3 Steps the main identified parameters to be investigated have been associated in Table 13.

Table 13: Main identified parameters to be investigated in each step

STEP 1 Functional analysis (Laboratory)	STEP 2 Usability evaluation (Laboratory)	STEP 3 Workplace & task analysis (Industry)
EFFICACY PARAMETERS		
Support force	Muscular activity	
Exoskeleton range of motion (ROM)	Exoskeleton-human range of motion (ROM)	
	Interface pressures	
	Heart rate	Heart rate
	Oxygen consumption	
	Metabolic consumption	
	Task accuracy and precision	
	Rate of Perceived Exertion (RPE) (Borg Scale)	
	Ground force and Center of pressure (CoP)	
		Ergonomic indexes
		Total workload (NASA-TLX)
USABILITY / SATISFACTION PARAMETERS		
	System Usability Scale (SUS)	
	Usability Metric for User Experience (UMUX)	Usability Metric for User Experience (UMUX)
		Acceptability questionnaire (Technology Acceptance Model)
		Open questions adapted to the environment use

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

EFFICIENCY PARAMETERS		
	Task execution time	Task execution time
Endurance time		
Donning/Doffing time		
COMFORT PARAMETERS		
Interface pressures		
	Local Perceived Pressures (LPP)	Local Perceived Pressures (LPP)
	Visual Analogue Discomfort Scale (VADS)	Visual Analogue Discomfort Scale (VADS)
	Corlett and Bishop's discomfort scale	Corlett and Bishop's discomfort scale

Parallel considerations referring to the biomechanical load can be performed in the simulation by specific software (e.g. AnyBody, 3DSSPP Software) considering the exoskeleton through the interface forces exchanged with the user.

4) Description of Key Performance Indicators (KPI) from the parameters

For each parameter identified the characteristics are described in Annex C. The following questions are answered in Annex C for each investigated parameter from Table 14:

- *What should be measured?*
- *Why should it be measured?*
- *Where should it be measured?*
- *When should it be measured?*
- *Who should measure it?*
- *How should it be measured?*

Table 14: Main KPIs for the IP identified

Investigated parameter (IP)	Comparison between with and without exoskeleton	Unit of measurement	Threshold
Support force	Force exercised for the support of the body district of interest	Newton	>= 40% of the body district weight
Muscular activity	=100*(RMS[63]/MVC[64] without exo - RMS/MVC with exo)/ RMS/MVC without exo	Percentage	>= 30% of activity reduction
Exoskeleton ROM	Angle allowed by the exo[65] structure	Degree	-
Exoskeleton-human ROM	=100*(human joint angle without exo - human joint angle with exo)/ human joint angle without exo	Percentage	<= 20% of movement reduction per joint
Interface pressures	Peak pressure measured at the exoskeleton-human body interface	kPa	<= 4.3 kPa

[63] RMS - Root Mean Square
[64] MVC - Maximal Voluntary Contraction
[65] exo - Exoskeleton

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Heart rate	=100*(heart rate without exo – heart rate with exo)/ heart rate with exo	Percentage	>= 10% of heart rate reduction
Oxygen consumption	=100*(oxygen consumption without exo – oxygen consumption with exo)/ oxygen consumption with exo	Percentage	>= 10% of heart rate reduction
Metabolic consumption	=100* (metabolic consumption without exo – metabolic consumption with exo)/ metabolic consumption with exo	Percentage	>= 10% of heart rate reduction
Task accuracy & precision	Distance of the position reached with exo respect to the target position	mm	<= 12 mm
Rate of Perceived Exertion (RPE) (Borg Scale)	=100*(Borg score without exo – borg score with exo) / Borg score without exo	Percentage	>= 20% of perceived exertion reduction
Ground force and Center of Pressure (CoP)	=100*(Average CoP[66] without exo – average CoP with exo) average CoP without exo	Percentage	<= 20% difference positioning
Total workload (NASA TLX)	=100*(Nasa score without exo – Nasa score with exo) / Nasa score without exo	Percentage	>= 20% of perceived exertion reduction
System Usability Scale (SUS)	=100*(SUS score without exo – SUS score with exo) / SUS score without exo	Percentage	>= 20% of perceived exertion reduction
Usability Metric for User Experience (UMUX)	=100*(UMUX score without exo – UMUX score with exo) / UMUX score without exo	Percentage	>= 20% of perceived exertion reduction
Acceptability questionnaire (TAM)	=100*(TAM score without exo – TAM score with exo) / TAM score without exo	Percentage	>= 20% of perceived exertion reduction
Open questions	Qualitative measure	-	-
Task execution time	=100*(Task time without exo – Task time with exo) / Task time without exo	Percentage	~ 0% of time difference between the conditions with and without exoskeleton
Endurance time	=100*(Task time without exo – Task time with exo) / Task time without exo	Percentage	>= 30% of endurance time with exoskeleton
Donning/Doffing time	Time to wear the exoskeleton	seconds	< 30 s
Local Perceived Pressures (LPP)	=100*(Borg score without exo – borg score with exo) / Borg score without exo	Percentage	>= 20% of perceived exertion reduction
Visual Analogue Discomfort Scale (VADS)	=100*(Borg score without exo – borg score with exo) / Borg score without exo	Percentage	>= 20% of perceived exertion reduction
Corlett and Bishop's discomfort scale	=100*(Borg score without exo – borg score with exo) / Borg score without exo	Percentage	>= 20% of perceived exertion reduction

Defining a strategy for developing a standard is a process that requires the synergy of different skills. As far as exoskeletons are concerned, many studies are in progress, but there is no clear legislation regulating their scope, use, performance evaluation and safety. The White Paper

[66] COP - Center of pressure

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

presents a description of the reasons of interest that underlie the need for regulation as well as a summary of the methodology used in the scientific literature to study exoskeletons, which may represent a starting point for the definition of the regulation. The collection of what a future standard on exoskeletons should cover can be the basis for a new standardisation work item. A "Research and Innovation Action" under Horizon Europe could for example pick up the work and initiate the development of a standard or CWA.

7.2 Medical surgical robots in the healthcare domain

Following the same philosophy explained above for the exoskeletons in the manufacturing domain, a summarised approach is presented in the following section for the case of medical interactive robots, specifically for those which are teleoperated surgical robots. It covers the definition of their specific features, parameters and associated KPIs (key performance indicators). The test methods imply a wide variability, since a teleoperated surgical robot may be used in different surgical procedures with different level of requirements.

Example Title: Medical electrical equipment – Performance criteria and indicators to be measured for teleoperated surgical robots
Example Scope: Description of which performance indicators, in specific application contexts, should be considered for the evaluation of the performance of a teleoperated surgical robot. The standard defines which performance indicators should be considered, but an evaluation of the performance level is not envisaged to be included.

1) Features of medical (teleoperated) surgical robots

The domain for medical robots comprises very different kinds of interactive robot configurations: exoskeletons for rehabilitation, prosthesis and prevention of muscle disorders, mobile robotics for assistive purposes and drug delivery in hospitals, teleoperated or autonomous robotic arms for surgery and rehabilitation.

In surgical robotics, also known as medical electrical equipment, most of them are teleoperated, which means that the input movements made by a surgeon are replicated in the end effector of the teleoperated robot, with the aim to access the body cavity with the surgical instruments handled by the robot. The surgeon sees the cavity through an endoscope, whose 3D image is shown on a screen in the operating room.

In most advanced surgical robots, the surgeon perceives the exerted force by means of haptic interface. This feature, together with the movement capacities of the robot and the 3D visualisation, determine to a great extent the performance of the surgical task. So, there is a need to measure the overall input vs. output motion, precision of the movement, haptic feedback and correlation between visual clues and real movements (see Figure 11).

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

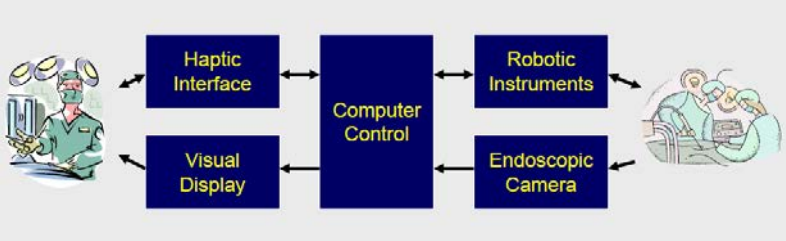

Figure 11: Control loop in teleoperated robots[67]

However, since this is a robotic system teleoperated by a human, the surgeon's training also plays an important role. This is because of the differences between the surgeon's hand coordinate system (input movement) and the robot´s coordinate system of the surgical tool (output movement), as shown in Figure 12. And the differences among surgical procedures make the measurements more complex.

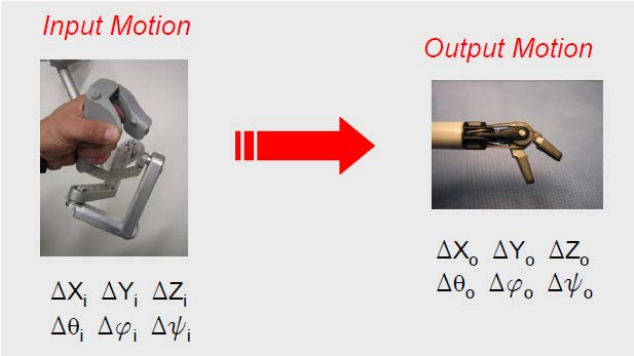

Figure 12: Measurement of input movements vs. output movements[68]

2) Extraction of the system abilities for medical (teleoperated) surgical robot evaluation

The consulted bibliography (see Annex D) results in the extraction of the system abilities for the case of (teleoperated) surgical robotic systems, as shown in Table 15.

Table 15. Main system abilities for surgical (teleoperated) robots

System abilitiy	Description
Dexterity	Mapping between robot's movements and surgeon's movements
Motion Ability	Robot motion taking into account mechanical limits
Human-Robot Interaction	Usability, comfort and satisfaction of the surgeon
Dependability	Related to failure / success
Task Adaptability	Transitions between different tasks
Cognition	Level of difficulty when sending commands from surgeon to the robot
Perception	Feedback of sensory information from the instrument tip to the surgeon (visual, tactile)
Medical Assessment	Related to patient's health

[67] Presentation from William J. Peine (2006) on "Standard and Metrology Needs for Surgical Robotics" (nist.gov)
[68] Presentation from William J. Peine (2006) on "Standard and Metrology Needs for Surgical Robotics" (nist.gov)

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

3) Description of Performance Indicators (PI) of the system abilities

The PIs of interest for teleoperated robots are shown in Table 16.

Table 16: PIs of interest for teleoperated robots

System abilitiy	Performance indicators	Unit of measurement
Dexterity	Synchronisation time between visualisation and movement	Time (s)
	Overall Input / Output motion	Distance (mm)
	Dynamic behaviour and smoothness	Force (N)
	Non-linearity and deformation under loading	Force (N)
	Overall Input / Output force feedback	Force (N)
Motion Ability	Minimum task time for successful task	Time (s)
	Time between a specific event and a reaction movement (reaction time)	Time (s)
	Precision of task execution - distance to desired trajectory (tracking error)	Distance (mm)
	Time the robot takes to perform compensating movement (perturbation reaction time)	Time (s)
Human-Robot-Interaction	Comfort	Questionnaire (NASA-TLX)
	Safety	Yes/No
Dependability	Success rate (falling/failure detection)	Percentage
Task Adaptability	Percentage of performance degradation due to the task transitions (Task Adaptability)	Percentage
Cognition	Number of external commands required for the intended use (self-government)	Integer number
Perception	Repeatability	Percentage
	Accuracy of the acquired data (sensor precision)	Percentage
Medical Assessment	Readmission rate of patients after surgery, due to relapse (frequency of readmission)	Percentage

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

8.Key findings

The White Paper on standardisation and interactive robots provides an overview of the current standardisation landscape and potential future standardisation activities. The key findings per section are summarised below.

Key findings section: Introduction to standardisation

a) *The traditional standardisation system and its processes are well defined on national, European and international level.*
b) *Standards provide common rules, guidelines or characteristics with the purpose of achieving an optimal degree of order.*
c) *They are minimum safety requirements and the basis for mutual understanding amongst individuals, businesses, and public authorities.*
d) *Standardisation of interactive robotics needs two types of actors: Technological experts and standardisation organisations, which jointly develop technical standards, specifications and agreements.*
e) *The use of standards is voluntary; they become mandatory if they are referred to in contracts, laws or regulations.*
f) *European directives lay down essential requirements for products and harmonised standards reflect the state of the art approaches of establishing safety.*

Key findings section: Domains of interactive robots

a) *In the manufacturing domain interactive robots are used to improve the workers' capabilities and to support the working activities. Therefore the devices are used by trained workers. Three main categories of interactive robots in the manufacturing domain are considered: exoskeletons and wearable robots, human-robot collaborative (HRC), and automatic guided vehicles (AGV) as well as autonomous mobile robots (AMR).*
b) *Healthcare robots are operated by or interact with professionals or untrained people. Interactive robots are used from the operating room to the family home, by the young to the very old with different physical and cognitive capabilities or deficits. Three main categories of interactive robots in the healthcare domain are considered: Clinical robots, rehabilitation robots, and assistive robots. Also, different types of IRs cover these domains: from mobile small robots to big multi-arm robotic systems.*
c) *Consumer robots are operated by, or interact with, untrained, or minimally trained people in everyday environments. Typically, these robots will be bought or leased and used to provide services to individuals.*

Key findings section: State of the art – standardisation landscape

a) *There are different types of standardisation documents: standards, specifications, reports, and agreements.*
b) *Standards are developed on state-of-the-art technologies, while specifications and agreements are developed on innovative topics.*
c) *The conducted standards research identified standardisation documents that are of relevance to interactive robots. These documents were categorised into ten groups.*
d) *The categorisation revealed that the majority of the identified standards belong to the safety category.*
e) *From the total list of standards only 29 are directly related to robots. The remaining standards are beneficial for interactive robots, but have to be adapted to specific needs.*

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

f) Organisations prefer standardisation on international level, because of the global character of the robotic market.
g) The European and international TCs are connected through liaisons and the current field of activity of ISO/ TC 299 on robotics lies in the standardisation of service robots.
h) The INBOTS standardisation survey shows that organisations use standards mainly to conform to regulations, to improve quality and to fulfil customer requirements as well as to get additional marketing advantages.
i) The decisive reason for organisations not to use standards are interpretation problems. Organisations also stated that they do not use standards because they do not know which standards they should follow and the costs of standards are also an issue.

Key findings section: Potentials for future standards

a) This section focused on standards that currently do not exist, but are demanded by the robotics community. The INBOTS consortium identified standardisation potentials concerning general requirements, test methods, measurements, performance criteria, data confidentiality, and end-user requirements.
b) A general observation is that the safety aspect seems to be well covered in standards, while performance related aspects are less covered. There is a need to define standards for specific technologies.
c) For some technologies standardisation activities are more advanced, e.g. COBOTS, while in manufacturing there is no standard for exoskeletons and AGVs.
d) There is also a regulation need to define the boundaries between different applications and domains. For Example, a mobile robot can be used in a manufacturing environment and can also give support to elderly people. The robotic device may be similar, but the domains (and their implications) are very different.
e) Standardisation activities concerning ethical issues are currently increasing. In the future more guidance documents on how to apply a standard or a standard series should be developed.
f) Standardisation of technologies is getting more challenging, because of the speed with which they change. The functional behaviour of the devices must therefore be standardised considering also the adaptive systems, because otherwise it will be exceeded by technology.

Key findings section:Standardisation tools for future activities

a) Standardisation activities can be initiated for different types of document, e.g. standard, specification, report and agreement.
b) Research funding programs usually either develop strategic standardisation documents or specifications and agreements.
c) The development of specifications is done by TCs while agreements are developed in an open workshop atmosphere.
d) Therefore, the identified INBOTS potentials can either be further elaborated by research projects in a workshop with an NSB as the project manager or be transfered to a TC that may start the work to develop a standard or sprecification on the identified potential.

Key findings section: Challenges and recommended solutions

a) It is found to be difficult to identify sources of harm as well as to identify and apply standards. A potential solution is an open access benchmark database that covers many situations in real scenarios for different applications and tracks the effects of different interactive robots in the long term. Another solution could be subsidized advisory services on standards by eligible companies.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

b) There is a lack of ethics recommendations in robotics. Basic guidelines that are universally applicable (e.g. dignity, avoidance of harm, non-discrimination) could be developed and the standardisation working groups could be extended to include other collaborators different from industry / technical field.
c) There is a lack of a performance index for robots used in certain applications. One solution could be the funding of research projects to identify a performance index and the initiation of standardisation activities on the identified measures and test methods.
d) There is a shortage of Notified Bodies under the new Medical Device Regulation. Increasing incentives could encourage the accreditation of more Notified Bodies under Regulation (EU) 2017/745 on Medical Devices.
e) Due to a lack of resources for participating in standardisation working groups (e.g. membership costs of standardisation bodies, time required for participation and follow-up), smaller companies are not sufficiently represented in the development of standards. The financial support of research projects (Innovation Actions) by the EU enables research partners to participate in standardisation, e.g. development of a CEN Workshop Agreement out of a research project.

Key findings section: Strategy for new standard

a) At the beginning of the development of a new standard, a collection of knowledge must always be carried out to determine what the proposed standard should cover. For the INBOTS project a literature search and the identification of benchmarks for exoskeletons in the manufacturing domain and surgical teleoperated robots in the healthcare domain was carried out.
b) An identification of benchmark analysing methodologies and the extraction of parameters for a consolidated evaluation took place. There are 22 parameters identified for performance evaluation of active exoskeleton. Based on the nature of the parameters, each of them has been classified in efficacy, efficiency, usability satisfaction, and comfort.
c) The exoskeleton environment must be defined. First, a functional analysis and subsequently a usability assessment must be carried out in the laboratory. Finally, a test in the factory workplace and the task analysis must be performed.
d) The test protocol should include: User sample, evaluation methods, metrics used to quantify human and/or system performance, resources and user training, as well as safety and risk mitigation.
e) Surgical robots are medical electrical equipment and it is essential that they follow high safety standards, when performing a surgery on a vulnerable person.
f) Surgical robots are mostly teleoperated devices, meaning that the input movements made by a surgeon are replicated in the end effector of the teleoperated robot. The aim is to access the body cavity with the surgical instruments handed by the robot. Performance is very important after safety matters.
g) There are eight system abilities presented, identified from a literature review: Dexterity, Motion Ability, Human-Robot Interaction, Dependability, Task Adaptability, Cognition, Perception, and Medical Assessment.
h) The parameters identified for performance evaluation of surgical robots are 17 and, based on the nature of the parameters, each of them has been classified to the system abilities.
i) The identified key performance indicators are a starting point and further investigation in TCs and research has to be conducted to develop a set of standards on test methods and performance criteria.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Annex A – Standardisation survey

The INBOTS standardisation survey intended to gain knowledge of the robotics communities` requirements in terms of standardisation and the regulatory framework in the manufacturing, healthcare and consumer domain. INBOTS therefore invited stakeholders engaged in the development, manufacturing and employment of interactive robots to share their experiences on this topic. The survey was structured in five sections (see below).

1) *Association information*
2) *Challenges with standardisation system*
3) *Usage of standards*
4) *Satisfaction with standard quantity*
5) *Challenges with regulatory framework*

The amount of answers varies, since not all questions were mandatory. There is no information on the amount of the statistical population that could have answered the survey. Furthermore the survey was anonymous; participants had the option to enter their E-Mail addresses if they wanted to receive the results of the survey and if they were open for possible check back question on their answers.

The INBOTS standardisation survey was distributed through various channels:

- *social media (LinkedIn, Twitter),*
- *websites (INBOTS, Project Partner Websites),*
- *conferences (INBOTS, ICNR, WeRob 2018),*
- *standardisation technical committees (ISO/ TC 299 Robotics, CEN/ TC 310 Advanced Manufacturing Technologies, ISO/ TC 159 and CEN/ TC 122 Ergonomics, CEN/ TC 293 Assistive products and accessibility),*
- *mailing lists (EU Robotics),*
- *newsletters (DIN, INBOTS),*
- *other related research projects (COVR, COROMA, EUROBENCH).*

The manufacturing domain is the oldest domain and therefore it is reasonable that 59 % of the organisations that answered the INBOTS standardisation survey are active in the manufacturing domain (see Figure A.1). The consumer domain is relatively new and this is why only 17 % of the organisations are representing this domain. Thus, the historic growth of interactive robots in various areas is also reflected in the INBOTS standardisation survey. In total, 44 people from different organisations answered the mandatory question from which domain they respond to the survey.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

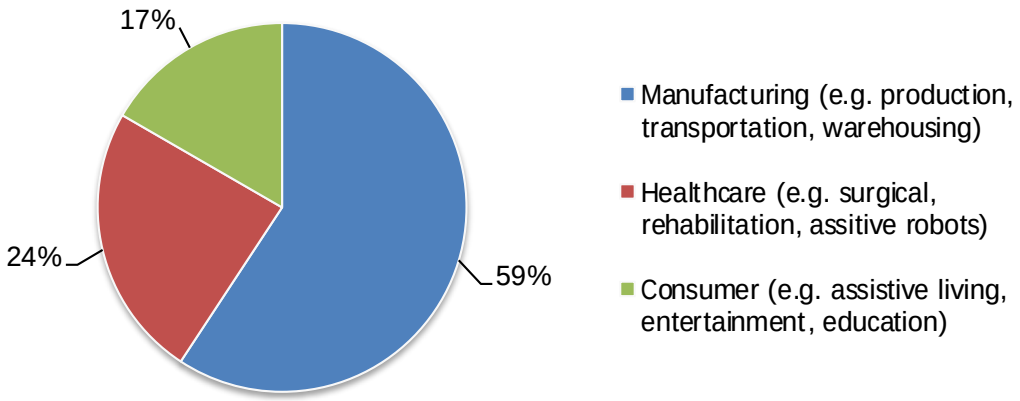

Figure A.1: Surveyed organisations and their domains

The majority of the 44 organisations that answered the standardisation survey are large organisations (see Figure A.2). Surprisingly, there is a fair amount of micro-sized organisations (14 %) that answered the survey besides medium- (18 %) and small-sized organisations (9 %). The survey was distributed at the INBOTS conference, where a lot of micro-sized organisations took part. The survey was also distributed in the INBOTS network to for example spin-offs, which are usually rather small organisations.

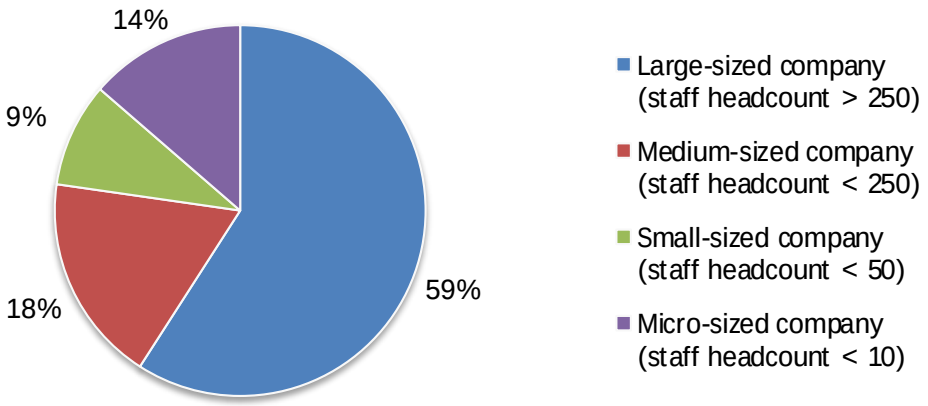

Figure A.2: Surveyed organisations sizes

Only answers from European countries were taken into account. The majority of the 44 organisations that answered the survey are from Germany (30 %), France (23 %), and Spain (16 %) (see Figure A.3).

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

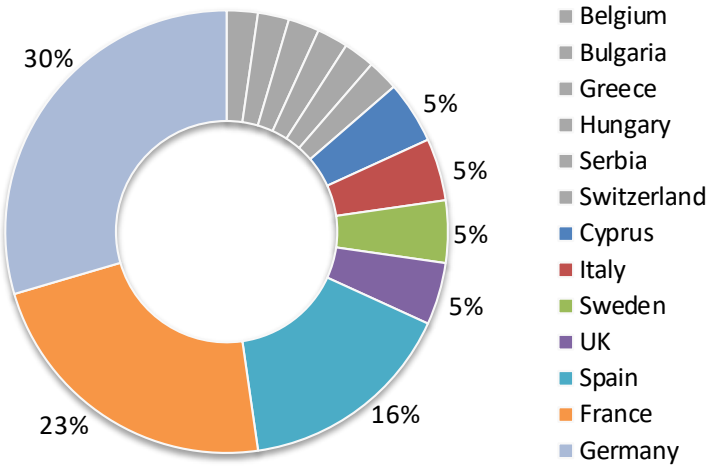

Figure A.3: Surveyed organisations origin

The 44 organisations were asked which type of robotic product they develop, manufacture, integrate or use (see Figure A.4). Most answers from companies comprised industrial robots (28 %), rehabilitation robots (17 %) and service robots (13 %).

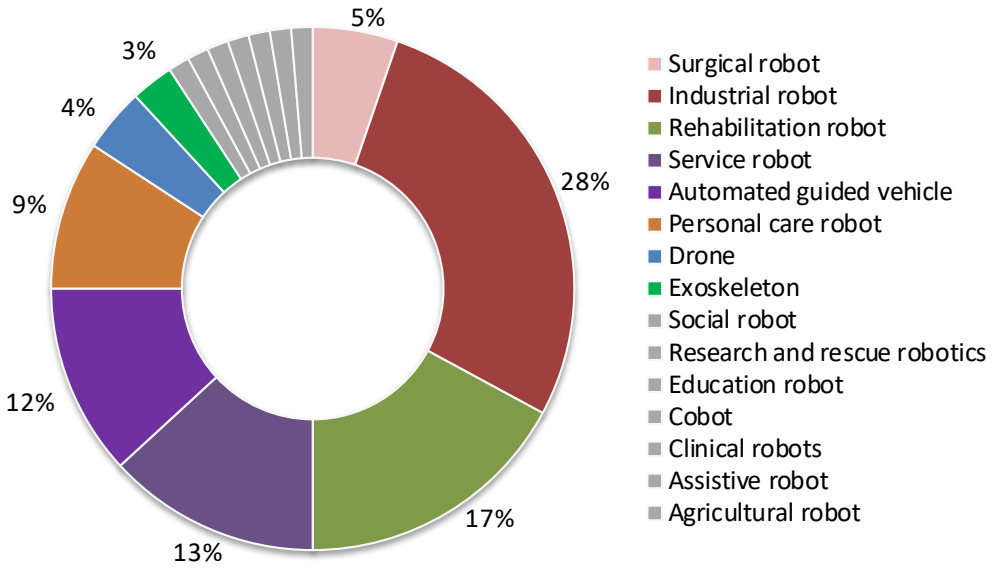

Figure A.4: Surveyed organisations robot overview

The majority of participating organisations are large in size, in the manufacturing and/or healthcare domain and they manufacture, develop or use industrial robots and rehabilitation robots. The survey also showed that the larger the organisation, the more domains they are working on. The survey was mostly answered by researchers followed by system integrators and robot manufacturers.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Organisations use formal standards mainly to conform to regulations, to improve quality and to fulfil customer requirements as well as to get additional marketing advantages (see Figure A.6). Organisations neither consider standards as legal protection from litigation nor as good guidance's. The question was multiple-choice and not mandatory. In total 40 organisations answered the question on why they use formal standards.

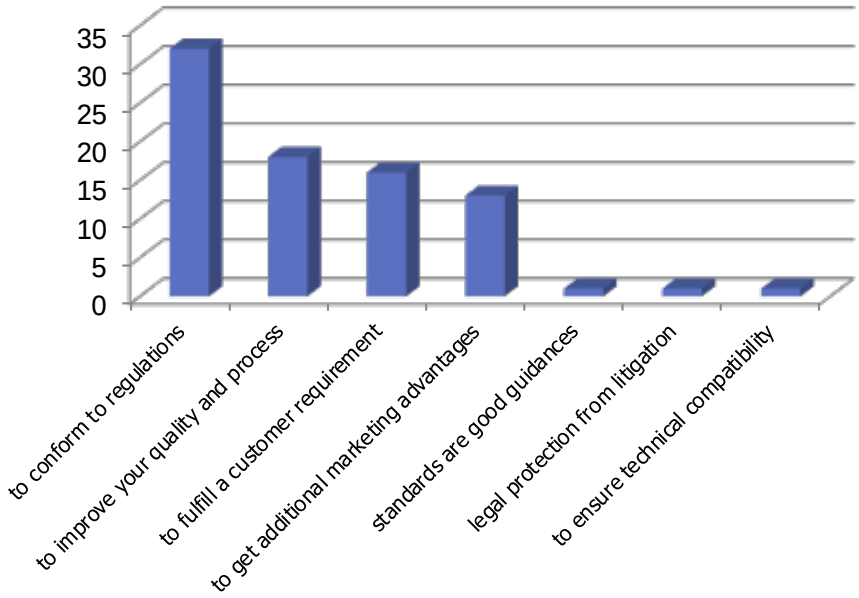

Figure A.5: Why do organisations use formal standards?

The decisive reason for organisations not to use formal standards is that they have interpretation problems (see Figure A.7). Organisations also stated that they do not use formal standards, because they do not know which standards they should follow. The access to standards also seems to be an issue. Fewer organisations stated that inconsistency between standards and inaccuracy of standards are reasons for not using standards. It also seems to be less of an issue that topics are not covered by standards. The question was multiple-choice and not mandatory. In total 26 organisations answered the question on why they are not using formal standards.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

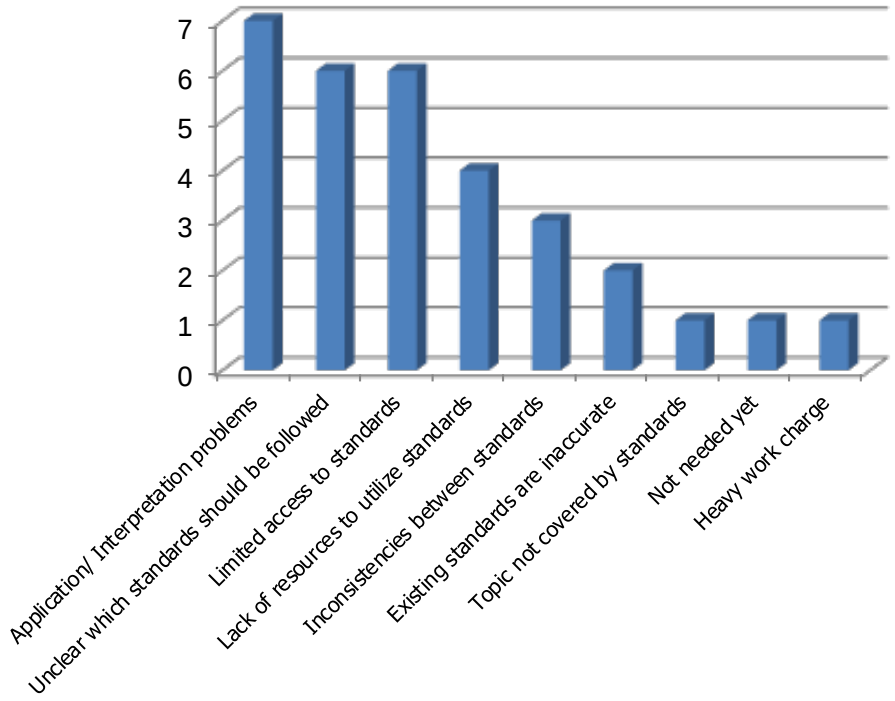

Figure A.6: Why are organisations not using formal standards?

The INBOTS standardisation survey provided an opportunity for organisations outside of the INBOTS consortium to comment on their level of satisfaction with the current standard quantity. Organisations were asked the mandatory question to what extent they are satisfied with the coverage of the topics below related to interactive robots in current standardisation by using a matrix question type. Participants answered per category, whether they are very satisfied, satisfied, neutral, dissatisfied, or very dissatisfied. They also had the option not to give an answer. With this question, INBOTS focused on the identification of gaps and therefore the question relates to the quantity rather than the quality of standards.

Table A.1: Satisfaction with standards quantity – Topics

Topic	Definition
Human-robot interaction safety	Safe interaction between human and robot to prevent accidents.
Data security	Security is of importance in many personal applications of interactive robots particularly where the users are elderly or vulnerable.
Performance/ System abilities	System abilities capture the performance of interactive robots. This includes for example interaction, dependability, perception, autonomy as well as the cognitive ability of an interactive robot.
Ergonomic design	Ergonomics is the process of designing or arranging workplaces, products and systems so that they fit the people who use them.
Ethical behaviour	Ethical behaviour refers to the design of robots and how they should be designed such as they act "ethically".
Interoperability of machines or systems	Interoperability belongs to the system abilities topic, but is looked at separately. Interoperability refers to a system's ability to interact with different machines and systems even though they are from different equipment manufacturers.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Environmental impact/ Life cycle issues	This category refers to sustainable and environmental supportive standards. This could for example include repair, remanufacture and recycle.

Participants were asked beforehand how aware they are of relevant standardisation documents in terms of interactive robots (possible answers: not aware, little aware, aware, well-aware, fully aware) on a five digit scale. The information was considered important, because only answers from participants that stated that they are "aware" to "fully aware" were taken into account. The majority of participants stated that they are neutral; they are neither satisfied nor dissatisfied with the current robotics standards quantity.

Figure A.9 gives an overview of the total answers per topic. The x-axis shows the amount of participants and the y-axis the satisfaction degree, e.g. 11 participants stated that they are dissatisfied with the standards quantity in terms of data security.

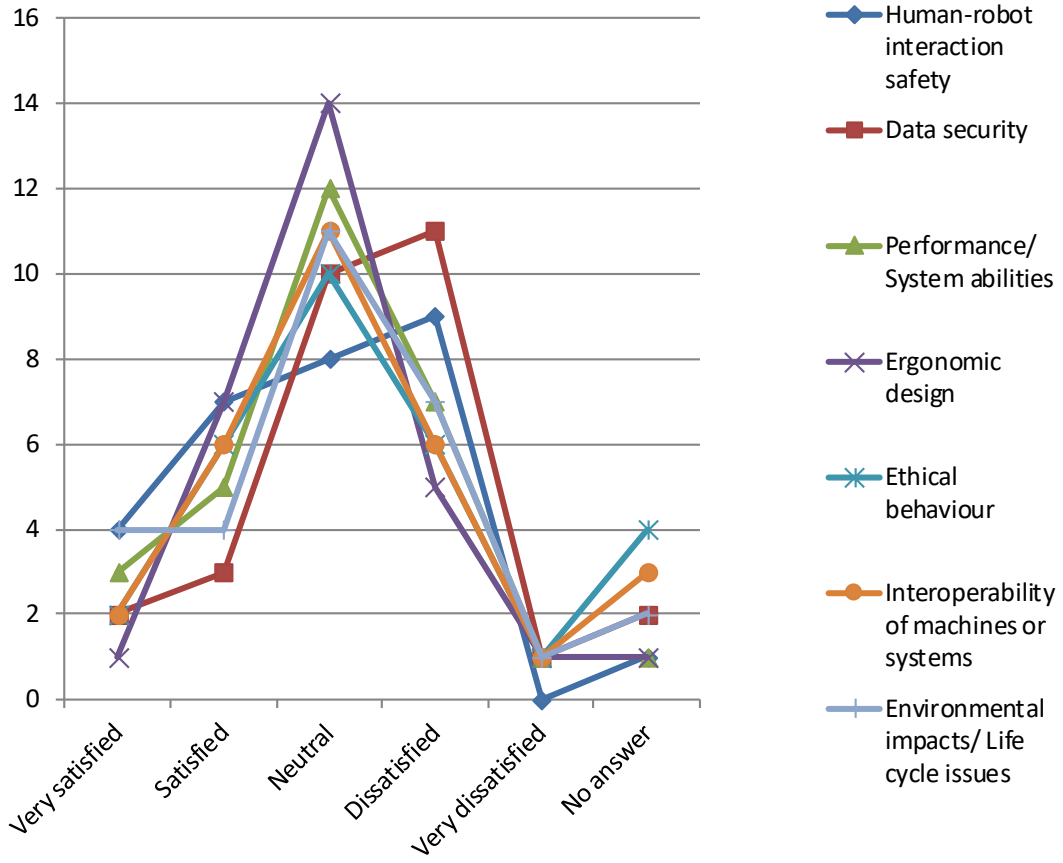

Figure A.7: Satisfaction with standards quantity

The participants were additionally asked which types of standards would increase their satisfaction. The question on what would increase the satisfaction of the robotics community was not mandatory and only the answers from participants that are "aware" to "fully aware" of robotic standards were taken into account. The number of answers is insufficient and therefore the results show only directions that need to be checked before further pursuit.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Annex B – Literature research on exoskeletons for the manufacturing domain

Koopman, A. S., Kingma, I., Faber, G. S., de Looze, M. P., & van Dieën, J. H. (2019). Effects of a passive exoskeleton on the mechanical loading of the low back in static holding tasks. *Journal of biomechanics*, *83*, 97-103.

Bogue, R. (2018). Exoskeletons–a review of industrial applications. *Industrial Robot: An International Journal*.

Dahmen, C., & Hefferle, M. (2018, June). Application of Ergonomic Assessment Methods on an Exoskeleton Centered Workplace. In *Proceedings of the XXXth Annual Occupational Ergonomics and Safety Conference, Pittsburgh, PA, USA* (pp. 7-8).

Dahmen, C., & Constantinescu, C. (2018). Methodology for Evaluation of the Time-Management impact of Exoskeleton-centred workplaces. *ACTA TECHNICA NAPOCENSIS-Series: APPLIED MATHEMATICS, MECHANICS, and ENGINEERING*, *61*(4).

Dahmen, C., Hölzel, C., Wöllecke, F., & Constantinescu, C. (2018). Approach of optimized planning process for exoskeleton centered workplace design. *Procedia CIRP*, *72*, 1277-1282.

Dahmen, C., Wöllecke, F., & Constantinescu, C. (2018). Challenges and possible solutions for enhancing the workplaces of the future by integrating smart and adaptive exoskeletons. *Procedia CIRP*, *67*, 268-273.

Christopher Reid. Boeing webinar: Crawl, walk, run, fly: incremental returns on investment (ROI) for Boeing industrial exoskeletons. March 4th, 2019

Hansen, C., Gosselin, F., Mansour, K. B., Devos, P., & Marin, F. (2018). Design-validation of a hand exoskeleton using musculoskeletal modeling. *Applied ergonomics*, *68*, 283-288.

Constantinescu, C., Todorovic, O., & Ippolito, D. (2019). Comprehensive modelling and simulation towards the identification of critical parameters for evaluation of exoskeleton-centred workplaces. *Procedia CIRP*, *79*, 176-179.

Weston, E. B., Alizadeh, M., Knapik, G. G., Wang, X., & Marras, W. S. (2018). Biomechanical evaluation of exoskeleton use on loading of the lumbar spine. *Applied ergonomics*, *68*, 101-108.

Perez Luque, E. (2019). Evaluation of the Use of Exoskeletons in the Range of Motion of Workers.

Crowell, H. P., Kanagaki, G. B., O'Donovan, M. P., Haynes, C. A., Park, J. H., Neugebauer, J. M., ... & Girolamo, H. J. (2018). *Methodologies for evaluating the effects of physical augmentation technologies on Soldier performance*. US Army Research Laboratory Aberdeen Proving Ground United States.

HuMan (Human Manufacturing) EU Funded Project. ''Evaluation methodology'', Deliverable n°: D7.1.

Maurice, P., Čamernik, J., Gorjan, D., Schirrmeister, B., Bornmann, J., Tagliapietra, L., ... & Babič, J. (2019). Objective and subjective effects of a passive exoskeleton on overhead work. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, *28*(1), 152-164.

Kim, S., Nussbaum, M. A., Esfahani, M. I. M., Alemi, M. M., Alabdulkarim, S., & Rashedi, E. (2018). Assessing the influence of a passive, upper extremity exoskeletal vest for tasks requiring arm

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

elevation: Part I–"Expected" effects on discomfort, shoulder muscle activity, and work task performance. *Applied ergonomics*, *70*, 315-322.

Kim, S., Nussbaum, M. A., Esfahani, M. I. M., Alemi, M. M., Jia, B., & Rashedi, E. (2018). Assessing the influence of a passive, upper extremity exoskeletal vest for tasks requiring arm elevation: Part II–"Unexpected" effects on shoulder motion, balance, and spine loading. *Applied Ergonomics*, *70*, 323-330.

Huysamen, K., de Looze, M., Bosch, T., Ortiz, J., Toxiri, S., & O'Sullivan, L. W. (2018). Assessment of an active industrial exoskeleton to aid dynamic lifting and lowering manual handling tasks. *Applied ergonomics*, *68*, 125-131.

Huysamen, K., Bosch, T., de Looze, M., Stadler, K. S., Graf, E., & O'Sullivan, L. W. (2018). Evaluation of a passive exoskeleton for static upper limb activities. *Applied ergonomics*, *70*, 148-155.

Mudie, K. L., Boynton, A. C., Karakolis, T., O'Donovan, M. P., Kanagaki, G. B., Crowell, H. P., ... & Billing, D. C. (2018). Consensus paper on testing and evaluation of military exoskeletons for the dismounted combatant. *Journal of science and medicine in sport*, *21*(11), 1154-1161.

Wioland, L., Debay, L., & Atain-Kouadio, J. J. (2019). Acceptation des exosquelettes par les opérateurs: étude exploratoire. *Références en santé au travail*, *157*, 45-61.

Sposito, M., Toxiri, S., Caldwell, D. G., Ortiz, J., & De Momi, E. (2018, October). Towards design guidelines for physical interfaces on industrial exoskeletons: overview on evaluation metrics. In *International Symposium on Wearable Robotics* (pp. 170-174). Springer, Cham.

Masood, J., Dacal-Nieto, A., Alonso-Ramos, V., Fontano, M. I., Voilqué, A., & Bou, J. (2018, October). Industrial Wearable Exoskeletons and Exosuits Assessment Process. In *International Symposium on Wearable Robotics* (pp. 234-238). Springer, Cham.

Gull, M. A., Bai, S., & Bak, T. (2020). A review on design of upper limb exoskeletons. *Robotics*, *9*(1), 16.

Todorovic, O., Constantinescu, C., & Popescu, D. (2018). Foundations for economic evaluation of exoskeletons in manufacturing. *Acta Technica Napocensis-Series: Applied Mathematics, Mechanics, and Engineering*, *61*(3_Spe).

Parola A., Gazzoni M., Botter A., Vieira Dos Anjos F. Master Thesis: Evaluation of changes in lumbar muscle activity induced by the use of an exoskeleton during simulated working tasks (2018).

Maurice, P., Čamernik, J., Gorjan, D., Schirrmeister, B., Bornmann, J., Tagliapietra, L., ... & Babič, J. (2019). Objective and subjective effects of a passive exoskeleton on overhead work. *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, *28*(1), 152-164.

Hensel, R., & Keil, M. (2019). Subjective evaluation of a passive industrial exoskeleton for lower-back support: A field study in the automotive sector. *IISE Transactions on Occupational Ergonomics and Human Factors*, *7*(3-4), 213-221.

Bostelman, R., & Hong, T. (2018). Test methods for exoskeletons—Lessons learned from industrial and response robotics. *Wearable Exoskeleton Syst. Des. Control Appl*, *13*, 335-361.

Baltrusch, S. J., Van Dieën, J. H., Van Bennekom, C. A. M., & Houdijk, H. (2018). The effect of a passive trunk exoskeleton on functional performance in healthy individuals. *Applied ergonomics*, *72*, 94-106.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Baltrusch, S. J., Van Dieën, J. H., Bruijn, S. M., Koopman, A. S., Van Bennekom, C. A. M., & Houdijk, H. (2019). The effect of a passive trunk exoskeleton on metabolic costs during lifting and walking. *Ergonomics*.

Spada, S., Ghibaudo, L., Carnazzo, C., Di Pardo, M., Chander, D. S., Gastaldi, L., & Cavatorta, M. P. (2018, August). Physical and virtual assessment of a passive exoskeleton. In *Congress of the International Ergonomics Association* (pp. 247-257). Springer, Cham.

Spada, S., Ghibaudo, L., Carnazzo, C., Gastaldi, L., & Cavatorta, M. P. (2018, August). Passive upper limb exoskeletons: an experimental campaign with workers. In *Congress of the International Ergonomics Association* (pp. 230-239). Springer, Cham.

Spada, S., Ghibaudo, L., Gilotta, S., Gastaldi, L., & Cavatorta, M. P. (2017, July). Analysis of exoskeleton introduction in industrial reality: main issues and EAWS risk assessment. In *International Conference on Applied Human Factors and Ergonomics* (pp. 236-244). Springer, Cham.

Luger, T., Cobb, T. J., Seibt, R., Rieger, M. A., & Steinhilber, B. (2019). Subjective evaluation of a passive lower-limb industrial exoskeleton used during simulated assembly. *IISE Transactions on Occupational Ergonomics and Human Factors*, *7*(3-4), 175-184.

Bostelman, R., Messina, E., & Foufou, S. (2017). Cross-industry standard test method developments: from manufacturing to wearable robots. *Frontiers of Information Technology & Electronic Engineering*, *18*(10), 1447-1457.

Reid, C. R., Nussbaum, M. A., Gregorczyk, K., Harris-Adamson, C., Kyte, K., Lowe, B., & Zmijewski, R. (2017, September). Industrial exoskeletons: are we ready for prime time yet?. In *Proceedings of the Human Factors and Ergonomics Society Annual Meeting* (Vol. 61, No. 1, pp. 1000-1004). Sage CA: Los Angeles, CA: SAGE Publications.

Carisa Harris-Adamson. '' The evaluation and application of passive exoskeletons''.

Kadon Kyte, Christopher R. Reid. ''The potential of industrial exoskeletons in aerospace manufacturing''.

Marty Smets. ''Perspectives from automotive manufacturing: effective implementation in a unionized work environment''.

Brian Lowe. ''Exoskeletons & musculoskeletal health''.

Spada, S., Ghibaudo, L., Gilotta, S., Gastaldi, L., & Cavatorta, M. P. (2017). Investigation into the applicability of a passive upper-limb exoskeleton in automotive industry. *Procedia Manufacturing*, *11*, 1255-1262.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Annex C – Overview of parameters investigated

C1. Efficacy parameters investigated

Support force (STEP 1)

What: Force exerted by the exoskeleton to support the user, which can be generated by passive elements (springs, dampers) or electrically powered actuators.

Why: Verification of the force exerted by the exoskeleton in support of the person, both of a commercial product (for comparison with what the supplier declares) and of a prototype to evaluate the correct realisation of the product.

Where: This type of testing should be reserved for a protected environment where the testing conditions are under control and established (Step 1).

When: This measurement can be carried out in two stages depending on whether the exoskeleton is a purchased product or a prototype under development. In the first case, the test can be part of the initial checks on the product, in the second case the design assumptions are verified.

Who: The evaluation team of Step 1, can involve engineers and physicists to properly measure the parameter.

How: The supporting force can be measured using special measuring systems and protocols. An example is given for a trunk exoskeleton. The exoskeleton is placed inside a vice that locks its lower part beyond the hip hinge. An electrogoniometer is placed upstream and downstream of the hip joint to measure the degree of flexure of the exoskeleton. The upper part is pulled with the help of a towing dynamometer which hooks into the chest pad maintaining a direction perpendicular to the face of the surface. The data recorded by the electrogoniometer and the dynamometer are cross-referenced to obtain a graph showing the flexion angle in the abscissae and the corresponding measured force value in the ordinate.

Discussion: Nowadays it is not clear what level of force is acceptable to establish an exoskeleton effectively according to this parameter. In general, the support strength should never be equal to the strength generated by the weight of the body part that needs to be supported, because the user is a healthy person able to develop muscle action even at rest and to avoid muscle weakening. Most of the exoskeletons provide support ranging from 40% to 100% of the weight of the body part to be supported. Some of them also allow the adjustment of the support strength, which can then vary in a predefined range.

Exoskeleton ROM (STEP 1)

What: Range of Movement (ROM) of the exoskeleton means the freedom of movement allowed by the joints of the exoskeleton, through the evaluation of the degrees of freedom of the angular joints movement.

Why: It is advisable to evaluate the degrees of freedom of the exoskeleton before it is worn by the user to immediately understand the availability of permitted movements. In addition, the evaluation of the exoskeleton ROMs may be different from that of the exoskeleton and user system.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Where: This type of testing should be reserved for a protected environment where the testing conditions are under control and established (Step 1).

When: This measurement can be carried out in two stages depending on whether the exoskeleton is a purchased product or a prototype under development. In the first case, the test can be part of the initial checks on the product, in the second case the design assumptions are verified.

Who: The evaluation team of Step 1, can involve engineers to properly measure the parameter.

Muscular activity (STEP 2) [69, 70, 71, 72, 73, 74, 75]

What: Muscle activity can be detected through the use of superficial electrodes that detect muscle activity levels over time. It determines what muscles are stressed. The identification of the muscles is fundamental to assess the real benefit provided by the exoskeleton in supporting the person. The definition of the muscles under study depends both on the type of exoskeleton (for arms, legs, trunk, full body) and on the expected movements with the help of the exoskeleton. In addition, a reference electrode, often positioned on the spinous process C7, must be provided. Table C1 summarizes the main muscles investigated in the exoskeleton performance tests.

Table C1: Main muscles investigated in the exoskeletons performance tests

Trunk	Arms	Abdomen	Legs
Longissimus thoracis (LT)	Deltoid	Rectus Abdominis	Biceps Femoris
Lliocostalis lumborum (IL)	Biceps Brachii		Rectus Femoris
Longissimus lumborum (LL)			Tibialis Anterior
External oblique muscles (EO)			Gastrocnemius
			Vastus medialis (VM)

Why: The electromyography (EMG) signal associated to the exoskeleton allows the investigation on the impacted limbs of the reduction of agonist muscle effort and the detection of side effects as the no increase of effort in non-targeted muscles. The use of an exoskeleton, in fact, should not increase biomechanical strain on other parts of the body.

[69] Gillette, J. C., & Stephenson, M. L. (2017). EMG assessment of a shoulder support exoskeleton during on-site job tasks. *Proc. Am. Soc. Biomech. Annu. Meet. Boulder CO USA*.
[70] Weston, E. B., Alizadeh, M., Knapik, G. G., Wang, X., & Marras, W. S. (2018). Biomechanical evaluation of exoskeleton use on loading of the lumbar spine. Applied ergonomics, 68, 101-108.
[71] Huysamen, K., de Looze, M., Bosch, T., Ortiz, J., Toxiri, S., & O'Sullivan, L. W. (2018). Assessment of an active industrial exoskeleton to aid dynamic lifting and lowering manual handling tasks. Applied ergonomics, 68, 125-131.
[72] Crowell, H. P., Kanagaki, G. B., O'Donovan, M. P., Haynes, C. A., Park, J. H., Neugebauer, J. M., ... & Girolamo, H. J. (2018). Methodologies for evaluating the effects of physical augmentation technologies on Soldier performance. US Army Research Laboratory Aberdeen Proving Ground United States.
[73] Maurice, P., Čamernik, J., Gorjan, D., Schirrmeister, B., Bornmann, J., Tagliapietra, L., ... & Babič, J. (2019). Objective and subjective effects of a passive exoskeleton on overhead work. IEEE Transactions on Neural Systems and Rehabilitation Engineering, 28(1), 152-164.
[74] Mudie, K. L., Boynton, A. C., Karakolis, T., O'Donovan, M. P., Kanagaki, G. B., Crowell, H. P., ... & Billing, D. C. (2018). Consensus paper on testing and evaluation of military exoskeletons for the dismounted combatant. Journal of science and medicine in sport, 21(11), 1154-1161.
[75] Huysamen, K., Bosch, T., de Looze, M., Stadler, K. S., Graf, E., & O'Sullivan, L. W. (2018). Evaluation of a passive exoskeleton for static upper limb activities. Applied ergonomics, 70, 148-155.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Where: This type of testing should be reserved to a protected environment where the testing conditions are under control and established on simple and easily repeatable work tasks that do not require previous experience in carrying out.

When: The EMG analysis can be addressed in usability tests in laboratory with a well-defined test sample and test conditions.

Who: The evaluator team for this parameter should be composed by experts in its detection and analysis, as for example engineers.

How: Data are collected using different portable EMG systems, with different sampling rate (that must be at least 1000 Hz) and through bipolar or matrix electrodes placed over each muscle (inter-electrode distance: 20 mm). The positioning of the electrodes is fundamental to obtain valuable results, a guide can be the SENIAM protocol. Before electrodes are applied, the skin must be shaved, scrubbed and cleaned with alcohol.

Discussion: The definition of the muscles to be investigated is fundamental to have a clear evaluation of the exoskeleton effect on the muscular-skeletal human system. Some studies make some approximation, for example excluding co-contraction of antagonist muscles or the antagonist muscle activity. Furthermore, the majority of the studies focuses on the muscles supported by the exoskeletons, resulting in a superficial examination of the side effects. Finally, another issue is the sweating caused by the use of the exoskeleton. At the same time, the exoskeleton might therefore press on EMG sensors and disturb the measurement, which becomes unreliable. With additional sensors, the space to position them on the body to be compatible with the use of an exoskeleton becomes an issue.

Exoskeleton-human range of motion (ROM) (STEP 2)[76, 77, 78, 79, 80]

What: Measuring the range of motion of the human exoskeletal system allows to determine the influence of an exoskeleton on movement strategy, i.e. joint kinematics. The measure can be intended as the maximal value, average value (mostly for static tasks), or temporal profile.

Why: The use of an exoskeleton could change the normal movement of the person due to its weight or its own range of movement. For instance, disruption of natural movement may cause awkward postures or require time to learn a new motor strategy.

[76] Maurice, P., Čamernik, J., Gorjan, D., Schirrmeister, B., Bornmann, J., Tagliapietra, L., ... & Babič, J. (2019). Objective and subjective effects of a passive exoskeleton on overhead work. IEEE Transactions on Neural Systems and Rehabilitation Engineering, 28(1), 152-164.
[77] Kim, S., Nussbaum, M. A., Esfahani, M. I. M., Alemi, M. M., Jia, B., & Rashedi, E. (2018). Assessing the influence of a passive, upper extremity exoskeletal vest for tasks requiring arm elevation: Part II–"Unexpected" effects on shoulder motion, balance, and spine loading. Applied Ergonomics, 70, 323-330.
[78] Baltrusch, S. J., Van Dieën, J. H., Bruijn, S. M., Koopman, A. S., Van Bennekom, C. A. M., & Houdijk, H. (2019). The effect of a passive trunk exoskeleton on metabolic costs during lifting and walking. Ergonomics.
[79] Bosch, T., van Eck, J., Knitel, K., & de Looze, M. (2016). The effects of a passive exoskeleton on muscle activity, discomfort and endurance time in forward bending work. Applied ergonomics, 54, 212-217.
[80] Sylla, N., Bonnet, V., Colledani, F., & Fraisse, P. (2014). Ergonomic contribution of ABLE exoskeleton in automotive industry. International Journal of Industrial Ergonomics, 44(4), 475-481.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Where: This type of testing should be reserved to a protected environment where the testing conditions are under control and established on simple and easily repeatable work tasks that do not require previous experience in carrying out.

When: The exoskeleton-human ROM analysis can be addressed in usability tests with a well-defined test sample and test conditions.

Who: The evaluation team for this parameter should be composed by experts in its detection and analysis, as for example engineers and orthopaedists.

How: The kinematic analysis of the exoskeleton system can be carried out by means of motion recording with inertial sensors (i.e. Xsens inertial motion tracking suit) or not inertial ones (e.g. OptiTrack, Vicon Vero). In any case, the sensors must be positioned appropriately on the user's body. Additional sensors can be inserted on the exoskeleton to evaluate their own movement in relation to that of the person to denote the presence of any movements that generate force actions on the person. Both inertial and non-inertial sensors require initial calibration after positioning to correctly record the movement of the user-exoskeleton system.

Discussion: When making a motion analysis it is very important to consider that both inertial and non-inertial sensors have pros and cons. Inertial sensors in particular may suffer from electromagnetic interference, while non-inertial optical sensors may have occlusion or light interference problems and therefore are not suitable for outdoor measurements. The use of video cameras and artificial intelligence algorithms for the reconstruction of movement, could allow to measure the ROM of the exoskeleton system even in real environment (STEP 3).

Interface pressures (STEP 2)[81, 82]

What: The measurement involves recording the pressures exerted by the exoskeleton at the interface with the user. In order to provide support, in fact, the exoskeleton exchange forces through specific areas with the body. Other pressures may be exerted at the force relief points or depending on the fit of the exoskeleton. This measure is also a comfort parameter.

Why: Physical interfaces refers to braces, cuffs or any other attachment to the wearer's body. An interface is responsible for the transmission of assistive forces from the actuators and the overall wearing comfort. It can happen that part of the exoskeleton power can be lost due to the physical interface dynamics, dissipating the force in shear stresses, compression and misalignment over the body. Moreover, this inefficiency generates discomfort to the end user, compromising acceptance of the device. Therefore, design criteria for exoskeleton interfaces are desirable.

Where: This type of testing should be reserved to a protected environment where the testing conditions are under control and established on simple and easily repeatable work tasks that do not require previous experience in carrying out. If the pressure sensors are integrated in the exoskeleton and their handling is easy and robust, they can also be tested in a real environment (STEP 3).

---

[81] Sposito, M., Toxiri, S., Caldwell, D. G., Ortiz, J., & De Momi, E. (2018, October). Towards design guidelines for physical interfaces on industrial exoskeletons: overview on evaluation metrics. In International Symposium on Wearable Robotics (pp. 170-174). Springer, Cham.

[82] Kermavnar, T., Power, V., de Eyto, A., & O'Sullivan, L. W. (2018). Computerized cuff pressure algometry as guidance for circumferential tissue compression for wearable soft robotic applications: A systematic review. Soft robotics, 5(1), 1-16.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

When: The interface pressure analysis can be addressed in usability tests with a well-defined test sample and test conditions.

Who: The evaluator team for this parameter should be composed of experts in its detection and analysis, as for example engineers and medics.

How: Contact pressure at the interface between the human and the exoskeleton can be measured through stretchable sensors as for example BodiTrak pressure measurement mats, or Xsensor mats. The mats can be inserted between the exoskeleton and the body identifying the exoskeleton portions in which it is in contact with the human and in which it exert the forces. The sensing area, sensor arrangement and sensor quantity depend on the exoskeleton's structure.

Discussion: There are no interface pressure values recognised as not acceptable from the discomfort point of view (32 mmHg (4.3 kPa) is the blocking pressure for skin capillary flow). However superficial pressure during sitting is well above that threshold (22 kPa) suggesting a compensatory effect.

Heart rate (STEP 2 and 3)[83, 84, 85]

What: Heart rate, or pulse, is the number of times the heart beats per minute. Normal heart rate varies from person to person. It is lower when at rest and higher when exercising. The best places to detect the pulse are the:

- *wrists,*
- *inside of the elbow,*
- *side of the neck, and*
- *top of the foot.*

The resting heart rate is the heart pumping the lowest amount of blood needed. When sitting or lying the heart rate is normally between 60 (beats per minute) and 100 (beats per minute). The heart rate is separate from blood pressure that is the force of the blood against the walls of the blood vessels.

Why: As the heart rate vary depending on the physical activity, it is used to understand if the use of an exoskeleton, that support the worker, could determine a reduction of cardiovascular demand and metabolic consumption while working. The gold standard measure is the energy expenditure. Among standard methods for measuring energy expenditure, oxygen consumption is a good compromise between accuracy and ease-of-use. It is therefore widely used, and has already been proposed for exoskeleton assessment. Measurement of oxygen consumption however requires an invasive mask. Thus, heart rate is sometimes preferred, especially for field testing. Though less accurate than oxygen consumption, heart rate correctly estimates energy expenditure in moderate to vigorous activities. Peak, average and percentage heart rate reserve are used to assess changes in whole body physiological workload.

---

[83] Ndahimana, D., & Kim, E. K. (2017). Measurement methods for physical activity and energy expenditure: a review. Clinical nutrition research, 6(2), 68.
[84] Whitfield, B. H., Costigan, P. A., Stevenson, J. M., & Smallman, C. L. (2014). Effect of an on-body ergonomic aid on oxygen consumption during a repetitive lifting task. *International Journal of Industrial Ergonomics*, *44*(1), 39-44.
[85] Theurel, J., Desbrosses, K., Roux, T., & Savescu, A. (2018). Physiological consequences of using an upper limb exoskeleton during manual handling tasks. *Applied ergonomics*, *67*, 211-217.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Where: Depending on the invasiveness of the measuring instrument, it can be measured both in usability tests in the laboratory and in real-environment evaluations.

When: Heart rate analysis can be addressed in usability testing in the laboratory or in a real-world environment, when the subject performs a work task, as an aspect of the exoskeleton's effectiveness.

Who: The evaluator team for this parameter should be composed by experts in its detection and analysis, as for example engineers and medics.

How: Different instruments allow the detection of the heart rate to be positioned on the user wrist or chest bands. Data can be recorded using a mobile application provided with the sensors and that communicate with them by Bluetooth. As each users have a personal rest heart rate, it is recommended to normalise the recorded heart rate using maximum and minimum values of the participant.

Oxygen consumption (STEP 2)[86]

What: Oxygen consumption is the amount of oxygen that the body takes up and utilises. This is an outcome used in exercise physiology as it is reflective of the oxygen uptake at the exercising muscle. Oxygen is taken up in the lungs and is carried around the body by the blood until it is released at the exercising tissues. Oxygen uptake can be measured by gas analysis of the oxygen content of the inhaled air vs. the oxygen content of the exhaled air. During exercise at a constant workload, oxygen consumption increases exponentially at the start of exercise until it reaches the point at which oxygen supply matches oxygen demand and then it plateaus, this plateau is termed steady-state.

Why: In physiology, to assess the extent of the processes underlying aerobic metabolism, it is usual to measure the volume of oxygen consumed in a given time. This volume is usually indicated by the acronym VO2. When doing physical activity, particularly during prolonged activities such as running or cycling, our body meets increased energy demands through the consumption of high energy molecules such as sugars, starches and lipids. In order for these molecules to produce energy, however, there must be oxygen available within the muscle fibres and mitochondria that is "consumed" during the energy production process. Consequently, the more VO2 consumed during the activity, the more energy will have been produced. VO2 is therefore the main parameter to define an individual's aerobic capacity, i.e. the ability to produce energy through mechanisms that require the use of oxygen. In this case, we speak of maximum consumption of oxygen or VO2 max. Referring to exoskeletons, in particular, we want to investigate whether the use of the support given by the device is able to reduce the demand for necessary oxygen to cope with a physical effort.

Where: This type of testing should be reserved to a protected environment where the testing conditions are under control and established on simple and easily repeatable work tasks that do not require previous experience in carrying out.

When: The VO2 analysis can be addressed in usability tests in a laboratory with a well-defined test sample and test conditions.

[86] Glynn, A. J., & Fiddler, H. (2009). The Physiotherapist's Pocket Guide to Exercise E-Book: Assessment, Prescription and Training. Elsevier Health Sciences.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Who: The evaluation team for this parameter should be composed of experts in its detection and analysis, such as engineers and medics.

How: Direct measurement of maximum oxygen consumption (VO2 max) using a metabolimeter for gas exchange analysis (VO2 and VCO2) during stress testing. Oxygen consumption must be normalised by the participant's weight.

Discussion: There is a negative relationship between maximum acceptable work time and physical workload, measured in terms of aerobic strain.

Metabolic consumption (STEP 2 and 3)

What: The metabolic consumption is due to the following:

- *basal metabolism (energy needed to maintain vital functions at rest (e.g. breathing, circulating blood, keeping the nervous system active)), which is responsible for consuming 60-80% of the calories spend every day;*
- *thermal effect of food (heat lost from the digestion of food); and*
- *energy expenditure related to physical activity, which includes sports and work activities.*

Why: The analysis of metabolic consumption is aimed at investigating whether the exoskeleton introduces change in work technique. In fact, possible changes in the strategy of the work action could be evident through an increase or decrease in energy expenditure necessary to carry out that action.

Where: Depending on the measurement system, this testing can be performed in laboratory or in real environment.

When: The metabolic consumption analysis can be addressed in usability tests in laboratory (STEP 2) as well as in real work environment (STEP 3).

Who: The evaluation team for this parameter should be composed of experts in its detection and analysis, such as engineers and medics.

How: Metabolic consumption can be estimated from the measurement of oxygen consumed (VO2) in performing an activity. On average, an individual at rest consumes 1 MET (metabolic equivalent), or 1 kcal per kilogram of weight per hour. At the same time, however, 1 MET is also equivalent to 3.5 ml of oxygen consumed per kilo of weight per minute. This relationship between METs and VO2 is of fundamental importance because it allows to estimate, starting from VO2, the energy expenditure of a given physical activity and of a person even at rest. Therefore, it is not only possible to assess the aerobic capacity of an individual, but also to estimate the basal metabolism and energy expenditure during the activity.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Task accuracy and precision (STEP 2 and 3)[87, 88, 89]

What: The precision of a task depends on the ability of the operator to accurately perform a defined task.

Why: This parameter is important to assess whether the use of the exoskeleton may change the accuracy of the execution of an assigned task as a result of changing the ROM or execution speed.

Where: It can be measured in a laboratory on simple tasks to avoid the interference with the production activity. If then the laboratory tests are good enough, the precision can be measured on a real activity.

When: The accuracy analysis can be conducted in usability tests in the laboratory, and subsequently on the production line.

Who: If the accuracy is assessed in laboratory activities, the team of evaluators should be composed of engineers and scientists, when the test is carried out in a real environment it is appropriate to involve plant managers.

How: In the latter case, there is no dedicated tool, rather it is important to define the reference task and evaluate on a case-by-case basis how to identify what accuracy is. Spada et al. proposed a test in which a continuous wavy line is drawn between two pre-marked traces on a paper attached to a billboard. A felt-tip pen is used to trace the line, the billboard is placed at the individual height of the participant's shoulder. The subject is standing, with the predominant arm almost extended (Figure C1) and is not allowed to lower the arm except at the end of the task. As can be observed in Figure C1, five different wavy rows (with 27 arches per row) are on the paper at different heights. The subject started at shoulder height and progressively moved upward to an overhead position. The participant is asked to maintain an upright trunk and extended arm, but is allowed to move parallel to the wall. The end of the task is at the subject's will or at the end of the pre-marked guides. The data collected includes the line drawn by the operator, execution time, video assessment of the maintenance of an upright trunk and extended arms, and fatigue or discomfort sensation experienced by the subject.

[87] Spada, S., Ghibaudo, L., Carnazzo, C., Gastaldi, L., & Cavatorta, M. P. (2018, August). Passive upper limb exoskeletons: an experimental campaign with workers. In *Congress of the International Ergonomics Association* (pp. 230-239). Springer, Cham.

[88] Spada, S., Ghibaudo, L., Carnazzo, C., Di Pardo, M., Chander, D. S., Gastaldi, L., & Cavatorta, M. P. (2018, August). Physical and virtual assessment of a passive exoskeleton. In *Congress of the International Ergonomics Association* (pp. 247-257). Springer, Cham.

[89] Borg, G. A. (1982). Psychophysical bases of perceived exertion. Medicine & science in sports & exercise.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

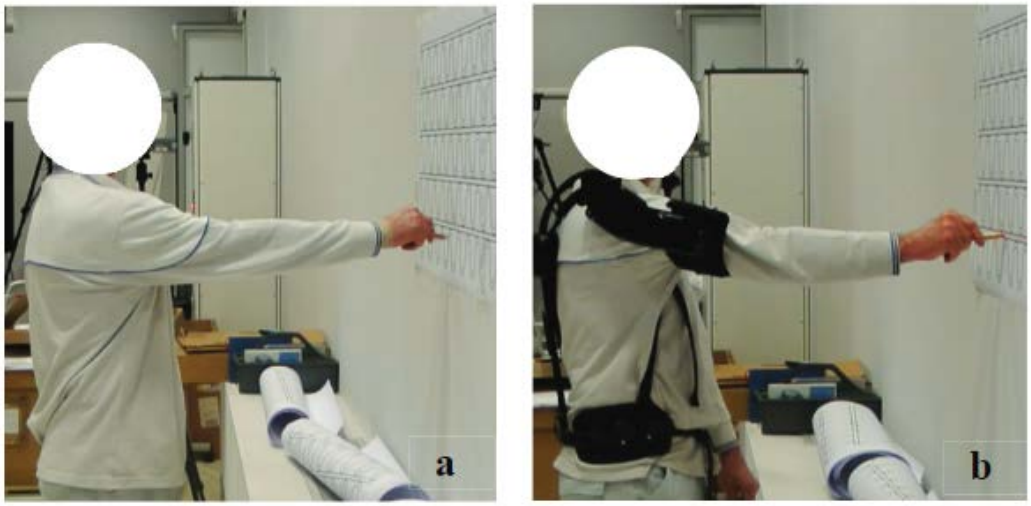

Figure C1. Example of precision test

Rate Perceived Exertion (RPE) (BORG Scale) (STEP 2 and 3)[90]

What: Borg Scale intends to investigate how hard a person is exercising. The Borg Scale takes into account the fitness level. It uses numbers from 6 to 20 to indicate how hard a person feels they are exercising, so it is a "relative" scale. The scale starts with "no feeling of exertion", which rates a 6, and ends with "very, very hard", which rates a 20. Moderate activities register 11 to 14 on the Borg scale ("fairly light" to "somewhat hard"), while vigorous activities usually rate a 15 or higher ("hard" to "very, very hard"). Dr. Gunnar Borg, who created the scale, set it to run from 6 to 20 as a simple way to estimate the heart rate. The multiplication of the Borg score by 10 gives an approximate heart rate for a particular level of activity.

The use of the Borg Scale either on its own or in combination with other measures, such as the Borg CR10, a Visual Analogue Scale (VAS) and Likert scales, is widespread across the world in many scientific studies but particularly in the field of sports medicine, where it is used by trainers to plan the intensity of training regimes, and in the workplace, where it is used to assess the exertion used in manual handling and physically active work.

Why: Perceived effort assessment can support the analysis of exoskeleton efficacy as a complement to EMG analysis, heart rate and metabolic consumption, depending on the user's perception.

Where: It can be used in both laboratory and real environment, as it is only a questionnaire. The laboratory and real environment assessments also help to understand whether differences in the environment can influence the final evaluation of the exoskeleton and how. Studies performed in controlled environments have shown a close relationship between perceived physical exertion and work demands expressed as percentage of the individual physical capacity. This is true for both cardiovascular and muscular work; however, studies comparing laboratory findings and real workplace scenarios remain relatively uncommon.

[90] Williams, N. (2017). The Borg rating of perceived exertion (RPE) scale. Occupational Medicine, 67(5), 404-405.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

When: The evaluation of perceived effort is usually conducted in the usability investigations (STEP 2 and 3) at the end of the task. However, on long tasks in the assembly line it could be conducted at a defined time and evaluate its evolution in the day or days/months.

Who: The subjective analysis should be performed by the support of occupational psychologists and cognitive ergonomists.

How: The analysis is carried out by submitting the scale of evaluation to the tester and it can be referred to a global effort or to an effort located in the area of interest.

Ground force and CoP (STEP 2)[91, 92, 93]

What: In biomechanics, center of pressure (CoP) is the term given to the point of application of the ground reaction force vector. The ground reaction force vector represents the sum of all forces acting between a physical object and its supporting surface. Analysis of the center of pressure is common in studies on human postural control and gait. It is thought that changes in motor control may be reflected in changes in the center of pressure. In biomechanical studies, the effect of some experimental condition on movement execution will regularly be quantified by alterations in the center of pressure. The center of pressure is not a static outcome measure. For instance, during human walking, the center of pressure is near the heel at the time of heel strike and moves anteriorly throughout the step, being located near the toes at toe-off. For this reason, analysis of the center of pressure will need to take into account the dynamic nature of the signal. In the scientific literature various methods for the analysis of center of pressure time series have been proposed.

Why: CoP and center of gravity are both related to balance in that they are dependent on the position of the body with respect to the supporting surface. Center of gravity is subject to change based on posture. Center of pressure is the location on the supporting surface where the resultant vertical force vector would act if it could be considered to have a single point of application.

A shift of CoP is an indirect measure of postural sway and thus a measure of a person's ability to maintain balance. All people would sway in the anterior-posterior direction (forward and backward) and the medial-lateral direction (side-to-side) when they are simply standing still. This comes as a result of small contractions of muscles in the body to maintain an upright position. An increase in sway is not necessarily an indicator of poorer balance so much as it is an indicator of decreased neuromuscular control although it has been noted that postural sway is a precursor to a fall.

Where: This type of testing should be reserved to a protected environment where the testing conditions are under control and perfectly established on simple and easily repeatable work tasks that do not require previous experience in carrying out.

When: The CoP analysis can be addressed in usability tests in a laboratory with a well-defined test sample and test conditions.

---

[91] Gribble, P. A., & Hertel, J. (2004). Effect of lower-extremity muscle fatigue on postural control. Archives of physical medicine and rehabilitation, 85(4), 589-592.
[92] Fernie, G. R., Gryfe, C. I., Holliday, P. J., & Llewellyn, A. (1982). The relationship of postural sway in standing to the incidence of falls in geriatric subjects. Age and ageing, 11(1), 11-16.
[93] Hart, S. G., & Staveland, L. E. (1988). Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research. In Advances in psychology (Vol. 52, pp. 139-183). North-Holland.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Who: The evaluation team for this parameter should be composed of experts in its detection and analysis, such as engineers.

How: CoP measurements are commonly gathered through the use of a force plate. A force plate gathers data in the anterior-posterior direction (forward and backward), the medial-lateral direction (side-to-side) and the vertical direction, as well as moments about all 3 axes. Together, these can be used to calculate the position of the center of pressure relative to the origin of the force plate.

KPI: Strength deviation caused from wearing a load greater than 6 kg.

Total workload (STEP 2 and 3)[94, 95, 96]

What: The Nasa-TLX is a combined measure taking into account 6 factors – mental demand, physical demand, temporal demand, performance, effort and frustration – each assessed on a 20-point scale. A global score is calculated by weighing each factor with task and participant-specific weights. Though Nasa-TLX has not previously been used for exoskeleton evaluation, it is a validated measure which covers physical and cognitive aspects.

Why: Instead if Borg Scale, the Nasa Task Load Index (Nasa-TLX) is used to assess the global perceived workload.

Where: It can be used in both laboratory and real environment, as it is only a questionnaire. Laboratory and real-environment assessments also help to understand whether differences in the environment can influence the final assessment of the exoskeleton and how.

When: The evaluation of the 6 Nasa-TLX factors is usually conducted in the usability investigations (STEP 2 and 3) at the end of the task. However, on long tasks in the assembly line it could be conducted at a defined time and evaluate its evolution throughout the day or days/months.

Who: The subjective analysis should be performed by the support of occupational psychologists and cognitive ergonomists.

How: The 6 factors of the Nasa-TLX questionnaire can be evaluated by the participants after each session. Conversely, the weights of each factor were selected only once at the end of the experiment so that they were the same for the two conditions. The official NASA-TLX can be administered using a paper and pencil version, or using the official NASA TLX for Apple iOS App.

[94] Maurice, P., Čamernik, J., Gorjan, D., Schirrmeister, B., Bornmann, J., Tagliapietra, L., ... & Babič, J. (2019). Objective and subjective effects of a passive exoskeleton on overhead work. IEEE Transactions on Neural Systems and Rehabilitation Engineering, 28(1), 152-164.
[95] Brooke, J. (1996). Sus: a "quick and dirty'usability. Usability evaluation in industry, 189.
[96] Spada, S., Ghibaudo, L., Carnazzo, C., Gastaldi, L., & Cavatorta, M. P. (2018, August). Passive upper limb exoskeletons: an experimental campaign with workers. In Congress of the International Ergonomics Association (pp. 230-239). Springer, Cham.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

C2. Usability/ Satisfaction parameters investigated

System Usability Scale (STEP 2 and 3)[97, 98, 99, 100]

What: The System Usability Scale (SUS) provides a quick reliable tool for measuring the usability. It consists of a 10 item questionnaire with five response options for respondents; from "Strongly agree" to "Strongly disagree". Originally created by John Brooke in 1986, it allows to evaluate a wide variety of products and services, including hardware, software, mobile devices, websites and applications. The participant's scores for each question are converted to a new number, added together and then multiplied by 2.5 to convert the original scores of 0-40 to 0-100. Though the scores are 0-100, these are not percentages and should be considered only in terms of their percentile ranking.

Based on research, a SUS score above a 68 would be considered above average and anything below 68 is below average, however the best way to interpret results involves "normalising" the scores to produce a percentile ranking.

Why: In general, the main benefits of using the SUS to evaluate the subjective usability are:

- *it is a very easy scale to administer to participants,*
- *it can be used on small sample sizes with reliable results,*
- *it can be used to effectively differentiate between usable and unusable systems.*

Where: It can be used in both laboratory and real environment, as it is only a questionnaire. The laboratory and real environment assessments also help to understand whether differences in the environment can influence the final evaluation of the exoskeleton and how.

When: The evaluation of the subjective usability is usually conducted in the usability investigations (STEP 2 and 3) at the end of the task. However, on long tasks in the assembly line it could be conducted at a defined time and evaluate its evolution throughout the day or days/months.

Who: The subjective analysis should be performed by the support of occupational psychologists and cognitive ergonomists.

How: When a SUS is used, participants are asked to score 10 statements with one of five responses that range from "Strongly Agree" to "Strongly disagree". An example of the questionnaire is shown in Figure C2.

[97] Brooke, J. (1996). Sus: a "quick and dirty usability. Usability evaluation in industry, 189.
[98] Brooke, J. (2013). SUS: a retrospective. Journal of usability studies, 8(2), 29-40.
[99] Bangor, A., Kortum, P., & Miller, J. (2009). Determining what individual SUS scores mean: Adding an adjective rating scale. *Journal of usability studies*, *4*(3), 114-123.
[100] Bangor, A., Kortum, P., & Miller, J. (2009). Determining what individual SUS scores mean: Adding an adjective rating scale. Journal of usability studies, 4(3), 114-123.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

	Strongly Disagree				Strongly Agree
1. I think that I would like to use this product frequently.	1	2	3	4	5
2. I found the product unnecessarily complex.	1	2	3	4	5
3. I thought the product was easy to use.	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this product.	1	2	3	4	5
5. I found the various functions in the product were well integrated.	1	2	3	4	5
6. I thought there was too much inconsistency in this product.	1	2	3	4	5
7. I imagine that most people would learn to use this product very quickly.	1	2	3	4	5
8. I found the product very awkward to use.	1	2	3	4	5
9. I felt very confident using the product.	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this product.	1	2	3	4	5

Figure C2: System Usability Scale (SUS) – Example of questions

Discussion: When using a SUS, the following should be kept in mind.

- *The scoring system is complex.*
- *There is a temptation to interpret the scores as percentages, they are not.*
- *The best way to interpret results is by normalising the scores.*
- *SUS is not diagnostic; its use is in classifying the usability of the tested site, application or environment.*

UMUX (Usability Metric for User Experience) (STEP 2 and 3)[101, 102, 103]

What: The Usability Metric for User Experience (UMUX) is a four-item scale used for the subjective assessment of an application's perceived usability. It is designed to provide results similar to those obtained with the 10-item System Usability Scale, and is organised around ISO 9241-11 definition of usability. UMUX is a simple four-item questionnaire listing two positive and two negative statements to which respondents are asked to rate their agreement on a five or seven-point Likert scale (see Figure C3).

[101] ISO 9241-11 Ergonomics of human-system interaction - Part 11: Usability: Definitions and concepts
[102] Finstad, K. (2010). The usability metric for user experience. Interacting with Computers, 22(5), 323-327.
[103] Hensel, R., & Keil, M. (2019). Subjective evaluation of a passive industrial exoskeleton for lower-back support: A field study in the automotive sector. IISE Transactions on Occupational Ergonomics and Human Factors, 7(3-4), 213-221.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

1.	[This system's] capabilities meet my requirements.						
	1	2	3	4	5	6	7
	Strongly Disagree						Strongly Agree
2.	Using [this system] is a frustrating experience.						
	1	2	3	4	5	6	7
	Strongly Disagree						Strongly Agree
3.	[This system] is easy to use.						
	1	2	3	4	5	6	7
	Strongly Disagree						Strongly Agree
4.	I have to spend too much time correcting things with [this system].						
	1	2	3	4	5	6	7
	Strongly Disagree						Strongly Agree

Figure C3: UMUX – questionnaire listing

Why: With respect to the SUS, the development of a concise scale that would more closely conform to the ISO 9241-11 definition of usability, would minimise bias and language issues, and would still perform as well as the baseline it was intended to replace.

Where: It can be used in both laboratory and real environment, as it is only a questionnaire. The laboratory and real environment assessments also help to understand whether differences in the environment can influence the final evaluation of the exoskeleton and how.

When: Like most of the usability templates, UMUX is a great questionnaire to use after usability testing. UMUX is considered a great tool for evaluating usability through product use due to its compactness. It can be used as a one-time solution for specific use cases or during different phases of the design process like prototyping and validation.

Who: The subjective analysis should be performed by occupational psychologists and cognitive ergonomists.

How: The UMUX questionnaire can be filled out by the subject at the end of the task and the final UMUX Score can be calculated as follows:

- *Odd items are scored as [user score - 1]. Even items are scored as [user score - 7].*
- *Add up these differences and divide the sum by 24 (the highest possible score).*
- *Multiply your quotient by 100.*
- *Average your results across users.*

Discussion: Since UMUX is still fairly new in comparison to other standardised usability questionnaires such as SUS, there is not much benchmark data to help interpret the score obtained.

Technology Acceptance Model (TAM) (STEP 2 and 3)

What: The Technology Acceptance Model (TAM) has been one of the most influential models of technology acceptance, with two primary factors influencing an individual's intention to use new technology: perceived ease of use and perceived usefulness. Perceived usefulness is defined as being the degree to which a person believes that the use of a system will improve his performance. Perceived ease of use refers to the degree to which a person believes that the use of a system will be effortless. Several factorial analyses demonstrated that perceived usefulness and perceived ease of use can be considered as two different dimensions.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Where: It can be used in both laboratory and real environment, as it is a questionnaire. The laboratory and real environment assessments also help to understand whether differences in the environment can influence the final evaluation of the exoskeleton and how.

When: The evaluation of the acceptability is usually conducted in the usability investigations (STEP 2 and 3) at the end of the task. However, on long tasks in the assembly line it could be conducted at a defined time and evaluate its evolution throughout the day or days/months.

Who: The subjective analysis should be performed by occupational psychologists and cognitive ergonomists.

How: As all the subjective investigations, the acceptability questions can be prepared and then shown to the user. Questions must be appropriate to the user's experience with the exoskeleton.

Open questions (STEP 3)

What: Specific questions about the field of application of the investigated technology can be added to the usability and acceptability questionnaires.

Why: Each type of technology and environment may require the addition of specific questions to fully understand user satisfaction. It is therefore suggested, if deemed appropriate, to add specific questions in addition to the questionnaires explained above.

Where: The investigation of specific items related to the real technological applicability can be performed in the real testing environment, to detect particular information related to the particular use.

When: The open questions can be asked at the end of the work activity or while the subject is performing the task, to detect all the main aspects of the use of the exoskeleton.

Who: The subjective analysis should be performed by occupational psychologists, cognitive ergonomists, but also dedicated people from the plant management.

How: As all the subjective investigations, the specific questions can be prepared and then shown to the user. Questions must be appropriate to the user's experience with the exoskeleton.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

C3. Efficiency parameters investigated

Task execution-, endurance-, and donning/doffing time (STEP 2 and 3)[104, 105, 106]

What: The introduction of a wearable device could change not only the geometry of the user's movement, but also the speed and agility of movement. This also implies a change in the execution time of the task, be it static or dynamic. In addition, it is worth considering, in order to be able to integrate an exoskeleton in industrial environments, the time needed to don and doff the device.

Where: The speed and agility of movement, due to the measurement instrumentation, can be evaluated in a laboratory environment (STEP 2), with ad hoc tests. The same applies to endurance time, as endurance tests are necessary and are hardly possible in the working environment (STEP 2). The execution time of the task, on the other hand, can be evaluated both in a laboratory environment and in real life (STEP 2 and 3). The time needed to don and doff the device is a characteristic of the exoskeleton, as it depends on the complexity of the device and can be easily measured in the laboratory (STEP 2), in anticipation of use in an industrial environment.

When: Efficiency measurements are performed during the execution of the task, with the exception of the measurement of the time needed to don and doff the device, which is to be measured in the phases before and after the task.

Who: The evaluation team for this parameter should be composed of experts in its detection and analysis, such as engineers and dedicated people from the plant management

How: The speed and agility of movement can be evaluated using a motion capture system, such as the one capable of capturing the user's ROM. While time measurements (task execution, endurance and dressing/undressing) can be conducted using a stopwatch.

[104] Dahmen, C., & Constantinescu, C. (2018). Methodology for Evaluation of the Time-Management impact of Exoskeleton-centred workplaces. ACTA TECHNICA NAPOCENSIS-Series: APPLIED MATHEMATICS, MECHANICS, and ENGINEERING, 61(4).
[105] Sposito, M., Toxiri, S., Caldwell, D. G., Ortiz, J., & De Momi, E. (2018, October). Towards design guidelines for physical interfaces on industrial exoskeletons: overview on evaluation metrics. In International Symposium on Wearable Robotics (pp. 170-174). Springer, Cham.
[106] Spada, S., Ghibaudo, L., Gilotta, S., Gastaldi, L., & Cavatorta, M. P. (2017, July). Analysis of exoskeleton introduction in industrial reality: main issues and EAWS risk assessment. In International Conference on Applied Human Factors and Ergonomics (pp. 236-244). Springer, Cham.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

C4. Comfort parameters investigated

Local Perceived Pressure (LPP) (STEP 2 and 3)

What: Among the subjective evaluations of the perceived pressure, the LPP method is used to identify interface pressure points and/or areas and the arising of pressure points over time. The rating scale and the body areas in which the pressure is investigated are shown below in Figure C4.

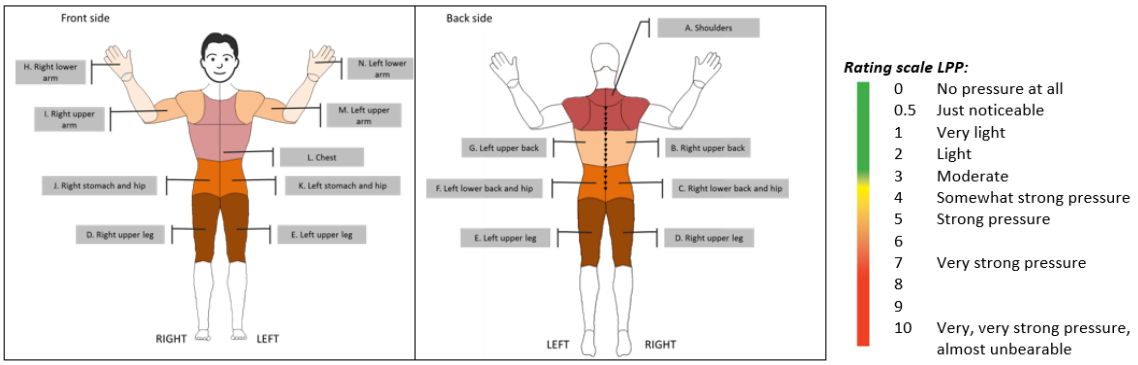

Figure C4: Local Perceived pressure (LPP) rating scale

Why: Subjective evaluation of interface pressures is useful for evaluating how the exoskeleton exchanges support forces with the user, how these are felt and for assessing whether additional forces causing discomfort are present at the interface with other body areas.

Where: It can be used in both laboratory and real environment, as it is a questionnaire. Laboratory and online assessments also allow to understand whether differences in the environment can influence the final assessment of the exoskeleton and how.

When: The evaluation of perceived pressures can be carried out during the task, to study their evolution during the work activity, and at the end of the task to understand their effects globally. It can be conducted in both the laboratory and the real environment (STEP 2 and 3). In the real environment it can be conducted after a certain period of use of the device, to ensure that the results are derived from a subject that has learned to use the device correctly.

Who: The subjective analysis should be performed by occupational psychologists and cognitive ergonomists

How: At given points in time, the test leader shows the worker two schematic images, one of the front side of the body, one of the back. The test leader also shows an adapted Borg scale according to which the worker can rate the amount of pressure from the exoskeleton on certain parts of the body.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Visual Analogue Discomfort Scale (VADS) (STEP 2 and 3)[107]

What: The Visual Analougue Discomfort Scale (VADS) metric can estimate the PDT (Pressure Detection Threshold) and PTT (Pressure Tolerance Threshold) for each interface and user by associating a discomfort scale to different body areas. Similar to LLP, the VADS does not define a prioritisation the body areas.

Why: Subjective evaluation of interface pressures is useful for evaluating how the exoskeleton exchanges support forces with the user, how these are felt and for assessing whether additional forces causing discomfort are present at the interface with other body areas.

Where: It can be used in both laboratory and real environment, as it is a questionnaire. Laboratory and online assessments also allow to understand whether differences in the environment can influence the final assessment of the exoskeleton and how.

When: The evaluation of perceived pressures can be carried out during the task, to study their evolution during the work activity, and at the end of the task to understand their effects globally. It can be conducted in both the laboratory and the real environment. In the real environment it can be conducted after a certain period of use of the device, to ensure that the results are derived from a subject that has learned to use the device correctly.

Who: The subjective analysis should be performed by occupational psychologists and cognitive ergonomists.

How: At given points in time, the test leader shows the worker two schematic images, one of the front side of the body, one of the back. The test leader also shows the VADS scale according to which the worker can rate the amount of pressure from the exoskeleton on certain parts of the body.

Corlett and Bishop's body district discomfort scale[108]

What: Corlett and Bishop's (1976) body part discomfort scale is a subjective symptom survey tool that evaluates the respondent's direct experience of discomfort at different body parts from 0 (no discomfort), to 10 (extremely high).

Why: Subjective evaluation of interface pressures is useful for evaluating how the exoskeleton exchanges support forces with the user and how these forces are felt and for assessing whether additional forces causing discomfort are present at the interface with other body areas.

Where: It can be used in laboratory and real environment, as it is a questionnaire. Laboratory and online assessments also allow to understand whether differences in the environment can influence the final assessment of the exoskeleton and how.

When: The evaluation of perceived pressures can be carried out during the task, to study their evolution during the work activity, and at the end of the task to understand their effects globally. It can be conducted in both the laboratory and the real environment. In the real environment it can

[107] Maurice, P., Čamernik, J., Gorjan, D., Schirrmeister, B., Bornmann, J., Tagliapietra, L., ... & Babič, J. (2019). Objective and subjective effects of a passive exoskeleton on overhead work. IEEE Transactions on Neural Systems and Rehabilitation Engineering, 28(1), 152-164.

[108] Corlett, E. N., & Bishop, R. P. (1976). A technique for assessing postural discomfort. Ergonomics, 19(2), 175-182.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

be conducted after a certain period of use of the device, to ensure that the results are derived from a subject that has learned to use the device correctly.

Who: The subjective analysis should be performed by occupational psychologists and cognitive ergonomists.

How: At given points in time, the test leader shows the worker two schematic images, one of the front side of the body, one of the back. The test leader also shows the discomfort scale according to which the worker can rate the amount of pressure from the exoskeleton on certain parts of the body.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Annex D – Literature research on surgical robots for the healthcare domain

Guiochet, J., Machin, M., & Waeselynck, H. (2017). Safety-critical advanced robots: A survey. *Robotics and Autonomous Systems*, *94*, 43-52.

William J. Peine (2006). Mechanical Engineering Purdue University. Presentation on: Standard and Metrology Needs for Surgical Robotics. Last retrieved March 2021 on: https://www.nist.gov/system/files/documents/el/isd/Standard_and_Metrology_Needs_for_Surgical_Robotics-_Peine.pdf.

Lasota, P. A., Fong, T., & Shah, J. A. (2017). *A survey of methods for safe human-robot interaction*. Now Publishers.

Medical Device Coordination Group (MDCG) (2019). Summary of safety and clinical performance - A guide for manufacturers and notified bodies. Last retrieved March 2021 on: https://ec.europa.eu/docsroom/documents/37323.

Pruthi, S. (2012). Wireless robotics: A history, an overview, and the need for standardization. *Wireless Personal Communications*, *64*(3), 597-609.

Haidegger, T., Barreto, M., Gonçalves, P., Habib, M. K., Ragavan, S. K. V., Li, H., ... & Prestes, E. (2013). Applied ontologies and standards for service robots. *Robotics and Autonomous Systems*, *61*(11), 1215-1223.

Guiochet, J., Do Hoang, Q. A., Kaâniche, M., & Powell, D. (2012, October). Applying existing standards to a medical rehabilitation robot: Limits and challenges. In *Workshop FW5: Safety in Human-Robot Coexistence & Interaction: How can Standardization and Research benefit from each other?, IEEE/RSJ Intern. Conference Intelligent Robots and Systems (IROS2012)*.

Takayama, L. (2009). Toward a science of robotics: Goals and standards for experimental research. In *RSS workshop on good experimental methodology in robotics*.

Universal robots - The Top 5 Cobot KPIs (2019). *How to measure and improve the performance of collaborative robots*. Last retrieved March 2021 on:https://voelker-controls.com/wp-content/uploads/2019/01/UR_Robotiq__Ebook_5-Cobot_KPIs-.pdf.

Estes, S. J., Goldenberg, D., Winder, J. S., Juza, R. M., & Lyn-Sue, J. R. (2017). *Best practices for robotic surgery programs*. JSLS: Journal of the Society of Laparoendoscopic Surgeons, 21(2).

Narazaki, K., Oleynikov, D., & Stergiou, N. (2006). *Robotic surgery training and performance*. Surgical Endoscopy And Other Interventional Techniques, 20(1), 96-103.

Jacobs, T., Veneman, J., Virk, G. S., & Haidegger, T. (2018). T*he flourishing landscape of robot standardization [industrial activities]*. IEEE Robotics & Automation Magazine, 25(1), 8-15.

Matthias, B., Oberer-Treitz, S., Staab, H., Schuller, E., & Peldschus, S. (2010, June). *Injury risk quantification for industrial robots in collaborative operation with humans*. In ISR 2010 (41st International Symposium on Robotics) and ROBOTIK 2010 (6th German Conference on Robotics) (pp. 1-6). VDE.

Matthias, B. (2014, March). *Industrial safety requirements for collaborative robots and applications*. In ERF 2014 Workshop: Workspace Safety in Industrial Robotics: trends, integration, and standards.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Terms and definitions

Terms	Definitions
Standard	Document, established by consensus and approved by a recognised body, which provides common rules, guidelines or characteristics for activities or their results having the purpose of achieving an optimal degree of order in a given context (Source: EN 45020:2006, Term 3.2).
Robot	Actuated mechanism programmable in two or more axes with a degree of autonomy moving within its environment, to perform intended tasks (Source: ISO 8373:2012, Term 2.6)
Machine	Assembly, fitted with or intended to be fitted with a drive system consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application (Source: EN ISO 12100:2011, Term 3.1).
Robotic device	Actuated mechanism fulfilling the characteristics of an industrial robot or service robot, but lacking either the number of programmable axes or the degree of autonomy (Source: ISO 13482:2014, Term 3.3).
Industrial robot	Automatically controlled, reprogrammable, multipurpose manipulator, programmable in three or more axes, which ca be either fixed n place or mobile for use in industrial automation applications (Source: ISO 8373:2012, Term 2.9).
Service robot	Robot that performs useful tasks for humans or equipment excluding industrial automation applications (ISO 8373:2012, Term 2.10).
Personal care robot	Service robot that performs actions contributing directly toward improvement in the quality of life of humans, excluding medical applications (Source: ISO 13482:2014, Term 3.13).
Physical assistant robot	Personal care robot that physically assist a user to perform required tasks by providing supplementation or augmentation of personal capabilities (e.g. exoskeletons) (Source: ISO 13482:2014, Term 3.15).
Mobile servant robot	Personal care robot that is capable of travelling to perform serving tasks in interaction with humans, such as handling objects or exchanging information (Source: ISO 13482:2014, Term 3.14).
Person carrier robot	Personal care robot with the purpose of transporting humans to an intended destination (Source: ISO 13482:2014, Term 3.16).
Collaborative robot	Robot designed for direct interaction with a human within a defined collaborative workspace (Source: ISO 10218-2:2011, Term 3.2)
Medical robot	Robot intended to be used as medical electrical equipment (MEE) or medical electrical system (MES) (Source: IEC/TR 60601-4-1:2017, Term 3.20).
Medical electrical equipment	Electrical equipment having an applied part or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is a) provided with not more than one connection to a particular supply mains, and b) intended by its manufacturer to be used in the diagnosis, treatment, or monitoring of a patient, or - for compensation or alleviation of disease, injury or disability (Source: EN 60601-1:2005, Term 3.63).
Medical electrical system	Combination, as specified by its manufacturer, of items of equipment, at least one of which is MEE to be interconnected by functional connection or by use of a multiple socket-outlet (Source: EN 60601-1:2005, Term 3.64).
Assistive product	Any product (including devices, equipment, instruments and software), especially produced or generally available, used by or for persons with disability for participation, to protect, support, train, measure or substitute for body functions/ structures and activities, or to prevent impairment, activity limitations or participation restrictions Source: ISO 9999:2016, Term 2.3).
Prosthesis	External applied device consisting of a single component or an assembly of components used to replace wholly, or in part, an absent or deficient lower or upper limb segment Source: ISO 22523:2006, Term 3.2).
Orthosis	External applied device used to compensate for impairment of the structure and function of the neuro-muscular and skeleton system (Source: ISO 8549-1:2020; Term 3.1.2).

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Wearable device	A wearable device is mechanical or mechatronic device attached to the human body for supplementing and augmenting of motor functions (Source: CWA 17664:2021, Term 3.1).
Medical device	Instrument, apparatus, implement, machine, application, implant, reagend for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific purpose(s) of: - diagnosis, prevention, monitoring, treatment or alleviation of disease, - diagnosis, monitoring, treatment, alleviation of or compensation for an injury, - investigation, replacement, modification, or support of the anatomy or of a physiological process, - control of conception, - disinfection of medical devices, - providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means (Source: Regulation (EU) 2017/745 on Medical Devices).
Exoskeleton	Multi-segment wearable device working in parallel with the human body used to compensate for impairment of the structure and function of the neuro-muscular and skeleton system.
Automated Guided Vehicle (AGV)	Mobile platform following a predetermined path indicated by markers or external guidance commands, typically in the factory (Source: ISO 8373:2012, Term 3.20).
Autonomous Mobile Robots (AMR)	Automated Guided Vehicle with increased autonomy capability.
Clinical robot	Robotic systems that support care and cure processes, primarily in diagnosis, treatment, surgical intervention and medication, but also emergency healthcare. These robots are operated by clinical staff or other trained care personnel.
Rehabilitation robot	Cover post-operative or post injury care where direct physical interaction with a robot system will either enhance recovery or act as a replacement for lost function (e.g. Prosthesis, Orthosis).
Assistive robot	Covers aspects of robotics within the healthcare process where the primary function of the robotic system is to provide assistive help either to carers or directly to patients either in hospital or in a specialist care facility.
Consumer robot	Consumer robots are operated by, or interact with, untrained, or minimally trained people in everyday environments (e.g. domestic applications, window cleaning or security robots).
Technical Report	Provides specifications of a recommendatory and explanatory nature.
Technical Specification	Type of document that aims to aid market development and growth for products or methods that are still in the development and/or trial phase.
CEN Workshop Agreement	Agreement developed and approved in a CEN Workshop.
Basic standard	Wide-ranging coverage or contains general provisions for one particular field, e.g. terminology.
Test standard	Concerned with test methods, sometimes supplemented with other provisions related to testing.
Particular standard	Defines the characteristics of a product (product standard), service (service standard) or process (process standard) and their performance thresholds such as fitness for use, interface and interchangeability, health and safety, environmental protection.
Supplementary standard	Document that refers to other standards for example as a guideline of use of these standards.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Abbreviations

- AGV Automated Guided Vehicle
- AMR Autonomous Mobile Robots
- ANSI American National Standards Institute
- ASTM American Society for Testing and Materials
- AWI Approved Work Item
- CCMC CEN/CENELEC Management Centre
- CD Committee Draft
- CEN European Committee for Standardisation
- CENELC European Committee for Electrotechnical Standardisation
- CIB Committee Internal Balloting
- CLC CENELEC (in document references)
- COBOTS Collaborative robots
- CoP Center of Pressure
- CSA Coordination and Support Action
- CWA CEN Workshop Agreement
- DIS Draft International Standard
- EC European Commission
- EEC European Economic Community
- EFTA European Free Trade Association
- EMC Electromagnetic compatibility
- EN European Standard
- EPO European Patent Office
- ETSI European Telecommunications Standards Institute
- Exo Exoskeleton
- FDIS Final Draft Standard
- HRC Human-Robot Collaboration
- IEC International Electrotechnical Commission
- ISO International Organisation for Standardisation
- IWA International Workshop Agreement
- JTC Joint Technical Committee
- JWG Joint Working Group
- LPP Local Perceived Pressure
- MAR Multi Annual Roadmap
- MDR Medical Device Regulation
- MoU Memorandum of Understanding
- MSD Musculoskeletal Disorders
- MVC Maximal Voluntary Contraction
- NA Normenausschuss (German for TC)
- NSB National Standardisation Body
- NWIP New Work Item Proposal
- OJEU Official Journal of the European Union
- PSDO Partner Standards Development Organisation
- PWI Preliminary Work Item
- RMS Root Mean Square
- ROM Read-Only Memory
- RPE Rate of Perceived Exertion
- SC Sub Committee
- STAIR STAndards, Innovation and Research

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

- SUS System Usability Scale
- TC Technical Committee
- TR Technical Report
- TRL Technical Readiness Level
- TS Technical Specification
- UI Unique Device Identification
- UMUX Usability Metric for User Experience
- VADS Visual Analogue Discomfort Scale
- WG Working Group

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

References

Agreement on technical co-operation between ISO and CEN (Vienna Agreement, 1991).

Baltrusch, S. J., Van Dieën, J. H., Bruijn, S. M., Koopman, A. S., Van Bennekom, C. A. M., & Houdijk, H. (2019). *The effect of a passive trunk exoskeleton on metabolic costs during lifting and walking*. Ergonomics.

Bangor, A., Kortum, P., & Miller, J. (2009). *Determining what individual SUS scores mean: Adding an adjective rating scale*. Journal of usability studies, 4(3), 114-123.

BCC-Research-Staff, *Robotics: Technologies and Global Markets*, BCC Research Report, 2010.

Borg, G. A. (1982). *Psychophysical bases of perceived exertion*. Medicine & science in sports & exercise.

Bosch, T., van Eck, J., Knitel, K., & de Looze, M. (2016). T*he effects of a passive exoskeleton on muscle activity, discomfort and endurance time in forward bending work*. Applied ergonomics, 54, 212-217.

Brooke, J. (1996). *Sus: a "quick and dirty usability*. Usability evaluation in industry, 189.

Brooke, J. (2013). *SUS: a retrospective*. Journal of usability studies, 8(2), 29-40.

CEN/CENELEC Guide 25 (2017), *The concept of Partnership with European Organizations and other stakeholders*.

CEN/CENELEC Internal Regulations Part 2 - Common rules for standardisation work (2017).

CEN/CENELEC Regulation – Part 3: Principles and rules for the structure and drafting of CEN and CENELEC documents.

Corlett, E. N., & Bishop, R. P. (1976). *A technique for assessing postural discomfort*. Ergonomics, 19(2), 175-182.

COVR, accessed March 4, 2021: https://www.safearoundrobots.com/home.

Crowell, H. P., Kanagaki, G. B., O'Donovan, M. P., Haynes, C. A., Park, J. H., Neugebauer, J. M., ... & Girolamo, H. J. (2018). *Methodologies for evaluating the effects of physical augmentation technologies on Soldier performance*. US Army Research Laboratory Aberdeen Proving Ground United States.

Dahmen, C., & Constantinescu, C. (2018). *Methodology for Evaluation of the Time-Management impact of Exoskeleton-centred workplaces*. ACTA TECHNICA NAPOCENSIS-Series: APPLIED MATHEMATICS, MECHANICS, and ENGINEERING, 61(4).

De Looze, M. P., Bosch, T., Krause, F., Stadler, K. S., & O'Sullivan, L. W. (2016). *Exoskeletons for industrial application and their potential effects on physical work load*. Ergonomics, 59(5), 671-681.

Directive 2006/42/EC of the European Parliament and of the Council on machinery, May 17, 2006.

EN 45020 Standardisation and related activities – General vocabulary.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

EN ISO 10218-1 Robots and robotic devices - Safety requirements for industrial robots - Part 1: Robots.

EN ISO 10218-2 Robots and robotic devices - Safety requirements for industrial robots - Part 2: Robot systems and integration.

EN ISO 12100 Safety of machinery - General principles for design - Risk assessment and risk reduction.

ErgoPlus, *The Definition and Causes of Musculoskeletal Disorders*, accessed March 4, 2021: https://ergo-plus.com/musculoskeletal-disorders-msd/.

EU-Robotics, *Robotics 2020 - Multi Annual Roadmap*, accessed March 4, 2021, https://www.eu-robotics.net/cms/upload/downloads/ppp-documents/Multi-Annual_Roadmap2020_ICT-24_Rev_B_full.pdf.

EU-Robotics, *Strategic Research Agenda – For Robotics in Europe 2014 – 2020*, accessed March 4, 2021: https://www.eu-robotics.net/cms/upload/topic_groups/SRA2020_SPARC.pdf.

European Agency for Safety and Health at Work, *OSH in figures: Work-related musculoskeletal disorders in the EU – Facts and figures*, accessed March 4, 2021: https://osha.europa.eu/en/tools-and-publications/publications/reports/TERO09009ENC/view.

European Agency for Safety and Health at Work, *Work-related accidents and injuries cost EU €476 billion a year according to new global estimates*, accessed March 4, 2021: https://www.eurofound.europa.eu/news/news-articles/eu-osha-work-related-accidents-and-injuries-cost-eu-eu476-billion-a-year-according-to-new-global.

European Commission, accessed March 4, 2021: https://ec.europa.eu/research/industrial_technologies/pdf/workshop-innovation-report_en.pdf.

Fernie, G. R., Gryfe, C. I., Holliday, P. J., & Llewellyn, A. (1982). *The relationship of postural sway in standing to the incidence of falls in geriatric subjects*. Age and ageing, 11(1), 11-16.

Finstad, K. (2010). *The usability metric for user experience*. Interacting with Computers, 22(5), 323-327.

German Institute for Standardisation, *An introduction to standardisation – a practical guide for small businesses*, accessed March 4, 2021: https://www.din.de/resource/blob/195038/64b75612aae6d6e7341e815becadb5d9/an-introduction-to-standardization-data.pdf.

Gillette, J. C., & Stephenson, M. L. (2017). *EMG assessment of a shoulder support exoskeleton during on-site job tasks*. Proc. Am. Soc. Biomech. Annu. Meet. Boulder CO USA.

Glynn, A. J., & Fiddler, H. (2009). *The Physiotherapist's Pocket Guide to Exercise E-Book: Assessment*, Prescription and Training. Elsevier Health Sciences.

Gopura, R. A. R. C., & Kiguchi, K. (2009, June). *Mechanical designs of active upper-limb exoskeleton robots: State-of-the-art and design difficulties*. In 2009 IEEE International Conference on Rehabilitation Robotics (pp. 178-187). IEEE.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Gribble, P. A., & Hertel, J. (2004). *Effect of lower-extremity muscle fatigue on postural control. Archives of physical medicine and rehabilitation*, 85(4), 589-592.

Hart, S. G., & Staveland, L. E. (1988). *Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research*. In Advances in psychology (Vol. 52, pp. 139-183). North-Holland.

Hensel, R., & Keil, M. (2019). *Subjective evaluation of a passive industrial exoskeleton for lower-back support: A field study in the automotive sector*. IISE Transactions on Occupational Ergonomics and Human Factors, 7(3-4), 213-221.

Huysamen, K., Bosch, T., de Looze, M., Stadler, K. S., Graf, E., & O'Sullivan, L. W. (2018). *Evaluation of a passive exoskeleton for static upper limb activities*. Applied ergonomics, 70, 148-155.

Huysamen, K., de Looze, M., Bosch, T., Ortiz, J., Toxiri, S., & O'Sullivan, L. W. (2018). *Assessment of an active industrial exoskeleton to aid dynamic lifting and lowering manual handling tasks*. Applied ergonomics, 68, 125-131.

IEC 60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

IEC/TR 60601-4-1 Medical electrical equipment – Part 4-1: Guidance and interpretation - Medical electrical equipment and medical electrical systems employing a degree of autonomy.

International Organisation for Standardisation, "Developing ISO standards", accessed March 4, 2021: https://www.iso.org/developing-standards.html.

ISO 13482 Robots and robotic devices - Safety requirements for personal care robots.

ISO 8373 Robots and robotic devices - Vocabulary.

ISO 8549-1 Prosthetics & orthotics – Vocabulary – Part 1: General terms for external limb prostheses & external orthoses.

ISO 9241-11 Ergonomics of human-system interaction - Part 11: Usability: Definitions and concepts.

ISO TR 23482-1 Robotics – Application of ISO 13482 – Part 1: Safety-related test methods.

ISO/DIS 18646-4 Robotics – Performance criteria and related test methods for service robots – Part 4: Wearable robots.

ISO/IEC Directive – Part 1 Procedures for the technical work.

ISO/IEC Directive – Part 2 Principles and rules for structure and drafting of ISO and OEC documents.

ISO/TS 15066:2016 Robots and robotic devices – Collaborative robots.

Kermavnar, T., Power, V., de Eyto, A., & O'Sullivan, L. W. (2018). *Computerized cuff pressure algometry as guidance for circumferential tissue compression for wearable soft robotic applications: A systematic review*. Soft robotics, 5(1), 1-16.

Kim, S., Nussbaum, M. A., Esfahani, M. I. M., Alemi, M. M., Jia, B., & Rashedi, E. (2018). *Assessing the influence of a passive, upper extremity exoskeletal vest for tasks requiring arm elevation: Part II–"Unexpected" effects on shoulder motion, balance, and spine loading*. Applied Ergonomics, 70, 323-330.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Maurice, P., Čamernik, J., Gorjan, D., Schirrmeister, B., Bornmann, J., Tagliapietra, L., ... & Babič, J. (2019). *Objective and subjective effects of a passive exoskeleton on overhead work*. IEEE Transactions on Neural Systems and Rehabilitation Engineering, 28(1), 152-164.

Mudie, K. L., Boynton, A. C., Karakolis, T., O'Donovan, M. P., Kanagaki, G. B., Crowell, H. P., ... & Billing, D. C. (2018). *Consensus paper on testing and evaluation of military exoskeletons for the dismounted combatant*. Journal of science and medicine in sport, 21(11), 1154-1161.

Ndahimana, D., & Kim, E. K. (2017). *Measurement methods for physical activity and energy expenditure: a review*. Clinical nutrition research, 6(2), 68.

Presentation from William J. Peine (2006) on "Standard and Metrology Needs for Surgical Robotics" (nist.gov).

Regulation (EU) No 1025/2012 of the European Parliament and the Council on European Standardisation.

Spada, S., Ghibaudo, L., Carnazzo, C., Di Pardo, M., Chander, D. S., Gastaldi, L., & Cavatorta, M. P. (2018, August). *Physical and virtual assessment of a passive exoskeleton*. In Congress of the International Ergonomics Association (pp. 247-257). Springer, Cham.

Spada, S., Ghibaudo, L., Carnazzo, C., Gastaldi, L., & Cavatorta, M. P. (2018, August). *Passive upper limb exoskeletons: an experimental campaign with workers*. In Congress of the International Ergonomics Association (pp. 230-239). Springer, Cham.

Spada, S., Ghibaudo, L., Gilotta, S., Gastaldi, L., & Cavatorta, M. P. (2017, July). *Analysis of exoskeleton introduction in industrial reality: main issues and EAWS risk assessment*. In International Conference on Applied Human Factors and Ergonomics (pp. 236-244). Springer, Cham.

Sposito, M., Toxiri, S., Caldwell, D. G., Ortiz, J., & De Momi, E. (2018, October). *Towards design guidelines for physical interfaces on industrial exoskeletons: overview on evaluation metrics*. In International Symposium on Wearable Robotics (pp. 170-174). Springer, Cham.

Standards plus Innovation, accessed March 4, 2021: https://www.standardsplusinnovation.eu/.

Sylla, N., Bonnet, V., Colledani, F., & Fraisse, P. (2014). *Ergonomic contribution of ABLE exoskeleton in automotive industry*. International Journal of Industrial Ergonomics, 44(4), 475-481.

The European Union Medical Device Regulation of 2017, accessed March 4, 2021, https://eumdr.com/.

Theurel, J., Desbrosses, K., Roux, T., & Savescu, A. (2018). *Physiological consequences of using an upper limb exoskeleton during manual handling tasks*. Applied ergonomics, 67, 211-217.

Tiwari, P., Warren, J., Day, K. J., & MacDonald, B. (2010). *Some non-technology implications for wider application of robots to assist older people*. Health Care and Informatics Review Online.

Veneman, J. F. (2017). *Safety standardization of wearable robots - The need for testing methods*. In Wearable Robotics: Challenges and Trends (pp. 189-193). Springer, Cham.

Villaronga, E. F. (2019). *Robots, standards and the law: Rivalries between private standards and public policymaking for robot governance*. Computer Law & Security Review, 35(2), 129-144.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

Weston, E. B., Alizadeh, M., Knapik, G. G., Wang, X., & Marras, W. S. (2018). *Biomechanical evaluation of exoskeleton use on loading of the lumbar spine*. Applied ergonomics, 68, 101-108.

Whitfield, B. H., Costigan, P. A., Stevenson, J. M., & Smallman, C. L. (2014). *Effect of an on-body ergonomic aid on oxygen consumption during a repetitive lifting task*. International Journal of Industrial Ergonomics, 44(1), 39-44.

Williams, N. (2017). *The Borg rating of perceived exertion (RPE) scale*. Occupational Medicine, 67(5), 404-405.

Xu, H., & Borson, J. E. (2018, October). *The Future of Legal and Ethical Regulations for Autonomous Robotics*. In 2018 IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS) (pp. 2362-2366). IEEE.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.

INBOTS

Inclusive Robotics for a better Society

www.inbots.eu

@INBOTS_CSA

@INBOTS_CSA

@INBOTS_CSA

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 780073.