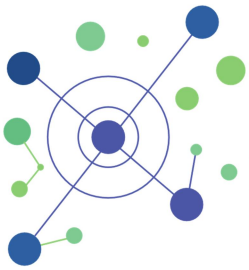
INBOTS
Inclusive Robotics for a better Society

PRELIMINARY WHITE PAPER ON 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.



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Versioning and Contribution History

Version	Date	Modified by	Modification reason
v.01			
v.02			
v.03			

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1. Executive Summary

The Preliminary White Paper is dedicated to possible future interactive robotic standardisation activities. An interactive robot is a programmable mechanism with a degree of autonomy moving within its environment to perform intended tasks in close proximity with humans. 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 Preliminary 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. It has to be discussed in the future if and how the structure of standards and standardisation in general can be improved.

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2. Preface

The aim of this Preliminary White Paper is to disseminate knowledge about current and future standardisation topics within the scope of interactive robots. The target group of this Preliminary White Paper are stakeholders engaged in the development, manufacturing and employment of interactive robots as well as the European Commission (EC). The document is structured in nine 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 3rd section. The standardisation organisations are introduced and frequently asked questions are addressed and answered. 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 4. Each domain describes the devices usually used and the technologies behind them. The categorisation focuses on where the interactive robots are primarily used. This is only one option to access interactive robots and it is closely related to the structure of European directives e.g. Directive 2006/42/EC on Machinery or Directive 93/42/EEC on Medical Devices. 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 5. The different types of standards, the search methodology as well as the technical committees and interactive 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 6. 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 7th section is related to the INBOTS standardisation survey and describes the findings pertinent to the challenges that the robotics community faces in terms of standardisation and the legal framework.

Section 8 is supposed to complete the picture by showing how the identified standardisation potentials can become standardisation activities and section 9 gives an overview of the key findings of this Preliminary White Paper.

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

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3. Introduction to standardisation

This section introduces the structure of the standardisation system. The functions of the European and International standardisation organisations, fundamental questions on standardisation and legal subjects are explained.

1. European and international standardisation

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. Standards provide a basis for mutual understanding amongst individuals, businesses, public authorities and other kinds of organisations. They facilitate communication, commerce, measurement and manufacturing.

European standardisation

The European standardisation organisations are umbrella organisations that consist of NSBs, including the European Union member states and other countries that are part of the European single market. The three recognised European standardisation organisations are:

- ***European Committee for Standardisation***

- ***European Committee for Electrotechnical Standardisation***

- ***European Telecommunications Standards Institute***

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.

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

[1] EN 45020:2006 Standardisation and related activities – General vocabulary.

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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

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

NSBs represent the national interests in the following international organisations:

- ***International Organisation for Standardisation***

- ***International Electrotechnical Commission***

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. The mirror committees also decide whether an international standard should be adopted as a national standard[4].

2. Fundamental questions on standardisation

Who are the stakeholders that take part in standardisation?

Standardisation is open to everybody. Stakeholders in standardisation include for example: manufacturers, consumers, tradespersons, researchers, insurance companies, government agencies and testing bodies. Organisations send their employees to participate in working groups of technical committees and consumers are represented by the consumer council.

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

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Who develops standards?

The content of standards is developed by stakeholders and not by NSBs; the latter ones are responsible for the project management of standardisation activities. The NSBs coordinate the work at national, European and international level[5].

What are the benefits of using standards?

- ***Complying with standards facilitates market access***
- ***Removes trade barriers***
- ***Standards support the dissemination of technology knowledge and accelerate the introduction of innovations on the market***
- ***Standards ensure that products and services are state-of-the-art***
- ***Standards ensure safety, for example within the framework of CE marking***
- ***Standards reduce product liability risks***
- ***Cost reduction through mass production and global purchasing, reduced transaction costs, lower adjustment costs, and shorter development times***
- ***Standards define interfaces and compatibility requirements[6]***

What efforts are required to use standards?

Potential robotic standard users often like to know how much effort it takes to use and apply standards, but there is no simple answer to this question. Users have to evaluate for themselves if the benefits of using standards are higher than the costs for the resources spent to apply them.

Why are standards not free of charge available?

Standards contain the combined knowledge of all market partners which is gathered during a fair process moderated by the NSB. By purchasing standards, standards users ensure the private financing of standards work. In fact, most of NSB's work (largely the management of standards projects) is financed through the sales of standards. The cost of developing standards is thus distributed among those who gain the most benefits from them. In this way industry itself determines which standards are in line with the market[7].

How can an organisation take part in standardisation?

The nature of participation depends on the interests and resources of the organisation. For the participation in standardisation for interested organisations, the following options apply:

- ***Proposal for revising standard or developing a new standard***
- ***Standards work within a technical committee***
- ***Commenting on draft standard***

For further information contact your NSB.

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[5] DIN 820-1:2014 Standardisation – Part 1: Principles.
[6] European Commission, "Benefits of standards", accessed July 2, 2019, https://ec.europa.eu/growth/single-market/european-standards/policy/benefits_en.
[7] German Institute for Standardisation, "FAQ", accessed July 2, 2019, https://www.din.de/en/about-standards/benefits-for-the-private-sector/sme-commission-kommit/faq.

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3. Legal significance of (safety) standards in Europe

The European standards published by CEN, CENELEC or ETSI 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.

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 greatly 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 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.

Standards can help to determine if a product is "fault free"

Technical standards play a special role in commercial law, because courts can use them to help determine whether a product is defective or not. Written by neutral experts, standards describe what it takes to make a good or service fault-free. Because courts deem standards to be acknowledged rules of technology, they often assume a product has been manufactured with due care if it complies with the relevant standards. However, where the use of a standard has not been made mandatory, non-compliance does not necessarily mean the product is defective. After all, products can be manufactured with due care even where standards have not been consulted, especially as their use is voluntary. In such cases, the seller or manufacturer has to find another way to prove that the product fulfils the customary requirements. If this cannot be done, the buyer can then assert statutory warranty rights. These rights include the removal of the fault, delivery of a fault-free product, or compensation for any damages arising from the absence of warranted characteristics.

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In exceptional cases a product may be deemed faulty in a legal sense even if it complies with the relevant technical rules. This is the case, for example, if further legal provisions apply that are not laid down in the standard, or if certain risks have not been considered in the standard.

"Presumption of conformity" in European law

Many European directives and national legislations lay down essential requirements for products, which are then explained in more detail in standards. 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.

Harmonised European 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. 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[8].

CE marking

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. Some directives require conformity assessment by a neutral third party, called a notified body, before the marking can be applied. By applying the CE mark, a manufacturer declares on his/her sole responsibility that the product meets all the legal requirements and can thus be placed on the European market. 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.

[8] German Institute for Standardisation, "An introduction to standardisation – a practical guide for small businesses", accessed July 2, 2019, https://www.din.de/blob/195038/64b75612aae6d6e7341e815becadb5d9/an-introduction-to-standardization-data.pdf.

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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].

4. 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 Preliminary White Paper focused on and the technologies behind them. The section introduces the INBOTS standardisation survey, which was conducted to acquire an inside perspective from interactive robotic experts on their needs and challenges in robotic standardisation.

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

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

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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[10].

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[11]:

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

Exoskeletons are wearable, external mechanical structures that help or enhance the abilities of a person[12]. 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[13]. 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.

[10] ISO 8373:2012 Robots and robotic devices – Vocabulary.
[11] 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.
[12] Michiel De Looze, Tim Bosch, Frank Krause, Konrad S. Stadler, and Leonard W. O'Sullivan. "Exoskeletons for industrial application and their potential effects on physical work load", Ergonomics 59, no. 5 (2016):671-681.
[13] R. A. Gopura and Kazuo Kiguchi, "Mechanical Designs of Active Upper-limb Exoskeleton Robots", 2009 IEEE International Conference on Rehabilitation Robotics, pp. 178-187, 2009.

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MSDs are injuries and disorders that affect the human body's movement or musculoskeletal system (e.g. muscles, tendons, ligaments, nerves, discs, blood vessels)[14]. 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 %[15] and the impact on the gross domestic product of the related countries (up to 3.3 %) increases the focus on the phenomenon[16]. 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.

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[17], 10218-2:2011[18] and ISO/TS 15066[19]. 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

[14] ErgoPlus, "The Definition and Causes of Musculoskeletal Disorders", accessed July 2, 2019, https://ergo-plus.com/musculoskeletal-disorders-msd/.
[15] European Agency for Safety and Health at Work, "OSH in figures: Work-related musculoskeletal disorders in the EU – Facts and figures", accessed July 2, 2019, https://osha.europa.eu/en/tools-and-publications/publications/reports/TERO09009ENC/view.
[16] 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 July 2, 2019, https://osha.europa.eu/en/about-eu-osha/press-room/eu-osha-presents-new-figures-costs-poor-workplace-safety-and-health-world.
[17] ISO 10218-1:2011 Robots and robotic devices – Safety requirements for industrial robots – Part 1: Robots.
[18] ISO 10218-2:2011 Robots and robotic devices – Safety requirements for industrial robots – Part 1: Robot systems and integration.
[19] ISO/TS 15066:2016 Robots and robotic devices – Collaborative robots.

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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.

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)

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"[20].

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 B56.5:2013[21]), while AGVs in Europe follow the Machinery Directive 2006/42/EC (e.g. EN 1525:1997[22] or ISO/FDIS 3691-4[23]).

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

[20] ISO 8373:2012 Robots and robotic devices – Vocabulary.
[21] ANSI B56.5:2013 Safety Standard for Driverless, Automatic Guided Industrial Vehicles and Automated Functions of Manned Industrial Vehicles.
[22] EN 1525:1997 Safety of industrial trucks - Driverless trucks and their systems.
[23] ISO/FDIS 3691-4 Industrial trucks – Safety requirements and verification - Part 4: Driverless industrial trucks and their systems.

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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 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. 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. 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[24].

[24] Priyesh Tiwari, Jim Warren, Karen J. Day, and Bruce MacDonald, "Some non-technology implications for wider application of robots to assist older people", Health Care and Informatics Review Online. 2010.

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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[25].

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[26].

Main applicable standards and regulations for interactive robotics in the healthcare domain are summarised in section 5. 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. 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).

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.

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.

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

[25] BCC-Research-Staff, "Robotics: Technologies and Global Markets", BCC Research Report, 2010.
[26] 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.

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hospital or in a specialist care facility. 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.

Rehabilitation and assistive robots are covered by ISO 13482:201427. This standard focuses on personal care robots, which are service robots that perform actions contributing directly towards the improvement of the quality of life of humans, excluding medical applications. The standard covers mobile servant robots, physical assistant robots and person carrier robots. A personal care robot is a service robot that performs actions contributing directly towards improvement in the quality of life of humans, excluding medical applications like clinical robots.

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 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[28].

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.

4. Service robots

A service robot performs useful tasks for humans or equipment excluding industrial automation applications[29]. 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

[27] ISO 13482:2014 Robots and robotic devices – Safety requirements for personal care robots.
[28] 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.
[29] ISO 8373:2012 Robots and robotic devices – Vocabulary.

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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.

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 Directive. 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. Other technologies are simply used in a single domain. Thus, the technologies set the capabilities and the domains the requirements[30].

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.

6. INBOTS standardisation survey

The survey was developed by the INBOTS project and 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

[30] 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.

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engaged in the development, manufacturing and employment of interactive robots to share their experiences on this topic. The survey was structured in five sections:

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)***

Information on the surveyed organisations

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 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.

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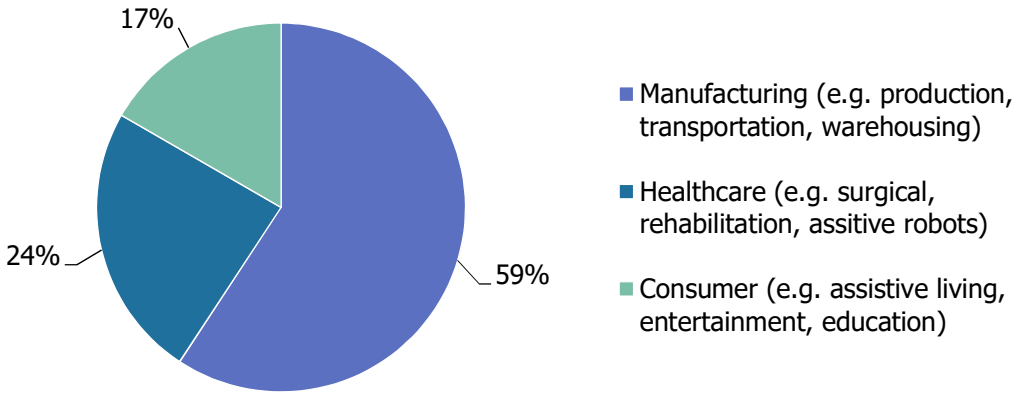

Figure 1: Surveyed organisations and their domains

The majority of the 44 organisations that answered the standardisation survey are large organisations (see Figure 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 and in the INBOTS network are spin-offs, which are usually rather small organisations.

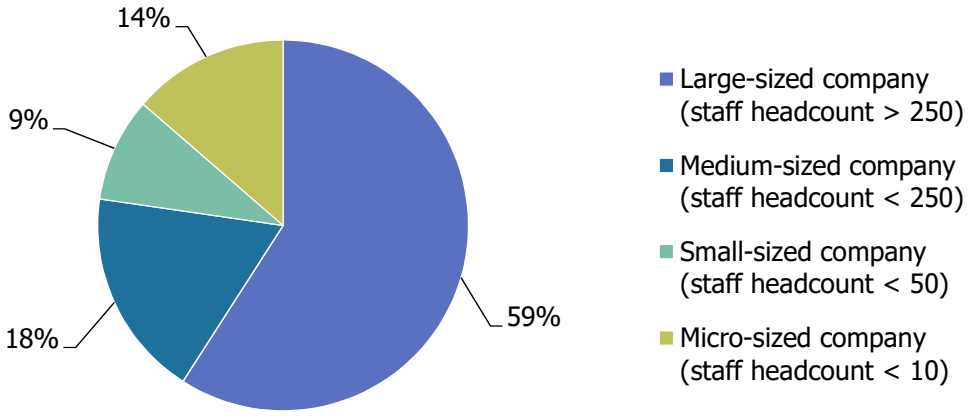

Figure 2: Surveyed organisations sizes

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 3).

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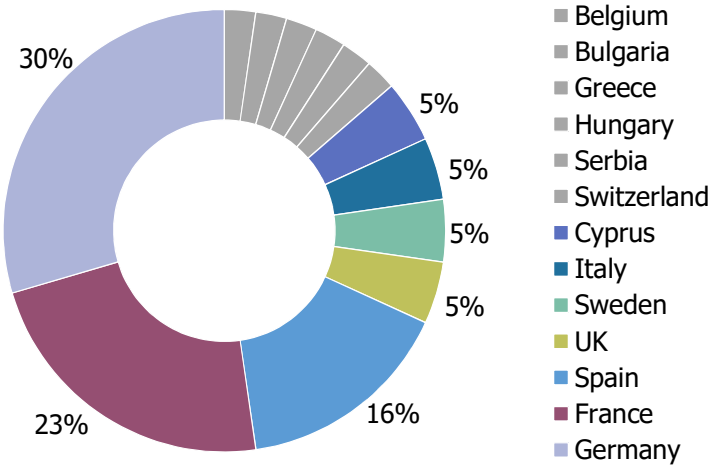

Figure 3: Surveyed organisations origin

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

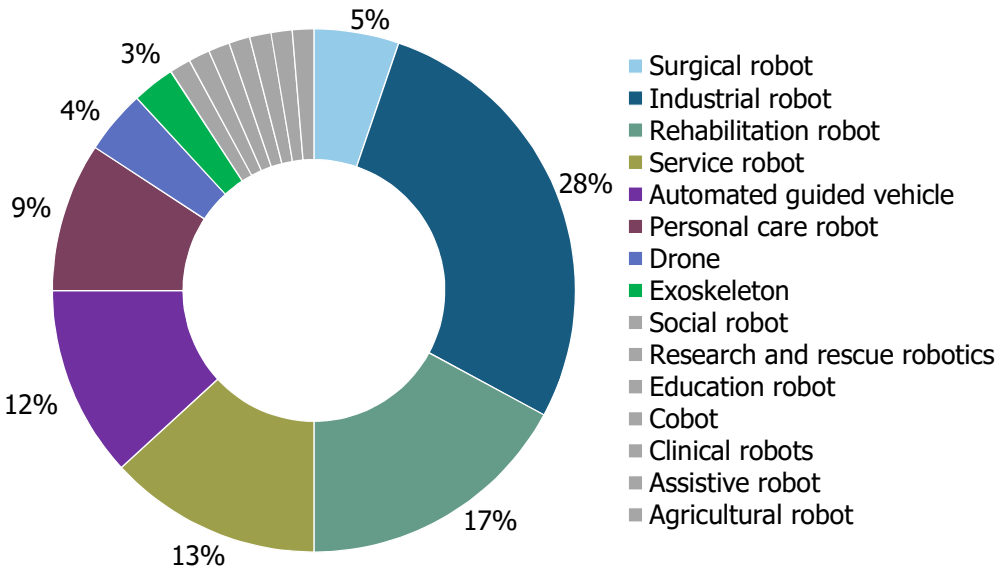

Figure 4: Surveyed organisations robot overview

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.

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5. State of the art – standardisation landscape

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. This section gives an overview of the standards, TCs that develop standards for interactive robots and the liaisons of TCs.

With this section the readers gain an overview of potentially relevant standards for their interactive robots. The research gives an indication of 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.

1. International standardisation activities

The following international 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.

ISO/TC 299 Robotics

ISO/TC 299 is active in the field of robotics in the manufacturing, healthcare and consumer domain, excluding toys and military applications. They develop standards on for example personal care robots, service robots, industrial robots, mobile robots, medical electrical equipment, and collaborative robots. The TC has *liaisons with: ISO/TC 199 Safety of machinery, ISO/TC 184 Automation systems and integration, ISO/TC 173 Assistive products, and ISO/IEC JTC 1/SC 35 User interfaces* [31].

IEC/SC 62 Electrical equipment in medical practice

IEC/SC 62 prepares international standards and other publications concerning electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment. The TC has liaisons with: IEC/TC 124 *Wearable electronic devices and technologies* and SyC AAL *Active Assisted Living* as well as with ISO/TC 215 *Health informatics* [32].

ISO/TC 173 Assistive products

ISO/TC 173 is active in the field of assistive products and related services to assist a person in compensating for reduced abilities. The TC has liaisons with: ISO/TC 299 *Robotics*, ISO/TC 168 *Prosthetics and orthotics*, and ISO/TC 159 *Ergonomics* [33].

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[31] International Organization for Standardization, "ISO/TC 299 Robotics", accessed July 2, 2019, https://www.iso.org/committee/5915511.html.
[32] International Electrotechnical Commission, "TC 62 Electrical equipment in medical practice", accessed July 2, 2019, https://www.iec.ch/dyn/www/f?p=103:7:0:::FSP_ORG_ID,FSP_LANG_ID:1245,25.
[33] International Organization for Standardization, "ISO/TC 173 Assistive products", accessed July 2, 2019, https://www.iso.org/committee/53782.html.

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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, including people having accessibility or other specific needs, with a priority of meeting the JTC 1 requirements for cultural and linguistic adaptability. The TC has liaisons with: ISO/TC 299 *Robotics*, ISO/TC 159 Ergonomics, ISO/TC 173 *Assistive products*, and ISO/IEC JTC 1 *Information technology* [34].

ISO/TC 159 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. The TC has liaisons with: ISO/TC 199 *Safety of machinery*, ISO/TC 173 *Assistive products*, and ISO/IEC JTC 1/SC 35 *User interfaces* [35].

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[36]. A wearable is a robot operating alongside human limbs, as is the case in orthotic robots, exoskeletons or robotic suits. The TC has liaisons with: ISO/TC 173 *Assistive products* [37].

ISO/TC 199 Safety of machinery

ISO/TC 199 standardises basic concepts and general principles for safety of machinery incorporating terminology, methodology, guards, risk assessments and safety devices. Excluding product safety standards, which are explicitly covered by the work of other ISO or IEC technical committees. The TC has liaisons with: ISO/TC 299 *Robotic* and ISO/TC 159 *Ergonomics* [38].

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[34] International Organization for Standardization, "ISO/IEC JTC 1/SC 35 User interface", accessed July 2, 2019, https://www.iso.org/committee/45382.html.
[35] International Organization for Standardization, "ISO/TC 159 Ergonomics", accessed July 2, 2019, https://www.iso.org/committee/53348.html.
[36] ISO 8549-1:2011 Prosthetics and orthotics – Vocabulary – Part 1: General terms for external limb prostheses and external orthoses.
[37] International Organization for Standardization, "ISO/TC 168 Prosthetics and orthotics", accessed July 2, 2019, https://www.iso.org/committee/53630.html.
[38] International Organization for Standardization, "ISO/TC 199 Safety of Machinery", accessed July 2, 2019, https://www.iso.org/committee/54604.html.

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ISO/IEC JTC 1/SC 27 IT Security techniques

ISO/IEC JTC 1/SC 27 develops standards for the protection of information and ICT. This includes generic methods, techniques and guidelines to address both security and privacy aspects[39].

2. European standardisation activities

The following European technical committees develop standards that are relevant for interactive robots. European technical committees develop standards themselves and also mirror international standards according to the Vienna Agreement. There is no European technical committee that is merely dedicated to robotics. Robotic standardisation is mainly carried out on international level with European technical committees taking over international standards on European level.

CEN/TC 310 Advanced Manufacturing Technologies

CEN/TC 310 is active in the field of automation systems to ensure the availability of standards for design, manufacturing, maintenance and disposal of products and their associated services. Areas of standardisation may include enterprise modelling and system architecture, information and its supporting systems, robotics for fixed and mobile robots in industrial and specific non-industrial environments, automation and control equipment and software, human and mechanical aspects, integration technologies and system operational aspects. This TC does currently not work on European standards - the TC mirrors the international work of for example ISO/TC 299 *Robotics* [40]. There is no information available on the liaisons of CEN/TC 310.

CLC/TC 44X Safety of machinery – Electrotechnical aspects

CLC/TC 44X prepares harmonised standards primarily relating to electrical and electronic equipment and systems of machines (including a group of machines working together in a coordinated manner excluding higher-level systems aspects) not portable by hand while working, but which may include mobile equipment. The equipment covered commences at the point of connection of the electrical supply to the machine. There is no information available on the liaisons of CLC/TC 44X[41].

CLC/TC 62 Electrical equipment in medical practice

CLC/TC 62 mirrors the work of IEC/TC 62 and its sub-committees and therefore has the same scope as IEC/SC 62 *Electrical equipment in medical practice.* The IEC/TC 62 standards are published as identical European standards. The IEC/EN 60601 family is, together with its

[39] International Organization for Standardization, "ISO/IEC JTC 1 /SC 27 Information security, cybersecurity and privacy protection", accessed July 2, 2019, https://www.iso.org/committee/45306.html.
[40] European Committee for Standardization, "CEN/TC 310 Advanced automation technologies and their applications", accessed July 2, 2019, https://kurzelinks.de/9um9.
[41] European Committee for Electrotechnical Standardization, "CLC/TC 44x Safety of machinery: electrotechnical aspects", accessed July 2, 2019, https://kurzelinks.de/zyqc.

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collateral standards, the foundation for standards for medical electrical equipment and systems[42].

CEN/TC 114 Safety of machinery

CEN/TC 114 standardises general principles for safety of machinery incorporating terminology and methodology. Development of general machinery standards (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. The TC has liaisons with: CEN/TC 122 *Ergonomics*, CEN/TC 211 *Acoustics*, CLC/TC 44X *Safety of machinery - Electrotechnical aspects*, and ISO/TC 199 *Safety of machinery*[43].

CEN/TC 122 Ergonomics

CEN/TC 122 is active in the field of ergonomic principles and requirements for the design of work systems and work environments, including machinery and personal protective equipment, to promote the health, safety and well-being of the human operator and the effectiveness of the work systems. There is no information available on the liaisons of CEN/TC 122[44].

CEN/TC 293 Assistive products and accessibility

CEN/TC 293 is active in the field of assistive products and related services including interoperability/interface between assistive and mainstream products to achieve accessibility. The major product categories that CEN/TC 293 presently deals with are wheelchairs, accessories to wheelchairs and assistive products for walking. There is no information available on the liaisons of CEN/TC 293[45].

3. Analysis of standards

This subsection describes the different types of standard documents focusing on two categorisation options - consensus degree and content of standards. 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 identified relevant directives and harmonised standards of interactive robots will also be examined. In the end, the outcome of the survey on standardisation in terms of the usage of standards is evaluated.

a. 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

[42] European Committee for Electrotechnical Standardization, "CLC/TC 62 Electrotechnical equipment in medical practice", accessed July 2, 2019, https://kurzelinks.de/7805.
[43] European Committee for Standardization, "CEN/TC 114 Safety of machinery", accessed July 2, 2019, https://kurzelinks.de/n6no.
[44] European Committee for Standardization, "CEN/TC 122 Ergonomics", accessed July 2, 2019, https://kurzelinks.de/kih8.
[45] European Committee for Standardization, "CEN/TC 293 Assistive products and accessibility", accessed July 2, 2019, https://kurzelinks.de/ji7d.

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should be based on the consolidated results of science, technology and experience, aiming at the promotion of the optimum community benefits.

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.

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.

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

While the above 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[46, 47].

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.

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

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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

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.

b. Search methodology

With the support of search terms, the identification of existing standards and ongoing standardisation activities led to a list of 148 interactive robot related standards. The results can be downloaded from the INBOTS website[48]. 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

[48] INBOTS, "Standardisation", accessed July 2, 2019, http://inbots.eu/contributing-to-inbots/standardisation/.

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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 ICT, general issues as well as testing. The complete overview is shown in Figure 5.

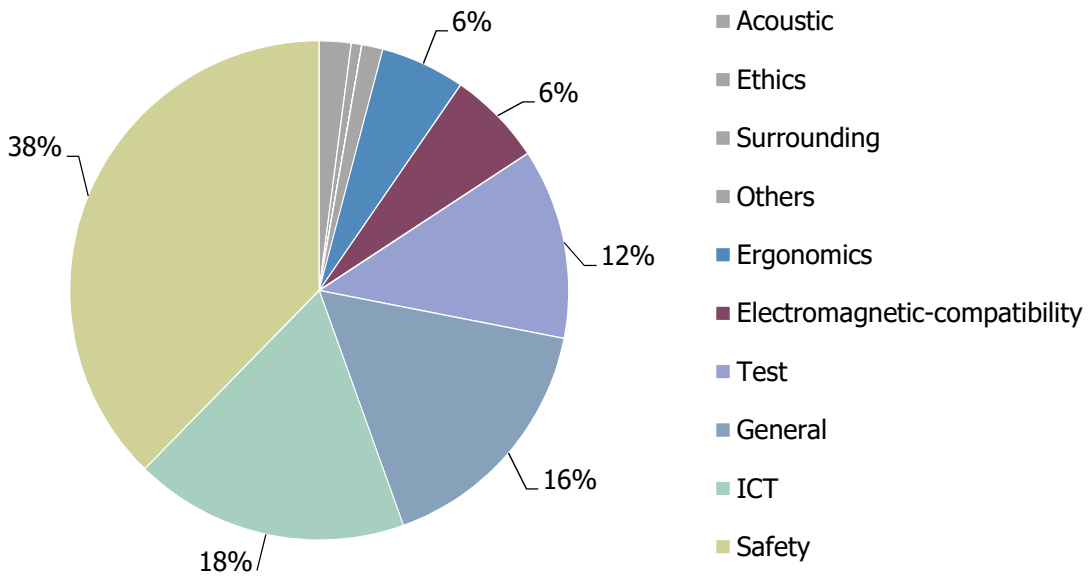

Figure 5: Standardisation landscape - percentage distribution per category

c. Identified 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 148 standards, only 30 standards are directly related to robots. The remaining 108 standards are beneficial for

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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. This aligns with the outcome of the survey on standardisation of interactive robots. To the question of the preferred level of standardisation the questioned stated that they are in favour of the international rather than the European standardisation level. In total 44 organisations answered the question and 84 % advocate the international level. The questioned stated the following reasons for their preference:

- ***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).***

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 seem to be mainly 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.

Standards on industrial robots focus on vocabulary, performance criteria, test methods, characteristics, interfaces, collaboration, and safety requirements. 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 robot.
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

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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
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

Standards on personal care robots focus on safety requirements, test methods and an application guide (see Table 4). ISO 13482 focuses on mobile servant robots, physical assistant robots, and person carrier robots. The standard describes hazards associated with the use of these robots, and provides requirements to eliminate, or reduce, the risks associated with these hazards to an acceptable level. ISO/DTR 23482-1 is currently under development to support the application of EN ISO 13482.

Table 4: Overview of personal care robot standards

No.	Title
ISO 13482	Robots and robotic devices - **Safety requirements** for personal care robots (ISO 13482:2014)
ISO/DTR 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**

Service robot standards focus on performance criteria and test methods for wheeled robots as shown in Table 5. ISO 18646-1 for example describes methods for specifying and evaluating

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the locomotion performance of wheeled robots in indoor environments. Standards concerning navigation, manipulation, wearable robots and modularity are currently under development.

Table 5: Overview of service robot standards

No.	Title
ISO 19649	Mobile robots – **Vocabulary** Note: This standard applies to industrial and service robot.
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/CD 18646-3	Robotics - **Performance criteria** and related **test methods** for service robots - Part 3: Manipulation
ISO/CD 18646-4	Robotics - **Performance criteria** and related **test methods** for service robots - Part 4: Wearable robots
ISO/CD 22166-1	Robotics - Part 1: **Modularity** for service robots - Part 1: General requirements

Standards on medical electrical equipment focus on steps to be taken to perform a detailed risk management for systems employing a degree of autonomy. Currently under development are standards on the basic safety and essential performance of medial robots for surgery and medical robots for rehabilitation, as shown in Table 6.

Medical electrical equipment refers to 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: 1) in the diagnosis, treatment, or monitoring of a patient; or 2) for compensation or alleviation of disease, injury or disability[49].

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

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

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IEC/FDIS 80601-2-77	Medical electrical equipment - Part 2-77: Particular requirements for the **basic safety and essential performance** of **medical robots for surgery**
IEC/FDIS 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

d. European directives and harmonised standards

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)[50].

Manufacturers that conform with 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"[51].

Directive 2006/42/EC on Machinery

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:

[50] European Committee for Standardization, "European Standardization", accessed July 2, 2019, https://www.cen.eu/you/EuropeanStandardization/Pages/default.aspx.
[51] Directive 2006/42/EC of the European Parliament and of the Council on machinery, May 17, 2006.

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- ***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). In total, there are 35 harmonised standards of the machinery directive applicable to interactive robots (see list of standards on INBOTS website).

Directive 93/42/EEC on Medical Devices

Medical devices in this directive refer to any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- ***diagnosis, prevention, monitoring, treatment or alleviation of a disease;***
- ***diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap;***
- ***investigation, replacement or modification of the anatomy or of a physiological process.***

In total, there are 18 harmonised standards of the medical device directive applicable to interactive robots (see list of standards on INBOTS website).

Regulation (EU) 2017/745 on Medical Devices

The new European Medical Device Regulation (EU MDR) will replace the current directive 93/42/EEC in 2020. The changes were published on May 2017 and will come into force on May 2020. The main changes are listed below[52]:

- ***Any existing products with the CE marking under previous regulations/directives must be recertified and a Unique Device Identification (UI) will be 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, cleaning products, and liposuction equipment.***
- ***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.***

It is suspected by INBOTS that because of the new EU MDR, the OJEU does not reflect the current standardisation landscape anymore. Harmonised standards that are for example referred to in the OJEU are already withdrawn from the market and replaced by a new version. The Journal does therefore not reflect the current state-of-the-art. For example EN ISO 11135-

[52] European Commission, "Regulator framework", accessed July 2, 2019, https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en.

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1:2007[53] is withdrawn from the market and was replaced by EN ISO 11135:2014, but there is no reference of the latest version in the OJEU.

Directive 2014/30/EU on Electromagnetic Compatibility

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. In total, there are 11 harmonised standards of the electromagnetic compatibility directive applicable to interactive robots (see list of standards on INBOTS website).

Directive 2014/35/EU on Low Voltage

The directive applies to electrical equipment designed for the use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current. It applies to a wide range of electrical equipment for both consumer and professional usage, such as: household appliances, cables, and power supply units. Harmonised standards of 2014/35/EU were not taken into account in the research of relevant standards. The harmonised standards need to be identified for specific interactive robots.

4. Usage of standards

The INBOTS standardisation survey included questions on the usage of standards. Results show that 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 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.

[53] EN ISO 11135-1:2007 Sterilization of health care products.

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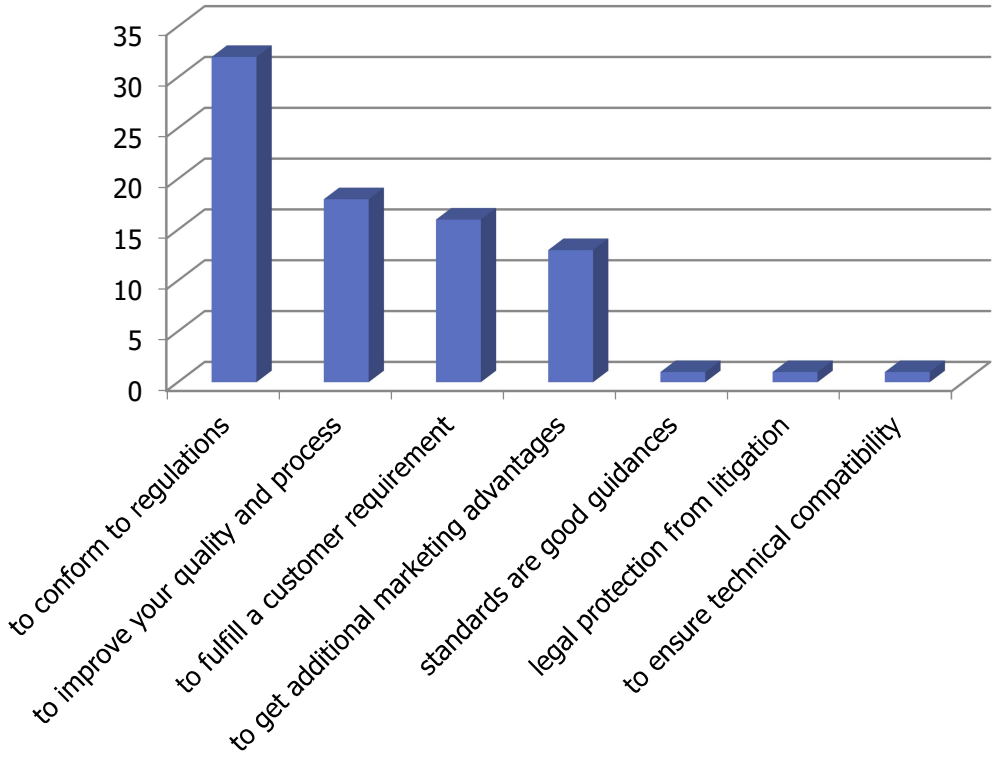

Figure 6: Why do organisations use formal standards?

The decisive reason for organisations not to use formal standards is that they have interpretation problems (see Figure 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 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. The question was multiple-choice and not mandatory. In total 26 organisations answered the question on why they are not using formal standards.

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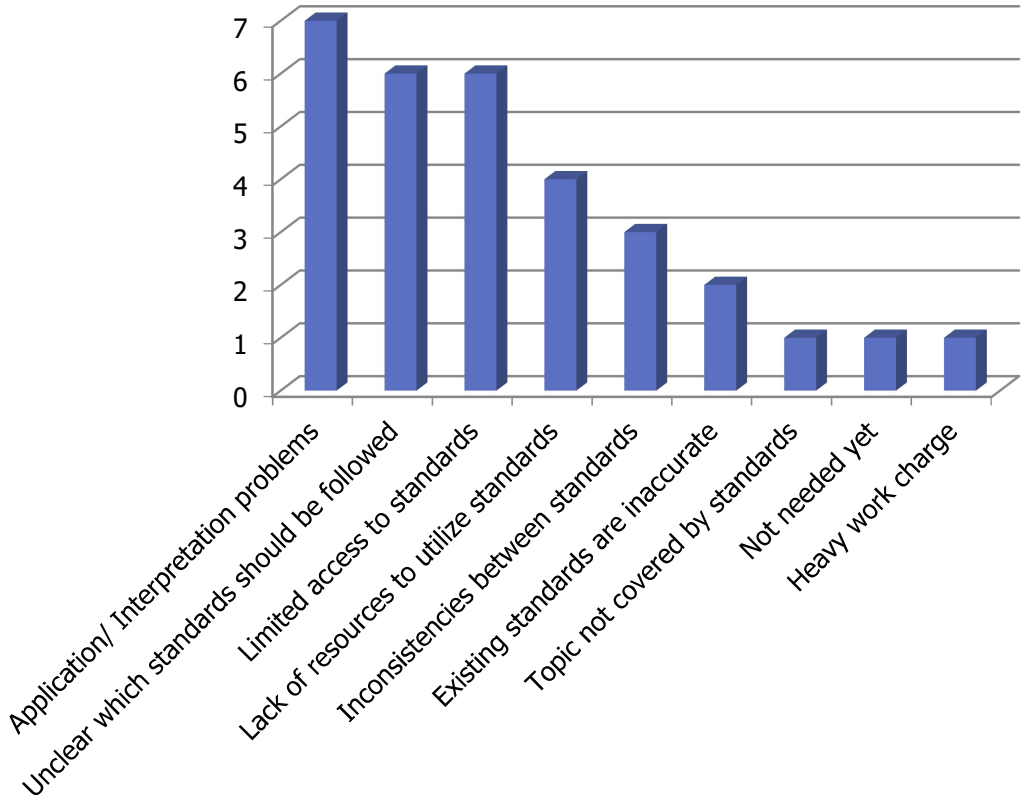

Figure 7: Why are organisations not using formal standards?

At the INBOTS conference 2018 and the European Robotics Forum 2019 participants stated the following issues:

- ***Standardisation system access challenging***
- ***Standards not detailed enough***
- ***Standards are no code books***
- ***Standards are too expensive***

6. Potentials for future standards

This section basically connects the state-of-the-art in terms of the standardisation of interactive robots to its potentials. The goal is to identify gaps between these two stages, and come up with an action plan to close them.

1. INBOTS consortium potentials

The following standardisation potentials were identified by the INBOTS consortium.

a) Title: Robotics – Measurement of autonomy

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

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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.

b) ***Title: Robotics – Performance criteria and related test methods for service robots – Definition of performance metrics for wearable robots***

Scope: This standard defines performance metrics that allow the characterisation and comparison of the assistive or augmentative potential of wearable robots. It describes metrics pertaining to mechanical and sensory functions, and presents measurement setups and protocols to determine these metrics for a specific device. This standard does not address a general performance index of a wearable robot and does not determine if it would or would not be suitable for a certain application. 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. Safety of devices is covered in other standards and regulations, so it is not considered in the scope of this standard.

Affected domains: Healthcare domain.

c) ***Title: Robotics – Performance criteria and related test methods for service robots – Device categories for wearable robots***

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) ***Title: Robotics – Contact surfaces in human-robot systems – General requirements***

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. It 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 standard does not apply to robots that are not body-worn, or

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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) Title: Robotics – Test methods for devices used by non-professionals

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 the European Medical Device Directive 93/42/EEC, which will be replaced by the new European Medical Device Regulation in 2020, 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 home environments and other 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) Title: Robotics – Data confidentiality of vulnerable groups – Children, elderly and disabled people

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 data conducted on them is needed. This standard does not apply for interactive robots that do not manage personal data.

Affected domains: Healthcare and consumer domain.

g) Title: Robotics – Human-robot interaction – End-user requirements

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 and healthcare domain.

h) Title: Robotics – Privacy – Impact assessment

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

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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.

i) Title: Industrial Robots – Performance criteria and related test methods – Evaluation of active exoskeletons as wearable robots

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.

2. Potentials from the INBOTS standardisation survey

The INBOTS standardisation survey gave organisations outside of the INBOTS consortium the opportunity to elaborate 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 below topics related to interactive robots in current standardisation (see Table 8) 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 8: 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.

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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.
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. Based on this, 29 answers were accepted on the satisfaction with the standards quantity. The majority of participants stated that they are neutral; they are neither satisfied nor dissatisfied with the current robotics standards quantity (see Figure 8).

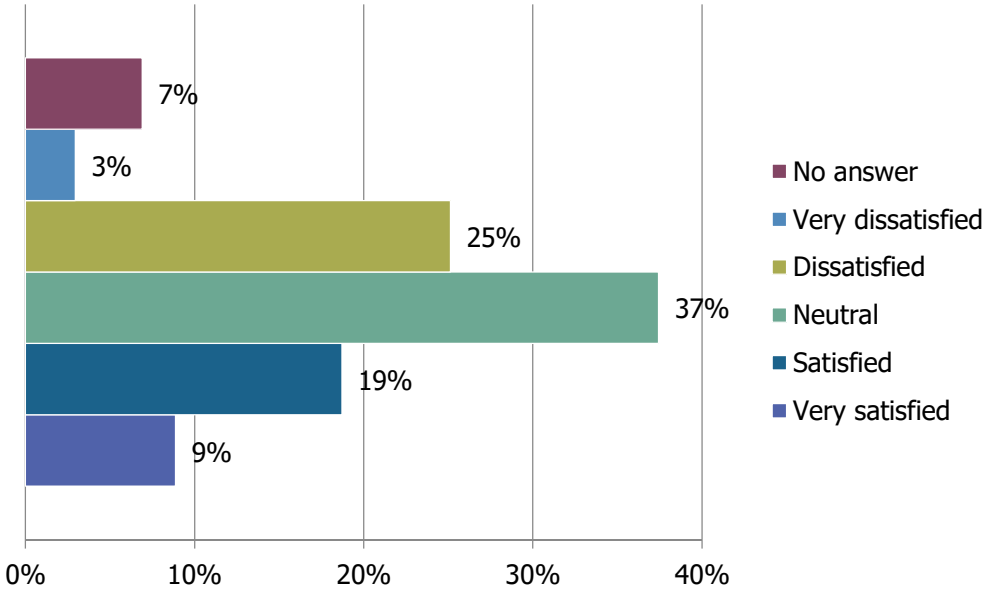

Figure 8: Satisfaction with standards quantity – Part 1/3

Figure 9 gives an overview of the total answers of the 29 participants 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.

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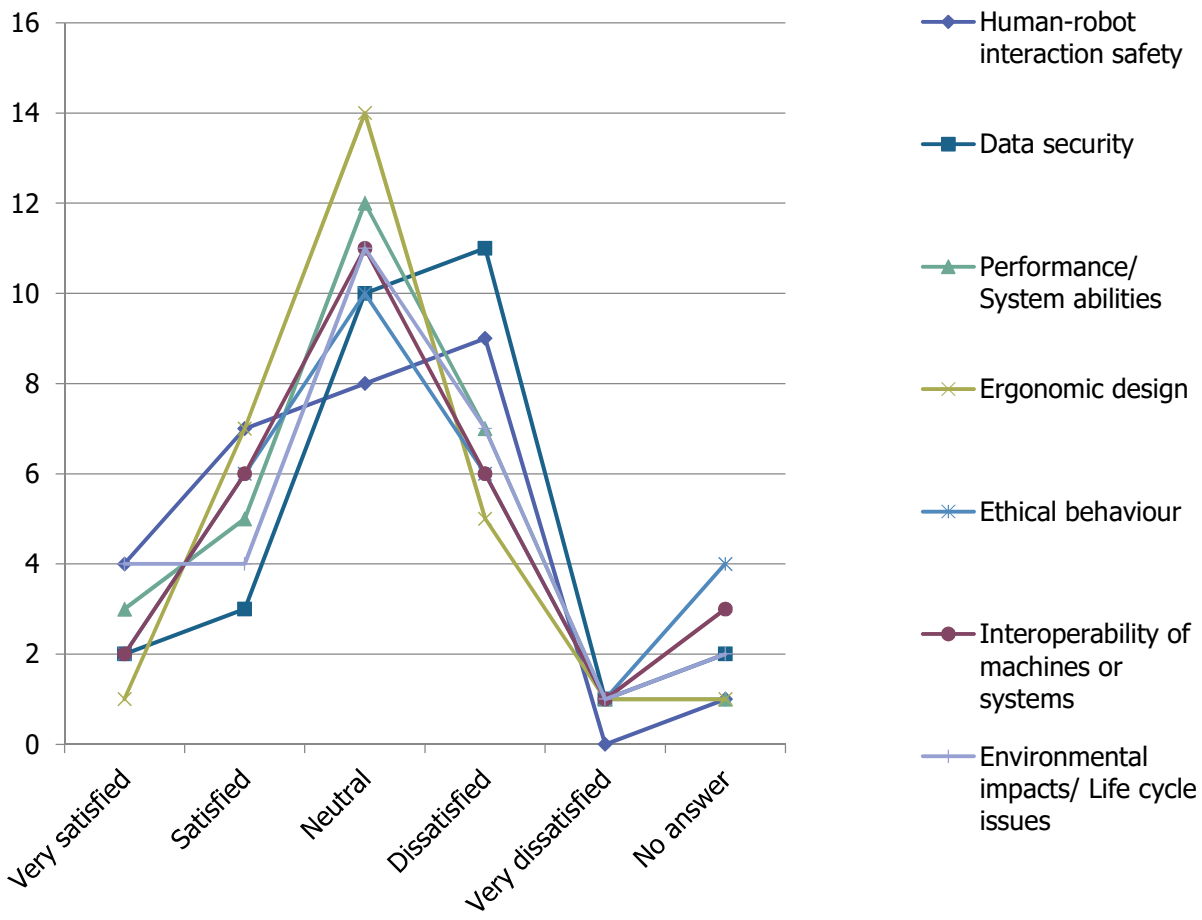

Figure 9: Satisfaction with standards quantity – Part 2/3

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. In total, 16 answers were accepted for the evaluation of this question. The number of answers is insufficient and therefore the results show only directions that need to be checked before further prosecution.

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 section 5 of this Preliminary White Paper on the usage of standards, very few people answered that they use standards because they are good guidances. Here they ask for guidelines and this shows that in general people want standards to be used as guidance documents, but currently only a few uses them in that way.

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In general, organisations ask for test, particular and supplementary standards, which have been described in section 5. In Table 9 the types of standards and the demands of the robotics community from the survey are connected.

Table 9: Satisfaction with standards quantity – Part 3/3

Type of standard	Definition
Test standard	**Test method**: Standard that is concerned with test methods, sometimes supplemented with other provisions related to testing, such as sampling, use of statistical methods or sequences of tests. Procedure that produces a test result. Question: How to measure something? **Metric:** Standard that contains a list of characteristics for which values or other data are to be stated for specifying the product, process or service. Refers for example to key performance indicators (quantitative description)[54]. Question: What is a sufficient and insufficient result?
Particular standard	**Characteristic**: Feature or ability of an interactive robot on which attributes data can be collected (qualitative description).
Supplementary standard	The following content is supplementary and can be described in a standard itself or in the annex of an existing one. **Benchmarks of best practices**: Standard that includes the description of the experience of others e.g. case studies, best practices. **Guideline:** A general principle or advice that determines a course of action.

3. Potentials from external sources other than the survey

The Robotics 2020 Multi Annual Roadmap (MAR) stated that there is a standardisation need for defining 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. The categorisation of standards per domain can support organisations in identifying useful standards for their products, services or processes. Human-robot interaction and environmental impact issues were also considered as standardisation potentials in the MAR[55].

Villaronga stated that ISO 13482:2014[56] focuses on physical safeguards and that this might not be sufficient to provide comprehensive protection to the user, because the standard disregards cognitive aspect. He also pointed out that current harmonised standards do not cover areas such as automated vehicles or collaborative robots/systems detailed enough[57]. 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 human shared space, e.g. regarding stability of the robot under different conditions, or the potential

[54] EN 45020:2006 Standardisation and related activities – General vocabulary.
[55] EU-Robotics, "Robotics 2020 - Multi Annual Roadmap". accessed July 2, 2019, https://www.eu-robotics.net/cms/upload/downloads/ppp-documents/Multi-Annual_Roadmap2020_ICT-24_Rev_B_full.pdf.
[56] ISO 13482:2014 Robots and robotic devices – Safety requirements for personal care robots focuses.
[57] Eduard Fosch Villaronga, "Robots, standards and the law: Rivalries between private standards and public policymaking for robot governance". Computer Law & Security Review 35, no. 2 (2019): 129-144.

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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/CD TR 23482-1[58].

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 on evaluating the potential physical risk to the person. Non-safety related performance testing will be described in ISO/CD 18646-4[59].

Villaronga has also stated that NSBs do not take enough consideration into non-technical, for example ethical issues, and that the industry dominates standardisation. In principle, everybody has the opportunity to comment on draft standards since they are publicly available. Not every private person uses 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 will develop a standardisation roadmap for Germany. In 2017, a joint initiative between ISO and IEC on artificial intelligence (ISO/IEC JTC 1/SC 42) was introduced. They are currently working on a standard on trustworthiness in Artificial Intelligence (ISO/IEC NP TR 24018). Thus, on national and international level the importance of ethical issues is being addressed increasingly.

Xu and Borson argued that for 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. The reasoning is based upon the fact that the differences between the different fields of autonomous robotics devices (autonomous cars, consumer electronics, and medical devices) are considerable[60].

Veneman reports the need for safety standards in wearable robotics, and more precisely 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[61].

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[62].

At the INBOTS conference 2018 participants stated the following issues:

- ***Hazards and risks not clearly defined with parameters and limits***
- ***Lack of performance measurement standards***

[58] ISO/CD TR 23482-1 Robotics – Application of ISO 13482 – Part 1: Safety-related test methods.
[59] ISO/CD 18646-4 Robotics – Performance criteria and related test methods for service robots – Part 4: Wearable robots.
[60] Huan Xu, and Joseph E. Borson, "The Future of Legal and Ethical Regulations for Autonomous Robotics", IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS), pp. 2362-2366. IEEE, 2018.
[61] Jan F. Veneman, "Safety standardisation of wearable robots – The need for testing methods", Wearable Robotics: Challenges and Trends, pp. 189-193, 2017.
[62] 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.

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- ***Modularity standards are missing***
- ***Active exoskeleton safety testing***
- ***Evaluation of industrial exoskeletons***
- ***Ethics of autonomous robots***

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. For the prosecution of standardisation potentials the standardisation body dealing with the potential should take the following points into account:

1) ***Impact on end-user of the potential standard (e.g. improvement of safety, cost savings for end-user organisation, improvement of robot capability)***
2) ***Impact on industry and research (e.g. increase of business opportunities, improvement of business quality management, Innovation progress, improvement of business functions)***
3) ***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.)***
4) ***Feasibility (e.g. expected support by standardisation member bodies, clear scope, clear work plan, properly balanced development team)***

7. General challenges

This section focuses on general challenges of the robotics community with standardisation and the regulatory framework. The basis is the INBOTS standardisation survey.

1. Standardisation

The INBOTS consortium wanted to know what reasons organisations have to not participate in the development of robotic standards. In total, 15 participants answered the not mandatory question why their organisations are not involved in the development of standards (see Figure 10). The organisations that are not active stated as the biggest reasons that the development process of standards is too time-consuming and complex and the study also shows that for smaller organisations standardisation has not been a topic so far. They usually do not want to use resources to send employees to participate in standardisation activities, because they do not consider standardisation as a strategic tool for their organisation besides patents. NSBs are aware of this issue and started initiatives to inform and attract start-ups as well as researchers. The research project BRIDGIT2 (long title: Bridge the gap between the research, innovation and standardisation community) for example seeks to improve the relation between the research and innovation community and standardisation (project receives funding from the European Union). The project consists of ten NSBs that work together to improve standardisation. Organisations also stated that the cost of time for participation and follow-up are too high and that the participation raises intellectual property issues. Especially the issue that the membership costs of standardisation bodies are too high is being worked on by NSBs with for example special deals for newcomers in standardisation.

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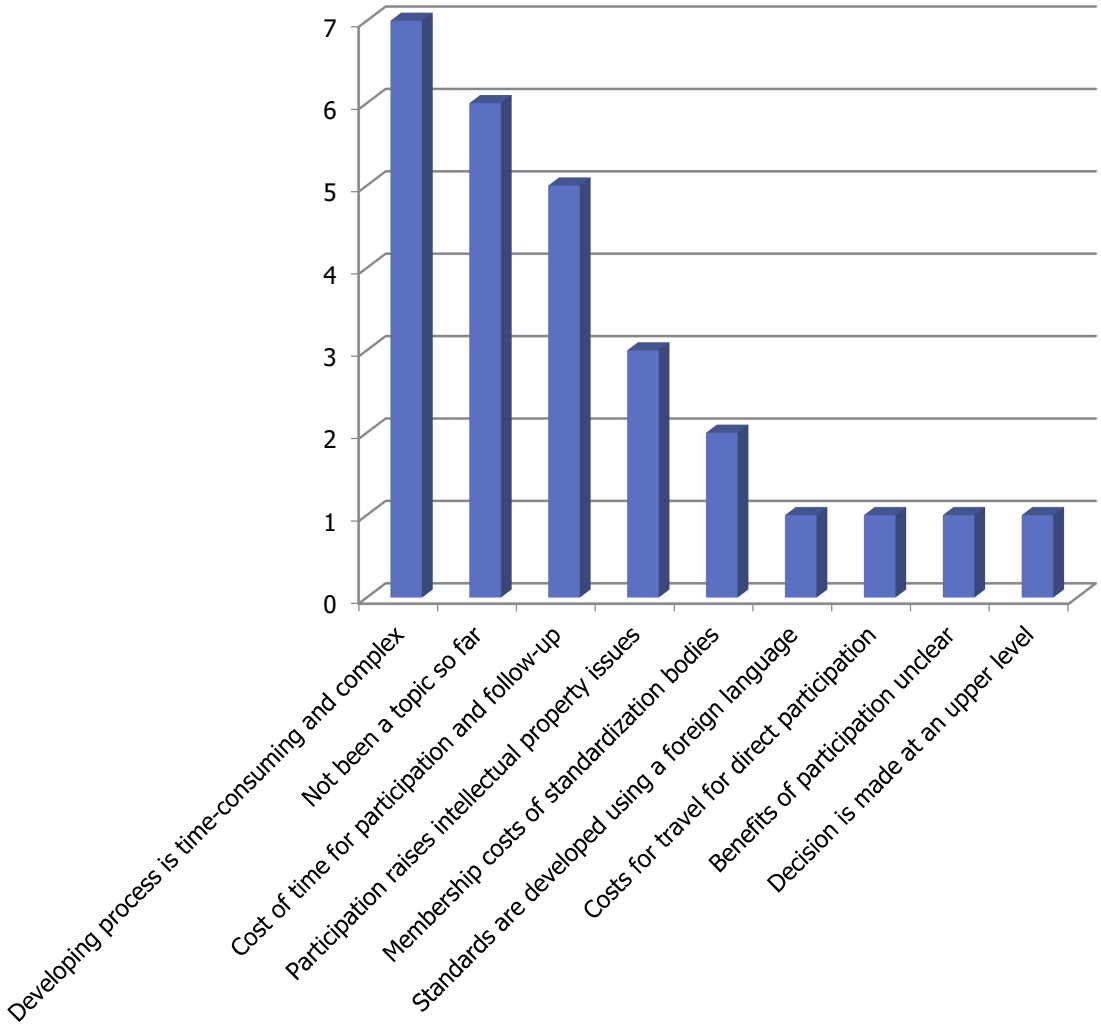

Figure 10: Reason for not participating in standardisation

The INBOTS consortium also wanted to understand the barriers for organisations that are active in robotic standardisation. The answers of the 27 organisations, which responded to the not mandatory multiple-choice question on their barriers, are summarized in Figure 11. They consider the time to market as the biggest barrier. The participants probably had formal standards and not specification or agreements in mind, which are usually developed in a couple of month. The second barrier is closely related to the first one, since the complex consensus-based decision process takes more time than voting. Companies involved also stated that they consider the drainage of know-how as an issue. By taking part in standardisation companies contribute to a greater good that will of course also support their own company.

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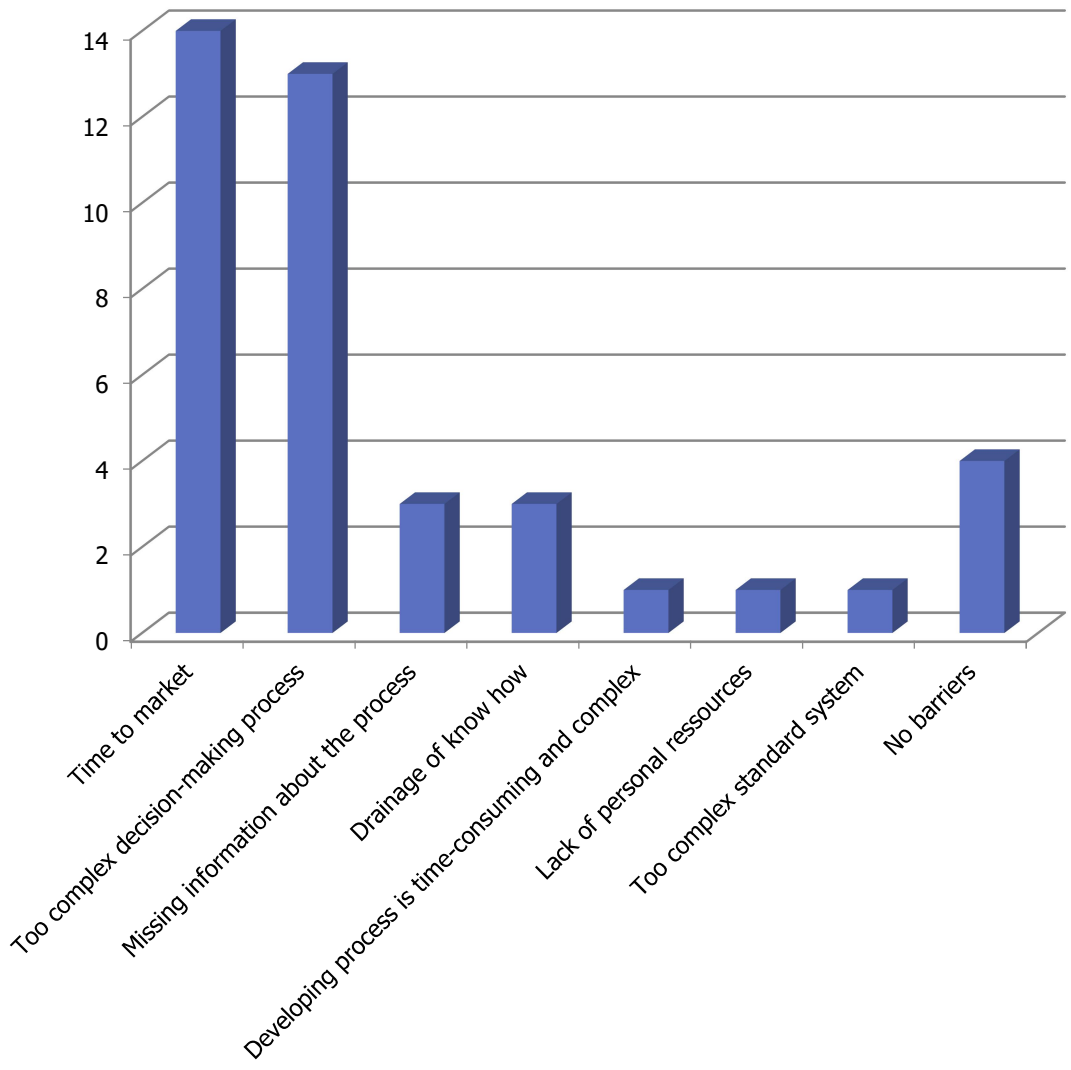

Figure 11: Barriers in the standardisation process

2. Regulatory framework

The INBOTS standardisation survey included a section with questions about the regulatory framework. The participants were asked to indicate how difficult it is to identify hazards and conduct a risk management in terms of interactive robots. Out of 43 participants, who answered the not mandatory question, 22 participants use and know about harmonised standards. Ten participants stated that it is difficult to very difficult while only four participants stated that it is easy to very easy (see Figure 12). Eight participants stated that it is neither easy nor difficult.

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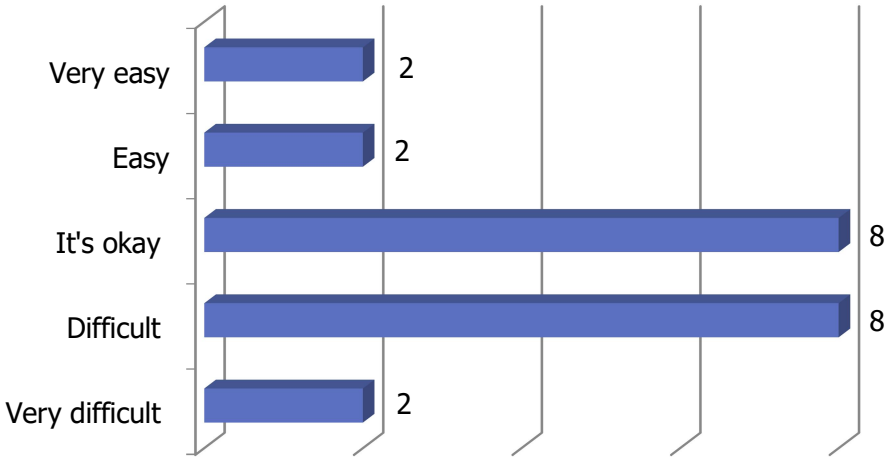

Figure 12: Identification of hazards and risk management

The participants were also asked to indicate how difficult it is to identify and apply (harmonised) standards to presume conformity with European directives. Out of 41 participants, who answered the not mandatory question, 22 participants use and know about harmonised standards. Nine participants stated that it is difficult to very difficult while only four people stated that it is easy to very easy (see Figure 13). Nine participants stated that it is neither easy nor difficult.

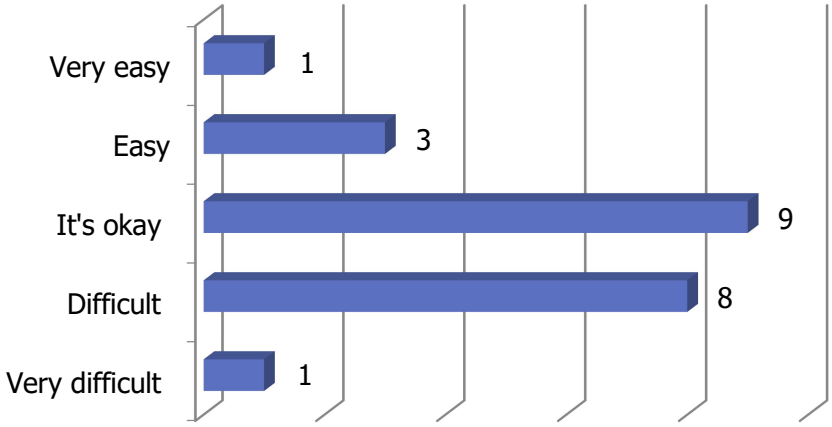

Figure 13: Difficulty to apply harmonised standards

Another question aligned with the above ones was that the people had to indicate how difficult it is to validate that their product is aligned with (harmonised) standards, so that they can presume the conformity with European directives. Out of 41 people who answered the not mandatory question, 22 people use and know about harmonised standards.

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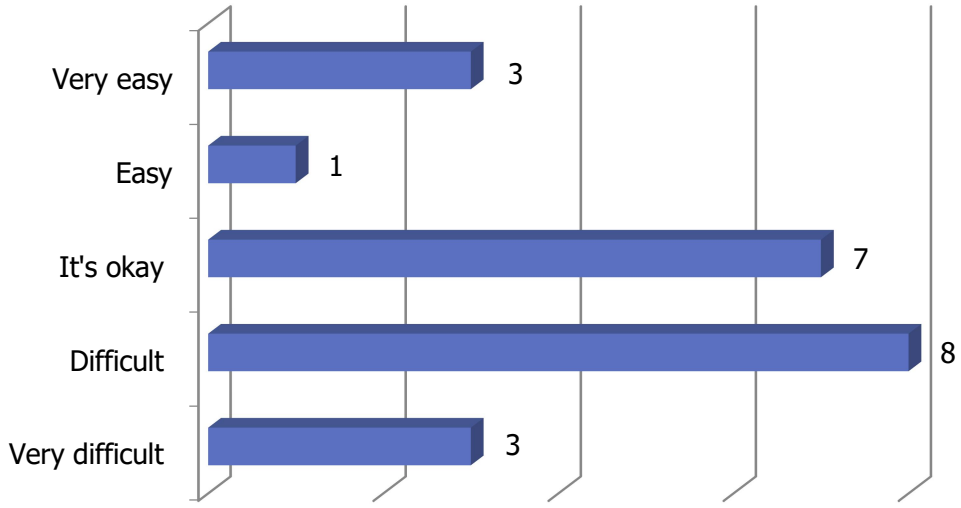

Figure 14: Difficulty to validate that a product is aligned with (harmonised) standards

Participants mentioned the following problems to apply (harmonised) standards for affixing the CE mark:

- ***Harmonised standards for particular robots are missing like service robots***
- ***Amount of resources spent to complete process of complying with the harmonised standards and the CE documentation is too high***
- ***Harmonised standard that regulates the relationship of the robot with the person is missing***
- ***New applications which are not yet fully covered by existing standards, e.g. mobile robots with manipulator in industrial environments***
- ***EC approach to manage harmonisation of standards is way too theoretical; EC shall limit themselves on the definition of generic requirements while standards translate these generic requirements into testable technical requirements***
- ***Expected and well-known shortage of Notified Bodies accredited under the Medical Device Regulation which is coming into force in early 2020 will hinder manufacturers from getting test reports in-time***

Participants mentioned the following solutions that would help to overcome the challenges for affixing the CE mark:

- ***Use of drafted upcoming standard which represent the state-of-the-art***
- ***Extend the CE marking for machinery by human-robot interaction***
- ***Regulation of the robot and its relationship with the person***
- ***Clearer view of the complete list of applicable standards and their relationships***
- ***Continues improvement of existing ISO/TC 299 standards***
- ***Process needs to be simplified***
- ***Have a reduced number of standards and guides to apply these standards***
- ***Add missing information about hazards and risks and hazardous situations***
- ***Guidelines published with a non-expert reader in mind***
- ***EC shall limit themselves on the definition of generic requirements while standards translate these generic requirements into testable technical requirements***

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At the INBOTS conference 2018 participants stated the following issues:

- ***Long CE process***
- ***Lack of EU certification organisation***
- ***Hazards and risks not clearly defined with parameters and limits***

8. Standardisation approach for future activities

This section introduces opportunities to transfer the identified standardisation potentials into standardisation activities. An introduction into specifications and agreements as well as new work item proposals is given.

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 5, 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 that are members of the TC. Thus, they are not instruments for consortia that are not active in standardisation. CEN Workshop Agreements (CWA) on the other hand 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 consumerism), but can be a consortium of partners agreeing to develop a document together. Ideally, all interested parties are represented. Such a document does not inhibit 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 inhibits a "pre-standard" character.

The nature and the procedure of a CWA is described in CEN-CENELEC Guide 29. The guide details the characteristics and the development process of a CWA. A CWA is basically a working platform open to the participation of any interested parties for elaboration of 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, a self-assessment and 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.

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The Project Plan of a CWA contains the CEN Workshop background, a description of the scope, the objectives, the time schedule of development 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 as well as the secretariat elected. The role of the Workshop participants is to provide comments and input on draft documents and the approval of the CWA (organisations approving CWA will be listed in CWA foreword).

The next step is the development phase. In order to finalize the CWA, the Workshop participants need to agree on the final document. Public consultation is mandatory if the CWA deals with safety aspects (the draft CWA will be posted on the CEN website for a minimum of 60 days). For any other workshop it is recommended, but not mandatory[63].

2. New Work Item Proposal

a. CEN New Work Item and liaison

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 state has a vote on whether to proceed with the NWIP or not, and the CEN member state votes according to the outcome of the national enquiry of this state. The national experts can leave comments and any information about deviating national regulation that might have to be taken into account and 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 participate actively in the work of the new Technical Body; and additionally 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 caused by 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 with the national standardisation body that will subsequently verify whether this work should potentially be carried out at the European level.

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

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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, the NWIP is submitted directly to the concerned CEN TC through.

When proposing a new work item, it is strongly advisable to deliver a first draft of the envisaged document in order to convince fellow members of a working group to also volunteer to work on the topic actively. Once the NWIP is accepted, there is a rather strict time frame to be followed, and the time up to the next stages, such as 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 the feasibility regarding that other projects might also have to be worked on. A tool available but used very rarely it 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 by a CEN deliverable.

Besides a comprehensive manuscript, factors to help the adoption of a NWIP are the presentation of the work proposed 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 that 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[64].

Another tool that can help the successful adoption of a NWIP is the prior formation of a liaison of the research project with a technical committee. In exchange for an annual fee for a TC and its corresponding Working Groups (WG), the liaison can be established. Partners of the research project 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, can help to identify gaps and be a platform for networking with other experts working in the field that can assess gaps and where the input of a European research project can be utilized and exploited[65].

Also mentioned should be the possibility of research projects to contribute to ongoing standardisation activities.

b. 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 (depending on the number of

[64] CEN/CENELEC Internal Regulations Part 2 – Common rules for standardisation work (2017).
[65] CEN/CENELEC Guide 25 – The concept of Partnership with European Organizations and other stakeholders (2017).

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members) countries volunteer to participate in the work and an approval of the work item by a 2/3 majority of the P-members (participating – active) of the technical committees or subcommittees voting is existent.

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 Body; 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[66,67].

c. 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; 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 NWI originate from the committee itself, not from people outside of the standardisation committee. The NSB, 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 initiate these activities.

9. Key findings

The Preliminary White Paper on standardisation and interactive robots provides an overview of the current standardisation landscape and potential future standardisation activities. In the following, key findings are summarized per section.

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 main actors: Technological enablers and standardisation organisations, which generate together with the technological enablers 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, which are then explained in more detail in harmonised standards.

[66] International Organization for Standardization, "Developing ISO standards", accessed July 2, 2019, https://www.iso.org/stages-and-resources-for-standards-development.html.
[67] ISO/IEC Directives Part 1 – Procedures specific to ISO (2019).

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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. Therefor 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 room, from the young to the very old and different physical and cognitive deficits. Three main categories of interactive robots in the healthcare domain are considered: Clinical robots, rehabilitation robots, and assistive robots.***
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 30 are directly related to robots. The remaining standards are beneficial for interactive robots, but have to be adapted to specific needs.***
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 standard, because they do not know which standards they should follow and the costs of standards are 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 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.***

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d) ***There is also a standardisation need to define the boundaries between different applications and domains.***
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: General challenges

a) ***Organisations face challenges with standardisation because of their too time-consuming and complex development process. The standardisation system already realised this issue and initiated countermeasure that shorten the process and foster the development of specifications and agreements, which can be developed in a short period of time.***
b) ***For most of the smaller companies' standardisation has not even been a topic so far.***
c) ***The organisations that are active in standardisation consider the time to market of standards as the biggest barrier.The second barrier is closely related to the first one, since the complex consensus-based decision process takes time.***
d) ***Organisations also face challenges to identify hazards and conduct a risk management in terms of interactive robots.***
e) ***They also think that it is difficult to identify and apply (harmonised) standards to presume conformity with European directives and it is difficult to validate that a product is aligned with (harmonised) standards, so that an organisation can presume conformity with European directives.***

Key findings section: Standardisation approach 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 specification and agreements.***
c) ***The development of specification is done by TCs and agreements are developed in an open workshop atmosphere.***
d) ***Therefore the identified INBOTS potentials can either be elaborated further by research projects in a workshop with an NSB as the project manager or be transfered to a TC that maybe will take up the work to develop a standard or sprecification on the identified potential.***

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10. Abbreviations

- **AGV** Automated Guided Vehicle
- **AMR** Autonomous Mobile Robots
- **ANSI** American National Standards Institute
- **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)
- **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
- **EN** European Standard
- **ETSI** European Telecommunications Standards Institute
- **HRC** Human-Robot Collaboration
- **ICT** Information and Communication Technology
- **IEC** International Electrotechnical Commission
- **ISO** International Organisation for Standardisation
- **IWA** International Workshop Agreement
- **JTC** Joint Technical Committee
- **MDR** Medical Device Regulation
- **MAR** Multi Annual Roadmap
- **MSD** Musculoskeletal Disorders
- **NSB** National Standardisation Body
- **NP** New Proposal
- **NWI** New Work Item
- **NWIP** New Work Item Proposal
- **OJEU** Official Journal of the European Union
- **RFID** Radio Frequency Identification
- **SC** Sub Committee
- **TC** Technical Committee
- **TR** Technical Report
- **TS** Technical Specification
- **UI** Unique Device Identification
- **WG** Working Group

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11. References

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

ANSI B56.5:2013 Safety Standard for Driverless, Automatic Guided Industrial Vehicles and Automated Functions of Manned Industrial Vehicles.

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

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

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

DIN 820-1:2014 Standardisation – Part 1: Principles.

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

Eduard Fosch Villaronga, "Robots, standards and the law: Rivalries between private standards and public policymaking for robot governance". Computer Law & Security Review 35, no. 2 (2019): 129-144.

EN 1525:1997 Safety of industrial trucks – Driverless trucks and their systems.

EN 45020:2006 Standardisation and related activities – General vocabulary.

EN ISO 11135-1:2007 Sterilization of health care products.

ErgoPlus, "The Definition and Causes of Musculoskeletal Disorders", accessed July 2, 2019, https://ergo-plus.com/musculoskeletal-disorders-msd/.

EU-Robotics, "Robotics 2020 - Multi Annual Roadmap". accessed July 2, 2019, 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 July 2, 2019, 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 July 2, 2019, 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 July 2, 2019, https://osha.europa.eu/en/about-eu-osha/press-room/eu-osha-presents-new-figures-costs-poor-workplace-safety-and-health-world.

European Commission, "Benefits of standards", accessed July 2, 2019, https://ec.europa.eu/growth/single-market/european-standards/policy/benefits_en.

European Commission, "Regulator framework", accessed July 2, 2019, https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en.

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

European Committee for Electrotechnical Standardization, "CLC/TC 44x Safety of machinery: electrotechnical aspects", accessed July 2, 2019, https://kurzelinks.de/zyqc.

European Committee for Electrotechnical Standardization, "CLC/TC 62 Electrotechnical equipment in medical practice", accessed July 2, 2019, https://kurzelinks.de/7805.

European Committee for Standardization, "CEN/TC 114 Safety of machinery", accessed July 2, 2019, https://kurzelinks.de/n6no.

European Committee for Standardization, "CEN/TC 122 Ergonomics", accessed July 2, 2019, https://kurzelinks.de/kih8.

European Committee for Standardization, "CEN/TC 293 Assistive products and accessibility", accessed July 2, 2019, https://kurzelinks.de/ji7d.

European Committee for Standardization, "CEN/TC 310 Advanced automation technologies and their applications", accessed July 2, 2019, https://kurzelinks.de/9um9.

European Committee for Standardization, "European Standardization", accessed July 2, 2019, https://www.cen.eu/you/EuropeanStandardization/Pages/default.aspx.

German Institute for Standardisation, "An introduction to standardisation – a practical guide for small businesses", accessed July 2, 2019, https://www.din.de/blob/195038/64b75612aae6d6e7341e815becadb5d9/an-introduction-to-standardization-data.pdf.

German Institute for Standardisation, "FAQ", accessed July 2, 2019, https://www.din.de/en/about-standards/benefits-for-the-private-sector/sme-commission-kommit/faq.

Huan Xu, and Joseph E. Borson, "The Future of Legal and Ethical Regulations for Autonomous Robotics", IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS), pp. 2362-2366. IEEE, 2018.

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

INBOTS, "Standardisation", accessed July 2, 2019, http://inbots.eu/contributing-to-inbots/standardisation/.

International Electrotechnical Commission, "TC 62 Electrical equipment in medical practice", accessed July 2, 2019, https://www.iec.ch/dyn/www/f?p=103:7:0::::FSP_ORG_ID,FSP_LANG_ID:1245,25.

International Organization for Standardization, "Developing ISO standards", accessed July 2, 2019, https://www.iso.org/stages-and-resources-for-standards-development.html.

International Organization for Standardization, "ISO/IEC JTC 1 /SC 27 Information security, cybersecurity and privacy protection", accessed July 2, 2019, https://www.iso.org/committee/45306.html.

International Organization for Standardization, "ISO/IEC JTC 1/SC 35 User interface", accessed July 2, 2019, https://www.iso.org/committee/45382.html.

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

International Organization for Standardization, "ISO/TC 159 Ergonomics", accessed July 2, 2019, https://www.iso.org/committee/53348.html.

International Organization for Standardization, "ISO/TC 168 Prosthetics and orthotics", accessed July 2, 2019, https://www.iso.org/committee/53630.html.

International Organization for Standardization, "ISO/TC 173 Assistive products", accessed July 2, 2019, https://www.iso.org/committee/53782.html.

International Organization for Standardization, "ISO/TC 199 Safety of Machinery", accessed July 2, 2019, https://www.iso.org/committee/54604.html.

International Organization for Standardization, "ISO/TC 299 Robotics", accessed July 2, 2019, https://www.iso.org/committee/5915511.html.

ISO 10218-1:2011 Robots and robotic devices – Safety requirements for industrial robots – Part 1: Robots

ISO 10218-2:2011 Robots and robotic devices – Safety requirements for industrial robots – Part 1: Robot systems and integration

ISO 13482:2014 Robots and robotic devices – Safety requirements for personal care robots.

ISO 8373:2012 Robots and robotic devices – Vocabulary.

ISO 8549-1:2011 Prosthetics and orthotics – Vocabulary – Part 1: General terms for external limb prostheses and external orthoses.

ISO/CD 18646-4 Robotics – Performance criteria and related test methods for service robots - Part 4: Wearable robots.

ISO/CD TR 23482-1 Robotics – Application of ISO 13482 – Part 1: Safety-related test methods.

ISO/FDIS 3691-4 Industrial trucks - Safety requirements and verification – Part 4: Driverless industrial trucks and their systems.

ISO/IEC Directives Part 1 – Procedures for the technical work (2019).

ISO/TS 15066:2016 Robots and robotic devices – Collaborative robots.

Jan F. Veneman, "Safety standardisation of wearable robots – The need for testing methods", Wearable Robotics: Challenges and Trends, pp. 189-193, 2017.

Michiel De Looze, Tim Bosch, Frank Krause, Konrad S. Stadler, and Leonard W. O'Sullivan. "Exoskeletons for industrial application and their potential effects on physical work load", Ergonomics 59, no. 5 (2016):671-681.

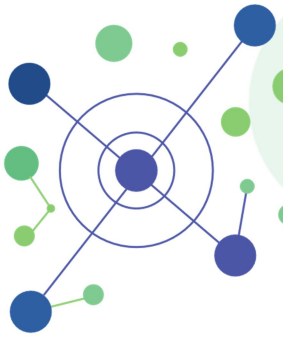
Priyesh Tiwari, Jim Warren, Karen J. Day, and Bruce MacDonald, "Some non-technology implications for wider application of robots to assist older people", Health Care and Informatics Review Online. 2010.

R. A. Gopura and Kazuo Kiguchi, "Mechanical Designs of Active Upper-limb Exoskeleton Robots", 2009 IEEE International Conference on Rehabilitation Robotics, pp. 178-187, 2009.

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

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.



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