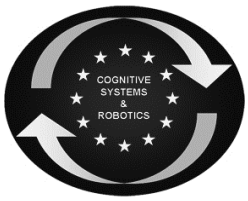
SAPHARI

SAFE AND AUTONOMOUS PHYSICAL HUMAN-AWARE ROBOT INTERACTION



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Deliverable D1.4.1

Existing standards and recommendations for future safety standards in robotics

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R = Report P = Prototype D = Demonstrator O = Other	PU = Public PP = Restricted to other programme participants (including the Commission Services) RE = Restricted to a group specified by the consortium (including the Commission Services) CO = Confidential, only for members of the consortium (including the Commission Services)

Executive Summary

This document strives to give a detailed overview of the standards most relevant to robotics. This overview includes details on the strengths and weaknesses of the current setup and ways to get involved. The deliverable summarises the work done within SAPHARI in the context of the standards. Besides an internal document (Milestone 19) it builds upon and extends the work done in the context of the PHRIENDS project, in particular on Deliverable D1.4.

Standardisation is an important process. Standards are strategic tool for reducing cost, minimizing error and increasing productivity. While safety standards themselves are not compulsory, they are an easy way for manufactures to complying with laws and regulations, which are mandatory. The most important standards for industrial robotics are ISO 10218:2011-1 and 10218:2011-2. The first part concerns robots, while the second part is for the integrators. With the introduction of collaborative robotics, service robotics and medical robotics the application of robotics is changing fundamentally and new standards are being generated. The development of these standards is in most cases still ongoing.

SAPHARI worked to help and influence the development of the new standards. The main contribution of SAPHARI concerned specifying and analysing collisions between humans and robots. In particular tests were executed in order to estimate the relevant collision parameters and suddenly evaluate the severity of a collision. SAPHARI investigated also medical robotics: robots in medical scenarios are a relatively new field of pHRI applications. Formally, these robots are considered to be medical devices. The working group developed a document on “medical products with some level of autonomy” which is a first step towards standardisation of robotics in the medical domain. Of course, the standardisation process never ends, but SAPHARI helped to set the right direction during this important phase of transition as described in this deliverable.

Chapter 1 introduces the concept of standardisation and explains why standardisation is an important process in robotics. In particular, the EC machinery directive, the EC medical device directive and important standards with respect to robot safety are explained. In chapter 2 the most important norms for safety in robotics are listed and the scope of each norm is explained. Chapter 3 presents the impact of SAPHARI on the standardisation process of the last years. Finally, in chapter 6, the conclusions of the work are presented.

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1 Introduction

1.1 Importance of standards

Standardization plays a key-role in the industrial and trade environment. Standards are strategic tools for reducing costs, minimizing errors and increasing productivity. Standards solve issues ranging from product compatibility to addressing consumer safety and health concerns. Standards also simplify product development and reduce non-value-adding costs thereby increasing a user's ability to compare competing products. They also are fundamental building blocks for international trade.

With the introduction of service robots at home and in the public and robot assistants at the workplace safety is becoming probably the most important issue. That is why any robot developer, be it mechanical, hardware, software, or application engineer needs to have at least a basic knowledge and understanding of the currently existing design and safety standards to be able to comply with them. This report aims at giving an overview of the relevant design and safety standards in the area of robotics.

1.2 The relationship between laws and standards

Following international standards is not mandatory, but they can help to fulfil mandatory guidelines which need to be fulfilled by every machine that is brought to market. An example of such laws is the European machinery directive issued on a European level and which has to be realised in national laws within their scope of application. Each such guideline has a number of standards which are "harmonised" under this guideline. These standards are supposed to detail and explain the requirements resulting from the corresponding guideline in the context of a certain field of application. The big advantage for manufacturers is that if they develop their products in accordance with such harmonised standards, compliance with the corresponding guideline can be assumed. This helps manufacturers to make sure they fulfil all legal requirements of the national law. A general overview of how guidelines, standards, and norms are related is provided in Figure 1.

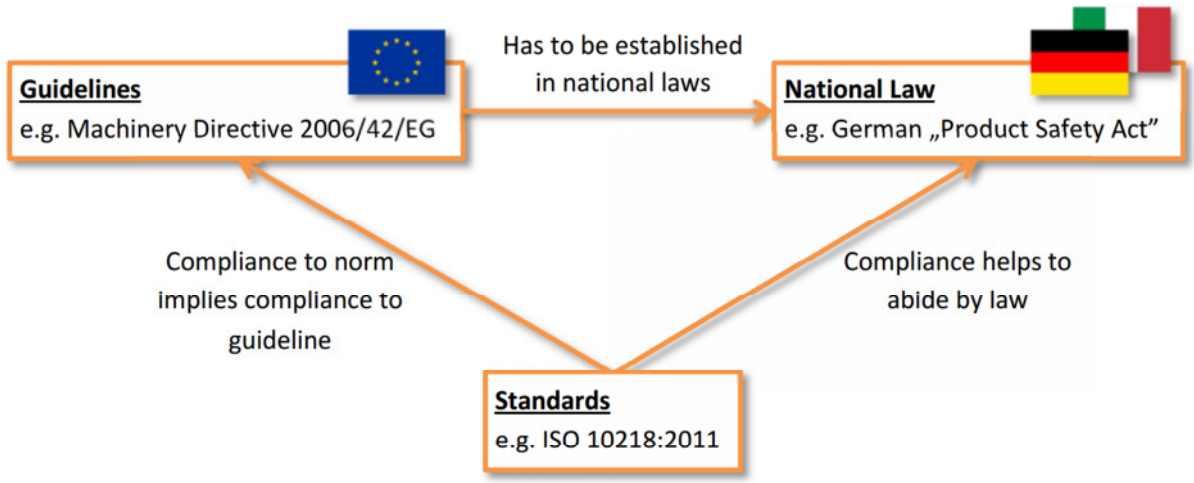

Figure 1: Guidelines, standards and norms

1.3 The international context

Standards in general are thought of as a means to comply with regulations or laws set by national or regional authorities. If a robot manufacturers states that it complies with a specific safety standard, it can be said that the manufacturer has done everything required by this particular standard with respect to the current state of the art to ensure the safety of its machinery. However, the world of standardization is divided into international, regional (e.g. European) and national areas of standardization, which makes harmonization across the regions difficult. Most of the time a harmonisation process takes place where ISO standards are adapted to EC and ANSI and EC is further adapted to the national standards (e.g. DIN).

However, comparing, for example, US and European standards reveals a significant difference [Fryman03]. From an international perspective the North American safety standards tend to be “user centric”, requesting from the end user of the equipment to be consistent with work place safety requirements and compliance with government regulations. In contrast, European safety standards tend to be “producer centric”, addressing the equipment manufacturer and implementing the manufacturers’ responsibility under European legislation. For this reason, the revised ISO 10218 was being proposed as a two-part document. With the overall title of the revised ISO 10218 being “Robots for Industrial Environment – Safety”; Part 1, entitled “Design, Construction and Installation”, is fully compliant with the European Machinery Directive and has already replaced the EN775. Part 2, has a title of “Application and Use of Robots in the Work Place” and addresses work place safety requirements and is directed more to the user than the manufacturer. The two parts of ISO 10218 allowed harmonizing the existing U.S. (American Standard ANSI/RIA R15.06-2012) and Canadian standards as well as to be adopted in Asia (e.g Japan).

So while an effort is made by the standardisation bodies to overcome national barriers and thereby enable international trade, international harmonisation is hard and not always possible. Hence, adhering to a national standard does not automatically results in compliance with the regional requirements elsewhere in the world. To be able to market and sell a product in different regions of the world, it is required to comply with all the norms valid in the specific market. Figure 2 gives an overview of the different standards from a German point of view.

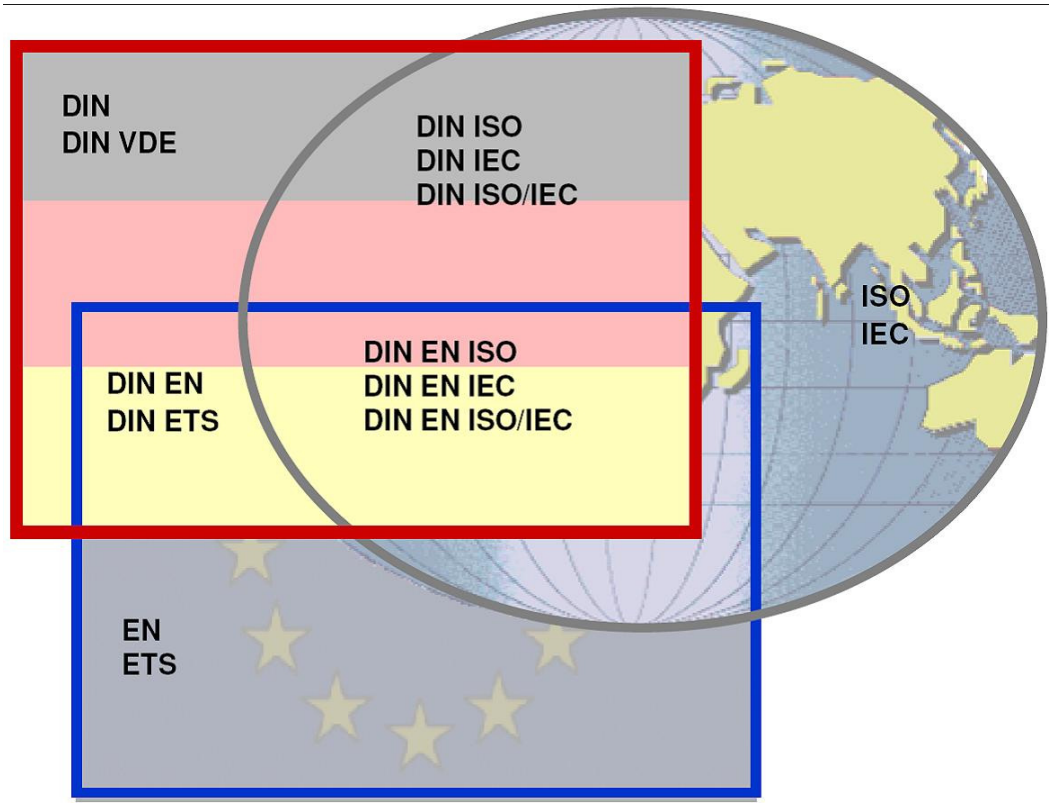

Figure 2: Standardizarion from a German point of view

Germany has a long tradition in robot safety standards, starting with the VDI (German Engineer Association) norm 2853 „Safety Requirements for Design, Equipment and Operation of Industrial Robots“. In 1992 the EN 775 / ISO 10218 (European/International) norms „Manipulating Industrial Robots – Safety” were established. This norm was updated in 2011 and is divided in two parts: part 1 focuses on requirements for robot manufacturers, while part 2 addresses topics that have to be regarded upon the integration of the robot into a full machine.

The European environment for robot safety standards is based on the EC directives, e.g., the Machinery Directive, which defines basic (safety) requirements for a product. The requirements of the European Machinery Directive are substantiated by means of the EN standards, which are divided into three hierarchically arranged type classifications A, B and C [Schmersal04]:

- Type A standards are so called “basic standards”, such as EN 292 “Safety of machines – Basic terms, general principles of design“ and EN 1050 “Safety of machines – Risk assessment” which cover basic rules for machine safety, and provide guidelines and basic terms.
- Type B standards are so called “group standards”, such as EN 954-1 “Safety-relevant parts of control systems”. They handle an aspect of safety that is applicable to a wide range of machines. They are sub-divided into the standard classifications B1 and B2. Type B1 standards cover rules for basic aspects of safety such as ergonomic principles and safety clearances / distances. Type B2 standards describe characteristics of protective equipment that can be used in various types of machines – such as EN 1088 “Interlocking devices with and without locking”.
- Type C standards are so called “product standards” which refer to individual types of machine or areas of application such as packing, moulding or bakery machines. They describe concrete

requirements and protective measures relating to all significant risks which can be derived from a single machine or all types in a machine group. Type C standards relate (as much as possible) to type A and B standards, but they can contain requirements which deviate from the group standards, thus acquiring greater importance as a result.

1.4 Adhering to standards

Processing the harmonised standards is an extremely demanding project which will still take years to complete. Some of the standards are still in the draft phase at present. This is in particular true for the C standards. Since they are focused on specific machines or areas, it is much harder to stay up to date on this detailed level. Designers therefore have to go back to the Type A and B standards and the "helpful national standards" published in the EC Gazette, which can be used in the intermediate period. It must however be noted that other national standards are being used in other EU countries. Finally, it should be observed that the standards are not laws, but are intended to provide assistance to the designer.

> *"NOTE 1: Not all of the hazards identified by ISO 10281 apply to every robot and nor will the level of risk associated with a given hazardous situation be the same from robot to robot. Consequently, the safety requirements and/or protective measures may vary from what is specified in ISO 10281. A risk assessment/risk reduction may be conducted to determine what the protective measures should be." [ISO 10218-1:2011 Introduction]*

1.5 Getting involved in standardisation

Many organizations participate in the standardization process (see also Chapter 1.5). ISO, IEC and IEEE have an established standards-setting process that offers companies the opportunity to take part in shaping the direction of technology and its marketplace application by developing industry-driven standards. Organizations that contribute to the development of standards benefit from a first-to-market opportunity. According to [ISO07] standards have the following benefits:

- make the development, manufacturing and supply of products and services more efficient, safer and cleaner
- facilitate trade between countries and make it fairer
- provide governments with a technical base for health, safety and environmental legislation, and conformity assessment
- share technological advances and good management practice
- disseminate innovation
- safeguard consumers, and users in general, of products and services
- make life simpler by providing solutions to common problems

From this list it is clear how important standards are to society and industry – obviously also in the context of robotics. The industrial robotics domain is already well covered by standards, but service robotics and other domains still lack standards. And even the robotic domain standards struggle to keep up with the current state-of-the-art in a rapidly evolving technical world. The ISO Advisory Group on standards for mobile service robots has identified a range of issues that are important and need to be addressed in the

long run [Virk06] and which may be taken as examples for all types of service robots. These issues include the following:

- definitions of service robots for professional and personal use
- up-to-date vocabulary
- black-box for on-line health checks and diagnosis as well as for post mortem analysis as used in the aerospace sector
- communication in-between system modules, between the system and the user and between the system and the environment
- common frameworks for operation including input modalities
- technical tasks classification
- maintenance standards
- environment classification
- performance metrics

International standards are developed in a clearly defined process as outlined in Figure 3. For companies it is very beneficial to contribute to standardisation committees. On one hand they can influence the international standards to fit their needs and products. On the other hand they gain timely access to information and knowledge which puts them ahead of competitors not participating. Thus they heavily reduce risks and costs involved in R&D.

In order to contribute to a standard development one has to become a member of a national or international standardisation committee (i.e. one of the technical committees mentioned in Figure 3). The international technical committees consist of expert representatives of industry, NGOs, governments and other stakeholders. These representatives are put forward by the national ISO members (e.g. the DIN in Germany). Currently, the ISO has over 250 technical committees that are further divided into subcommittees and working groups. The main technical committee for robotic topics is TC 184 *"Automation systems and integration"* which covers *"Robots and robotic devices"* in subcommittee SC2. The subcommittee itself comprises so-called working groups. The listing of the attended meetings in Table 2 also refers to these groups. The working groups cover more specific topics like industrial safety, personal care safety, and service robots. A joint working group (working in joint effort with IEC/SC 62A) discusses safety for medical devices that use robotic technology.

Figure 3: Standardisation process (adopted from www.iso.com)

2 Laws and standards relevant to robotics

In the last chapter an overview of the world of standardisation related to robotics was given. This chapter gives more details regarding current and currently reworked safety standards in robotics revering to the European Machinery Directive 2006/42/EC and the Medical Device Directive (93/42/EEC).

In this document the focus is set on laws and standards relevant to safety as this was the focus area of the SAPHARI project and as the topic of safety deserves careful attention in the context of robotics. The reason for this is that robots differ in a lot of ways from other kind of machinery for which basic safety directives already exist. “Robots are capable of high energy movements through a large operational volume. Additionally, the initiation of movement and the path of the robot arm are difficult to predict and can vary, for example due to changing environmental requirements” [ISO 10218-2 §4.1]. Current developments towards autonomous robots and robotic co-workers with non-deterministic behaviour add new requirements.

2.1 European Machinery Directive

The treaty of the European Union contains among other things regulations for safety at the workplace. The EC treaty is the base for a number of directives that describe the minimum requirements to conform to the treaty. According to EC rules, directives have to be converted into national law. One of the directives originating from EC treaties is the Machinery Directive 2006/42/EC, which replaces and improves Machine Directive 98/37/EC. It regulates product characteristics with the aim to improve product safety for the end users. Other possibly relevant directives for robotics are the “Low Voltage Directive” (Directive 06/95/EEC) and the directive on electromagnetic compatibility “EMC-Directive” (Directive 04/108/EG).

The Machinery Directive 2006/42/EC states in Article 4:

> *“Member States shall take all appropriate measures to ensure that machinery may be placed on the market and/or put into service only if it satisfies the relevant provisions of this Directive and does not endanger the health and safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen.*

and in Annex I:

> *“The essential health and safety requirements laid down in this Annex are mandatory; however, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.”*

With respect to mechanical requirements the following rules can be found:

> *“Machinery and its components and fittings must be stable enough to avoid overturning, falling or uncontrolled movements during transportation, assembly, dismantling and any other action involving the machinery. If the shape of the machinery itself or its intended*

> *installation does not offer sufficient stability, appropriate means of anchorage must be incorporated and indicated in the instructions."* (Annex I, 1.3.1 Stability).

and:

> *"The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used. The durability of the materials used must be adequate for the nature of the working environment foreseen by the manufacturer or his authorised representative, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion."* (Annex I, 1.3.2 Risk of breaking up during operation).

The requirements for the control system are found in Annex I, 1.2.1 Safety and Reliability of Control Systems:

> *"Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:*
>
> - *they can withstand the intended operating stresses and external influences,*
> - *a fault in the hardware or the software of the control system does not lead to hazardous situations,*
> - *errors in the control system logic do not lead to hazardous situations,*
> - *reasonably foreseeable human error during operation does not lead to hazardous situations."*

Figure 4 describes the process to comply with the European Machinery Directive. First, a hazard and risk assessment has to take place. This assessment is based on the Machinery Directive which contains basic safety requirements in annex I. Then the machinery has to comply with relevant safety norms, such as ISO 10218-1, which would be sufficient to eventually comply with the directive. It is important to note that machinery may be considered safe, even if it does not comply with current safety standards. In such a case the manufacturer has to prove that it has found solutions that guarantee an equal level of safety in a different way. Proof of necessary examinations, a technical documentation, and an instruction manual are requirements before a machine can be declared to be in conformity with the Machinery Directive. This has to be ensured by excessive risk and failure effects analysis as well as practical tests of the functions. In some cases, the safety functions are additionally reviewed and certified by external organizations (e.g. TUEV) to ensure the highest possible reliability, but this is not mandatory.

As mentioned above, Machinery Directive 2006/42/EC replaced Machine Directive 1998/37/EC on December 28th, 2009. Usually the new directive increases the requirements towards manufacturers and integrators of machinery. For robots, the current directive added four major changes :

- Robots were not covered 98/37/EC. Now a robot is considered an "incomplete machine" and manufacturers hence have to deliver a declaration of conformity. 2006/42/EC includes incomplete machines in general with the effect that the manufacturer has to perform and document a risk assessment, and provide documentation on assembly demands and an assembly manual.
- A risk assessment, described in ISO 14121, replaced the mandatory hazard analysis.

- Machinery in research institutes and temporary used machines in laboratories are excluded in the new version of the machinery directive. However the person in charge has to ensure the health and safety of employees by following the guidelines of labour protection.
- All safety related parts have to comply with ISO 13849, IEC 62061 or at least with an equal solution.

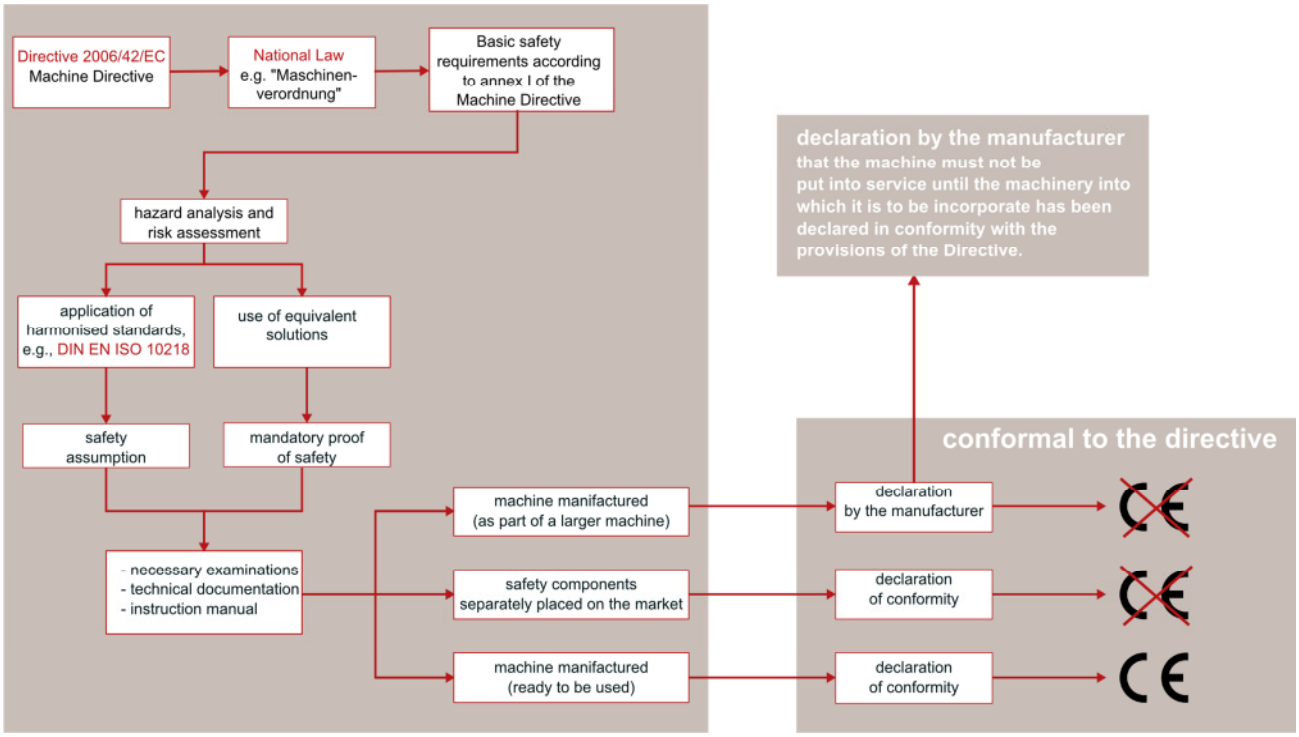

Figure 4: developing process for machinery complying with the Machinery Directive 2006/42/EC

2.2 Medical Device Directive

Robots that must operate in medical environment have to comply with Medical Device Directive 93/42/EEC. It's Motivation and Scope is declared as follows:

> *"This Directive shall apply to medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as medical devices in their own right. Both medical devices and accessories shall hereinafter be termed devices"*.

A Medical device is defined, in Article I, as:

> "*any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and 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 disease:*
> - *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*

- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception*"

The directive states in Annex I:

> *"The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.*
>
> *This shall include:*
>
> - *reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and*
> - *consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).*"

The conformity assessment procedure, which gives the possibility to assign the CE mark to a product, divides the devices in four classes:

Class	Description
I	Low risk devices
IIa and IIb	Medium risk devices
III	High risk devices

The purpose of this division is to allow the strictest control only to the devices which present a big safety risk. The conformity assessment ways are set out in the directive. Robots that for example have to be used as surgical robots, according to the classification made in Annex IX, belong to Class IIb.

Robots which belong to the medical should not comply with the Machinery Directive 2006/42/EC, but in the practice, in order to facilitate the development and certification process, many manufacturers try to follow also this guideline.

2.3 Overview of international and European robotics standards

Table 1 lists all international and European robot standards concerned with the design and safety of robots (see column "class": D = Design; S = Safety). The last column represents the year of the latest release or update.

Table 1: Overview of relevant standards

Norm	Title	Class	Year
ISO 8373	Manipulating industrial robots – Vocabulary		2012
ISO 9283	Manipulating industrial robotics – Performance criteria and related test methods		1998
ISO 9409-1	Manipulating industrial robots – Mechanical interfaces – Part 1: Plates	D	2004
ISO 9409-1	Manipulating industrial robots – Mechanical interfaces – Part 2: Shafts	D	2002
ISO 9787	Manipulating industrial robots – Coordinate systems and motion nomenclatures		2013
ISO 9946	Manipulating industrial robots –Presentation of characteristics		1999
ISO 10218-1	Robots for industrial environments – Safety requirements – Part 1: Industrial robots	S	2011
ISO 10218-2	Robots for industrial environments – Safety requirements – Part 2: Industrial robot system and integration	S	2011
ISO 11593	Manipulating industrial robots – Automatic end effector exchange systems – Vocabulary and presentation of characteristics		1996
ISO/TR	Manipulating industrial robots -- Informative guide on test		1995

13309	equipment and metrology methods of operation for robot performance evaluation in accordance with ISO 9283		
ISO 13482	Robots and robotic devices -- Safety requirements for personal care robots	S	2014
ISO 14539	Manipulating industrial robots – Object handling with grasp-type grippers – Vocabulary and presentation of characteristics		2000
ISO/DTS 15066	Robots and robotic devices -- Safety requirements for industrial robots -- Collaborative operation	S	under development
ISO/DIS 18646-1	Robots and robotic devices -- Performance criteria and related test methods for service robot -- Part 1: Locomotion for wheeled robots		under development
ISO/WD 18646-2	Robots and robotic devices -- Performance criteria and related test methods for service robot -- Part 2: Navigation		under development
ISO/CD 19649	Robots and robotic devices --- Vocabulary for mobile robots		under development
IEC/NP 80601-2-77	Medical Electrical Equipment -- Part 2-77: Particular requirements for the basic safety and essential performance of medical robots for surgery	S	under development
IEC/NP 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	S	under development

The efforts in SAPHARI focused mainly three areas:

- Industrial robot safety is covered by ISO 10218-1:2011 and ISO 10218-2:2011, both last published in 2011. These norms cover safety issues for industrial robots (part 1) and industrial robot systems and integration (part 2) and currently collecting issues for another update. Additionally the technical specification ISO TS15066 is under development, which is very important because it directly handles the hazards arising in human-robot collaboration.

- In the field non-industrial robot safety the efforts are concentrated on the final draft of the new ISO standard for safety requirements for personal care robots (ISO/DIS 13482:2011-09). This draft is currently at stage five of the standardisation process pictured in Figure 2, i.e. the voting on the final draft (FDIS).
- Medical robotics are approached by ISO/TC 184/SC 2/JWG 9. This joint working group with IEC has not developed a specific norm yet, so here is a very high potential of pushing SAPHARI results into a new standard.

It is important to note that a robot manufacturer may have to look at further standards depending on the nature of the product. If producing an autonomous wheelchair, to name an example, it may be advisable to adhere to the following standards in addition to the relevant robotics standards:

- EN 12184 for electric wheelchairs and scoot mobiles
- ISO 7176-series - the internationally accepted series of standards that describe the various testing methods for wheelchairs and scoot mobiles
- IEC 60601-1: general safety for medical electrical devices
- EN 12182: technical aids for disabled persons

2.3.1 Industrial robotics safety standards

The most important standards for machinery (robot) safety are:

- **ISO 10218-1:2011 / DIN EN ISO 10218-1:2011 (International/European) "Robots for industrial environments – Safety requirements – Part I: Industrial robot"**
  This standard addresses robot manufacturers and focusses on the manipulator arm, the robot controller and any external axes controlled by the robot controller.
- **ISO 10218-2:2011/ DIN EN ISO 10218-1:2011 "Robots for industrial environments – Safety requirements – Part II: Industrial robot system and integration"**
  This standard addresses robot integrators and focuses on the robot cell, the robot system as a whole, component devices for robot cells and collaborating operation between a robot and a human in the context of a cell.
- **IEC 60204-1 / DIN EN 60204-1 "Safety of machinery – Electrical equipment of machines"**
  This standard addresses electrical equipment and focusses on power supply and disconnection, overcurrent and overload protection, stop categories (0, 1, 2), equipment for emergency stop, conductors and cables, marking, warning signs and reference designations, technical documentation, and testing and verification.
- **ISO 13849-1 / DIN EN ISO 13849-1 "Safety of machinery – Safety-related parts of control systems"**
  This standard addresses safety related parts, in particular the safety related requirements, selection of the safety requirements and the safety category (1-4) for the safety related part of controller (see also [Hauke03, Hauke04])
- **IEC 62061 / DIN EN 62061 "Safety of machinery – Functional safety of safety related electrical, electronic and programmable electronic control systems"**
  This standard addresses the fact that more and more safety related parts are based on electronics and software based systems. It defines different safety levels (SIL-Level) and the principles behind realisation of safety software.

- **ISO 14121 / DIN EN ISO 14121 "Safety of machinery – Principles for risk assessment"**
  This standard describes how to carry out risk assessments and details the identification of hazards and suggests hazards to consider.
- **ISO 12100 / DIN EN ISO 12100 "Safety of machinery – Basic concepts, general principles for design"**
  This standard specifies the safety requirements of EU Machinery Directive and discusses risk reduction by design and the selection of safeguards.
- **ISO/PDTS 15066 "Robots and robotic devices - Collaborative robots"**
  This norm is still under development and addresses collaborative robots. Contact forces and shared workspaces are discussed to ensure safe collaborative tasks.

2.3.2 Service robotics safety standards

The current standard for safety in service robotics is ISO 13842:2014. This norm addresses service robot manufacturers and the safety requirements for service robots are defined. Service robotics has a wide range of robots; this is why a first classification between service robots is made. This classification is necessary to state reasonable safety requirements for each category. For example, there are major differences regarding the hazards of powerful exoskeletons and lightweight, small mobile assistants. KUKA worked during the last years in the development of this norm, delegates from KUKA attended meetings and took part in the reviewing process of this norm.

The development of ISO 13842 was followed by the development of ISO 18646: "Robots and robotic devices – Performance criteria and related test methods for service robot". It defines standardised test methods for service robots that allow verification and quantification of the performance evaluation of its features and functions.

2.3.3 Medical robotics safety standards

Standards specific to medical robotics are still under development. The most prominent activities are:

- JWG9 is working on developing **IEC/TR 60601-4-1: medical equipment - Part 4-1: Guidance and interpretation – Medical equipment and medical systems employing a degree of autonomy**. Extensive work has been done to define "degree of autonomy", how it can be classified from no autonomy to full autonomy as well as how autonomy affects the risk management process for medical electrical equipment. A number of examples are being developed and the TR is expected to be published in 2016.
- **ISO/TC 184, JWG 9 Committee Draft: Common aspects of electrical equipment used in medical practice.** It presents guidance on the following issues:
  - Formulation of key definitions for autonomy and DEGREE OF AUTONOMY (DOA)
  - How terms similar to DOA are being used in other standards to facilitate harmonisation
  - Formulation of methods for classifying and estimating DOA in Medical electrical equipment (MEE)
  - Performing risk management on a variety of MEE with DOA as examples to demonstrate its effect on BASIC SAFETY and ESSENTIAL PERFORMANCE.

- JWG9 has also been working on the possible new projects to develop particular standards for surgery robots and for rehabilitation robots. In this context two new joint working groups between SC2 and IEC SC62D were created in March 2015 via international balloting. The new 2 joint working groups are:
    - **JWG35 - Medical robots for surgery**.
      The JWG will work on producing **IEC 80601-2-77 (ed. 1) Medical Electrical Equipment - Part 2-77: Particular requirements for the basic safety and essential performance of medical robots for surgery.**
        - Scope: This International Standard applies to the basic safety and essential performance medical robot for surgery or surgical procedures, hereafter referred to as MEE together with its interconnection conditions and interface conditions.
        - Definitions: Required terms and definitions not found in IEC 60050 are being defined and may include the following: robotic surgery, stereotactic surgery, surgical procedure, microscopic surgery, and surgery
    - **JWG36 - Medical robots for rehabilitation, compensation or alleviation of disease, injury or disability.**
      The JWG will work on producing **IEC 80601-2-78 (ed. 1), 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.**
        - Scope: This International Standard applies to the general requirements for basic safety and essential performance of medical robots that physically assists a patient to perform rehabilitation, compensation or alleviation of disease, injury or disability. The borderline to prosthetics and orthotics is made clearly to ensure MEE already covered from other standards are not included in the new work project. Exoskeletons and continuous passive motion (CPM) devices should be covered in the new work item. Other possible rehabilitation robots having a mental or psychological impact should not be included in the project.
        - Definitions for following terms formulated: rehabilitation, rehabilitation robot, medical robot, physical compensation and physical alleviation.

3 SAPHARI's contribution to standardisation

The main goals of SAPHARI were to influence the work of the standardisation committees with results achieved within the project and to understand the current status of standardisation efforts and the concerns of the committee members in order to focus the work in SAPHARI. The development of standards is a continuous process. While the direct involvement of some of the partners was closely linked to SAPHARI KUKA has participated in standardisation committees for a long time and is going to continue this work after the SAPHARI project. Because of these reasons the progress described in this chapter can only be seen as a snapshot of the current standardisation status and not as a final result.

The SAPHARI partners undertook different kind of activities in order to influence the standardisation efforts using project results:

- Producing relevant results: the project members were well aware of the situation in standardisation and took this into consideration when planning executing and communicating their work. In other words they tried to produce results relevant to standardisation and to communicate the strengths and weaknesses of approaches accordingly.
- Talks at standardisation meetings: members of the consortium gave talks at standardisation meetings thereby ensuring maximum impact of the results presented.
- Attending standardisation meetings: as described in Section 1.5 any company representative approved to do so can attend the standardisation meetings and contribute of the discussions. KUKA took a very active role here attending working meetings regarding industrial, service robotics and medical robotics standards.
- Organising workshops and publications: the project organised several workshops and published many papers to disseminate the project results and to thereby influence the opinion in the community. By also addressing the general press, the project also helped shape the public opinion.
- Setting up use cases: by setting up demonstrators in several realistic environments the consortium evaluated the developed approaches. These setups are also ideal platforms to communicate the project results.
- Discussions with committee members: due to the excellent standing of several partners they were able, on many occasions, to discuss safety related issues directly with committee members known to them personally.

In this section the results and how they were communicated are summarised.

3.1 SAPHARI results relevant to standardisation

The results of SAPHARI WP1 are highly important for current efforts both in industrial and in service robotics safety standards. Many big companies currently try to introduce human-robot collaboration to their manufacturing sites. The robot companies trying to satisfy this need strongly rely on standards, both to ensure they fulfil all legal requirements and for a better access to international markets. Current robot safety standards and technical specifications feature some first guidelines on human-robot collaboration but they clearly lack a deeper understanding of the hazards and challenges coming with pHRI. They were

designed for a different kind of robotics, i.e. fully automated robots behind safety fences, and extended to allow for collaboration.

Within WP1 the biomechanical limits for human robot collisions investigated in T1.1 and the knowledge about safety/hazard levels of industrial objects gained in T1.2 are most valuable research results for standardisation. They help to understand the hazards in pHRI and how they can be tackled in robotic safety standards. The main goal here was to provide the scientific data which can help to differentiate between dangerous and harmless situations and hence to set sensible limits in the context of human robot interaction. Task 1.3 proposed both, a thorough method for carrying out risk analyses aided by tools decreasing the efforts required at the same time.

While for the results of WP1 it is the clear objective to update the current standards to incorporate these new insights, the objective in the context of the other SAPHARI results is slightly different. Here new technologies were developed which may help to produce safer robots in the future. Each result will be discussed briefly here.

SAPHARI dedicated significant effort to variable stiffness actuators (WP2 and 3). The advantage of these systems is that they can produce significant performance with fairly small actuators and that they can use built in “softness” to decrease the dangers of a potential impact. While the latter issue is a clear advantage, the former poses also additional safety challenges in the context of the methods used to achieve the former, especially if the variable stiffness is used to store energy temporarily.

Another focus area was how to control robots in the presence of human (WP3, 5, 6, 7). In other words, knowing where the human is, how to you re-plan the robots task to prevent it from colliding with the human and how do you plan the robots action to avoid the human causing collisions or other dangers. Another issue was how to best control a robot in a task where the robot and human are supposed to interact directly or perform a task together, e.g. by handling a work piece together. A further aspect covered was how a robot could understand gestures of a human to either interpret them as commands or to learn a task from a human.

To be able to achieve good results through the methods described in the last paragraph the robot needs to have an accurate model of where the human is and ideally also his intensions (WP4). Several tasks where hence focused on detecting the human and other obstacles in different situations and on interpreting their intentions and roles. Furthermore some work was conducted on how to detect faults and isolate them within the system.

For these results the main objective is to make sure that SAPHARI results become realisable in accordance to standards. This does not mean that each new research result has to be pushed into existing standards immediately. Nor does it mean that all approaches have to be realisable in safe technology straight away. But the committees have to ensure that new and existing standards are open enough to be able to allow new developments within the robotic safety domain. On the other hand, participating in standardisation committees helps to understand the concerns of the participants and therefore can be used to guide research in an optimal direction. This holds for all SAPHARI activities and is not limited to particular WPs or tasks.

3.2 Committee meetings attended

As mentioned above attending meetings and workshops were important dissemination measures. In this section results achieved in this context are given.

Table 2: Standardisation meetings attended

Date	Location	Attendees	Sessions attended	Results
01/02/2012-03/02/2012	Orlando	KUKA	ISO/TC184/SC2 JWG9 IEC/ISO meeting on medical robotics	Discussion which kind of standard is needed for medical robots.
06/02/2012-10/02/2012	Orlando	KUKA, DLR	ISO/TC184/SC2 WG7 ISO meeting on personal care robots	Haddadin: Presentation of biometric crash test results. Beck: Comments on many different topics of ISO 13482. For the improvement of the standard a second DIS was applied for by Germany and approved by plenary of TC184/SC2.
12/04/2012	Stuttgart	KUKA	national DIN Meeting	Preparation and coordination of German experts for the next international meeting in Washington
23/04/2012-27/04/2012	Tokyo	KUKA	ISO/TC184/SC2 WG7 ISO meeting on personal care robots	Resolving most comments for ISO 13482 for FDIS
03/07/2012-06/07/2012	Milano	KUKA	ISO/TC184/SC2 JWG9 IEC/ISO meeting on medical robotics; Workshop on medical Robots	Discussion of the purpose of a collateral standard for “medical devices using robotic technology”: Risk assessment, Boundaries to machinery directive and other standards for robots
09/07/2012-13/07/2012	Milano	KUKA	ISO/TC184/SC2 WG7 ISO meeting on personal care robots	Resolving comments on ISO 13482 for FDIS

15/10/2012-19/10/2012	Seoul	KUKA, DLR	ISO/TC184/SC2 WG7 ISO meeting on personal care robots	Beck: Comments on many different topics of ISO 13482. Resolving all comments on 2nd DIS. FDIS will be published in December (This is the first standard on robots outside the industrial area. Currently there is no reason why it should not be harmonised to the machinery directive)
22/10/2012-24/10/2012	Seoul	KUKA	ISO/TC184/SC2 JWG9 IEC/ISO meeting on medical robotics	Discussion of the purpose of a collateral standard for "medical devices using robotic technology": Risk assessment, Boundaries to machinery directive and other standards for Robots.
31/01/2013-01/02/2013	San Francisco	DLR	ISO/TC184/SC2 JWG9 IEC/ISO meeting on medical robotics	Haddadin participated for discussion on what could be done besides the standard. KUKA did not attend because status of standard was still FDIS.
31/01/2013-07/02/2013	San Francisco	KUKA	ISO/TC184/SC2 WG7 (personal care) + JWG9 ISO (medical robots)	WG 7 Discussions on further work projects (TR Verification and Validation (test methods) , Application Guide, normative human-robot data), discussion on robot impact dummies JWG 9 Discussion on boundary between medical and non-medical robots
15/01/2013	Germany	KUKA	Personal Care	Preparation for the next meeting, to harmonise the German opinion.
12/03/2013	Germany	KUKA	Industrial	Reports from the last meetings and other relevant news; preparation for the next meeting.

24/06/2013-26/06/2013	Bristol	KUKA	ISO/TC184/SC2 WG7 ISO meeting on personal care robots	Workshop on topics related to personal care robotics. Discussion on how the standard could be applied and how this should be formalised within the standard.
26/11/2013	Stuttgart	KUKA	national DIN Meeting	Preparation and coordination of German experts for the next international meeting in San Sebastian
11/02/2014-06/02/2014	San Sebastian	KUKA	ISO/TC184/SC2 WG7 (personal care) + JWG9 ISO (medical robots)	WG 7 Preparation of new TR for Verification and Validation of ISO 13482, Work on an application guide how to use ISO 13482 with examples JWG 7 discussion on degrees of autonomy and associated risks on base of examples
14/05/2014	Stuttgart	KUKA	national DIN Meeting	Preparation and coordination of German experts for the next international meeting in Washington
17/06/2014 **25/06/2014**	Washington	KUKA	ISO/TC184/SC2 WG7 + JWG9 ISO	WG 7 Continue work on TR proposal “Verification and Validation” for ISO 13482 JWG 7 Preparation proposal for TR 60601-4-1 Guidance and interpretation – Medical electrical equipment and medical electrical systems employing a degree of autonomy, continue discussions on degree of autonomy for robots and connected risks
27/08/2014	Stuttgart	KUKA	national DIN Meeting	Preparation and coordination of German experts for the next international meeting in Osaka

16/12/2014	Stuttgart	KUKA	national DIN Meeting	Preparation and coordination of German experts for the next international meeting in London
25/02/2015-27/02/2015	London	KUKA	ISO/TC184/SC2 JWG9 IEC/ISO meeting on medical robotics	Working on the IEC/TR 60601-4-1: Guidance and interpretation – Medical electrical equipment and medical electrical systems employing a degree of autonomy
07/07/2015-10/07/2015	Stuttgart	KUKA	ISO/TC184/SC2 JWG9/JWG35/JWG36 IEC/ISO meeting on medical robotics	Working on the comments for IEC/TR 60601-4-1, start working on the IEC 80601-2-77 and IEC 80601-2-78 (terms and definitions)
13/10/2015-16/10/2015	Hangzhou	KUKA	ISO/TC184/SC2 JWG9/JWG35/JWG36 IEC/ISO meeting on medical robotics	Additional work on the comments for IEC/TR 60601-4-1, proceed work on terms and definitions for IEC 80601-2-77 and IEC 80601-2-78

3.3 Workshops organised or attended

In addition to the attended standardisation meetings the partner DLR organised the following workshop: "*Sami Haddadin, Gurvinder Virk, Susanne Oberer, Yoji Yamada: IEEE/RSJ International Conference on Intelligent Robots and Systems: Workshop Safety in Human-Robot Coexistence & Interaction: How can Standardisation and Research benefit from each other?"* (7-12 October 2012 in Vilamoura, Portugal). The workshop was organised as a joint effort between the EU projects SAPHARI and ROSETTA. Furthermore, the convenor of the technical committee for the new service robotics standard ISO 13482 Gurvinder Virk and a member of the Japanese standardisation efforts Yoji Yamada were co-organisers. The aim of the workshop was to bring research, industry, and standardisation closer together to work on the standardisation of robots for interaction. As an outcome of this workshop, the organisers, presenters, and participants plan to formulate a position paper/white paper in the near future. Presentations from consortium partners were given by UNIPI, DLR, and EADS.

Another international workshop was attended during ICRA 2013 in Karlsruhe. The workshop title was *"Human Robot Interaction (HRI) for Assistance and Industrial Robots. Scientific Knowledge, Standards and Regulatory Framework. How do I design for the real world?".* It was held by Gurvinder Virk, the convenor of the technical committee for the new service robotics standard ISO 13482. It addressed evidence-based robotics and normative data for standardisation. The main goal was to find a common understanding of how normative data for standards could be collected and achieve an international consent on experiments for normative data acquisition. A follow-up of the workshop will be held at HRI 2014 conference (3-5 March 2014) in Bielefeld, Germany.

Finally, TUM organised the *"8th International Workshop on Human-Friendly Robotics (HFR)"* (21-23 October 2015) in Munich, Germany. The objective of the HFR workshop was to bring together researchers so to share knowledge on design, control, safety and ethical issues concerning the introduction of robots into everyday life. The third day was dedicated to disseminating SAPHARI results. This included a presentation by KUKA, EADS and DLR showing how the results achieved during the SAPHARI project were integrated into the use cases to showcase safe human-robot applications.

3.4 Impact of SAPHARI

Progress has been good and the objectives have been achieved. The project representatives attended ISO meetings as well as the related national coordination meetings and relevant conferences and workshops. At these meetings and workshops the results of the project were promoted and input was given in order to guide the standard development processes.

KUKA and DLR work closely together to bring the results from SAPHARI in the field of human injury analysis and reactive control into the two main robotics standards (ISO 10218: Industrial Robots and ISO 13482: Personal Care Robots). The main contribution of SAPHARI concerned collisions between humans and robots. The status of standardisation efforts on human-robot collisions can be roughly divided in two parts: the quasi-static collisions, which are already partly included in the current ISO/PDTS 15066, and the dynamic collisions which have been added to the discussion by the work done in SAPHARI and the previous PHRIENDS project. As for the quasi-static collisions, a set of values describing acceptability limits based on the experience of pain exists. Those values are quite well accepted, but are clearly not sufficient to describe or handle the dynamic collisions that can occur in typical pHRI applications. As for the dynamic human-robot collisions there is a common understanding in the committees that the limit values can be described with the physical quantities mass (mass moment of inertia), velocity, and contact area. The work of PHRIENDS and SAPHARI emphasised the relationship between robot input parameters and injury adopted by the standard. Furthermore, the collision scenarios in the standard match those that were identified by the project partners and the provided collision test results significantly influenced this standard. The collision tests related body parts, tool geometries, masses, velocities, and the injuries that result from different combinations. Further collision experiments verified the forces and pressures that occur in such collision experiments.

In this context the meetings listed above and the related national conciliation meetings were attended. DLR provided information to the standardisation committees directly through the attendance of meetings in Tokyo, Seoul and Orlando and indirectly by presenting relevant results to safety experts at KUKA, some of which attended further relevant ISO meetings. In more detail, DLR gave talks in the joint meeting in Orlando in two technical ISO committees presenting the consortium work on injury analysis in robotics. Furthermore, a plenary talk about the SAPHARI project was given. DLR and KUKA were able to provide new normative input regarding injury analysis and collision detection/reaction into the FDIS of ISO 13482 at the Seoul meeting. Furthermore, it was elected that two technical reports regarding injury analysis (under German lead) and safety testing (under Japanese lead) are to be drafted till end of January. This was a very important development for the SAPHARI project, as it made it possible to directly provide input for the international standardisation. At the Stuttgart meeting of the German DIN, DLR again presented their results on injury analysis and it was agreed on that in the Technical Specification 15066, which contained already some tables on human pain and is linked to from ISO 10218, a DIN technical group was to be

formed quickly to incorporate also the results from the SAPHARI project. The project partners further participated at meetings that try to coordinate European contributions to the international standardisation efforts, an effort organised by the FP7 projects euRobotics and RockEU. One effort undertaken was to look at third parties active in the area of standardisation (e.g. DKE http://www.dke.de) and tried to establish cooperation and alignment of efforts in Europe.

In WG 1 – "ISO 19649 – Robots and robotic devices" a standard for vocabulary is being developed. The project representative tried to ensure consistency between the vocabulary used in the standards and within SAPHARI.

SAPHARI also contribute to the efforts of WG 7 on a Type B standard for general normative human-machine safety data within TC199. Now a "Technical Report on Validation and Verification" for the new standard is in development finalisation being planned for 2017. Aim of the Technical Report on Validation and Verification is to give guidance how to test the requirements stated in ISO 13428. Special focus is on person impact tests, without the need of cost intensive car dummies from the automotive industry.

"ISO 18646 – Performance criteria and related test methods for service robots — Part 1: Locomotion for wheeled robots" is under development and currently in the enquiry Stage (DIS). The progress is being monitored and suggestions based on the partners experiences and SAPHARI results are being made. The same applies to "ISO 18646 – Performance criteria and related test methods for service robot — Part 2: Navigation" which is currently in preparation.

Robots in medical scenarios are a relatively new field of pHRI applications. Formally, these robots are considered to be medical devices which are hence bound to the requirements of the medical devices guideline 93/42/EEC. Under this guideline no norms for robotic devices and their safety aspects have been published so far. The efforts in this direction are bundled in the joint working group ISO/TC 184/SC 2/JWG 9. Since robotic devices are relatively new to most members of this group, consent on the requirements for a safety standard has not been reached yet. Discussions are going on whether to establish a new standard in this area or whether a formal standard is not needed. Currently the working group develops a document on "medical products with some level of autonomy" which is a first step towards standardisation of robotics in the medical domain.

Besides the work mentioned above the project has continued to monitor the efforts of some stakeholders to increase the number of standardisation committees. In order to avoid fragmentation and an overly complicated/ extensive/ numerous set of standards, the project has been arguing against the establishment of such new committees where appropriate. Results of SAPHARI and the efforts on standardisation were also promoted towards scientific groups interested in international standardisation and these groups were encouraged to participate in the standardisation effort. Particular attention was paid in this context to increasing European participation in order to better achieve a better balance in the light of the strong Asian delegations.

3.5 Future work

As pointed out above standardisation is a continuous, cyclic process. Therefore the efforts for pushing state-of-the-art research results into the committees have to be kept up in future. This chapter points out results and insights that have already been achieved within SAPHARI but are not yet fully accepted in the

standardisation committees. These results and insights might have to be further refined in order to meet the individual concerns of the committee members and achieve a higher acceptance.

The insights on human-robot collisions are quite well accepted in standardisation committees. However, internationally accepted specific values for safety limits are still under discussion. It was widely agreed that normative data on robot-human collisions for safety cannot be obtained or created by individual countries and several countries or groups need to work at this issues so that consensus can be reached. It is evident that the five main regions active in robotics (China, Japan, Korea, Europe and USA) need to collaborate on the development of such normative data.

As for the service robotics area, as ISO 13482 on personal care robots has been published only recently, the next step should be to ensure that this new standard is well understood and used correctly by manufacturers. For this, guidance as well as an appropriate verification and validation methodology need to be developed for the clauses presented in ISO 13482. Since this is the first standard in this area, standardisation can assist in improving the affordability of the systems and opening the markets by developing appropriate interoperability standards. Especially service robots need to be able to interact in challenging and various environments (e.g. children playing with robots) and deal safely with typical human behaviours. The use of the standard should hence be closely monitored to determine where revisions or clarifications are required. For example, ISO 13482 currently covers three types of robots and perhaps the scope could be too wide, so it may be advisable to divide the standard into several parts in the future. There is a need to consider and assist in defining acceptable risk limits with use of robots bearing in mind that overly strict limits will inhibit application domains and hinder development. Determining real-world user requirements is important and will lead to new research directions.

4 Conclusions

The goals of this document were to present the work done within SAPHARI in the context of the standardization process. In recent years pHRI is receiving considerable attention in robotics. Standardisation institutes (e.g. ISO) are spending a lot of effort developing norms concerning collaborative robotics. Of course, pHRI implies direct contact and collaboration between humans and robots and thereby requires a complete change of mind-set from the traditional approach of separating humans and robots. This topic raises a set of issues to consider, e.g. collision forces. SAPHARI continued the work started with PHRIENDS, in particular with regards to collision tests and studies on the injuries provoked by undesired human-robot collision. SAPHARI also worked towards improving medical robotics and service robotics. These are topics which are becoming always more relevant (e.g. service robots in a professional or public or private setting, surgical robotics, robotics for elderly people or personal care robotics), and where SAPHARI worked a lot in order to help the norm development process. During the project runtime significant steps have been undertaken and SAPHARI and the partners have had considerable influence. The resulting new standards follow the paradigms promoted and followed by SAPHARI.

Of course, none of these topics are closed. Standardisation is a long, cyclic process. Writing norms is not easy and requires a lot of effort. Pushing some concepts from research to standards requires time. SAPHARI tried to help this process, closing the gap between research and standardisation. A lot of work is yet to be done, but the right direction is set.

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