Considerations for developing safety standards for industrial exoskeletons

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**INTRODUCTION**

Emerging technology in human robot collaboration has transported fiction into reality, particularly in the arena of wearable robots that bestows super strength to users in the military services and transforms the lives of individuals with mobility issues. Examples include Cyberdyne's HAL\(^1\), Ekso Bionics' eLEGS\(^\text{TM}\)\(^2\) and ReWalk\(^\text{TM}\) Bionic Suit\(^3\).

The EU funded R&D project Robo-Mate is bringing exoskeletons into the industrial workplace setting, and creating a device that augments the capacity of workers involved in manual handling activities. These individuals, because of their task demands and working conditions, are exposed to risk factors that increase their likelihood of developing musculoskeletal disorders (MSDs) or exacerbating existing musculoskeletal disorder symptoms. The industrial exoskeleton has potential for use in many work environments where manual handling activities are required. Their use can reduce the burden on workers’ health while maintaining or increasing production efficiency.

However, the evolution of applicable standards does not coincide with emerging technology, specifically for industrial exoskeletons. The development of such a standard will assist in the design, manufacture, and composition of safe reliable exoskeletons that facilitate reducing workers risk of developing or exacerbating MSDs.

The purpose of this White Paper to inform the industrial community about the potential risk reduction benefits of the Robo-Mate industrial exoskeleton. Additionally, Robo-Mate introduces key safety and ergonomic knowledge to promote the development of standards that will have an application to the safety, reliability, and quality of industrial exoskeletons.

**WHY ARE INDUSTRIAL EXOSKELETONS REQUIRED?**

**Risk to workers who perform manual handling tasks**

Even in modern and high-tech manufacturing industry, many operations necessary in industrial manufacturing processes are difficult to automate. 64% of highly skilled manual workers perform lifting and carry loads for at least a quarter of their normal work time\(^4\). Consequently, workers frequently perform manual handling activities that are an intrinsic requirement in the manufacturing and auxiliary operations. Such activities expose workers to risk factors that increase the likelihood of injury, particularly the development of MSDs. MSDs remain the most common occupational disease in the European Union, and workers in all sectors and occupations can be affected\(^5\). The increasing prevalence of the disorders has a significant impact on both short and long-term sickness absences\(^6\). About 44 million EU workers are affected by MSDs at a total annual cost in excess of €240 billion to the European economy\(^7\).

**SAFETY AND HEALTH MANAGEMENT OPTIONS – WAYS TO REDUCE MSD RISK**

**Applying Ergonomics and Human Factors principles**

The concept of Ergonomics and Human Factors recommends designing work, work tasks, tools, equipment, and the working environment around the capacity and limitations of the workers\(^8\). When considering manual handling activity, if the activity cannot be eliminated, alternative measures must be applied to safeguard the wellbeing of the worker while optimising productivity and system performance. Consequently, to assist in productivity and enable workers complete their work in a safe and comfortable manner, work aids and tools have become mechanised, and work systems have become automated.
It is recommended that ergonomic principles be applied when organising work environments and when designing and manufacturing work aids and tools.

- [http://intl.eksobionics.com/ekso](http://intl.eksobionics.com/ekso)
- [http://www.rewalk.com/](http://www.rewalk.com/)

**Using emerging technologies - Robotic work aids**

Advancement in technology enables industry to adapt to market challenges. Innovative work aids and manufacturing systems enable shorter product life cycles, increased product diversity, and increased production output. In addition, technology has the capacity to enhance physical and mental capabilities, senses, dexterity, and intelligence.

To assist in manual handling activities, technological evolution has progressed from mechanised tools, to automated systems, to collaborative interactive robots, and of late, to wearable exoskeleton devices. While modern research and development of exoskeletons primarily focuses on military and rehabilitation environments, the devices have potential for development as a work aid that augments the workers’ capacity.

Using ergonomically designed exoskeletons will reduce the incidence and severity of manual handling related injuries for EU citizens and subsequently reduce associated financial burdens experienced by workers and society. Additionally, employers should have an overall positive financial return on their investment with reductions in MSD related absenteeism and improvements in the quantity and quality of productivity[9].

**Using Robo-Mate’s industrial exoskeleton**

Military and rehabilitation exoskeletons, particularly due to excessive weight, severe restriction of human movement and further inadequate functionality are ill suited for industrial work environments. In order to meet industrial needs and to minimise workers exposure to MSD risk factors, the Robo-Mate project was initiated to create the industrial worker’s lightweight, flexible, easy-to-wear, easy-to-manoeuvre, and intelligent exoskeleton in accordance with ergonomics principles.

*The industrial exoskeleton is “A user guided robot that is worn by or fits closely to his/her body with the purpose of aiding actions or performing actions that contribute directly towards improving the quality of the user’s work by augmenting the functions of their musculoskeletal system when performing physical work”*[10]

**Implementing Directives, Legislation and Standardisation**

European Directives and transposed legislation imposes a duty of care to produce safe reliable products in a safe manner while simultaneously protecting the wellbeing of those involved in the processes and protecting end-users.

Standards are written specifications that provide minimum acceptable guidance for products and services i.e. ergonomically safe and reliable products that are compatible with the human form and its capabilities/limitations[1]. While the implementation of standards is voluntary for organisations, products that are manufactured in compliance with applicable standards adhere to minimum quality and safety design criteria, are comprised of acceptable materials and components, and have been tested and evaluated. Additionally, the application of standards can assist in meeting legal requirements, can minimise costs associated with material selection and production, and facilitate interoperability within the European and global markets.

Countries are not obliged to implement standards developed by the International Standardisation Organisation (ISO) but these standards can be adopted regionally (e.g. European (EN)) or by individual countries. Standards developed by the European Committee for Standardisation (CEN), and the European Committee for Electrotechnical Standardisation (CENELEC) are European standards. They must be adopted by member states and can be adopted by ISO.
The development of standards is a complex process, takes approximately three years, and is initiated and coordinated by technical committees that are comprised of a panel of experts and associates. The process is usually instigated in response to research and technology development. In addition, standards that are already published can be amended or updated when new information becomes available.

**INDUSTRIAL EXOSKELETON STANDARD - THE WAY FORWARD**

*Exoskeletons and potential risk to user*

When being used as an assistive device, wearable robotic exoskeletons are designed to interact continuously with its user, are in continuous contact with the user, and occupy the same space and time. They can be directly controlled by the users’ body movements, mentally controlled, or controlled through sensor feedback systems. Based on users’ requirements, (military, rehabilitation or industrial), each exoskeleton device is designed to accomplish specific tasks within specific environments, and comprised of a set of components in a specific configuration.

The close proximity between users and exoskeletons exposes the users to multiples of hazards that require extreme consideration. While standards are published to guide the inherently safe design of service, industrial and personal care robots\textsuperscript{10} (ISO: 13482, ISO: 10218/1 and ISO: 10218/2) (Table 1), there are no standards currently published that manage industrial worker exoskeletons. Additionally, the harmonised standards published under the Machinery Directive do not relate to a machine and wearable tool combined device. Subsequently, guidance documents and standards require development and updating to accommodate exoskeleton technology.

<table>
<thead>
<tr>
<th>Published Standard\textsuperscript{(ii)}</th>
<th>Consideration for selecting to further develop</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 13482 – 2014: Robots and robotic devices - Safety requirements for personal care robots</td>
<td>Specifies requirements &amp; guidelines for the safe design, protective measures, and information for personal care robots. This is the only published standard in which the term exoskeleton is provided to refer to a physical assistant robot</td>
</tr>
<tr>
<td>ISO 10218 /1-2011 Robots and robotic devices - Safety requirements for Industrial Robots, Part 1 Robots</td>
<td>Specifies the requirements and guidelines for the inherent safe design, protective measures, and information for use of industrial robots</td>
</tr>
<tr>
<td>ISO 10218/2-2011 Robots And Robotic Devices- Safety Requirements for Industrial Robots: Part 2 Robot Systems &amp; Integration</td>
<td>Specifies requirements for the integration of industrial robots and industrial robot system as defined in ISO 10218 - 1</td>
</tr>
</tbody>
</table>

**Balancing old and new risks requires a new standard**

The introduction of industrial exoskeleton technology implies a paradigm shift in designing work places. This raises new demands on:

- The cost benefit ratio and selection of work aids
- Suitability and acceptability of exoskeletons as comfortable aids with added value
- Appropriate risk analysis and evaluation being integrated over its life cycle to explicitly and coherently deal with ergonomics, health and safety issues as new risks emerge
Health and safety management to monitor emerging safety and health issues arising from changes in work environments and task demands, and post market monitoring of emerging risk not foreseen by the supplier of an exoskeleton

Phase of the life cycle to be covered: design, testing, use and maintenance.

Key aspects for standardisation for industrial exoskeletons

An industrial exoskeleton standard can provide guidance and support to manufacturers, designers, safety engineers, risk managers, certification agencies, employers, and users and will promote safe, reliable, and functional products. The standards will provide details about hazards throughout the lifecycle, risk reduction strategies, minimum design requirements, assessment methodologies, and validation methods. The application of standards will increase customer and user confidence, and subsequently motivate the desire to use such an item in the work environment.

Robo-Mate as a contribution to the development of industrial exoskeleton standards

Robo-Mate, with its industrial exoskeleton research and technology advancement, can contribute to benchmarking in the fields of robotic-enabled, flexible production and manufacturing processes. The consortium promotes the development of standards to govern the safety, reliability, and quality of industrial exoskeletons on an international and European level. This may be achievable by developing a new industrial exoskeleton standard or amending currently published standards that correlate with the industrial exoskeleton. Benchmarking in this area will identify the highest standards of excellence for industrial assembly/dismantling or service-related processes and making the necessary improvements to reach or exceed those standards. Developing standards targeted at exoskeletons for use by industrial workers will assist in addressing the high prevalence of MSDs experienced by industrial workers (Table 2) and protect against new risks.

Robo-Mate experience contributes to risk management and standardisation

The design, structure, and composition of the Robo-Mate exoskeleton will result in a wearable robot that differs from other wearable robots already governed by currently published standards. A standard targeted at industrial exoskeletons requires clarity with the addition of more applicable terms and definitions. The specific environment of industrial application requires a systems view on risks that can emerge.

<table>
<thead>
<tr>
<th>Occupational health and safety</th>
<th>Product reliability</th>
<th>Product management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usability</td>
<td>Fault analysis</td>
<td>Product development, production, sales and</td>
</tr>
<tr>
<td>Training</td>
<td>Failure modes and effects</td>
<td>Aftersales service and monitoring performance</td>
</tr>
<tr>
<td>Injury prevention</td>
<td>Software &amp; controls reliability</td>
<td>Risk and safety management.</td>
</tr>
<tr>
<td>Monitoring of health and safety</td>
<td>Maintainability</td>
<td>Deal with emerging risks – post market monitoring</td>
</tr>
</tbody>
</table>

| Product health and safety                      |                                                                 |                                                                                  |
| Safety analysis                                 |                                                                 |                                                                                  |
| Ergonomic analysis                             |                                                                 |                                                                                  |
| Risk perception and acceptance of              |                                                                 |                                                                                  |
| exoskeleton (objective and subjective)         |                                                                 |                                                                                  |

<table>
<thead>
<tr>
<th>USE ENVIRONMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robo-Mate system</td>
</tr>
<tr>
<td>Robo-Mate user</td>
</tr>
<tr>
<td>Robo-Mate exoskeleton</td>
</tr>
<tr>
<td>Robo-Mate extensions</td>
</tr>
</tbody>
</table>

Table 2: Rewards for developing industrial exoskeleton standards

<table>
<thead>
<tr>
<th>Machine to work with spaces to be entered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products or tools to be manipulated</td>
</tr>
<tr>
<td>Bystanders and people passing</td>
</tr>
</tbody>
</table>

Figure 2: Two sides of safety: product design and safety at work (manufacturer and future use)
In the safety and risk management process of the project, risk assessment procedures are applied by Human Factors engineers, ergonomists, and designers. The process is coordinated by safety and health management experts throughout the project's lifecycle. Potential hazards are identified, and as the project progresses, intervention strategies are implemented to eliminate hazards where possible. Where risk cannot be eliminated, strategies to minimise risk associated with hazards are introduced. The resulting information about hazards and subsequent intervention strategies can be detailed in standards that are targeted at industrial exoskeletons.

As case study assessments and ergonomic principles guide the design of the Robo-Mate exoskeleton, the information and results from the project can be used to provide recommendations for industrial workplace environments:

**Specific design requirements for exoskeleton hardware & software components and systems**
- Actuating controls
- Moving components
- Normal and emergency start-up & stop controls
- Imitators - speed control, range of movement, support systems
- Safety mechanisms
- Operational systems

**Single/multiple user capabilities and limitations**
- User comfort
- Dimensions and robot shape of exoskeleton
- Enable free movement while augmenting user's physical abilities
- Limit extremes of movement, awkward postures,
- Easy to use and interact with
- Design of user interface
**Work environment conditions**
- Workplace layout design, storage, and operational space requirements
- Installation requirements – power sources, communication, and connection requirements

**Operation and usability**
- Putting on and taking off exoskeleton
- Man-machine interface
- Protective measures and safety device requirements in the event of emergency, error, or failure e.g. emergency release, emergency stop
- Instruction, training, maintenance and inspection requirements
- Markings requirements to comply with directives and standards

**Vision on exoskeleton standards**

**The scenarios for standardisation may be considered:**
- The development of a coherent family of standards dealing with robot safety in all fields.
- A C-type standard of CEN/CENELEC on exoskeleton safety as part of the EN-ISO 10218 series that supports compliance with the machinery directive.
- A guidance document that helps to interpret general standards dealing with machine and robot safety.
- A standard or guidance document to support managing risks of an exoskeleton from the perspective of the manufacturer and supplier.

**The content of the standard may relate to the following issues:**
- **Product management**
  - Product development, production, sales and
  - Risk and safety management.
- **Product reliability**
  - Failure modes and effects
  - Fault analysis
  - Software and controls reliability performance/integrity levels
  - Maintainability.
- **Product health and safety**
  - Safety analysis
  - Ergonomic analysis
  - Risk perception and acceptance of exoskeleton (objective and subjective).
- **Occupational health and safety**
  - Selection products fit for purpose and for user
  - Usability
  - Training
  - Injury prevention
  - Stress prevention
  - Monitoring of health and safety (Refer to Table 2)
- **Verification & Validation**
  - Testing in simulation, laboratory & work environments
  - Standard Operating Procedures (SOPs) outlining testing, validation & verification methodologies and requirements

In Table 3, synopses of the sections where Robo-Mate results have potential to further develop the content of the three robot and robotic standards to incorporate industrials exoskeletons is presented.
### POTENTIAL CONTENT INPUT FROM THE ROBO-MATE PROJECT THAT WILL SUPPORT THE FURTHER DEVELOPMENT OF CURRENTLY PUBLISHED STANDARDS TO INCORPORATE INDUSTRIAL EXOSKELETONS

<table>
<thead>
<tr>
<th>GENERAL</th>
<th>SPECIFIC HAZARD MANAGEMENT</th>
<th>SAFETY REQUIREMENTS &amp; PROTECTIVE MEASURES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terms &amp; definitions</td>
<td>Terms &amp; definitions</td>
<td>Terms &amp; definitions</td>
</tr>
<tr>
<td>Hazard management</td>
<td>Hazard management</td>
<td>Hazard management</td>
</tr>
<tr>
<td>Elimination &amp; risk reduction</td>
<td>Elimination &amp; risk reduction</td>
<td>Elimination &amp; risk reduction</td>
</tr>
<tr>
<td>List of significant hazards</td>
<td>List of significant hazards</td>
<td>List of significant hazards</td>
</tr>
<tr>
<td>Risk reduction strategies</td>
<td>Risk reduction strategies</td>
<td>Risk reduction strategies</td>
</tr>
<tr>
<td>Risk assessment guidelines</td>
<td>Risk assessment guidelines</td>
<td>Risk assessment guidelines</td>
</tr>
</tbody>
</table>

| Due to robot shape                                                     | Safety-related control                                                                    | Layout design                                                                                            |
| Due to stress, posture & use                                           | system performance                                                                        | Risk assessment                                                                                         |
| Due to robot motion                                                    | Operational modes                                                                         | Hazard identification                                                                                    |
| Due to insufficient durability                                         | Control of simultaneous motion                                                             | Hazard elimination & Risk reduction                                                                      |
| Due to incorrect decisions & actions                                  | Collaborative operation requirements                                                       |                                                                                                          |
| Due to contact with moving components                                 | Axis limiting                                                                             |                                                                                                          |
| Environmental conditions                                               | Movement without drive power                                                              |                                                                                                          |
| Due to localisation & navigation errors                                | Provisions for lifting                                                                     |                                                                                                          |

| Robot stopping functions                                               | Safety-related control                                                                    | Safety-related control system performance                                                                |
| Limits to operational spaces                                           | system performance                                                                        | Limiting robot motion                                                                                    |
| Safety-related speed control                                           | Layout                                                                                    | Layout                                                                                                   |
| Safety-related environmental sensing                                   | Robot system operational mode application                                                 | Robot system operational mode application                                                               |
| Stability control                                                      | Maintenance and repair                                                                    | Maintenance and repair                                                                                    |
| Safety-related force control                                           | Integrated manufacturing system interface                                                 | Safety-related force control                                                                             |
| Design of user interface                                               | Safeguarding                                                                              | Design of user interface                                                                                 |
| Operational modes                                                     | Collaborative robot operation                                                            | Operational modes                                                                                        |
| Manual control devices                                                 |                                                                                          | Manual control devices                                                                                   |

| Verification & validation                                              | Verification & validation methods                                                          | Verification & validation of protective equipment                                                        |
| User & Service manual                                                  | User & Service manual                                                                      |                                                                                                          |
| Labelling & Marking guidelines                                         | Labelling & Marking guidelines                                                              |                                                                                                          |
ABOUT THE ROBO-MATE PROJECT

Mission and tasks of the Robo-Mate project

The three-year Robo-Mate project started in September 2013 and is funded by the European Commission under the 7th Framework Programme for Research and Technological Development. Its consortium is comprised of twelve partners from seven countries, which includes end-users from automotive and dismantling industries, industrial robotics/technology developers, a robotics integrator, and ergonomics research groups. Their multi-disciplined expertise and competence embrace the fields of intelligent and assistive robot systems, robotics-enabled production processes, human-machine interfaces, ICT-based factory integration, electronic devices, control systems, ergonomics, biomechanics, production management, and safety management. This configuration forms a unique team that facilitates the management of critical challenges and enables the development of the next generation of manufacturing tools based on human-robot cooperation. The project addresses the European Factories of the Future Research Association research priorities and will design an innovative product that will be developed and marketed by European industry using European technology and intellectual property. The Robo-Mate exoskeleton will help reduce the social burden of workplace injuries within European society.

The 3 year EU-funded project commenced September 2013 and consists of partner-managed work packages carried out within pre-determined timelines, each generating deliverables in the form of written reports and the creation of exoskeleton prototypes. An array of applicable hardware and software technology and research methods is being applied throughout the project to ensure best practice guidelines are applied throughout the design process e.g. AnyBody, (etc– details to be added), detailed literature review, on-going risk assessments, brainstorming sessions, and the construction and testing of prototypes and the Robo-Mate exoskeleton end-product.

Throughout the project, participants are kept up to date with the research and development process and are informed about concepts, results, and information through the project’s Document Management System, email, online meetings, and regular progress meetings. Upon completion of the project, the Robo-Mate participants will gain expertise, knowledge, skills, information, and an array of scientific and technological results.
Robo-Mate project deliverables – Enhanced knowledge, skills, and information

- Initiated early in the project, and continued throughout the project, the consortium has carried out a detailed literature review to establish human capacities and limitations (e.g. joint ranges of motion, anthropometric measurements and dimensions (human body static & dynamic and strength), torque and muscle force strengths, and movement kinematic data as well as an evaluation of relevant safety issues.
- Ergonomic laboratory assessments are on-going throughout the project to evaluate the influences of working environments and manual handling activities (working heights, load weights, postures etc.) on human physical (musculoskeletal system) and psychological systems. The assessment scenarios are founded on work conditions and task demands identified in a variety of applicable industrial case studies (e.g. automotive, automotive components, dismantling, and scrap recycling).
- Proposed designs of exoskeletons and their influence on users are evaluated in simulated working environments (representing case study conditions) using appropriate software and technology (e.g. AnyBody, CAD and JACK). The results are further used to modify the exoskeleton design.
- Robo-Mate’s safety management team continuously monitor and communicate requirements to ensure the safe design of an ergonomic and functional exoskeleton that realised user’s needs.
- Risk management is continuous throughout the project to identify potential hazards and subsequent risk reduction strategies. Details are maintained and updated in a hazard management database.
- Published standards are reviewed to identify pertinent standards to ensure minimum ergonomic and safety criteria and design requirements are applied to the Robo-Mate exoskeleton.
- Participants of the Robo-Mate project gain expertise and knowledge regarding exoskeletons (throughout its lifecycle), the working conditions and task demands of the end-user, and holistic view of safety and health with respect to systems view. Additionally, the consortium has developed a significant network of connections in manufacturing industries, robotics industries, research industries, and regulatory bodies.

The knowledge, skills, information, and results gained from the literature review, on-going safety & risk management, workshops, brainstorming sessions, and evaluation testing of exoskeleton prototypes is regularly communicated to consortium members via the project’s document management system, emails, and frequently scheduled meetings. This collaboration and frequent communication enables increased awareness, and the exchange of knowledge, views, and experience that ensured continuity of knowledge transfer through the lifecycle of the Robo-Mate project. Additionally, the details are used to set minimum design requirements for the Robo-Mate exoskeleton that is being designed to enable its use by multiples of workers rather than targeted for use by a single worker.

Robo-Mate resources for standards development

In addition to publishing this White Paper, consortium members are actively distributing project details and results through a variety of mediums. Examples include the publication of regular newsletters (link), posting details on the Robo-Mate project website (www.Robo-Mate.eu) and on robotic organisation websites (EURobotics link), attending international conferences (www.ahfe2015.org), publishing journal papers. Additionally, members are liaising with connections in ISO, CEN and their National Standardisation Bodies.
References

[10] Definition considered for exoskeletons after carrying out a review of relevant standards and documents, and analysing a range of definitions
[12] HAL® for Medical Use, CYBERDYNE Inc. obtained CE Marking [CE 0197] for conformity to the requirements of Medical Device Directives in EU. CYBERDYNE Inc. received the certificate of ISO13485 (Medical Device)
[13] Further information from technical committee responsible for developing the standards - ISO TC184/SC2 Robots and robotic devices at:
http://www.iso.org/iso/home/standards_development/list_of_iso_technical_committees/iso_technical_committee.htm?commid=54138

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