InnoTecUK™

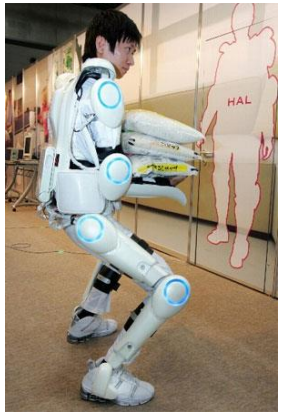
ISO TC299 Robotics

SG1: Gaps and structure

IEC TC62: Electrical equipment in medical practice
- SC 62A: Common aspects of electrical equipment used in medical practice
- SC52D: Electromedical equipment

MILITARY | INDUSTRIAL ROBOTS | PERSONAL CARE ROBOTS | MEDICAL ROBOTS | ME EQUIPMENT









JWG36: Rehabilitation

WG3: Industrial robots | WG2: Personal care robot safety | JWG9: MEE&S using robotic technology

Challenges in emerging service robots

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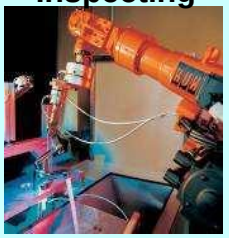
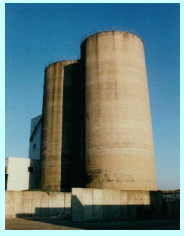
1) Convener: ISO TC 299/WG2: Personal care robot safety: 2006-2016
2) Convener: IEC SC62A & ISO TC 299 JWG9: MEE & S using robotic technology
3) Convener: ISO TC 299/WG06: Modularity for service robots
4) Convenor: ISO TC 299/SG1: Gaps and structure
5) Director: euRobotics Topic Group Standardisation for H2020

Main robot sectors

- **Industrial robots: powerful, precise robots for manufacturing**

Spot welding 
Handling 
Assembling 
Machining 
Polishing 
Inspecting 
Palletizing 

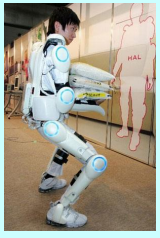
- **Robots for hazardous environments: Hazardous environments**

Power lines 
Petrochemical 
High buildings 
Oil tanks 
Power stations 
De-mining 

- **Service robots: Useful tasks for humans**

Medical robots

Garbage 
Domestic 
Servant 

Assistance 
Person carrier 
Rehabilitation 
Surgery 

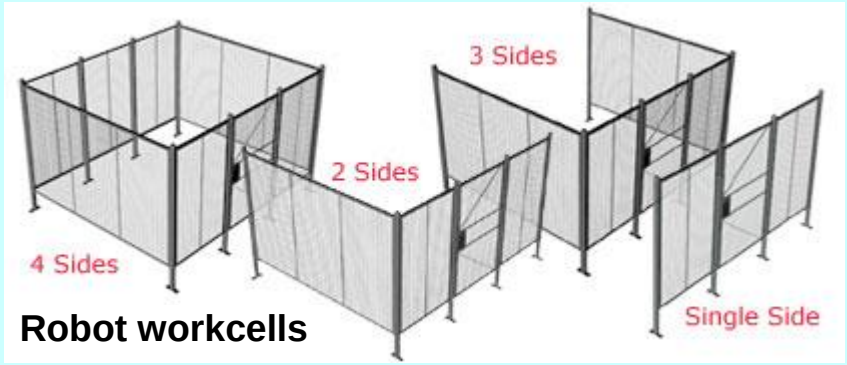
Summary of presentation

- **Robot safety and changing situation**
  - **Industrial ⇨ Service**
- **Role of regulation**
  - **Update on safety standardisation activities**
- **Wearable robots**
  - **Non-medical (ISO 13482)**
  - **Medical (IEC 60601-4-1, -2-77 and -2-78)**
- **Conclusions**

Robot are dangerous: Impacts

Traditional industrial robot applications

- **Powerful machines operating at high speeds and with great precision and dexterity**
- **Designed to operate in workcells separated from humans for safety**

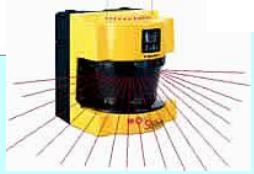


Robot workcells


Traditional robot workcell setup

Human access to the robot's operational space in the workcell is strictly controlled and regulated


Safety switches



Light curtains, lasers and pressure mats, etc

New ways of using industrial robots

KUKA KR500 heavy duty arm

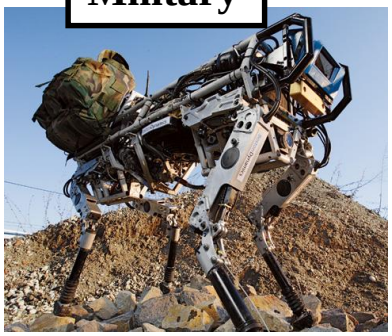
KUKA Robocoaster Robot

Changing scene of robotics: Industry to services

Manufacturing

Domestic

Military



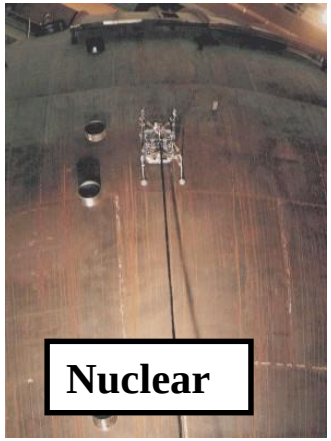
Medical

Collaborative

INDUSTRIAL - SERVICES

Mobile servant

Surgery

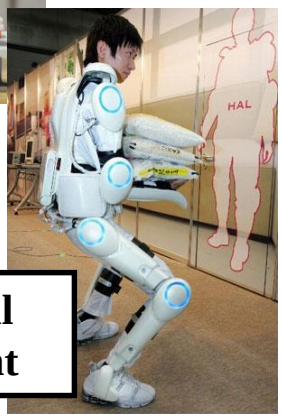


Nuclear

Security

Person carrier

Physical assistant



Future Needs: Manufacturing to Services

- **Robots to do tasks that must be done but can't be done any other way**
- **Robots need to move out of the factory to "everywhere"**
- **Robots need to do a WIDE variety of "service" tasks rather than only "manufacturing" operations**
- **Robotics has good potential because society is "ageing" and more dependent on technology**
  - **New tasks for robots emerging in everyday life**

Industrial / service robots: Distinctions and future requirements…. SAFETY issues

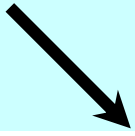
	Industrial Robots	Service Robots
Working environments	Controlled and defined environments	Information structured/ unstructured environments
Users	Training for specified tasks in defined environments	Training to cover wide range of tasks in info structured/ unstructured environments
Safety	Machine dependent (ISO 10218-1)	Dependent on the robot and the user (ISO 13482)
Working philosophy	To keep robots and humans separated (see ISO 10218-1, -2; ISO TS 15066)	Robots and humans must share workspace for providing/ receiving the services (see ISO 13482)
Machine design	Flexible on commissioning for defined task	Flexible on demand for generic tasks/ users

Need:

- **Flexibility**
- **Usability**
- **Safety**
- **Human-Robot Collaboration**
- **Effectiveness**
- **Reusable**

Role of regulation

- Countries need to regulate their own markets to ensure products are safe and organisational procedures reduce environmental impact to allow trade between countries to simplify procedures and make things work.
- Allow consumers to benefit by the knowledge that state-of-the-art practices are developed/adopted for global relevancy and standards help this process
- Types of standards: Safety, Quality, and efficiency specifications for products, services and systems
  - Minimum acceptable requirements for: Health, Safety, Environment
  - Metrics for assessing: Safety related performance, quality performance
  - Guidance documents: Test procedures
  - Other standards: Inter-operability, terminology

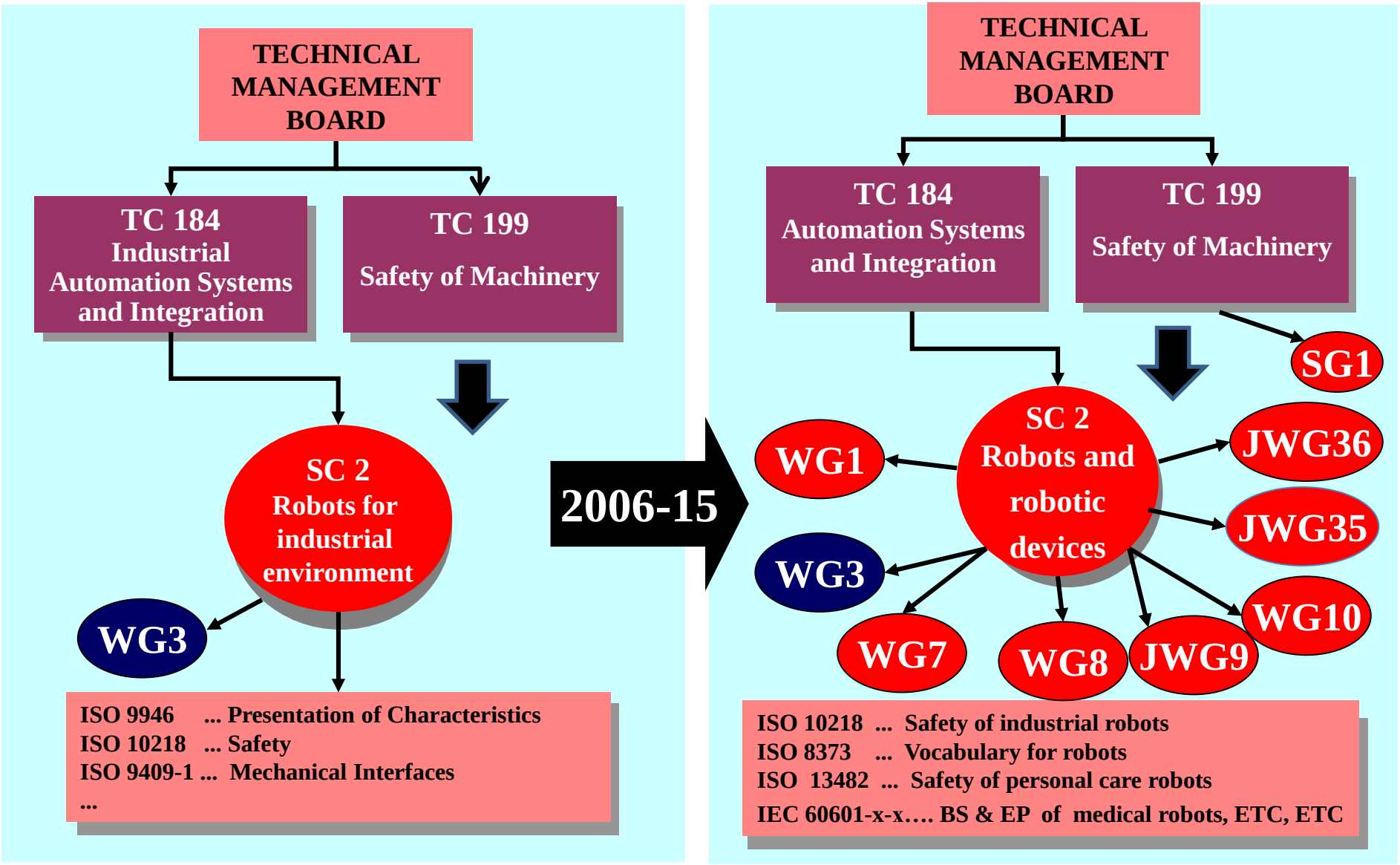


EC Directives
- Machinery Directive
- Medical Device Directive

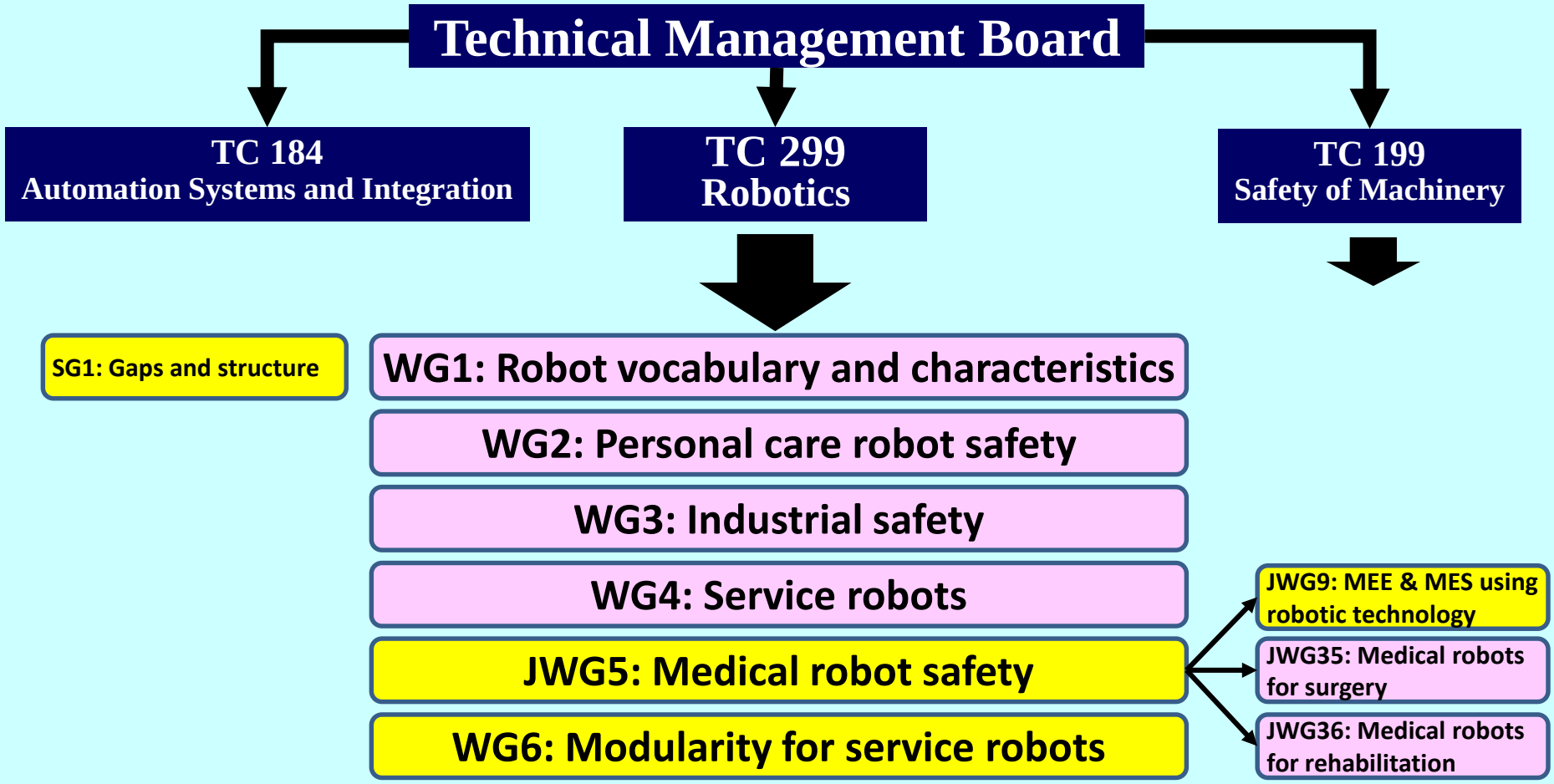
Generic safety design methodology

- **ISO 12100 defines a standard approach to designing machines to achieve safety requirements:**
  1. **First, try to achieve the safety requirements by means of *inherently safe design***
  2. **If inherently safe designs are not possible, then try to achieve the requirements by means of *safeguarding or protective measures***
  3. **If neither of these solutions are possible, then provide *information for use* to the operator (warnings, instructions) to assist the operator in achieving acceptable safety**
  4. **(implicit) If none of these are possible, then acceptable safety cannot be achieved and the machine should not be used**
- **Harmonised safety standards for robots**
  - **EN ISO 10218-1:2011, Safety requirements for industrial robots – Robots**
  - **EN ISO 10218-2:2011, Safety requirements for industrial robots – Robot systems and integration**
  - **ISO TS 15066:2016, Collaborative industrial robots**
  - **EN ISO 13482:2014, Safety requirements for personal care robots**

Changing face of ISO robot standardization



From Jan 2016: ISO TC 299 Robotics



- ISO 10218-1:2011, Safety requirements for industrial robots: Robot
- ISO 10218-2:2011, Robot systems and integration
- ISO TS 15066:2016, Collaborative (industrial) robots
- ISO 18646-1, Perf test methods-Locomotion for wheeled robots
- ISO 8373:2012, Vocabulary for robots
- ISO 13482:2014, Safety requirements for personal care robots
- IEC 60601-4-1:2017, MEE with DOA

- WG1: ISO 19649, Vocabulary for mobile robots
- WG2: 23482-1: Safety-related test methods; 23482-2: App guide to 13482,
- WG3: NWPs on End of arm tooling, manual load stations
- WG4: ISO 18646-2 Navigation for wheeled robots
- JWG5: IEC 80601-2-77, BS&EP Med robots for surgery; IEC 80601-2-78, BS&EP Med robots for rehab
- WG6: ISO WD 22166-1 Modularity for service robots – Part 1: General requirements

Definitions: Machinery & Medical devices

Broadest definition of machinery given within the EC's Machinery Directive is:

- **an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application**

Definition of medical device; IEC 60601-1 Definition 3.63, 3.64:

- **medical device shall assume the same meaning as MEDICAL ELECTRICAL EQUIPMENT or ME SYSTEM**
- **ME EQUIPMENT: electrical equipment having an applied part or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is:**
  - **a. provided with not more than one connection to a particular supply mains; and**
  - **b. intended by its manufacturer to be used:**
    1. **in the diagnosis, treatment, or monitoring of a patient; or**
    2. **for compensation or alleviation of disease, injury or disability**
- **ME SYSTEM: combination, as specified by its manufacturer, of items of equipment, at least one of which is ME EQUIPMENT to be inter-connected by functional connection or by use of a multiple socket-outlet**

Machine/ Medical Device safety

- **ISO 12100:2010, Safety of machinery – General principles for design – Risk assessment and risk reduction, defines a standardised (3 step) approach for designing machines to achieve safety requirements:**
  1. **Try to achieve the safety requirements by means of inherently safe design**
  2. **If inherently safe designs are not possible, then try to achieve the requirements by means of safeguarding or protective measures**
  3. **If neither of these solutions are possible, then provide information for use to the operator (warnings, instructions) to assist the operator in achieving acceptable safety**

- **ISO 14971:2007, Medical devices –Application of risk management to medical devices, deals with the processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment and the environment. The risk management comprises systematic application of management procedures and practices to the tasks of:**
  1. **Risk analysis + Risk evaluation + Risk control**
  2. **Evaluation of overall residual risk acceptability (risk-benefit balance)**
  3. **Risk management report**
  4. **Production and Post production information (Monitoring)**

WG1: Latest robot definitions

- **robot:** programmed actuated mechanism with a degree of autonomy, moving within its environment, to perform intended tasks
- **service robot:** robot that performs useful tasks for humans or equipment excluding industrial automation applications
- **industrial robot:** automatically controlled, reprogrammable multipurpose manipulator, programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications
- **autonomy:** ability to perform the intended tasks based on current state and sensing, without human intervention
- **personal care robot:** service robot that performs actions contributing directly towards improvement in the quality of life of humans, excluding medical applications
- **medical robot:** a robot intended to be used as medical electrical equipment (MEE) or as medical electrical systems (MES)

Safety requirements for personal care robots

WG2: Personal care robot safety (non-medical). EN ISO 13482: 2014

1. **Mobile servant robot:** personal care robot that is capable of travelling to perform serving tasks in interaction with humans, such as handling objects or exchanging information
2. **Physical assistant robot (PAR):** personal care robot that physically assists a user to perform required tasks by providing supplementation or augmentation of personal capabilities
   - restraint type PAR: PAR that is fastened to a human during use
   - restraint-free type PAR: PAR that is not fastened to a human during use
3. **Person carrier robot:** personal care robot with the purpose of transporting humans to an intended destination.

Mobile servant

Physical assistant

Person carrier robots

Service robots developed

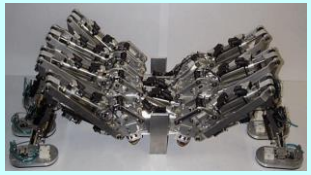
CLAWAR, locomotion, hazardous, bio-inspired, modular, etc


Bigfoot

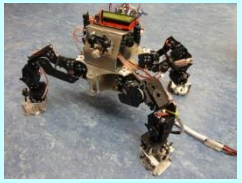

Nero III


Robug 2s


Robug 3


Robug 4


Robovolc


Winspecbot-walking Climbing


BIRAW

Wearable mobility exoskeletons: medical and non-medical

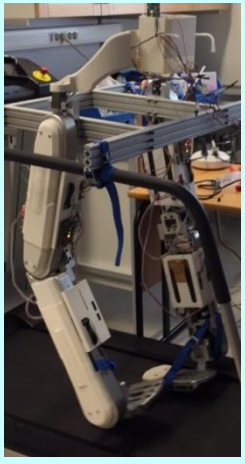
Exoskeleton legs for elderly persons (EXO-LEGS): AAL Call 4 project: 1 Oct 2012 -31 March 2016, €4.55M

AAL Mobility requirements

- Basic
- Standard
- Deluxe

EXO Components

- Modelling
- Modular framework
- Design Basic EXO
- Build EXO
- Test EXO with ethics



EXO-LEGS Movies

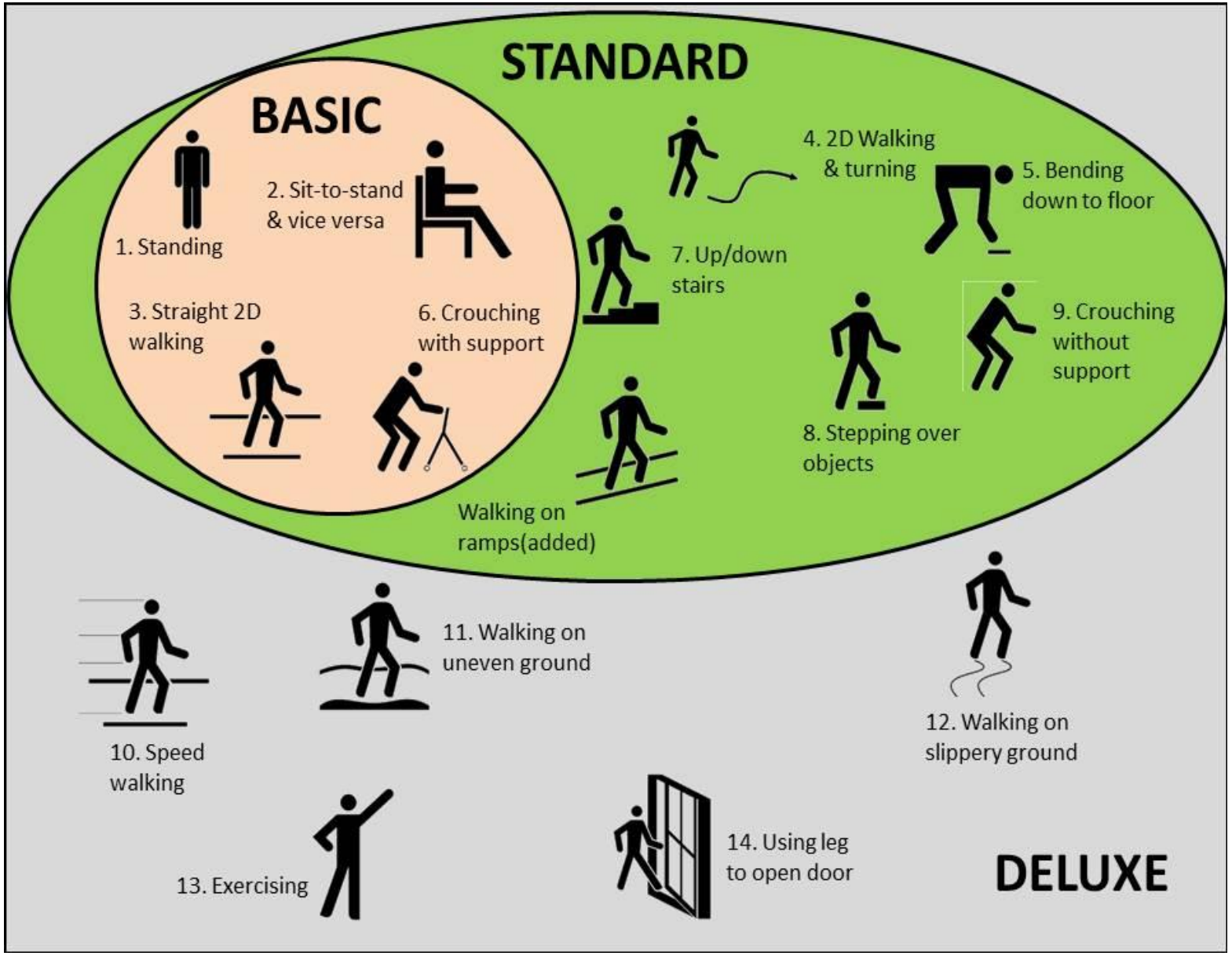
- Harmonised controller
- Commissioning EXO
- Walking Tests
- STS Tests

- Use ISO 13482 safety standard for personal care robots (non-medical)
- Use IEC TR 60601-4-1 MEE using a degree of autonomy (medical)
- Use IEC 60601-2-77 Basic safety and essential performance standard for surgically assisted robotic equipment (medical)
- Use IEC 60601-2-78 basic safety and essential performance standard for RACA robots (medical)

Conclusions

- **Robotics evolving to new applications and new challenges emerging for**
  - **Industrial robots: H-R collaboration**
  - **Personal care robots (close H-R interaction+contact)**
  - **Medical robots (safety and essential performance)**
- **Standardization vital for ensuring safety and success for the new needed robots**
  - **Safety requirements**
  - **Quality and efficiency metrics also needed**

EXO-LEGS mobility requirements



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