Understanding ISO Standards for Personal Care Robots

Once a dream of sci-fi novelists, robots are now taking their place alongside humans in their daily activities. They’re being deployed by delivery services to move packages short distances. They’re using sensors and screens to recognize people and exchange information. They’re patrolling the aisles of grocery stores, spotting spills and swooping in to clean them up.

Robots are nothing new on the factory floor, handling the repetitive and precise tasks that wear down their human counterparts. But these new robots – referred to as personal care robots – are an entirely different type of robot. As a consequence, the standards for ensuring they do their work safely are different than those for industrial robots. In the pages that follow, we’ll describe those standards and what manufacturers and businesses need to be aware if they plan to enter this new, rapidly growing market.

How are personal care robots categorized?

Broadly speaking, personal care robots are designed to improve the quality of life for humans. The International Standards Organization (ISO) developed a standard, ISO 13482, explicitly for such robots and defined three different types:

**MOBILE SERVANT ROBOT**
A robot that travels as it performs tasks for humans, such as handling objects or exchanging information.

**PHYSICAL ASSISTANT ROBOT**
A robot that physically assists a human to perform physical tasks, supplementing or augmenting the user’s personal capabilities.

**PERSON CARRIER ROBOT**
A robot that transports humans to an intended destination.
More specifically, the activities these robots can perform include:

- Travelling in homes or public buildings without colliding into stationary objects and moving obstacles that pose safety hazards. This travel could include pose-to-pose motion as well as full area coverage.
- Interacting with humans, including object exchange. The robot may assume an active or passive role.
- Handling small and medium-sized objects (e.g., coffee cups, plates, books). These actions include grasping, manipulating, and transporting objects, as well as placing them on a surface or passing them to a human.
- Handling large, constrained objects, such as opening a door, a window, a drawer, or a dishwasher. These activities may also require the robot to travel.
- Physically transporting a person between locations on a smooth surface using a wheeled mobile platform, either autonomously or manually.
- Robots that reduce the load a person is carrying or moving by providing support or helping with mobility.

Such robots are becoming more commonplace, with annual growth rates predicted at 19% annually through 2024 when it’s expected to reach $10 billion in annual sales. Consumers may not have come into contact with these types of robots yet, but they’re likely to do so shortly.

Typical safety standards for industrial robots assume the end-user has been trained on interacting with the robot and the environment can be tightly controlled. The standards don’t make that assumption with personal care robots: They’re expected to be used by anyone. The standards also have different expectations regarding the environment in which they’re used. Industrial robots are deployed to locations that are well-defined and tasks are repetitive. Personal care robots are expected to function in much less predictable environments and to perform activities that are not nearly as well-defined as their industrial counterparts. Consequently, personal care robots are potentially dangerous to the untrained people with whom they come into contact – everyone from infants to the elderly – and safety considerations are essential to minimize that risk.
Current industry safety standards for personal care robots

ISO 13482 addresses safe design and protective measures for personal care robots, covering their use in human-robot physical contact applications but not medical or military activities. This standard is harmonized under the Machinery Directive (2006/42/EC) and is adopted in Japan as JIS B 8445. Also available is an applications guide (ISO/TR 23482-2) on designing personal care robots so they conform with the requirements of ISO 13482. Note that ISO 13482 is an international standard, with no U.S. or Canadian equivalents, and therefore is the only standard to follow currently to achieve full compliance.

Who should be aware of ISO 13482 and its safety implications?

Manufacturers and business that use personal care robots need to adhere to the standard and seek certification. For manufacturers, complying with ISO 13482 is critical to help ensure they’re selling a safe product. North America, Europe and Japan all require manufacturers to be evaluated and certified. Failing to do so exposes manufacturers to liability claims.

By the same token, businesses deploying personal care robots need to be certain the robots have been certified to meet ISO 13482 and/or JIS B 8445 standards by an accredited testing agency. An accident involving a non-certified personal care robot could subject a business to the same legal risks and potentially significant PR problems.

Also note that both the personal care robot and the device used to charge its batteries must be evaluated and certified to meet all safety requirements.
Major safety considerations for ISO 13482 and JIS B 8445

These standards describe the hazards these robots pose and provide requirements to lower the risk of these hazards to an acceptable level. The standards are largely risk-assessment based, with such assessments conducted by the manufacturer in accordance with ISO 12100 with the information from ISO 13482. The following main hazards are considered:

1. Hazards related to batteries and battery charging
2. Hazards due to energy storage and supply, including electrical and non-electrical
3. Hazards due to robot start-up and restart of regular operation
4. Hazards due to electrostatic potential
5. Hazards due to electromagnetic interference and emissions
6. Hazards due to stress, posture and usage
7. Hazards due to robot motion
8. Hazards due to insufficient durability
9. Hazards due to incorrect autonomous decisions and actions
10. Hazards due to contact with moving components
11. Hazards due to lack of awareness of robots by humans
12. Hazards due to environmental conditions
13. Hazards due to localization and navigation errors

For each applicable hazard, a risk assessment is conducted. If the hazard cannot be eliminated through inherently safe design measures, the standard requires manufacturers to apply appropriate safeguarding and complementary protective measures.
Safety-related control system requirements and functional safety

In personal care robot designs that implement protective measures through a control system, the required performance level (PL) or safety integrity level (SIL) of the control system functions (electric, hydraulic, pneumatic, and software) will be determined by risk assessment and be required to conform to either ISO 13849-1 or IEC 62061. These may include the following safety functions:

1. Emergency stop
2. Protective stop
3. Limits to workspace (including forbidden area avoidance)
4. Safety-related speed control
5. Safety-related force control
6. Hazardous collision avoidance
7. Stability control (including overload protection)

Based on the manufacturer’s assessment of the robot type (risk level), the risk assessment and ISO 13482 suggestion, each safety function will be required to be tested and certified to a specific PL or SIL to ensure the function has a reliability level commensurate with the overall risk.

Personal care robot evaluations

The testing and certification according to ISO 13482 and JIS B 8445 may consist of many parts, depending on the nature of the robot and the intended use. These tests and certifications are tailored to a specific product, based on the requirements of the standard. The main areas are the following:

- Risk assessment and documentation review
- Mechanical and electrical construction review
- Testing and validation of safety measures
- Testing and validation of electrical safety
- Functional safety review
- EMC and wireless testing
- Environmental testing
TÜV Rheinland’s services for personal care robots

TÜV Rheinland’s extensive knowledge and experience in the robotics industry allows our experts to provide services that can boost your company’s competitive edge, including performing both risk assessments and safety circuit evaluations. With state-of-the-art laboratories located around the world and an international reputation for excellence, TÜV Rheinland is proud to support your goals for compliance, safety and functionality in the fast-paced robotics industry.

NRTL COMPLIANCE
To ensure product quality, the U.S. and Canadian governments have clearly defined regulations applicable to electronics and other products and equipment. These regulations must be satisfied before these products can be approved for sale or for use in the workplace or with the public. Because manufacturers typically have constrained budgets and tight development timelines, the Nationally Recognized Testing Laboratory (NRTL) they choose is critical. TÜV Rheinland is accredited as an NRTL by the Occupational Safety and Health Administration (OSHA) and as a Product Certification Body by the Standards Council of Canada (SCC). NRTL indicators, such as the cTUVus Mark issued by TÜV Rheinland, inform consumers and business partners that a manufacturer’s products have been thoroughly tested and specifically certified to comply with electrical and fire safety regulations. TÜV Rheinland is recognized as the leading North American certification organization due to cost savings, worldwide acceptance, and responsive customer service.

RISK ASSESSMENT ASSISTANCE
For manufacturers unsure how to conduct a risk assessment, TÜV can facilitate a risk assessment review and provide guidance through the process, as dictated in ISO 13482 and ISO 12100. This provides manufacturers a risk assessment that forms the framework of their safe product and the product assessments.

FUNCTIONAL SAFETY
Manufacturers, plant operators, and end-users need to be mindful of reducing potential safety risks in products, components and systems within machines, systems, and safety-related applications. Safety, reliability, and quality are paramount in a product’s complete lifecycle – from the concept phase to its decommissioning. TÜV Rheinland offers functional safety services for the robotics and machinery industries according to worldwide relevant standards IEC 61508, IEC 62061, ISO 13489-1, and others.

EU MACHINERY DIRECTIVE
As technologies continue to evolve, machinery and robots are being subjected to increasing regulatory scrutiny. EU member states require a CE marking for any product falling under Annex IV of the Machinery Directive 2006/42/EC that is placed on the market or put into operation. The mark shows to regulatory bodies that the product complies with essential safety requirements and industry standards. TÜV Rheinland provides market access through testing and evaluation of equipment to harmonized standards, identifying areas of non-conformance and helping manufacturers understand how to resolve those areas through issuance of reports and final certificates.
**CYBERSECURITY**

Personal care robots frequently are monitored or manipulated through networked control systems to ensure they’re operating properly and efficiently. While advantageous, this connectivity poses safety concerns because these robots are rarely developed with cybersecurity in mind. Intentional and accidental infection of personal care robots with malware and other cyberattacks is increasing, so it’s essential that systems are tested for cybersecurity vulnerabilities.

According to IEC 61508: “If the hazard analysis identifies that malevolent or unauthorized action, constituting a security threat, as being reasonably foreseeable, then a security threats analysis should be carried out. If security threats are identified, then a vulnerability analysis should be undertaken in order to specify security requirements.” The standard also recommends using the guidance given in the IEC 62443 series.

**EMC**

For many electrical devices and products bound for the global marketplace, electromagnetic compatibility (EMC) testing has become more daunting than ever. Any manufacturer wanting to bring such products onto the market has to comply with the EMC directive 2014/30/EU. In addition, specific EMC testing can be required for functional safety purposes, by a standard such as ISO 13482 or by a specific country. As an authorized body and international service provider, we offer a flexible, competent service to help you meet the requirements of this directive. Our conveniently located, state-of-the-art EMC testing facilities can meet any of your EMC testing needs.

**WIRELESS TESTING**

TÜV Rheinland offers comprehensive services for wireless testing and certification. Leveraging local service and a global network, TÜV Rheinland provides an end-to-end wireless and IoT test solution. Our service portfolio includes regulatory, interoperability, performance, safety, and security. We test with industry alliances for both long and short-range devices across various industries including Automotive, Medical, Industrial IoT, Smart Home and Consumer Products.