Industrial robots
Industrial robots
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This DGUV Information has been prepared in the Subcommittee Machinery, Systems and Automation of the Expert Committee Woodworking and Metalworking at the DGUV (Sachgebiet Maschinen, Anlagen und Fertigungsausautomation des Fachbereichs Holz und Metall der DGUV). It is primarily addressed to the users in the company. This DGUV Information indicates the most important technical safety features of industrial robots. It also mentions the most important requirements of the current laws and “translates” them for practice. It is intended to provide fast access to all aspects which have to be considered at planning, approval, monitoring and operation of industrial robots and industrial robot systems.

Concerning the annotation of requirements from legislative texts and standards, the binding character of the original sources is pointed out. In particular, it may occur that requirements from legal provisions and standards change after this Information has been printed. Therefore, the current issue should be verified with the publisher prior to applying the relevant document.

We would particularly like to thank Mr. Richard Schwarz, Mr. Weiland Link and Dr. Matthias Umbreit for preparing the draft version of this DGUV Information.

For further information, it is referred to specialist literature as well as to the applicable standards series for the safety of industrial robots DIN EN ISO 10218 “Robots and robotic devices - Safety requirements for industrial robots”.

This publication replaces the BG Information “Industrieroboter” (BGi 5123) of June 2008.
1 Introduction

1.1 Types of robots

Robots kinematics
The mechanical structure of an industrial robot consists of a spatial layout of axes of motion. Axes 1 – 3 are called main axes, axes 4 – 6 are called wrist axes or hand axes. As a function of the executable axis movement (translatory, rotational) a distinction is made between different robot types.

Arrangement of main axes
Robots primarily differ in the type of kinematics of the main axes.

A distinction is made between axes with translatory movement (T) and axes with rotational movement (R).

Serial kinematics
Serial kinematics consist of a number of arm elements being connected with joints. The last joint carries the tool.
Inside the robot hand, further axes of motion for the positioning and orientation of the tool/gripper are arranged.

**Vertical articulated robot**

The most common representative type of serial kinematics is the vertical articulated robot. A classic vertically articulated robot has three rotational basic axes and at least one but mostly three rotational hand axes. The advantages of this kinematics are the low space required and the universal fields of application (Figure 4).

By assembling two articulated robots on a common column, the universality is further extended (Figure 5).
The term “SCARA-robot” stands for “Selective Compliance Assembly Robot Arm”. These robots usually have 4 axes; the first, second and fourth axes are rotational, the third axis is transatory. Because of its kinematics, this robot type is capable to carry out very fast movements and is mainly used for Pick-and-Place-applications (Figure 6).

Gantry robots are applied for the automation of machine tools or injection moulding machines. By loading and unloading from the top, free accessibility to the machine for maintenance and set-up activities is ensured.

Gantry robots are available in many versions. The most common type is the linear gantry, which consists of a horizontal and a vertical linear axis to which either a gripper is mounted directly or additional rotational hand axes are mounted in between.

Area gantries dispose of a second horizontal axis which results in large workspaces (Figure 7).

Gantry robots and articulated robots are also combined. On a horizontal gantry axis, a 6-axes robot is mounted laterally or hanging. This creates maximum and flexible workspaces even under spatially limited conditions.
Parallel kinematics
The arms of the parallel kinematic robot (also called Delta-robot or simply parallel robot) rest on a common base plate. Variant types of this kinematics with 3 up to 6 axes are common (Figure 8 and Figure 9). It can either be mounted hanging from the ceiling or on the floor.

By the coordinated control of all motors, a three-dimensional movement of the end-effector is achieved. If more than 3 independently driven arms are used, the tool can even be turned and/or tilted.

Parallel kinematic robots are applied if simple sequences of motions with a high repetition accuracy and high speed within a limited workspace are required.

Typical applications of Delta-robots are fast Pick-and-Place applications with partially structured parts placement, also with assembly line tracking for handling, assembly and packing tasks (Figure 8).

Hexapod-robots are particularly suitable for machining tasks, e.g. drilling, grinding, cutting, or for assembly processes. They are characterized by an extreme rigidity along with a high repetition accuracy. The working space is very limited (Figure 9).
1.2 Robot applications

Fields of application for industrial robots
Industrial robots can be found in numerous fields in industry, e. g. car manufacturers and suppliers, aerospace, food and beverages, textile, wood and furniture, printing and paper, rubber and plastics, chemistry and pharmacy, household appliance industry, precision mechanics, construction, foundry, pottery and stone, etc. In addition, they are already being applied in research and education or in agriculture.

Robots are used nowadays in a variety of applications, e. g.:
- Gas-shielded metal-arc welding, spot welding, laser welding, soldering
- Palettising, packaging and picking
- Handling on other machinery, loading and unloading of machines, varnishing, surface treatment, enameling, adhesive and sealant application, coating
- Laser cutting, plasma cutting, water jet cutting, mechanical machining
- Fixing, feeding, loading, assembling, dismantling
- Measuring, testing, inspecting, etc.

The technical safety requirements for industrial robots and their applications in robot systems are comprehensively described in the following chapters. For non-industrial robots, this document only provides a short overview in the following.

Non-industrial robot applications
Besides in industrial applications, nowadays robots can for example also be found in the entertainment industry, in medical engineering, as service robot or in military. The pertinent product safety standards for industrial robots do not apply here. However, as long as no applicable standards for the non-industrial area are provided, the requirements stated in the standard for industrial robots may be applied to non-industrial applications as well. This is explained in EN ISO 10218-1 (see also 2.1.2).
**Entertainment robots**

Entertainment robots as fairground rides are excluded from the scope of the Machinery Directive. They belong to the “Fairground and amusement park machinery and structures” the safety requirements of which are stated in the European Standard EN 13814 [4].

Particular requirements are specified for the clearance. This is the space around the gondola which must not be “intruded” during operation or in case of malfunction, neither by the own mechanics nor by the surrounding scene. This clearance is usually kept by means of mechanical axis limitations. Control solutions for axis and space limiting have the disadvantage that safely reproducible stopping distances can only be implemented with great effort.

**Medical robots**

Medical robots are medical devices and fall within the scope of the European Medical Devices Directive 93/42/EC [12].

The standards listed under this EC Directive cover the hazards presented by robots only incompletely. Therefore, it is reasonable to apply protective measures as described in EN ISO 10218-1 (e.g. reduced speed and other requirements for collaborative robots).

**Service robots**

Service robots are intended to carry out e.g. household tasks. For individual service robots, special standards are already available, e.g. for robot lawn mowers (EN 60335-2-107). The requirements, however, cannot be transferred to other robots and service robots.

**1.3 Accident situation and particular hazards at industrial robots**

Besides the known hazards, e.g. crushing between stationary and movable parts and ejection of parts, industrial robots involve hazards which are atypical in comparison to other machines. This includes in particular the complexity of the production process, the hazards of which cannot be estimated solely by observation.
Hazards due to the complexity of production are particularly created by:

- a high number of robots and machines being linked to each other
- complex sequences of motion
- unforeseeable changes of position and speed
- waiting positions and unexpected start-up
- secondary hazards related to the process, e.g. laser

Causes of accident are, among others, of technical nature, such as e.g. the failure of components. Other causes such as e.g. falling down or bypassing safeguards are, however, also included in the statistics.

Despite economic fluctuations, the accident figures recorded by the German Social Accident Insurance (DGUV) show a downward trend for industrial robots as well as for other branches of industry. This becomes clearer if the accident figures are regarded in proportion to the systems being installed. Within the period from 2005 to 2012, the number of robot systems installed in Germany increased from 126,000 to 161,988. The so-called “robot density”, i.e. the number of robots per 10,000 employees, amounted to 273 in 2012 in Germany. This is the third-highest worldwide [17].

![Fig. 14](image-url) Notifiable occupational accidents\(^1\) on/with industrial robot systems\(^3\) in Germany [H]

1) Loss of working hours of more than three days
2) Payment of accident benefits, e.g. in case of loss of limbs or fatal occupational accident
3) Besides accidents on robots, accidents on automatic machines with transfer systems are also covered. This includes, e.g., single- and two-axes systems (e.g. gantry) and handling systems, but no machine tools.
2 Legal basis

2.1 European rules for industrial robots

2.1.1 European rules

The European Union (EU) has introduced far-reaching changes for industry in the field of regulations with effects for both the technical safety design of machines and systems and the industrial companies using them.

This mainly includes EC-Directives. All member states of the EU are obliged to implement the European regulations into their national law and to withdraw their national regulations in that area. This procedure is also known under the term harmonization. This measure is one of the basic preconditions for the free movement of goods within the EU.

All goods/products intended to be placed on the market in the EU, shall thus meet the relevant EU-regulations, regardless of whether they have been produced in the EU or imported into the EU.

Fig. 15 European legal framework for machinery [H]
**Directives under article 153** are the legal basis for occupational safety and health and stipulate basic obligations of employers and employees.

They only contain minimum requirements so that also higher safety requirements may be stated on a national level. The national provisions may vary among the member states (Figure 15).

**Directives under article 114** of the EU treaty establish the basic principles for the free movement of goods within the member states by stating basic standard safety requirements for products. National deviations are not admitted during implementation. Visible mark on the product is the CE mark (CE).

*Each robot cell or robot system has to be provided with an EC Declaration of Conformity and a CE mark as soon as being placed on the market.*

The most important EC Directives for industrial robots are:

- Low Voltage Directive [14]
- EMC-Directive [15]

Moreover, industrial robot systems may be covered by further EC Directives, e.g. Pressure Equipment Directive [16]. The applicable EC Directives have to be cited in the EC Declaration of Conformity (see clause 3.1).

The EC Directives under article 114 are addressed to the manufacturers of products and have been drafted according to the so-called new approach. According to that, the technical requirements are not expressed in detail in the relevant Directives. Directives according to the new approach only contain the mandatory and essential safety and health requirements.

The EC Directives are implemented into national law by the German Product Safety Act (ProdSG).

In order to facilitate the verification of conformity with these essential requirements for the manufacturers and to enable the verification of conformity, standards are developed on mandate of the European Commission which are intended for “the prevention of risks arising out of the design and construction of machinery”, known as harmonized standards (see clause 2.1.2).

**European Standardization Organizations**

CEN, CENELEC and ETSI are the three big European standardization organizations and exclusively authorized to publish the standards mandated under the EC Directives. Their headquarters are in Brussels. CENELEC is responsible for standardization in the electro-technical field, ETSI for standardization in the telecommunication sector and CEN for standardization in all remaining technical fields.

CEN = Comité Européen de Normalisation;
CENELEC = Comité Européen de Normalisation Électrotechnique
ETSI = European Telecommunications Standards Institute

**International standardization**

ISO, IEC and ITU are the international counterparts to the European standardization organisations. Their headquarters are in Geneva. IEC is responsible for standardization in the field of electrotechnology, ITU for standardization in the telecommunication sector and ISO for standardization in all remaining technical fields.

ISO = International Organization for Standardization
Cooperation between European and international standardization

There are agreements between ISO and CEN (Vienna Agreement) as well as between IEC and CENELEC (Dresden Agreement), to carry out standardization work if at all possible on international level only. The standards that have been developed in this way are incorporated in the European body of standards. Thus, compliance of the requirements of European and international standards is achieved.

2.1.2 Harmonized standards

Harmonized standards are standards which are developed by the European standardization organizations on behalf of the European Commission. They specify the basic requirements of EC Directives. Annex ZA of a harmonized standard indicates which clauses of the relevant standard fulfill the essential requirements of the EC Directive.

The Official Journal of the EU publishes the references of the harmonized standards besides the date of the beginning of the presumption of conformity and, if applicable, the transition periods. At publication in the Journal of the EU, the so-called presumption of conformity applies. This means that, if the standard is applied, it can be assumed that the basic requirements of the relevant Directive are fulfilled. Despite the resulting high significance of harmonized standards, their application is voluntary. If the machine manufacturer does not or only partially apply harmonized standards, he or she has to indicate in the technical documentation both the risk assessment and the measures which have been initiated in order to comply with the essential occupational safety and health requirements.

Harmonized standards have to be implemented into national standards. The responsible authority in Germany is the Deutsches Institut für Normung (DIN). The references to these standards are published in the Joint Ministerial Gazette.

Fig. 17 Three different types of standards have to be distinguished: A-type standards, B-type standards and C-type standards [G]
A-type standards are called basic standards since they basically deal with hazards and risks (catalogue of all known hazards) and state how to prepare hazard analyses and risk assessments. Currently, only one A-type standard is available: EN ISO 12100.

B-type standards are also called group standards. As B1-type standards, they deal with safety aspects such as body sizes and speeds of movements of humans, their sensitivity to the temperatures of touchable surfaces etc.

As B2-type standards, they cover applicable protective devices, e.g. two-hand control devices, light barriers, light grids, light curtains, laser scanners, pressure sensitive plates, pressure sensitive mats, guards (e.g. fences, monitored access doors in fences) as well as emergency stop devices.

C-type standards are European product standards which fully describe a machine type with regard to its technical safety aspects, such as industrial robots, presses, machine tools etc.

If a C-type standard deviates from one or several specifications which are dealt with in an A-type or B-type standard, the specifications of the C-type standard always prevail.

C-type standard for industrial robots
For industrial robots, a two-part C-type standard is available: EN ISO 10218-1 and -2: Industrial robots – Safety requirements – Part 1 Robots and Part 2 Robot systems and integration.

EN ISO 10218-1
EN ISO 10218-1 applies to industrial robots, i.e. automatically controlled, freely programmable multi task manipulators. They are programmable in three or more axes and can be arranged either at a stationary location or movable if intended to be used in automation [5]. The standard specifies requirements and provides guidance for an inherently safe design, protective measures and the information for use. It describes basic hazards associated with robots and how to eliminate or adequately reduce the associated risks. It does not apply to non industrial robots but may be used for them (in the absence of other relevant standards).

EN ISO 10218-2
This part of ISO 10218 provides guidance on how safety can be ensured with the integration and installation of robots [6]. It is complementary and an addition to ISO 10218-1.

The standard provides guidance on how to identify and respond to unique hazards presented by the integration, installation and the requirements for use of industrial robots. The standard includes the safety measures for robot integration including the risks resulting from application, tool and workpiece.

2.2 “Substantial modifications” on robot systems
The former Equipment and Product Safety Act generally stated that machines and machine systems, which have been substantially modified after having been placed on the market for the first time, have to be adjusted again to the regulations which were applicable at the time of the changes. This means in clear words: awarding a new CE mark in case of a substantial modification. This provision is no longer included in the current Product Safety Act.

On adaptation of the Product Safety Act to the regulation EC 765/2008, the term “substantially modified products” is cancelled. This does, however, not include a change of the facts.

The publication of a corresponding interpretation paper by the Federal Ministry of Labour and Social Affairs was imminent at the time of printing of this DGUV Information.

Maintenance and repair, a tool change and also the improvement of the safety level are generally considered as “non-substantial modifications”. But when is the reconstruction of a robot system considered as a “substantial modification”? The statements mentioned above naturally leave a broad room for interpretation.

The current expert opinion on the issue “substantial modification of machinery” is particularly based on the following question:

Does the reconstruction involve new risks to a considerable extent, which are not compatible with the existing protection concept?
If this question can be answered with YES, we deal with a substantial modification requiring a new EC conformity assessment. The decision has to be taken by the party on whose behalf a robot system is modified with utmost care.

In case of a non-substantial modification it is important to carry out reconstruction work on an existing system in such a way that the modified parts correspond with the present/new regulations. This cannot always be achieved, e.g. for the calculation of the Performance Level for control systems. At least the selected components should, however, correspond with the current state of safety technology.

“Performance Level” = discrete level which specifies the capability of safety-related parts of a control system to perform a safety function under foreseeable conditions (see also clause 4.3).

This procedure is of importance in so far as each reconstruction is associated with an improvement of safety of the entire system, although, strictly speaking this is not required by the Ordinance on Industrial Safety and Health. If, however, the modified parts on an existing system largely correspond to the current state of the art or to the requirements of the Machinery Directive, the question whether or not it is a substantial modification becomes less important. In practice, experience has shown that most cases involve non-substantial modifications.

It is important to note in this context that there is also a legal frame for non-substantial modifications, i.e. that according to the Ordinance on Industrial Safety and Health. Similar to the provisions of the Machinery Directive, it states that the party which initiates the reconstruction is obliged to carry out and document a risk assessment. Exceptional tests such as visual and function tests have to be provided for as well.

The obligation for documentation thus applies to substantial and non-substantial modifications equally. It includes e.g. the completion of hazard/risk assessments, circuit diagrams, operating instructions, PLC-programs, maintenance and inspection instructions and cleaning instructions, if needed. In case of substantial modifications, a new EC Declaration of Conformity has to be issued additionally.

Finally, it has to be emphasized that also the extent of a reconstruction is of importance. If a reconstruction virtually results in the assembly of a new system, this is considered to be similar to the first placing on the market, along with the corresponding legal provisions according to EC Directives (see also the following examples).

Examples of non-substantial modifications

- In a robot system with manual workpiece loading, (e.g. loading of parts in a rotary table), the original gripper is provided with additional grippers due to the enlargement of the workpiece range (fixed flange connection of the different grippers). Even the modification of the gripper flange into a gripper-changing system would not constitute a substantial modification since in both cases it does not go along with a substantial modification of the hazard and risk situation for operating and programming personnel according to the above mentioned criteria.

- At a robot system (one or several robots), e.g. for arc welding, a customer imposes higher requirements on the welding seam quality. The system has been planned and built without an option for process observation under actual production conditions. The retrofitting of the process observation function within the system does not represent a substantial modification since this function does not generate new risks to a considerable extent. This additional function which is also permitted in the relevant standards, finally represents an improvement of the system’s safety since the incentive for bypassing is eliminated. See also EN ISO 10218-2, clause 5.5.4.

Examples of substantial modifications

- A robot system with vacuum grippers for packing parts in a carton box is reconstructed into a welding robot system. This completely modified function with fundamentally new and significant risks requires a fundamentally new system layout. Such a substantial modification requires a new risk assessment and operating instructions as well as the new issue of an EC Declaration of Conformity. The technical documentation has to be adapted to the state of the art of safety technology.

- A robot system is almost completely dismantled and scrapped inside the existing protective fence. Inside this protective fence, a new robot system is built which, however, involves similar risks as the previous system. In this case, the extent of the reconstruction plays a role since it is no longer considered to be a
reconstruction but a placing on the market of a new system. Despite the inessential change of risk, a new EC conformity assessment has to be carried out. This includes the provision of a new risk assessment and new operating instructions. A new EC Declaration of Conformity has to be issued.

Additional information:
In case of a substantial modification, robots and robot systems have to comply with the current legal regulations. This includes EN ISO 10218 parts 1 and 2, which also includes the standard for control systems EN ISO 13849-1 with Performance Level d. The safety-related control systems, however, do not yet need to be mandatorily adjusted to the protection level of this standard in case of a substantial modification. In the majority of cases, this is not possible because of the missing database for calculating the Performance Level. Therefore, it is sufficient in this case, if the safety-related circuits of a robot system, e.g.:

- emergency-stop
- enabling device
- electro-sensitive protective equipment (e.g. light barriers, laser scanners)
- tactile protective devices (e.g. pressure sensitive mats, pressure sensitive plates, bumpers)
- remote-hold protection devices (e.g. two-hand control devices)
- door monitoring circuits with and without guard locking
- safe individual operation of a robot for systems with several robots (e.g. for programming purposes or readjustment)

comply at least with category 3 according to EN 954-1 (dual-channel design).

This also applies to non-substantial modifications, if, e.g., new robots are used again in existing old systems. [18].

See also clause 4
Automation of old machinery

In many cases, old machines are automated, e.g. by robot loading instead of manual loading on machine tools. In such a case, the question arises whether a separate evaluation is possible:

- Part A: automation, consisting of robot, gripper, feed systems, fencing etc. according to the requirements for new machinery (Machinery Directive /CE).
- Part B: old machine according to the applicable requirements for old machinery (Ordinance on Industrial Safety and Health and DGUV Rules).

Such an approach is suitable if the safety-related interfaces can be clearly defined. The interfaces are e.g. those for emergency-stop and protective door circuits. They have to be precisely documented by circuit diagrams, so that it can be seen at any time how the signals of machine A are transferred to machine B and vice versa. If necessary, the responsible accident insurance institution should be contacted for advice.

2.3 Robot systems/Assembly of machinery

According to the EC Machinery Directive, not only machines which are supplied, mounted and put into service as a complete unit are subject to the “CE provisions”, but also machines, which are assembled from completed and partly completed machines and function as an assembly. These assemblies of machinery (linked systems) are widespread in the field of robots, e.g. press linking or manufacturing lines in automotive engineering (Figure 18 and Figure 19). But there are also robot systems, each individual station of which can be considered to be an individual machine, i.e. without linking. But how is the distinction made? Or more precisely: at what point may an arrangement of machines no longer be provided with individual CE marks and Declarations of Conformity, but has to be provided with a superior CE mark including a Declaration of Conformity?
To answer this question, reference is made to the interpretation paper of the Bundesministerium für Arbeit und Soziales [1]. This interpretation paper formulates very good introductory questions:

- Can an incident which occurs on a component part of the system lead to a hazard at another part of the system?

and

- Shall safety measures be taken to prevent this hazard?

This is e. g. the case with press linking: The press setter cannot set the press without exposure to a hazard if the safe state of the loading and unloading robot is not simultaneously ensured. Therefore, we deal with a linking of press and robot here.

In a manufacturing line in the automotive body shell production, linking normally takes place by conveyor systems for onward transportation of the automotive bodies: When entering a cell area, it shall be ensured that also the conveying system in the adjacent cell is shut off safely. Thus, here as well we deal with a linked system in a technical safety sense.

A purely functional interaction is not sufficient to achieve a linking in terms of the Machinery Directive. This also becomes obvious in the flow diagram of the aforementioned interpretation paper (Figure 20). Likewise, a superior emergency-stop device alone is no criterion for a linked system.

If we deal, however, with a linked system, the safety functions, such as emergency-stop, protective door interlocking circuits and enabling circuits normally need to be adjusted. An explanation of overlapping effective areas of safety functions is also included in EN ISO 11161 [7].

The specific steps to be followed, i. e. which protective door circuit covers which adjacent circuit, has to be the result of a risk assessment of the entire system. This risk assessment may be based on existing risk assessments for the individual machines, so that only the interfaces need to be considered.

![Flow diagram according to the interpretation paper of the Bundesministerium für Arbeit und Soziales BMAS [1]](image)

Fig. 20 Flow diagram according to the interpretation paper of the Bundesministerium für Arbeit und Soziales BMAS [1]

Minimum requirement: Machines which are intended to be linked to each other but which are also ready for use as individual machines, have to be provided with the usual accompanying documents (EC Declaration of Conformity, CE mark, instructions for use). For partly completed machinery, the declaration of incorporation and the assembly instructions are required. The following should be additionally taken into account when ordering individual machines and partly completed machinery intended to be assembled to a linked system. The list goes beyond the legal minimum requirements:

- Get a confirmation of compliance with specific technical standards, e. g. EN ISO 10218-1 for robots, EN 12417 for machining centres
• For partly completed machinery, supply of operating instructions, if e.g. actuators are available
• Provision of programming instructions, if e.g. operating personnel has to carry out occasional program changes
• Provision of a technical documentation as far as required
• Provision of a risk assessment
• Precise interface descriptions, i.e. electric plans for emergency-stop interfaces, protective door circuits etc., drawings of mechanical interfaces, written documentation

The party who carries out the linking has to prepare the following documents:
• EC Declaration of Conformity for the entire system/CE mark
• Operating instructions for the entire system
• Risk assessment and description of protective measures at least for hazards relating to interfaces. The provision of the risk assessment to the future user may be agreed on e.g. in the specifications sheet (important for subsequent reconstructions)
• Documentation by using the documentation of the linked systems, partly completed machinery and components

In case of large systems, the linking may spread over complete production halls, in some cases even throughout different buildings. Those cases require the creation of reasonable interfaces. Suitable interfaces may e.g. be rework stations or buffer stores.
3 Operating instructions and technical documentation

3.1 Technical documentation for machinery

The technical documentation for machinery is composed of the technical documents and the operating instructions.

3.1.1 Technical documents for machinery

The technical documents include all documents which are required to assess the conformity of the machine with the requirements of the Machinery Directive. They have to be presented to the competent authorities on reasoned request and have to be available for at least 10 years following the date of completion of the machine. For series manufacture, this period starts after completion of the last unit of the series produced.

3.1.2 Operating instructions

The operating instructions have to be provided in the official language or languages of the country in which the machine is placed on the market for the first time and in the original version. Information has to be unambiguously assigned to the machine type. It should be drafted as simple and concise as possible. Terms should be used consistently and specific terms should be explained.

If the operating instructions are provided electronically, at least the safety-related information has to be provided in addition as hard copy.

The provision of circuit diagrams, apart from the already mentioned plans for the interfaces which are required for setting and installation, is not necessary.

The information for use provided by the robot manufacturer or by other manufacturers of partly completed machines, are used by the system integrator for drafting the operating instructions or will directly become a part of it.

3.1.3 Technical documentation for partly completed machinery

Industrial robots are considered to be partly completed machines or partial machines since they are mostly supplied without external safeguards.

The Machinery Directive 98/37/EC which was effective until the end of 2009 did not require a documentation for such partly completed machines; the obligation to supply an information for use only resulted if compliance with standards requiring such an information was confirmed in the manufacturer’s declaration. The Directive 2006/42/EC which is applicable since December 30, 2009 has corrected this shortcoming and adapted the requirements for partly completed machinery to those for completed machinery.

The verification documentation, which is called “technical file” in the Machinery Directive represents the most extensive part. This technical file need not be forwarded to the customer. It remains with the manufacturer unless the supply of these documents is subject to a contractual agreement.

3.1.4 Relevant technical documentation for partly completed machinery

The Machinery Directive specifies which documents are required for the assessment of conformity with the essential health and safety requirements applied. The extent covers the design, construction and functioning of the partly completed machinery.

A list of the documents required for the verification documentation can be found in Annex 3: Checklist Technical Documentation (verification documentation).
Operating instructions and technical documentation

Extract from Directive 2006/42/EC:

ANNEX VII

B. Relevant technical documentation for partly completed machinery
The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to the competent authorities of the Member States. It does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation. Failure to present the relevant technical documentation in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the partly completed machinery with the essential health and safety requirements applied and attested.

Extract from Directive 2006/42/EC:

ANNEX VI

Assembly instructions for partly completed machinery
The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as not to compromise safety and health.

The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative. The Machinery Directive does not require further information for use for partly completed machinery in addition to the assembly instructions, i.e. the obligation to supply operating instructions as it is required for completed machines does not apply to partly completed machinery.

3.1.5 Assembly instructions
The manufacturer or the distributor of the partly completed machine is obliged to supply assembly instructions in addition to the declaration of incorporation. The assembly instructions remain with the party who incorporates the partly completed machine into a machine or who assembles it with other parts to a machine. They become part of the technical file of the machine.

3.1.6 Information for use
An obligation for the robot manufacturer to provide additional information which go beyond the contents of the assembly instructions results from the application of EN ISO 10218-1.

A listing of minimum information for this „Information for use“ can be found in Annex 2.: Check list Information for use. The information for use is mostly used by the system integrator for preparing the operating instructions or is a direct part of it.

3.1.7 Stopping time and overtravel
EN ISO 10218-1 requires in Annex B information from the robot manufacturer as to the stopping time and overtravel. This information is particularly needed for calculating the safety distance for the application of safeguards. Even for specifying the restricted space, the actual stopping position has to be determined taking into account the overtravel.

The stopping time is understood to be the total time from the initiation of a stop until standstill of the robot axes. The same applies in the figurative sense to the overtravel.
The stopping time consists of the reaction time and the braking time. The reaction time is dependent on the transmission time, the processing time within the control system and the switching times of relays, contactors and brake lifting devices. It is almost constant and has only a low tolerance. The braking distance is dependent on the factors load, speed and extension. For “stop category 0”, the temperature of the brakes, the wear and the degree of pollution have to be added. In case of “stop-category 1”, the brake is used as holding brake only and therefore has no influence on the braking time. For explanations to stop category 1 and stop category 0, see clause 4.1.9.

Fig. 22  Stopping time [G]

<table>
<thead>
<tr>
<th>Extension 100 %</th>
<th>Extension 66 %</th>
<th>Extension 33 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>axis 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>38°</td>
<td>28°</td>
<td>20°</td>
</tr>
<tr>
<td>63°</td>
<td></td>
<td></td>
</tr>
<tr>
<td>axis 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22°</td>
<td>18°</td>
<td>18°</td>
</tr>
<tr>
<td>40°</td>
<td></td>
<td></td>
</tr>
<tr>
<td>axis 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17°</td>
<td>30°</td>
<td></td>
</tr>
</tbody>
</table>

Fig. 23  Example of stopping distances of the three main axes of an articulated robot at maximum load and maximum speed [G]
The specifications to be indicated by the manufacturer in his/her user documentation according to EN ISO 10218-1 are limited to the stopping distance and the stopping time after a stop for the three axes with the largest extension. Depending on the practicability, the distance may be indicated in linear or angular units. For stop category 0, these values have to be indicated for the maximum load, maximum speed and maximum extension. If a robot has a stop category 1 function, the braking distances at 100 %, 66 % and 33 % of load, speed and extension have to be indicated.

The values provided by the manufacturer in the user documentation can only be standard values. They need to be validated under real conditions. The manufacturer has to indicate how the integrator can measure the stopping distances and stopping times on the real robot system.

For measuring the stopping distances and stopping times, the individual robot manufacturers indicate different methods, e. g.:

- an integrated trace-function which, on initiation of a stop, records and displays the stopping distance and the stopping time on the display of the teach pendant
- a tool which has been specifically developed for determining the stopping distance and the stopping time and which supplies the requested data numerically or graphically on the display of the teach pendant or as a hard copy
- external measuring devices, such as e. g. a thread speedometer or a laser measuring device
- light barrier and measuring tape

Fig. 24 Example of specifications in the information for use according to EN ISO 10218-1, Annex B [G]
4 Protective measures for industrial robots and robot systems

4.1 Hierarchy of protective measures

Similar to other systems, the totality of protective measures on a robot system is often a combination of measures being applied by the system designer in the design stage, e.g. protective devices, and measures which have to be taken by the user, e.g. behavioral requirements and personal protective equipment. But, as a matter of principle, measures which can be considered already during the design stage have priority over all measures which have to be taken by the user.

Explanations as to a systematic procedure for specifying protective measures by the designer are described in EN ISO 12100. One of the main contents is the hierarchy of the measures to be taken (Figure 25). The 3-step method describes that hazards are to be eliminated by design first (safety by design). If this is not entirely possible, safeguards have to be provided. Only if neither design measures nor safeguards can completely eliminate the hazards, indicative measures may be applied.

4.1.1 Modes of operation of robots (without periphery)

Generally, it is unavoidable that setting work with robots cannot be exclusively done from outside the safeguarded space but has to be carried out inside the safeguarded space as well. Therefore, operation modes for setting and programming have already been provided for each “bare” industrial robot which can then be installed by the system designer.

According to EN ISO 10218-1, industrial robots have to be equipped with the modes of operation shown in Table 1. For the modes of operation T1 and T2 as well as for special operation modes, skilled personnel have to be deployed.

For selecting the modes of operation, a lockable mode selection switch has to be provided which can be removed in each position (Figure 26). Alternative selection devices such as e.g. access codes are also permissible, if they provide an equal level of safety. Attention should be paid to the control safety (category and PL) and the possibility of defeating protective measures (foreseeable misuse).

Selecting the high operating speed in operation mode T2 requires an additional pressing of the button, e.g. on the teach pendant, and the measures mentioned in Table 1. The option to use the high operating speed expires as soon as the enabling switch remains non-activated over a period of more than 5 minutes. If a return to high operating speed is intended, it has to be preselected again by a rotary switch or by a push button. The demanded time monitoring of 5 min is no safety function.

Another feature of operation mode T2 is that with parallel use of this operation mode on several robots in one cell, the overlapping of ranges of motion represents a high risk. A safe stand has to be ensured for each operator.

The reduced speed of 250 mm/s during setting and programming which is indicated in Table 1 refers to the movement, measured at the robot’s tool holder. Generally, only a bumping hazard exists.
<table>
<thead>
<tr>
<th>Mode of operation</th>
<th>Protective measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manually reduced speed (T1)</td>
<td>Safeguards may be open or ineffective</td>
</tr>
<tr>
<td>e. g. for setting and programming</td>
<td>• separate position of mode selection switch and</td>
</tr>
<tr>
<td></td>
<td>• reduced speed(^*) (≤ 250 mm/s) in conjunction with enabling switch and hold-to-run control</td>
</tr>
<tr>
<td>Manual high speed (T2)</td>
<td>Safeguards may be open or ineffective</td>
</tr>
<tr>
<td>e. g. for testing with operating speed</td>
<td>• separate position of mode selection switch or additional mode selection switch and</td>
</tr>
<tr>
<td></td>
<td>• travel speed up to full operating speed and</td>
</tr>
<tr>
<td></td>
<td>• hold-to-run control in conjunction with enabling device and</td>
</tr>
<tr>
<td></td>
<td>• protected position for the machine setter, i. e. at least a distance of 0.5 m between fence and robot, e. g. by restricted range of motion (see also clause 4.2.1.3)</td>
</tr>
<tr>
<td>Automatic</td>
<td>Safeguards have to be closed or effective</td>
</tr>
<tr>
<td></td>
<td>• separate position of mode selection switch</td>
</tr>
</tbody>
</table>

\(^*\) Reduced speed in operation mode T1 should be provided wherever possible according to the current state of the art (clause 4.1.3).

Tab. 1  Modes of operation [F]
In case of crushing or shearing hazards, e. g. when positioning a device, this speed should be further reduced according to the risk assessment.

The speed value of the reduced speed (250 mm/s) should be monitored by a safe control system (see clause 4.1.3). EN ISO 10218-1, however, also permits the possibility that the speed is not safely monitored and that the safety of persons is solely ensured by the safe enabling switch. Whether or not this option is applied results from the risk assessment, in particular with regard to the stopping distances.

In collaborative operation, the reduced speed shall always be safely monitored (clause 5).

4.1.2 Enabling device
An enabling device (enabling switch) is an additional manually operated control device which is used in conjunction with a start control and which, if being continuously actuated, permits a machine function. An actuation of the enabling device alone must not initiate a movement. The enabling device has to be designed in a way to allow machine movements only in a specific position. In older systems, two-position versions of enabling devices can still be found. (Table 2).

For industrial robots which have been produced after EN ISO 10218-1 came into effect (Feb. 2007), only three-position enabling switches may be applied. For old machine stocks and possible retrofitting, no European regulations are available. But there may be internal company provisions. Due to the accident history or the consistency of the equipment, they may stipulate a particular type of design. If nothing comparable exists, the decision should be taken by considering the existing risks. Three-position enabling devices switch off safely even in case of “seizing”. Two-position enabling

In Table 2, the types of enabling devices are listed:

<table>
<thead>
<tr>
<th>Position 1</th>
<th>Position 2</th>
<th>Position 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>neutral position</td>
<td>release position</td>
<td>panic position</td>
</tr>
<tr>
<td>Off-function (control element is not actuated)</td>
<td>Enabling function (control element is actuated)</td>
<td>Off-function (control element is actuated beyond its center enabled position)</td>
</tr>
</tbody>
</table>

Tab. 2 Types of enabling devices
switches may offer ergonomic advantages when being continuously actuated for a longer time since no pressure point has to be kept. In case of very confined spaces, the selection of a three-position design should be preferred (reaction time, seizing).

The functions indicated in Table 2 solely refer to the switching device. The further processing of the signals has to proceed in safe technology, e.g. not via standard bus systems. If switching back from the third into the second position on actuation of the three-position type, the enabling function must not generate an enabling signal. No movements must be initiated by the enabling device alone. An additional control device, e.g. hold-to-run control, is required.

The signals of this additional hold-to-run control do not need to be processed in “failsafe technology”. This also means that just pressing the enabling switch in the enabling position can enable a start of the robot movements even if the actual hold-to-run control key has not yet been actuated.

Although this must not be planned as intended purpose, it may result from the low safety requirements for the hold-to-run control, e.g. due to a control error that occurred over time. This fact should be mentioned in training courses for employees.

If not specified by the risk assessment, enabling devices and hold-to-run control keys for axis travel do not need to be designed as two-hand control devices.

It can be assumed that only the programmer is present in the hazard zone during setting/programming. Accordingly, the protective measures mentioned in Table 1 can be considered as protection for the programmer. If further persons have to stay in the hazard zone due to technological reasons, additional protective measures have to be provided, e.g. additional enabling switches.

An interface for the connection of further enabling switches should be provided by the machine manufacturer from the very start in order to allow subsequent expansions.

4.1.3 Functional safety of the control system

For safety-related parts of control systems, the product standards for industrial robots EN ISO 10218-1 and EN ISO 10218-2 require single-fault safety with partial fault identification. At the same time, information is given that these requirements are met by measures according to EN ISO 13849-1 or EN 62061. The following safety-related control system performance is indicated:

- PLd (Performance Level d) associated with structure category 3 or
- SIL 2 (Safety Integrity Level 2) associated with hardware fault tolerance 1.

In most cases, these requirements necessitate a dual-channel control structure according to Figure 29. Thus, the free selection of the category or PL or SIL by means of a risk graph (Figure 30) is limited.

In a justified individual case, it is allowed to deviate from these provisions as a result of a comprehensive risk assessment for the robot system and its application. For selecting an alternative control category, /PL/ SIL, the risk graphs according to EN ISO 13849-1 can be used as an aid (Figure 30).
The safety-related parts of control systems include e. g.:
- electric interlockings of protective devices
- enabling switches
- limits or monitoring of the range of motion of robots
- limit or monitoring of speed
- limit or monitoring of force for collaborative robots
- signals from light curtains
- emergency-stop
- safety stop
- mode selection switch

Examples of determining the Performance Levels, see clause 4.3

4.1.4 Safely monitored robot control system
A safe electronic protection system on a microprocessor basis offers a number of advantages in comparison with contact-based electro-mechanical technology, e. g.:
- no wear out of limit switches
- enhanced diagnostic options
- shorter reaction times possible

The electronic program control (task program) designed for production tasks does, however, normally not fulfill the safety requirements (see clause 4.1.3). This requires an independent superior dual channel protection system. The required technical effort has been considered to be unjustifiable for a long time. New powerful microprocessors, however, also enable the safe monitoring of industrial robots.

[Figures 29 and 30: Redundant control system structure with cross data comparison in accordance with control category 3 (H) and Risk graph according to EN ISO 13849-1 with example of PLd selection. [8]]

Key
- S = Severity of injury
- S1 = Slight (normally reversible injury)
- S2 = Serious (normally irreversible injury or death)
- F = Frequency and/or exposure to hazard
- F1 = Seldom-to-less often and/or exposure time is short
- F2 = Frequent-to-continuous and/or exposure time is long
- P = Possibility of avoiding hazard or limiting harm
- P1 = Possible under specific conditions
- P2 = Scarcely possible
The following safety functions are provided by most robot manufacturers:

- Safely reduced speed, e.g. monitoring of tool mounting flange when setting with 250 mm/s or in collaborative operation.
- Safe cartesian restriction of range of motion, e.g. for safely limiting the range of motion or for determining a restricted space (see clause 4.2.1.3).
- Safe axis-specific restriction of range of motion, e.g. for safely limiting the range of motion or for determining a restricted space (see clause 4.2.1.3).
- Safely monitored stop, e.g. by actuating protective devices (see clause 4.1.5).
- Safe deceleration ramps, e.g. for emergency stop, enabling devices

For collaborative robots in the function Power and Force Limiting, a safely monitored force limitation is additionally required.

4.1.5 Protective stop

Each industrial robot shall have an option for the connection of external protective devices, e.g. for the connection of light curtains and and protective door switches. This interface is called protective stop input. It has to be physically available in addition to the emergency stop input, e.g. by additional terminals.

The stop reaction of the robot in case of a protective stop has to take place according to EN 60204-1 in stop category 0 or 1 [9]. Stop category 2 may be applied in addition if the standstill is safely monitored.
4.1.6 Emergency-stop

Industrial robots have to be equipped with one or more emergency-stop devices. At the same time, an option for the connection of the external emergency-stop devices has to be provided, e.g. a terminal.

The term „Emergency-Off“ as used e.g. in the former German DIN EN 775 must not be applied for new systems anymore. Emergency-Off is reserved for electric (galvanic) isolation from the energy supply.

The emergency-stop circuits have to be designed with failsafe technology according to EN 60204-1. The functional safety of the emergency-stop circuit has to be designed according to EN ISO 10218-1 in single-fault safety (see clause 4.1.3). Emergency-stop devices have to be clearly visible and easily accessible. They have to be provided at least at each place of operation.

After unlocking the emergency-stop control device, the system shall not immediately restart. Restart may only take place after actuation of an additional start device.

4.1.7 System-Emergency-Stop

Normally, the emergency-stop circuit has to be designed in such a way that on actuation of the emergency-stop, the hazardous movements and the hazardous process functions of the entire system are stopped. In case of very spacious robot systems, it is permissible to divide the emergency-stop devices into defined sections (see EN ISO 11161). The precondition is that they are identifiable as partial sections by the constructual layout of the system. In addition, signs have to be fixed at the emergency-stop devices. The personnel has to be familiarized with the effects of operation of these emergency-stop devices by appropriate training.

Particular attention has to be given to the interfaces of adjoining system parts. If necessary, emergency-stop circuits need to be effective at the interfaces on adjoining system parts, if their further operation represents a hazard (e.g. material handling). See clause 2.3.

4.1.8 Teach pendant (TP)

Each teach pendant has to be provided with an emergency-stop device. The safety-related lines which are inside the flexible supply line of the teach pendant, e.g. emergency-stop and enabling device, have to be protected against short and cross circuit, e.g. by redundancy and monitoring.
In practice, occasionally teach pendants with grey emergency-stop actuators can be encountered, which are not permitted according to EN ISO 10218-1. Emergency-stop devices shall be marked in red on a yellow background. Even wireless-operated teach pendants shall have a fully effective emergency-stop device which shall be marked in red/yellow as well.

Inactive plug-in teach pendants have to be stored in such a way that inadvertent actuation of the emergency-stop control device on the pendant which is inactive at that time is prevented. The system supplier has to provide relevant information in the operating instructions. The user of the system has to instruct the employees accordingly.

For linked systems comprising several robots, it may be necessary to disconnect the teach pendant during the running operation if it is needed at a different station or for a different robot.

Without additional control measures, the removal of the plug would lead to an immediate standstill of the entire system. The reason is the emergency stop device on the teach pendant which is designed as closed circuit. In this case, a circuit for the temporary by-passing of the relevant emergency-stop circuit is required. The relevant standards do not include provisions on how such a circuit has to be designed. In the course of the risk assessment, however, the sticking of pushbuttons which are used for bypass should be taken into account as well as the deliberate locking for reasons of convenience.

A monitoring of time is thus reasonable in any case. Figure 34 shows an example circuit with a dummy plug (short-circuiting plug). Since the time monitoring has no direct influence on the safety function, an off-delay relay or an electronic component (e.g. PLC) can be applied. Isolation has to be considered. The time setting should provide additional time for replugging (e.g. several minutes), so that no unintended shutdowns occur.

**4.1.9 Stop as quickly as possible**

The Machinery Directive and EN 60204-1 unanimously require a stop as quickly as possible for applying the stop function for emergency-stop. The term “as quickly as possible”, however, is extensible and requires additional consideration.

The interconnection of the emergency-stop signals or protective door signals with the immediate isolation of energy (stop category 0) and the simultaneously acting mechanical brakes may cause a fast braking process but leads to wear of the brakes. This impairs the safety of the system. A controlled stop on which the energy to the machine actuators is maintained in order to achieve a stop spares the machine. Energy is only interrupted when the standstill has been achieved (stop category 1). The electronic drive units required for braking are, however, normally not suited for safety functions. The case of failure, where the electronics fail at the moment of emergency-stop or on opening the protective door, is rather unlikely but cannot be excluded. As a consequence, this may lead to an uncontrolled running down or further acceleration of the drives.

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**Fig. 34** Example of temporary by-pass of the emergency-stop circuit during replugging the teach pendant [H]
Since the drive control electronics are also used during normal operation, it is assumed that such faults become already apparent during production by malfunctions. For the time being, safe time monitoring of the deceleration ramps is still sufficient. More recent control systems, however, already dispose of so-called deceleration ramp monitoring which can also monitor the course of the deceleration ramp.

Applicable standards do no specify, which time function is to be selected for the electronically controlled stop. A stop on a geometrical path is just as admissible as a stop at the current limit. The decision is left to the manufacturer’s risk assessment. Isolation of energy after the time scheduled has to be ensured. This necessitates safe time elements.

For enabling switches, stop category 0 or stop category 1 with monitored deceleration ramp should be selected.

### 4.1.10 Axes limiting

According to EN ISO 10218-1, at least the main axis, i.e. the axis with the largest extension, has to be provided with the option to mount mechanical fixed stops. For axes two and three (axes with second and third largest extension) there has to be the option to provide mechanical, electromechanical or electronic axes limiting.

Where and to which radius axis limiting for the safety of persons has to be provided, depends on the risk assessment of the system. This requires the specification of the so-called restricted space according to EN ISO 10218-1.

<table>
<thead>
<tr>
<th>Stop function</th>
<th>Description</th>
<th>Suitability for safety functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stop category 0</td>
<td>Stopping by immediate removal of power to the machine actuators</td>
<td>Yes</td>
</tr>
<tr>
<td>Stop category 1</td>
<td>A controlled stop with power available to the machine actuators to achieve the stop and then removal of power when the stop is achieved.</td>
<td>Yes</td>
</tr>
<tr>
<td>Stop category 2</td>
<td>A controlled stop with power left available to the machine actuators</td>
<td>Yes, but with additional measures</td>
</tr>
</tbody>
</table>

Tab. 3 Stop functions according to EN 60204-1

Maximum space: space which can be swept by the moving parts of the robot, as defined by the manufacturer plus the space which can be swept by the end-effector and the workpiece.

Restricted space: portion of the maximum space restricted by limiting devices that establish limits which will not be exceeded.

Limiting devices by means of the control system have to be designed in failsafe technology (see clause 4.1.3).

In new systems, axis limiting as shown in Figure 35 is rarely used today. Most of the time, safely monitored robot control systems are used (see clause 4.2.1.3).

![Fig. 35 Limitation of three ranges of motion at the main axis by safe electro-magnetic switches](image)
4.2 Protective devices for robot cells and systems

On industrial robots and robot systems, a variety of hazardous points with mechanical hazards exist, e.g. by crushing and shearing. In order to ensure protection against manual intervention and access, robot systems have to be enclosed by protective devices. An exception are workplaces with collaborative robots which are specifically designed for the collaboration human/robot (clause 5). In most cases, protective fences as well as fixed enclosures in association with light curtains, roller shutters and similar are suitable.

There are additional hazards as a result of the technical process (welding, laser), which may require additional protective devices. e.g. glare protection, extraction system, personal protective equipment (PPE).

4.2.1 Guards

4.2.1.1 Safety distances

With regard to safety distances, EN ISO 10218-2 refers to EN ISO 13857. As protection against climbing over, the minimum height of guards is 1400 mm, if points of hazard cannot be reached when reaching over. For manual loading places, a lower height can be chosen for ergonomic reasons. (see clause 4.2.1.4). The distance of the lower edge of the guard to the floor must not exceed 180 mm at maximum (creep zone).

If hazardous points can be reached upon reaching over, the safety distances have to be determined according to EN ISO 13857 (Figure 36). Table 4 shows the safety distances for „high” risks which can usually be expected for robots, e.g. crushing, shearing. Table 5 for „low” risks needs to be considered for robot systems only rarely, e.g. on touching or bumping.

![Fig. 36 Safety distances according to EN ISO 13857 (H)](image)
### Tab. 4  Safety distances c with regard to reaching over according to EN ISO 13857 for high risk [10]

<table>
<thead>
<tr>
<th>Height of hazard zone a</th>
<th>Height of protective structure b</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1000</td>
</tr>
<tr>
<td>2700</td>
<td>0</td>
</tr>
<tr>
<td>2600</td>
<td>900</td>
</tr>
<tr>
<td>2400</td>
<td>1100</td>
</tr>
<tr>
<td>2200</td>
<td>1300</td>
</tr>
<tr>
<td>2000</td>
<td>1400</td>
</tr>
<tr>
<td>1800</td>
<td>1500</td>
</tr>
<tr>
<td>1600</td>
<td>1500</td>
</tr>
<tr>
<td>1400</td>
<td>1500</td>
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<tr>
<td>1200</td>
<td>1500</td>
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<tr>
<td>1000</td>
<td>1500</td>
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<tr>
<td>800</td>
<td>1500</td>
</tr>
<tr>
<td>600</td>
<td>1400</td>
</tr>
<tr>
<td>400</td>
<td>1400</td>
</tr>
<tr>
<td>200</td>
<td>1200</td>
</tr>
<tr>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

### Tab. 5  Safety distances c with regard to reaching over according to EN ISO 13857 for low risk [10]

<table>
<thead>
<tr>
<th>Height of hazard zone a</th>
<th>Height of protective structure b</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1000</td>
</tr>
<tr>
<td>2500</td>
<td>0</td>
</tr>
<tr>
<td>2400</td>
<td>100</td>
</tr>
<tr>
<td>2200</td>
<td>600</td>
</tr>
<tr>
<td>2000</td>
<td>1100</td>
</tr>
<tr>
<td>1800</td>
<td>1100</td>
</tr>
<tr>
<td>1600</td>
<td>1300</td>
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<tr>
<td>1400</td>
<td>1300</td>
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<td>1200</td>
<td>1400</td>
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<td>1000</td>
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<td>800</td>
<td>1300</td>
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<tr>
<td>600</td>
<td>1200</td>
</tr>
<tr>
<td>400</td>
<td>1200</td>
</tr>
<tr>
<td>200</td>
<td>1100</td>
</tr>
<tr>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>
4.2.1.2 Fixed guards

Fixed guards have to be inseparably linked with the machine or the environment (by welding, riveting etc.) or they may only be able to be removed or opened by use of tools. For systems, which were placed on the market for the first time as from 29-12-2009, so-called permanent fasteners have to be provided in addition. After the guards have been removed, the fasteners shall remain linked to the guards or to the machine. However, this does only apply if it is foreseeable that e.g. specific sections of the fence or covers have to be removed for regular cleaning and maintenance work. For systems providing a sufficient number of access doors, it can be assumed that cleaning spots can be accessed through the protective doors.

Professional suppliers of protective machine fences usually offer fence systems from the outset which comply with the aforementioned criteria (Figure 37).

The impact resistance of guards towards mechanical influences is not generally specified. If it can be expected that ejected parts, e.g. fragments of machining tools, penetrate or inadmissibly deform the guards, measures have to be taken as part of the risk assessment.

The relevant European standards for turning, milling and drilling processes include Tables with values for designing guards consisting of steel and polycarbonate. The dimensioning of guards with regard to other mechanical influences has to be done as a result of relevant calculations or tests.

Guards should have basic stability properties, independent of additional requirements. A person who is falling down or who rests against the guard should be safely held by it.

Fig. 37 Fixtures remain connected to the protective devices or to the machine after removing the protective devices (example). [H]
4.2.1.3 Restricted range of motion

A restricted space (see also clause 4.1.10) has to be arranged at least at those locations where persons are frequently present. Even outside the fence, people have to be protected against incorrect movements of the robot by additional protective measures. These measures have to be selected in accordance with the local conditions and the risk to be reduced. Suitable measures are:

- sufficient distance of the robot to the fence
- mechanical stops (buffers)
- sufficient strength of the fence
- a safely monitored robot control system
- safe contact-based or safe electronic axis cams
- inside light barriers or curtains

According to EN ISO 10218-2, the perimeter safeguards shall not be installed closer to the hazard than the restricted space unless the perimeter safeguards are designed to be the limiting devices in accordance with EN ISO 10218-2, 5.4.3, or the risk assessment indicates that other technical measures are suitable.

The following distinction between a low and a high exposure level for persons provides information on the execution of such a risk assessment.

Within the scope of the risk assessment of the system manufacturer in cooperation with the user, companies of the automotive or automotive supply industry presently indicate a guide value of 1-2 hours/day as a high personal exposure. If this exposure time is lower, it can be considered as a short time exposure.

The safe restriction of the range of motion with new systems is increasingly implemented by means of safely monitored robot control systems (4.1.4). Within the scope of the risk assessment, the system manufacturer should define a system safety layout together with the future user. The areas which have to be protected by a monitored safety robot control system or by equivalent measures have to be marked therein (Figure 39).

![Diagram of a selection of the areas to be protected](image)

Fig. 38 Example of a selection of the areas to be protected [H]
4.2.1.4 Stations for manual loading and unloading

For protective devices at stations for manual loading and unloading, basically the same requirements as for other protective devices apply. Access to the hazard zone shall be safeguarded primarily by technical measures. Operators must not be exposed to process-related hazards, e.g. by ejected parts, welding sparks, etc., either.

For manual loading and unloading stations with alternating intervention by robot and operator (e.g. clamping stations), no further protective devices are required in accordance with EN ISO 10218-2, if the barrier between the human and the robot has a height of at least 1400 mm. This barrier only serves as protection against climbing through the hazard zone of the system. Independent of that, hazardous movement which can be directly reached by the operator at the station (e.g. clamping device, robot arm, tool) shall always be safeguarded, e.g. by a laser scanner (Figure 40).

For ergonomic reasons, the above mentioned barrier height of 1400 mm is usually not acceptable. EN ISO 10218-2 therefore admits in a Note that heights between 1400 and 1000 mm are also acceptable, depending on the protective effect by the shape of the barrier and the results of the risk assessment.

The standard committee in charge of industrial robots (NAM) of DIN has discussed this matter several times and considered a height of at least 1000 mm as sufficient in accordance with the state of the art, provided this has been determined by the risk assessment. This corresponds with the requirements in EN ISO 11161.

In case of barrier heights of less than 1000 mm, further protective measures have to be provided. Suitable measures are e.g. optical protective devices which detect a person entering the hazardous area of a system and stop the hazardous movements.

Due to the shape of tools and components, the barrier is not always of a consistent height. The barrier height should be larger than 1000 mm, if ergonomically possible. Due to e.g. the part geometry, there may be empty spaces which fall below 1000 mm. By means of the risk assessment it has to be evaluated if this creates an increased risk. In particular, it has to be checked whether...
those empty spaces can be used as ascent due to their size and geometry.

Besides the provision of the aforementioned technical protective measures, the requirements concerning the manufacturer’s operating instructions and the resulting instructions by the user of the system apply.

4.2.2 Movable guards

Movable guards have to be interlocked with the hazardous movements. This means, the hazardous movements have to be stopped as soon as a protective device is opened. The hazardous movements shall come to a standstill before they can be reached by persons. According to EN ISO 13855, a walking/gripping speed of 1.6 m/s is taken as a basis.

The control systems of interlocking devices shall be designed in failsafe technology (clause 4.1.3).

4.2.2.1 Protective doors

Where access of persons to the system is required, protective doors have to be provided. For larger systems, normally several protective doors have to be provided in order to reduce the risk of bypassing protective devices to a minimum.

If the risk of persons being trapped inside the system and not being able to free themselves on their own exists, it shall be possible to open protective doors from the inside (escape release, Figure 41).

Guard locking shall be provided if hazardous points can be reached before the hazardous machine functions have come to a standstill. Guard locking shall only be released from the machine control system for opening if
the hazardous points cannot be reached anymore taking into account the access speed. Release may take place in a timed manner or as a function of a process signal, e.g. zero speed signal. Normally, the guard locking also provides protection of the production process. The release only takes place if enabled by the process flow.

Guard locking is not obligatory. The necessity results from the aforementioned considerations.

For electromagnetic guard locking, two different systems (types) are available:

- De-energized opening: in the event of electric power failure, the guard locking is released. Not recommended if frequent power failures with simultaneous long running hazardous movements are to be expected.
- De-energized locking: guard locking is released by applying a switching signal. In the event of power failure, the locking is maintained. Disadvantage: On failure of the mains supply, access is only possible by means of an emergency release.

A selection of the above mentioned types of guard locking is done in accordance with the risk assessment of the machine manufacturer. A general preference of a particular type does not exist. The electrical signal which activates and deactivates the lock is normally not safety-related since the monitoring contacts of the protective door are effective even in case of an incorrect locking signal.

4.2.2.2 Roller shutters

In comparison to electro-sensitive protective equipment, roller shutters have the advantage that they can be positioned nearer to the hazardous points since, due to the hand-arm speed, a safety distance as for light barriers does not need to be considered. This may be of advantage at loading places and clamping stations since long distances for operators are avoided. Roller
shutters shall be of sufficient stability in order to absorb forces due to the falling or resting of the operator. Provided that the robot’s range of motion reaches into the roller shutter, the robot has to be protected separately against moving in this area, if frequent presence of the operator at the roller shutter has to be assumed. (see also clause 4.2.1.3). If this is not possible, the distance has to be designed sufficiently.

The safeguarding of the closing edges of roller shutters has to be considered. According to EN 12453, the static forces which occur when arms and hands are being trapped between closing edge and opposite closing edge shall not exceed 150 N. For a short time (0.75 s at maximum), up to 400 N may occur. If higher forces occur, pressure sensitive edges have to be used which safely interrupt the roller shutter movement upon contact with an obstacle. But even on the use of pressure sensitive edges, the maximum forces indicated for the closing edges must not be exceeded. In addition, a large-area contacting is assumed, i.e. no sharp edges.

Since roller shutters often consist of plastic material, the resistance against process-related loads, e.g. during welding, has to be ensured.

4.2.2.3 Defeating by simple means (bypassing)
The protective devices as well as the interlocking devices have to be designed in such a way that they cannot be bypassed, i.e. defeated by simple means. The defeating by simple means has to be already prevented by the machine design. According to EN ISO 14119, a typical „defeating in a reasonably foreseeable manner“ may be an intentional attempt to bypass an interlocking device either manually or by using an easily available object.

If the risk assessment shows a motivation for defeating protective devices already at the design stage, e.g. due to inadequate operability, the protection against defeating shall be increased according to EN ISO 14119. The use of a separate control actuator (tongue) by the user has to be made more difficult, e.g. by a concealed installation.

However, it is much more reasonable to design the
operability of the machine from the very beginning in such a way that a motive for defeating the protective devices is prevented.

4.2.3 Electro-sensitive protective equipment (ESPE)

Electro-sensitive protective equipment includes light barriers and curtains, laser scanners, camera systems, passive infra-red systems, ultrasonic systems etc. In the robotics sector, mainly multiple infra-red beam barriers and light curtains as well as laser scanners are applied. According to EN ISO 10218-2, the safety distances for electro-sensitive protective equipment have to be designed according to EN ISO 13855.

Due to the unavoidable overtravel of the robot axes or the devices when entering into the hazard zone, a safety distance has to be provided according to EN ISO 13855. For a vertically arranged light curtain, the necessary safety distance to the hazardous point is defined by the detection capability (resolution or distance of the light beams from each other). Due to the overtravel of the hazardous movements, the distance of the light curtain with low resolution to the hazardous point needs to be larger than for a light curtain with a high resolution. The overtravel can be determined by calculation or test.

4.2.4 Step-behind protective devices, reset

Usually, robot systems are walkable. Measures have to be provided which prevent a start of hazardous movements as long as persons are present in the hazardous space. This equally applies to access paths through electro-sensitive protective equipment (e.g. light curtains) and movable guards (e.g. protective doors). Two cases can be distinguished:

Hazardous space observable:
If the operator can view the workspace, a reset button is sufficient to reset signals from protective devices such as protective doors and light curtains and to enable the start of the hazardous movements (Figure 44). For reset buttons, generally the following applies:

- A reset button shall be placed at a location outside the protective devices.
- It must not be accessible from inside.
- The location of the reset button shall provide a good view on the hazardous movements.
- The signal processing shall ensure that sticking of the button or the deliberate fixation of the buttons are detected, e.g. by signal ramp detection.
- The instruction manual of the system has to include the information that the person who actuates the reset button shall make sure that no person stays in the hazardous space anymore.

If obstacles impair the view, several reset buttons which have to be actuated successively may be required or vision panels have to be provided to allow view into the
hazardous space on reset, e.g. for robot welding systems (Figure 45).

**Hazardous space not observable:**
In this case, the use of reset buttons as only measure is not sufficient since persons may be present in the workspace. They may not be seen from the point of action since they are covered, e.g. by equipment. In these areas, the installation of design elements can prevent the presence of persons, e.g. by tilted metal sheets (prevention of presence). Visibility can also be improved by mirrors. Furthermore, partially person-detecting protective devices can be provided, e.g. horizontal light curtains, scanners, pressure sensitive mats, pressure sensitive plates.

In case of large-scale systems, a complete detection by such equipment is not feasible both in technical and economical respect due to the constructional obstacles, e.g. in the automotive body construction. In this case, reset buttons have to be placed at least at the individual access doors which provide maximum view into the system. Additional protective measures have to be provided in accordance with EN ISO 10218-2, e.g. start-up warnings and so-called Lock Out. Audible and optical start-up warnings, however, cannot not be recommended since they are perceived as annoying by the employees. Sooner or later they are not perceived anymore, dismantled or made ineffective. In automotive engineering, the so-called Lock-Out has proven its worth. For this purpose, protective door switches are provided at the accesses which offer the option to insert locks (Lock Out) or equivalent person-dependent securing means (Figure 46).

4.2.5 **Non-step-behind protective devices**
If the workspace is sufficiently small so that an undetected presence of persons can be excluded, reset devices can be dispensed with (see EN 692). The relevant succeeding operating cycle can then be initiated immediately on closure of the protective door contacts or upon release of the electro-sensitive protective equipment. The size of the hazardous space or the workspace should not exceed the dimensions specified for presses:
- workspace height: max 600 mm
- workspace depth: max 1000 mm
Possible gaps between ESPD and the hazardous space (e.g. table) must not exceed 75 mm in width so that no person can be present in the gap. If the hazardous space exceeds the aforementioned dimensions, a reset device is indispensable, unless the workspace is entirely monitored, e.g. by laser scanners.

4.2.6 Two-hand control devices
Clamping processes normally have to be inititated with the protective device open since the proper positioning of the part to be clamped has to be controlled by the operator. Since all hazardous movements have to be safely disconnected by the electrical interlocking of the protective device, an additional switching device is required which makes the clamping commands effective.

If the clamping strokes exceed 4 mm and injuries have to be expected due to the clamping forces, measures for hand and finger protection have to be provided, e.g. two-hand control devices. According to the manufacturer's risk assessment, two-hand control devices of type I, II or III in compliance with EN 547 (in future EN ISO 13851) can be applied. Two-hand control devices of type III offer the highest level of safety. It has to be ensured that the switching commands of the two-hand control device are safely processed in the control system of the machine. The processing of the signals solely through the functional PLC or through standard bus systems is not sufficient.

For the distance of the two-hand control device from the hazardous area, the overtravel of the hazardous movement is decisive. According to EN ISO 13855, a gripping speed of 2 m/s has to be assumed.

4.2.7 Compensating measures for defective protective devices
Just like production equipment on machines, protective devices are subject to normal wear. Depending on the environmental conditions, a failure of protective devices even has to be expected. The requirements, in particular for the safety-related control technology of robot systems cause a "failsafe" state in the majority of cases. Failure of electronic or electromechanic components of the protection system does not lead to a hazardous situation but to the standstill of the machine.

The future user of the system should contact the supplier in due time to find possible solutions. If the failure of protective devices – and thus a standstill of the machine – cannot not be coped with for economical reasons, precautionary measures have to be taken already at the design stage. In practice, the following procedures have proven their worth depending on the hazard and the urgency of repair measures:

- Precautionary installation of redundant protective devices: e.g. roller shutters which frequently fail due to mechanical wear are combined with optical protection systems. On failure of the roller shutter, e.g. a light curtain becomes active. This normally results in a larger safety distance, which however can be handled for a certain period of time.
- Spare-parts stocking of critical protective devices and components: e.g. door interlocking switch, light curtains, laser scanners.
- Temporary replacement of complex protective devices by more simple protective devices: e.g. laser scanners are not immediately ready to operate due to their missing programming. Alternatively, universal light curtains may be installed vertically or horizontally. Not fully designed protective fields can be temporarily compensated by instructions given to the personnel.

On no account protective devices shall be deactivated without alternative protective measures!

4.3 Calculation example of Performance Levels for the safety functions of a robot cell

4.3.1 Calculation of the Performance Levels for the safety functions for new systems
A robot cell with a loading station and a maintenance door is considered. The loading station is safeguarded by a safety mat and a working space monitoring. Access to the workspace is provided through a maintenance door which is equipped with a door safety switch.

For the connection with other machines or machine parts which are not considered here, external signals are connected through a safety PLC. The functional logic connection of the maintenance door function with the automatic operation mode is already implemented in the robot control system.
All robot axes are stopped simultaneously by power supply interruption of the intermediate circuit.

The assessment is done in 4 steps:
1. specifying the safety functions
2. determining the required Performance Level for the relevant safety function
3. identifying the safety components involved
4. calculating the Performance Level achieved

**Step 1: Specifying the safety functions**

- Safety function 1: emergency stop
  - stopping the robot on actuation of the emergency stop push button

- Safety function 2: maintenance door
  - stopping the robot on opening the maintenance door in automatic mode

- Safety function 3: safety mat
  - stopping the robot on stepping onto the safety mat with robot in the loading area

Fig. 47 Example of a robot cell with loading station, emergency stop and maintenance door [G]

Fig. 48 Specifying the safety functions [G]
**Step 2: Determining the required normative Performance Level for the relevant safety function**

As a C-type standard for industrial robots, EN ISO 10218-1 states requirements on the safety-related control system performance and stipulates their level:

- A single fault shall not lead to the loss of the safety function.
- Whenever reasonably practicable, the single fault shall be detected at or before the next demand upon the safety function.
- When the single fault occurs, the safety function shall always be performed and a safe state shall be maintained until the detected fault is corrected.
- All reasonably foreseeable faults shall be detected.

This requirement is considered to be equivalent to Performance Level d with category 3 according to ISO 13849-1 and Safety Integrity Level 2 (SIL 2) with hardware fault tolerance 1 (HFT1) according to EN 62061.

**“Performance Level” describes the safety performance capabilities of a safety function (see clause 4.1.3). The 5 steps a to e are specified with defined sections of the probability of dangerous failure per hour (PFH<sub>D</sub>).**

<table>
<thead>
<tr>
<th>Performance Level</th>
<th>Average probability of dangerous failure per hour 1/h (PFH&lt;sub&gt;D&lt;/sub&gt;)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>≥ 10&lt;sup&gt;-5&lt;/sup&gt; bis &lt; 10&lt;sup&gt;-4&lt;/sup&gt;</td>
</tr>
<tr>
<td>b</td>
<td>≥ 3 \cdot 10&lt;sup&gt;-4&lt;/sup&gt; bis &lt; 10&lt;sup&gt;-5&lt;/sup&gt;</td>
</tr>
<tr>
<td>c</td>
<td>≥ 10&lt;sup&gt;-6&lt;/sup&gt; bis &lt; 3 \cdot 10&lt;sup&gt;-6&lt;/sup&gt;</td>
</tr>
<tr>
<td>d</td>
<td>≥ 10&lt;sup&gt;-7&lt;/sup&gt; bis &lt; 10&lt;sup&gt;-6&lt;/sup&gt;</td>
</tr>
<tr>
<td>e</td>
<td>≥ 10&lt;sup&gt;-8&lt;/sup&gt; bis &lt; 10&lt;sup&gt;-7&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Tab. 6 Performance Levels according to EN ISO 13849-1

In North America, the following 4 requirement classes for safety functions are known:

- SIMPLE
- SINGLE CHANNEL
- SINGLE CHANNEL, MONITORED
- CONTROL RELIABLE

The requirements stated in EN ISO 10218-1 correspond to the highest class – control reliable.

**Step 3: Identifying the safety components involved**

Safety components involved at safety function 1 (emergency stop):

<table>
<thead>
<tr>
<th>Component Description</th>
<th>Performer Level</th>
<th>SIL/Control System</th>
<th>PFH&lt;sub&gt;D&lt;/sub&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency stop push button contacts 2-channel</td>
<td>Fault exclusion</td>
<td>6500 switching cycles</td>
<td></td>
</tr>
<tr>
<td>Safety PLC (manufacturer's specifications)</td>
<td>SIL 3, HFT 1</td>
<td>PFH&lt;sub&gt;D&lt;/sub&gt; = 1\times10&lt;sup&gt;-8&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Robot function emergency stop</td>
<td>Pld, category 3</td>
<td>PFH&lt;sub&gt;D&lt;/sub&gt; = 1\times10&lt;sup&gt;-7&lt;/sup&gt;</td>
<td></td>
</tr>
</tbody>
</table>

In North America, the following 4 requirement classes for safety functions are known:

- SIMPLE
- SINGLE CHANNEL
- SINGLE CHANNEL, MONITORED
- CONTROL RELIABLE

The requirements stated in EN ISO 10218-1 correspond to the highest class – control reliable.

EN ISO 10218-1 permits that a different level may be admissible as a result of a comprehensive risk assessment which may deviate from the specified performance requirements.

**Step 3: Identifying the safety components involved**

Safety components involved at safety function 1 (emergency stop):

<table>
<thead>
<tr>
<th>Component Description</th>
<th>Performer Level</th>
<th>SIL/Control System</th>
<th>PFH&lt;sub&gt;D&lt;/sub&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency stop push button contacts 2-channel</td>
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<tr>
<td>Robot function emergency stop</td>
<td>Pld, category 3</td>
<td>PFH&lt;sub&gt;D&lt;/sub&gt; = 1\times10&lt;sup&gt;-7&lt;/sup&gt;</td>
<td></td>
</tr>
</tbody>
</table>

Since the mechanism of the emergency stop push button is only single-channel, the application of a category 3 control system is only possible if a fault exclusion can be assumed. According to EN ISO 13849-1 Table C.1, the mechanical lifetime which is at least required for an emergency stop push button amounts to 6500 switching cycles. Under these conditions, a fault exclusion can be assumed for the mechanically positive operation.

For an expected lifetime of at least 20 years which can also be assumed according to EN ISO 13849-1, 325 switching cycles may result, i.e. approx. one operation per day. If this complies with the practice of the planned system, the fault exclusion is admissible. Since the electric contacts of emergency stop push buttons are positively driven, the fault exclusion is permissible for both the mechanical rod and the electrical contacts.

\[
\frac{6500 \text{ switching cycles}}{20 \text{ years}} = 325 \text{ switching cycles/year}
\]
Safety components involved at safety function 2 (maintenance door)

<table>
<thead>
<tr>
<th>Door interlocking switch</th>
<th>Fault exclusion for actuator, 2-channel contact</th>
<th>PFH(_d) = 1,01 x 10(^{-7})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety-PLC (manufacturer’s specification)</td>
<td>SIL 3, HFT 1</td>
<td>PFH(_d) = 1 x 10(^{-8})</td>
</tr>
<tr>
<td>Robot function protective stop (manufacturer’s specification)</td>
<td>PLd, category 3</td>
<td>PFH(_d) = 1 x 10(^{-7})</td>
</tr>
</tbody>
</table>

A door interlocking switch type 2 with a separate actuator (tongue) is applied. Since the tongue exists only once, it has to be checked again whether a fault exclusion with regard to breakage is permissible. This fault exclusion is permissible for the majority of switches of type 2 in a normal industrial environment. No fault exclusion is possible in case of extreme environmental conditions, e.g. ingress of adhesives, which may cause the tongue to tear off while in the inserted position.

The value for the lifetime of the door interlocking switch is indicated by the manufacturer in B10\(_d\). B10\(_d\) indicates the medium number of switching cycles up to which 10 % of the components may fail to danger.

In order to achieve a MTTF\(_d\) and subsequently a PFH\(_d\)-value from this B10\(_d\)-value, the medium number of switching cycles per year (n\(_{op}\)) is required. Based on a 6-days week and a 2-shift operation, the calculation is as follows:

\[
\begin{align*}
B10_d & = 3 \times 10^6 \\
\text{d}_{op} & = 300 \\
\text{h}_{op} & = 16 \\
\text{t}_{cycle} & = 3600 \text{ sec (access 1 x per hour)} \\
\end{align*}
\]

\[
\begin{align*}
n_{op} & = \frac{\text{d}_{op} \times \text{h}_{op} \times 3600}{\text{t}_{cycle}} = \frac{300 \times 16 \times 3600}{3600} = 4800 \\
\text{MTTF}_d & = \frac{B10_d}{0,1 \times n_{op}} = \frac{3 \times 10^6}{0,1 \times 4800} = 6250 \text{ years}
\end{align*}
\]

The PFH\(_d\)-value can be taken from EN ISO 13849-1 Table K.1 under the following preconditions:

- MTTF\(_d\) is generally capped to 100 years for values exceeding 100 years (6250 years → 100 years).
- The control structure is category 3.
- Monitoring of the contacts of the door interlocking switch takes place by means of the subsequent safety PLC. Since access through the maintenance door and thus the possibility for fault detection is not frequent, only a low fault detection rate DC\(_{avg}\) is assumed.

Thus, the average probability of a hazardous failure per hour is as follows

\[
\frac{1}{\text{PFH}_d} = 1,01 x 10^{-7}\text{ hour}^{-1}
\]

Safety components involved at safety function 3 (safety mat)

<table>
<thead>
<tr>
<th>Safety mat (manufacturer’s specification)</th>
<th>PLd, category 3</th>
<th>PFH(_d) = 3,25 x 10(^{-8})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety-PLC (manufacturer’s specification)</td>
<td>SIL 3, HFT 1</td>
<td>PFH(_d) = 1 x 10(^{-8})</td>
</tr>
<tr>
<td>Robot function working space monitoring (manufacturer’s specification)</td>
<td>PLd, category 3</td>
<td>PFH(_d) = 1 x 10(^{-7})</td>
</tr>
</tbody>
</table>

Protective measures for industrial robots and robot systems
Step 4: Calculating the Performance Level achieved

Calculation of safety function 1 (emergency stop)

Component 1 emergency stop push button
Component 2 safety PLC SIL 3, HFT 1 PFH₀ = 1 x 10⁻⁸
Component 3 robot function emergency stop PFH₀ = 1 x 10⁻⁷
Cat. 3 PL₃
Fault exclusion PFH₀ Comp. 2 + PFH₀ Comp. 3 = 1,1 x 10⁻⁷

Calculation of safety function 2 (maintenance door)

Component 1 door interlocking switch PFH₀ = 1,01 x 10⁻⁷
Component 2 safety PLC SIL 3, HFT 1 PFH₀ = 1 x 10⁻⁸
Component 3 robot function protective stop PFH₀ = 1 x 10⁻⁷
Cat. 3 PL₃
PFH₀ Comp. 1 PFH₀ Comp. 2 + PFH₀ Comp. 3 = 2,11 x 10⁻⁷

Calculation of safety function 3 (safety mat)

Component 1 safety mat PLd, category 3 PFH₀ = 3,25 x 10⁻⁸
Component 2 safety PLC SIL 3, HFT 1 PFH₀ = 1 x 10⁻⁸
Component 3 robot function working space monitoring PFH₀ = 1 x 10⁻⁷
Cat. 3 PL₃
PFH₀ Comp. 1 PFH₀ Comp. 2 + PFH₀ Comp. 3 = 1,42 x 10⁻⁷

New system assessed according to EN 13849-1

Fig. 49 System layout with new and used robots [G]
4.3.2 Calculation of the Performance Level for safety functions on the reuse of used robots in new systems

If the data acquisition for determining the Performance Levels for safety functions of used industrial robots is not possible, the partial functions, which are not evaluated according to EN ISO 13849-1, can be indicated with their category only (see also [19]).

The present example deals with a robot cell with 2 new industrial robots and 1 used industrial robot. For the evaluation, the subsystems “new” and “old” are separated and the safety functions are considered individually (Figure 49).

**Evaluation of safety function maintenance door**

**a. For the new system part**

<table>
<thead>
<tr>
<th>Subsystem</th>
<th>Function</th>
<th>SIL</th>
<th>HFT</th>
<th>PFHD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subsystem 1</td>
<td>door interlocking switch, 2-channel</td>
<td>SIL 3, HFT 1</td>
<td>$\text{PFHD} = 6 \times 10^{-8}$</td>
<td></td>
</tr>
<tr>
<td>Subsystem 3</td>
<td>safety-PLC</td>
<td>SIL 3, HFT 1</td>
<td>$\text{PFHD} = 1 \times 10^{-8}$</td>
<td></td>
</tr>
<tr>
<td>Subsystem 4 or 5</td>
<td>robot function</td>
<td></td>
<td>$\text{PFHD} = 1 \times 10^{-7}$</td>
<td></td>
</tr>
</tbody>
</table>

Fault exclusion: $\text{PFHD}_{T1} + \text{PFHD}_{T2} + \text{PFHD}_{T3} = 1.7 \times 10^{-7}$

**b. For the system part with used robot**

<table>
<thead>
<tr>
<th>Subsystem</th>
<th>Function</th>
<th>SIL</th>
<th>HFT</th>
<th>PFHD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subsystem 1</td>
<td>door interlocking switch, 2-channel</td>
<td>SIL 3, HFT 1</td>
<td>$\text{PFHD} = 6 \times 10^{-8}$</td>
<td></td>
</tr>
<tr>
<td>Subsystem 3</td>
<td>safety-PLC</td>
<td>SIL 3, HFT 1</td>
<td>$\text{PFHD} = 1 \times 10^{-7}$</td>
<td></td>
</tr>
<tr>
<td>Subsystem 6</td>
<td>robot function</td>
<td></td>
<td></td>
<td>$\text{PFHD} = 1 \times 10^{-7}$</td>
</tr>
</tbody>
</table>

Fault exclusion: $\text{PFHD}_{T1} = \text{Cat. 3 PL}_3$

**Evaluation of safety function emergency stop**

**c. For the new system part**

<table>
<thead>
<tr>
<th>Subsystem</th>
<th>Function</th>
<th>SIL</th>
<th>HFT</th>
<th>PFHD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subsystem 2</td>
<td>emergency stop push button, 2-channel</td>
<td>SIL 3, HFT 1</td>
<td>$\text{PFHD} = 1 \times 10^{-8}$</td>
<td></td>
</tr>
<tr>
<td>Subsystem 3</td>
<td>safety-PLC</td>
<td>SIL 3, HFT 1</td>
<td>$\text{PFHD} = 1 \times 10^{-7}$</td>
<td></td>
</tr>
<tr>
<td>Subsystem 4 or 5</td>
<td>robot function</td>
<td></td>
<td></td>
<td>$\text{PFHD} = 1 \times 10^{-7}$</td>
</tr>
</tbody>
</table>

Fault exclusion: $\text{PFHD}_{T2} + \text{PFHD}_{T3} = 1.1 \times 10^{-7}$

**d. For the system part with used robot**

<table>
<thead>
<tr>
<th>Subsystem</th>
<th>Function</th>
<th>SIL</th>
<th>HFT</th>
<th>PFHD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subsystem 1</td>
<td>emergency stop push button fault exclusion</td>
<td>SIL 3, HFT 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subsystem 3</td>
<td>safety-PLC</td>
<td>SIL 3, HFT 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subsystem 6</td>
<td>robot function emergency stop category 3</td>
<td></td>
<td></td>
<td>$\text{PFHD} = 1 \times 10^{-7}$</td>
</tr>
</tbody>
</table>

Fault exclusion: $\text{PFHD}_{T1} = \text{Cat. 3 without PL}$
Traditional industrial robot systems can only automate processes which can completely do without human intervention. So far, it has in particular often not been possible to automate assembly work since individual tasks cannot be done without the motor skills of a human. A human can work without data transmitters and sensors. Even the assembly of elastic parts is no problem for him/her. It is the aim of collaborative robots to combine these capabilities: the human with his/her capabilities for the imprecise and the robot with its advantages in force, endurance and speed. Workplaces with collaborative robots are intended to be managed completely or partially without protective fences.

According to the definition of EN ISO 10218-1, the collaborative operation is a state in which purposely designed robots work in direct cooperation with a human within a defined workspace, i.e. they share one workspace. Collaborative robots are often called assisting robots as well.

Service robots or robots in the rehabilitation sector (medical robots) are not dealt with here.

Only collaborative industrial robots according to EN ISO 10218-1 and EN ISO 10218-2 are considered. The technical safety requirements largely depend on the application and spread over both parts of the standard. The requirements with respect to the preferred applications in practice are shown hereafter.

The collaborative operation should not be confused with setting/teaching. The collaborative operation is applied in production, i.e. it is normally a special case of automatic operation.

5.1 General minimum requirements

EN ISO 10218-1 states requirements for collaborative operation. Since this standard applies to the “bare” robot without periphery, it is often assumed that a safe robot can be designed and certified if solely these requirements are met. This is not true since even a collaborative robot with grippers and devices which are required for the task constitutes a machine according to the Machinery Directive. The system integrator has to draw up an EC Declaration of Conformity as for any other robot application and fix a CE mark on the application.

The certification of collaborative robots should also include one or more typical applications to enable a reliable assessment.

The requirements of EN ISO 10218-1 and EN ISO 10218-2 apply to collaborative robots as well.

The additional requirements for collaborative robots were still very rudimentary at the time when this DGUV Information was ready to be printed. An applicable requirement is an optical indication for robots which can change over from a non-collaborative (conventional) to a collaborative operation. Provisions about the quality of this indication do not exist. Therefore, an indication on the control panel can be sufficient.

In addition, EN ISO 10218-2 includes further requirements for collaborative operation. These requirements refer to possible applications. In the following, selected requirements are described in more detail.

When this DGUV Information was ready to be printed, the international technical specification ISO TS 15066 was in preparation. This technical specification is intended to specify further requirements during the development of new types of collaborative robot systems in order to include them in the standard series EN ISO 10218 later on.

5.2 Hand guiding

If the robot is intended for hand guiding, the hand guiding equipment shall be located close to the end-effector. This may e.g. be a force/moment sensor which enables the robot to be guided manually, similar to a manipulator. The robot has to be operated with safely reduced speed. The safely reduced speed shall fulfill the requirements set out in clause 4.1.3.

The speed level is not stipulated. It results from the risk assessment.

In addition, an easily accessible enabling device as well as an emergency stop device have to be provided. Enabling device and emergency stop device shall also be of safety-related design.

Similar devices can be found among lifting equipment, which, however, are covered by other standards. For industrial robots which are intended for hand guiding, the requirements of EN ISO 10218-1 and EN ISO 10218-2 shall always be complied with even if lifting processes are concerned.
5.3 Force and/or power limiting

5.3.1 Principle
Generally, it has to be ensured that on contact between a robot or tool and a person, particular load characteristics are not exceeded.

Reliable limit values for these medical and biomechanical requirements were in preparation when this DGUV Information was ready to be printed. As to current limit values, please refer to the Deutsche Gesetzliche Unfallversicherung (German Social Accident Insurance) or to your responsible Social Accident Insurance Institution.

An earlier edition of EN ISO 10218-1 from 2006 indicated a maximum power of 80 W or a maximum force of 150 N at the tool holder. These general values were deleted in the follow-up edition of the aforementioned standard. It had been found that biomechanical limit values have to be regarded on a differentiated basis dependent on the body regions.

In order to reduce the pressure on the body regions, generally all edges of the robot system including tools should be rounded.

One possibility to limit contact forces is the application of protective devices directly on the robot and, if necessary, on the tool. Tactile protective devices are particularly suitable for this purpose. They initiate a stop on contact with a person. A combination of tactile protective devices with capacitive or inductive protective devices is also possible (Figure 51).

5.3.2 Measurement of force and pressure
Within the scope of the risk assessment of the application it has to be specified which positions of the robot including the tool have to be selected for measuring purposes. For the corresponding body regions, typically the following has to be assumed:
- operator's intervention in the tool area
- observation of the work process
- observation of disorders
- bumping of robot arms on the body
- bumping of tool and workpiece on the body

The force or pressure effects depend on the shaping of the robot, the tool, the workpiece and all other devices involved in the work process (see EN ISO 10218-2). Large, angular and heavy workpieces are not suited for this kind of collaboration taking into account the current state of the art. Merely the inertia of these workpieces normally leads to exceeding the force or pressure limits.

The deposit of parts in devices has also proven to be very critical. Industry demands utmost precision, so that e. g. at the gripper centering devices are used. The resulting shearing edges cannot be controlled due to the occurring pressures. Shearing edges are to be generally prevented.
Furthermore, the admissible positions of the robot are decisive for the collaborative operation. Normally, the robot’s transverse paths need to be limited by the function „safe position“ in order to exclude e.g. sensitive parts of the body such as head or neck from the working space.

5.3.3 Safety functions
The requirements according to EN ISO 10218-1 and EN ISO 10218-2 also apply to collaborative robots. Besides the obligatory safety functions specified therein such as emergency stop, protective stop and enabling device, a robot in the function Power and Force Limiting normally has to be provided with at least the following additional safety functions:

Safe monitoring of torque and force
Taking into account the edge geometries of all robot system surfaces being involved in the work process, the monitoring of pressure inside the robot system also results from the robot force or torque monitoring.

Safe speed monitoring
In order to ensure that the speed does not change to incorrect values on an occurring or impending contact, the speed also needs to be safely monitored in order to maintain the force to be ensured in case of contact.

Safe position monitoring
In order to define and separate working spaces according to the load limits which are assigned to the body regions, the robot shall have a safely monitored position.

The safety functions shall comply with category 3/PLd i.e. the safety functions shall be provided even under fault conditions. It is e.g. not sufficient to measure and document the force in the normal condition only. Even in case of failure of components or hardware and software faults, the force must not be exceeded. The same applies to all other safety functions (see clause 4.1.3).

Alternatively, a safe force limiting may e.g. be implemented by inherently safe design.

5.4 Speed and separation monitoring
In case of speed and separation monitoring, protective devices are applied in such a way that persons can access the robot at any time without being exposed to a hazard.

Suitable safeguards are e.g. optical laser scanners or 3D cameras. They have to detect the approach of persons safely and decelerate or stop the robot motion accordingly. When the distance is increasing, the robot continues its motion without reset. The speed shall be safely monitored.
Like the other safety-related control system of the robot system, these optical safeguards shall also fulfill the requirements of EN ISO 13849-1 PLd in association with category 3 (see clause 4.1.3).

The safety distances shall be in compliance with EN ISO 13855. Therefore, the speed and separation monitoring is normally only applicable where sufficient space is available. In addition, it has to be considered that not only can a person approach the hazardous point, but that also the hazardous point (robot system) can approach the person.

5.5 Safety-related stop

A safety-related stop constitutes a special case in terms of speed and separation monitoring. On access to the collaborative workspace, the drives are immediately stopped and transferred to a safe operational stop according to EN 61800-5-2 (Safe Operating Stop/SOS). On leaving the collaborative workspace, the robot continues its motion without reset. The speed rate is specified according to the risk assessment.

Fig. 54  Speed and separation monitoring – approach robot/person [D]
6 Special modes of operation for process observation

6.1 Trouble-shooting – process observation with enabling switch

For trouble-shooting it may be necessary to provide one or several modes of operation in addition to the normative modes of operation T1, T2 (see clause 4.1.1). This should already be included in the risk assessment and the design during the system planning in order to enable the maintenance personnel to work safely. Even bypassing of safeguards can thus be prevented.

Trouble-shooting has to be carried out initially from outside the hazardous areas. Furthermore, it has to be checked whether the robot modes of operation T1 and T2 which are intended by the manufacturer of the robot or the machine can be applied. If this is not possible, a special mode of operation can be provided as follows:

- Selection with key switch only
- Enabling switch and hold-to run operation, if possible with reduced speed. The enabling switch releases (enables) the process to be observed and stops it immediately upon release.
- All other hazardous movements remain safely stopped.
- Specify safe position for observation in the system layout
- Particular work instructions, e.g. access by one person only, observation from outside the safeguards by another person
- Authorization by executives

if specific process operations require temporary visual observation which cannot be implemented by the normatively intended modes of operation and safeguards (e.g. enabling switch) due to the duration of actuation. The probably high economic damage in case of inadvertent release of the enabling switch has also to be taken into account.

The decision-making basis for a special mode of operation “process observation” is the risk assessment of the machine manufacturer (integrator). The manufacturer has to work in close cooperation with the future user during the preparation of the risk assessment, in order to include his or her experience in the risk assessment, e.g. ergonomic problems to be expected, disturbances, material damages.

As a result of the risk assessment, an individual package of measures composed of technical and organizational protective measures has to be specified for the present particular case in question (Figure 56). The special mode of operation “process observation” is therefore no mode of operation for the ordinary process flow.

6.2 Process observation without enabling switch

The special mode of operation “process observation” without enabling device is dealt with in EN ISO 10218-2 in the informative annex G. More detailed information is included in standard EN ISO 11161 which is also harmonized in the EU.

This special mode of operation allows the temporary observation of processes within a workspace in exceptional cases without requiring the continuous actuation of a switching device, e.g. an enabling device. This mode of operation should only be applied if the analysis of the planned manufacturing conditions shows that a production under the normatively intended modes of operation is impossible (automatic, T1, T2). This is e.g. the case,
Has the future user convincingly explained that a special mode of operation is absolutely necessary?

- yes: Special mode of operation may be provided
- no: Special mode of operation must not be provided

Has a sufficient risk reduction been achieved?

- yes: Reduce risks by technical safety measures
  - provide additional mode selection switch
  - positive initiation of operation to the required minimum that is necessary for the special mode of operation
  - provide further technical safety measures, as far as possible
- no: Are the technical measures exhausted?

Are the technical measures exhausted?

- yes: Is the user able to make the necessary contribution for a risk reduction by additional measures?
- no: Carry out hazard analysis and risk assessment for the special mode of operation according to EN ISO 12100

Is the user able to make the necessary contribution for a risk reduction by additional measures?

- yes: Specify instructions for the user in the operation manual
- no: yes

Record handling of special mode of operation in the operation manual

Yes

Special mode of operation may be provided

No

Special mode of operation must not be provided

Fig. 56 Special mode of operation “process observation” [6]
General information on maintenance in industrial companies is contained in DGUV Information 209-015 „Instandhalter“ (up to now BGI 577). Therefore, the present document only deals with some robot specific requirements.

7.1 Information provided in the operating instructions

The operating instructions of the robot system manufacturer shall include information on maintenance. If this information is missing, it is recommended to push on the preparation and handing over of the corresponding documents prior to the commissioning of the system. The manufacturer is obliged to do so (EN ISO 10218-2, Machinery Directive Annex I).

Attention: It is not legally stipulated to which extent such documents have to be provided. This also includes circuit diagrams, CLP programs and similar. Therefore, it is always recommended to stipulate the scope of supply in this regard by contract, e.g. in the requirements specifications.

7.2 Technical protective measures

Maintenance work have to be carried out if at all possible with the robot system in the OFF position. Measures have to be provided which prevent a restart by unauthorized persons, e.g. locking of the energy isolating devices, signs (Figure 58). Energy stores have to be relieved, e.g. by mechanical springs. Pressure accumulators (see DGUV Information 209-070; up to now BGI/GUV-I 5100). Particular attention should be paid to parts on the robots, e.g. axes, which may sink or fall down due to gravity. If the operator sometimes has to stay under the axis, additional technical measures have to be already taken during the design stage in order to prevent a sudden failure of the holding brakes, e.g. cyclic brake test, redundant brakes, automatic mechanical locks. For maintenance work, axes have to be additionally secured, e.g. by supports or by locks.

If it is not possible to carry out maintenance and servicing tasks with the system totally shut off, supplementary safety measures have to be provided as far as possible. This includes enabling switches, hold-to run operation, reduced speed or mechanical auxiliary devices, such as magnetic grippers and devices. Maintenance and servicing tasks, especially when safeguards are suspended, shall only be carried out by qualified personnel.
The personnel shall be informed on all hazards it deals with, and in particular on hazards which are difficult to identify.

Regular instructions have to be carried out. It is recommended that persons who have been instructed confirm the instruction received by their signature.

If access by unauthorized persons has to be expected, additional signs and caution tapes have to be provided. For this purpose, standardized signs according to DIN 4844-2 should be used.

Hazards which are difficult to identify even for instructed personnel include particularly the automatic processes of robot systems which seem to be in a safe state when the system is at a standstill. In order to continue the production as fast as possible, there might be the temptation to get into the system by suspending the interlocking devices. The accidental attenuation of one of the numerous electro-magnetic switches which are provided within the system, e.g. by means of a tool or by parts of the workpiece, may start the next operation command of the robot, or initiate a clamping movement or similar.

Provisions by design for a failure scenario of electro-sensitive protective equipment are described in clause 4.2.7.

7.3 Remote diagnosis

Modern robot systems are provided with interfaces for remote diagnosis. They can be connected to the internet or the public telephone network. This enables the robot manufacturer to diagnose specific faults of the robot without the presence of service personnel at the manufacturer’s premises. By means of these devices, the robot control system programs can be partially or completely modified. Furthermore, it is possible to issue operation commands to the robot without requiring the actuation of the relevant local actuators. This shows that the use of remote diagnosis systems requires particular caution. Protection is only given by the measures described under 4, i.e. enabling switch or equal superior safety measures, which are independent from the remote control and comprehensive instructions on the hazards given to employees.

The instructions should also point out the hazards due to tying or clamping the enabling switches. In case of some robot types, the speed reduction is done solely by the software. Uncontrolled robot movements even with higher speeds cannot be excluded. Only an effective enabling switch offers adequate protection in such situations.

7.4 Maintenance requirements for design

The specific maintenance requirements should already be queried in good time and be included in the design of the system in the scope of the risk assessment. This includes e.g. control devices which possibly should be positioned completely outside the safeguards, e.g. electric, pneumatic and hydraulic display devices, terminal boxes and control cabinets. Thus, it can be prevented that employees are forced to suspend safeguards for trouble-shooting.

This also includes the planning of passages and ascents. This is particularly important if e.g. control cabinets are relocated to an elevated position due to the confined space conditions which frequently can be found at the place of installation (Figure 59).

Note: All switching cabinets, displays, panels and similar which require regular access, e.g. for operation, maintenance or cleaning, shall be provided with fixed means of access, e.g. platforms, ladders. Mobile ladders are not sufficient.

Fig. 59 Fixed access to the control cabinet with ladder and platform [H]
7.5 Periodic tests

The most important periodic tests for robot systems are summarized in Table 7. Further tests may be required in addition if, due to additional hazards, further accident prevention regulations or other rules and regulations apply.

Robot systems in operation fall within the scope of the accident prevention regulation „Principles of Prevention“ (DGUV Regulation 1; up to now BGV/GUV-V A1) and the Ordinance on Industrial Safety and Health (BetrSichV). Both regulations require periodic tests. The technical rule TRBS 1201 to the Ordinance on Industrial safety and health applies as well. Test intervals have to be derived from the risk assessment of the individual workplaces. They have to be specified such that the robot system can be safely used between two tests according to generally available sources of experience and company internal experience. They depend on the following criteria:

- Manufacturer’s information
- Wear of safety-related components
- Accident occurrence and near accidents
- Company internal experience

<table>
<thead>
<tr>
<th>Testing object</th>
<th>Testing principle</th>
<th>Testing interval</th>
<th>Testing scope</th>
<th>Tester</th>
</tr>
</thead>
</table>
| Protective devices e. g.:           | DGUV regulation 1; up to now BGV/GUV-V A1, | annually<sup>6</sup> | Visual check and functional test                   | Qualified person<sup>2)<sup>  

| Emergency-stop                      | DGUV regulation 1; up to now BGV/GUV-V A1, | annually<sup>6</sup> | Visual check and functional test                   | Qualified person<sup>2)<sup> 

| Electrical equipment                | DGUV regulation 3; up to now BGV/GUV-V A3, VDE 0105-100 | 4 years<sup>5</sup> | • Visual check and functional test  
|                                     |                                                       |                  | • Measurement of protective earth conductor resistance  
|                                     |                                                       |                  | • Measurement of the isolation resistance  
|                                     |                                                       |                  | Electrically skilled person |

| Pressure equipment, e. g. hydraulic accumulators | BetrSichV | 2, 5 and 10 years | Outer, inner and strength test | Approved inspection authority |

<sup>1</sup> recommended, as far as not otherwise specified by the risk assessment at the workplace  
<sup>2)</sup> corresponds to the current qualification of experts or electrically skilled person

Tab. 7 Periodic tests
### Annex 1

**Checklist: Operating instructions for machinery**

**Minimum requirements according to MD 2006/42/EC**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Complete?</th>
</tr>
</thead>
<tbody>
<tr>
<td>The business name and full address of the manufacturer and of his/her authorised representatives</td>
<td></td>
</tr>
<tr>
<td>The designation of the machinery as marked on the machinery itself, except for the serial number</td>
<td></td>
</tr>
<tr>
<td>The EC Declaration of Conformity, or a document setting out the contents of the EC Declaration of Conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature</td>
<td></td>
</tr>
<tr>
<td>A general description of the machinery</td>
<td></td>
</tr>
<tr>
<td>A description of the workstation(s) likely to be occupied by operators</td>
<td></td>
</tr>
<tr>
<td>A description of the intended use of the machinery</td>
<td></td>
</tr>
<tr>
<td>Warnings concerning ways in which the machinery must not be used that experience has shown might occur</td>
<td></td>
</tr>
<tr>
<td>Assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted</td>
<td></td>
</tr>
<tr>
<td>Instructions relating to installation and assembly for reducing noise or vibration</td>
<td></td>
</tr>
<tr>
<td>Instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators</td>
<td></td>
</tr>
<tr>
<td>Information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted</td>
<td></td>
</tr>
<tr>
<td>Instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided</td>
<td></td>
</tr>
<tr>
<td>The essential characteristics of tools which may be fitted to the machinery</td>
<td></td>
</tr>
<tr>
<td>The conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling, when out of service, during testing or foreseeable breakdown</td>
<td></td>
</tr>
<tr>
<td>Instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately</td>
<td></td>
</tr>
<tr>
<td>The operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked</td>
<td></td>
</tr>
<tr>
<td>The description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed</td>
<td></td>
</tr>
<tr>
<td>Instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations</td>
<td></td>
</tr>
<tr>
<td>The specifications of the spare parts to be used, when these affect the health and safety of operators</td>
<td></td>
</tr>
</tbody>
</table>

The following information on airborne noise emissions:

- the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,
- the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μPa),
- the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A).
## Annex 2

### Checklist: User information

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>The business name, full address, and necessary contact information of the manufacturer or supplier</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information on relevant standards the robot meets, including any that have been certified by a third party</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Instructions for commissioning, restarting and programming</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Installation requirements such as e.g. environmental conditions, utility needs, floor loading, etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Instructions for how the initial test and examination of the robot and its protective measures are to be carried out before first use and being placed into production, including functional testing of reduced speed control</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Instructions for any test or examination necessary after change or replacement of component parts or addition of optional equipment which can affect the safety-related functions, including associated outputs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Instructions for safe operation, setting and maintenance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Instructions for safe working practices</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Instructions to avoid errors of fitting during maintenance of the machine</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hazardous energy control procedures</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Instructions for the training of operators</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Instructions on the location and the function of all control system components</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Diagrams of the interface of electrical, hydraulic, and pneumatic systems necessary for setup and installation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Instructions on the manual high speed mode of operation including safe working practices</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Instructions that the manual operating modes should be performed with all persons outside the safeguarded space</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Information on the use of enabling devices</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Instructions for the installation of additional enabling devices</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Capability of safety-related circuits (category and Performance Level or SIL) if necessary, with all restrictions and additional conditions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Description of the installation of limiting devices</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number, location, implementation, range of adjustment and degree of adjustment of any mechanical and non-mechanical limiting devices</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Information on the stopping time and distance or angle from initiation of the stop signal of the three axes with the greatest extension and motion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>The specification for any lubricants, fluids and other process-unique expendables internal to the robot, including guidance on correct selection, preparation, application and maintenance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Guidance on the means for the release of persons trapped in or by the robot</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warnings that gravity and the release of braking devices can create additional hazards</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Instructions for responding to emergency or abnormal situations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information defining the limits for the range of motion and load capacity, including position of the centre of gravity of the tool</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All information required for the installation or attachment of additional sets</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**In addition, if axis and space limiting is implemented by safety-rated software:**

| A detailed description of the function with indication of capabilities (PL or SIL) |   |
| The Worst-Case-stopping time at maximum speed, including monitoring time and distance travelled and the actual stopping position to be expected |   |

**In addition for cableless or detachable teach pendants:**

| The maximum response times for data communication (including error correction) |   |
| The maximum response times for data loss |   |
| Instructions to the user on how to prevent confusing of activated and deactivated emergency-stop devices |   |
Annex 3
Checklist: Technical documentation (verifying documentation)

<table>
<thead>
<tr>
<th>Item (for partly completed machinery)</th>
<th>Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>General description of the machinery</td>
<td>☐</td>
</tr>
<tr>
<td>Overall drawing of the (partly completed) machinery</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Drawings of the control circuits</td>
<td>☐</td>
</tr>
<tr>
<td>Pertinent descriptions and explanations necessary for understanding the operation of the machinery</td>
<td>☐</td>
</tr>
<tr>
<td>Fully detailed drawings with calculation notes, test results, certificates, etc., required to check the conformity of the (partly completed) machinery with the essential health and safety requirements</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>The documentation on risk assessment demonstrating the procedure followed</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>A list of the essential health and safety requirements which apply to the machinery</td>
<td>☐</td>
</tr>
<tr>
<td>A list of the essential health and safety requirements applied and fulfilled</td>
<td>☐</td>
</tr>
<tr>
<td>Description of the protective measures implemented</td>
<td>☐</td>
</tr>
<tr>
<td>Indication of the residual risks</td>
<td>☐</td>
</tr>
<tr>
<td>The standards and other technical specifications used</td>
<td>☐</td>
</tr>
<tr>
<td>The essential health and safety requirements covered by these standards</td>
<td>☐</td>
</tr>
<tr>
<td>Any technical report giving the results of the tests carried out at the (partly completed) machinery</td>
<td>☐</td>
</tr>
<tr>
<td>Results of tests and research which have been carried out to determine whether the (partly completed) machinery is capable of being assembled and safely used due to its design or construction</td>
<td>☐</td>
</tr>
<tr>
<td>Operating instructions for the machinery</td>
<td>☐</td>
</tr>
<tr>
<td>A copy of the assembly instructions for the partly completed machinery</td>
<td>☐</td>
</tr>
<tr>
<td>Where appropriate, the declaration of incorporation and the assembly instructions of the partly completed machinery applied</td>
<td>☐</td>
</tr>
<tr>
<td>Copy of the EC Declaration of Conformity of machinery or other products incorporated into the machinery</td>
<td>☐</td>
</tr>
<tr>
<td>Copy of the EC Declaration of Conformity</td>
<td>☐</td>
</tr>
</tbody>
</table>

For series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the provisions of this Directive.

For series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.
Declaration of Incorporation
according to Machinery Directive 2006/42/EC, Annex II B

The manufacturer/distributor

Industrieroboter GmbH
Industriestraße 1
D-10101 Musterhausen

hereby declares that the following product:

Product designation: 6-axes industrial robot
Model: Herkules 500
Commercial name: H 500-6
Serial number: 20100001

meets the requirements listed in Annex I of Directive 2006/42/EC and complies in addition with the following applicable Directives:


Furthermore, we declare that the relevant technical documentation for this partly completed machine has been compiled in accordance with Annex VII Part B. We undertake to transmit in response to a reasoned request this relevant technical documentation to the market surveillance authorities by our documentation department.

Authorized representative for the compilation of the technical documentation:

Industrieroboter GmbH
Egon Sample, Technical Documentation Dept.
Industriestraße 1
D-10101 Musterhausen

The putting into service of the partly completed machinery is prohibited until the partly completed machinery is incorporated into a machine. Prior to putting into service it has to be checked, where appropriate, if the machine complies with the provisions of the EC Machinery Directive.

Place, Date
Musterhausen, 4 January 2015

CEO
(signature)

Annex 1: List of the essential requirements complied with according to Annex I, Directive 2006/42/EC
Annex 2: Assembly instructions according to Annex VI, Directive 2006/42/EC
### Example

List of essential requirements complied with according to Annex I Directive 2006/42/EC

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Essential safety and health requirements</td>
</tr>
<tr>
<td>1.1</td>
<td>General</td>
</tr>
<tr>
<td>1.1.1</td>
<td>Definitions</td>
</tr>
<tr>
<td>1.1.2</td>
<td>Principles of safety integration</td>
</tr>
<tr>
<td>1.1.3</td>
<td>Materials and products</td>
</tr>
<tr>
<td>1.1.4</td>
<td>Lighting</td>
</tr>
<tr>
<td>1.1.5</td>
<td>Design of machinery to facilitate its handling</td>
</tr>
<tr>
<td>1.1.6</td>
<td>Ergonomics</td>
</tr>
<tr>
<td>1.1.7</td>
<td>Operating positions</td>
</tr>
<tr>
<td>1.1.8</td>
<td>Seating</td>
</tr>
<tr>
<td>1.2</td>
<td>Control systems</td>
</tr>
<tr>
<td>1.2.1</td>
<td>Safety and reliability of control systems</td>
</tr>
<tr>
<td>1.2.2</td>
<td>Control devices</td>
</tr>
<tr>
<td>1.2.3</td>
<td>Starting</td>
</tr>
<tr>
<td>1.2.4</td>
<td>Stopping</td>
</tr>
<tr>
<td>1.2.4.1</td>
<td>Normal stop</td>
</tr>
<tr>
<td>1.2.4.2</td>
<td>Operational stop</td>
</tr>
<tr>
<td>1.2.4.3</td>
<td>Emergency stop</td>
</tr>
<tr>
<td>1.2.5</td>
<td>Selection of control or operating modes</td>
</tr>
<tr>
<td>1.2.6</td>
<td>Failure of the power supply</td>
</tr>
<tr>
<td>1.3</td>
<td>Protection against mechanical hazards</td>
</tr>
<tr>
<td>1.3.1</td>
<td>Risk of loss of stability</td>
</tr>
<tr>
<td>1.3.2</td>
<td>Risk of break-up during operation</td>
</tr>
<tr>
<td>1.3.3</td>
<td>Risks due to falling or ejected objects</td>
</tr>
<tr>
<td>1.3.4</td>
<td>Risks due to surfaces, edges or angles</td>
</tr>
<tr>
<td>1.3.5</td>
<td>Risks related to combined machinery</td>
</tr>
<tr>
<td>1.3.6</td>
<td>Risks related to variations in operating conditions</td>
</tr>
<tr>
<td>1.3.7</td>
<td>Risks related to moving parts</td>
</tr>
</tbody>
</table>

Product designation: 6-axes industrial robot
Model: Herkules 500
Commercial name: H 500-6

To be accomplished by the system integrator for the entire machine
Fulfilled for the scope of the partial machine (robot)
To be accomplished by the system integrator for the entire machine
Fulfilled for the scope of the partial machine (robot)

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3.8</td>
<td>Choice of protection against risks arising from moving parts</td>
</tr>
<tr>
<td>1.3.8.1</td>
<td>Moving transmission parts</td>
</tr>
<tr>
<td>1.3.8</td>
<td>Moving parts involved in the process</td>
</tr>
<tr>
<td>1.3.9</td>
<td>Risks of uncontrolled movements</td>
</tr>
<tr>
<td>1.4</td>
<td>Required characteristics of guards and protective devices</td>
</tr>
<tr>
<td>1.4.1</td>
<td>General requirements</td>
</tr>
<tr>
<td>1.4.2</td>
<td>Special requirements for guards</td>
</tr>
<tr>
<td>1.4.2.1</td>
<td>Fixed guards</td>
</tr>
<tr>
<td>1.4.2.2</td>
<td>Interlocking movable guards</td>
</tr>
<tr>
<td>1.4.2.3</td>
<td>Adjustable guards restricting access</td>
</tr>
<tr>
<td>1.4.3</td>
<td>Special requirements for protective devices</td>
</tr>
<tr>
<td>1.5</td>
<td>Risks due to other hazards</td>
</tr>
<tr>
<td>1.5.1</td>
<td>Electricity supply</td>
</tr>
<tr>
<td>1.5.2</td>
<td>Static electricity</td>
</tr>
<tr>
<td>1.5.3</td>
<td>Energy supply other than electricity</td>
</tr>
<tr>
<td>1.5.4</td>
<td>Errors of fitting</td>
</tr>
<tr>
<td>1.5.5</td>
<td>Extreme temperatures</td>
</tr>
<tr>
<td>1.5.6</td>
<td>Fire</td>
</tr>
<tr>
<td>1.5.7</td>
<td>Explosion</td>
</tr>
<tr>
<td>1.5.8</td>
<td>Noise</td>
</tr>
<tr>
<td>1.5.9</td>
<td>Vibrations</td>
</tr>
<tr>
<td>1.5.10</td>
<td>Radiation</td>
</tr>
<tr>
<td>1.5.11</td>
<td>External radiation</td>
</tr>
<tr>
<td>1.5.12</td>
<td>Laser radiation</td>
</tr>
<tr>
<td>1.5.13</td>
<td>Emissions of hazardous materials and substances</td>
</tr>
<tr>
<td>1.5.14</td>
<td>Risk of being trapped in a machine</td>
</tr>
<tr>
<td>1.5.15</td>
<td>Risk of slipping, tripping or falling</td>
</tr>
<tr>
<td>1.5.16</td>
<td>Lightning</td>
</tr>
<tr>
<td>Chapter</td>
<td>Requirements</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1.6</td>
<td>Maintenance</td>
</tr>
<tr>
<td>1.6.1</td>
<td>Machinery maintenance</td>
</tr>
<tr>
<td>1.6.2</td>
<td>Access to operating positions and servicing points</td>
</tr>
<tr>
<td>1.6.3</td>
<td>Isolation of energy sources</td>
</tr>
<tr>
<td>1.6.4</td>
<td>Operator intervention</td>
</tr>
<tr>
<td>1.6.5</td>
<td>Cleaning of internal parts</td>
</tr>
<tr>
<td>1.7</td>
<td>Information</td>
</tr>
<tr>
<td>1.7.1</td>
<td>Information and warnings on the machinery</td>
</tr>
<tr>
<td>1.7.1.1</td>
<td>Information and information devices</td>
</tr>
<tr>
<td>1.7.1.2</td>
<td>Warning devices</td>
</tr>
<tr>
<td>1.7.2</td>
<td>Warning of residual risks</td>
</tr>
<tr>
<td>1.7.3</td>
<td>Marking of machinery</td>
</tr>
<tr>
<td>1.7.4</td>
<td>Instructions</td>
</tr>
<tr>
<td>1.7.4.1</td>
<td>General principles for the drafting of instructions</td>
</tr>
<tr>
<td>1.7.4.2</td>
<td>Contents of the instructions</td>
</tr>
<tr>
<td>1.7.4.3</td>
<td>Sales literature</td>
</tr>
<tr>
<td>2</td>
<td>Supplementary essential health and safety requirements for certain categories of machinery</td>
</tr>
<tr>
<td>2.1</td>
<td>Foodstuffs machinery and machinery for cosmetics or pharmaceutical products</td>
</tr>
<tr>
<td>2.2</td>
<td>Portable hand-held and/or hand-guided machinery</td>
</tr>
<tr>
<td>3</td>
<td>Supplementary essential health and safety requirements to offset hazards due to the mobility of machinery</td>
</tr>
<tr>
<td>4</td>
<td>Supplementary essential health and safety requirements to offset hazards due to lifting operations</td>
</tr>
<tr>
<td>5</td>
<td>Supplementary essential health and safety requirements for machinery intended for underground work</td>
</tr>
<tr>
<td>6</td>
<td>Supplementary essential health and safety requirements for machinery presenting particular hazards due to the lifting of persons</td>
</tr>
</tbody>
</table>
Annex 5
Example of assembly instructions according to Annex VI, Directive 2006/42/EC (extract)

Product designation: 6-axes industrial robot
Model: Herkules 500
Commercial name: H 500-6

The following instructions provide the required information to the party who incorporates the above mentioned partly completed machinery into a machine or who assembles it with other parts to a completed machinery. It includes in particular information on the safety-related interfaces for the proper assembly without impairing the safety or health of people.

In addition to these assembly instructions, the relevant European Directives and national regulations have to be complied with.

To be in accordance with the essential requirements of the EC-Machinery Directive it is recommended to apply both standards for industrial robots – safety requirements EN ISO 10218-1 and EN ISO 10218-2.

The assembly instructions together with the Declaration of Incorporation remain at the partly completed machinery until its incorporation in the completed machinery and have to be added afterwards to the technical documentation of the completed machinery.

Contents of the assembly instructions
1. Essential safety regulations
2. Intended use
3. Technical data
4. Environmental conditions
5. Foundation and subframe
6. Tool fitting
7. Limits of loads
8. Power supply conditions
9. Safety-related functions
10. Types of stops and stopping distances
11. Modes of operation
12. Emergency stop
13. Protective stop
14. External enabling process
15. Safeguards
16. Interlocking of guards
17. Description of physical interfaces for safety-related signals
18. Performance Level and control category
Annex 6
Example of an EC Declaration of Conformity for a robot cell

EC Declaration of Conformity
according to Machinery Directive 2006/42/EC, Annex II A

The manufacturer/distributor
Industrieanlagenbau GmbH
Industriestraße 2
D-10101 Musterhausen

hereby declares that the product:

Product designation: robot cell
Model: RZ 100
Serial number: 0100002

is in conformity with the provisions of Directive 2006/42/EC
and the following other Directives:

Directive 2014/29/EU (Simple Pressure Vessels Directive)

The following harmonized standards have been applied:

EN ISO 12100, EN ISO 10218-1, EN ISO 10218-2,
EN ISO 13855, EN ISO 13857, EN 60204-1, EN ISO 13849-1, EN ISO 13850

Authorized representative for the compilation of the technical documentation:
Egon Sample
Industriestraße 1
D-10101 Musterhausen

Place, Date
Musterhausen, 4 January 2015

CEO
(signature)
Annex 7
Example of a risk assessment for a robot system

Note: According to Directive 2006/42/EC (Machinery Directive) Annex VII, written documents on the risk assessment have to be provided in the scope of the manufacturer’s internal documentation. In case of doubt as to the safety of the machine, the responsible authorities may request access to the documents (e.g. market surveillance).

There is no requested format for drafting the documentation of the risk assessment. The following description represents a procedure which is currently preferred among experts.

In many cases, solely the worksheet of the risk assessment (Item 2 of this Annex) is documented. Item 1, however, represents a useful extension, since generally the definition of the limits of the machine should be the starting point of each risk assessment.

According to the worksheet of the risk assessment, (Item 2 of this Annex), the risk level is determined twice: once before and once after the individual protective measure. Even this procedure is not obligatory, but it has been established especially in the recent past. Furthermore, it corresponds to both ISO TR 14121-2 [11] and ANSI B11 TR3 [19] and is therefore also known in the US.

This example does not claim to be exhaustive.

Other documents of the manufacturer’s internal documentation which are required according to Annex VII of the Machinery Directive are not listed here.

Contents

1 Limits of the machinery
   1.1 Description of the machinery
   1.2 Limits of application – Intended use and foreseeable misuse
   1.3 Space limits – technical data
   1.4 Life phases – time limits
   1.5 Standards and Directives

2 Risk assessment – worksheet

1 Limits of the machine

1.1 Description of the machinery
The machine IR-D5 is an industrial robot system for the automatic machining of plastic tanks for automotive production. The raw pieces are placed manually on a 5-segment turntable by a person. After reset and start at the control desk, the automatic transport of the part to the industrial robot 1 takes place (flame treatment). By the flame treatment, the plastic surface is prepared for the subsequent primer application at industrial robot 2. The deposit on the picking belt is done by industrial robot 3.
1.2 Limits of application – intended use and foreseeable misuse

The machine must only be used for the process materials and auxiliary materials mentioned in the operating instructions. Only those process parameters which are indicated in the operating instructions/technical data may be applied. If deviating process parameters/technical data are set or deviating process materials or auxiliary materials are used it is recommended to seek information from the machinery manufacturer.

The risk assessment cannot cover risks which have been caused by deviating process parameters/technical data and deviating materials and auxiliary materials. The same applies to reconstructions performed after placing onto the market. In these cases, it is recommended to have a risk assessment carried out by the machine user according to the Ordinance on Industrial Safety and Health and, if necessary, state complementary protective measures. It is possible that due to significant changes of the risks identified in this risk assessment, a so-called substantial modification arises which requires a new assessment of conformity of the machine including a new risk assessment.

A list of the process materials and auxiliary materials is part of the operating instructions.

1.3 Space limits – Technical data (extract)

The space limits of the machine are defined in the layout plan of the machine. The layout plan also specifies the interfaces to the customer’s supply and disposal devices as well as environmental requirements.

Technical data (extract):

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrical power ratings</td>
<td>Supply voltage: 3x400 V, 50/60 Hz, fuse rating 25 A</td>
</tr>
<tr>
<td>Compressed air supply outlet:</td>
<td>6 bar, consumption 2,5 m³/h</td>
</tr>
<tr>
<td>Gas supply pressure:</td>
<td>20 mbar</td>
</tr>
<tr>
<td>Mass:</td>
<td>4500 kg</td>
</tr>
<tr>
<td>Ambient temperature:</td>
<td>5 °C - 45 °C</td>
</tr>
<tr>
<td>Relative humidity:</td>
<td>Max. 95 %</td>
</tr>
<tr>
<td>Noise emission:</td>
<td>76 dB(A) at the workplaces</td>
</tr>
<tr>
<td>Dimensions L/B/H:</td>
<td>6500 mm/4200 mm/3200 mm</td>
</tr>
</tbody>
</table>

1.4 Life phases – time limits

This risk assessment comprises the life phases operation/production (automatic operation, set-up operation), cleaning, maintenance and disposal. Previous life phases such as e.g. mounting, assembly, commissioning and trial operation are not included in this risk assessment, since they form a part of the manufacturing process for this machine.

1.5 Standards and Directives

This risk assessment has been prepared in accordance with the principles of the EC-Directive 2006/42/EC (Machinery Directive) and the harmonized standards and technical specifications EN ISO 10218-1, EN ISO 10218-2, EN ISO 12100 and ISO/TR 14121-2.2.
## Risk assessment – Worksheet

The following worksheet of a risk assessment is based on ISO/TR 14121-2 Table A.3 (equivalent to ANSI B11 TR3).

<table>
<thead>
<tr>
<th>Probability of occurrence of harm</th>
<th>Severity of harm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Catastrophic</td>
</tr>
<tr>
<td>Very likely</td>
<td>High</td>
</tr>
<tr>
<td>Likely</td>
<td>High</td>
</tr>
<tr>
<td>Unlikely</td>
<td>Medium</td>
</tr>
<tr>
<td>Remote</td>
<td>Low</td>
</tr>
</tbody>
</table>

**Key**

**Severity of harm:**

- **Catastrophic:** death or permanent disabling injury or illness (unable to return to work)
- **Serious:** severe debilitating injury or illness (able to return to work at some point)
- **Moderate:** significant injury or illness requiring more than First Aid (able to return to the same job)
- **Minor:** no injury or slight injury requiring no more than First Aid (little or no lost work time)

**Probability of occurrence of harm**

- **Very likely:** near certain to occur
- **Likely:** can occur
- **Unlikely:** not likely to occur
- **Remote:** so unlikely as to be near zero
## Life phase/mode of operation

<table>
<thead>
<tr>
<th>Hazard (from catalogue of hazards according to EN ISO 12100)</th>
<th>Hazardous situation, point of hazard</th>
<th>Risk estimation accord. to ISO/TR 14121-2 Table A.3</th>
<th>Protective measure</th>
<th>Risk estimation according to ISO/TR 14121-2 Table A.3</th>
<th>Reference to standard or directive</th>
<th>Risk reduction sufficient?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automatic mode of operation</td>
<td>Crushing, impact</td>
<td>Serious/likely</td>
<td>High</td>
<td>The entire range of motion of the robots is enclosed with guards and protective devices. A sufficient number of protective doors with interlocking and guard locking is available. On request, the system can be entered for trouble shooting through the protection doors. Electrical interlocking of protection doors with the hazardous movements (robot and turntable) according to EN ISO 13849-1 category 3, Plfd. Robots drive in “safe position”. Drives remain controlled. On non-actuated safe position and simultaneous door opening, drives are stopped by contact means. All axes including turntable can be operated with reduced speed and enabling switch with protection doors open.</td>
<td>Serious/remote Low Directive 2006/42/EC EN ISO 10218-1 EN ISO 10218-2</td>
<td>Yes</td>
</tr>
<tr>
<td>Crushing, impact</td>
<td>Crushing of persons if robots continue to run during loading</td>
<td>Serious/likely</td>
<td>High</td>
<td>Turning partition plates (segments) on the turntable, safe axis limitations of the robots according to EN ISO 13849-1 category 3, Plfd.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entanglement</td>
<td>Entanglement of operator at loading station by turntable</td>
<td>Serious/likely</td>
<td>High</td>
<td>Safe disconnection of turntable by safety light curtain type 4, Resolution 14 mm. Distance to hazardous point according to EN ISO 13855. Horizontal light curtain as step-behind protection. Reset button outside on the column, not reachable from inside. Good view from reset position. Information on the loading of the system in operating instructions. Reset must only be effected if no persons are present in the hazardous space.</td>
<td>Serious/remote Low EN ISO 13855 EN ISO 10218-1 EN ISO 10218-2</td>
<td>Yes</td>
</tr>
<tr>
<td>Crushing</td>
<td>Crushing at the picking belt between stop and part</td>
<td>Moderate/likely</td>
<td>Medium</td>
<td>Stop cam-shaped. Crushing hazard eliminated. Plastic parts of low weight. Belt speed 6 m/min at maximum</td>
<td>Minor/remote Negligible EN ISO 10218-1 EN ISO 10218-2</td>
<td>Yes</td>
</tr>
<tr>
<td>Noise</td>
<td>Hearing damage due to production noise</td>
<td>Minor/unlikely</td>
<td>Negligible</td>
<td>Sound pressure level at the workplace to be measured and indicated in the operating instructions</td>
<td>Minor/unlikely Negligible EN ISO 10218-2</td>
<td>Yes</td>
</tr>
<tr>
<td>Fire</td>
<td>Unexpected burning of parts due to malfunction</td>
<td>Minor/likely</td>
<td>Low</td>
<td>Hand-operated fire extinguisher at the system. Emergency stop safely turns off flames.</td>
<td>Minor/unlikely Negligible</td>
<td>Yes</td>
</tr>
<tr>
<td>Automatic mode of operation</td>
<td>Accumulation of exhaust gases due to flame treatment</td>
<td>Minor/unlikely</td>
<td>Negligible</td>
<td>Exhaust gas generation is low on consideration of process parameters. Proper ventilation of production hall is sufficient.</td>
<td>Minor/unlikely Negligible</td>
<td>Yes</td>
</tr>
<tr>
<td>Burns</td>
<td>Access to workspace during running flame treatment</td>
<td>Minor/unlikely</td>
<td>Negligible</td>
<td>Access is prevented by guard locking. On reaching the safe position, a flame monitoring becomes effective.</td>
<td>Minor/remote Negligible</td>
<td>Yes</td>
</tr>
<tr>
<td>Life phase/ mode of operation</td>
<td>Hazard (from catalogue of hazards according to EN ISO 12100)</td>
<td>Hazardous situation, point of hazard</td>
<td>Risk estimation accord. to ISO/TR 14121-2 Table A.3 prior to protective measure</td>
<td>Protective measure</td>
<td>Risk estimation accord. to ISO/TR 14121-2 Table A.3 After protective measure</td>
<td>Reference to standard or directive</td>
</tr>
<tr>
<td>------------------------------</td>
<td>---------------------------------------------------------------</td>
<td>-------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td><strong>Ergonomics</strong></td>
<td>Non-ergonomic access for filling the containers</td>
<td>Moderate/ likely</td>
<td>Medium</td>
<td>Filling nozzle easily accessible from outside the protective fence</td>
<td>Minor/remote</td>
<td>Negligible</td>
</tr>
<tr>
<td><strong>Set-up/programming</strong></td>
<td>Crushing, impact</td>
<td>Programming of robot system within the protective devices</td>
<td>Serious/likely</td>
<td>Three-position enabling switch in teach pendant. Circuitry design for mode selection and enabling function according to category 3, Pl.d.</td>
<td>Serious/remote</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Crushing, impact</strong></td>
<td>Crushing while turntable is indexing to the next position from inside the workspace</td>
<td>Serious/likely</td>
<td>High</td>
<td>Indexing of the table only with remote-hold enabling device (permanently attached)</td>
<td>Serious/remote</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Falling, Falling down</strong></td>
<td>Falling of the robot</td>
<td>Serious/likely</td>
<td>High</td>
<td>Floor anchoring of the robot sufficiently dimensioned The robot must not be overloaded, e.g. by mounting a gripper which is too heavy. Maximum load, see type plate Robot must not move against solid objects, safety requirements in operating instructions</td>
<td>Serious/remote</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Crushing, impact</strong></td>
<td>Fall due to gravity</td>
<td>Moderate/likely</td>
<td>Medium</td>
<td>All powered axes are equipped with holding brakes. Provide automatic brake test.</td>
<td>Moderate/remote</td>
<td>Negligible</td>
</tr>
<tr>
<td><strong>Cleaning</strong></td>
<td>Crushing, shearing, entanglement, impact</td>
<td>Trapped in the workspace</td>
<td>Serious/unlikely</td>
<td>Reset button on each access door which offers good view to the hazardous space. Not accessible from inside. Unintended closure of doors prevented by a lock. Guard locking de-energized release; information in operating instructions on reset of protection doors.</td>
<td>Serious/remote</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Maintenance</strong></td>
<td>Hazard due to materials</td>
<td>Filling in primer material, liquid splashes on parts of the body.</td>
<td>Moderate/likely</td>
<td>Supply personal protective equipment (safety googles) or indicate particular type. Indicate type selection of primer in operating instructions. Maintenance must only be performed by instructed expert personnel with adequate working clothes. Information in operating instructions</td>
<td>Moderate/unlikely</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Ergonomics</strong></td>
<td>Non-ergonomic access to maintenance points</td>
<td>Moderate/likely</td>
<td>Medium</td>
<td>Distribution boxes, control cabinets, fluid shut-off valves accessible from outside the protective fence</td>
<td>Minor/remote</td>
<td>Negligible</td>
</tr>
<tr>
<td><strong>Shearing, impact</strong></td>
<td>Falling of components due to gravity on release of holding brakes</td>
<td>Moderate/likely</td>
<td>Medium</td>
<td>Provide automatic brake test. Support axes for repair and maintenance work. Information in operating instructions. Point to gravity-loaded axes by means of warning sign.</td>
<td>Moderate/remote</td>
<td>Negligible</td>
</tr>
<tr>
<td><strong>Shearing, impact</strong></td>
<td>Unexpected start-up</td>
<td>Moderate/likely</td>
<td>Medium</td>
<td>All external energy sources, elektric, hydraulic, compressed air, shall be lockable and secured against reconnection.</td>
<td>Moderate/unlikely</td>
<td>Low</td>
</tr>
</tbody>
</table>

Product: Industrial robot system
Type IR-DS
Ser.-No. 01
Year of construction: 2015
Customer: XYZ Ltd.
Person in charge: Mr./Mrs. Sampleman
Date: 

File: 

Risk assessment worksheet according to ISO/TR 14121-2
<table>
<thead>
<tr>
<th>Life phase/mode of operation</th>
<th>Hazard (from catalogue of hazards according to EN ISO 12100)</th>
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<tr>
<td>Contact with live parts</td>
<td>Maintenance personnel working at live parts of the system</td>
<td>Serious/likely</td>
<td>High</td>
<td>Prior to maintenance work, switch off mains switch and secure against reconnection. Maintenance personnel shall be instructed. Working at live parts only in exceptional cases by qualified electricians Information in operating instructions Training of service personnel by manufacturer</td>
<td>Minor/unlikely</td>
<td>Negligible</td>
<td>EN ISO 10218-2</td>
</tr>
<tr>
<td>Disposal</td>
<td>Substances hazardous to health</td>
<td>Improper disposal on system scrapping</td>
<td>Moderate/likely</td>
<td>Describe correct disposal in operating instructions. Declaration of substances being hazardous to health and environment</td>
<td>Moderate/unlikely</td>
<td>Low</td>
<td>Yes</td>
</tr>
<tr>
<td>All life phases</td>
<td>Electricity</td>
<td>Hazard by electric shock</td>
<td>Moderate/likely</td>
<td>System design according to EN 60204-1. Execution of tests - visual inspection - resistance of PE-system - insulation resistance</td>
<td>Moderate/remote</td>
<td>Negligible</td>
<td>EN ISO 10218-2</td>
</tr>
</tbody>
</table>
In the following, the pertinent regulations, rules and information which are to be observed are listed:

1 Acts, Ordinances

Reference:
Book shops and Internet, e.g. www.gesetze-im-internet.de


2 Regulations and Information for Occupational Health and Safety

Reference:
To be obtained from your responsible insurer
For addresses see www.dguv.de/publikationen

Information

- „Schwerkraftbelastete Achsen (Vertikalachsen)“
  Fachbereichs-Informationsblatt Nr. 005
  Ausgabe 09/2012 [3]; English version „Gravity-loaded axes (vertical axes)”

3 Standards/VDE-regulations

Reference:
Beuth-Verlag GmbH, Burggrafenstraße 6, 10787 Berlin bzw. VDE-Verlag, Bismarckstraße 33, 10625 Berlin

- DIN EN 13814 Safety of amusement rides and amusement devices – Safety, German version prEN 13814:2013 [4]

- DIN EN ISO 13849-1 Safety of machinery – Safety – related parts of control systems - Part 1: General principles for design (ISO 13849-1:2006); German version (ISO 13849-1:2006); [8]
- DIN EN ISO 13857 Safety of machinery – Safety distances to prevent hazard zones being reached by upper and lower limbs (ISO 13857:2008); German version EN ISO 13857:2008 [10]

4 EC-Directives

Reference:
Bundesanzeiger Verlagsgesellschaft mbH, Postfach 100534, 50445 Köln


5 Other sources

World Robotics Report 2013 Industrial Robots; IFR General Secretary / IFR Statistical Department, Lyoner Str. 18, 60528 Frankfurt am Main [17]

Umbreit, Dr. Matthias: Re-Use und Re-Invest – Zweites Leben für Maschinen VMBG-Mitteilungen Heft 4/2009 [18]

ANSI B11 TR 3 Risk Assessment and Risk Reduction [19]
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