

Normative Safety Regulations for Collaborative Robots

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Abstract—Collaborative robots (cobots) are designed to operate alongside humans in shared workspaces, enhancing efficiency and flexibility. Like all machines and robots, they are regulated by the EU Machinery Regulation and must bear the CE marking before market introduction. While the regulation provides broad and general safety requirements, harmonized standards such as ISO 12100, ISO 13849, and IEC 62061 offer more specific guidance for achieving safety in machinery design. For industrial robots, ISO 10218 outlines safety requirements, with the technical specification ISO/TS 15066 further addressing unique considerations of collaborative industrial robots. By providing a comprehensive overview of these regulations and standards, this paper aims to guide manufacturers through the critical steps required for achieving legal compliance and ensuring safe market introduction of cobots in Europe.

I. INTRODUCTION

Robots can perform repetitive tasks with high precision and speed, which is why they are often used to increase productivity in industry. Nevertheless, robots usually do not have the human ability to solve imprecisely defined tasks, which is why human intervention is often necessary. To ensure safety, traditional industrial robot applications typically restrict operator access to the robot's workspace while it is active. This limitation often prevents full automation of processes requiring human involvement. Collaborative robots (cobots), on the other hand, are designed to enable humans and robots to share the same workspace [1]. Industrial robots are predominantly deployed in the automotive industry, with 135,000 units installed annually in 2023, followed closely by the electrical and electronics sector, which accounted for 126,000 installations. Cobots represented 10% of the total industrial robot market share in 2023 [2].

Since cobots are designed for direct human interaction, current research in human-robot interaction increasingly focuses on understanding how comfortable and confident people feel when working alongside cobots (see [3], [4], [5]). While perceived safety plays a crucial role in fostering effective human-robot collaboration, physical safety of cobots is essential to prevent injuries and hazardous situations. To address this, cobots must be equipped with safety features to comply with applicable safety standards. The introduction

of new safety features for cobots to the market requires a comprehensive process to ensure compliance with relevant regulations and standards for industrial and collaborative robots. This process involves identifying applicable regulations, conducting thorough risk assessments to identify potential hazards, and implementing protective measures to ensure both safety and legal approval. Given the variations in safety standards across regions, this work specifically addresses the safety standards applicable to the European market.

II. LEGAL BASIS FOR COBOTS

Products sold in the European Union need to meet the EU safety, health and environmental protection requirements. It is the manufacturers responsibility to check and ensure that the product meets all applicable EU regulations before placing the product on the EU market. Only products that meet the requirements of all applicable EU regulations and directives may bear the CE marking which represents European Conformity [6]. To affix the CE marking to a product, the manufacturer needs to follow the subsequent steps [6]: First, identify the applicable directives and harmonised standards. Then, verify the product specific requirements. Identify whether an independent conformity assessment by a notified body is necessary. After the product is tested and its conformity is checked, draw up and keep available the required technical documentation. Finally affix the CE marking and draw up the EU Declaration of Conformity. The official EU website on single market and standards [6] lists 26 product groups and the respective regulations and directives that are applicable for this product group. Safety features for cobots may fall in the following product groups as shown in table I. The first regulation is about the general product safety for machinery. Electrical and electronic products are also subject to the electromagnetic compatibility (EMC) directive and the restriction of hazardous substances in electrical and electronic equipment (RoHS). Depending on the specific product, the directives on voltage limits and radio equipment may or may not be applicable depending if the product is intended for nominal voltage between 50 V AC to 1000 V AC or 75 V DC to 1000 V DC or if it uses wireless communication.

Harmonised standards are developed by recognized European standardization organizations. These standards are harmonised at the European level and are published in the Official Journal of the European Union. They support the implementation of EU legislation by providing detailed technical requirements to ensure products meet the essential requirements set out in relevant EU directives and regula-

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TABLE I
APPLICABLE EU REGULATIONS AND DIRECTIVES FOR COBOTS

Product group	Applicable EU regulation or directive
Machinery	Regulation 2023/1230 on machinery (repealing directive 2006/42/EC on machinery)
Electromagnetic compatibility	Directive 2014/30/EU on electromagnetic compatibility
Electrical and electronic equipment	Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment
Low voltage	Directive 2014/35/EU on electrical equipment designed for use within certain voltage limits
Radio equipment	Directive 2014/53/EU on radio equipment

tions [6]. The advantage of harmonised standards is that they are directly linked to specific EU directives and regulations by providing a clear and precise way on how to comply with the requirements of the regulations and directives.

To conduct a conformity assessment it needs to be checked whether the product requires an independent assessment by a notified body or whether the manufacturer may carry it out himself. While the EMC and RoHS directives do not require the involvement of a notified body, the machinery regulation specifies 25 categories as exceptions in annex I [7]. If the product belongs to one of these categories and does not comply with a harmonised standard, the involvement of a notified body is required. One of these categories defined in the Machinery Regulation are protective devices intended to detect the presence of a person [7]. However, if the product complies with the applicable harmonised standards, a notified body is not required, but can be consulted in any case.

Once the compliance of the product with the applicable EU legislation is assessed and ensured either by the manufacturer itself or a notified body and the technical documentation of the product is available, the manufacturer may affix the CE marking on the product and draw up the EU Declaration of Conformity [6]. For complex products such as robots, only the end product needs to bear the CE marking and not all the individual parts. But if an individual part has its own function or is placed on the market as a separate product, it also needs to bear the CE marking [6].

The following section will focus on the harmonised standards for the machinery directive. While compliance with the other directives is not less important, they generally apply to all electrical and electronic equipment and have no specifics in relation to collaborative robots. They are therefore not discussed further here.

III. HARMONISED STANDARDS FOR COBOTS

While the compliance to applicable EU regulations and directives is mandatory for each product, the use of harmonised standards is voluntary. Manufacturers can choose other methods to demonstrate compliance with the applicable EU requirements. However, harmonised standards provide a straightforward way to demonstrate that the product complies with relevant EU legislation.

The concept of machine safety considers the ability of a machine to perform its intended functions during its service life with the risk sufficiently reduced [8]. Recognized as a harmonised standard under the machinery regulation, ISO 12100 provides general principles and methodologies for achieving safety in machinery design by a comprehensive framework for risk assessment and risk reduction. Furthermore this international standard forms the basis for a series of harmonised standards which are clustered in type A, type B and type C standards. The following structure of safety standards for machinery is defined in ISO 12100 [8]:

- Type A standards are basic safety standards that deal with basic terms, design principles and general aspects that can be applied to machines.
- Type B standards are generic safety standards that can be used for a whole range of machinery and are split into two parts: Type B1 standards for specific safety aspects (e.g. safety distances, surface temperature, noise); Type B2 standards for protective devices (e.g. two-hand controls, interlocking devices, pressure-sensitive protective devices, guards).
- Type C standards are specific machine safety standards that deal with detailed safety requirements for a specific machine or group of machines. If a type C standard deviates from a type A or B standard, the type C standard has priority over the others.

A. Basic Requirements from Type A Standards

1) *ISO 12100*: ISO 12100 is the type A standard for safety of machinery that covers general principles for the design of machines as well as general strategies for risk assessment and risk reduction. In the first step, ISO 12100 is used to assess the risk of a machine. The designer of a machine must carry out the following steps [8]:

- Determine the limits of the machine, including its intended use and reasonably foreseeable misuse.
- Identifying hazards and associated hazardous situations.
- Assessing the risk for each identified hazard and hazardous situation.
- Assess the risk and make decisions about the need for risk reduction.
- Eliminate the hazard or reduce the risk associated with the hazard by protective measures.

If the risk assessment shows that risk-reducing measures are required, then the following three protective measurements can be applied iteratively [8]:

- 1) Inherently safe construction
- 2) Technical and additional protective measures
- 3) User information (on the machine or user manual)

B. Generic Requirements from Type B Standards

1) *ISO 13849*: The designer of a machine can reduce the risk by installing protective measures that may have safety functions. Parts of machine control systems that are intended to provide safety functions are referred to as safety-related parts of control systems (SRP/CS) [9]. The first part of this

standard (ISO 13849-1) describes a process to determine the required performance level (PL_r) of a safety function performed by the SRP/CS. The second part (ISO 13849-2) specifies the validation procedure for the safety functions, categories and performance levels (PLs) [10].

In reference to the above mentioned three-step iterative protective process, the technical protective measures may be covered by safety-related parts of control systems [9]. Therefore, ISO 13849 can be applied. Within this standard the following iterative process is described [9]: As part of the safety requirements specification, all safety functions need to be defined and the respective required PL needs to be determined. Then the safety-related part of the control system that executes the safety function needs to be designed according to the safety requirements specification. Afterwards, it is required to evaluate which performance level (PL) can be achieved. During verification it will be checked whether the achieved PL is equal or greater than the required PL_r . The purpose of the subsequent validation is to ensure that the safety-related part of the control system fulfills the safety requirements specification. If either the verification or the validation is not successful, the design of the system needs to be adapted iteratively.

a) Determination of required performance level (PL_r): ISO 13849-1 describes a generic approach to estimate the PL_r as it can be seen in Fig. 1. The required PL_r is depending on three parameters [9]: Severity (S) of harm, frequency (F) and duration of exposure to the hazard as well as the possibility (P) of avoiding or limiting the damage. A detailed description of the procedure for estimating the required PL_r is omitted here, as special requirements for the PL_r apply to industrial robots, as will follow in section III-C. Nevertheless, a detailed generic guideline for the selection of the parameters S, F and P and the estimation of the required PL_r can be found in annex A of ISO 13849-1 [9].

b) Evaluation of achieved performance level (PL): The performance level of a safety function corresponds to the risk minimization that the safety function needs to provide. The higher the required risk minimization, the higher the required safety-related PL needs to be. The PL of a safety function is defined based on the maximal allowed probability

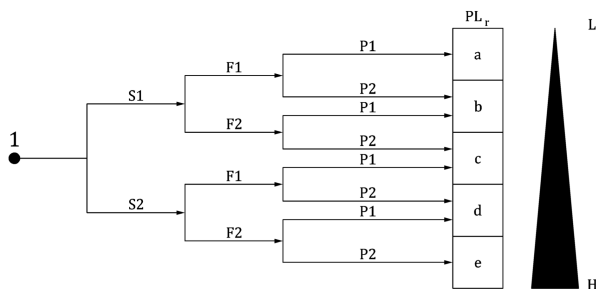


Fig. 1. Risk graph for the determination of the required performance level (PL_r) of a safety function. S1 refers to light severity, S2 to serious severity. F1 refers to low frequency, F2 to high frequency. P1 refers to low possibility, P2 to high possibility. The resulting PL_r reaches from low contribution to risk reduction (a) until high contribution to risk reduction (e). Figure taken from ISO 13849-1 Fig. A.1 [9].

of a dangerous failure per hour (PFH_D) [9]. The PFH_D thresholds for the distinction of the PLs can be seen in Fig. 2. High failure probability ($> 10^{-5} 1/h$ and $< 10^{-4} 1/h$) corresponds to PL *a* and low failure probability ($< 10^{-7} 1/h$) corresponds to PL *e* [9]. This means that a safety function with PL *a* has low contribution to the risk reduction and PL *e* has high contribution to the risk reduction.

Depending on the required PL_r , the safety-related parts of control systems (SRP/CS) have to reach a certain safety category, which is characterized by failure resilience. Category B is the basic category in which the occurrence of an error can lead to a subsystem failure. In category 1, the occurrence of an error can also lead to a subsystem failure, but with lower probability. From category 2 to category 4, failure resilience is increased from subsystem failure detection until subsystem failure prevention through single and multiple failure detection [9]. For each category, there is a proposed architecture that meets the requirements of the associated category as it can be seen in table II. The category classification depends on the required risk minimization to be achieved by the safety function, the required PL_r , the used technology, the impact on the subsystem in the event of a failure and the possibility of failure avoidance [9]. This can be specified by the following parameters [9]:

- mttfd: For constant failure rates equal to the inverse of the probability of a dangerous failure per hour (PFH_D).
- dc: Ratio between rate of detected and rate of all dangerous failures.
- ccf: Probability that two or more separate errors have a common cause.

ISO 13849-1 describes a simplified procedure for the estimation of the PL that is based on the following assumptions [9]: The duration in use is 20 years, the failure rates within the service life are constant and sufficient measures are applied to avoid common cause failure (CCF). With those assumptions, the category can be determined dependent on the mean time to dangerous failure ($MTTF_D$) and the diagnostic coverage level (DC). The vertical bands in Fig. 2 show the performance range that can be expected for each combination of category, $MTTF_D$ and average DC. Depending on the parameters, a safety function of category 2 can for example lead to a performance range between PL *a* and PL *d*, whereas a function of category 4 can lead to a performance range between PL *d* and PL *e*.

2) IEC 62061: An alternative method to design safety-related control systems (SCS) for risk reduction of machinery is described in IEC 62061 [11]. While ISO 13849 applies to a wide range of machinery including mechanical, electrical and electronic control systems, IEC 62061 specifically focuses on electrical, electronic and programmable electronic control systems for machinery. ISO 13849 focuses on individual safety parts of machines, while IEC 62061 focuses on system-level integrity. Instead of determining performance levels (PLs) for safety parts, IEC 62061 uses safety integrity levels (SILs) to define the required level of risk reduction for a safety-related control systems (SCS).

The maximum reachable SIL of a SCS is limited by the

TABLE II
PROPOSED ARCHITECTURE FOR MEETING CATEGORY REQUIREMENTS

Cat.	Proposed Architecture		Behaviour of Safety Function
	No. of channels	Diagnostic function	
B	Single channel	Not required	Single failure might lead to an accident
1	Single channel	Not required	Single failure might lead to an accident, but with lower probability than in category B
2	Single channel	Required	Detection of single failure accidents
3	Two channels	Required	Single failure is detected and cannot lead to accident
4	Two channels	Required	Single failure is detected and cannot lead to accident, detecting of error accumulations

Based on ISO 13849-1 table 5 [9].

sum of the PFH_D values of all subsystems as shown in table III. It also shows the correspondence between PL and SIL. Subsystems that are designed in accordance with ISO 13849 can be integrated in a SCS of IEC 62061 if they fulfill at minimum the PL that corresponds to the required SIL. The SIL of the safety-related control systems (SCS) is smaller or equal to the lowest SIL of all subsystems [11].

a) *Determination of required safety integrity level (SIL):* The required SIL depends on the following parameters [11]: Severity (Se) of harm, frequency (Fr) and duration of exposure to the hazard, probability (Pr) of occurrence and possibility of avoiding (Av) or limiting the damage. The sum of Fr , Pr and Av is called the class (Cl) of probability of damage. Each of the three parameters is rated between 1 and 5, so the class can range from 1 to 15. Depending on the severity (Se) and the probability class (Cl), measures may be required to reduce the risk of the SCS to an acceptable

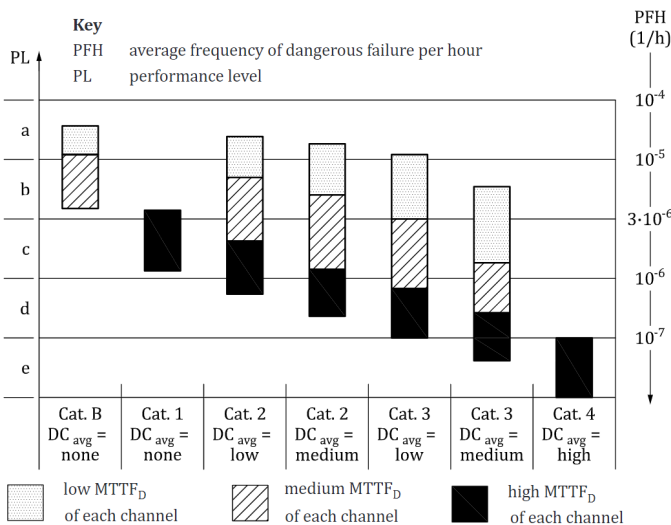


Fig. 2. The PL can be determined based on the combination of category, $MTTF_D$ and average DC. Low $MTTF_D$ corresponds to 3-10 years, medium $MTTF_D$ to 10-30 years and high $MTTF_D$ to 30-100 years. No DC corresponds to $< 60\%$, low DC to $60\% - 90\%$, medium DC to $90\% - 99\%$ and high DC to $> 99\%$. Figure taken from ISO 13849-1 Fig. 12 [9].

TABLE III
CORRESPONDENCE BETWEEN PERFORMANCE LEVEL (PL) AND SAFETY INTEGRITY LEVEL (SIL)

PL	SIL	PFH_D
ISO 13849-1	IEC 62061	1/h
a	–	$< 10^{-4}$
b	1	$< 10^{-5}$
c	1	$< 3 \cdot 10^{-6}$
d	2	$< 10^{-6}$
e	3	$< 10^{-7}$

Based on ISO 13849-1 table 2 and table 4 [9].

level. Table IV shows the SIL (or PL) that is needed to meet the required risk reduction.

b) *Evaluation of achieved safety integrity level (SIL):* IEC 62061 uses quantitative requirements to determine the probability of a dangerous failure per hour (PFH_D), which is used to evaluate the safety integrity level (SIL) of a SCS. The maximum achievable SIL for a given SCS is limited by the hardware fault tolerance (HFT) and the safe failure fraction (SFF) of its subsystems that are executing the safety functions as shown in table V [11]. The architecture can either be single-channel without diagnostic (A) or with diagnostic function (C) or two-channel without diagnostic (B) or with diagnostic function (D) [11]. A single channel architecture corresponds to a hardware fault tolerance (HFT) value of 0, a two-channel architecture corresponds to a HFT value of 1 (1 failure is detected and cannot lead to loss of safety function, > 1 failure can lead to loss of safety function) [11]. The SFF corresponds to the fraction of failures that lead to a safe state compared to the total number of failures. The SFF needs to be estimated for each subsystem individually through an analysis such as failure tree analysis (FTA).

3) *Other Relevant Standards:* With ISO 13849 and IEC 62061 the two most prominent type B standards for machinery are presented. Apart from those two, there are other not less important type B standards that specify general requirements such as an emergency stop functionality or minimum required gaps as listed in table VI. These functionalities and requirements are taken up again in the next chapter with regard to the requirements from the specific type C standards.

C. Specific Requirements from Type C Standards

In addition to the generic safety requirements for machinery from type B standards, there are type C standards that take into account the specific hazards of industrial robots and industrial robot systems. It needs to be noted that if the specifications of a type C standard differ from those in type A or type B standards, the specifications of the type C standard must be given priority. ISO 10218 is the standard that takes the specific hazards of industrial robots into account. The first part (ISO 10218-1) defines requirements and guidance for the three protective measures with respect to industrial robots [12]. It describes fundamental hazards associated with robots and sets requirements to eliminate or sufficiently

TABLE IV

DETERMINATION OF REQUIRED SIL (OR PL) FOR A SAFETY FUNCTION

Consequence	Reversible injury, first aid		Reversible injury, medical care		Permanent injury, loss of a finger		Loss of an eye or arm		
Severity (Se)	1		2		3		4		
Class Cl = Fr + Pr + Av	3	No SIL or PL required		No SIL or PL required		No SIL or PL required		SIL 1	PL b
	4							PL c	
	5								
	6								
	7								
	8	OM	PL a	SIL 1	PL b	SIL 2	PL d		
	9			PL c					
	10								
	11	OM	PL a	SIL 1	PL b	SIL 2	PL d		
	12			PL c					
	13								
	14	SIL 1	PL b	SIL 2	PL d	SIL 3	PL e		
	15		PL c		PL e				

Based on IEC 62061 table A.6 [11]. OM = other measures

reduce the risks associated with these hazards [12]. The second part (ISO 10218-2) focuses on the particular hazards of industrial robot systems that arise during integration and installation in industrial robot cells and lines [13]. The technical specification ISO/TS 15066 focuses specifically on collaborative robots and thus complements the ISO 10218-1/2 standards [1].

According to the general strategies described in the type A standard ISO 12100, the following steps need to be performed for assessing and reducing the risk of a machine.

1) *Determination of Limits of the Collaborative Robotic System:* Risk assessment starts with defining the limits of the machinery, taking into account all phases of the machinery's life [8]. This means that the characteristics and performance of the robot system as well as the humans involved in the process and the environment should be precisely determined with regard to the limits of the robot. The following is a proposal for possible limitations for collaborative robots [1]:

- Limits of the collaboration space: Spatial limits of the collaboration space; external influences on collaboration space; required free spaces around obstacles; intended and reasonably foreseeable contacts between robot and operator; access routes for operators and material.
- Ergonomic limits and robot-human interface: User friendliness of control devices; intended or unintended misuse by an operator; possible reflex behaviour of an operator; required level of training and skills of the operator; reasonable bio-mechanic limits of human body; possible consequences of human-robot contacts.
- Application specific limits: Description of required tasks; access restriction to authorized operators; possible intended and unintended contact situations.
- Temporal limits: Start and end of collaboration; transition between collaborative and non-collaborative operation.

2) *Hazard Identification and Risk Assessment:* Due to the potential reduction in the spatial separation of humans and robots in the collaboration space, physical human-robot-contacts can occur during operation [13]. Therefore, a risk as-

TABLE V

MAXIMUM ACHIEVABLE SIL DUE TO ARCHITECTURE LIMITATIONS

SFF	HFT				
	0		1		2
	SIL	Arch.	SIL	Arch.	SIL
< 60%	not allowed	A	SIL 1	B	SIL 2
60% – 90%	SIL 1	C	SIL 2	D	SIL 3
90% – 99%	SIL 2	C	SIL 3	D	SIL 3
≥ 99%	SIL 3	C	SIL 3	D	SIL 3

Based on IEC 62061 table 6 and table 7 [11].

essment needs to be performed that considers the whole collaborative task as well as the collaborative space. ISO 10218-2 contains in annex A a list of significant hazards associated with industrial robots and robotic systems that have been identified according to the process described in the type A standard ISO 12100. Depending on the specific collaborative application, the list must be adapted or expanded, but at least the following points must be taken into account [1]:

- Robot related hazards: Robot characteristics such as load, speed, force and energy; possibilities for quasi-static contacts with robot (contacts where the operator could be clamped between the robot and another object); position of the operator in relation to the robot.
- Robot system related hazards: Hazards caused by the end effector including the work piece such as sharp edges; movement and position of the operator in relation to objects that belong to the robotic system; arrangement of the robotic system; determination whether contact is transient or quasi-static and the affected parts of the operators body; design and position of robot hand guiding devices; environmental conditions.
- Application specific hazards: Process specific hazards such as temperature; limitations due to required personal protective equipment.

3) *Hazard Elimination and Risk Reduction:* Elimination of hazards and reduction of the risk can be achieved by either inherent safe construction of the machine, protective measures or additional measures such as user information. For usual industrial robot systems, risk reduction is mostly achieved by protective measures that separate the operator from the robot such as protective fences. However, for collaborative robotic systems, it is mainly achieved by the design and application of the robot system as well as of the collaboration space [1].

a) *Safety-related performance of the control system:* All safety-related parts of control systems (SRP/CS) need to be constructed such that they fulfill at least PL d with category 3 (according to ISO 13849-1) or SIL 2 with a HFT of 1 (according to IEC 62061) [12]. Each safety-related function in the cobot system must fulfill this performance requirement.

b) *Design of the collaborative space:* The collaborative space is that part of the robot's workspace, in which the operator and the robot can interact. The collaborative space must be designed in such a way, that the operator can perform all its foreseen tasks. All risks from the robot system and the

TABLE VI
RELEVANT TYPE B STANDARDS FOR ROBOT APPLICATIONS

Standard	Description
ISO 13850	Safety of machinery – Emergency stop function
ISO 13851	Safety of machinery – Two-hand-control devices
ISO 13854	Safety of machinery – Minimum gaps to avoid crushing of parts of human body
ISO 13855	Safety of machinery – Positioning of safeguards with respect to the approach speeds of parts of human body
ISO 13856	Safety of machinery – Pressure-sensitive protective devices
ISO 13857	Safety of machinery – Safety distances to prevent hazard zones being reached by upper and lower limbs
ISO 14120	Safety of machinery – Guards – General requirements for the design and construction of fixed and movable guards
ISO 13732	Ergonomics of the thermal environment – Methods for the assessment of human responses to contact with surfaces

collaborative space need to be sufficiently reduced. Each person in the collaborative space must be secured by respective protective measures. If possible, safety-related software for axis and space limitation according to ISO 10218-1 must be applied such that the size of the movement space of the robot gets limited [1]. Risks for trapping the operators body between the robotic system and other surrounding objects must be eliminated or controlled securely. A minimum of 50 cm of free space from any accessible position of the robot arm to the next object that could represent a pinch or crushing point for the operator must be guaranteed [13].

c) Design of collaborative robot operations: Each detected failure of a safety-related function must lead to an emergency stop. The operation may not be resumed until it is reset by a manual conscious action to restart while the operator is outside the collaborative space [1]. Additionally, the technical protective measures must be designed in such a way that they prevent or detect the approach of a person to enter the protected area beyond the collaboration space. Entry into the protected area must cause the robot to stop and all hazardous machine functions to be terminated. Robots that meet the requirements for collaborative operations should be marked with the appropriate symbol in accordance with ISO 10218-2 [13]. The transition between collaboration and manual or autonomous operation must be designed that no operator can be harmed [13]. Furthermore, the robot must be equipped with a visual indicator that shows when the robot is in collaborative operation [12]. During collaborative operation, the operator must be able to stop the robot's movement to any time by only one action or to leave the collaboration space via an obstacle-free path [1]. Stopping of the robot's movement could be realized with an emergency-stop function or a consent option mechanism. The consent option must have three-stages and may only allow robot movements and all other hazards controlled by the robot by continuously holding it in the middle position [12]. A hand guiding device to manually control the robot's movement must contain an emergency stop function and a consent option [12].

d) Collaborative operation: Collaboration can be implemented as one or more of the following operation modes.

Safety-rated monitored stop: If the robot performs a task in the collaborative space and the operator wants to enter this space, the robot needs to perform a protective stop [12]. After the operator has finished his task and left the collaborative space, the robot can return to its autonomous operation. This is the simplest type of collaborative operation, since the robot and the human can work together, but not at the same time. If the operator wants to enter the collaborative space while the robot is working outside of the collaborative space, the robot can continue with its task but is not allowed to enter the collaborative space while the person is working there.

Hand guiding: Human and robot can also work together collaboratively, with the operator controlling the robot's movement. Similar to the previous scenario, the robot also needs to perform a protective stop in the collaborative space before the operator can enter it. Additionally, the operator can then activate the hand guiding mode, in which he can manually guide the robot's movement. During hand guiding, the speed of the work piece in the robot's arm needs to be monitored. If the speed exceeds the limit that is specified in the risk assessment, a protective stop must be performed [12]. Once the operator deactivates the hand guidance mode, the robot must perform a protective stop again and cannot continue in autonomous mode until the operator has left the collaborative space [1].

This operation mode requires safety-rated monitored stop functionality as well as safety-rated monitored speed. If the safety of the operator is depending on the movement space of the robot, then the robot must use safety-related software for axis and space limitation. The hand guiding equipment needs to be located near the end effector and must provide an emergency stop function and a consent option mechanism [12]. If an emergency stop has been activated, the robot needs to stop and all hazardous machine functions need to be terminated. It can only be reset by manual operation, which does not trigger a restart, but only allows the restart.

Speed and separation monitoring: Human and robot can work simultaneously together in the collaborative space if the robot ensures a safe distance between them. As long as a protective separation distance between operator and robot is guaranteed, the robot can continue its work in the shared space. However, if the protective separation distance is exceeded, the robot must carry out a protective stop. Since the minimum required separation distance depends on the robot's speed, the robot is able to adjust its speed depending on the distance to the operator [1]. When the operator enters the collaboration space, the robot can continue its work at full speed. Only when the distance between the robot and the operator becomes too short, the robot needs to either perform a protective stop or can continue at a safety-rated reduced speed [14]. If the distance falls below the required minimum distance, a protective stop must be performed. As soon as the operator leaves the critical zone, the robot can continue its movement at a reduced speed or full speed depending on the distance. This operation mode requires safety-rated monitored stop as well as safety-rated monitored

speed and distance functionality. Fig. 3 represents the robot's speed before, during and after a protective stop and its corresponding distance from the operator. According to the graphical representation, the protective separation distance (S_p) at time t_0 can be calculated as

$$S_p(t_0) = S_h + S_r + S_s + C + Z_d + Z_r. \quad (1)$$

The distance corresponds to the sum of the operator's change in location (S_h), the distance related to the robot system's reaction time (S_r), the robot system's stopping distance (S_s), the intrusion distance (C) (which is the distance that a part of the body can intrude into the sensing field before it is detected [1]), as well as the position uncertainty of the operator (Z_d) and of the robot system (Z_r) due to measurement tolerances [1]. The stopping distance S_s is the factor that largely depends on the robot's speed.

Power and force limiting: This is the most complex collaboration scenario, in which the operator can work side by side with the robot and contact between the robot system and the operator can occur [14]. The contact can either be intentionally as part of an application sequence or unintentionally either by accidental contact as a consequence of not following the working procedure or by technical failure [1].

The type of contact is differentiated into quasi-static contact and transient contact. Quasi-static contact situations are those in which a part of the body is trapped or clamped between the robot and another object so that the power or force is applied for a longer duration [1]. Transient contact refers to contact situations in which a body part has contact with the robot system, but where the human has the opportunity to retreat or be pushed back, so that the power or force is only applied for a short moment [1]. The robot

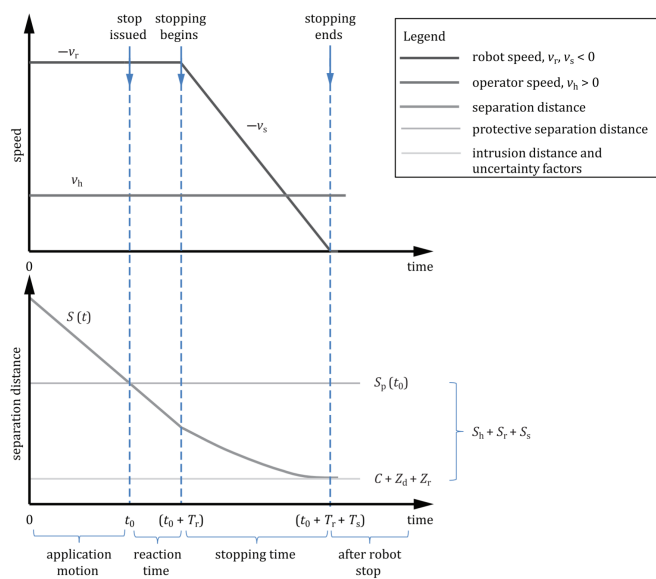


Fig. 3. Robot's speed and distance to the operator before, during and after a protective stop. The stopping is splitted into reaction time and stopping time. The graphical representation contains the individual contributions to the protective separation distance over time. Figure taken from ISO/TS 15066 [1] Fig. 3.

system and the collaborative space must be designed in such a way that contacts are avoided wherever possible. For the remaining unavoidable collisions, protective measures must be applied to keep the consequences as low as possible so that humans are not harmed [14]. One option for reducing the risk are passive safety methods such as increasing of the contact surface by rounded edges, increasing the energy absorption by padding or compliant joints or limiting the moving masses [1]. On the other hand, active methods for risk reduction can be realized by power and force limitation, speed limitation, use of axis and space limiting software, use of monitored stop function or use of sensing to anticipate or detect contact [1].

If the movement of the robot can result in clamping a body part, then the speed of the robot must be limited so that the robot system can comply with the protective limits for force and pressure associated with the exposed body part [1], as shown in Fig. 4. The maximum acceptable force or pressure limit depends on the type of robot-human contact. ISO/TS 15066 defines in annex A a full human body model with empirically determined limits for quasi-static and transient contact. The body model consists of 29 specific body areas. For each body area, specific biomechanical limits were empirically determined. Fig. 5 shows an extract of the maximum permissible pressure and force limits. It contains the specific maximum permissible pressure and force values for quasi-static contacts and a factor for the maximum permissible pressure and force for transient contacts. Both the pressure limits and the force limits must be observed at all times. These limits can be used to calculate the maximum permissible speed of the robot

$$v_{rel,max} = \frac{F_{max}}{\sqrt{\mu k}} = \frac{p_{max} A}{\sqrt{\mu k}} \quad (2)$$

at which the robot is able to move through the collaboration

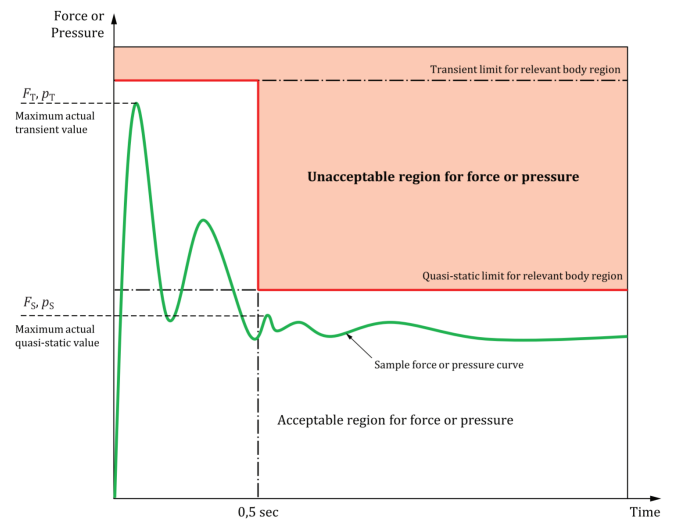


Fig. 4. Acceptable and unacceptable forces or pressures of a robot system on humans. The maximum acceptable force or pressure for quasi-static contacts is significant lower than for transient contacts. Figure taken from ISO/TS 15066 [1] Fig. 4.

Body region	Specific body area	Quasi-static contact		Transient contact	
		Maximum permissible pressure p_s N/cm ²	Maximum permissible force ^b N	Maximum permissible pressure multiplier ^c P_T	Maximum permissible force multiplier ^c F_T
Hands and fingers	17 Forefinger pad D	300	140	2	2
	18 Forefinger pad ND	270		2	
	19 Forefinger end joint D	280		2	
	20 Forefinger end joint ND	220		2	
	21 Thenar eminence	200		2	
	22 Palm D	260		2	
	23 Palm ND	260		2	
	24 Back of the hand D	200		2	
	25 Back of the hand ND	190		2	
Thighs and knees	26 High muscle	250	220	2	2
	27 Kneecap	220		2	
Lower legs	28 Middle of shin	220	130	2	2
	29 Calf muscle	210		2	

Fig. 5. Biomechanical pressure and force limits for body areas. Limits specified for quasi-static contact and multiplier for transient contact. This figure is an extract of the 29 body areas from ISO/TS 15066 [1] table A.2.

space while keeping the possible pressure and force values below the limits in the event of contact [1]. F_{max} and p_{max} are the force and power limits of the specific body area given in table A.1 of ISO/TS 15066 [1]. μ is the reduced mass of the two body system based on the robot's mass and the human's mass [1]. The effective spring constant k of the specific body area is given in table A.3 of ISO/TS 15066 [1]. The contact area A is defined by the smaller value of the surface areas of the robot and the operator [1].

4) *Verification and Validation*: The risk assessment should be reviewed to ensure that all reasonably foreseeable hazards have been identified and corrective actions are taken [12]. ISO 10218-1 lists specific performance requirements in table F.1 that are considered essential for the safety of a robot and that must be verified and/or validated [12]. ISO 10218-2 lists the corresponding requirements to be verified and/or validated specific for robot systems in table G.1. Both tables contain a specific subsection with requirements specifically for collaborative robots. To determine whether the requirements have been adequately met in the design and construction of the robot, they must be assessed using appropriate methods [12]. The standards suggest one or more suitable methods (e.g. visual inspection, measurement, observation, review of documents, ...) for each requirement [12]. Additionally, protective devices that are installed to reduce identified risks must be verified to ensure that they comply with the manufacturers instructions and are used correctly on the robot system [13]. Mainly it needs to be ensured that hazards are avoided before they are reached, that the installed protective devices fulfill all requirements and that additional protective measures such as instructions or warning are intended [13].

IV. CONCLUSION AND DISCUSSION

This survey serves as a valuable resource, offering a structured approach to navigate the complex regulatory landscape surrounding cobots. It provides a clear understanding of key EU regulations, such as the Machinery Regulation, and key safety standards, including ISO 13849, IEC 62061,

ISO 10218, and ISO/TS 15066. This knowledge supports informed decision-making and facilitates the development of safe, compliant cobot systems. By outlining essential steps in assessing and reducing risks—such as determining limits of cobots, identifying and eliminating cobot related hazards, and conducting thorough verification and validation—this survey equips readers with a framework for understanding the complexities of bringing cobot safety features to market in compliance with EU regulations.

While manufacturers are responsible for designing cobots in accordance with legal requirements, they have significant flexibility in choosing the technology, as long as it meets the applicable requirements. Therefore, the practical implementation of these standards can be challenging and may require careful, context-specific assessment. Future research could focus on the practical application of cobot safety features, incorporating detailed case studies to illustrate how regulations are implemented in real-world scenarios. Additionally, such studies could address the practical challenges manufacturers face during the development and integration of cobots into varied operational environments.

In conclusion, this survey provides a crucial resource for collaborative robotics stakeholders, guiding them through regulatory requirements and supporting the development of safe, compliant robots.

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