

TECHNICAL REPORT

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Safety of machinery — Risk assessment —

Part 2:

Practical guidance and examples of methods

Sécurité des machines — Appréciation du risque —

Partie 2: Lignes directrices pratiques et exemples de méthodes



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Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Preparation for risk assessment	1
4.1 General	1
4.2 Using the team approach for risk assessment	2
5 Risk assessment process	3
5.1 General	3
5.2 Determination of the limits of the machinery	3
5.3 Hazard identification	4
5.4 Risk estimation	6
6 Risk estimation tools	9
6.1 General	9
6.2 Risk matrix	9
6.3 Risk graph	12
6.4 Numerical scoring	14
6.5 Hybrid tool	15
7 Risk evaluation	19
8 Risk reduction	19
8.1 General	19
8.2 Inherently safe design	19
8.3 Safeguarding	20
8.4 Complementary protective/risk reduction measures	21
8.5 Information for use	21
8.6 Standard operating procedures	22
9 Risk assessment iteration	22
10 Documentation of risk assessment	22
Annex A (informative) Example application of the process of risk assessment and risk reduction	23
Bibliography	38

ISO/TR 14121-2:2012(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 14121-2 was prepared by Technical Committee ISO/TC 199, *Safety of machinery*.

This second edition cancels and replaces the first edition (ISO/TR 14121-2:2007), which has been revised as follows:

- the examples previously given in Annex A, as well as the description of quantified risk estimation, have been deleted;
- the explanations of the methods or tools, taken from Annex A, are now presented in 5.3.5 for hazard identification and 5.4.4.1 for risk estimation;
- the terminology and criteria have been revised;

Consequently, the information is given more clearly and completely, and in line with ISO 12100. (ISO 14121-1 was withdrawn after having been replaced by ISO 12100:2010.)

Introduction

The purpose of risk assessment is to identify hazards, and to estimate and evaluate risks so that they can be reduced. There are many methods and tools available for this purpose and several are described in this document. The method or tool chosen will largely be a matter of industry, company or personal preference. The choice of a specific method or tool is less important than the process itself. The benefits of risk assessment come from the discipline of the process rather than the precision of the results: as long as a systematic approach is taken to get from hazard identification to risk reduction and all the elements of risk are considered.

Adding protective/risk reduction measures to a design can increase costs and can restrict the facility of use of the machine if added after a design has been finalized or the machinery itself has already been built. Changes to machinery are generally less expensive and more effective at the design stage, so it is advantageous to perform risk assessment during machinery design.

It can be useful to review the risk assessment when the design has been finalised, when a prototype exists and after experience of the use of the machinery.

Apart from the risk assessment made at the design stage, during construction and commissioning, the principles and methods presented in this document can also be applied to existing machinery during revision or modification of machinery or at any time for the purpose of assessing existing machinery, for example, in the case of mishaps or malfunctions.

Safety of machinery — Risk assessment —

Part 2: Practical guidance and examples of methods

1 Scope

This Technical Report gives practical guidance on conducting risk assessment for machinery in accordance with ISO 12100 and describes various methods and tools for each step in the process. It gives examples of different measures that can be used to reduce risk and is intended to be used for risk assessment on a wide variety of machinery in terms of complexity and potential for harm. Its intended users are those involved in the design, installation or modification of machinery (for example, designers, technicians or safety specialists).

Annex A provides a specific example for a risk assessment and a risk reduction process.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 12100 and the following apply.

3.1

manufacturer supplier

entity (for example, designer, manufacturer, contractor, installer, integrator) who provides equipment or services associated with machinery or parts of machinery.

Note to entry: A user can also act in the capacity of a supplier to himself.

4 Preparation for risk assessment

4.1 General

The objectives and scope for any risk assessment should be defined at the outset.

The risk assessment based on ISO 12100 covers the whole machinery, including the control system of the machinery and should be carried out by the manufacturer.

NOTE See Clause 1 for suggested uses/users of risk assessment.

ISO/TR 14121-2:2012(E)

4.2 Using the team approach for risk assessment

4.2.1 General

Risk assessment is generally more thorough and effective when performed by a team. The size of a team varies according to

- a) the risk assessment approach selected,
- b) the complexity of the machine, and
- c) the process within which the machine is utilized.

The team should bring together knowledge on different disciplines and a variety of experience and expertise. However, a team that is too large can lead to difficulty remaining focused or with reaching consensus. The composition of the team can vary during the risk assessment process according to the expertise required for a specific problem. A team leader, dedicated to the project, should be clearly identified as the success of the risk assessment depends on his or her skills.

As risk estimation should be done by a team and generate consensus, it cannot be expected that the detailed results will always be the same with different teams analysing similar situations. However, it is not always practical to set up a team for risk assessment and it can be unnecessary for machinery where the hazards are well understood.

NOTE Confidence in the findings of a risk assessment can be improved by consulting others with the knowledge and expertise such as that outlined in 4.2.2 and by another competent person reviewing the risk assessment.

4.2.2 Composition and role of team members

The team should have a team leader. The team leader should be fully responsible for ensuring that all the tasks involved in planning, performing and documenting (in accordance with ISO 12100:2010, Clause 7) the risk assessment are carried out and the results/recommendations are reported to the appropriate person(s).

Team members should be selected according to the skills and expertise required for the risk assessment. The team should include those people who

- a) can answer technical questions about the design and functions of the machinery,
- b) have actual experience of how the machinery is operated, set-up, maintained, serviced, etc.,
- c) have knowledge of the accident history of this type of machinery,
- d) have a good understanding of the relevant regulations, standards, in particular ISO 12100, and any specific safety issues associated with the machinery, and
- e) understand human factors (see ISO 12100:2010, 5.5.3.4).

4.2.3 Selection of methods and tools

This document is intended to be used for risk assessment on a wide variety of machinery in terms of complexity and potential for harm. There are also a variety of methods and tools for conducting risk estimation (see 5.4.4). When selecting a method or tool for estimating risk consideration should be given to the machinery, the likely nature of the hazards and the purpose of the risk assessment. Consideration should also be given to the skills, experience and preferences of the team for particular methods. Clause 5 offers additional information on criteria for the selection of appropriate methods and tools for each step of the risk assessment process.

4.2.4 Source of information for risk assessment

The information required for risk assessment is listed in ISO 12100:2010, 5.2. This information can take a variety of forms, including technical drawings, diagrams, photos, video footage, information for use [including

maintenance information and standard operating procedures (SOP)] as available. Access to similar machinery or a prototype of the design, where available, is often useful.

5 Risk assessment process

5.1 General

The following subclauses explain what has to be considered at each step of the risk assessment process as shown in ISO 12100:2010, Figure 1.

5.2 Determination of the limits of the machinery

5.2.1 General

NOTE This subclause elaborates on some of the requirements of ISO 12100:2010, 5.3.

The objective of this step is to have a clear description of the mechanical and physical properties, functional capabilities of the machinery, its intended use and reasonably foreseeable misuse, and the type of environment in which it is likely to be used and maintained.

This is facilitated by an examination of the functions of the machinery and the tasks associated with how the machinery is used.

5.2.2 Functions of the machinery (machine-based)

Machinery can be described in terms of distinct parts, mechanisms or functions based on its construction and operation such as

- power supply,
- control,
- modes of operation,
- feeding,
- movement/travelling,
- lifting,
- machine frame or chassis which provides stability/mobility, and
- attachments.

When protective/risk reduction measures are introduced into the design their functions and their interaction with the other functions of the machinery should be described.

A risk assessment should include a look at each functional part in turn, making sure that every mode of operation and all phases of use are properly considered, including the human-machine interaction in relation to the identified functions or functional parts.

5.2.3 Uses of the machinery (task based)

By considering all persons who are intended to interact with the machinery in a given environment (for example, factory, domestic), the use of the machinery can be described in terms of the tasks associated with the intended use and the reasonably foreseeable misuse of the machinery.

NOTE See ISO 12100:2010, Table B.3 for a list of typical/generic machinery tasks.

ISO/TR 14121-2:2012(E)

Machinery manufacturer/supplier and user should communicate with one another wherever possible in order to be sure that all uses of the machinery, including reasonably foreseeable misuses, are identified. Analysis of tasks and work situations should therefore involve operation and maintenance personnel. The following should also be considered:

- a) information for use supplied with the machinery as available,
- b) the easiest or quickest way to carry out a task can be different from the tasks stipulated in manuals, procedures and instructions,
- c) reflex behaviour of a person when faced with a malfunction, incident or failure when using the machine, and
- d) human error.

The consideration of individual conditions for the use/operation of a machine are valid as far as this knowledge can reasonably be achieved by the designer/manufacturer. In those cases the manufacturer should consider the intended use and the reasonably foreseeable misuse.

5.3 Hazard identification

5.3.1 General

NOTE 1 See ISO 12100:2010, 5.4.

The objective of hazard identification is to produce a list of hazards, hazardous situations and/or hazardous events that allows the possible accident scenarios to be described in terms of how and when a hazardous situation can lead to harm. A useful starting point for relevant hazards is ISO 12100:2010, Annex B, which can be used as a generic checklist. Other sources for hazard identification could be based on the information indicated in ISO 12100:2010, 5.4.

NOTE 2 An example of a tool for hazard identification is given in 5.3.5.

It is useful for both hazard identification and anticipating protective/risk reduction measures, to reference any International Standards that are relevant to a specific hazard or safety of a specific type of machinery.

NOTE 3 An example of a standard relevant to specific hazards is IEC 60204-1, which deals with electrical hazards.

NOTE 4 Examples of machinery-specific safety standards are ISO 10218, related to robots, ISO 11111, related to textile machinery, and ISO 3691, related to industrial trucks.

Hazard identification is the most important step in any risk assessment. Only when a hazard has been identified, is it possible to take action to reduce the risks associated with it, see Clause 6. Unidentified hazards can lead to harm. It is therefore vitally important to ensure that hazard identification is as systematic and comprehensive as practicable, taking into account the relevant aspects described in ISO 12100:2010, 5.5.3.

5.3.2 Methods for hazard identification

The most effective methods or tools are those that are structured to ensure that all phases of the machinery life cycle, modes of operation, functions and tasks associated with the machinery are thoroughly examined.

Various methods for structured hazard identification are available. In general most follow one of the two approaches described below (see Figure 1):

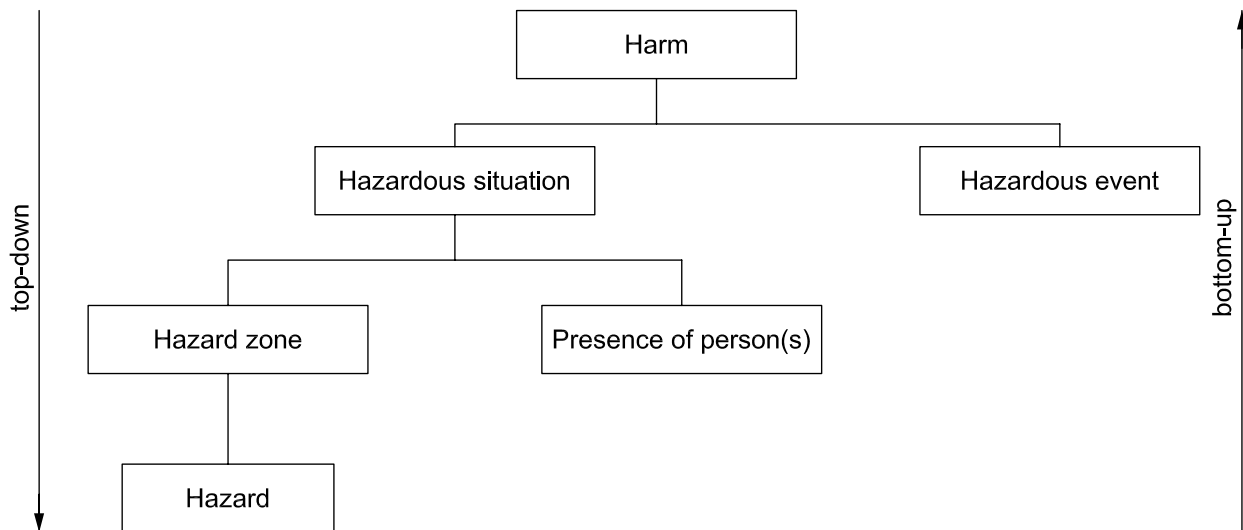


Figure 1 — Top-down and bottom-up approaches

A *top-down* approach is one that takes as its starting point a check-list of potential consequences (for example, cutting, crushing, hearing loss — see potential consequences in ISO 12100:2010, Tables B.1 and B.2) and establishes what could cause harm (working back from the hazardous event to the hazardous situation and thence the hazard itself). Every item in the checklist is applied to every phase of use of the machinery and every part/function and/or task in turn. One of the drawbacks of a top-down approach is the over-reliance of the team on the checklist, which may be incomplete. An inexperienced team will not necessarily appreciate this. Therefore, checklists should not be interpreted as exhaustive, but should encourage creative thinking beyond the list.

A *bottom-up* approach starts by examining all the hazards and considering all possible ways that something can go wrong in a defined hazardous situation (for example, failure of component, human error, malfunction or unexpected action of the machinery) and how this can lead to harm. See ISO 12100:2010, Tables B.1 and B.2. The bottom-up approach can be more comprehensive and thorough than the top-down but can also be prohibitively time-consuming.

NOTE Figure 1 explains the structure of the hazard identification approaches, but it is not intended to define relationship between hazardous situation, hazardous event and harm in the way of a flowchart.

5.3.3 Recording of information

The hazard identification should be recorded as it progresses. Any system for recording the information should be organized in such a way as to ensure that the following are clearly described, as appropriate:

- a) the hazard and its location (hazard zone),
- b) the hazardous situation, indicating the different types of people (such as maintenance personnel, operators, passers-by) and the tasks or activities they are intended to do that can expose them to a hazard,
- c) how the hazardous situation can lead to harm as a result of a hazardous event or prolonged exposure, at which stage of the risk assessment process sometimes the following information can also be anticipated and usefully recorded:
 - 1) the nature and severity of the harm (consequences) in machinery-specific (for example, fingers crushed by down-stroke of press when adjusting work-piece) rather than generic (for example, crushing) terms, and
 - 2) existing protective/risk reduction measures and their effectiveness.

ISO/TR 14121-2:2012(E)

5.3.4 Example of a tool for hazard identification

5.3.4.1 Hazard identification by application of forms

5.3.4.1.1 General

The aim of this subclause is to show a method for hazard identification (see ISO 12100:2010, 5.4) using as the main tool the checklists given in ISO 12100:2010, B.2 to B.4.

These checklists should be used as the starting point for identifying relevant hazards. Then, in order to ensure a more complete hazard identification, other sources such as regulations, standards and engineering knowledge should be taken into account.

This method can be complemented with other methods based on, for example, brainstorming, comparison with similar machinery, review of data about accidents and/or incidents of similar machinery.

This method will be more effective the more complete and detailed are the available information for risk assessment (see ISO 12100:2010, 5.2) and the determination of the limits of the machinery (see 5.2 and ISO 12100:2010, 5.3).

The method is applicable to any phase of the machine life cycle.

5.3.4.1.2 Description of the tool or method

Taking into account the limits of the machine, the first step is to determine the extent of the system to be analysed, for example, the phase(s) of the machine life cycle, the part(s) and/or function(s) of the machine.

The second step is to define the tasks to be performed by people interacting with or near the machine or the operations to be performed by the machine, in each of the selected phases. In this step the list of tasks detailed in ISO 12100:2010, Table B.3, could be used.

The third step is to examine, for each task or operation in each particular hazard zone, the relevant hazards and the possible hazardous situations. This can be carried out by using either a top-down approach, if the starting point is the potential consequence (harm), or a bottom-up approach, if the starting point is the origin of the hazard. In this step, ISO 12100:2010, Table B.1, for description of origins of hazards, ISO 12100:2010, Table B.3, for description of hazardous situations, and ISO 12100:2010, Table B.4, for description of hazardous events, can be used.

5.3.4.1.3 Documentation

The blank form given in Table A.3 can be used to document the results of hazard identification.

5.4 Risk estimation

5.4.1 General

NOTE See ISO 12100:2010, 5.5.

By definition the two main elements of risk are severity of harm and the probability of occurrence of that severity of harm. The purpose of risk estimation (see ISO 12100:2010, Figure 3) is to determine the highest risk arising from each hazardous situation. The estimated risk is generally expressed as a level, index or score but can also be descriptive.

There are many different approaches to risk estimation, ranging from the simple qualitative to the detailed quantitative. The essential features of these different approaches are described below.

5.4.2 Severity of harm

NOTE 1 See ISO 12100:2010, 5.5.2.2.

Each hazard has the potential to result in several different severities of harm. It can be helpful to estimate the risk of a range of representative severities and to consider the most severe harm that can realistically occur (worst credible).

However severity of harm to be considered is not always easy. The most severe can be very improbable and the most probable severity can be inconsequential so that using either could lead to an inappropriate estimation of risk. For example, it is almost always possible that death will be the severity of harm: a cut can kill if it becomes septic or severs an artery; however, although the probability of receiving a cut is high, death is nevertheless usually a remote probability. It can, therefore, be helpful to estimate the risk of a range of representative severities and use the one that gives the highest risk.

NOTE 2 In general, the lower the energy of the hazard, the lower the severity of the related potential harm. The severity of potential harm can also be related to the part of the body that is exposed, for example, a hazard that can cause crushing injuries is generally fatal if the whole body or head is exposed.

For examples of different ways of classifying severity, see the risk estimation tools described in 5.4.4.

5.4.3 Probability of occurrence of harm

5.4.3.1 General

NOTE See ISO 12100:2010, 5.5.2.3.

All approaches to risk estimation should require the estimation of the probability of an occurrence of harm by considering the

- a) exposure of person(s) to the hazard (see ISO 12100:2010, 5.5.2.3.1),
- b) probability of occurrence of a hazardous event (see ISO 12100:2010, 5.5.2.3.2), and
- c) technical and human possibilities to avoid or limit the harm (see ISO 12100:2010, 5.5.2.3.3).

A hazardous situation exists when one or more persons are exposed to a hazard. Harm occurs as a result of a hazardous event as illustrated in Figure 2.

When estimating the probability of harm the relevant aspects described in ISO 12100:2010, 5.5.3, should also be considered.

ISO/TR 14121-2:2012(E)

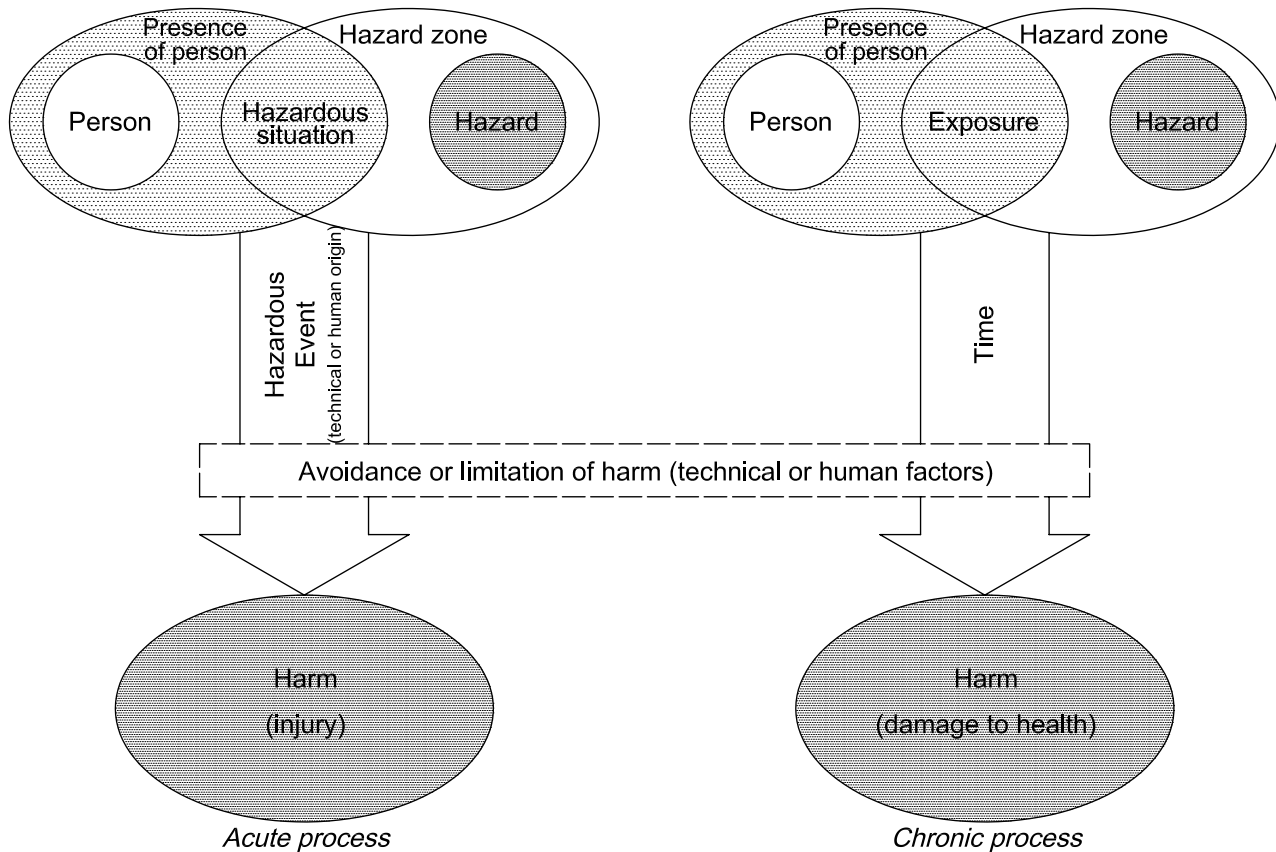


Figure 2— Conditions of occurrence of harm

5.4.3.2 Probability of occurrence of cumulative harm (health aspects)

Hazardous situations that lead to harm due to a cumulative exposure over a period of time (such as dermatitis, occupational asthma, hearing loss or repetitive strain injury) need to be handled differently from those that lead to acute sudden harm (such as cuts, broken bones, amputations, short-term respiratory problems).

A chronic health condition (for example, hearing loss) can occur due to exposure above a harmful level. The probability of harm is dependent on the total dose over time. Total dose can be made up of a number of different exposures of different durations and levels from several sources.

EXAMPLE For respiratory harm the damage is dependent on the dose and/or the concentration of the substance. For hearing loss the damage is dependent on noise levels and the duration of exposure and for repetitive strain injuries on the strain involved and the repetitiveness of the action.

The difference between harm caused suddenly and harm caused by prolonged exposure can be illustrated by two different causes of lower back injury. The first can be caused immediately on picking up a load that is too heavy. The latter can be caused by repeatedly handling relatively light loads.

NOTE The probability of occurrence of cumulative harm (health aspects) is closely related to the particular conditions for machine use (in particular, the level and duration of an individual exposure). Under normal circumstances the designer or manufacturer of a machine could provide only the actual emission data (e. g. for noise and vibration) relevant for a machine. This data could be used by the user (having a detailed knowledge about the individual conditions for machine use) to determine the probability of occurrence of cumulative harm (health aspects).

6 Risk estimation tools

6.1 General

In order to support a risk estimation process, one of various risk estimation tools can be selected and used. Most of the available risk estimation tools use one of the three following tools or methods:

- a) risk matrix (see 6.2),
- b) risk graph (see 6.3),
- c) numerical scoring (see 6.4).

There are also hybrid tools that use a combination of methods (see 6.5).

The choice of a specific risk estimation tool is less important than the process itself. The benefit of risk assessment comes from the discipline of the process rather than in the absolute precision of the results, as long as all the elements of risk as described in ISO 12100:2010, 5.5.2, are fully considered. Moreover, resources are better directed at risk reduction efforts rather than attempting to achieve absolute precision in risk estimation.

Any risk estimation tool should deal with at least two parameters representing the elements of risk. One parameter is severity of harm (see 5.4.2), the other parameter is probability of occurrence of that harm (see 5.4.3).

Some tools or methods break the two parameters down into elements of risks such as exposure, probability of occurrence of the hazardous event and the individual's possibility to avoid or limit the harm (see ISO 12100:2010, 5.5.2).

For a specific risk estimation tool, one class for each parameter is chosen that best corresponds to the hazardous situation/hazardous event (i.e. accident scenario). The classes chosen are then combined, using simple arithmetic, tables, charts or diagrams in order to estimate the risk.

6.2 Risk matrix

6.2.1 General

A risk matrix is a multidimensional table allowing the combination of any class of severity of harm (see 5.4.2) with any class of probability of occurrence of that harm (see 5.4.3). The more common matrices are two-dimensional but they can have up to four dimensions.

The use of a risk matrix is simple. For each hazardous situation that has been identified, one class for each parameter is selected, on the basis of the definitions given. The content of the cell where the columns and rows corresponding to each selected class intersect gives the estimated risk level for the identified hazardous situation. This can be expressed as an index (for example, from 1 to 6, or from A to D) or a qualitative term such as "low", "medium", "high", or similar.

The number of cells can vary widely from very small (for example, four cells) to quite large (for example, 36 cells). Cells can be grouped to reduce the number of classifications of risk. Too few classifications may not provide sufficient information on whether protective/risk reduction measures provide adequate risk reduction. Too many cells can make the matrix confusing to use.

Although there are many different matrices for estimating risk an example of a risk matrix tool or method is given in 6.2.2.

6.2.2 Example of a risk matrix tool or method

6.2.2.1 General

There are four steps to the risk matrix approach according to 6.2.2.2 to 6.2.2.5.

ISO/TR 14121-2:2012(E)

6.2.2.2 Selection of a risk matrix

Risk matrices have been used for many years, and many different variations exist. An example is shown in Table 1.

As shown in Table 1, different risk matrices use different levels for each risk factor – for example, Table 1 has four levels of probability. Levels usually range from three to up to ten, with four or five being the most common.

Table 1 — Risk estimation matrix (example)

Probability of occurrence of harm	Severity of harm			
	Catastrophic	Serious	Moderate	Minor
Very likely	High	High	High	Medium
Likely	High	High	Medium	Low
Unlikely	Medium	Medium	Low	Negligible
Remote	Low	Low	Negligible	Negligible

6.2.2.3 Estimation of severity

For each hazard or hazardous situation (task), the severity of harm or consequences that could result should be estimated. Historical data can be of great value as a baseline. Severity is often estimated as personal injury or damage to health.

Estimation of severity can be accomplished using the selected risk matrix. As an example, the severity levels in Table 1 are:

- **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 same job);
- **minor** – no injury or slight injury requiring no more than first aid (little or no lost work time).

Estimation of severity usually focuses on the worst severe harm that can realistically occur (worst credible) rather than the worst conceivable consequence.

6.2.2.4 Estimation of probability of occurrence of harm

For each hazard or hazardous situation (task), the probability of occurrence of harm should be estimated. Unless empirical data are available, and that would be rare, the process of selecting the probability of an incident occurring will again be subjective. For this reason brainstorming with knowledgeable people is advantageous.

Estimation of the probability of occurrence of harm can include (see ISO 12100:2010, 5.5.2.3)

- a) frequency and duration of exposure to a hazard,
- b) number of persons exposed,
- c) personnel who perform tasks,
- d) machine/task history,
- e) workplace environment,
- f) human factors,
- g) reliability of safety functions,
- h) possibility to defeat or circumvent protective/risk reduction measures,
- i) ability to maintain protective/risk reduction measures, and
- j) ability to avoid harm.

Similar to severity, there are many scales used to estimate the probability of occurrence of harm. Some methods do not provide descriptions other than the terms used. Other matrices provide additional descriptions as in Table 1:

- **very likely** – near certain to occur;
- **likely** – can occur;
- **unlikely** – not likely to occur;
- **remote** – so unlikely as to be near zero.

Some methods draw a distinction between probability and likelihood; where probability is a numerical value between 0 and 1 and likelihood is a qualitative description of probability. However, many methods do not distinguish between the terms probability and likelihood and use them synonymously.

Probability should be related to an interval base of some sort, such as a unit of time or activity, events, units produced, or the life cycle of a facility, equipment, process or product. The unit of time can be the intended lifetime of the machine.

6.2.2.5 Derivation of the risk level

Once the severity and probability are estimated, an initial risk level can be derived from the selected risk matrix. The risk matrix maps the risk factors to risk levels as shown in Table 1.

Using Table 1 as an example, a “serious” severity and “likely” probability yields a “high” risk level. How the risk factors of severity and probability are combined varies with different risk matrices. The result of this combination will typically yield an array of low to high risks. Since the risk estimation is usually subjective, the risk levels will also be subjective.

6.2.2.6 Discussion

The risk matrix method provides a simple and efficient method of estimating risks.

ISO/TR 14121-2:2012(E)

6.3 Risk graph

6.3.1 General

A risk graph is based on a decision tree. Each node in the graph represents a parameter of risk (severity, exposure, probability of occurrence of a hazardous event, possibility of avoidance) and each branch from a node represents a class of the parameter (for example, slight severity or serious severity).

For each hazardous situation, a class should be allocated to each parameter. The path on the risk graph is then followed from the starting point. At each joint the path proceeds on the appropriate branch in accordance with the selected class. The final branch points at the level or index of risk associated with the combination of classes (branches) that have been chosen. The end result is an estimation of risk qualified with terms such as 'high', 'medium', 'low', a number, for example, 1 to 6, or a letter, for example, A to F.

Risk graphs are useful for illustrating the amount of risk reduction provided by a protective/risk reduction measure and which parameter of risk it influences.

Risk graphs become very cumbersome and cluttered if there are more than two branches for more than one of the parameters of risk. For this reason hybrid methods tend to combine a risk graph with a matrix for one of the parameters, see 6.5.

An example of a risk graph tool or method is given in 6.3.2.

6.3.2 Example of a risk graph tool or method

Before the risk is estimated using the risk graph, the associated hazard, hazardous situation, hazardous event and possible harm should be described in accordance with ISO 12100:2010, 5.4 (see blank form given as Table A.4). A risk index is then calculated using the risk graph given in Figure 3, based on the four following parameters, corresponding to the four elements of risk as defined in ISO 12100:2010, 5.5.2.1, each one having its particular limits:

Severity of the harm: S

- S1: slight injury (usually reversible; examples: scratch, laceration, bruise, light wound requiring first aid, etc.) nor more than two days incapable of performing the same task;
- S2: serious injury (usually irreversible, including fatality; examples: broken or torn-out or crushed limb, fracture, serious injury requiring stitches, major musculoskeletal trauma (MST) etc.). More than two days incapable of performing the same task.

Frequency and/or duration of exposure to hazard: F

- F1: seldom to quite often and/or short duration of exposure
Twice or less per work shift or less than 15 min cumulated exposure per work shift;
- F2: frequent to continuous and/or long duration of exposure
More than twice per work shift or more than 15 min cumulated exposure per work shift.

Probability of occurrence of a hazardous event: O

- O1: low (so unlikely that it can be assumed that occurrence may not be experienced)
Mature technology, proven and recognized in safety application; robustness.
- O2: medium (likely to occur sometime)
Technical failure observed in the two last years. Inappropriate human action by a well-trained person aware of the risk and having more than six months experience on the work station.

- O3: high (likely to occur frequently)

Technical failure regularly observed (every six months or less). Inappropriate human action by an untrained person having less than six months experience on the work station.

Possibility of avoidance or reduction of harm: A

- A1: possible under some conditions:

- If parts move at a speed less than $0,25 \text{ m} \cdot \text{s}^{-1}$ and the exposed worker is familiar with the risk and with the indication of a hazardous situation or impending event; the worker also has to be capable of noticing the hazardous situation and being capable of reacting.
- depending on particular conditions (temperature, noise, ergonomic, etc.).

- A2: impossible.

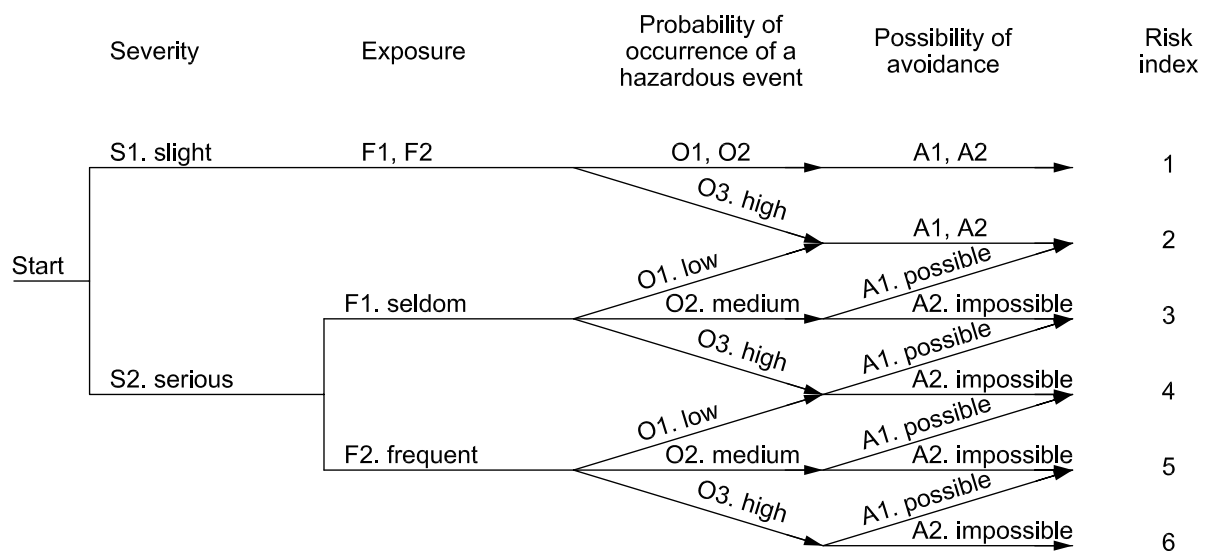


Figure 3 — Example of a risk graph for risk estimation

A form is filled in with the result of this first risk estimation; each hazardous situation is allocated a risk index. In this example, the estimation of each hazardous situation is done considering that

- a risk index of 1 or 2 corresponds to the lowest risk,
- a risk index of 3 or 4 corresponds to a medium risk, and
- a risk index of 5 or 6 corresponds to the highest risk.

After consideration of possible means to reduce risk, the risk is then estimated again for the final design using the same risk graph in the same way as for the initial design.

NOTE The blank form given as Table A.4 can be used to document the results of this first risk estimation.

6.3.3 Discussion

This risk graph can be used to estimate a risk index mostly for hazardous situations that can induce acute harms (mechanical, electrical or, to a certain extent, thermal hazards). The proposed risk graph is not very appropriate to estimate risks related to some health hazards such as noise or ergonomics. In these cases, the results obtained with this risk graph tool should be compared with the result obtained with specific tools dedicated to noise or ergonomics.

ISO/TR 14121-2:2012(E)

It has been found convenient by some industries to adapt slightly the parameters and the limits of the risk graph; these changes might induce different results.

The risk graph used in this example is equivalent to the risk matrix given in Figure 4.

		Risk index calculation					
		O1		O2		O3	
		A1	A2	A1	A2	A1	A2
S1	F1	1				2	
	F2	1				2	
S2	F1	2		3		4	
	F2	3	4	5	6	5	6

Figure 4 — Risk matrix equivalent to the risk graph in Figure 3

6.4 Numerical scoring

6.4.1 General

Numerical scoring tools have two or more parameters that are broken down into a number of classes in much the same way as risk matrices and risk graphs. However different numerical values are associated with the classes instead of a qualitative term. A class is chosen for each parameter and the associated values (or scores) are then combined (for example, by addition and/or multiplication) to give a numerical score for the estimated risk. In some instances these assigned values are represented in table(s) so their use is very similar to that of a matrix (see 6.2).

Scoring systems allow parameters to be easily and explicitly weighted. The use of numbers can give an impression of objectivity in the risk level even though the allocation of scores for each element of risk is highly subjective. However this can be counteracted by grouping the scores into qualitative classifications of risk such as high, medium and low.

There are many different numerical scoring tools used to estimate risk. An example of a risk numerical scoring tool or method is given in 6.4.2.

6.4.2 Example of a risk numerical scoring tool or method

In this example there are two parameters (severity and probability of occurrence of harm) and each of these parameters is divided into the four classes shown.

The severity parameter has the following severity scores (SS):

- catastrophic SS = 100,
- serious 99 ≥ SS ≥ 90,
- moderate 89 ≥ SS ≥ 30,
- minor 29 ≥ SS ≥ 0.

The probability of occurrence of harm parameter has the following probability scores (PS):

—	very likely	PS = 100	likely or certain to occur,
—	likely	99 ≥ PS ≥ 70	can occur (but not probable),
—	unlikely	69 ≥ PS ≥ 30	not likely to occur,
—	remote	29 ≥ PS ≥ 0	occurrence so remote as to be essentially zero.

In this example, the formula for combining probability of occurrence of harm and severity is given by Equation (1):

$$PS + SS = RS \tag{1}$$

where RS is the risk score.

The risk score can then be interpreted according to Table 2.

Table 2 — Risk score categories used

—	high	≥ 160
159 ≥	medium	≥ 120
119 ≥	low	≥ 90
89 ≥	negligible	≥ 0

EXAMPLE A task-hazard that is associated with very severe injury can have SS = 95, and its probability can be in the likely range PS = 80. The risk score for this task-hazard is then high (95 + 80 = 175 > 160).

6.4.3 Discussion

Some people find it easier to think about risk and how it is derived in terms of numbers. This is not at all unusual in our digital age. Being able to see risk represented by a number somehow adds specificity to the process of risk reduction. The ability to select one number from within the integer range within classes can allow for more refined choices than are permitted by qualitative terms but can give a false impression of numerical accuracy.

6.5 Hybrid tool

6.5.1 General

Hybrid tools or methods for risk estimation exist that combine two of the approaches described above. Commonly these are risk graphs that contain within them either matrices or scoring systems for one of the elements of risk. A certain amount of quantification can also be incorporated into any of the qualitative approaches, such as by giving frequency ranges to probabilities or exposures. For example, something that is 'likely' can be expressed as being once a year, a 'high' exposure can be specified as being hourly.

An example of a hybrid tool or method for risk estimation is given in 6.5.2.

6.5.2 Example of a hybrid tool or method for risk estimation

This risk estimation tool or method quantifies the qualitative parameters. It is a hybrid method of a numerical scoring and a risk matrix.

The form reproduced on page 18 should be used in conjunction with the following guidance information.

Pre-risk estimation

Ticking this box indicates this is the first risk estimation. It is done in the concept phase where only specification and sketches are available. No detail drawings are made at this stage. It is used to decide on the major systems of a machine, for example, mechanical drive line or servo drives, hot air or ultra sonic sealing, movable guard or light barrier.

ISO/TR 14121-2:2012(E)

Intermediate risk estimation

The intermediate risk estimation box is ticked for all intermediate risk estimations performed during the development of a machine. Two sets of hazards are dealt with in this phase. Where in the pre-risk estimation phase protective/risk reduction measures were indicated, these are implemented and assessed again in this phase. The design of the machine changes during the development. Risk assessments have to follow together with the design review along the project. New hazards are dealt with in this phase.

Follow-up risk estimation

This box is ticked at the follow-up risk estimation. Follow-up is done on implemented protective/risk reduction measures. No new hazard should appear in this phase. Nevertheless, where a new hazard is identified when following up on protective/risk reduction measures, this new hazard is also estimated and evaluated in this phase. If it requires a protective/risk reduction measure, a follow-up has to be done again on this protective measure/risk reduction.

Reference number (ref. no.)

The reference number, or serial number, is used to give each identified hazard a number for reference purposes.

Type hazard number (type no.)

Type no., hazard type or group number is used to classify the hazards. The numbers refer to those given for the type or group according to ISO 12100:2010, Table B.1.

Hazard

Describe the hazard. The type no. identifies the type or group of hazard. Indicate the origin of the hazard type or group. For example, if the hazard is a crushing hazard this is indicated by "1" in the type no. column and by "crushing" in the hazard column.

The same hazard can require several estimations due to different hazardous situations and hazardous events.

Severity, Se

Se is the severity of possible harm as an outcome from the identified hazard. The severity is scored as follows:

- 1 scratches, bruises that are cured by first aid or similar;
- 2 more severe scratches, bruises, stabbing, which require medical attention from professionals;
- 3 normally irreversible injury; it will be slightly difficult to continue work after healing;
- 4 irreversible injury in such a way that it will be very difficult to continue work after healing, if possible at all.

Frequency, Fr

Fr is the average interval between frequency of exposure and its duration. The frequency is scored as follows:

- 2 interval between exposure is more than a year;
- 3 interval between exposure is more than two weeks but less than or equal to a year;
- 4 interval between exposure is more than a day but less than or equal to two weeks;
- 5 interval between exposure is more than a hour but less than or equal to a day;

where the duration is shorter than 10 min, the above values may be decreased to the next level;

- 5 interval less than or equal to an hour — this value is not to be decreased at any time.

Probability, Pr

Pr is the probability of occurrence of a hazardous event. Consider, for example, human behaviour, reliability of components, accident history and the nature of the component or system (for example, a knife is always sharp, a flue exhaust pipe is always hot, electricity is dangerous by its nature) to determine the level of probability. The probability is scored as follows.

- 1 Negligible: for example, this kind of component never fails so that a hazardous event occurs. No possibility of human error.
- 2 Rarely: for example, it is unlikely this kind of component will fail so that a hazardous event occurs. Human error is unlikely.
- 3 Possible: for example, this kind of component can fail so that a hazardous event occurs. Human error is possible.
- 4 Likely: for example, this kind of component will probably fail so that a hazardous event occurs. Human error is likely.
- 5 Very high: for example, this kind of component is not made for this application. It will fail so that a hazardous event occurs. Human behaviour is such that the likelihood of error is very high.

Avoidance, Av

Av is the possibility of avoiding or limiting harm. Consider, for example, whether the machine to be operated by skilled or unskilled persons, how quickly a hazardous situation can lead to harm, and the awareness of risk by means of general information, direct observation or through warning signs, so as to determine the level of avoidance. The possibility of avoidance is scored as follows:

- 1 Likely: for example, it is likely that contact with moving parts behind an interlocked guard will be avoided in most cases should the interlocking fail and the movements continue.
- 3 Possible: for example, it is possible to avoid an entanglement hazard where the speed is slow and there is sufficient space or otherwise it is easy to avoid moving parts of machinery.
- 5 Impossible: for example, it is impossible to avoid a sudden appearance of a powerful laser beam, or in case of an explosion.

Class, Cl

Cl is the class. Fr, Pr and Av are the constituent factors that form the probability of occurrence of harm as described in ISO 12100:2010, 5.5.2.3. Each of the three factors should be estimated independently of each other. The worst credible assumption should be used for each factor. Fr, Pr and Av are added together in Cl. The Cl is the sum of Fr, Pr and Av, i.e. $Cl = Fr + Pr + Av$.

Risk estimation

The risk is estimated by using the matrix in the middle of the upper part of the form reproduced on the next page.

Where the severity, Se, crosses the class, Cl, in the black area, the risk is high.

Where the severity, Se, crosses the class, Cl, in the grey area, the risk is medium.

Where the severity, Se, crosses the class, Cl, in the remaining area, the risk is low.

Details

The accident scenario should be described here. Put the hazard reference number for the particular hazard in the left column and describe the accident scenario in the right. Where photos are used, the reference to them can be made here.

ISO/TR 14121-2:2012(E)

Risk estimation

Product: _____

Issued by: _____

Date: _____

Document no.: _____

Part of doc. no: _____

Preliminary risk estimation

Black area = High risk
 Grey area = Medium risk
 White area = Low risk

Consequences	Severity Se	Class CI (Fr+Pr+Av)						Probability Pr	Avoidance Av
		4	5-7	8-10	11-13	14-15	Fr		
Death, losing an eye or arm	4						≥1 h	5 very high	5
Permanent, losing fingers	3						< 1 h to ≥ 24 h	5 likely	4
Reversible, medical attention	2						< 24 h to ≥ 1 y	4 possible	3 impossible
Reversible, first aid	1						< 2 w to ≥ 1 y	3 rarely	2 possible
							< 1 y	2 negligible	1 likely

Ref. Typ. no. Hzd. No.	Hazard	Se	Fr	Pr	Av	CI
1						
2						
3						

Details (description of the accident scenario) of ref. no.

- 1 _____
- 2 _____
- 3 _____

7 Risk evaluation

NOTE See ISO 12100:2010, 5.6.

The objectives of risk evaluation are

- to decide which, if any, hazardous situations require further risk reduction, and
- to determine whether the required risk reduction has been achieved without introducing further hazards or increasing other risks.

When protective/risk reduction measures are applied as a result of the risk evaluation, a new iteration of the risk assessment should be made to verify its effectiveness in risk reduction.

Some hazardous situations can be recorded as being excluded from further consideration due to having an extremely low (trivial) risk. Those that pose a significant risk should be reduced in accordance with ISO 12100. For those hazardous situations that pose a high risk, a more detailed risk estimation can be useful.

The risk evaluation should ensure that the requirements of relevant standards (for example, product standards or hazard specific standards such as IEC 60204-1) are considered, whilst taking into account any limitations of the standard with respect to the protective/risk reduction measures of the machinery being assessed.

As a general rule the estimated risk is only one input to the decision to stop the iterative process of risk reduction. This decision should include other considerations such as regulations, laws, work organization and practices, technical limits and economics. See ISO 12100:2010, Figure 1 and 5.6.2.

Care should be taken that simple and effective measures for reducing relatively low risks are not overlooked due to an exclusive focus on the highest risks.

8 Risk reduction

NOTE See ISO 12100:2010, Clause 6.

8.1 General

Risk reduction is achieved by implementing protective/risk reduction measures in accordance with ISO 12100 being developed during the risk assessment. During risk reduction, decisions are made regarding what needs to be done, by whom, when and at what cost.

Different types of protective/risk reduction measures, in order of preference, are given below. Explanations are provided as to their influence on the reduction of a particular risk element.

NOTE This information is provided for illustrative purposes only. It is not comprehensive. For more information, see ISO 12100.

8.2 Inherently safe design

8.2.1 Elimination of hazards by design

The first priority in the risk reduction process is the elimination of the hazard by design. Eliminating hazards by design is the most effective method for reducing risk because it removes the source of harm.

The following are examples of the methods for elimination of the hazard:

- substitution of hazardous materials and substances;
- modification of physical features (for example, elimination of sharp edges and shear points);
- elimination of repetitive activities and harmful postures.

ISO/TR 14121-2:2012(E)

8.2.2 Risk reduction by design

If hazards cannot be eliminated by design, then other inherently safe design measures should be applied in order to reduce risks. These measures are based on a suitable choice of design features of the machine itself and/or interaction between the exposed persons and the machine. These can be considered in terms of the components of risk reduction.

Examples of methods for risk reduction by design whose greatest effect is on the severity of harm are:

- reducing energy (for example, lower force, lower hydraulic/pneumatic pressure, reduced working height, reduced speed);
- utilising technical safety equipment to prevent/reduce a hazard (for example, a ventilation system prevents explosions/reduces hazardous vapours)

Examples of methods for risk reduction by design whose greatest effect is on the exposure to the hazard are:

- reducing the need of being in a hazardous situation (limiting exposure to hazards through mechanization or automation of loading/unloading or feeding/removal operations; location of the setting and maintenance points outside of danger zones);
- relocating the source(s) of harm.

Examples of methods for risk reduction by design whose greatest effect is on the occurrence of hazardous event(s) are:

- improving of reliability of components of the machine (mechanical, electrical/electronic, hydraulic/pneumatic components and software) whose failure can result in harm;
- applying safe design measures to safety related parts of control systems (basic safety principles, well-trying safety principles and/or components, redundancy, monitoring) whose failure can result in harm.

Where a protective/risk reduction measure is implemented by means of a control system safety function, it should be implemented in accordance with the relevant International Standards, for example, ISO 13849-1 and ISO 13849-2.

8.3 Safeguarding

If hazards cannot be eliminated or risks cannot be reduced adequately by design measures, safeguarding (protective/risk reduction measures using guards and protective devices) should be applied that results in restricting exposure to hazards, lowering the probability of the hazardous event, or improving the possibility of avoiding or limiting harm.

When risk is reduced with the use of safeguards such as those listed in a) and b), there is little, if any, impact on the severity of harm. The greatest impact is on exposure (as long as the guard is being used as intended and is functioning properly), see ISO 12100:2010, 6.3.2 to 6.3.4:

- a) fixed guards, fencing or enclosures for the prevention of access to hazard zones;
- b) interlocking guards preventing access to hazardous areas (for example, interlocks with or without guard locking, interlock keys).

When risk is reduced with the use of safeguards such as those listed in c) to e), there is little, if any, impact on the severity of harm. The greatest impact is on the occurrence of a hazardous event, with little impact on exposure:

- c) sensitive protective equipment (SPE) for the detection of persons entering into, or present in, the hazard zone (for example, light curtains, pressure-sensitive mats);
- d) devices associated with safety-related functions of the control system of the machine (for example, enabling device, limited movement control device, hold-to-run control device);
- e) limiting devices (for example, overloading and moment limiting devices, devices for limiting pressure or temperature, over-speed switches, devices for monitoring emissions).

Where a protective/risk reduction measure is implemented by means of a control system safety function, it should be implemented in accordance with the relevant International Standards, for example, ISO 13849-1 and ISO 13849-2.

8.4 Complementary protective/risk reduction measures

Complementary protective/risk reduction measures may have to be implemented as required by the intended use and the reasonable foreseeable misuse of the machine to achieve further risk reduction. Examples of complementary protective/risk reduction measures whose greatest effect is on the ability of avoiding or limiting harm are:

- emergency stop (see ISO 12100:2010, 6.3.5.2);
- measures for the escape and rescue of trapped persons (see ISO 12100:2010, 6.3.5.3);
- measures for safe access to machinery (see ISO 12100:2010, 6.3.5.6);
- provisions for easy and safe handling of machines and their heavy component parts (see ISO 12100:2010, 6.3.5.5).

An example of complementary protective/risk reduction measures whose greatest effect is on exposure are measures for isolation and energy dissipation (for example, isolation valves or switches, locking devices, mechanical blocks to prevent movement).

8.5 Information for use

NOTE See ISO 12100:2010, 6.4.

8.5.1 General

The information for use provides guidance for the correct and safe use of machinery, informs and, if necessary, warns the user about the risks that remain after risk reduction by design and safeguarding.

Information for use impacts mainly the ability of avoiding the harm and its efficacy is depending on persons' ability to understand the information and respond in an appropriate manner.

The documentation provided can include also information about required training and use of personal protective equipment.

8.5.2 Consideration of training

The instruction handbook can contain any training necessary to ensure that persons know how to correctly use the machinery and apply any protective/risk reduction measure. This training and competency is most important when the effectiveness of the protective/risk reduction measure depends on human behaviour.

Regular review and checking of the effectiveness of training can be necessary to ensure its long-term effectiveness. Training mainly has an impact on the ability of persons to avoid harm and can also reduce exposure and the probability of occurrence of a hazardous event.

8.5.3 Consideration of personal protective equipment

The information for use can provide guidance if any personal protective equipment should be used to protect persons from the hazards associated with the residual risk.

The reliability and maintenance of the personal protective equipment is very important for ensuring its long-term efficiency.

Personal protective equipment impacts the exposure and the ability of avoiding or limiting harm.

ISO/TR 14121-2:2012(E)

8.6 Standard operating procedures

The supplier should give details of any standard operating procedures (SOP) that the user should adopt to operate or maintain the machine in the instruction handbook. These procedures could include the following:

- work planning and organization;
- clarification/harmonization of tasks, authority, responsibilities;
- supervision;
- lock-out procedures;
- safe operating methods and procedures.

NOTE When residual risk reduction is provided by organizational measures, it is important to ensure, as far as possible, that they are followed and cannot be circumvented.

9 Risk assessment iteration

NOTE See ISO 12100:2010, 5.6.2

Once protective/risk reduction measures have been incorporated, in order to reduce risk, all stages of risk assessment should be repeated to check whether

- a) there are any changes to the limits of the machinery;
- b) any new hazards or hazardous situations have been introduced;
- c) risks from any existing hazardous situations have been increased;
- d) the protective/risk reduction measures reduce risk sufficiently;
- e) any additional protective/risk reduction measures are required;
- f) risk reduction objectives have been achieved.

Risk assessment iteration should be carried out taking into account the reliability, ease of use, possibility of defeating or circumventing the protective/risk reduction measures, and the ability to maintain them in accordance with ISO 12100:2010, 5.5.3.5, 5.5.3.6 and 5.5.3.7.

10 Documentation of risk assessment

NOTE See ISO 12100:2010, Clause 7.

Written records of the risk assessment should be made and retained. These should not be confused with the information for use of the machine provided by the supplier to the user. However, the risk assessment documentation can be a useful reference when writing the information for use.

It is important that the process be properly documented in order to allow examination of decisions at a later date. This documentation should record the results of the assessment in accordance with ISO 12100:2010, Clause 7. It should include a description of the method(s) and tool(s) that have been used to conduct the assessment and the results. Figures (photographs, diagrams, drawings etc.) of the machinery including hazard zones, hazards and applied protective/risk reduction measures are useful.

When documenting protective/risk reduction measures that have been implemented, a description of those measures that are needed to ensure that they remain effective should be included (for example, maintenance, periodic user inspection).

Annex A (informative)

Example application of the process of risk assessment and risk reduction

A.1 General

The aim of this example is to show, in a non-exhaustive way, an application of the process of the risk assessment and risk reduction during the design of a single-spindle vertical moulding machine, in accordance with the general principles set out in ISO 12100.

This example does not seek to embrace the complete design of this type of machine, nor to be a model to follow. It represents only an attempt to present sufficient information so that the reader has an overall idea of a possible way of applying the principles set out in ISO 12100.

A.2 and A.3 have been applied taking into account the whole life cycle of the machine. However, from A.4 the example is limited exclusively to the phase of use and, in particular to the setting and operation of the machine.

A.2 Information for the risk assessment

NOTE See ISO 12100:2010, 5.2.

A.2.1 Initial specifications of the machine

A.2.1.1 General

The machine is intended to be designed according to the initial specifications given in A.2.1.2 to A.2.1.4.

A.2.1.2 Basic specifications

The machine covered by this example is a stationary single-spindle vertical moulding machine

- for indoor use,
- used by one operator,
- hand-fed, and
- electrically supplied.

A.2.1.3 Work to be performed with the machine

The intended use of the machine is to modify the profile of square or rectangular cross-section wooden pieces and analogous materials (cork, chip board, fibre board and hard plastic) by moulding, rebating and grooving.

The work to be performed with this machine is as follows:

— Straight work

This is the shaping of a workpiece with one face in contact with the table and a second with the fence, where the work starts at one end of the workpiece and continues through to the other end.

— Stopped straight work

This is the machining of only a part of the workpiece length.

ISO/TR 14121-2:2012(E)

— Curved work

This is the machining of a curve on a workpiece by having one side in contact with the table (or, if held in a jig, with the jig in contact with the table) and the other in contact with the vertical reference of a steady or ball ring guide when using a jig.

The machine is not intended for tenoning.

Only wood products clear of foreign objects (for example, nails) are intended to be processed.

The machine is not intended to work metallic materials.

The work is to be performed with standard cutting tools that are available in the market.

The machine will be provided with different spindle speeds in order to use a wide range of tools and to suit most materials.

The spindle height will be adjustable to enable setting of the cutting tool height.

All adjustable parts of the machine (for example, tool change, speed change) will be manually operated.

A.2.1.4 Description of the machine-concept

NOTE See Figure A.1

The milling process is performed by a cutter tool mounted on a vertical spindle. The spindle turns in only one direction and can be raised and lowered through a hand-wheel (spindle unit). The spindle can turn at four different speeds (see spindle speeds below), driven by an electric motor and a set of pulleys (driver unit).

The spindle unit and the driver unit are anchored to a cast iron table that rests on a steel cabinet. Both the table and the cabinet provide good support for the workpiece and are of a height ensuring an ergonomically upright posture.

In order to guide the workpiece during the work, the machine incorporates appropriate guides.

The spindle speed is manually selected by changing a transmission belt from one pulley to another.

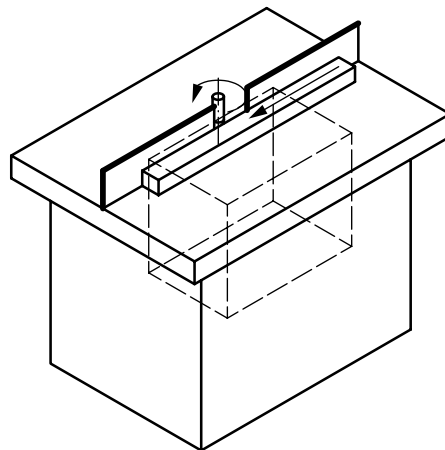


Figure A.1 — Machine concept

A.2.2 Experience of use

According to statistical information, most reported accidents happen by contact with the tool. This contact is due to workpiece kickback and tool snatching, mainly during machining straight work. Common causes of accidents on this kind of machine include:

- not using a guard;
- using an inappropriate guard;
- not using guide rails (false fences), pressure pads, jigs, templates or end stops.

Other less frequent accidents are impacts due to kickback of the workpiece, the ejection of chips or parts of the tools or machine, or fire from wood dust/chips.

Damage to health can result from emissions or materials used, such as:

- noise generated at the milling process;
- wood dust;
- fumes or substances released while milling impregnated or treated (preserved) wood.

A.2.3 Regulations, normative references and technical sheets

The following standards have been initially considered: ISO 12100, ISO 13849-1, ISO 13849-2, ISO 13852, ISO 14118, ISO 14119, ISO 14120, IEC 60204-1 as well as EN 614-1 on ergonomics and ISO/TR 11688-1 on acoustics, etc.

Furthermore, technical sheets about this kind of machine issued by national health and safety institutions INRS, HSE, BG, and OSHA¹⁾ have been consulted.

NOTE Other documents that should have been taken into account are the regional or national applicable regulations and machine specific standards such as EN 847-1 and EN 848-1; however, for the objectives of this example they have not been used.

A.2.4 Preliminary design of the machine

With consideration being given to all the above information, the following technical specifications have been made:

- electrical supply (frequency, number of phases, nominal voltage): 50 Hz/3/400 V/PE;
- power supply earthing: TT system;
- motor power: 4 kW;
- table dimensions: 1250 mm × 700 mm;
- spindle characteristics: diameter: 50 mm; useful length: 180 mm; range of vertical adjustment (manually adjustable): 200 mm;
- spindle speeds (manual change of the position of the belt on the pulleys): 3 000 min⁻¹, 4 500 min⁻¹, 6 000 min⁻¹ and 7 500 min⁻¹; the selected speed depending on the material, diameter and height of the tool;
- tool diameter: for example, from 120 mm to 220 mm (maximum diameter of the tool).

NOTE Other specifications not relevant to the example (surface finishing of the table, flatness, run out of the spindle, etc.) have been omitted.

Consequently, a preliminary design of the machine has been drawn up as follows (see Figures A.2 and A.3).

1) *Institut national de recherche et de sécurité* (France), Health and Safety Executive (UK), *Berufsgenossenschaften* (Germany), Occupational Safety and Health Administration (USA).

ISO/TR 14121-2:2012(E)

The machine consists of a steel cabinet and a cast iron table that rests on the cabinet. Inside the cabinet there are an actuator (electric motor), the transmission system and the spindle unit (mechanism for the vertical movement and rotation of the spindle).

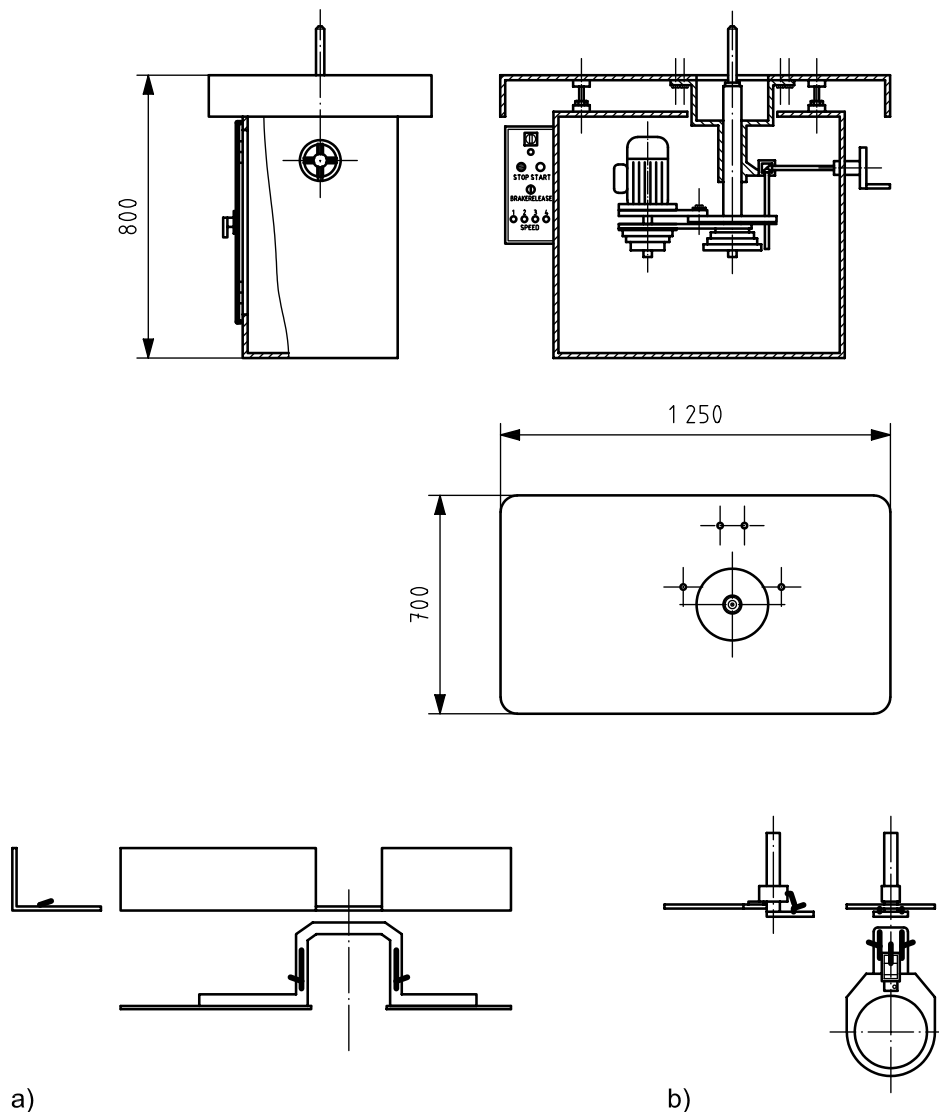
The cabinet is provided with an opening for access to the transmission system during speed changing. This opening is closed with a door.

The table is used as a horizontal reference for the piece of wood to be processed and has a hole through which the spindle passes. The machine is equipped with guides to perform the different operations.

The spindle has been sized to enable the use of most standard cutting tools available in the market.

The actuator is an electrical asynchronous motor of three phases, 400 V and with a power of 4 kW. The motor incorporates a brake that acts every time that a stop command is given for quickly stopping the movement of the spindle. The brake can be released when some operations are performed (for example, speed changing). This motor transmits the power to the spindle through the pulleys and a trapezoidal belt.

Dimensions in millimetres



Key

- a) Guide for straight work
- b) Guide for curved work

Figure A.2 — Preliminary design drawings

On the motor and on the spindle there are two sets of four pulleys that provide four different working speeds. A working speed is selected by manually changing the belt from one pulley to another one. The motor and the pulleys associated with it can be easily moved by means of a lever (without the need to use a tool) in order to change the belt. A mechanism detects the position of the belt and indicates the selected speed through a set of lamps.

The vertical adjustment of the spindle is achieved by a rack and pinion mechanism. It has no accessible moving elements.

The control circuit is in a cabinet placed in front of the machine. It includes basically the control actuators (start and stop push buttons, etc.), lamps to indicate the selected speed, and the control and power circuits (electrical protective devices, contactors, etc.). All the electrical components (conductors and cables, control devices, motor, electrical equipment protective devices, etc.) are selected, assembled and combined according to IEC 60204-1. See Figure A.3 for the electric circuit diagram.

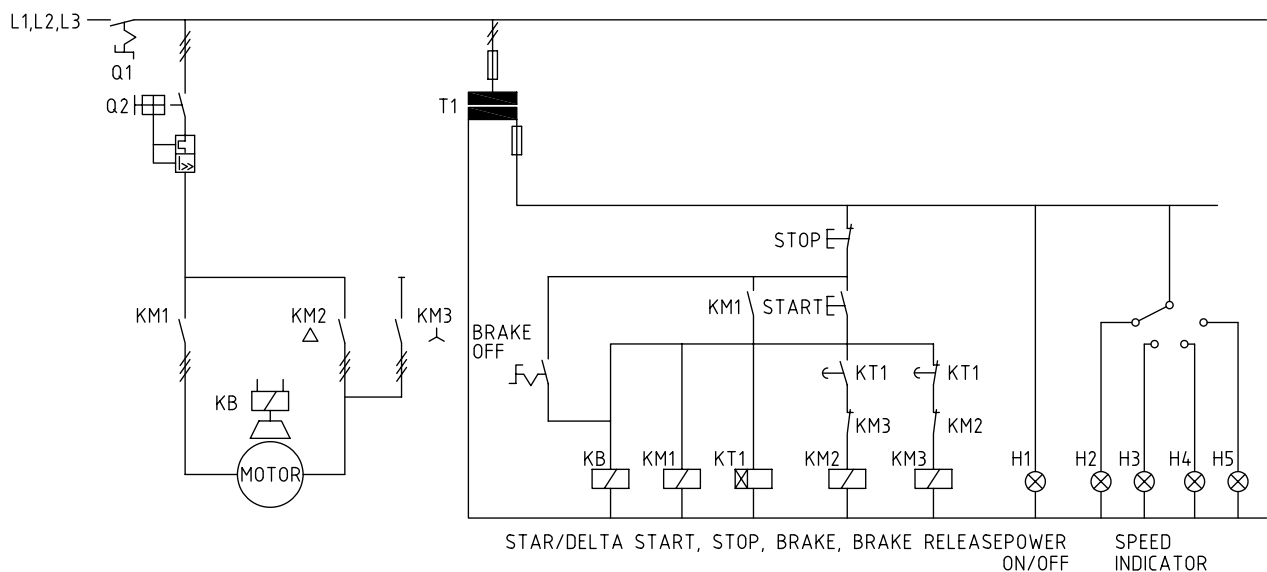


Figure A.3 — Preliminary design of the electric circuit

A.3 Determination of the limits of the machinery

A.3.1 Description of the various phases of the whole life cycle of the machinery

The phases of the life cycle of this machinery considered significant in this example are the following.

— Transport

All transport tasks that may be performed by the machine user, in this case internal transport, removing, etc.

— Assembly, installation and commissioning

Removal of transport-related parts (for example, covers, fixing bolts), fixing the machine to the floor; connection to the electric power supply; checking of proper installation (correct direction of rotation of the tool), checking the functioning of all controls and the ability of the machine to perform its required operations.

— Setting

Changing a tool on the spindle; mounting and adjusting of guides; changing the spindle speed and trials.

— Operation

Hand-fed milling.

ISO/TR 14121-2:2012(E)

— **Cleaning, maintenance**

Greasing of rotating and transmission elements, changing of belts, cleaning of internal parts of the machine.

— **Fault finding/trouble shooting**

Operations in case of malfunction of the machine and after the actuation of protective devices.

— **Decommissioning, dismantling**

Disposal by the user of all parts of the machine.

A.3.2 Use limits

A.3.2.1 Intended use

The machine is intended for modifying the profile of square or rectangular cross-section wooden pieces and analogous materials (cork, chip board, fibre board and hard plastic) by moulding, rebating and grooving.

The work to be performed with this machine is as follows:

- straight work;
- stopped straight work;
- curved work.

The machine is intended only for professional use.

The machine is intended to be used by a person with knowledge and experience in the use of this type of machine, without limitations in the physical abilities of the upper limbs and no uncorrected visual impairment.

The machine is intended to be operated with the operator in an upright standing position. The operator holds and moves the workpiece during the milling process.

The machine is intended to be maintained by a skilled/qualified operator following the instructions given in the operating instruction manual.

The spindle can turn at four different speeds. The speed is manually selected by changing the position of the belt.

Only the use of appropriate and standardized cutting tools is considered.

A.3.2.2 Reasonably foreseeable misuse

The reasonably foreseeable misuse taken into account is as follows:

- processing materials other than those intended by the designer (see A.2.1.3), such as rubber, stone, metals or wood products containing of foreign objects;
- processing products with unsuitable cross-sections (cylindrical, elliptical);
- tenoning;
- use of inappropriate tooling;
- replacing components or spare parts with ones other than those specified;
- use of the machine by untrained operators.

A.3.3 Space limits

The machine is intended for use in an indoor industrial environment.

For installation and use, a flat area of at least 3 000 mm × 3 000 mm, free of obstacles, columns, etc., is required.

The machine is intended to be connected by the user to a dust extraction system.

The machine is not intended to be used at locations having an explosion or fire hazard.

The machine is intended to be connected to an electrical power supply of 400 V, three phases + PE.

A.3.4 Time limits

The machine is intended for an operational life of 20 000 h.

The machine has some wear parts that need to be checked and/or replaced as follows:

- belts: verify state and tension every 500 h;
- brake: verify that the stopping time is less than 10 s, every day;
- tools: verify state and sharpen, according to the tool manufacturer's instructions.

Cleaning of visible and reachable surfaces, including moveable parts and guiding surfaces, is to be carried out every shift.

A general cleaning of the machine is to be carried out every six months.

A.4 Hazard identification

A.4.1 Extent of the system analysed

As already set out in A.1, hazard identification is limited in this example to the phase of use and, in particular, to the setting and operation of the machine.

A.4.2 Tasks to be performed

During setting of the machine, the following tasks are to be performed:

- changing the tool on the stopped spindle;
- mounting and adjusting the appropriate guide (for straight work or curved work);
- changing the spindle speed;
- trials, feeding/machining workpieces to check whether the cutting depth, the adjusted spindle height, etc., are appropriate or, if it is necessary, to re-adjust the tool height or the fence position.

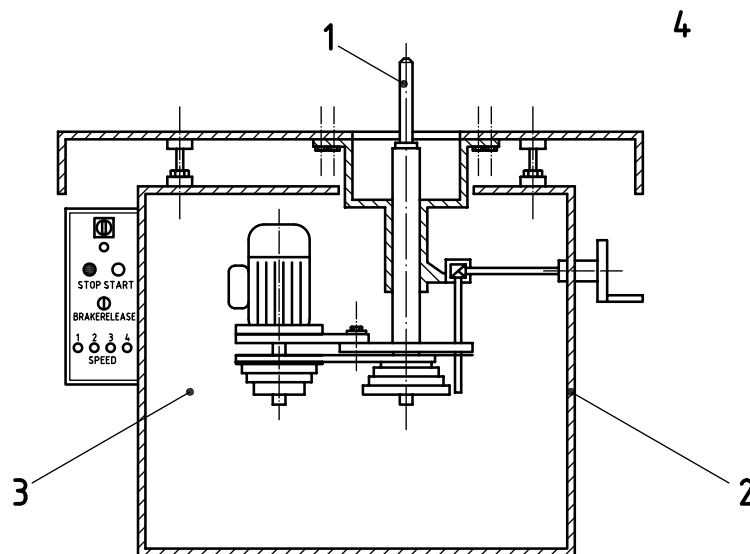
During machine operation the following task is performed: milling or moulding the workpiece.

NOTE All adjustment tasks have been considered under the setting of the machine, so operation only deals with the milling process (manually feeding of the workpiece and holding it during the machining process).

A.4.3 Relevant hazards and accident scenarios

The hazard zones are defined as given in Figure A.4.

ISO/TR 14121-2:2012(E)



Key

- 1 working zone (zone 1)
- 2 machine frame (zone 2)
- 3 transmission zone (zone 3)
- 4 machine surroundings (zone 4)

NOTE See Table A.1 for hazard identification.

Figure A.4 — Hazard zones

A.5 Risk estimation, risk evaluation and risk reduction

A.5.1 Risk estimation method

For risk estimation, the risk graph method as described in 6.3 has been used.

As this method is not very appropriate to estimate risks related with health or ergonomic hazards, nor fire hazards, the following assumptions have been applied for these risks:

— Health and ergonomic hazards

Health risks mainly depend on the type of toxic (hazardous properties), the concentration and the duration of exposure. Similarly, ergonomic risks are estimated considering factors such as repetitiveness, force, posture, movements, duration and time to recovery, which might be distributed also under the parameters of severity and exposure.

Thus for these types of risk it seems that the estimation of the probability of occurrence of a hazardous event and the possibility of avoidance has little sense.

For this reason, from the method above, only severity and exposure have been considered, and for the probability of occurrence of a hazardous event and the possibility of avoidance, the most conservative value has been taken/assumed.

— Fire hazards

The risk of fire depends on the presence of combustible substances or materials, the oxygen and the ignition sources. The parameters of severity, exposure and probability of the hazardous event can be associated respectively to the size and strength of the potential fire, the duration of the hazardous situation and the probability of the machine catching fire. Where there is a possibility of avoidance, it appears difficult to make a real estimation so the most conservative value has been assumed.

Despite the rough estimation of the risk index, if after application of well-tried protective/risk reduction measures it is considered that the risk is adequately reduced, no further actions will be required. Otherwise, a specific risk estimation method should be used.

A.5.2 Risk estimation, Risk evaluation and Risk reduction

See Table A.2 for risk estimation, risk evaluation and risk reduction.

The abbreviations used in Table A.2 are as follows:

S	Severity	F	Exposure	O	Probability of occurrence of the hazardous event	A	Possibility of avoidance
S1	slight	F1	seldom	O1	very low	A1	possible
S2	serious	F2	frequent	O2	medium	A2	impossible
				O3	high		
RI	risk index: from 1 (min.) to 6 (max.)						

ISO/TR 14121-2:2012(E)

Table A.1 —Hazard identification (for illustration only)

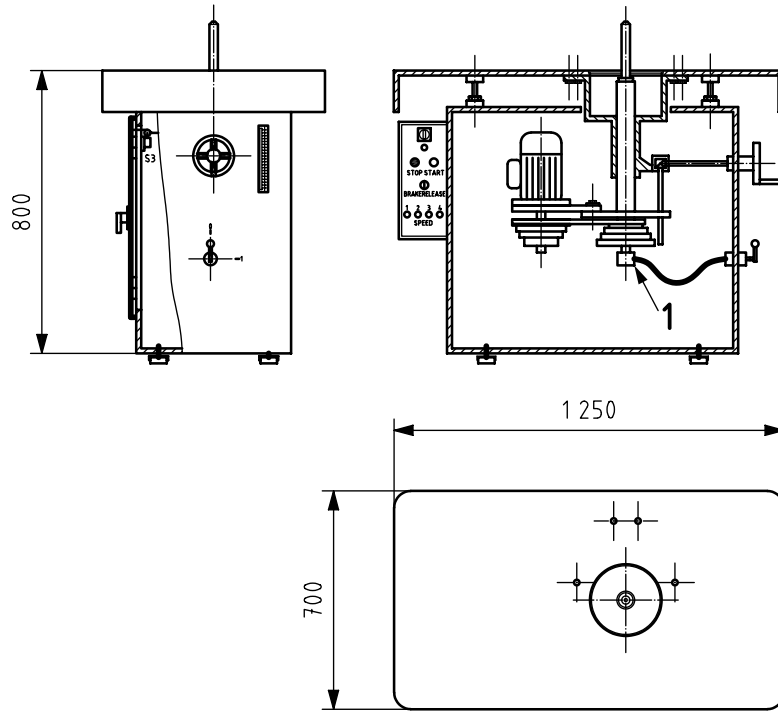
Risk assessment (hazard identification)									
Machine		Vertical spindle moulding machine							
Sources		Specifications, preliminary design							
Extent		Use phase: setting and operation							
Method		Checklists: ISO 12100:2010, Annex B							
Ref. no.		Life cycle	Task	Hazard zone	Hazard	Accident scenario		Hazardous event	Ref. no.
						Hazardous situation			
2	Use phase: setting		Changing tools	Working zone	Cutting fingers or hands at sharp tool edges	Working near/with the tool (fastening/unfastening)		Contact with sharp edges due to spindle rotation caused by fastening/unfastening force	2
3								Contact with sharp edges due to loss of control, tool slipping by use of unsuitable hand tools	3
9				Transmission zone	Parts which have become live under fault conditions	Work at a machine with exposed live parts		Indirect contact	9
16			Trials	Working zone and machine surrounding	Impact by ejected tools, parts of the machine (for example, guide)	Operator and other people exposed to ejection of parts (adjusting the spindle height, feeding workpieces)		Break-up of the tool or parts of the guide (caused by an incorrect adjustment of the spindle height, an undue adjustment of the guide, a workpiece inadequate by its material, size or shape, an inadequate tool, an inadequate speed of the tool, inadequate fastening etc.)	16
18	Use phase: operation		Milling	Working zone	Cutting of fingers or hands, entanglement by rotating elements (tool)	Working near the tool (feeding workpieces)		Contact with moving parts due to loss of workpiece control (defective workpiece material, feeding the workpiece in the same direction as the rotation of the tool - climb cutting -, inadequate workpiece feeding speed etc.)	18
28					Fire	Operator and other people exposed		Ignition of dust/chips due to electrical sources	28

Table A.2 — Risk assessment (risk estimation and risk evaluation) and risk reduction (for illustration only)

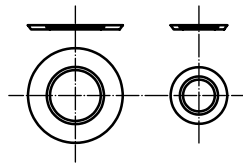
Machine		Risk assessment (risk estimation and risk evaluation) and risk reduction										
Vertical spindle moulding machine		Analyst		<Name>								
Sources		Current version		2.0								
Extent		Date		September 2010								
Method		Page		1								
Ref. no.	Risk estimation (initial risk)				Risk reduction Protective/risk reduction measures	Risk estimation (after risk reduction)				Further risk reduction required	Ref. no.	
	S	F	O	A		RI	S	F	O			A
2	1	1	3	2	2	1	1	1	2	1	No	2
3	1	1	3	2	2	1	1	1	2	1	No	3
9	2	1	2	2	3	1	1	1	1	2	No	9
16	2	1	2	2	3	2	1	1	2	2	No	16
18	2	2	2	2	5	2	1	1	1	2	Yes (see Note)	18
28	1	2	2	1	2	1	2	1	1	1	No	28

NOTE In reference number 18 a demountable power feed unit is proposed as a protective/risk reduction measure. The iterative process of the risk assessment would require, taking into account the instructions given by its manufacturer, a further consideration of the potential hazards generated by this unit during the whole life cycle of the machine and, if necessary the taking of new risk reduction measures (for example, appropriate interlocking between the control functions of the spindle unit and the power feed unit, provision of an emergency stop control, appropriate adjustment).

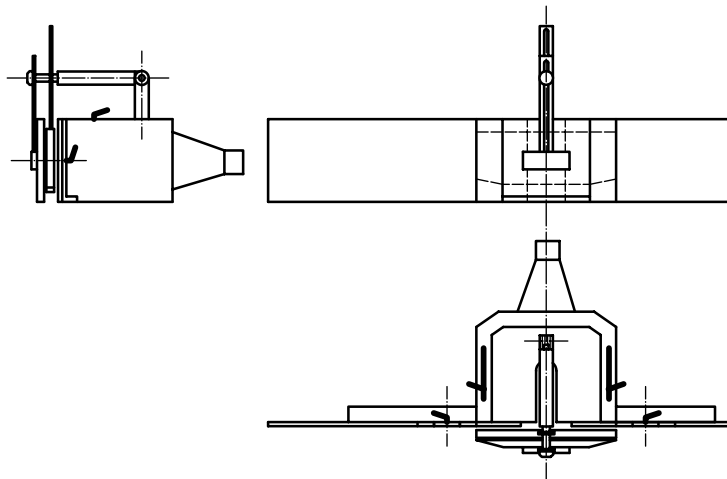
ISO/TR 14121-2:2012(E)



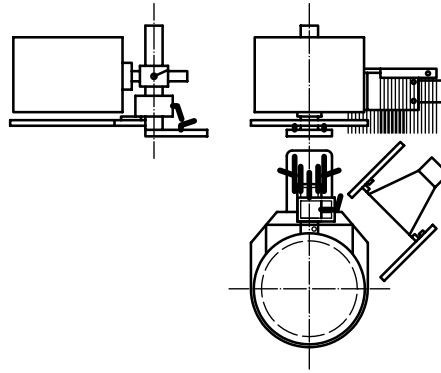
a) Frame of the machine and internal parts



b) Rings for reducing table gaps



c) Guide with guard for straight work



d) Guide with guard for curved work

Figure A.5 — Final design of the machine

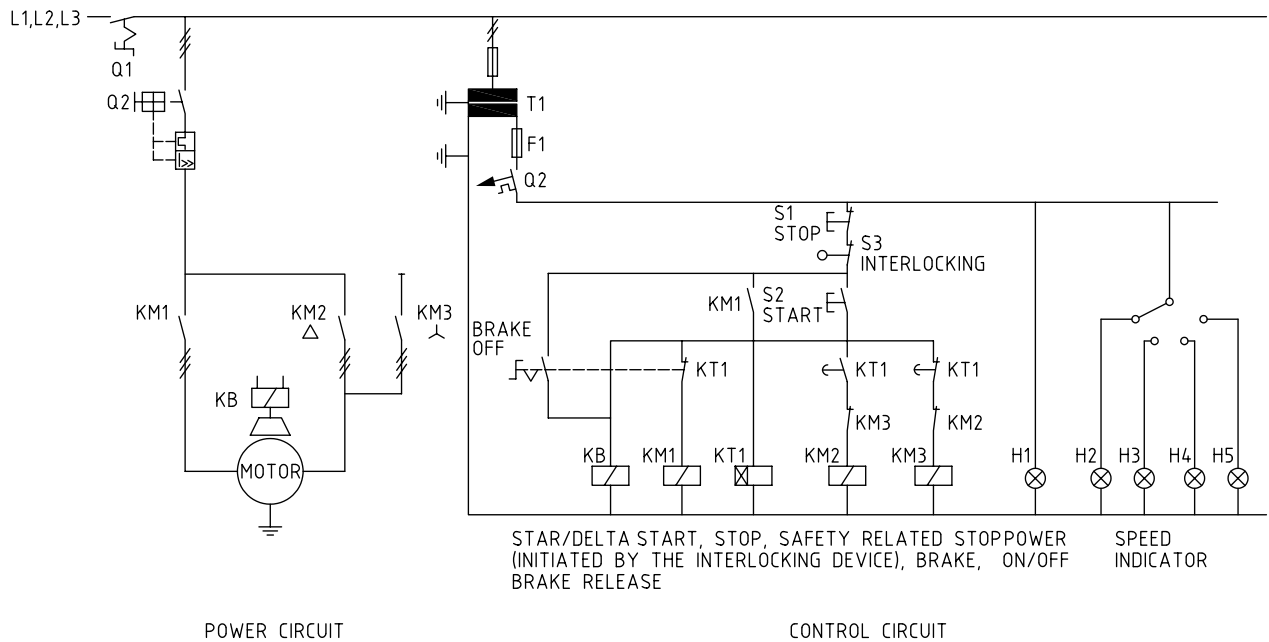


Figure A.6 — Final electrical circuit

A.6 Blank forms

See Table A.3 for a blank form example for hazard identification and Table A.4 for a blank form example for the risk graph method.

ISO/TR 14121-2:2012(E)

Table A.3 — Example of a blank form for hazard identification

Machine (identification)		Hazard identification				
Sources (for example, preliminary design documentation, technical file, construction file)		Method/tool		Ref. no.		
		Analyst	Current version			
Extent (for example, phase of the life cycle, part/function of the machine)		Date		Ref. no.		
Ref. no.	Hazard zone	Task / Operation (ISO 12100:2010, Table B.3)	Hazard (ISO 12100:2010, Table B.1)	Accident scenario Hazardous situation (ISO 12100:2010, Table B.3)	Hazardous event (ISO 12100:2010, Table B.4)	Ref. no.
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Table A.4 — Example of a risk graph blank form

Activity		Initial risk analysis / Risk analysis after risk reduction				Risk estimation				
		Hazardous conditions		Possible harm		Risk index calculation		Risk index (1 to 6)		
No.	Activity	Hazard	Hazardous situation	Hazardous event	Possible harm	Severity (S1/S2)	Frequency/Exposure (F1/F2)	Probability of occurrence (O1/O2/O3)	Possibility of avoidance (A1/A2)	Risk index (1 to 6)
1										
2										
3										
4										
5										
6										

Bibliography

- [1] ISO 3691 (all parts), *Industrial trucks — Safety requirements and verification*
- [2] ISO 10218, *Manipulating industrial robots — Safety*
- [3] ISO 11111 (all parts), *Textile machinery — Safety requirements*
- [4] ISO/TR 11688-1, *Acoustics — Recommended practice for the design of low-noise machinery and equipment — Part 1: Planning*
- [5] ISO 13732-1, *Ergonomics of the thermal environment — Methods for the assessment of human responses to contact with surfaces — Part 1: Hot surfaces*
- [6] ISO 13849-1, *Safety of machinery — Safety related parts of control systems — Part 1: General principles for design*
- [7] ISO 13849-2, *Safety of machinery — Safety related parts of control systems — Part 2: Validation*
- [8] ISO 13852, *Safety of machinery — Safety distances to prevent danger zones being reached by the upper limbs*
- [9] ISO 14118, *Safety of machinery — Prevention of unexpected start-up*
- [10] ISO 14119, *Safety of machinery — Interlocking devices associated with guards — Principles for the design and selection*
- [11] ISO 14120, *Safety of machinery — Guards — General requirements for the design and construction of fixed and movable guards*
- [12] IEC 60204-1, *Electrical equipment of industrial machines — Part 1: General requirements*
- [13] IEC 62061, *Safety of machinery — Functional safety of safety-related electrical, electronic and programmable electronic control systems*
- [14] EN 614-1, *Safety of machinery — Ergonomic design principles — Part 1: Terminology and general principles*
- [15] EN 847-1, *Tools for woodworking — Safety requirements — Part 1: Milling tools, circular saw blades*
- [16] EN 848-1, *Safety of woodworking machines — One side moulding machines with rotating tool — Part 1: Single spindle vertical moulding machines*
- [17] ANSI B11.0:2010, *Safety of machinery — General requirements and risk assessment*

ISO/TR 14121-2:2012(E)

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