Five Steps to Safe Machines

- Risk assessment
- Minimization
- Successful testing
- Documentation
- Validation in mechanical engineering

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As partner for all safety issues, we not only offer high-quality products and systems, but also competently help you to comply with international standards and regulations – with safety trainings, functional examples and certified products.

Competent support throughout the entire lifecycle
With our innovative and comprehensive safety technology product portfolio as well as competent support services, we offer substantial advantages – throughout all phases of the product lifecycle.
Risk assessment

- Risk assessment represents the first step towards safe machine concepts.
- The 2006/42/EC Machinery Directive calls for mandatory risk assessment for the construction or modification of a machine or machine part.
- Risk assessment is to be implemented and documented by competent qualified personnel.

Description of the machine

Excerpt from the machine description:
- Intended use
- Use limits
- User groups
- Time limits
- Space limits

Identification of hazards

Systematic identification of all reasonably foreseeable hazards across all lifecycle phases and operating modes of the machine.

Evaluation of risks

- Description and evaluation of the machine and the risks posed by the machine.
- The risk assessment result serves as the basis of the safety concept for risk minimization.
- An accusation of negligence in case of damage can be rejected on the basis of a correct risk assessment.
The target of risk reduction lies in the attainment of an acceptable residual risk. For this purpose, suitable safety measures are defined on the basis of the 3-step method by a team from the respective specialist departments. The architecture of the safety functions is defined and the overall safety concept is implemented and commissioned in the further steps.

### Definition and evaluation of safety measures (3-step method)

1. **Safe design**
   - Appropriate risk reduction?
     - Yes
     - No

2. **Technical measures**
   - Appropriate risk reduction?
     - Yes
     - No

3. **User information on residual risks**
   - Appropriate risk reduction?
     - Yes
     - No

**Renewed risk assessment**

### Definition of technical protective measures as safety functions

- **Enclosure**
  - Avoidance of direct contact by means of enclosure

- **Protective door**
  - Glazed door facilitates monitoring of the process and access to the machine

- **Position switch**
  - Door monitoring

- **E-STOP commanding device**
  - The operator panel is supplemented by an E-STOP commanding device

### Specification of safety requirements in accordance with ISO 13849-1 (PL) or IEC 62061 (SIL)

**Simplified representation:** Reduction of...

- **...lowest risk**
  - Avoidable minor injury
  - Lowest probability of occurrence
    - PL a

- **...low risk**
  - Minor injury
  - Low probability of occurrence
    - PL b, PL c, SIL 1

- **...average risk**
  - Minor to severe injury
  - Average probability of occurrence
    - PL d, SIL 2

- **...high risk**
  - Severe injury or death
  - High probability of occurrence
    - PL e, SIL 3

The actually required safety level can only be determined by means of standard-specific specifications based on the risk graphs.
3 Implementation of technical protective measures

Component selection in accordance with the applied standard’s requirements.

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- The implemented design and technical measures have reduced the risk to such an extent that no further technical measures are required.
- The application of certified, state-of-the-art safety technology products eases the proof of the technical protective measure’s standard-compliant implementation.
- Further residual risks have to be pointed out through user information in the form of warning notes or within the scope of trainings.
Verification and validation form part of the safety proof.
In addition, conformity with the relevant standards has to be proven by means of a conformity evaluation procedure.
Subsequently, the declaration of conformity can be filled in and the CE mark can be attached.

**Documentation of measures**

The manufacturer prepares the technical documents as proof of conformity. The technical documents’ relevant contents are specified in Annex VII of the Machinery Directive.

**Validation**

Overall release of a machine in consideration of all verification points.

**Planning**

Preparation of a validation plan on the basis of which validation is carried out

**Analysis**

Theoretical examination of all safety functions

**Testing**

Practical examination of all safety functions

**Documentation**

Preparation of the documentation specified in the Machinery Directive

**Verification**

In case of damage, the manufacturer can verify that his machine’s design is compliant with the directive.
Compliance verification provides better protection against liability claims and accusations of negligence which may entail high claims for damages.
Directives and CE marking

CE marking has to be carried out in accordance with the Machinery Directive:

- Only with the specified type face
- Clearly visible, legible and permanently attached to the product

With the CE marking, the manufacturer confirms compliance with all relevant directives.
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