Kommission
Arbeitsschutz und
Normung

31

Ergonomics Guidelines for the Design of Medical Devices

VFA
Verein zur
Förderung
der Arbeitssicherheit
in Europa

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Table of Contents

This Report

The Commission for Occupational Health, Safety and Standardization (KAN) was founded in 1994 to assert German interests in OH&S matters, especially with regard to European standardization. KAN is composed of representatives of the social partners (employers, employees), the state (federal states and Laender), the Hauptverband der gewerblichen Berufsgenossenschaften (HVBG, Federation of institutions for statutory accident insurance and prevention) and the German Standards Institute (DIN). One of KAN's tasks is to pool the public interests in the field of occupational health and safety and to exert influence on current and future standardization projects by issuing comments on specific subjects.

KAN procures studies and expert opinions in order to analyze occupational health and safety aspects in standardization and to reveal deficiencies or erroneous developments in standardization work.

This study was based on the following task in hand:

Background

A collateral standard (IEC 60601-1-6 "Medical electrical equipment – Part 1: General requirements for safety – 6. Collateral Standard: Usability: Analysis, test and validation of human factors compatibility") relating to the basic safety standard for medical electrical equipment (IEC 60601-1 "Medical electrical equipment – Part 1: General requirements for safety") is currently[1] being drawn up. The collateral standard deals with fitness for purpose and thus with ergonomic aspects and user safety. The draft version of IEC 60601-1-6, dated 15 December 1999, makes the following statement concerning hazards for operators of medical electrical equipment:

"46.202.1. SAFETY HAZARDS for the OPERATOR

To reduce SAFETY HAZARDS for the OPERATOR of EQUIPMENT ergonomic principles shall be taken into account.

To guide the application of HUMAN FACTORS ENGINEERING principles, potential SAFETY HAZARDS for the OPERATOR of EQUIPMENT as mentioned in IEC/ISO/DIS 14971 /Annex D) have been supplied in the form of a checklist in ANNEX 2 of this collateral standard. Reference is made to essential requirements (in terms of achievable values or input in the design process) defined by ergonomic standards."

In the mirror committee (DKE/AK 811.0.4), KAN proposed that the approach taken in the ergonomics guidelines for machinery design (prEN 13861 Safety of machinery - Guidance for the application of ergonomics standards in the design of machinery) be used for the design of medical electrical equipment too and put forward a suggestion for the checklist to be included in the annex (mentioned in the quote above) to draft standard IEC 60601-1-6. The German mirror committee concluded that there were two points requiring clarification in order for this to be done:

[1] In this context, "currently" means 2000, the year in which the invitation to bid for the study was published.

- the ergonomics guidelines for the machinery sector are based on the hazards specified in EN 1050. Other specific hazards might be relevant for the design of medical devices; and
- for the most part, the ergonomics guidelines for the machinery sector list European standards, draft standards and work items relating to ergonomic aspects. It is doubtful whether these can be referred to in an international IEC standard.

These were the reasons which led KAN to commission a study with the objective described below.

Objective of the Study

The aim of the study was to prepare guidelines, based on a hazard analysis and risk estimation, on systematic consideration of the relevant ergonomic aspects when designing medical devices. To this end, the goal was to adapt the ergonomics guidelines developed for machinery design (prEN 13861) to the special requirements of medical-device design.

The specific project tasks were:

- preparation of guidelines on systematic consideration of the relevant ergonomic aspects when designing medical devices (unlike with the machinery sector, the standardization is carried out at the international level by IEC; according to ISO/IEC 14971, medical devices are subject to special hazards). The following questions had to be answered in this context:
  a) Which of the hazards listed in the ergonomics guidelines for the machinery sector are also of relevance for users of medical devices?
  b) Are there – e.g. in ISO/DIS 14971 – other user hazards specific to medical devices which can be caused if ergonomic principles are not observed but which have so far not been documented?
- proposals for content for an annex to draft standard IEC 60601-1-6 which is being prepared by IEC TC/62A (WG 5); and
- development of arguments to be presented by KAN in its comments concerning the potential hazard for users as a result of ergonomic principles not being observed.

KAN wishes to thank the authors for conducting the project and submitting the report. Thanks also go to the following experts for their supervision and support during the evaluation of the study:

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KAN approved the following study and the recommendations in May 2003.

Summary of the Study

Legal Framework

On the European single market, directives 90/385/EEC (Active implantable medical devices), 93/42/EEC (Medical devices) and 98/79/EC (In-vitro diagnostic medical devices), which are based on Article 95 of the EC Treaty (previously Article 100a), specify the characteristics of medial devices[2]. The essential requirements in these European product directives are intended to ensure "the health and necessary protection of patients, *users* [authors' italics] and third parties" (Section 1 of the German Medical Devices Act).

For the purposes of occupational health and safety, the *user's* health and safety are of primary concern in the design of medical devices. Users of medical devices include, for example, nursing staff and doctors but also service technicians. The patient can also be the user if he or she uses a medical device themselves. A key aspect for users' health and safety is ergonomic product design.

The legislation explicitly stipulates that medical devices to be placed on the market must comply with harmonized standards (Sections 8 (1) and 3 (18) of the Medical Devices Act). As well as safety requirements, standards can also include guidance on ergonomic design. Thus, standards should help designers of medical devices by showing them how they can prevent hazards to patients and users due to ergonomic principles not being observed.

Standardization in the Field of Medical-Device Design

The basic standards for medical devices are primarily drawn up at the international level. In this work, ISO/IEC follow a risk-management concept. This type of concept is defined as "systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk" (DIN EN ISO 14971 "Medical devices – Application of risk management to medical devices").

The basic standard regarding safety of medical electrical equipment is IEC 60601-1 "Medical electrical equipment - Part 1: General requirements for safety". This standard does not explicitly deal with the ergonomics of medical devices or the hazard to the user due to ergonomic principles not being observed. There are no other basic standards specifically concerned with the ergonomics of medical devices.

Draft standard CD IEC 60601-1-6 "Medical electrical equipment - Part 1-6: General requirements for safety – Collateral standard: Usability" is the first to deal with medical devices' fitness for purpose.

The work already done in the area of machinery safety can serve as a basis for listing aspects which should be taken into account in ergonomic design of medical

[2] Medical devices are predominantly intended for medical purposes and achieve their principal effect in or on the human body and not – in contrast to drugs – by pharmacological means. The exact definition can be found in Section 3 of the Act on Medical Devices (which can be viewed at http://bundesrecht.juris.de/bundesrecht/mpg) and in extracts thereof in Chapter 1.1 of this report.

devices. The guidelines (prEN 13861 Safety of machinery - Guidance for the application of ergonomics standards in the design of machinery) developed in this area are particularly intended as an aid to designers on how to give more consideration to ergonomic aspects when designing machinery. Taking these guidelines as the basis, a similar aid, tailored to medical electrical equipment, should be developed.

Research Findings

Deficits in the consideration awarded to ergonomic principles when designing medical electrical equipment devices often turn out to be deficits in fitness for purpose. The term "fitness for purpose" describes the extent to which a medical device is suited to the task, use, user's anatomy, expectations and abilities and his or her surroundings. In the US, fitness for purpose is already used as a criterion for approving new medical devices.

The risk-management concept presented in EN ISO 14971 covers the question of whether risks exist because of deficient fitness for purpose but does not provide for any specific risk-control measures. Consequently, is does not call for ergonomic principles to be taken into consideration when designing products either. It is not until the risk-assessment step that measures are taken to check whether a relevant hazard demands special (counter) measures on the part of the designer in order to eliminate or reduce the risk. If it does, the risk-assessment stage concludes by designating the hazard a "significant hazard".

The authors of these ergonomic guidelines for medical devices were asked to divide hazards resulting from ergonomic principles being neglected into relevant (theoretical) and significant (real) hazards. However, it proved difficult to compile a list of significant hazards. A field survey and the feedback from the parties involved in the KAN study illustrated that only very few injuries or near-misses involving medical devices were reported by the users concerned. In addition, incidents with ergonomic causes do not have to be reported and neglect of ergonomic principles is more likely to lead to harm of a long-term nature. Thus, the causal relationship between the incident and the harm is not obvious and the incident is not reported.

This report provides the following reference tools and aids for designers and developers of medical devices:

- a checklist, based on DIN EN ISO 14971, which helps the designer to identify occupational health and safety hazards and general safety-critical conditions of use;
- a table, based on EN 1050, with which to determine the hazards which are caused by ergonomic principles being neglected in product design. The comparisons with the contents of standards in the field of medical devices (EN IEC 60601-1 and EN ISO 14971) are intended to ensure that all hazards of relevance to the risk-management process are included;
- a list with brief details of the contents of selected ergonomics standards, intended to help designers, after they have analyzed the hazards, to design medical devices in an ergonomic manner.

Conclusion

A number of medical devices are produced by small and medium-sized companies which often do not have special departments responsible for managing quality and keeping abreast of new technical rules. These guidelines aim to help those target groups, in particular, so that they do not only take the common, obvious hazards related to medical devices (e.g. electrical hazards) into account, but also hazards due to ergonomic principles not being observed in the design.

Taking DIN EN ISO 14971 as their basis, these guidelines offer a clear introduction to the concepts and the system of risk analysis, evaluation and control for medical devices. During this study it became evident that there is presently not sufficient empirical data available on injuries or near-miss accidents from the user's point of view. It is therefore difficult, when conducting the risk-management process, to distinguish between significant and relevant hazards caused by ergonomic design principles not being taken into account.

The checklist, dealing with occupational health and safety aspects, is intended to draw attention to the fact that hazards to *users* of medical devices also have to be identified and considered. The guidelines also provide references to relevant standards for developers and designers, where they can discover what values, measuring methods and solutions can be of help for specific ergonomic issues.

Furthermore, the guidelines offer a sound foundation upon which to prepare practice-oriented instructions in the future.

Recommendations

Recommendations to KAN

- The authors request that the KAN secretariat produce an abridged version of the guidelines itself or have it produced by another party; the abridged version should offer practice-oriented, clear instructions particularly for manufacturers (developers, designers).
- The project team's report is to be published as a KAN report. When it is posted on the Internet, users should be able to choose between two versions (the abridged version for a compact overview and the long version for additional theoretical background information).
- KAN should use the guidelines as the basis for its comments concerning ergonomic design of medical devices.

Recommendations to DIN/DKE

The authors request that the DIN/DKE standards bodies examine whether the guidelines can be used as an informative annex to standard IEC 60601-1-6 ("MEDICAL ELECTRICAL EQUIPMENT – Part 1: General requirements for safety – 6. Collateral Standard: Usability") and whether the guidelines' contents can be incorporated into other standards concerning medical devices.

Recommendations to the Federal Institute for Drugs and Medical Devices (BfArM) and the Federal Institute for Occupational Safety and Health (BAuA)

The data on injuries involving medical devices available to the study's authors is currently not sufficient to be able to distinguish between relevant and significant hazards. The authors therefore ask BfArM and BAuA to launch a study to record the necessary data. Research should be done in healthcare institutions to identify injuries/near-miss accidents and long-term phenomena which have led or can lead to hazards for employees due to medical devices not being fit for their purpose. The related ergonomic factors should be analyzed and a risk evaluation carried out. The addition of the findings of such a study to these guidelines would be desirable.

Ergonomics Guidelines for the Design of Medical Devices

1 Introduction

1.1 Aim of these Guidelines

In the field of European standardization on "Safety of machinery", EN 13861 proposes "Guidance for the application of ergonomics standards in the design of machinery".

The aim of EN 13861 is to incite machinery manufacturers to ensure that their development and design work identifies and eliminates potential hazards to employees.

By bearing occupational health and safety (OH&S) and user safety in mind when creating their products, manufacturers also assist the employers in the enterprises where the products are used since the employers have to meet a series of requirements set forth in the German Occupational Health and Safety Act (ArbSchG).

The Act defines OH&S measures as:

"Measures aimed at preventing accidents at the workplace and work-related health risks, including human-friendly work-design measures" (Section 2 (1) of the German Occupational Health and Safety Act).

Applying "ergonomics standards" to machinery design is an excellent means of ensuring such *human-friendly design*. Taking ergonomic principles into account also increases the user's performance and improves the results of the work.

So far, there is no comparable approach with regard to the design of medical devices[3]. But it makes sense to take the experiences gained in the preparation of the document on guidance for the design of machinery and transfer them to the design of medical devices. Above all, ergonomics guidelines developed on this basis for medical devices should serve as an aid to "product standardizers" and manufacturers when considering and incorporating ergonomic aspects in product standards and product design.

Manufacturers of medical devices are only permitted to place medical devices on the market if there are no grounds for suspicion
“that the safety and health of patients, users or third persons could be compromised to a degree which exceeds tolerable limits according to medical scientific knowledge when properly operated, maintained and used in accordance with their intended purpose“ (Section 4 (1) (1) of the German Medical Devices Act)

[3] For a detailed definition of ‘medical products’, refer to Annex 5.

The legislation explicitly stipulates that medical devices to be placed on the market must comply with harmonized standards (Section 8 (1) of the German Medical Devices Act).

This compliance with harmonized standards is intended
“to ensure adequate health protection of patients, users and other persons” (Section 1 of the German Medical Devices Act).

In contrast to the Medical Devices Act, the Occupational Health and Safety Act aims to protect employees only, i.e.

"...to safeguard and improve the safety and health of *employees* at the workplace by means of occupational health and safety measures" (Section 1 (1) of the Occupational Health and Safety Act).

The Occupational Health and Safety Act expressly refers to the following potential hazards (Section 5 (3)):

- the design of and the equipment at the workplace,
- physical, chemical and biological influences,
- the design, selection and use of work equipment, especially substances, machinery, equipment and installations and the way they are handled,
- the design of work and production procedures, workflows and working time and the relationship between them and
- inadequate training and instruction of employees.

In order to investigate whether such hazards exist for employees, employers must assess the working conditions. This investigation process is referred to as a "risk assessment" (Federal Ministry of Labour and Social Affairs, 1997[4]).

With prEN ISO/DIS 6385, international standards bodies have already agreed on a more comprehensive definition of ergonomics, as compared to the narrower view of "ergonomic principles" taken in German OH&S regulations, as follows:

"Ergonomics (or human factors) is the scientific discipline concerned with the understanding of the interactions among human and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimise human well-being and overall system performance."

Statistics from the United Kingdom prove that ergonomic aspects for medical-device design are highly significant – for the patient group too. With around 850,000 "incidents" per year in the United Kingdom, the Department of Health expects costs totalling £ 400 million as a result of "user errors". Urgent calls have been made for "more user-focussed medical equipment" in order to reduce the number of such incidents[5].

Thus, these Ergonomics Guidelines are primarily aimed at developers and designers of medical devices as well as the bodies responsible for product-specific

[4] Common principles for the drafting of guidelines for risk assessment according to the Employees’ Health and Safety Act; Gemeinsame Grundsätze zur Erstellung von Handlungshilfen für eine Gefährdungsbeurteiloung nach dem Arbeitsschutzgesetz (Common principles for the drafting of guidelines for risk assessment according to the Employees’ Health and Safety Act); Published by the Federal Ministry of Labour (BMA) on 1 September 1997 – IIIb 1-34502/4 (Federal Labour Gazette 11/97 p. 74).

[5] "The Ergonomist", June 2002, Number 348 and www-edc.eng.cam.ac.uk/medical

conformity assessment, including the "notified bodies", in accordance with Section 15 of the German Medical Devices Act.

1.2 Differences between the Standardization Concepts for Machinery Design and Medical-Device Design

The draft ergonomics standard on guidance for machinery design is based on a risk-assessment concept which aims to include "knowledge and experience of design, use, incidents, accidents and harm." The standard sets out to enable the designer "to assess the risks during all phases of the life cycle of the machinery" (EN 13861)[6]. The introduction makes explicit mention (with reference to EN 1050, Annex A) of hazards which can be caused by "neglecting ergonomic principles".

European standardization of machinery design by CEN is thus based on the concept of risk assessment as described in the requirements in the EU Machinery Directive (98/37/EC[7]).

By contrast, international standardization of medical devices by ISO/IEC follows the concept of a "risk-management process"[8]. This is defined as "systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk" (EN ISO 14971, 2.18).

However, the concept for the risk-management process fails to give an explicit reference to possible hazards caused by "neglecting ergonomic principles". The possible hazards listed in chapter 4 of these guidelines only cover part of the subject of neglect of ergonomic principles in connection with "man-machine communication"[9].

But chapter 4 also includes some hazards which can be considered to be connected with neglect of ergonomic principles, such as the ambient factors of heat and vibration or "insufficient visibility or audibility"[10]

This is also true of the concept of "human factors compatibility" advocated in CD IEC 60601-1-6[11], which so far primarily only deals with hazards to the patient due to use errors (46.202: Safety hazards to the patient) and provides examples of such hazards (Annex CCC). *User* protection is only discussed in general (46.202.2: Safety hazards to the operator or other persons) without giving any details in the Annex on how to meet the protection targets.

The appreciation of the importance of ergonomic principles in medical-device design is as yet under-developed. This becomes evident, too, in the provisions of

[6] "The designer of machinery is under an obligation to assess the risks during all phases of the life cycle of the machinery […]. This includes knowledge and experience of the design, use, incidents, accidents and harm."
[7] "Under the intended conditions of use, the discomfort, fatigue and psychological stress faced by the operator must be reduced to the minimum possible taking ergonomic principles into account" (98/37/EC, Annex I, 1.1.2)
[8] "The manufacturer shall establish and maintain a process for identifying hazards associated with a medical device, estimating and evaluating the associated risks, controlling these risks and monitoring the effectiveness of the control" (ISO 14971, 3.1)
[9] EN ISO 14971, Annex D.7: Inappropriate, inadequate or over-complicated user interface (man-machine communication)
[10] EN ISO 14971, Annex D.7: Insufficient visibility, audibility or tactility
[11] The document was published as a CDV (document 62A/422/CDV) in 2003 and was approved at the final voting. The document including all comments will be published as an FDIS in early 2004.

the German Medical Devices Act concerning the scope of responsibility, the prerequisites for placing medical devices on the market (Section 4 of the German Medical Devices Act)[12] and the obligation to report incidents as stipulated in the German Regulation for Medical-Device Operators[13]. Having said that, a change appears to be on its way with the German Regulation on the Recording and Evaluation of and Protection against Risks Posed by Medical Devices (Safety Plan for Medical Devices).

The user of a medical device is the person who handles and operates the device. A variety of groups can be considered users, including nursing staff, doctors and service technicians. Even the patient can be the user if he or she operates the device. It is obvious that the users of the various devices can differ significantly in terms of education, experience, age, health, mother tongue, etc. Naturally, this in turn means that the user-protection requirements can differ considerably too.

The authors of these "Ergonomics Guidelines for the Design of Medical Devices" have therefore focussed on the deficits in the consideration of "ergonomic principles“ which become evident in particular when comparing medical device standardization with machinery standardization. There are a number of medical devices for which EN ISO 14971 does not actually apply and Annex A4 of these guidelines is particularly intended for persons who are therefore not familiar with the standard.

1.3 Significance of Fitness for Purpose in the Design of Medical Devices

Deficits in the consideration awarded to "ergonomic principles" often turn out to be deficits in fitness for purpose.

The term "fitness for purpose" describes the extent to which a medical device is suited to the task, use, user's anatomy, expectations and abilities and his or her surroundings.

By analyzing operating errors which have caused incidents, one can see how significant fitness for purpose is. From 1984 to 1991, the Federal Food and Drug Administration (FDA) in the US recorded around 130,000 incident reports. The majority of those reports were concerned with hazards for the patient; however, hazards for the user were not explicitly excluded. The findings show that incorrect operation was at least a *contributing* factor in up to 60% of cases. The devices most often involved were blood glucose meters, infusion pumps and HF surgical equipment. This finding was one of the reasons why the FDA decided that new medical devices must be designed to be fit for purpose in order to be approved. This requirement for fitness for purpose is not only concerned with patient safety but also encompasses OH&S aspects.

[12] It is prohibited for medical devices to be placed on the market, installed, put into service, operated or used if there are grounds to suspect that the safety and health of patients, users or third persons could be compromised to a degree which exceeds tolerable limits according to medical scientific knowledge when properly operated, maintained and used in accordance with their intended purpose…

[13] The operator or user must advise the *Bundesinstitut für Arzneimittel und Medizinprodukte* (Federal Institute for Drugs and Medical Devices) immediately of

1. every malfunction,
2. every change in the characteristics or performance and
3. every case of improper labelling or instructions

of/for a medical device which resulted or could have resulted in the death or a serious decline in the health of a patient, an employee or another person.

Technical error is also becoming a less frequent cause of incidents outside the world of medicine. The "actual technology" poses a much lower level of risk today thanks to various safety standards. By contrast, operating errors due to deficient fitness for purpose have become the chief cause of incidents. Consequently, new devices and systems have for some time been being checked and optimized for fitness for purpose, particularly in aviation and major control rooms.

These measures are based on the realization that users are subject to a lower level of risk and rarely make mistakes if they are in a familiar environment with a small amount of distraction. Moreover, those few mistakes can be recognized and corrected quickly. However, if one or several factors change and the stress level increases, operators make considerably more mistakes. If a mistake is difficult to recognize or the user is busy with another activity, no correction is undertaken and an incident occurs which is nowadays then usually described, in an incorrectly simplified manner in analogy to "technical error", as "human error".

Analyses have shown that latent fitness-for-purpose defects are usually the cause of such human error and that it is they that actually make possible or even provoke excessive strain or incorrect operation.

Latent defects are created during the device-development stage but are usually not evident and do not have an impact until later in critical situations. Such latent defects are often the result of unclear presentation of operating status or unclear alarm signals or measurements, inappropriate linking of operating functions and displays, illogical operating sequences or a lack of functional transparency. Consequently, the aim of optimizing medical devices' fitness for purpose is to ensure that they can be operated effectively[14] and efficiently[15] even in unfavourable circumstances and, in particular, in typical stress situations. The UK's Health and Safety Executive, for instance, has reported an increased illness rate amongst nurses as a result of work-related stress symptoms[16]. Thus, medical devices' fitness for purpose also serves to reduce the number of such "work-related health risks" as described in Section 2 of the German Occupational Health and Safety Act.

Cognitive psychology illustrates that errors are everywhere and are committed by everyone. Although incidents are ultimately often triggered by an "operating error", the operator, who is held responsible for the incident, can rarely influence the causes. Operating errors generally do not reflect the user's lack of ability but are an indication of a mismatch between the situation, the user, the device and the task.

When it comes to implementing the German Medical Devices Act and the German Regulation for Medical-Device Operators, this means that medical devices' fitness for purpose should not only be tested in an informal clinical trial[17] before being procured by a hospital. Hospitals *do* know that ease of use increases job satisfaction and quality of work, reduces turnaround times and training effort and cuts the costs for first-line service and thus the overall operating costs too. But, as a rule, critical combinations of attendant factors do not occur during these routine-

[14] effectively = achieving the correct objective
[15] efficiently = achieving an objective with minimum effort
[16] Controlling stress at work in hospitals: from "The Ergonomist", July 2002, Number 358 and http://www.hse.gov.uk/press/2002/e02090.htm
[17] voluntary procedure which is not required for regulatory approval

operation informal clinical trials which means that the effect of such combinations does not come to light.

In routine operation, however, critical combinations of attendant factors can lead to work-related stress symptoms in the long run. In most cases, hospitals can only pay marginal attention or no attention at all to the safety provided by the fitness for purpose of a product which they are intending to buy. The general impressions gained during the informal clinical trial only reveal general, basic flaws. Consequently, it remains up to the manufacturer to assess the level of safety provided by the device's fitness for purpose.

These guidelines will endeavour to utilize, above all, the potential for improvement with regard to the causes of incidents. This focus on causes is also the reason why standards and drafts now only use the term "use error" instead of "user error", thus referring to the mismatch situation and not to any personal fault.

1.4 Points to Remember

The protection targets set forth in the German Medical Devices Act cover protection for patients and third parties as well as for users. OH&S regulations only consider the user's safety.

The risk-management concept in the international standard for medical devices is comprehensive to the extent that it looks for risks caused by deficient fitness for purpose. However, the concept does not call for risk-control measures to be proposed. There is thus also no requirement for ergonomic principles to be taken into account.

Medical devices' fitness for purpose is an ergonomic principle in its own right and the FDA (US) already applies it as a criterion for approving new medical devices.

2 Terminological Background

2.1 The Term "Hazard"

The term "hazard" is defined as a "*potential* source of harm" in clause 2.3 of EN ISO 14971.

According to Article 2 of the EU Directive on Medical Devices[18] and the German Medical Devices Act[19] based on that directive, this means *potential* hazards to the "safety and health of patients, users [= employees, see above] and, where applicable, other persons".

The definitions set forth in the European standards on safety of machinery can also be used for these Ergonomics Guidelines for the Design of Medical Devices, as shown in Table 1. The wording can be easily adapted by replacing the word "machine" with "medical device".

Another argument in favour of such a move is that these adapted definitions can be easily incorporated into the international standards because the "Basic terminology, methodology" in prEN 292-1 is supposed to be the same as in ISO 12100-1.

Hazard	A potential source of *harm*[20][21]
Hazard, relevant	Hazard which is identified as being present at or associated with the machine [with the medical device] (as the result of one step of the process described in EN 1050)
Hazard, significant	Hazard which has been identified as relevant and which requires specific action by the designer to eliminate or reduce the *risk* according to the *risk assessment*.

Table 1: Definitions of the term "hazard" as given in prEN 292-1:2000 and EN 1050:1996. Annex 5 contains a list of key terms and definitions

2.2 The Terms "Risk" and "Harm"

Table 2 compares the definitions given in EN ISO 14971 with those in prEN 292-1. The terms in EN ISO 14971 are an extended version of the risk-assessment terms used in the standards on safety of machinery with the addition of the risk-control aspect for medical devices.

Term	EN ISO 14971 and ISO/IEC Guide 51[22]	prEN 292-1:04.2000
Risk management	Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk.	The concept of risk management is not included in the method described
Risk	Combination of the probability of occurrence of harm and the severity of that harm.	Combination of the probability of occurrence of harm and the severity of that harm.

[18] "Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose." (Directive 93/42/EEC)

[19] Sections 1 and 4

20 Note in prEN 292-1:2000: The term hazard can be qualified in order to define its origin or the nature of the expected harm (e.g. electric shock hazard, crushing hazard, cutting hazard, toxic hazard, fire hazard)

21 For more definitions of "harm", see Table 3

22 For the most part, the definitions in EN ISO 14971 correspond to those in ISO/IEC Guide 51

Term	EN ISO 14971 and ISO/IEC Guide 51[22]	prEN 292-1:04.2000
Risk, tolerable	Not defined. The standard uses the term without specifying acceptability values for RISKS. It refers to the acceptable values of society.	Risk which is accepted in a given context based on the current values of society (e.g. national regulations or laws).
Risk analysis	Systematic use of available information to identify hazards and to estimate the risk.	Combination of the determination of the limits of the machine, hazard identification and risk estimation.
Risk evaluation	Judgement, on the basis of risk analysis, of whether a risk which is acceptable has been achieved in a given context based on the current values of society.	Judgement, on the basis of risk analysis, of whether a tolerable risk has been achieved.
Risk assessment	Overall process comprising a risk analysis and a risk evaluation.	The overall process of risk analysis and risk evaluation.
Risk control	Process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels.	The concept of risk control is not covered in the European standards on safety of machinery

Table 2: Comparison of definitions of the term "risk management" and related terms

The term "risk estimation" is not defined in the standards listed in Table 2. However, it is used in EN 1050 and ISO/IEC Guide 51 without being defined.

In the international standard on medical devices, the definition of the term "harm" as mentioned in Tables 1 and 2 covers a larger scope than in the European standards on safety of machinery since it includes the environment (see Table 3).

Term	EN ISO 14971 [23]	prEN 292-1	EN 1050
Harm	Physical injury or damage to the health of people, or damage to property or the environment.	Physical injury or damage to health	Physical injury and/or damage to health or property

Table 3: Definitions of the term "harm"

2.3 Risk Acceptability

Ultimately, it is only the manufacturer who decides, as part of the conformity-assessment procedure, whether the risks posed by a medical device are acceptable. EN ISO 14971 therefore deliberately does not comment on which risks are acceptable since risks are evaluated differently by different people.

EN ISO 14971 states the following in the introduction:

“The acceptability of a risk to a stakeholder is influenced by these components [probability of occurrence and consequences of harm] and by the stakeholder's perception of the risk.”

These concepts are particularly important in relation to medical devices because of the variety of stakeholders including medical practitioners, the organizations providing health care, governments, industry, patients and members of the public.

All stakeholders need to understand that the use of a medical device entails some degree of risk. Factors affecting each stakeholder's perception of the risks include the socio-economic and educational background of the society concerned and the actual and perceived state of health of the patient. The way a risk is perceived also takes into account, for example, whether exposure to the risk seems to be involuntary, avoidable, from a man-made source, due to negligence, arising from

23 For the most part, the definitions in EN ISO 14971 correspond to those in ISO/IEC Guide 51

a poorly understood cause, or directed at a vulnerable group within society. The decision to embark upon a clinical procedure utilizing a medical device requires the residual risks to be balanced against the anticipated benefits of the procedure. Such judgements should taken into account the intended use/intended purpose, performance and risks associated with the medical device, as well as the risks and benefits associated with the clinical procedure or the circumstances of use. Some of these judgements may be made only by a qualified medical practitioner with knowledge of the state of health of an individual patient or the patient's own opinion."

As a logical follow-on, clause 6.5 of EN ISO 14971 specifies the following for the risk/benefit analysis (see also A4.4):

"If the residual risk is judged unacceptable...and further risk control is impractical, the manufacturer shall ...determine if they [the medical benefits] outweigh the residual risk. If this evidence does not support the conclusion that the medical benefits outweigh the residual risk, then the risk remains unacceptable."

For this reason, the scope EN ISO 14971 points out that the standard merely describes a procedure and "does not specify acceptable risk levels."

These Guidelines therefore also follow this procedure and do not specify criteria for evaluating or assessing risk acceptability.

2.4 Points to Remember

These Ergonomics Guidelines for Medical Devices are intended to help assess relevant hazards resulting from ergonomic principles being neglected.

In the risk-assessment procedure, the manufacturer examines which of the relevant hazards necessitate specific measures on the part of the designer in order to eliminate or reduce the risk. Such hazards are referred to as "significant hazards".

Design processes for medical devices should go beyond risk assessment and take in the aspect of risk control as well.

These Ergonomics Guidelines for Medical Devices does not offer any criteria for evaluating risk acceptability.

3 Risk Assessment

3.1. Limits of Use

The general guidelines for inclusion of safety aspects in standards (ISO/IEC Guide 51) require the risk *analysis* (as part of the risk *assessment*) to be linked to the task of risk *reduction* in an iterative process (see Figure 1).

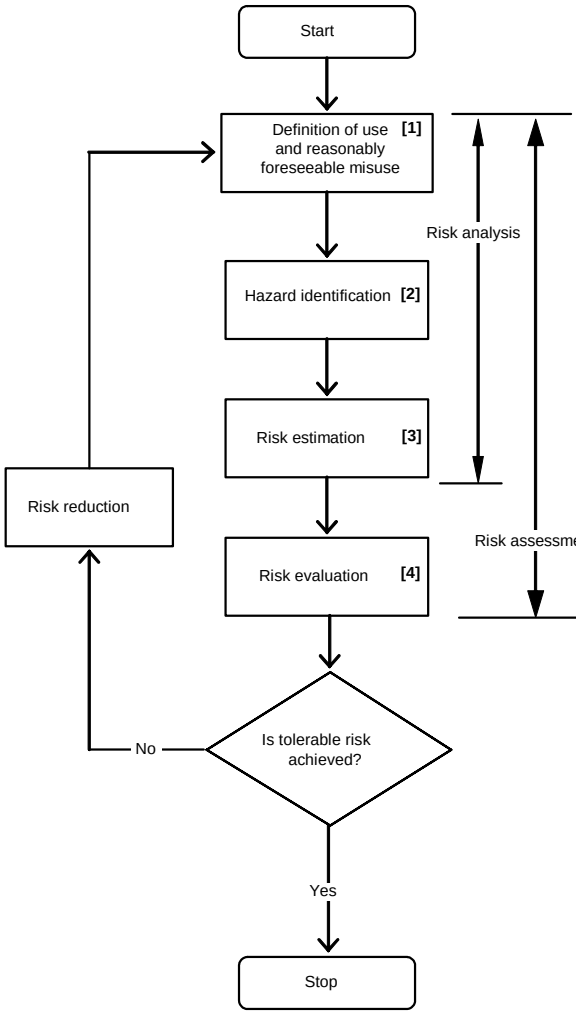


Figure 1: Risk analysis and assessment as elements of an iterative process based on ISO/IEC Guide 51

This general procedure can be used as the underlying concept for these Ergonomics Guidelines provided that it permits "ergonomic principles" to be taken into account.

The risk-management process for the use of medical devices also begins with a risk analysis (Figure 2). Thus, in the manner of a basic standard, the risk-analysis task does not depend on whether the risk assessment is being carried out for machinery or medical devices. In both cases, the risk analysis is the first part of the risk-assessment process. The first task **[1]** within the risk analysis is – in keeping with the introductory remarks on fitness for purpose (cf. Chapter 1.3) – to

identify the intended use or purpose according to DIN EN ISO 14971 (see Figure 2).

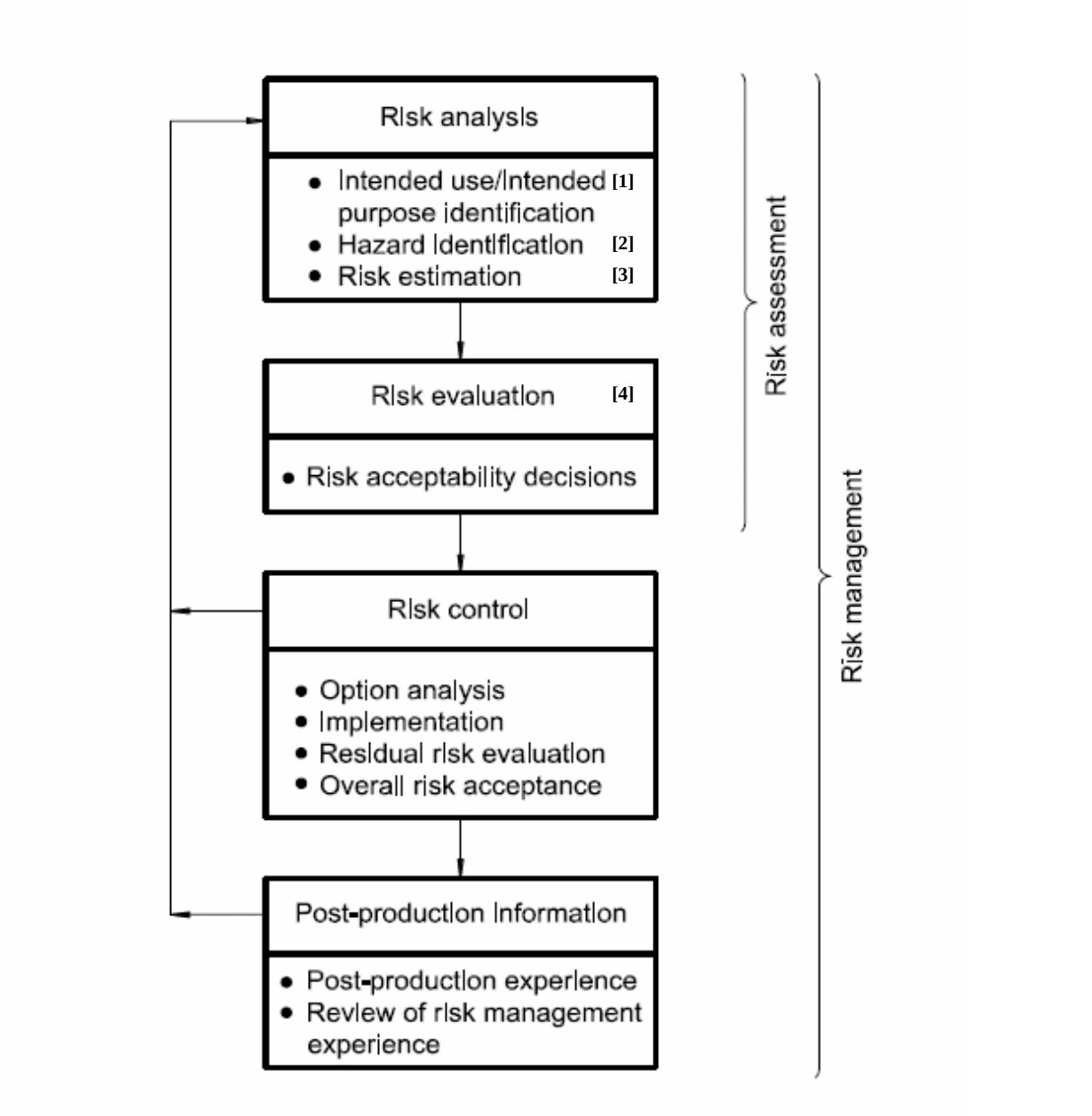


Figure 2: Risk-management process based on EN ISO 14971

The entire range of risk-analysis methods proposed in the basic standards on safety of machinery can be transferred to medical devices. In accordance with the step model introduced in EN 13861, the first task is to "specify the limits of the machine" with respect to ergonomics.

To this end, a distinction is made between:

- *use limits* based, for example, on the intended user groups (see Annex B.1.1 of EN 13861: age groups or level of training);
- *space limits* not only for the machine itself but also for accessories and component parts as well as for accessibility for purposes such as cleaning, maintenance or fault-finding (B.1.2);
- *time limits* due to, for example, the foreseeable duration and frequency of use (B.1.3).

The environmental conditions of the intended workplace which are not related to machinery design are also mentioned as limits, (B.1.4 "climate", "noise", lighting" and "vibration").

Additional limits and conditions related to the work tasks are listed in Table 4.

Intended and expected types of job (B.2.1):
▪ Production task [correspondingly “task specific to medical device”]
▪ Control task
▪ General work or precision work
▪ At a fixed work station or a mobile station
▪ Sitting/standing/walking work etc.
▪ Work with a low force exertion: head/neck/eyes
▪ Work with a high force exertion: leg/foot/shoulder/arm/hand
▪ Work with a high mental load (stress)
Expected use of personal protective equipment (B.2.2):
▪ If it cannot be avoided in the foreseeable conditions of use
▪ NOT related to the machinery design or medical device design
▪ Work which tends to increase the mental load
Foreseeable misuse in terms of ergonomics (prEN 292-1:2000, 3.12)
▪ Use by others than the intended user group
▪ Use in an incorrect working posture
▪ Use in unsafe and unhealthy conditions
▪ Use without proper training

Table 4: Limits in connection with the work tasks as defined in EN 13861, Annex B

When transferred to medical-device design, only the *"production task"* type of job is superfluous and would have to be replaced with a similar "type of job" for the use of medical devices. *"Task specific to medical devices"* would be a recommendable specification for this type of job.

In accordance with Section 3 of the German Medical Devices Act, such work is for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation or compensation of injuries or handicaps,
- investigation, replacement or modification of the anatomy or of a physiological process or
- control of conception.

3.2 Identification of Hazards

Identifying the “intended use or purpose” of a medical device also includes examining all possible misuses.

In order to identify the hazards, it makes sense to examine the "selected" hazards[24] listed in Annex A.1 of EN 13861 as to whether they could apply to the design and use of medical devices, whether they are exhaustive[25] and whether they could be *relevant* to safety.

Consequently, on the basis of EN 13861 Annex A (which makes reference to Table A1 of EN 1050), Table 5 only contains the hazards which can be assumed to be relevant to the use of medical devices and which, of course, include reasonably foreseeable misuse.

Hazards according to EN 13861	Clause in EN 1050 (Table A1)
… **generated by** neglecting ergonomic principles in medical-device design	8
□ Unhealthy postures or excessive effort	8.1
□ Inadequate consideration of hand- arm and foot- leg anatomy	8.2
□ Neglected use of personal protective equipment	8.3
□ Inadequate local lighting	8.4
□ Mental overload and underload, stress	8.5
□ Human error, human behaviour	8.6
□ inadequate design or location or indication of controls	8.7
□ inadequate design or location of visual displays	8.8
… **generated by** vibration	5
□ Use of hand-held machines resulting in a variety of neurological and vascular disorders	5.1
… **generated by** noise	4
□ Interference with speech communication, acoustic signals, etc.	4.2
… **due to** mobility linked to work position on the machine	21
□ Fall of persons during access to (or at/ from) the work position	21.1
□ Lifting when moving medical devices	29
□ Rolling over feet when moving a wheeled medical device	21.4
□ Lack of stability when moving a wheeled medical device	27.1.1
□ Insufficient visibility from the work position	21.5
□ Inadequate lighting	21.6
□ Inadequate seating	21.8
… **in connection** with a medical device's control system	22
□ Inadequate location of controls/control devices	22.1
□ Inadequate design of the actuation mode and/or action mode of controls	22.2

Table 5: Relevant hazards for medical devices, caused by ergonomic principles being neglected, taken from the field of standardization of machinery safety (EN 13861/EN 1050). For systematic reasons, the order in which the hazards are listed is not the same as in EN 13861.

Compared to the hazards listed in Table 5, the "Examples of possible hazards and contributing factors associated with medical devices" listed in EN ISO 14971

[24] One of the "selection" criteria in EN 13861 is whether the hazard is "generated by neglecting ergonomics principles" (4.2 – Step 2)

[25] This also applies to the proposals in CD IEC 60601-1-6: General requirements for safety – 6. Collateral Standard: Usability

(Annex D) only include one hazard category which could be classified as a case of ergonomic principles being neglected (D.7):

"Inappropriate, inadequate or over-complicated user interface (man/machine communication)".

As Table 6 shows, some of the items listed in D.7. correspond to items listed in Table 5.

Chapter 4.2 provides assistance on how to identify hazards.

Hazards or factors contributing to hazards taken from EN ISO 14971; the right hand column indicates the corresponding clauses in Table A1 of EN 1050 (where applicable).	
... due to an inappropriate, inadequate or over-complicated user interface	
□ Mistakes and judgement errors	-
□ Lapses and cognitive recall errors	8.5
□ Slips and blunders (mental or physical)	8.6
□ Violation or abbreviation of instructions, procedures, etc.	-
□ Complex or confusing control system	22
□ Ambiguous or unclear device state	22.2
□ Ambiguous or unclear presentation of settings, measurements or other information	22.2
□ Misinterpretation of results	
□ Insufficient visibility, audibility or tactility	8.7, 8.8
□ Poor mapping of controls to action or of displayed information to actual state	22
□ Controversial modes or mappings as compared to existing equipment	-

Table 6: Relevant hazards, caused by neglecting ergonomic principles, taken from the field of standardization concerning safety of medical devices (EN ISO 14971)

3.3 Risk Evaluation

3.3.1 Definition and Concept

The term "risk evaluation" is not explicitly defined in the standard on the safety of medical devices even though it is specified as Step 3 of the risk-management process within the risk analysis (cf. Task **[3]** in Figure 2). EN ISO 14971 (4.4) makes the following provision for "Estimation of the risk(s) for each hazard":

"For each identified hazard, the RISK(S) in both normal and fault conditions shall be *estimated* using available information or data. For hazards for which the probability of the occurrence of harm cannot be *estimated*, a listing of the possible consequences of the hazard shall be prepared."

Defining "risk estimation" in more detail, the Annex E.1 of EN ISO 14971 states:

"Risk estimation should examine the initiating events or circumstances, the sequence of events that are of concern, any mitigating features, and the nature and frequency of the possible deleterious consequences of the identified hazards."

With regard to the relevance of hazards resulting from ergonomic principles being neglected, the following statements in EN ISO 14971 (4.4 note 1) are of interest:

"NOTE 1 Risk estimation incorporates an analysis of the probability of occurrence and the consequences. Depending on the area of application, only certain **elements** of the risk estimation process may need to be considered. For example, in some instances it will not be necessary to go beyond an initial hazard and consequence analysis."

However, no explanation is given as to what is meant by "elements of the risk estimation process".

By comparison, the risk-estimation process in the standard on safety of machinery (EN 1050) [26] seems more specific:

"After hazard identification*..., risk estimation* [guideline authors' italics] shall be carried out for each hazard by determining the *elements of risk* [guideline authors' italics] given in 7.2."

Figure 3 shows the underlying risk-estimation concept using risk elements as described in EN 1050.

RISK, related to the considered hazard
is a function of
SEVERITY of the possible harm that can result from the considered hazard
and
PROBABILITY OF OCCURENCE of that ham a) frequency and duration of exposure b) probability of occurrence of hazardous event c) possibility to avoid or limit the harm

Figure 3: Risk estimation based on determination of risk elements as described in EN 1050 (7.2)

In EN ISO 14971, the risk element corresponding to "severity of the possible harm" is referred to as the "severity level" (E.2.2). Commenting that "severity" is a "continuum", the standard suggests that discrete levels could be used in practice:

"In this case, the manufacturer decides how many categories are needed and how they are to be defined." (E.2.2)

When establishing the relevance of hazards resulting from ergonomic principles being neglected, these categories can be determined relatively easily if the risk elements in EN 1050 are applied and adapted to the tasks specific to medical devices.

[26] EN 1050, 7.1 Risk estimation - Principles for risk assessment

3.3.2 Risk Elements

3.3.2.1 Severity of Harm

Thus, the severity of the possible harm for *tasks specific to medical devices* should be estimated on the basis of the following criteria:

1) the nature of what is to be protected:
- persons,
- property or
- the environment;

2) the severity of injuries or damage to health:

- negligible (always quickly reversible),
- slight (normally reversible),
- serious (normally irreversible) or
- death;

3) the extent of harm

- one person or
- several persons.

3.3.2.2 Probability of Occurrence of Harm

The exposure to harm can be derived from:

- the necessity to access the hazard zone[27],
- the nature of such access,
- the frequency of such access,
- the period during which the user subjects himself or herself to the risk and
- the probability of a hazardous event[28] occurring.

The probability of a hazardous event occurring is derived from:

- reliability data and other statistical data,
- feedback on incidents,
- details of damage to health or accidents and
- possibilities for preventing or restricting harm.

Possibilities for preventing or restricting harm can be derived from:

1) the way in which the medical device is used:

- by medical practitioners,
- not by medical practitioners or
- automatic operation;

2) the speed with which a hazardous event occurs:

[27] Any zone within and/or around machinery [a medical device] in which a person is exposed to a hazardous situation (prEN 292-1)
[28] Event that can cause harm (EN 1050)

- suddenly,
- quickly,
- slowly;

3) the risk awareness generated by:

- general information,
- direct observation or
- by warning signals and display devices;

4) the possibility for humans to prevent or restrict the harm:

- possible,
- possible in certain conditions or
- not possible;

5) the practical experience and knowledge of:

- the medical device being used,
- similar medical devices,
- the task specific to the medical device
- or the lack of experience.

3.4 Risk Evaluation

The last stage of risk assessment is risk evaluation[29] (Task **[4]** in Figure 2). This means that after the risk evaluation a decision has to be made as to whether risk reduction is necessary or whether the medical device complies with all of the ergonomic principles.

In line with the definition of the term "relevant hazard", it is thus necessary to investigate which of the relevant hazards listed in Table 5 and Table 6 become significant hazards. The latter necessitate "specific action"[30] in order to eliminate or reduce the risk by means of risk control.

A field survey and database research at Germany's *Bundesinstitut für Arzneimittel und Medizinprodukte* (Federal Institute for Drugs and Medical Devices) produced only very few instances of harm to users of medical devices caused by poor fitness for purpose. Furthermore, most of the findings indicated that the cause was a device failure.

These findings can be attributed to various reasons, i.e.:

- the real risks are minor ⇨ the hazards are relevant but not significant,
- incidents are not always reported ⇨ low reported-incident figures,
- currently, incidents with ergonomic causes do not have to be reported ⇨ low reported-incident figures,

[29] EN ISO 14971
[30] prEN 292-1 Section 3.5 B

- when incidents have ergonomic causes, the users blame themselves and thus do not report the incident ⇨ low reported-incident figures for incidents caused by ergonomic factors,
- neglecting ergonomic principles leads to harm of a more long-term nature. The causal relationship between the incident and the harm is thus not obvious so the incident is not reported.

Consequently, possible harm which can occur due to ergonomic principles being neglected in the design and use of medical devices is generally only classified as "negligible" or "minor" (cf. Chapter 3.3.2.1 b) in the proposed severity levels of injuries and damage to health.

To sum up, the "traditional" risk-evaluation categories of "injury", "damage to health" or "impairment of health" do not take into account all of the impacts of ergonomic principles being neglected in the design and use of medical devices; ergonomic criteria also include the efficiency with which a task is performed, and satisfaction.

3.5 Points to Remember

Application of risk management to medical devices requires a risk assessment, consisting of a risk analysis followed by a risk evaluation, to be carried out at the **design** stage.

Standards concerning safety of machinery can also be consulted in order to identify relevant hazards caused by neglecting ergonomic principles.

The estimation, required for the risk evaluation, of the risk during use of the medical device is based on the expected severity of any harm and the probability of harm occurring.

The risk evaluation should also consider which risks have an impact on performance and the results of the work.

The process of identifying hazards resulting from foreseeable misuse must be iterative.

4 Hazards and Selection of Standards Concerning Consideration of Ergonomic Principles

These guidelines propose a checklist with questions for identifying hazards. Other questions can be added if appropriate for the medical device concerned[31] (4.1).

The checklist is supplemented by a systemized list of possible hazards. For some of the hazards, references are given to standards which might assist assessment (4.2).

An outline of the contents of selected standards is provided as an aid for checking whether hazards can be reduced or prevented by observing ergonomic principles (4.3).

Details regarding risk concepts applied to medical devices and risk management are given in the Annex.

4.1 Checklist for Safety-Critical Features[32]

The checklist[33] can be used for the risk-analysis tasks of "identification of hazards" (Chapter 3.2) and identification of general safety-critical conditions of use (see Chapter 3.1). In connection with chapters 4.2 and 4.3, it is intended to help the respondent select appropriate standards concerning consideration of ergonomic principles.

The questions reflect the perspectives of all stakeholders, such as users, maintenance technicians and patients, in order to provide as complete a range as possible of ways to identify possible hazards. Within these guidelines, with their OH&S background, the main focus is on the **user**. However, to ensure complete risk management, the manufacturer must also pay adequate attention to the risks for patients and third parties. The checklist questions are only examples - additional questions can be added if deemed appropriate for the medical device concerned.

Checklist Questions

1. What is the intended use / intended purpose and how is the medical device to be used?

- Factors that should be considered include the intended user, the mental and physical abilities, skill and training of the user, ergonomic aspects, the environment in which it is to be used, by whom it will be installed and whether the patient can control or influence the use of the medical device. Special attention should be paid to intended users with special needs such as handicapped persons, the elderly and children. Their special needs might require assistance by another person to enable the use of a medical device. Is the

[31] Drawing up an exhaustive list of present and future medical devices is neither practicable nor reasonable. The designer therefore needs to complete the list.
[32] Here, “safety-critical” refers not only to features which can lead to accidents but also to those which can impair the user's safety and health.
[33] Using the questions presented in EN ISO 14971 with slight changes.

medical device intended to be used by individuals with various skill levels and cultural backgrounds?

- Is special intervention necessary in the case of failure of the medical device? Are there special concerns about interface design features that could contribute to inadvertent use error?

2. Is the medical device intended to contact the patient or other persons?

- Factors that should be considered include the nature of the intended contact and, for each type, the period and frequency of contact.

3. What materials and/or components are incorporated in the medical device or are used with, or are in contact with, the medical device?

- Factors that should be considered include whether characteristics relevant to safety are known.

4. Is energy delivered to and/or extracted from the patient and to what extent can this affect the user?

- Factors that should be considered include the type of energy transferred and its control, quality, quantity and duration.

5. Are substances delivered to and/or extracted from the patient and to what extent can this affect the user?

- The design of the medical device also influences the user's contact with the substances. Factors that should be considered include whether the rules which have to be adhered to when using the medical device in the work process meet the expectations and requirements of the user so as to rule out any hazardous contact as far as possible[34].

6. Is the medical device intended to be routinely cleaned and disinfected by the user?

- The design of the medical device can influence the user's contact with the cleaning and disinfection agents to be used.

7. Is the medical device intended to modify the patient environment and to what extent can this affect the user?

- Factors that should be considered include temperature, humidity, atmospheric gas composition, pressure and light.

8. Is the medical device intended for use in conjunction with other devices?

- Factors that should be considered include identifying any other devices which can be involved and the potential interactions.

9.Are there unwanted outputs of energy?

[34] Examples of critical processes include administering of cytostatics and handling of infectious substances

- Energy-related factors that should be considered include noise and vibration, heat, radiation (including ionizing, non-ionizing and ultraviolet/visible/infrared radiation), contact temperatures, leakage currents and electric and/or magnetic fields.

10. Is the medical device susceptible to environmental influences?

- Factors that should be considered include the operational, transport and storage environments. These include light, temperature, vibrations, spillage, susceptibility to variations in power and cooling supplies, and electromagnetic interference. Can a change to the environmental influences cause the medical device to pose hazards for the user?

11. Are there essential consumables or accessories associated with the medical device?

- Factors that should be considered include specifications for such consumables or accessories and any restrictions placed upon users in their selection of these.

12. Is maintenance and/or calibration necessary?

- Factors that should be considered include whether maintenance and/or calibration are to be carried out by the operator or user or by a specialist. Are special substances or equipment necessary for proper maintenance and/or calibration?

13. Are there any delayed and/or long-term use effects?

- Factors that should be considered include ergonomic and cumulative effects.

14. What mechanical forces does the user have to apply when using the device?

- Factors that should be considered include whether hazards may arise from the forces which the user has to apply.

15. Is safe decommissioning or disposal of the medical device necessary?

- Factors that should be considered include processes and waste products that are generated during the disposal of the medical device itself.

16. Does installation of the medical device require special training?

- Factors that should be considered include compiling and handing over to the end user and whether it is possible that installation can be carried out by people without the necessary skills.

17. Is successful application of the medical device critically dependent on the user interface?

- Factors that should be considered are user interface design features that can contribute to use error. Features should be designed so that hazards to users are ruled out as much as possible, even in the case of frequent distractions. This

applies to e.g. device control, symbols used, ergonomic features, physical design and layout, hierarchy of operation, menus for software driven devices, visibility of warnings, audibility of alarms and standardized colour coding. Questions to be asked include:

a) Does the medical device have connecting parts or accessories?

Factors that should be considered include the possibility of wrong connections, differentiation, similarity to other products' connections, connection force, feedback on connection integrity, and over- and under-tightening.

b) Does the medical device have a control interface?

Factors that should be considered include spacing, coding, grouping of the operating elements, necessary forces for and frequency of operation of the operating elements, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, and whether the controls are continuous or discrete, and the reversibility of settings or actions.

c) Does the medical device display information?

Factors that should be considered include visibility in various environments, orientation, populations, perspectives, and the clarity of the presented information, units, colour coding, and the accessibility of critical information.

d) Is the medical device controlled by a menu?

Factors that should be considered include complexity and number of layers, awareness of state, location of settings, navigation method, correction of incorrect entries, number of steps per action, and sequence clarity and memorization problems, and importance of control function relative to its accessibility.

e) Are symbols used with the medical product?

Where symbols are used, it is particularly necessary to check whether the users can adequately use (learn, understand, distinguish, recognize, remember…) the type and number of symbols. It is not possible to assume that they *can* simply because there are various standardized symbols for medical devices.

f) Is the medical device intended to be mobile or portable?

Factors that should be considered are the necessary grips, handles, wheels, brakes and the necessary forces and posture for transport. Any mechanical stability and durability required should also be considered.

4.2 Examples of Possible Hazards

4.2.1 General Information

The following table (Table 7) is intended to assist in identifying hazards which might be related to a particular medical device. This overview of hazards follows the structure of EN 1050. It is to assist the designer in drawing up checklists without having to combine different sources. The table lists selected hazards according to EN 1050 together with applicable type B standards or group standards related to medical devices. In addition to hazards arising from ergonomic principles being neglected, other hazards from EN 1050 are listed which are not addressed in EN 13861.

Table 7: List of selected hazards according to EN 1050 and applicable type B standards (according to EN 13861 and group standards related to medical products)[35]

Section	Hazards (EN 1050, Annex A)	Type-B standard related to ergonomics (according to EN 13861)				Medical-device group standard: EN IEC 60601-1 or EN ISO 14971
		Definition	Require-ments/design process	Measure	Test method	
1	**Mechanical hazards due to:**					
1.1	Crushing					EN IEC 60601-1 Section 22: moving parts; no explicit provisions for hazards to user, just risk analysis.
1.2	Shearing					See 1.1
1.3	Cutting or severing					See 1.1 and EN IEC 60601-1 Section 23: Surfaces, corners and edges
1.4	Entanglement					See 1.1
1.5	Drawing-in or trapping					See 1.1
1.6	Impact					EN IEC 60601-1 Section 25: Expelled parts
1.7	Stabbing or puncture					See 1.1
1.8	Friction or abrasion					-
1.9	High pressure fluid injection or ejection hazard					EN IEC 60601-1 Section 27: Pneumatic and hydraulic pressure: No general statement. No explicit provisions for hazards to user, just risk analysis.
2	**Electrical hazards due to:**					Main subject of EN IEC 60601-1
2.1	Contact of persons with live parts					See EN IEC 60601-1: Sections 13 ff.

[35] A blank field signifies that the authors did not have copies of the standards or that the hazard is not addressed in EN 13861. For Sections 1, 2 and 7 of EN 1050 in particular (hazards which are not part of ergonomics in the narrower sense and which are therefore not addressed in EN 13861), standards exist in the field of safety of machinery; however, these standards are not listed here.

Section	Hazards (EN 1050, Annex A)	Type-B standard related to ergonomics (according to EN 13861)				Medical-device group standard: EN IEC 60601-1 or EN ISO 14971
		Definition	Require-ments/design process	Measure	Test method	
2.2	Contact of persons with parts which have become live under faulty conditions					See 2.1
2.3	Approach to live parts under high voltage					See 2.1
2.4	Electrostatic phenomena					See EN IEC 60601-1: Section 47
2.5	Thermal radiation or other phenomena such as the projection of molten particles and chemical effects from short circuits, overloads, etc.					See EN IEC 60601-1: Sections 42 ff.
3	**Thermal hazards, resulting in:**					
3.1	Burns and scalds by a possible contact of persons, by flames or explosions and also by the radiation of heat sources	EN 563 prEN13732-3	EN 563 prEN13732-3	prEN 13202	EN 563 prEN13732-3	Maximum temperatures: Section 42 Minimum temperatures: no provisions! e.g. liquid nitrogen ⇒ action needed
3.2	Damage to health by hot or cold work environment	EN ISO 13731	EN 27243 EN ISO 7730 prEN 14386 ENV ISO 11079		EN 27726 EN 12515 EN 28996	Environmental variables are not discussed in these standards
4	**Hazards generated by noise:**					

Section	Hazards (EN 1050, Annex A)	Type-B standard related to ergonomics (according to EN 13861)				Medical-device group standard: EN IEC 60601-1 or EN ISO 14971
		Definition	Require-ments/design process	Measure	Test method	
4.1	Hearing loss (deafness), other physiological disorders	EN 1746	EN ISO 11688-1 EN ISO 11688-2 EN ISO 11690-1 ISO 1999	EN ISO 11688-1 EN ISO 11688-2 EN ISO 11690-2	EN ISO 11200 EN ISO 11201 EN ISO 11204 EN ISO 3744 EN ISO 4871	EN IEC 60601-1 Section 35 : No general statement Section 26: No general statement.
4.2	Interference with speech communication, acoustic signals, etc.	EN 1746	EN ISO 11690-1 ISO 9921-1 EN 457 EN 894-2	EN ISO 11688-1 EN ISO 11688-2 EN ISO 11690-2	EN ISO 11200 EN ISO 11201 EN ISO 11204 EN ISO 3744 EN ISO 4871	Not relevant in the case of simple devices for the same reasons Possibly in the case of equipment where the patient and user are in different rooms
5	**Hazards generated by vibration**					
5.1	Use of hand-held machines resulting in a variety of neurological and vascular disorders	ISO 2041 ISO 5805		CR 1030-1	EN 1033 EN ISO 5349--2 ISO 2631-1 ENV 28041	EN IEC 60601-1 Section 26: Noise and vibration: No general statement. Usually not relevant since always applied for a short period only
5.2	Whole body vibration, particularly when combined with poor postures	EN 1032 EN 12786 ISO 2041 ISO 5805 ISO 8727	EN 1032 prEN 14386	EN 1299	EN 1032 EN 30326-1 ENV 28041	See 5.1
6	**Hazards generated by radiation**					

Section	Hazards (EN 1050, Annex A)	Type-B standard related to ergonomics (according to EN 13861)				Medical-device group standard: EN IEC 60601-1 or EN ISO 14971
		Definition	Require-ments/design process	Measure	Test method	
6.1	Low frequency, radio frequency radiation, microwaves		ENV 50166-1 ENV 50166-2 EN 12198-1	EN 12198-1	ENV 50166-1 ENV 50166-2	Radio waves: EN IEC 60601-1-2 EMV, EN IEC 60601-1 Section 36: No general statement Microwaves: EN IEC 60601-1 Section 31: No general statement Light waves: EN IEC 60601-1 Sections 32-34: No general statement
7	**Hazards generated by materials and substances (and their constituent elements) processed or used by the machinery:**					EN IEC 60601-1 Section 48 Biocompatibility, inspection in accordance with ISO 10993-1
7.1	Hazards due to contact with or inhalation of harmful fluids, gases, mists, fumes, and dusts					Hazard depends on device (tightness of seals/joints ⇒ contamination rate) and environment (air dilution, change of air). Hazard relevant, e.g. in the case of anaesthetic equipment, aerosol devices or cytostatic devices
7.2	Fire or explosion hazards					EN IEC 60601-1 Section 37 – 41
7.3	Biological or microbiological (viral or bacterial) hazards					EN IEC 60601-1 Section 44.7 requires devices to be cleanable; the actual cleaning process is set forth in the hospital's hygiene regulations; no need for action

Section	Hazards (EN 1050, Annex A)	Type-B standard related to ergonomics (according to EN 13861)				Medical-device group standard: EN IEC 60601-1 or EN ISO 14971
		Definition	Require-ments/design process	Measure	Test method	
8	**Hazards generated by neglecting ergonomic principles in machinery design**					
8.1 8.2 8.3	Unhealthy postures or excessive effort Inadequate consideration of hand-arm and foot-leg anatomy Neglected use of personal protective equipment*)	EN ISO 7250 EN 1005-1	EN 60204-1 EN 547-1 EN 547-2 EN 547-3 EN ISO 14738 prEN 14386	EN 547-2 EN 1005-2 EN 1005-3 EN ISO 14738 EN ISO 7250 EN ISO 11064-02 prEN ISO 11064-6	prEN 1005-2 prEN 1005-3 prEN 1005-4 prEN ISO 15537	Currently not covered in CD EN IEC 60601-1-6
8.4	Inadequate local lighting	EN 842 EN 894-2 EN 894-3 EN 12665 ISO 8995	EN 60204-1 EN 61310-1 EN 842 EN 894-2 EN 894-3 EN 1837 ISO 8995		EN 842 ISO 8995	Not covered
8.5	Mental overload and underload, stress	prEN ISO10075-1	EN 614-2	EN 614-2	prEN ISO 10075-3	Is covered in CD EN IEC 60601-1-6

*) Use of PPE can only be governed by national regulations, not by product standards.

Section	Hazards (EN 1050, Annex A)	Type-B standard related to ergonomics (according to EN 13861)				Medical-device group standard: EN IEC 60601-1 or EN ISO 14971
		Definition	Require-ments/design process	Measure	Test method	
8.6	Human error, human behaviour	EN 457 EN 842 EN 894-1 EN 894-2 EN 894-3 EN 981	EN 457 EN 60073 EN 60204-1 EN 60447 EN 61310-1 EN 842 EN 894-1 EN 894-2 EN 894-3 EN 981 EN 61310-2 EN 61310-3		EN 457 EN 842 EN 894-3 EN 981	Is covered in CD EN IEC 60601-1-6
21	**Additional hazards and hazardous events due to mobility linked to the work position on the machine**					
21.1	Fall of persons during access to (or at/from) the work position	EN ISO 7250	EN 547-1 EN 547-2 EN 547-3 EN ISO 14738 prEN 14386		prEN ISO 15537	
21.5	Insufficient visibility from the work positions	EN 842 EN 894-2 EN 894-3	EN 61310-1 EN 61310-2 EN 842 EN 894-2 prEN 14386		EN 894-3	
21.6	Inadequate lighting	EN 12665 ISO 8995	EN 1837 ISO 8995		ISO 8995	

Section	Hazards (EN 1050, Annex A)	Type-B standard related to ergonomics (according to EN 13861)				Medical-device group standard: EN IEC 60601-1 or EN ISO 14971
		Definition	Require-ments/design process	Measure	Test method	
21.7	Inadequate seating	EN ISO 7250 EN 1005-1	EN 60204-1 prEN 1005-4 prEN ISO 14738 prEN 14386	EN ISO 14738	prEN 1005-4 prEN ISO 15537	
21.8	Noise at the work position	EN 1746	EN 547-1 EN 547-2 EN 547-3 prEN 1005-4 EN ISO 11688-1 EN ISO 11690-1 EN ISO 14738 prEN 14386 EN ISO 11201 ISO 1999	EN ISO 11690-2 EN ISO 11688-2	EN ISO 11200 EN ISO 11201 EN ISO 11202 EN ISO 11203 EN ISO 11204	
21.9	Vibration at the work position	EN 12786 ISO 2041 ISO 5805	EN 547-1 EN 547-2 EN 547-3 EN ISO 14738	CR 1030-1	EN 1033 ISO 2631-1 ENV 28041 prEN ISO 15537	
22	**Additional hazards and hazardous events due to the control system**					

Section	Hazards (EN 1050, Annex A)	Type-B standard related to ergonomics (according to EN 13861)				Medical-device group standard: EN IEC 60601-1 or EN ISO 14971
		Definition	Require-ments/design process	Measure	Test method	
22.1	Inadequate location of manual controls	EN ISO 7250 EN 894-2 prEN 894-3 EN 1005-1	EN IEC 60073 EN 60204-1 EN 894-2 EN 894-3 EN 1005-3 prEN 1005-4 EN ISO 14738 prEN 14386	EN ISO 14738	EN 894-3 EN 1005-3 prEN 1005-4 prEN ISO 15537	Implicit in CD EN IEC 60601-1-6
22.2	Inadequate design of manual controls and their mode of operation	EN 894-2 EN 894-3 EN 1005-1	EN IEC 60073 EN 60204-1 EN 547-1 EN 547-2 EN 547-3 EN 894-2 EN 894-3 EN 1005-3 prEN 1005-4		EN 894-3 EN 1005-3 prEN 1005-4	Implicit in CD EN IEC 60601-1-6
29	**Additional hazards and hazardous events due to lifting; hazards generated by neglecting ergonomic principles**					
29.1	Insufficient visibility from the driving position	EN ISO 7250 EN 1005-1	EN 60204-1 EN 547-1 EN 547-2 EN 547-3 EN 894-2 prEN 1005-4 EN ISO 14738 prEN 14386	EN ISO 14738	prEN 1005-4 prEN ISO 15537	Note: As far as the authors are aware, no medical products currently exist to which this question might be relevant.

Further possible hazards which might be relevant in the risk-management process: [36]

- Hazards related to the use of the medical device and contributory factors. These include:
  - inadequate labelling,
  - inadequate operating instructions, such as
    a) inadequate specification of accessories to be used with the medical device,
    b) inadequate specification of pre-use checks,
    c) over-complicated operating instructions,
  - inadequate specification of service and maintenance,
  - use by unskilled/untrained personnel,
  - reasonably foreseeable misuse,
  - insufficient warning of side effects,
  - inadequate warning of hazards likely with re-use of single-use medical devices,
  - incorrect measurement and other metrological aspects,
  - incompatibility with consumables/accessories/other medical devices,
  - sharp edges or points.

- Hazards resulting from inappropriate, inadequate or over-complicated user interface (man/machine communication). These include:
  - mistakes and judgement errors,
  - lapses and cognitive recall errors,
  - slips and blunders (mental or physical),
  - violation or abbreviation of instructions, procedures, etc.,
  - complex or confusing control system,
  - ambiguous or unclear device state,
  - ambiguous or unclear presentation of settings, measurements or other information,
  - misrepresentation of results,
  - insufficient visibility, audibility or tactility,
  - poor mapping of controls to action, or of displayed information to actual state,
  - controversial modes or mappings as compared to existing equipment.

- Hazards arising from functional failure, maintenance and ageing and contributory factors[37]

These include
  - erroneous data transfer,
  - lack of, or inadequate specification for maintenance including inadequate specification of post-maintenance functional checks,
  - inadequate maintenance,
  - lack of adequate determination of the end of life of the medical device,
  - loss of electrical/mechanical integrity,
  - inadequate packaging (contamination and/or deterioration of the medical device),

[36] As listed in EN ISO 14971
[37] As listed in EN ISO 14971

- re-use and/or improper re-use,
- deterioration in function (e.g. gradual occlusion of fluid/gas path, or change in resistance to flow, electrical conductivity) as a result of repeated use.

4.3 Selected Standards Aimed at Preventing Hazards Caused by Neglecting Ergonomic Principles

This list follows EN 13861 and only includes standards which appear to be suitable for designing medical devices in such a way as to reduce hazards. It has been completed and updated with further standards. The standards are listed by document number, regardless of their nature as EN, ISO, prEN etc.

EN 418 (1992):
Safety of machinery; Emergency stop equipment, functional aspects; Principles for design

EN 457 (1992):
Safety of machinery - Auditory danger signals - General requirements, design and testing (ISO 7731:1986, modified)
Specifies the safety and ergonomic requirements and the corresponding test methods for auditory danger signals and gives guidelines for the design of the signal to be clearly perceived and differentiated as required in 5.3 of EN 292-2. This Standard does not apply to verbal danger warnings (e.g. shouts, loudspeaker announcements).

EN 547-1 (1996):
Safety of machinery - Human body measurements - Part 1: Principles for determining the dimensions required for openings for whole body access into machinery
Specifies the dimensions of openings for whole body access as applied to machinery as defined in EN 292-1. It provides the dimensions to which the values given in EN 547-3 are applicable. Values for additional space requirements are given in annex A. Has been prepared primarily for non-mobile machinery, there may be additional specific requirements for mobile machinery.

EN 547-2 (1996):
Safety of machinery - Human body measurements - Part 2: Principles for determining the dimensions required for access openings
Specifies the dimensions of openings for access as applied to machinery as defined in EN 292-1. It provides the dimensions to which the values given in EN 547-3 are applicable. Values for additional space requirements are given in annex A. Has been prepared primarily for non-mobile machinery, there may be additional specific requirements for mobile machinery.

EN 547-3 (1996):
Safety of machinery - Human body measurements - Part 3: Anthropometric data
Specifies current requirements for human body measurements (anthropometric data) that are required by EN 547-1 and EN 547-2 for the calculation of access opening dimensions as applied to machinery. The anthropometric data originate from static measurements of nude persons and do not take into account body movements, clothing, equipment, machinery operating conditions or environmental conditions.

EN 563 (1994):
Safety of machinery - Temperatures of touchable surfaces - Ergonomics data to establish temperature limit values for hot surfaces
This is a type B1 safety standard concerned with the risk of burns caused by contact between human skin and hot surfaces. This standard applies to hot surfaces of all products and equipment that must or can be touched during their normal use. That includes the area of safety of machinery as well as any other applications. This standard provides data concerning circumstances under which contact with a hot surface may lead to skin burns. These data allow the assessment of risks of burning. This standard also provides data to be used to establish temperature limit values for hot surfaces to protect against skin burns. These data can be used in the development of standards for specific equipment where temperature limits are required. This standard does not apply, if a large area of the skin (approximately 10% or more of the skin of the whole body) can be in contact with the hot surface. This standard also does not apply to skin contact with more than 10% of the head or contact which could result in burns of vital areas of the face (e.g. burns resulting in the restriction of airways). In these cases severe injuries may occur, even if the surface temperature does not exceed the values specified in this standard. The data of this standard apply to surfaces of objects with relatively high thermal capacity when compared with that of the skin of the human body. This standard applies to the skin of adults. As far as there are no special data for the skin of children this standard may also be used to assess the risk of burning of children's skin in contact with hot surfaces. This standard does not provide data for the protection against pain. If the burn thresholds specified in this are not exceeded, there is normally no risk of burning, when the skin comes in contact with the hot surface, but pain may occur nevertheless. If there is also a need for protection against pain, surface temperature values should be taken from other suitable sources.

EN 614-1 (1995):
Safety of machinery - Ergonomic design principles - Part 1: Terminology and general principles
Establishes the ergonomics principles to be followed during the process of design of work equipment, especially machinery. Although the principles in this standard are orientated towards equipment for occupational use, they are applicable also to equipment for private use. This standard applies to the interactions between the operator and the work equipment when installing, operating, adjusting, maintaining, cleaning, repairing or transporting equipment and outlines the principles to be followed in taking the health and safety of the operator fully into account. The ergonomics principles given in this standard fully apply to all ranges of individual ability. Information on dimensions will need to be interpreted to suit the intended population.

EN 614-2 (2000):
Safety of machinery - Ergonomic design principles - Part 2: Interaction between the design of machinery and work tasks
Establishes the ergonomics principles and procedures to be followed during the design process of machinery and user work tasks. Deals specifically with task design in the context of machinery design, but the principles and methods may also be applied to job design. Is directed to designers and manufacturers of machinery and other work equipment. It will also be helpful to those who are concerned with the use of machinery and work equipment, e.g. to managers, organizers, operators and supervisors. The designer refers to the person or group of persons responsible for the design.

EN 842 (1996)
Safety of machinery - Visual danger signals - General requirements, design and testing
Specifies the safety and ergonomic requirements and the corresponding test methods for visual danger signals. It also provides guidance for the design of the signals to be clearly identified and distinguished as required in 5.3 of EN 292-2:1991. It does not apply to danger indicators - presented either in written or pictorial form - transmitted by data display units. Special regulations, such as those for public disaster and public transport, are not affected by this standard.

EN 894-1 (1997):
Safety of machinery - Ergonomics requirements for the design of displays and control actuators - Part 1:
General principles for human interactions with displays and control actuators
Applies to design of displays and control actuators on machinery. It specifies general principles for human interaction with displays and control actuators, to minimize operator errors and to ensure an efficient interaction between the operator and the equipment. It is particularly important to observe these principles when an operator error may lead to injury or damage to health.

EN 894-2 (1997):
Safety of machinery - Ergonomics requirements for the design of displays and control actuators - Part 2: Displays
Gives guidance on the selection, design and location of displays to avoid potential ergonomic hazards associated with their use. It specifies ergonomics requirements and covers visual, audible and tactile displays.

EN 894-3 (2000):
Safety of machinery - Ergonomics requirements for the design of displays and control actuators - Part 3: Control actuators
This Standard gives recommendations on the selection, design and location of control actuators so that they are adapted to the requirements of the user and take account of the circumstances of their use. It applies to manual control actuators used in equipment for occupational and private use. It is particularly important to observe the recommendations in this Standard where operating a control actuator may lead to injury or damage to health, either directly or as a result of a human error.

EN 980
This European Standard specifies graphical symbols for use in the information supplied by the manufacturer with medical devices. Graphical symbols for use in the labelling of medical devices

EN 981 (1996):
Safety of machinery - System of auditory and visual danger and information signals
Is applicable to all danger and information signals which have to be clearly perceived and differentiated as specified in 5.3 of EN 292-2:1991, by other requirements or by the work situation, and to all degrees of urgency –from extreme urgency to an ALL CLEAR situation. Where visual signals are to be complementary to sound signals, the signal character is specified for both.

EN 1005-1 (2001):

Safety of machinery - Human physical performance - Part 1: Terms and definitions
Provides terms and definitions on concepts and parameters used for EN 1005 Parts 2 to 4. Basic concepts and general ergonomic principles for the design of machinery are dealt with in EN 292-1 and EN 292-2 and EN 614-1.

EN 1005-2 (2003):
Safety of machinery - Human physical performance - Part 2: Manual handling of machinery and component parts of machinery
Specifies ergonomic requirements for the design of machinery concerned with manual handling in industrial and professional applications. This standard applies to the manual handling of objects of 3 kg or more. The standard provides data for ergonomic design and risk assessment concerning lifting, lowering and carrying in relation to the construction, transport and commissioning (assembly, installation, adjustment), use (operation, cleaning, fault finding, maintenance, setting, teaching or process changeover) and decommissioning, disposal and dismantling of machinery.

EN 1005-3 (2001):
Safety of machinery - Human physical performance - Part 3: Recommended force limits for machinery operation
Presents guidance to the designer of machinery or its component parts and the writer of C-standards in controlling health risks due to machine-related muscular force exertion. Specifies recommended force limits for actions during machinery operation including construction, transport and commissioning (assembly, installation, adjustment), use (operation, cleaning, fault finding, maintenance, setting, teaching or process changeover) decommissioning, disposal and dismantling. Applies primarily to machines which are manufactured after the date of issue of the standard. Applies on one hand to machinery for professional use operated by the adult working population, who are healthy workers with ordinary physical capacity, and on the other hand to machinery for domestic use operated by the whole population including youth and old people. The recommendations are derived from research on European population.

prEN 1005-4 (2002):
Safety of machinery - Human physical performance - Part 4: Evaluation of working postures in relation to machinery
Presents guidance to the designer of machinery or its components parts in assessing and controlling health risks due to machine-related postures and movements, i.e. during assembly, installation, operation, adjustment, maintenance, cleaning, repair, transport, and dismantlement. The standard specifies recommendations for postures and movements with minimal external force exertion. The recommendations are intended to reduce the risks for nearly all healthy adults.

CR 1030-1 (1995):
Hand-arm vibration - Guidelines for vibration hazards reduction - Part 1: Engineering methods by design of machinery
These guidelines outline feasible ways in which possible hand-arm vibration hazards associated with hand-held, hand-guided and other machinery, may be reduced by machinery design in order to provide practical professional aid to designers and manufactures of machinery. The document covers four principal aspects of the reduction of the effects arising from exposure to hazardous machinery vibration: reduction of vibration magnitude at source; reduction of vibration transmission from the source to handles and other surfaces in contact

with the hands; reduction of vibration transmission from the grips or handles of the machine to the hand-arm system of the user by ergonomic design measures; thermal design to optimize hand temperature.

EN 1041 (1998):
The document specifies the information to be supplied by a manufacturer for different categories of medical devices, as required by the relevant EC Directives. It does not specify the language to be used for such information.

EN 1299 (1997):
Vibration isolation of machines - Information for the application of source isolation
Gives guidelines to ensure that manufactures of machines provide adequate information on application of vibration isolation of their machines. Guidelines are also provided to ensure that users furnish sufficient information regarding their applications to suppliers to enable the optimum selection and design of vibration isolation. This standard is restricted to source isolation.

EN 1837 (1999):
Safety of machinery - Integral lighting of machines
Specifies the parameters of integral lighting systems designed to provide illumination in and/or at both stationary and mobile machines to enable the safe use of the machine and the efficient performance of the visual task within and/or at the machine to be carried out.

prEN ISO 6385 (2002):
Ergonomic principles in the design of work systems (ISO/DIS 6385:2002)
This basic standard establishes the fundamental principles of ergonomics as basic guidelines for the design of work systems. The intention is to improve, (re)design or change work systems. A work system involves a combination of people and equipment, within a given space and environment, and the interactions between these components within a work organization.

EN ISO 7250 (1997):
Basic human body measurements for technological design
Provides a basic list of anthropometric measurements for use in the establishment of common comparative definitions of population groups. The basic list specified in this standard is intended to serve as a guide for ergonomists who are required to define population groups and apply their knowledge to the geometric design of the places where people work and live. This list is not intended to serve as a guide for how to take anthropometric measurements but it shall give information to the ergonomist and designer on the anatomical and anthropometrical basis and principles of measurements which are applied in the solution of design tasks. This standard may be used in conjunction with national or international regulations or agreements to assure harmony in defining population groups. In its various applications, it is anticipated that the basic list will be supplemented by specific additional measurements.

EN ISO 7730 (1995):
Moderate thermal environments - Determination of the PMV and PPD indices and specification of the conditions for thermal comfort
The purpose of this International Standard is a) to present a method for predicting the thermal sensation and the degree of discomfort (thermal dissatisfaction) of people exposed to moderate thermal environments; b) to specify acceptable thermal environmental conditions for comfort. The International Standard applies

to healthy men and women and was originally based on studies of North American and European subjects but agrees also well with recent studies of Japanese subjects and is expected to apply with good approximation in most parts of the world. Applies to people exposed to indoor environments where the aim is to attain thermal comfort, or indoor environments where moderate deviations from comfort occur.

ISO 8995 (2002):
Lighting of indoor work places
Presents the criteria that have to be satisfied in order to achieve an acceptable visual environment. It is applicable to working areas in industrial buildings, offices and hospitals

ISO 9186 (2001):
Graphical symbols – Test methods for judged comprehensibility and for comprehension
Specifies preparations for the standards development process, methods for selection of the most suitable variant of a symbol, and methods to be used in testing the extent to which a variant of a symbol communicates its intended message.

ISO 9921-1 (1996):
Ergonomic assessment of speech communication -Part 1: Speech interference level and communication distances for persons with normal hearing capacity in direct communication (SIL method)
Provides a method for the prediction of the effectiveness of speech communication in the presence of noise generated by machinery as well as in noisy environments. Parameters are the ambient noise at the speaker's position, ambient noise at the listener's position, distance between the communication partners and a great number of physical and personal conditions.

prEN ISO 9921 (2003): Ergonomics – Assessment of speech communication (Revised version of ISO 9921-1:1996)

The standard specifies the requirements for the performance of speech communication for verbal alert and danger signals, information messages, and speech communication in general. Methods to predict and to assess the performance in practical applications are described and examples are given. Acoustical danger and warning signals are in general omni-directional and therefore may be universal in many situations. Auditory warnings are of great benefit in situations where smoke, darkness or other obstructions interfere with visual warnings. It is essential that, in the case of verbal messages, a sufficient level of intelligibility is achieved in the coverage area. If this cannot be achieved non-voice warning signals (see ISO 7731, IEC 60849) or visual warning signals (ISO 11429) may be preferable.

ISO 10075-1 (2000):
Ergonomic principles related to mental work-load – General terms and definitions
Carries on from ISO 6385 3.7 to 3.9 and gives more detailed definitions of the terms.

ISO 10075-2 (2000):
Ergonomic principles related to mental workload – Part 2: Design principles
The document gives guidance on the design of work systems, including task and equipment design and design of the workplace, as well as working conditions, emphasizing mental workload and its effects, as specified in ISO 1075. It applies to the adequate design of work and use of human capacities.

EN ISO 11688-1 (1998)
Acoustics - Recommended practice for the design of low-noise machinery and equipment - Part 1: Planning
Serves as an aid to understanding the basic concepts of noise control in machinery and equipment. The recommended practice presented is intended to assist the designer at any design stage to control the noise of the final product. Makes references to numerous technical publications dealing with acoustical problems.

EN ISO 11688-2 (2000):
Acoustics - Recommended practice for the design of low-noise machinery and equipment - Part 2: Introduction to the physics of low-noise design
Provides the physical background for the low-noise design rules and examples given in Part 1 and supports the use of extensive special literature. Is intended for use by designers of machinery and equipment as well as users and/or buyers of machines and authorities in the field of legislation, supervision and inspection. Equation given in this standard shall improve the general understanding of noise control. In many cases they allow a comparison of different versions of design, but they are not useful for the prediction of absolute noise emission values.

EN 12464-1 (2003):
Light and lighting – Lighting of workplaces – Part 1: Indoor work places
This standard provides extensive coverage of the medical field and addresses maintenance values for lighting.

EN 12665 (1996):
Lighting applications - Basic terms and criteria for specifying lighting requirements
Defines basic terms for use in all lighting applications; specialist terms with limited applications are given in individual standards. This standard also sets out a framework for the specification of lighting requirements, giving details of aspects which shall be considered when setting those requirements.

EN 13202 (2000):
Ergonomics of the thermal environment - Temperatures of touchable hot surfaces - Guidance for establishing surface temperature limit values in production standards with the aid of EN 563
This guidance document describes methods for the assessment of the risk of burning when a hot surface is touched by unprotected skin. It also describes how surface temperature limit values can be established in product standards with the aid of EN 563. The guidance is for establishing temperature limit values in all fields, where surface temperature limit values are required. Its field of application is not restricted to the safety of machinery. It is applicable for all kinds of products where hot surfaces cause a risk of burning. It applies as well for electrically powered products as for all other products.

This document does not set surface temperature limit values. It provides guidance to Technical Committees to carry out assessments of the risk of burning and to establish appropriate surface temperature limit values if necessary. Provides the possibility of harmonizing surface temperature limit values in standards for all kind of products. Provides additional information not contained in EN 563, including burn thresholds for contact periods below 1 s, burn thresholds for different textures of material and the assessment of burning risks for people other than healthy adults.

prEN ISO 13732-3 (2002):

Ergonomics of the thermal environment - Touching of cold surfaces - Part 3: Ergonomics data and guidance for application (ISO/DIS 13732-3:2002).

prEN 14386 (2002):
Safety of machinery - Ergonomic design principles for the operability of mobile machinery
Establishes the ergonomic principles to be followed during the design process for mobile machinery with special emphasis on the points where mobile machinery differs from static machinery. This European Standard applies to the interactions between an operator and the mobile machinery when operating or transporting and outlines the principles to be followed in taking the health and safety of the operator fully into account.

EN ISO 14738 (2002):
Safety of machinery - Anthropometric requirements for the design of workstations at machinery
Establishes principles for deriving dimensions from anthropometric measurements and applying them to the design of workstations at non-mobile machinery. It is based on current ergonomic knowledge and anthropometric measurements.

EN IEC 60073 (1998):
Basic and safety principles for man-machine interface, marking and identification - Coding principles for indication devices and actuators
Establishes general rules for assigning particular meanings to certain visual, acoustic and tactile indications in order to

- increase the safety of persons, property and/or the environment through the safe monitoring and control of the equipment or process;
- facilitate the proper monitoring, control and maintenance of the equipment or process;
- facilitate the rapid recognition of control conditions and actuator positions.

EN 60447 (1996):
Man-machine interface (MMI); actuating principles (IEC 60447:1993)
This standard establishes general actuating principles for manually operated actuators forming part of the man-machine interface associated with electric equipment, in order to:

- increase the safety (e.g. of persons, property, the environment) through the safe operation of the equipment;
- facilitate the proper and timely operation of the actuators.

These principles apply not only for the operation of electrical equipment, machines, or complete plant under normal conditions, but also under fault or emergency conditions.

EN 61310-1 (1995):
Safety of machinery - Indication, marking and actuation - Part 1: Requirements for visual, auditory and tactile signals (IEC 61310-1:1995)
Specifies safety-related information requirements, at the man-machine interface and for exposed persons. It gives general rules for a system of colours, safety signs, markings and other warnings, giving information for use for the indication of hazardous conditions, for warning of health hazards and for meeting certain emergencies. It also specifies ways of coding visual, audible and tactile signals for indicating and actuating devices in order to facilitate the safe use and monitoring of the machinery.

Annex A1: Risk Concepts Applied to Medical Devices
(Taken from EN ISO 14971, Annex E, with minor changes)

A1.1 Risk Estimation

Various methods can be used to estimate risk. While EN ISO 14971 requires that risk estimation be carried out (see chapter 3), it does not specify a particular method to be used. Quantitative risk estimation is possible when suitable data are available. Other methods for quantitative risk estimation could be based upon the adaptation of a qualitative method, for example.

A risk chart such as Figure 4 can be used as to define risk. Figure 4 is an example of a risk chart and is included only to show the method. This does not imply that it has general application to medical devices. If a risk chart approach is used for estimating risk, the particular risk chart and the interpretation used should be justified for that application.

The concept of risk is defined as the combination of two components:
- the probability of occurrence of harm, that is, how often the harm may occur and
- the consequences of that harm, that is, how severe it might be.

Risk estimation should examine the initiating events or circumstances, the sequence of events that are of concern, any mitigating features, and the nature and frequency of the possible deleterious consequences of the identified hazards. Risk should be expressed in terms that facilitate risk control decision making. In order to analyse risks, their components, i.e. probability and severity, should be analysed separately.

A1.1.1 Probability estimation

In appropriate situations where sufficient data are available, a quantitative categorization of probability levels is to be preferred. If this is not possible, the manufacturer should give a qualitative description. It should be obvious that a qualitatively good description is preferable to quantitative inaccuracy. For a qualitative categorization of probability levels, the manufacturer can use descriptors appropriate for the medical device. The concept is in reality a continuum, however in practice a number of discrete levels can be used. In this case, the manufacturer decides how many categories are needed and how they are to be defined. The levels can be descriptive (e.g. incredible, improbable, remote, occasional, probable, frequent) or symbolic (P1, P2, etc.).

Probability estimation examines the initiating events or circumstances and the sequence of events that are of concern. This includes answering the following questions.
- Does the hazard occur in the absence of a failure?
- Does the hazard occur in a failure mode?
- Does the hazard occur only in a multiple-fault condition?

The probability of each undesired event occurring is identified at the hazard-identification stage (see fig. 1 and 2). This sub-process is part of step 3 in figure 5 (Estimate risk(s) for each hazard). Three approaches are commonly employed to estimate probabilities, as follows:
- use of relevant historical data,
- prediction of probabilities using analytical or simulation techniques,

 use of expert judgement.

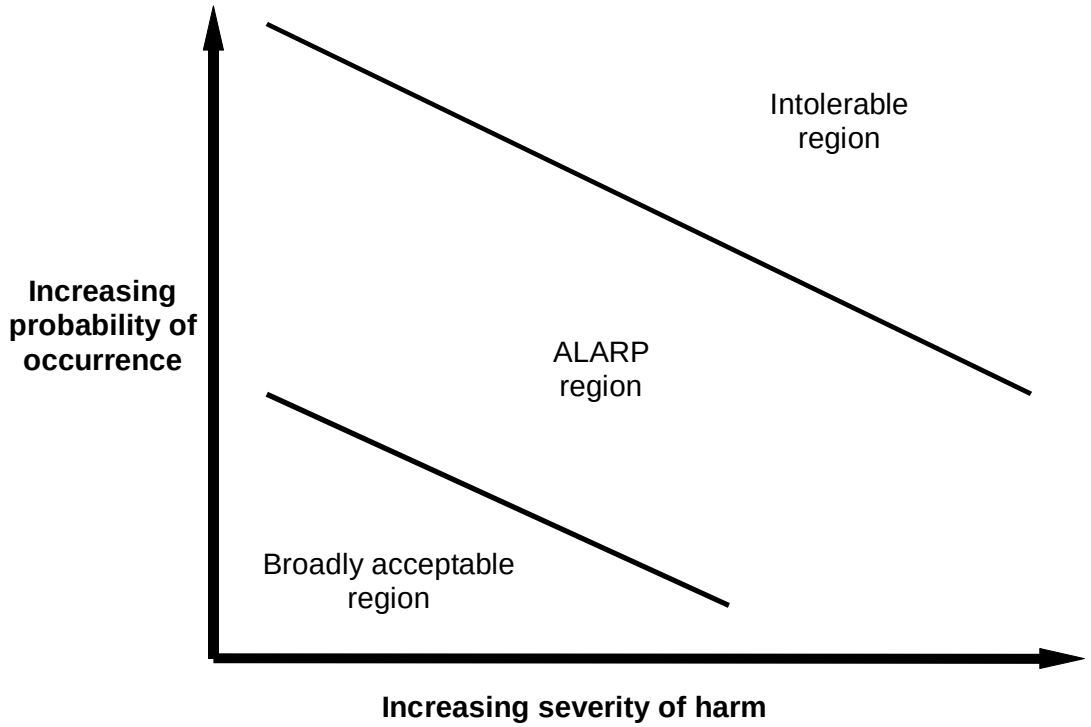


Figure 4: Example of a three-region risk chart
ALARP region: As Low As Reasonably Practicable

All these approaches can be used individually or jointly. The first two approaches are complementary; each has strength where the other has weaknesses. Wherever possible, both should be used. In this way, they can be used as independent checks on each other, and this might serve to increase confidence in the results. When these cannot be used or are not sufficient, it is necessary to rely on expert judgement.

Some hazards occur because of systematic rather than random failures. For example, hazards derived from software failures are due to systematic failures. For more information on systematic failures, see A1.4.3. Systematic Failure.

A1.1.2 Severity levels

The concept of severity is in reality a continuum, however in practice a number of discrete levels can be used. In this case, the manufacturer decides how many categories are needed and how they are to be defined. The levels may be descriptive (e.g. negligible, marginal, critical, serious, catastrophic) or symbolic (S1, S2, etc.).

These levels need to be customized by the manufacturer for a particular medical device considering both short-term and long-term effects.

A1.2 Risk Acceptability

A1.2.1 General

The standard EN ISO 14971 does not specify acceptable risk. Methods of determining acceptable risk include the following:

- using applicable standards that specify requirements which, if implemented, will indicate achievement of acceptability concerning particular kinds of medical devices or particular risks;
- following appropriate guidance, for example that obtained by using the single-fault principle (for details, see 9.10 of IEC/TR 60513:1994);
- comparing levels of risk which have proved effective for medical devices already in use

A three-region concept of risk is illustrated in Figure 4. These regions differentiate between acceptable and intolerable risks and will need to be customized for a particular medical device.

Examples of the use of numerical probability and severity estimates are quoted in EN ISO 14971.

A1.2.2 Broadly Acceptable Region

In some cases, a risk is so low that it is negligible in comparison with other risks and in view of the benefit of using the medical device. In such cases, the risk is acceptable and risk control need not be actively pursued.

A1.2.3 ALARP Region

If only the medical benefit is considered, it might be thought that any RISK associated with a MEDICAL DEVICE would be acceptable if the patient's prognosis were improved. However, improvement of the prognosis cannot be used as a rationale for the acceptance of unnecessary RISK. Any RISK should be reduced to the lowest level practicable, bearing in mind the benefits of accepting the risk and the practicability of further reduction.

Practicability refers to the ability of a manufacturer to reduce the risk. Practicability has two components:

- technical practicability, and
- economic practicability.

Technical practicability refers to the ability to reduce the risk regardless of cost. Economic practicability refers to the ability to reduce the risk without making the provision of the medical device an unsound economic proposition. Cost and availability implications are considered in deciding what is practicable to the extent that these impact upon the preservation, promotion or improvement of human health.

Major risks should normally be reduced even at considerable cost. Near the broadly acceptable region, a balance between risk and benefit may suffice.

A1.2.4 Risk-Acceptability Decisions

When a hazard has been identified and the risk estimated, the first question to be asked is whether the risk is already so low that there is no need to consider risk reduction. This decision is made once for each hazard.

If the decision at the first stage is that the risk is not broadly acceptable, the next stage is to progress to risk reduction. Risk reduction might or might not be

practicable but it should be considered. The possible outcomes of this second stage are as follows:

- that one or more risk-reduction measures bring the risk down to a level where it is not necessary to consider it further; or
- that, whether or not some risk reduction is feasible, reducing the risk down to the broadly acceptable level is not practicable.

In the latter case, the risk should be reduced to a level as low as reasonably practicable (ALARP), and then the risk and benefit should be compared. If the risk is outweighed by the benefit, then the risk may be accepted. If the risk is not outweighed by the benefit, then it is unacceptable and the technical concept giving rise to this risk should be abandoned.

Finally, once all risks have been found to be acceptable, the overall residual risk is evaluated to assure that the risk/benefit balance is still maintained.

Thus there are three decision points in the process, where different questions are asked about the acceptability of risks.

1. Whether the risk is so low that there is no need to consider it?
2. Whether there is no longer any reason to consider the risk, **or** the risk is as low as is reasonably practicable **and** outweighed by the benefit?
3. Whether the overall balance of all the risks with all the benefits is acceptable?

A1.3 Cause of Failure

A1.3.1 Failure Types

A hazardous situation can result from the failure of a system. There are two possible types of failure:

- random failures, and
- systematic failures.

A1.3.2 Random Failure

For many events, a statistical probability of failure can be assigned (e.g. the probability of failure of an assembly is often estimated from the failure probabilities of the components which make up the assembly). In this case, a numerical value can be given for the probability of failure. An essential presumption is that the failures are random in nature. Hardware is assumed to fail either in a random or in a systematic manner. Software is assumed to fail in a systematic manner.

A1.4.3 Systematic Failure

Systematic failures are due to errors (including errors of commission and omission) in any activity which, under some particular combination of inputs or environmental conditions, will permit a failure.

The error leading to systematic failures can occur in both hardware and software, and can be introduced at any time during a medical device's development, manufacture or maintenance. Examples of a systematic failure are as follows.

1. A fuse might fail. The fuse rating might have been incorrectly specified, incorrectly fitted during manufacture, or incorrectly replaced during repair.
2. The use of incorrect material results in excessive wear and premature failure. The incorrect material might have been incorrectly specified, or incorrectly used during manufacture.
3. A software database does not provide for the condition of full database. If the database is full, it is not clear what the software will do. A possible consequence is that the system will delete existing records to make room for new ones.

The accurate estimation of systematic failure rates is difficult. This occurs primarily for the two following reasons.

1. Systematic failure rates are laborious and expensive to measure. Achieving a reasonable level of confidence in the result will not be possible without a long history of measuring failure rates.
2. Consensus does not exist for a method of estimating systematic failure rates quantitatively.

In cases where an appropriate level of confidence cannot be established for the estimation of systematic failures, the risk should be managed based on the severity of the harm resulting from the hazard. Initially, the risk estimation for systematic faults should be based on the presumption that systematic failure will occur at an unacceptable rate.

There is a relationship between the quality of the development processes used and the possibility of a systematic fault being introduced or remaining undetected. The severity of the consequence of the systematic faults and the effect of external risk-control measures are therefore to be taken into account. The worse is the consequence and the less is the effect of external risk-control measures, the higher is the required quality of the development process.

Annex A2: Guidance for Risk Analysis for In Vitro Diagnostic Medical Devices

A2.1 General

This annex provides additional guidance on the risk analysis of in vitro diagnostic medical devices, taking into account the particularities of these medical devices. Under certain circumstances indirect risks may result from hazards associated with in vitro diagnostic medical devices. Use-related hazards and their associated risks should be considered.

A2.2 Identification of hazards

In addition to those aspects mentioned in annex 4.2.3, the following aspects should be considered in identifying potential hazards for the patient or the user:

- stability problems (in storage, in shipping, in use, after first opening of the container);
- problems related to taking, preparation and stability of specimens.

Potential hazards for the user can arise from radioactive, infectious, toxic or otherwise hazardous ingredients of reagents and from the packaging design. For instruments, the problem of potential contamination during handling, operation and maintenance should be considered in addition to the non-specific instrument-related hazards (e.g. energy hazards).

A2.3 Risk estimation

In estimating the risk for each hazard, the following aspects should be taken into account:

- detectability of deficiencies/errors;
- situations of use (e.g. emergency cases);
- professional use/non-professional use.

Annex A3: Guidance on risk analysis procedure for toxicological hazards

A3.1 General

This annex provides guidance on the application of risk analysis, with respect to toxicological hazards. Toxicological hazards are due to chemical constituents causing biological harm. ISO 10993-1 sets out the general principles for the biological evaluation of materials/medical devices. Efforts should be made to avoid unnecessary testing using animals. Attention is drawn to ISO 10993-2 on animal welfare requirements, and to relevant national or regional regulations which may indicate that tests should be omitted if the omission can be scientifically justified.

A3.2 Estimation of toxicological risks

Factors to be taken into account

The toxicological risk analysis should take account of
- the chemical nature of the materials,
- prior use of the materials, and
- biological safety test data.

The amount of data required and the depth of the investigation will vary with the intended use/intended purpose and are dependent upon the nature and duration of user contact. Data requirements are usually less stringent for packaging materials, medical devices contacting intact skin, and any component of a medical device that does not come into direct contact with body tissues, infusible liquids, mucous membranes or compromised skin.

Current knowledge of the material/medical device provided by scientific literature, previous clinical experience and other relevant data should be reviewed to establish any need for additional data. In some cases, it can become necessary to obtain formulation data, residue data (e.g. from sterilization processes, monomers), biological test data, etc.

Chemical nature of the materials

Information characterizing the chemical identity and biological response of materials is useful in assessing a medical device for its intended use/intended purpose. Some factors that can affect the biocompatibility of the material include
- the identity, concentration, availability and toxicity of all constituents (e.g. additives, processing aids, monomers, catalysts, reaction products), and
- the influence of biodegradation and corrosion on the material.

Where reactive or hazardous ingredients have been used in, or can be formed by, the production, processing, storage or degradation of a material, the possibility of exposure to residues should be considered. Information on residue concentration and/or leaching can be necessary. This can take the form of experimental data or information on the chemistry of the materials involved.

Where the necessary data (e.g. complete formulation data) are not available to a manufacturer because of confidentiality, verification should be obtained that an assessment has been carried out of the suitability of the material for use in the proposed application.

Prior use
Available information on previous uses of each material or intended additive and on any adverse reactions encountered should be reviewed. However, the previous use of an ingredient or material does not necessarily assure its suitability in similar applications. Account should be taken of the intended use/intended purpose, the concentration of the ingredients and current toxicological information.

Biological safety test data
ISO 10993-1 gives guidance on which tests should be considered for a particular application. The need for testing should be reviewed on a case-by-case basis in the light of existing data, so that unnecessary testing is avoided.

Annex A4: Risk Management

This annex sets out the concept described in EN ISO 14971 so that the guidance provided in that key standard is also available to manufacturers of medical devices which are not subject to the standard and who thus do not have a copy of it.

A4.1 General Requirements for Risk Management

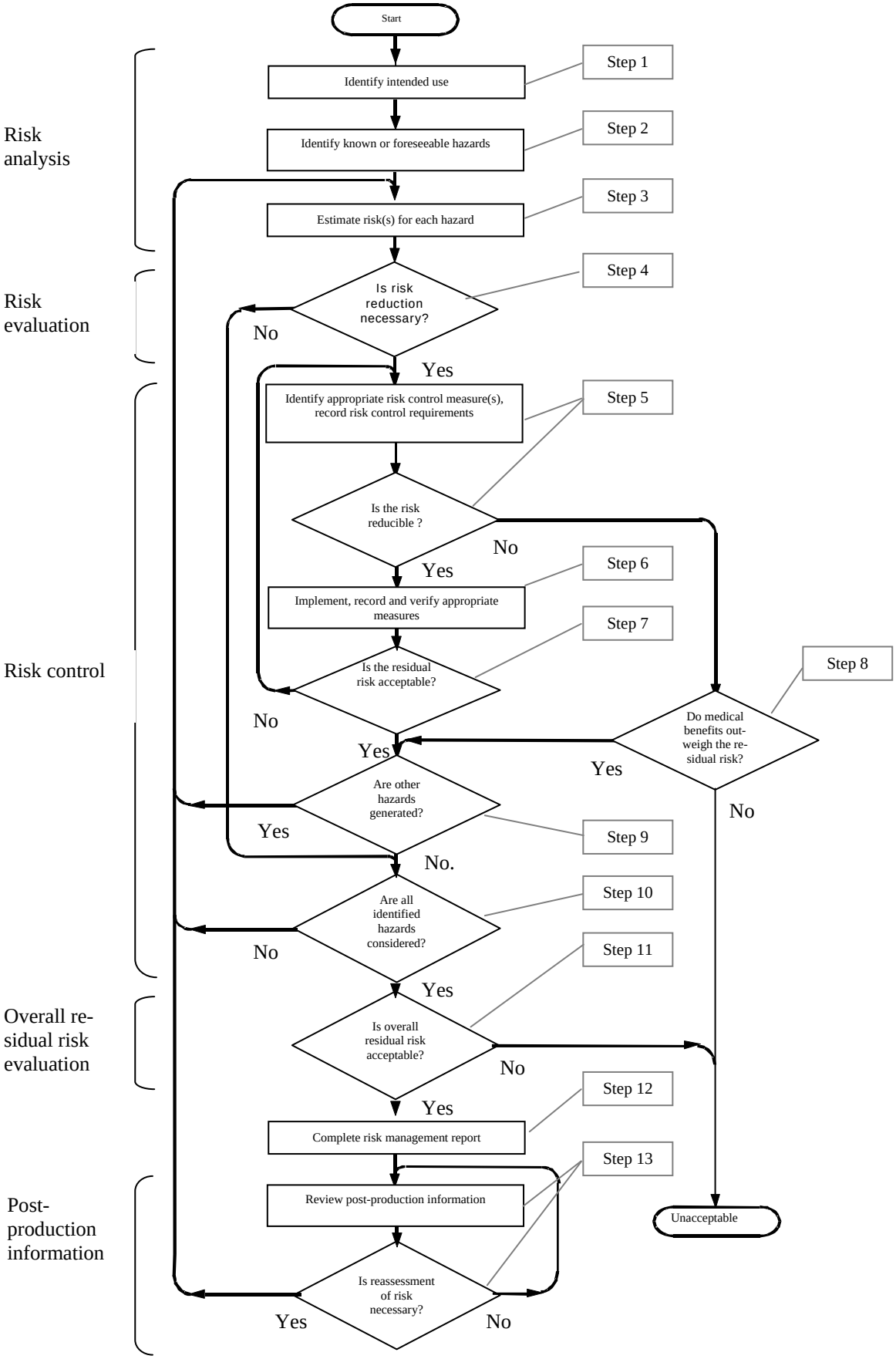
Risk management process

In order to ensure that medical devices placed on the market are safe, each manufacturer shall identify the hazards associated with a medical device and estimate the associated risks. Following evaluation, it is necessary to control these risks and to monitor the effectiveness of the control. This process shall include the following elements:

- risk analysis;
- risk evaluation;
- risk control; and
- post-production information.

An detailed overview of the risk management process is provided in figure 5.

Figure 5:
Overview of risk management activities as applied to medical devices (EN ISO 14971)



A4.2 Risk analysis (Steps 1, 2 and 3 of Figure 5)

Risk-analysis procedure

A risk analysis, as described in Chapter 3, should be performed.

NOTE: If a risk analysis is available for a medical device with the same intended purpose and a similar design, it may be used as a reference provided it can be demonstrated that the processes are similar or that the changes that have been made will not introduce significant differences in results. This should be based on a systematic evaluation of the changes and the ways they can influence the various hazards present.

Identification of characteristics related to the safety of the medical device (Step 1 of Figure 5)

For the particular medical device or accessory being considered, the manufacturer shall describe the intended use/intended purpose and any reasonably foreseeable misuse. The manufacturer shall list all those qualitative and quantitative characteristics that could affect the safety of the medical device and, where appropriate, their defined limits.

NOTE: Chapter 4.1 contains questions that can serve as a useful guide in drawing up such a list.

Identification of known or foreseeable hazards (Step 2 of Figure 5)

The manufacturer shall compile a list of known or foreseeable hazards associated with the medical device in both normal and fault conditions and in reasonably foreseeable cases of misuse. Previously recognized hazards shall be identified.

Foreseeable sequences of events that may result in a hazardous situation shall be considered and recorded.

NOTE: The examples of possible hazards listed in Chapter 4.2 can be used as an aide-memoire. To identify hazards not previously recognized, systematic methods covering the specific situation can be used. These Ergonomics Guidelines on the Design of Medical Devices have already mentioned the need to consider chemical and biological risks for the user as well in Chapter 1, Introduction, with reference to Section 5 (3) of the German Occupational Health and Safety Act. The EN ISO 14971 statements given in the annexes have therefore been adapted accordingly.

Estimation of the risk(s) for each hazard (Step 3 of Figure 5)

For each identified hazard, the risk(s) in both normal and fault conditions and in reasonably foreseeable cases of misuse shall be estimated using available information or data. For hazards for which the probability of the occurrence of harm cannot be estimated, a listing of the possible consequences of the hazard shall be prepared.

NOTE: Information or data for estimating risks can be obtained, for example, from
- published standards,
- scientific technical data,

- field data from medical devices already in use including published reported incidents,
- usability tests employing typical users,
- clinical evidence,
- results of appropriate investigations,
- expert opinion,
- external quality assessment.

A4.3 Risk evaluation

For each identified hazard, the manufacturer shall decide whether the estimated risk(s) is (are) so low that risk reduction need not be pursued. In this case, Steps 5 to 9 do not apply for this hazard (i.e. proceed to Step 10).

NOTE: Application of relevant standards as part of the medical device design criteria might constitute risk control activities, thus necessitating application of Steps 6 to 9.

A4.4 Risk control

Risk reduction
When risk reduction is required, the manufacturer shall follow Steps 5 to 10 to control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable.

Option analysis (Step 5 of Figure 5)
To reduce the risk(s) to an acceptable level, the manufacturer shall take one or more of the following measures in the priority order listed:

- inherent safety by design;
- protective measures in the medical device itself;
- information for safety.

NOTE: Measures of risk control can reduce the severity of the potential harm or reduce the probability of occurrence of the harm, or both.
Technical standards address inherent, protective and descriptive safety for many medical devices. These should be consulted as part of the risk management process.

If, during option analysis, the manufacturer determines that further risk reduction is impractical, the manufacturer shall conduct a risk/benefit analysis of the residual risk (see Step 8); otherwise, the manufacturer shall proceed to implement the selected risk control measures.

Implementation of risk control measure(s) (Step 6 of Figure 5)

The manufacturer shall implement the risk control measure(s) selected in Step 5. Implementation and effectiveness of the risk control measures shall be verified.

Residual risk evaluation (Step 7 of Figure 5)
Any residual risk that remains after the risk control measure(s) are applied shall be evaluated using the criteria defined in the risk management plan. The results of

this evaluation shall be recorded in the risk management file. If the residual risk does not meet these criteria, further risk control measures shall be applied (see Step 5).

Risk/benefit analysis (Step 8 of Figure 5)
If the residual risk is judged unacceptable and further risk control is impractical, the manufacturer shall gather and review data and literature on the medical benefits of the intended use/intended purpose to determine if they outweigh the residual risk. If this evidence does not support the conclusion that the medical benefits outweigh the residual risk, then the risk remains unacceptable. If the medical benefits outweigh the residual risk, then proceed to Step 9. Relevant information necessary to explain the residual risk shall be placed in the appropriate accompanying documents supplied by the manufacturer.

Other generated hazards (Step 9 of Figure 5)
The risk control measures shall be reviewed to identify if other hazards are introduced. If any new hazards are introduced by any risk control measures, the associated risk(s) must also be assessed (see Step 3).

Completeness of risk evaluation (Step 10 of Figure 5)
The manufacturer must assure that the risk(s) from all identified hazards have been evaluated.

A4.5 Overall residual risk evaluation (Step 11 of Figure 5)

After all risk control measures have been implemented and verified, the manufacturer must decide if the overall residual risk posed by the medical device is acceptable. If the medical benefits do not outweigh the overall residual risk, then the risk remains unacceptable.

A4.6 Post-production information (Step 13 of Figure 5)

The manufacturer shall establish and maintain a systematic procedure to review information gained about the medical device or similar devices in the post-production phase. The information shall be evaluated for possible relevance to safety, especially the following:
- if previously unrecognized hazards are present;
- if the risk(s) is(are) no longer acceptable;
- if the original assessment is otherwise invalidated.

If any of the above conditions is satisfied, the results of the evaluation shall be fed back as an input to a new risk management process (see Step 3).

If there is a potential that the residual risk(s) or its acceptability has changed, the impact on previously implemented risk control measures shall be evaluated.

NOTE: See also 4.14 of ISO 13485 "Corrective and preventive action" and "Particular requirements for all medical devices". Information may be found at any stage of the medical device life cycle from inception to post-production phases.

Annex A5: Terms and Definitions

In some cases, the same terms are defined differently in the machinery standards and the standards for medical devices. Though the terminology in EN 292-1 and EN ISO 14971 is the same, EN 1050 and EN ISO 14971 use different terms. This means that there is potential for conflicting interpretations. However, consistent terminology is required for these guidelines.

In prEN 292-1, for example, "harm" is defined as "physical injury or damage to health" except in the case of pets, property and the environment but EN 1050 defines it as "physical injury and/or damage to health or property" without any exceptions. In the context of EN ISO 14971, harm is "physical injury or damage to the health of people, or damage to property or the environment".

The terminology used in a study should be easily understood by its target group, in this case developers and test houses, as well as being compatible with the rest of the terminology used in the field it covers, e.g. as used in the relevant standards. After consultation with the work group supervising the project, it was decided that the definitions applicable to medical equipment would be used for these guidelines. For the purpose of clarity, the key definitions are listed below. In the field of medical equipment (with the focus more on devices than on disposable products), the following standards are of primary significance:

- EN ISO 14971

- EN 60601-1 with its collateral standards (EN IEC 60601-1-X) and the vertical standards for particular types of medical equipment (EN IEC 60601-2-X and, where appropriate, EN IEC 60601-3-X)[38].

For these guidelines, the terms in EN ISO 14971 and the EN IEC 60601 suite which correspond to the terms in ISO/IEC Guide 51 will be used (see glossary).

The third version of EN IEC 60601 is currently being prepared and is expected to be published in 2004. It will include some significant changes as compared to the current second version. In particular, it is expected to make explicit reference to risk management and the risks caused by deficient fitness for purpose. Since the structure and the wording are still very much in a state of flux, these guidelines refer to the current, second version.

[38] Hereinafter, the EN ISO 60601 standards as a whole will be referred to as the "EN 60601 suite".

The definitions applicable in these guidelines are listed below with their sources. In cases where a term is defined differently in different standards, all definitions are stated.

Comparison of risks

As part of the process of risk evaluation, the risks associated with the machinery can be compared with those of similar machinery…
[EN 1050]

Effectiveness

Accuracy and completeness with which OPERATORS achieve specified goals
[CD EN IEC 60601-1-6, quoted from ISO 9241-11]

Efficiency

Resources expended in relation to the accuracy and completeness with which operators achieve goals
[CD EN IEC 60601-1-6, quoted from ISO 9241-11]

Harm

Physical injury or damage to the health of people, or damage to property or the environment.
[EN ISO 14971]

Physical injury or damage to health.
[prEN 292-1]

Physical injury and/or damage to health or property
[EN 1050]

Hazard

1) Potential source of harm.[39]
[EN ISO 14971 and prEN 292-1]
2) Potentially detrimental effect on the patient, other persons, animals, ort he surroundings
[EN IEC 60601-1-4]

Hazard analysis

Identification of hazards and their initiating causes
[EN IEC 60601-1-4]

Hazard/danger zone

Any zone within and/or around machinery in which a person is exposed to a hazardous situation.
[prEN 292-1]

Hazard identification

All hazards, hazardous situations and hazardous events associated with the machinery shall be identified.
[EN 1050]

Hazard, relevant

39 The definition given in EN IEC 60601-1 “Potentially detrimental effect on the patient, other persons, animals, or the surroundings arising directly from equipment” is not as general which is why it is not used here.

Hazard which is identified as being present at or associated with the machine (as the result of one step of the process described in EN 1050).
[prEN 292-1]

Hazard, significant

A hazard which has been identified as relevant and which requires specific action by the designer to eliminate or reduce the risk according to the risk assessment .
[prEN 292-1]

Hazardous event

Event that can cause harm.
[EN 1050]

Hazardous situation

Circumstance in which people, property or the environment are exposed to one or more hazard(s)
[EN ISO 14971 and ISO/IEC Guide 51]

A circumstance in which a person is exposed to at least one hazard. The exposure can immediately or over a long period of time have the potential to result in harm.
[prEN 292-1]

Intended use / intended purpose

Use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer.
[EN ISO 14971]

Manufacturer

Natural or legal person with responsibility for the design, manufacture, packaging or labelling of a medical device, assembling a system, or adapting a medical device before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.
[EN ISO 14971]

Medical device

Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
[EN ISO 14971]

Protective safety measure

1) Measure intended to achieve risk reduction, implemented:
- by the designer (intrinsic design, safeguarding and complementary protective measures, information for use) and
- by the user (organisation: safe working procedures, supervision, permit-to-work systems; additional safeguards; personal protective equipment; training)

[prEN 292-1]

2) Means that eliminates a hazard or reduces a risk
[EN 1050]

Residual risk

1) Risk remaining after protective measures have been taken.
[ISO/IEC Guide 51, EN ISO 14971 and prEN 292-1]
2) Risk identified by hazard analysis, which remains after risk management has been completed.
[CD IEC 60601-1-4]

Responsible organization

Entity accountable for the use and maintenance of MEDICAL ELECTRICAL EQUIPMENT.
[EN IEC 60601-1]

Risk

1) Combination of the probability of occurrence of harm and the severity of that harm.
[ISO/IEC Guide 51:1999, Definition 3.2] and [prEN 292-1]

2) Probable rate of occurrence of a hazard causing harm, and the degree of severity of the harm.
[EN IEC 60601-1-4]

Risk analysis

1) Systematic use of available information to identify hazards and to estimate the risk.
[ISO/IEC Guide 51:1999, Definition 3.10]

2) Combination of the determination of the limits of the machine, hazard identification and risk estimation.
[prEN 292-1]

Risk assessment

Overall process comprising a risk analysis and a risk evaluation.
[ISO/IEC Guide 51, EN ISO 14971 and CD EN IEC 60601-1-6]
The overall process of risk analysis and risk evaluation
[prEN 292-1]

Risk control

Process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels.
[EN ISO 14971 and CD IEC 60601-1-6]

Risk, element of

as a function of:

- the frequency and duration of the exposure of persons to the hazard;
- the probability of occurrence of a hazardous event;
- the technical and human possibilities to avoid or limit the harm.

[prEN 292-1]

Risk estimation

Determination of the elements of risk for each hazard
- the severity of harm,
- the probability of occurrence of that harm

[prEN 292-1]

Risk evaluation

1) Judgement, on the basis of risk analysis, of whether a risk which is acceptable has been achieved in a given context based on the current values of society.
[EN ISO 14971 based on ISO/IEC Guide 51]
2) Judgement, on the basis of risk analysis of whether a tolerable risk has been achieved.
[prEN 292-1]

Risk management

Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk.
[EN ISO 14971 and CD IEC 60601-1-6]

Risk, maximum tolerable

Value of risk which is specified as the maximum which may be permitted.
[EN IEC 60601-1-4]

Risk, tolerable

Risk which is accepted in a given context based on the current values of society (e.g. national regulations or laws)
[prEN 292-1]

Safety

1) Freedom from unacceptable risk.
[ISO/IEC Guide 51, EN ISO 14971 and CD IEC 60601-1-6]
2) Freedom from unacceptable risk of harm.
[CD IEC 60601-1-4]

Severity

1) Criteria:
   a) the nature of what is to be protected:
      - persons;
      - property;
      - environment;
   b) the severity of injuries or damage to health:
      - slight (normally reversible);
      - serious (normally irreversible);
      - death;
   c) the extent of harm (for each machine):
      - one person;
      - several persons.

   [EN 1050]

2) Qualitative measure of the possible consequences of a hazard
[CD IEC 60601-1-4]
3) Measure of the possible consequences of a hazard.
[EN ISO 14971]

Usability

Characteristic that establishes learnability, EFFECTIVENESS, EFFICIENCY and satisfaction
[CD EN IEC 60601-1-6]

User / operator

Person handling equipment
[EN IEC 60601-1 2nd]

Validation

Process of evaluating a PEMS[40] or a component of a PEMS during or at the end of the development process to determine whether it satisfies the requirements for its intended use.
[CD IEC 60601-1-4]

Verification

Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
NOTE: In design and development, verification concerns the process of examining the result of a given activity to determine conformity with the stated requirement for that activity.
[EN ISO 14971]

Process of evaluating a PEMS or a component of a PEMS to determine whether the products of a given development phase satisfy the specified requirements imposed at the start of that phase.
[CD IEC 60601-1-4]

[40] Programmable, electrical, medical system

Bibliography

Please note: Standards listed in 4.2 and 4.3 are not listed here. To search for specific standards or exact titles, we recommend the following databases, which are regularly updated:

- NoRA (OH&S standards research tool) at www.kan.de/nora
- Search engine of the Beuth Verlag at www.beuth.de

Both search engines may be used free of charge; NoRA does not only list standards titles, but provides additional information.

ISO/IEC Guide 2:1996	Standardization and related activities – General vocabulary
ISO/IEC Guide 51:1999	Safety aspects -- Guidelines for their inclusion in standards
prEN 292-1:2000	Safety of machinery; basic concepts; general principles for design
EN 1050:1997	Safety of machinery - Principles for risk assessment
prEN ISO 6385:2002	Ergonomic principles in the design of work systems
ISO 8402:1994	Quality management and quality assurance – Vocabulary (withdrawn)
ISO 10993-1:1997	Biological evaluation of medical devices -- Part 1: Evaluation and testing
ISO/DIS 10993-17	Biological evaluation of medical devices – Part 17: Method for the establishment of allowable limits for leachable substances using health-based risk assessment.
ISO 12100-1:2003	Safety of machinery - Basic concepts, general principles for design - Part 1: Basic terminology, methodology
ISO 13485:1996	Quality systems - Medical devices - Particular requirements for the application of ISO 9001 (withdrawn, replaced by ISO 13485:2000 Medical devices – Quality Management)
ISO 13488:1996	Quality systems - Medical devices – Particular requirements for the application of ISO 9002 (withdrawn)
EN 13861:2002	Safety of machinery – Guidance for the application of ergonomics standards in the design of machinery
EN ISO 14971:2000	Medical devices - Application of risk management to medial devices
ISO 14969	Quality systems -- Medical devices -- Guidance on the application of ISO 13485 and ISO 13488
EN ISO 15189:2003	Quality management in the medical laboratory
IEC 60300-3-9:1995	Dependability management. Part 3: Application guide - Section 9: Risk analysis of technological systems
IEC/TR 60513:1994	Fundamental aspects of safety standards for medical electrical equipment
IEC 60601-1: 1988	Medical electrical equipment - Part 1: General requirements for safety

IEC 60601-1-4:1999	Medical electrical equipment: Part 1: General requirements for safety – 4 Collateral standard: Programmable electrical medical systems
CD IEC 60601-1-6:2001	Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability
IEC 60812:1985	Analysis techniques for system reliability - Procedure for failure mode and effects analysis (FMEA).
IEC 61025:1990	Fault tree analysis (FTA)
IEC/CDV 61882	Guide for hazard and operability studies (HAZOP)
EN 12442-1:2001	Animal tissues and their derivatives utilised in the manufacture of medical devices - Part 1; Risk analysis and management
90/385/EEC	Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
93/42/EEC	Council Directive of 14 June 1993 concerning medical devices
98/79/EC	Directive of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

List of Abbreviations

ALARP	As Low As Reasonably Possible, risk-evaluation criterion
BAuA	Federal Institute for Occupational Safety and Health
BfArM	Federal Institute for Drugs and Medical Devices
CD	Committee Draft
DIN	German Institute for Standardization
DIS	Draft International Standard
EC	European Community
EN	European standard
FDA	Federal Food and Drug Administration
FMEA	Failure Mode Effect Analysis
GHTF	Global Harmonisation Task Force
HSE	Health and Safety Executive
IEC	International Electrotechnical Commission
ISO	International Organization for Standards
PEMS	Programmable, electrical, medical systems
pr	Preliminary
SC	Steering Committee
TC	Technical Committee
WG	Working Group