Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Human Factors and Usability Engineering – Guidance for Medical Devices Including Drug-device Combination Products

Draft for comment

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Foreword

This guidance has come about thanks to the groundwork of CHI+MED (Computer-Human Interaction for Medical Devices), an EPSRC-funded project from 2009-2016 to improve the safety of interactive (programmable) medical devices, such as infusion pumps.

A presentation on the project led the MHRA to arrange a stakeholder day on 27 February 2015 to discuss how we could feed into the work already being done on human factors, focusing on regulation of medical devices and combination products. A 'task and finish' group was subsequently set up, led initially by Dr Peter Nightingale, Chairman of the recently created Devices Expert Advisory Committee, and later by Tony Sant, Group Manager, Devices Division at MHRA, with the aim of producing this guidance.

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Acknowledgements

This guidance was written by the MHRA Human Factors Task and Finish group, with representatives from MHRA, academia, NHS England, NICE, notified bodies, professional associations and trade bodies (see appendix 1).

1 Introduction and context

In its simplest terms, 'human factors' refers to how a person will interact with the systems surrounding them, including the technology they use – which will very much depend on what education and training that person has, and the environment in which they will be using the technology.

Human factors and ergonomics principles have been applied in the aviation and other transport sectors for many years, to minimise the risks from human error and ensure high-hazard industries are designed to promote safe practices and take advantage of technology that anticipates and mitigates human mistakes.

Human factors in healthcare has become an increasingly important and recognised topic in recent years. Following recognition of improvements that were required in healthcare, a concordat from the National Quality Board [1], published in November 2013 described human factors in healthcare as:

> 'Enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities and application of that knowledge in clinical settings'.

One part of this would be to design, evaluate and validate medical devices with human factors and ergonomics principles in mind.

In February 2015 MHRA held a stakeholder event focused on how to build better understandings of human factors into the design, regulation and use of medical devices to promote patient safety. The event recognised that there is a lot of activity taking place in relation to human factors and we aimed to share learning and identify how MHRA could contribute for the benefit of patient safety. Amongst the 75 stakeholders who attended the event, there were representatives from academia, charities, manufacturers, medical colleges, NHS trusts and notified bodies, (see appendix 2 for full list). There was strong support for a focus group to be formed and guidance to be developed to clarify the expectations for appropriate design of medical devices and drug-device combination products in line with the principles of human factors.

Human factors, ergonomics and usability engineering: why they matter for patient safety

The terms 'human factors' and 'ergonomics' may be considered interchangeable, although 'ergonomics' is often used in relation to the physical aspects of the environment, such as workstations and control panels, while 'human factors' is often used in relation to wider system in which people work (Chartered Institute of Ergonomics & Human Factors [2]).

The science-based discipline of ergonomics uses knowledge from such diverse subjects as anatomy, psychology, engineering and physiology to help design products that suit the user, for more effective and safer use of the product. Ergonomics takes into account features of the intended user population, such as age, size, strength, cognitive ability and training. Human factors design also takes into account the intended environment of use, such as

hospital wards, intensive care units, ambulances, or home environment; factors such as the potential competing distractions, lighting level, urgency of use will also be considered.

Medical devices are increasingly being used for monitoring and treating patients and errors in use leading to patient harm have been increasingly a cause for concern. Such errors may be due to poor device design, particularly where a complex user interface is involved. Medical device equipment, such as infusion pumps, ventilators, automatic electronic defibrillators and drug-device combination products e.g. auto-injectors are recognised as having use-related design problems which can result in overdoses, incorrect diagnoses or therapy and dangerous delays or problems with delivery of medication.

As medical devices become increasingly complex and the environment in which they are used becomes busier, with ever greater distractions and requirement for specialised training, the potential for human error also increases. Furthermore, as healthcare evolves, and patient care is transferred to the home environment, less skilled users, including patients and carers must learn how to use quite complex medical devices.

The USA's Food and Drug Administration (FDA) has made available an extensive amount of information and guidance relating to human factors engineering related to medical devices and a useful summary figure is shown below:

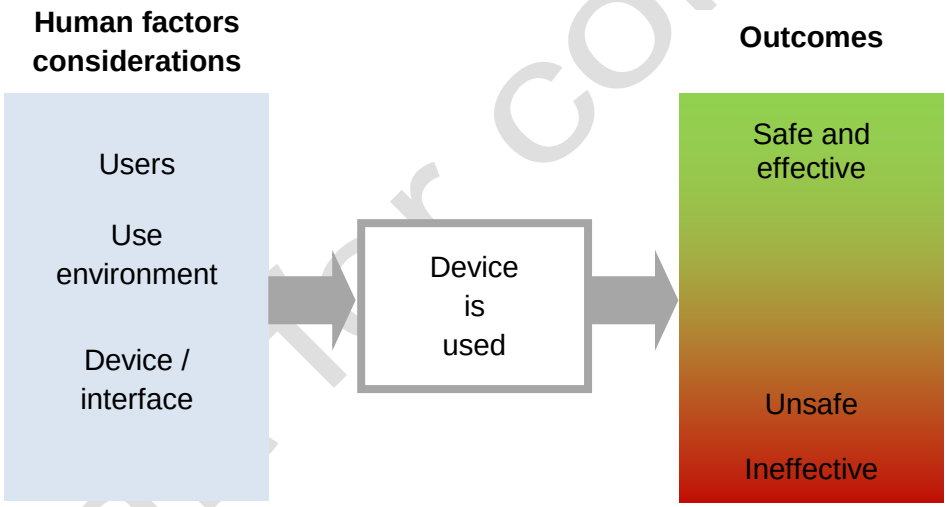

Figure 1 Human factors affect outcomes of using medical devices
Adapted from: FDA's 'Applying Human Factors and Usability Engineering to medical Devices to Optimize safety and Effectiveness in Design' draft guidance dated June 2011

A usability engineering (or human factors engineering) process can, and should, be applied by device manufacturers in the identification, assessment and mitigation of potential patient safety risks; also in the analysis of incidents that have occurred, in order to identify learning and put into place corrective actions to improve device design.

This guidance will focus on ways in which human factors, ergonomics and usability engineering can be applied to medical devices, so that they are designed and optimised for use by intended users, in the environment in which they are likely to be used, for safe and effective performance.

The guidance will complement the work being carried out by the NHS to apply human factors approaches in the ergonomic design of healthcare workplaces and practices.

Defining the terms

Human factors / ergonomics – see above

The following definitions are based on those in the standard EN 62366:2015 Part 1: Application of usability engineering to medical devices [3].

Usability engineering or human factors engineering: The application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of medical devices (including software), systems and tasks to achieve adequate usability

User: person interacting with (i.e. operating or handling) the medical device. (Note: There can be more than one user of a medical device and common users can include clinicians, healthcare professionals, carers, patients, cleaners, and maintenance and service personnel.)

User interface: means by which the user and the medical device interact. This includes all the elements of the medical device (including visual, auditory and tactile displays and accompanying information as well as software). A system of medical devices can be considered a single user interface.

Use error – an act or omission of an act, which has a different result to that intended by the manufacturer or expected by the operator of the medical device, and therefore included within the scope of this Human Factors guidance document.

Abnormal use – an act or omission of an act by the operator or user of a medical device as a result of conduct which is beyond any means of risk control by the manufacturer and therefore beyond the scope of this guidance.

Scope

This guidance is intended to be a useful resource on human factors and usability engineering principles, to clarify the expectations of the regulatory bodies i.e. notified bodies and competent authorities, around compliance with the current and future EU medical device legislation. It is aimed at manufacturers **of all device classes** who intend to market their device in the UK. The principles are also relevant to device components of drug-device combination products that are regulated as medicines. It may also be useful to commissioners of medical devices within the healthcare system and NICE, in order to investigate and challenge whether appropriate attention has been given to design features of a medical device to ensure safe and effective use in the intended environment.

The guidance clarifies that usability engineering is an iterative process, involving design, testing and validation of design stages; it also requires attention to the post-marketing

phase, since evidence may come to light in normal use that the design requires further improvement.

This guidance does not apply to clinical decision-making relating to the use of medical devices.

2 The regulatory framework

The regulatory framework for medical devices in the EU is specified in the Medical Devices Directives:

Annex I of the Medical Devices Directive 93/42/EC (MDD) [4] and Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) [5] lays down the essential requirements of medical devices, to ensure adequate safety and performance.

In 2010, Directive 2007/47/EC [6] amended the MDD and Recital 18 provided the background to the introduction of more specific ergonomic requirements into the MDD:

> ‘As design for patient safety initiatives play an increasing role in public health policy, **it is necessary to expressly set out the need to consider ergonomic design in the essential requirements**.
>
> In addition the **level of training and knowledge of the user**, such as in the case of a lay user, should be further emphasised within the essential requirements.
>
> **The manufacturer should place particular emphasis on the consequences of misuse of the product and its adverse effects on the human body.’**

Thus the essential requirements (ER) in Annex I of the MDD [4] include the requirements for ergonomics, specifically:

- ER 1….reducing, as far as possible, the risk of use error due to the **ergonomic features** of the device and the environment in which the device is intended to be used (design for patient safety)
- ER 9.2 the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate **ergonomic features**
- ER 10.2 The measurement, monitoring and display scale must be designed in line with **ergonomic principles**, taking account of the intended purpose of the device.
- ER 13.1 Each device must be accompanied by the information needed to use it **safely and properly**, taking account of the training and knowledge of the potential users, and to identify the manufacturer.’
- Other ERs that may be affected to some degree by ergonomics include 2, 3, 6, 12.8, and 12.9.

Similar requirements for ergonomics can be found in the AIMDD [5]

ER 1 … their **use** does not compromise the clinical condition or the safety of patients. They must not present any risk to the **persons implanting them or, where applicable, to other persons**.
ER 13 … device or its accessories bear instructions required for the operation of the device or indicate operating or adjustment parameters, by means of a visual system, such information must be **understandable to the user and, as appropriate, the patient**.

ER 15… information constituting the instructions for use **allowing the physician and, where appropriate, the patient to use the device**, its accessories and software correctly, as well as information on the nature, scope and times for operating controls and trials and, where appropriate, maintenance measures,

The principles above also apply to in vitro diagnostic devices (IVDs) but for self-test IVDs there are specific requirements laid down in the ERs of directive 98/79/EC [7]:
'ER 7.1. Devices for self-testing must be designed and manufactured in such a way as to:

- ensure that the device is easy to use by the intended lay user at all stages of the procedure, and
- reduce as far as practicable the risk of user error in the handling of the device and in the interpretation of the results.

ER 7.2. Devices for self-testing must, where reasonably possible, include user control, i.e. a procedure by which the user can verify that, at the time of use, the product will perform as intended.'

In addition, for self-test IVDs the manufacturer must have data showing the handling suitability of the device in view of its intended purpose for self-testing.

3 Standards

There are a number of relevant harmonised standards, compliance with which should provide a means of demonstrating conformance with the specific essential requirements of the Medical Devices Directives (90/385/EEC [5], 93/42/EEC [4] and 98/79/EC [7]). A list of harmonised standards can be found on the European Commission website.

However, the use of harmonised standards is not compulsory and there are other ways to demonstrate conformance with the essential requirements. Where harmonised standards are not used, or not used in full, a description of the solutions used to establish conformance with the essential requirements must be present within the device's technical documentation. These alternative solutions for the design and construction of the device must conform to the same safety principles, taking account of the generally acknowledged state of the art.

The latest versions of the three fundamental standards relating to the usability engineering process for medical devices are:

- EN 62366-1:2015 Medical devices, Part 1: Application of usability engineering to medical devices [3]
- IEC/TR 62366-2:2016. Medical devices, Part 2: Guidance on the application of usability engineering to medical devices [8]
- EN 60601-1-6:2010+A1:2015 Medical electrical equipment, Part 1-6 General requirements for basic safety and essential performance. Collateral standard. Usability. [9]

EN 62366-1:2015 Medical devices, Part 1 Application of usability engineering to medical devices [3] and IEC/TR 62366-2:2016 Medical devices, Part 2: Guidance on the application of usability engineering to medical devices [8]

EN 62366 has now been split into two parts. Part 1 is a normative standard which focuses on describing the usability engineering process using current usability engineering terminology. Part 2 is an informative IEC technical report (TR) with substantial guidance on how to plan and deliver the usability engineering process.

As a result of this split into two parts, the part 1 standard now only has 40 pages (the previous version had 100). The main steps of the usability engineering process have not changed but there are changes to terminology. The standard also makes it clear that the intent is to address medical device basic safety and essential clinical performance (part 2 includes consideration of non-safety related aspects). Part 1 clarifies how risk management integrates into the usability engineering process and needs to be performed iteratively throughout the development life cycle of the medical device.

The informative part 2 technical report has over 100 pages and includes a mapping between the requirements in the part 1 standard and the guidance in the part 2. Included in the part 2 guidance are usability engineering methods (Annex E) and usability test sample sizes (Annex K).

Note: The part 1 standard also includes, in Annex C, a process for devices or parts of devices that were already on the market prior to the publication of the standard (legacy products). This Annex allows an approach to be taken which looks at post-market data for unchanged portions of the design to assess whether any human factors issues / use errors are present. These are evaluated according to Annex C as ‘Usability of Unknown Provenance’.

It is important to note that although the standard is of particular importance to electromedical devices and other devices with complex user interfaces, it applies to all classes and types of medical devices and situations, for example:

- suitability of warnings in instructions for use and on label
- need for and effectiveness of essential user training
- being obvious when a single use device has already been used
- legibility of measuring gradations.

It is also worth noting that the standard is now considered to be more consistent with FDA guidance and requirements, which is helpful for global product development.

Other relevant standards:

- EN 60601-1:2006 3rd Ed + A1 2013 – Safety & Essential Performance [10]

  > Cl 12.2 Manufacturer shall address risk of poor usability, including marking and docs, through Usability Engineering process in accordance with EN 60601-1-6 (which references 62366)

- EN 60601-1-8 Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems [11]
- EN 980:2008 Symbols for use in the labelling of medical devices [12]
- EN 1041: 2008 (and EN 1041:2008+A1:2013) Information supplied by the manufacturer of medical devices [13]
- EN 15223-1 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements. [14]

Note: Requirements for usability have also been included in EN ISO 13485: 2016 [15]. Clause 7.3.3a) requires design and development inputs to include usability requirements according to the intended use. In addition, the significance of a change to usability is also added to clause 7.3.9 for the control of design and development changes.

4 Summary of the usability engineering process

The aims of ergonomic design and the usability engineering processes are to deliver products that enable users to give the best possible care to patients and be easy to use (whether by carers or patients themselves). Rather than expecting users to have to read, understand and remember complex instructions for use leaflets and adapt to the requirements of the device, or use it in an uncomfortable, incorrect and possibly dangerous way, a well-designed product will be easy to use, with a helpful, intuitive user interface.

In addition to safety considerations, products designed with human factors and ergonomics principles are more pleasing to use, therefore will be likely to lead to better adherence to correct use, at the required frequency. Human factors and ergonomics principles are therefore employed by many companies in design for customer loyalty and marketing purposes.

Figure 2 describes the stages of the process, illustrating its iterative nature. The process should be recorded in a usability engineering file of the device technical documentation. Depending on the risk classification of the device, the file may be requested for review by

regulatory bodies and would also be useful for commissioners of devices to review in order to understand how the process has been conducted and if their particular use scenario has been taken into account. A statement of ‘compliance with IEC 62366’ is not sufficient without supporting evidence.

Table 1 summarises widely used usability engineering techniques and aligns them with the stages of the human factors engineering process (Figure 2). In both the figure and the diagram, cross-references are to the sections of this document where these processes are described.

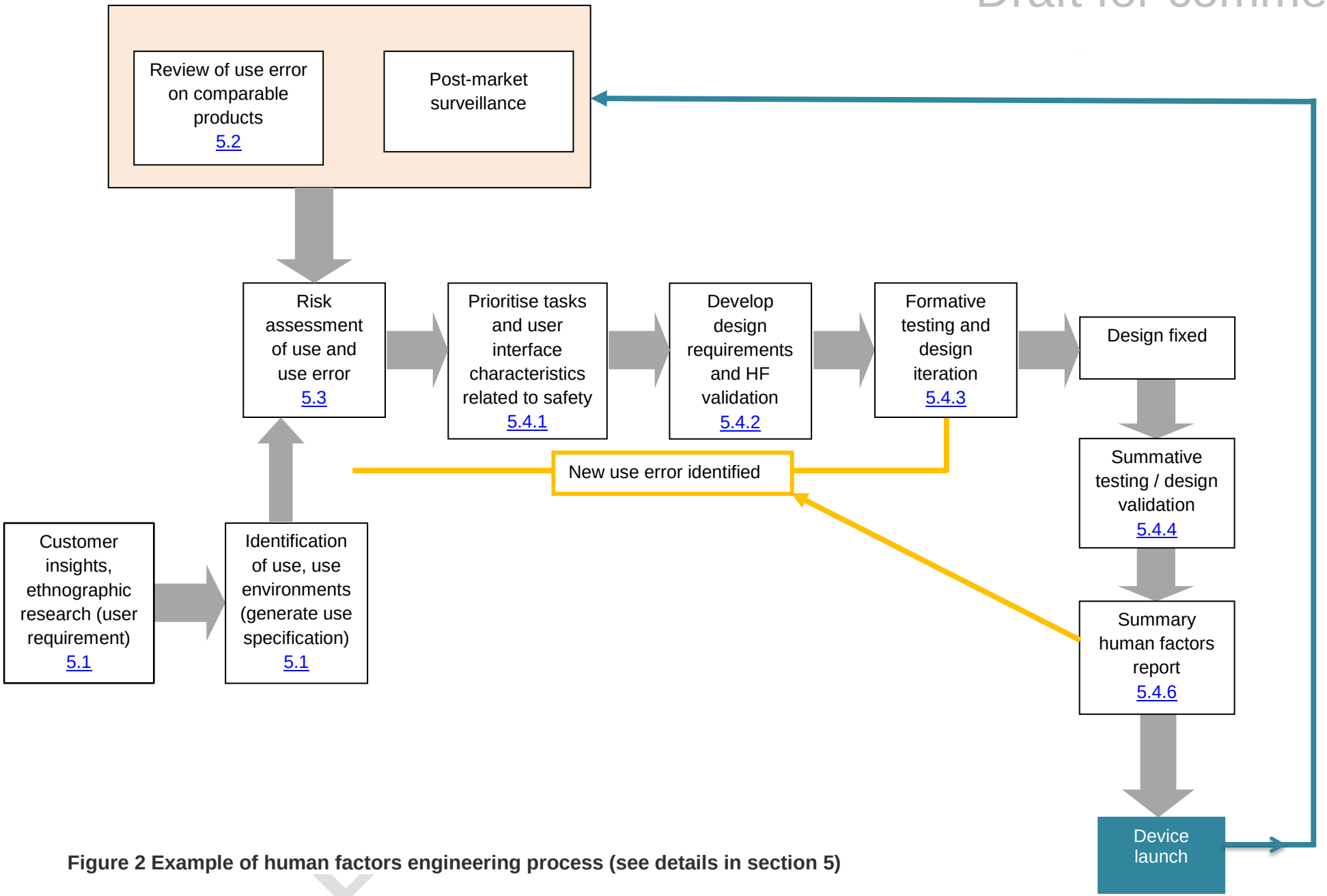

Figure 2 Example of human factors engineering process (see details in section 5)

Human factors engineering techniques	Features	Suited for	Considerations	Stages	Resources
Observation (sometimes called 'ethnography')	Observing people working and using devices	Gaining an understanding of what people really do in practice	Without complementary interviews, it can be difficult to make sense of what is observed	5.1	[17] (p.43); [18] (p.28); [19]
Semi-structured interviews	Interviewing people about their work, their experiences of technology, their requirements for future technology, etc.	Gathering people's perceptions and experiences	People have difficulty reporting accurately on what they do	5.1	[16] (p.16); [17] (p.56); [18] (p.44); [21]
Focus groups	A group interview, most commonly between people with similar backgrounds, about the work or device(s) of interest	Gathering perceptions and experiences, often with greater breadth but less depth than interviews	Focuses on perceptions rather than actions. Risk of 'group think' unless carefully managed but can help with consensus-building in well selected groups	5.1	[17] (p.55); [18] (p.46); [22]
Contextual inquiry	Combining observations and interviews to understand work and the use of devices	Gaining insights for design based on information flow, how current artefacts are used, etc. within work	Not suited to mobile settings. Takes place within the workplace.	5.1	[16] (p.16); [17] (p.44); [23]
Working with existing sources	Using existing sources (incident reports, academic literature, etc.) as data for understanding needs and practices	Building understanding based on existing information	Data was generated for a different purpose, so should only be used as background information	5.1, 5.2	
Questionnaires / surveys	A set of questions to be answered, most commonly by selecting between options. Free-form entry is also	For gathering perceptions and attitudes from a large number of people	Need to be carefully tested before being issued. Good for getting short responses from a lot of people, but not for gathering in-depth information	5.1, 5.2	[17] (p.58); [18] (p.49)

	possible				
Failure Modes and Effects Analysis (FMEA)	Analysis team 'brainstorms' likely causes and consequences of failures, including human error.	Reasoning about likely causes and consequences of device failure and human error	Needs expertise in human factors to be effective; subjective; focuses on failures	5.3	[16] (p.12); [18] (p.109)
Task analysis	Systematically decomposing tasks (that the device supports) into sub-tasks to analyse the sequence and performance criteria for tasks	Supports systematic thinking about user tasks and how they are achieved with the device	A good task analysis will be based on empirical data of real user tasks (and how these should map onto device tasks)	5.4.1	[16] (p.14); [17] (p.52); [18] (p.54); [21]
Personas	Rich descriptions of a few 'typical' users of the device	Helping the design team to keep the intended users in focus while developing the product	Good personas should be based on empirical evidence	5.4.1	[17] (p.50); [28]
Scenarios	Rich descriptions of key and typical scenarios of use of the device (from a user perspective)	Helping the design team to think about how the device will be used in practice	Good scenarios should be based on empirical evidence. The range of scenarios can sometimes become unmanageably large	5.4.1	[17] (p.51); [29]
Think-aloud	Users articulating thoughts while interacting with / using a device (as part of user testing)	Understanding how people perceive and experience a device, and how they use it to support their work	Requires access to functioning device. Data focuses on the device interaction (not the broader work context). Technique may be used in controlled ('lab') environment or in the real-world context (where safe to do so)	5.4.3 (formative assessment)	[20]
Heuristic evaluation	A checklist approach to checking the device interface for usability and safety based on 'rules of thumb'	Checking for obvious problems at early stages of development	Needs expertise in understanding and interpreting the heuristics. Dependent on the expertise (and biases) of the evaluators	5.4.3 (formative assessment)	[16] (p.15); [17] (p.48); [18] (p.65); [26]

Cognitive walkthrough	An expert review approach that involves 'walking through' the steps of an interaction between user and device, reasoning about possible user errors	Early review, focusing on user cognition	Should be conducted by experts in cognitive science. Assumes that the device is 'walk up and use'	5.4.3	[16] (p.18); [17] (p.40); [27]
User testing	Testing the device with representative users in a simulated use environment	Identifying which device features people find easy to use, and which cause problems	Most reliable when the users recruited to the testing are representative of the intended user population(s), and when the tasks used in testing provide good coverage of real-world use.	5.4.3, 5.4.4 (formative and summative assessment)	[16] (p.21); [17] (p.46); [18] (p.77)

Table 1: Key features of principal human factors engineering techniques for medical devices

5 Stages of a human factors engineering process

5.1 Identification of users, use environments, operational contexts of use and training

To design for real world use, it is important to understand who the users are, their experience, and the contexts within which they work. This information can be gathered in a number of ways: through interviews, ethnographic research, contextual inquiry, and similar approaches, as summarised in Table 1.

Understanding should include but is not limited to:

- user profiles: a description of the users (e.g. gender, age, height, education, experience, hearing, vision, computer literacy, values, motivations, etc.)
- use environment (temperature, humidity, light, noise, etc.)
- use scenarios or a user journey showing the goals and sequences of tasks performed by individual user groups
- training that the users would receive before using the product.

The rationale for selecting representative users, use environment and fidelity of test set should be documented based on the information gathered and should be consistent with the intended performance claims made for the product.

5.2 Identification of known use problems

It is necessary to review data for potential use error for similar products and comparable competitor products (through post-market surveillance, complaints, see section 7) and include this within the product risk assessment relating to use and use error (see EN ISO 14971 [30]). Ideally, other sources of information, including interviews with and observational studies of users, will also be used to identify lower level issues that may not have been implicated in patient harm but that nevertheless negatively affect user experience and efficiency.

5.3 Identification of hazards, hazardous situations and harm

This is required to identify the high level tasks and user interface characteristics that could be related to safety. This analysis can be carried out by using methods such as task analysis, expert analyses, contextual enquiry, and heuristic analysis and documenting the product risk assessment relating to use and use error (see EN ISO 14971 [30]). Human reliability analysis techniques (eg Bell & Holroyd, 2009 [31]) may also be useful.

All possible use errors associated with each step or user interface characteristic should be documented.

The use errors should be scored for severity of harm to enable prioritisation of development work in order to reduce risk through design.

Tasks which have potential use errors related to the safety of the user or the patient can be defined as **critical**. Critical tasks must be defined and prioritised by design teams based on the severity of harm presented.

Tasks which are required in order to use the device or deliver the therapy, or that are frequent, can be defined as **essential**.

5.4 Formative and summative evaluation

During development, any device should be subjected to rounds of formative evaluation in order to assess how well it addresses user needs and to identify opportunities for improvement. Towards the end of the development process, it is generally necessary to conduct summative evaluation to check that the device is fit for purpose (also known as validation testing). For both formative and summative evaluation, it is good practice to identify suitable tasks as a basis for evaluation.

5.4.1 Selection of tasks for evaluation

Tasks to be tested in any evaluation should be documented. This ensures that all aspects of the user interface which could affect the safety of the user or the patient are prioritised. The scale of the evaluation effort will be determined at this stage.

This can be:

- All hazard-related use scenarios
- A subset of the hazard-related use scenarios based on severity of harm (e.g. those which would require medical intervention); these are **critical tasks**
- **Essential tasks** that are required to use the device.

5.4.2 Usability design requirements

This should include the following:

- The design requirements identified to mitigate potential use error. These requirements should be **verified** on a representative final product to test whether the specific functional and operational requirements of the design have been met.

- The use requirements identified in the use risk assessment related to safe and effective use, which need to be **validated** by the intended users of the device, for the intended uses in the expected environment.

5.4.3 Formative testing (iterative testing during product development)

Testing can be carried out in order to make decisions, confirm designs and determine the safety and effectiveness of proposed design solutions. It is used to identify use errors which may lead to unacceptable risk. Formative testing can be carried out on all aspects of the design, including instructions for use and training documents.

These studies should be carried out on participants that represent the intended users Ideally studies should be carried out on between 5 and 8 participants from each identified user group in order to give the best chance of identifying use error (average 85% of use errors identified, Faulkner 2003 [32]).

Use errors identified in the formative studies should be reviewed against the use risk assessment for their severity and their acceptability determined.

Formative studies should be carried out until confidence is gained that the design is safe and effective (that is, that no use errors leading to unacceptable risk are encountered).

Patterns of use error on **essential** tasks should be documented and design improvements considered.

Effective formative assessment will result in good performance in subsequent user validation/summative testing, minimising design issues in late stage development.

5.4.4 Summative testing

5.4.4.1 Validation of the manual or instructions for use

The user manual or instructions for use are an important part of the user interface as they communicate important information for safety and how to use the product as intended. The manual content and format must be validated with its intended users. The format of the testing will involve ensuring users can follow relevant instructions in order to correctly use the product and comprehend the information provided for their safety. The study should be carried out in the same format as a summative test and must be on final text and layout. The manual validation should be completed before commencement of the overall summative study on the device.

5.4.4.2 Validation of device/system

Following finalisation of design and minimisation of risks identified through formative testing the summative study should be commenced. This is a design validation of **critical** tasks and information and must be carried out on a product representative of the launch product. The testing may incorporate other usability requirements as needed.

The study must:

Include all identified user groups (a minimum of 15 of each group identifies an average 97% of all use errors – Faulkner 2003 [32])

- Include all tasks which have identified use errors with a resulting harm (**critical task**).
- Be carried out in a realistic simulated environment or in a clinical setting if simulation cannot provide a realistic environment, on finished product (or product representative of finished product).
- Not include prompts or requests to review manual.

5.4.5 Summative testing reporting

Following the summative testing all use errors identified should be reviewed for root cause and assessed for residual risk. Patterns of use errors occurring on tasks which have been identified as **critical** (related to safety) should be carefully reviewed for acceptability. Those use errors resulting in an unacceptable risk will require further risk control activity/ design iteration and further usability testing to confirm that action has resolved issues.

Any new errors identified must be added to the risk assessment relating to use and use error and residual risk assessed for acceptability.

5.4.6 Human factors summary report

The report should comprise a report or files to summarise all the work carried out on the product.

All reports should include but are not limited to:

- Intended product users, uses, environments and training
- Description of the device user interface
- Summary of known use problems (product under consideration and other related products in market)
- User task selection and prioritisation
- Summary of formative evaluations
- Results of summative usability validation testing (including manual validation)
- The benefit-risk status of the device from the risk management file
- Conclusions

This report is a summary of all the usability/human factors activity on a project and should describe the mitigation and minimisation of risk to the user.

6 **Simulation**

Evaluation of human factors performance in medical devices requires interaction with end-users in an appropriate environment. This will not always be possible in a real-world scenario, especially when a novel device is being used for the first time.

Simulation allows human factors testing in a safe and repeatable format. It is widely used in aerospace applications for the training and revalidation of pilots. It has reached such a level of sophistication that training versions of new military planes are no longer required since all training takes part in a simulator with all the features of a real plane.

Clinical simulation is used extensively for the training of nurses in the USA, and in the UK it is used for the revalidation of medical practitioners. However, there is no standard in UK legislation for medical simulation.

To give information that is relevant to real-world situations, the issues that need to be addressed in simulation for the assessment of medical devices are:

6.1 Fidelity

1. Full-mission simulation

   Full-mission simulators replicate the environment of clinical care. This promotes suspension of disbelief in participants.

   Simple app-based simulation can emulate selected technical aspects of a scenario but do not immerse the participant in the environment.

2. Location

   High-fidelity simulation emulates all the characteristics of a healthcare environment, including background stimuli that are not a part of the core simulation. These stimuli may include background noises, distractions from other staff and alarms from monitoring equipment.

6.2 Moderation/facilitation

1. Skill-set of facilitator(s)
2. Professional competence

   The facilitator needs to be familiar with the scenario in which the medical device is being evaluated.

3. Training in simulation

   Specific training is needed to enable appropriate preparation before simulation and the subsequent effective de-briefing of participants.

6.3 Choice of participants

Medical devices are used on people with medical conditions. Human factors studies on some of these devices, such as those used on patients in the operating theatre, have to be simulated.

The regulatory expectations are that the usability engineering file of the technical documentation will address these issues.

7 Post-market surveillance

All EU medical device manufacturers are obliged under the various Annexes of routes to compliance given in the European General Medical Devices, Active Implantable Medical Device Directive and In vitro Diagnostics Directive to have a systematic procedure in place to review the experience gained from their devices in the post-market phase and to implement appropriate means to apply any necessary corrective action. This is often termed post-market surveillance (PMS). The required proactive PMS is extremely important to ensure that all relevant feedback is reviewed and where necessary acted upon to improve current and future medical device designs where necessary.

As part of these obligations, EU medical device manufacturers are obliged to inform relevant competent authorities of adverse incidents and field safety corrective actions concerning their products. Relevant guidance is contained in MEDDEV 2.12-1 rev 8, January 2013 – 'Guidelines on a Medical Devices Vigilance System' [33]. Feedback from competent authorities needs to be considered as part of PMS. This guidance makes a distinction between use error and abnormal use.

Manufacturers should actively and systematically seek views of users and also ensure they are aware of any issues on related device types that they would need to take into account. Such data is made publicly available in the FDA Manufacturer and User Facility Device Experience (MAUDE) database [34], FDA's MedSun: Medical Product Safety Network [35], EU field safety notices on competent authority websites, FDA's CDRH Medical Device Recalls [36] and the Australian TGA Device Adverse Event Notification (DAEN) database [37]. This review should include complaints data for potential use error for their own and similar products and comparable competitor products. This ongoing review of data should include updating their products risk assessment relating to use and use error (see ISO 14971 [30]). The evaluation is governed by risk management, usability engineering, design validation, and corrective and preventive action processes.

Ideally, other sources of information, including user studies and observational studies of users, will also be used to identify lower level issues that may not have been implicated in patient harm but that nevertheless negatively affect user experience and efficiency.

8 Product life-cycle and continuous improvement

Human factors engineering should be incorporated into the product design from the conception of the idea to the final validation of the device, as part of the benefit-risk profiling of the medical device / IVD (see Figure 3). Considering the wide range of medical devices and combination products, a flexible approach to the requirements is necessary, depending on the type of device, intended use and known use errors of similar devices. The principles outlined above should be taken into account in the earliest designs of the medical device as intended to be placed on the market. Early formative studies may be helpful at the clinical investigation (CI) stage when moving from the laboratory bench to proof of concept trials on volunteers, although a rationale may be provided for conducting them at a later stage with pre-production prototypes close to the final product. When use is limited to a number of highly- trained personnel (as is often the case in clinical investigations before the award of CE mark and subject to notice of no objection from the MHRA) the risks are more tightly managed and the user interface may be rudimentary, so it is not always relevant to include the assessment of human factors. However, if minimally-trained users or lay persons are involved or the potential for use error resulting in harm is high, human factors engineering needs greater consideration at an early stage in product development.

It is acknowledged that in many cases, the user interface will be under continual improvement throughout the lifecycle of the product, both during the initial development and the post-marketing phases. It will be important to discuss the design input factors at all stages of correspondence with regulators (clinical investigation and CE marking) with justification of the approach taken. It is stressed that formative studies are expected to be iterative, often small scale, from the earliest stages of development (early prototype) to ensure the appropriate prioritisation of design for users has been made. As far as possible, the final or summative validation should be on a fully representative product, although it is acknowledged that further design changes may be necessary following clinical studies.

It is also expected that device change management will occur throughout a product lifecycle, whether due to feedback from post-marketing surveillance, advances in technology or imposed through component supply issues. Any changes to the product should be evaluated and the need for additional human factor engineering studies considered and the approach justified in the technical file.

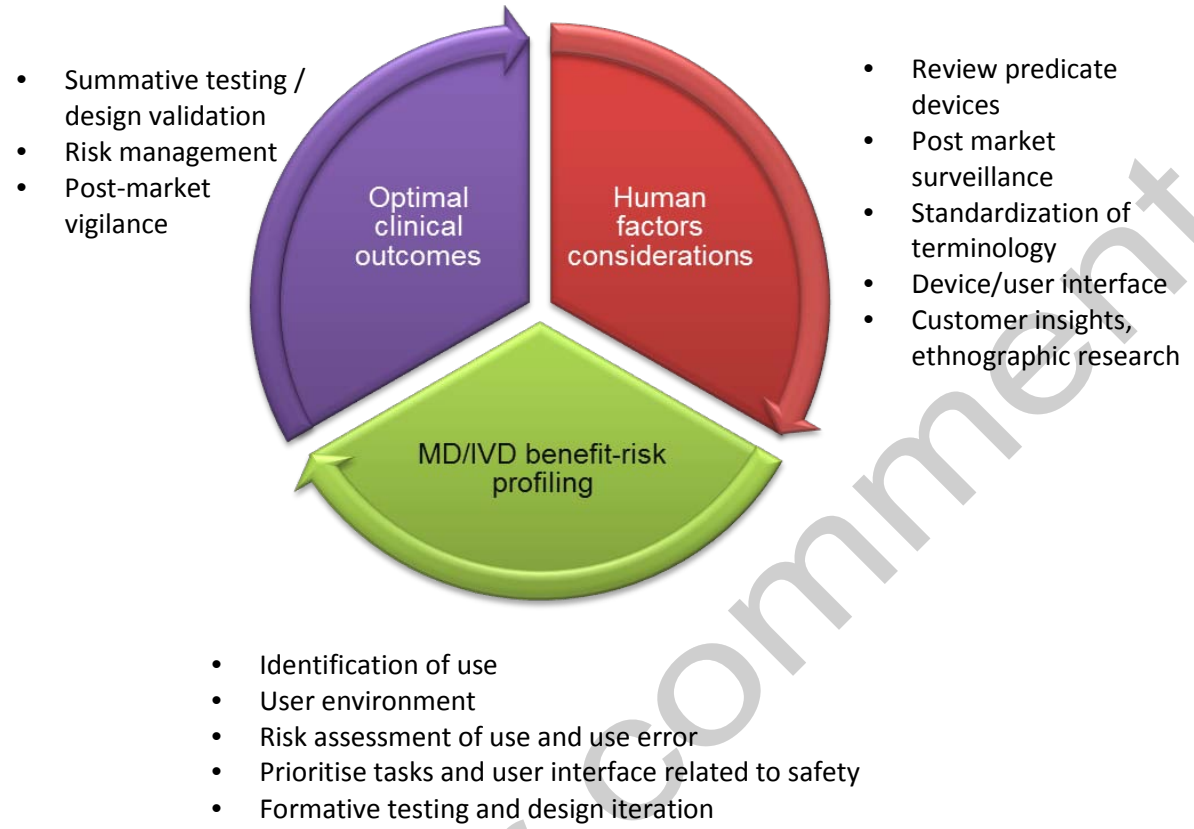

Figure 3 Human factors benefit-risk management cycle

9 Drug delivery devices and drug-device combination products

The focus of this guidance is on human factors and usability engineering of medical devices, which already encompasses a wide variety of different types of products and which may be used for delivery of medicines. For such products, the criticality and nature of the medicinal products to be delivered by the device should be taken into account in the risk analysis. There are also medicinal products that include a significant device component, either co-packaged with, or integral to the medicinal product.

For non-integral drug-device combination products (e.g. refillable pen injectors and their cartridge of medicinal product), the Medical Devices Directive (MDD) requirements will apply to the device as outlined above. In the case of combination products, where the device is marketed as an integral part of a single product (for example a non-refillable metered dose inhaler), both the device and medicinal component will be regulated as a single medicinal product. However, the essential requirements of Annex I of the MDD still apply with regard to safe and effective use of the device component.

Therefore, for drug-device combination products, the expectations for human factors and usability engineering considerations will be similar and should be discussed in the application for a marketing authorisation and subsequent variations, where relevant. Any differences between the device used in pivotal clinical studies and that proposed for marketing should be clearly explained and additional human factor engineering studies may be required. The risk of medication error due to the device component should be considered in the Risk Management Plan.

This is an evolving area and expectations in different jurisdictions may vary.

10 References

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3 EN 62366:2015 Medical devices -- Part 1: Application of usability engineering to medical devices http://www.iso.org/iso/catalogue_detail.htm?csnumber=63179

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6 Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market. Official Journal of the European Union L 24, 21.9.2007, p. 21–55

7 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Official Journal of the European Union L 331, 07/12/1998 P. 0001 - 0037

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33 European Commission MEDDEV 2.12-1 rev 8 January 2013 – Guidelines on a Medical Devices Vigilance System

34 FDA Manufacturer and User Facility Device Experience (MAUDE) database

35 FDA MedSun: Medical Product Safety Network

36 FDA CDRH Medical Device Recalls

37 Australian TGA Device Adverse Event Notification (DAEN) database

11 Further reading

FDA's List of Highest Priority Devices for Human Factors Review: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM484097.pdf

ANSI/AAMI **HE48** (1988-2009) 'Human factors engineering guidelines and preferred practices for the design of medical devices'

ANSI/AAMI **HE74** (2001-2010) 'Human factors design process for medical devices'

ANSI/AAMI **HE75** (2009-) 'Human factors engineering – Design of medical devices' (a tutorial to HE-74)

12 Appendix 1

Organisations represented in the MHRA task and finish group producing this draft guidance

Academy of Medical Royal Colleges
Acelity
AMTAC Certification Services Ltd (Intertek)
Association of British Healthcare Industries (ABHI)
Association of the British Pharmaceutical Industry (ABPI)
BSI Healthcare
Devices Expert Advisory Committee (DEAC)
Dexcom Inc.
Eucomed
Lloyd's Register Quality Assurance Ltd
National Institute for Health and Care Excellence (NICE)
NHS England
SGS United Kingdom Ltd
Smith & Nephew
UL International (UK) Ltd
University College London

13 Appendix 2

Organisations represented at the 2015 MHRA human factors event

Academy of Medical Royal Colleges
Academy of Medical Sciences
AJV Services
AMTAC Certification Services Limited t/a Intertek
Association of British Healthcare Industries (ABHI)
Brain Tumour Charity
British Heart Foundation
British Kidney Patient Association
British Standards Institution (BSI)
Cambridge University Hospitals NHS Foundation Trust
Clinical Research Network
DTC University of Leeds
Engineering and Physical Sciences Research Council
European Commission
General Pharmaceutical Council (GPC)
Human Fertilisation and Embryology Authority (HFEA)
Imperial College Healthcare NHS
Input Patient Advocacy
Knowledge Transfer Network
Lloyd's Register Quality Assurance (LRQA)
National Association of Medical Devices Educators and Trainers (NAMDET)
National Institute for Health and Care Excellence (NICE)
NHS England
Northampton General Hospital NHS Trust
Proprietary Association of Great Britain (PAGB)
Queen Mary, University of London
Renal Association/British Renal Society
Royal Brompton Hospital
Royal College of Anaesthetists
Royal College of Radiologists
Sensible Standards
Serious Hazards of Transfusion
Sheffield Teaching Hospitals NHS Foundation Trust
Surgical Materials Testing Laboratory (SMTL)
Swansea University
UCLH Trust
University College London Interaction Centre (UCLIC)
University of Nottingham
University of Warwick
University of York- Department of Computer Science

14 Appendix 3

Essential requirements (ER) of the Medical Devices Directive 93/42/EC

ER 1

The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons,

provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

This shall include:

— reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

— consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

ER 9.2

Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:

— the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,

— risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,

— the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,

— risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

ER 13.1

Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer

Other ERs that may be affected to some degree by ergonomics include:

ER 2

The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

— eliminate or reduce risks as far as possible (inherently safe design and construction),

— where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,

— inform users of the residual risks due to any shortcomings of the protection measures adopted.

ER 3

The devices must achieve the performances intended by the manufacturerand be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.

ER 6

Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

ER 12.8.

Protection against the risks posed to the patient by energy supplies or substances

12.8.1.

Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

12.8.2.

Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.

Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.

ER 12.9.

The function of the controls and indicators must be clearly specified on the devices.

Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient

Essential requirements (ER) of the Active Implantable Medical Devices Directive 90/385/EEC

ER 1
The devices must be designed and manufactured in such a way that, when implanted under the conditions and for the purposes laid down, their use does not compromise the clinical condition or the safety of patients. They must not present any risk to the persons implanting them or, where applicable, to other persons.

ER13
When a device or its accessories bear instructions required for the operation of the device or indicate operating or adjustment parameters, by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

ER15
When placed on the market, each device must be accompanied by instructions for use giving the following particulars:
— the year of authorization to affix the CE mark,

— the details referred to in 14,1 and 14.2, with the exception of those referred to in the eighth and ninth indents,
— the performances referred to in section 2 and any undesirable side effects,
— information allowing the physician to select a suitable device and the corresponding software and accessories,
— information constituting the instructions for use allowing the physician and, where appropriate, the patient to use the device, its accessories and software correctly, as well as information on the nature, scope and times for operating controls and trials and, where appropriate, maintenance measures,
— information allowing, if appropriate, certain risks in connection with implantation of the device to be avoided,
— information regarding the risks of reciprocal interference (1) in connection with the presence of the device during specific investigations or treatment,
— the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of resterilization,
— an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the essential requirements.
The instruction leaflet must also include details allowing the physician to brief the patient on the contra-indications and the precautions to be taken.
These details should cover in particular:
— information allowing the lifetime of the energy source to be established,
— precautions to be taken should changes occur in the device's performance,
— precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, etc.,
— adequate information regarding the medicinal products which the device in question is designed to administer,
— date of issue or the latest revision of the instructions for use.