



Medicines & Healthcare products
Regulatory Agency



Guidance on applying human factors and usability engineering to medical devices including drug-device combination products in Great Britain

Version 2.0

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The Medicines and Healthcare products Regulatory Agency is an Executive Agency of the Department of Health and Social Care and a government trading fund, with a mission to protect and improve the health of millions of people every day through the effective regulation of medicines, medical devices, blood and blood components, underpinned by science and research.

Acknowledgements

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Updates to this guidance

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This version reflects the changes to the regulation of medical devices in the UK as a result of exiting the EU. The updates are primarily around this guidance applying to Great Britain, but also include changes in references to legislation and the introduction of the new UKCA mark.

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1 Introduction and context

This guidance is specific to medical devices placed on the market in Great Britain (England, Wales, Scotland). For Northern Ireland, different rules apply to those in Great Britain. Refer to our guidance for more information on the [regulatory system for medical devices in Northern Ireland](#).

The safety of medical devices, including drug-device combination products, relies on them being used as intended, as well as being reliable. This requires that those involved in designing and evaluating medical devices take into account human factors within their processes.

This guidance is intended for manufacturers **of all device classes** and developers of medical devices and drug-device combination products, and UK Approved Bodies responsible for assuring the quality of those devices. Others, such as those involved in procurement and risk management of activities involving medical devices may also find this guidance relevant to their roles. Physicians, NHS, NICE, and other stakeholders may find this guidance useful, but it does not apply to them or other professionals making clinical decisions.

In its simplest terms, 'human factors' refers to how a person will interact with the systems surrounding them, including the technology they use. This will very much depend on the design of that technology, what education and training that person has, and the environment in which they will be using the technology. The science-based discipline of human factors 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. Human factors takes into account features of the intended user population, such as age, size, strength, cognitive ability and training. It also takes into account the intended environment of use, such as hospital wards, intensive care units, ambulances, or home environment; factors such as potential competing distractions, lighting level, or urgency of use will also be considered.

Human factors principles have been applied in high-hazard industries such as defence, nuclear, petrochemical and transport for many years, to minimise the risks from use error and promote safe practices and take advantage of technology that anticipates and mitigates use errors.

Human factors in healthcare has become increasingly recognised as an important topic. 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'.

In this document we use the term 'human factors' to encompass other terms such as ergonomics and usability. However, for consistency with key related documents, we refer to the process of achieving usable products that address user needs and fit with their practices as 'usability engineering' except when we quote other sources.

Although the guidance aims to clarify regulatory expectations of medical devices marketed in Great Britain, it does not represent a compliance requirement. Alternative approaches to demonstrating safe and effective use could be proposed by applicants. It applies to the design of future products and changes in user interfaces of existing products, rather than those already on the market.

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-market phase, since evidence may come to light while a device is being used in clinical practice that the design requires further improvement.

This guidance from the MHRA is not intended to be prescriptive, but to be advisory for developers and UK Approved Bodies, recognising the importance of human factors in managing patient safety. The USA Food and Drug Administration (FDA) has extensive information and [guidance on human factors related to medical devices](#) [2]; the MHRA guidance is intended to be consistent with both FDA guidance and the international standards referred to below.

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

Human factors: why they matter for patient safety

A growing number of medical devices are 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 devices, such as infusion pumps, ventilators, automatic electronic defibrillators and drug-device combination products (e.g. auto-injectors) are recognised as potentially having use-related design issues that can result in problems such as overdoses, incorrect therapy and dangerous delays or difficulties with delivery of medication.

As medical devices become increasingly diverse in their capabilities and the environments in which they are used becomes busier, with new distractions and requirements for specialised training, the potential for use error also increases. Furthermore, as healthcare evolves and patient care is transferred to the home or public environment, less skilled or even unskilled users, including patients and carers, must be able to use quite complex medical devices safely.

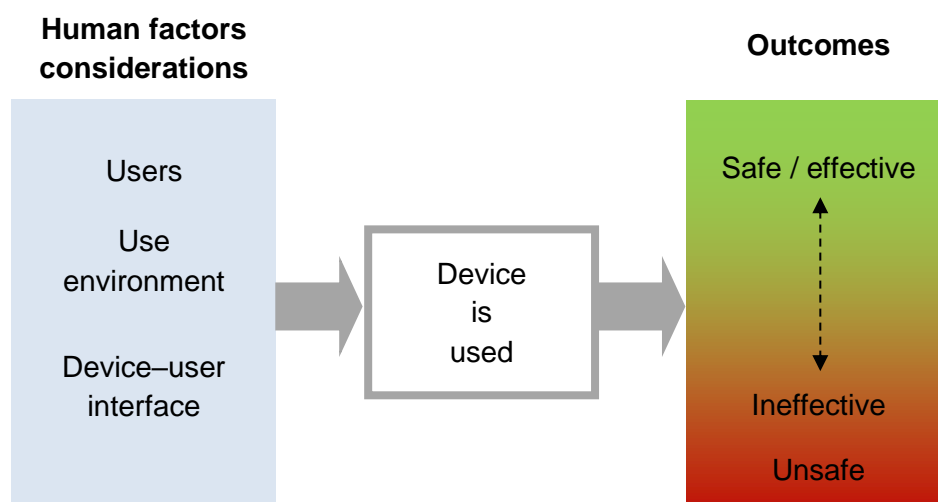


Figure 1 Human factors affect outcomes of using medical devices

Adapted from: FDA's '[Applying Human Factors and Usability Engineering to Medical Devices](#)' guidance February 2016 [2]

A usability engineering process can, and should, be applied by device manufacturers in the identification, assessment and mitigation of potential patient and user 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 focuses on ways in which human factors 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.

Defining the terms

'Ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance.' [3]

The following definitions are from the standard BS EN 62366 Part 1 2015: Application of usability engineering to medical devices [4] Please refer to this standard for the definition of other terms (see section 3 on standards below).

Abnormal use – conscious, intentional act or intentional omission of an act that is counter to or violates normal use and is also beyond any further reasonable means of user interface-related risk control by the manufacturer.

Examples: Reckless use or sabotage or intentional disregard of information for safety are such acts.

Usability engineering – human factors engineering 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.

Note

Achieving adequate USABILITY can result in acceptable RISK related to use.

Use error – user action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user.

Notes

- use error includes the inability of the user to complete a task
- use errors can result from a mismatch between the characteristics of the user, user interface, task, or use environment
- users might be aware or unaware that a use error has occurred
- an unexpected physiological response of the patient is not by itself considered use error
- a malfunction of a medical device that causes an unexpected result is not considered a use error.

User – person interacting with (i.e. operating or handling) the medical device.

Notes

- there can be more than one user of a medical device

- common users include clinicians, patients, cleaners, maintenance and service personnel.

User interface – means by which the user and the medical device interact.

Notes

- accompanying documentation is considered part of the medical device and its user interface
- user interface includes all the elements of the medical device with which the user interacts including the physical aspects of the medical device as well as visual, auditory, tactile displays and is not limited to a software interface.

2 The regulatory framework

In Great Britain, medical devices are regulated under the [UK Medical Devices Regulations 2002](#) (SI 2002 No 618, as amended) [5], which transposes the three EU Medical Device Directives:

- [Directive 90/385/EEC](#) on active implantable medical devices (AIMDD) [6]
- [Directive 93/42/EEC](#) on medical devices (MDD) [7]
- [Directive 98/79/EC](#) on in vitro diagnostic medical devices (IVDD) [8]

Part II of the UK MDR 2002, Annex I (for general medical devices) and Part III of the UK MDR 2002, Annex 1 (for active implantable medical devices) [as modified by Schedule 2A to the UK MDR 2002] lay down the essential requirements of medical devices, to ensure adequate safety and performance.

In 2010, Directive 2007/47 [9] amended the MDD. Recital 18 provided the background to the introduction of more specific human factors (ergonomics) 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.’

Note: the term ‘misuse’ in the Directive 2007/47 is best interpreted as ‘use error’ in this document, as distinct from ‘abnormal use’ as defined above.

The essential requirements (ER) for **medical devices** include requirements for human factors, which are highlighted below. These essential requirements are also relevant to device components of single-use drug-device combination products that are regulated as medicines (Regulation 9(8) of the UK MDR 2002).

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 **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.'

* this includes hardware, software, labelling and other user interface features (including video, mobile apps, etc)

In addition, Regulation 8(3) of the UK MDR 2002 covering essential requirements also states: 'where a hazard exists, devices which are also machinery shall also meet the essential health and safety requirements set out in Annex I to Directive 2006/42 [10] on machinery to the extent to which those essential health and safety requirements are more specific.'

Of relevance to this guidance is section 1.1.6. of Directive 2006/42, covering human factors (ergonomics), which states that

'Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic principles such as:

- allowing for the variability of the operator's physical dimensions, strength and stamina,
- providing enough space for movements of the parts of the operator's body,
- avoiding a machine-determined work rate,
- avoiding monitoring that requires lengthy concentration,
- adapting the man/machinery interface to the foreseeable characteristics of the operators.'

Other ERs that may be affected to some degree by human factors include 2, 3, 6, 12.8, and 12.9 of Part II (on general medical devices) of the UK MDR 2002, Annex I (as modified by Schedule 2A to the UK MDR 2002) (see appendix 2)

Similar requirements can be found in Part III (on active implantable medical devices) of the UK MDR 2002, Annex 1 (as modified by Schedule 2A to the UK MDR 2002).

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,

And again similar principles to the above can be found in the ERs of Part IV (on in vitro diagnostic medical devices) of the UK MDR 2002, Annex I (as modified by Schedule 2A to the UK MDR 2002), specifically:

ER 3.3...Devices must be designed and manufactured in such a way as to remove or reduce as far as possible:

- the risk of injury linked to their physical features (in particular aspects of volume x pressure, dimension and, where appropriate, **ergonomic features**),

ER 3.6...The measuring, monitoring or display scale (including colour change and other visual indicators) must be designed and manufactured in line with **ergonomic principles**, taking account of the intended purpose of the device.

For self-test IVDs there are in addition specific ergonomic requirements:

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 use 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.

Human factors studies that can be used to address the above regulatory requirements are outlined in section 5. Some of these (e.g. summative and formative evaluation) may require ethics approval and application to MHRA for a clinical investigation, section 5.4 provides further detail.

The MHRA ensures compliance with regulations in the first instance through the provision of advice and guidance (such as this document), audits of UK Approved Bodies and a market surveillance programme to determine levels of compliance. MHRA works with the relevant organisations to correct any identified non-compliance in a proportionate and consistent manner, with a clear focus on the desired outcome of safeguarding public health and maintaining future compliance. Nevertheless, in accordance with recommendations proposed by Government Better Regulation initiatives, and to protect public health, the MHRA strives to ensure that where people persistently break regulations, or where there is evidence to suggest significant criminal activity has taken place, that those responsible will be identified quickly and face proportionate and meaningful sanction. The MHRA can, and will, use all available powers to act against those who are responsible for the most serious breaches of legislation. For further details see: <https://www.gov.uk/government/publications/report-a-non-compliant-medical-device-enforcement-process>

3 Standards

There are a number of [relevant designated standards](#). Compliance should provide a means of demonstrating conformance with the specific essential requirements of the UK MDR 2002 [5].

MHRA encourages the use of designated standards but they are not compulsory and there are other ways to demonstrate conformance with the essential requirements. Where designated 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 two fundamental standards and an associated technical report, 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* [4]
- IEC/TR 62366-2:2016. Medical devices, Part 2: Guidance on the application of usability engineering to medical devices* [11]
- EN 60601-1-6:2010 Medical electrical equipment, Part 1-6 General requirements for basic safety and essential performance. Collateral standard. Usability [12].

**please note that these are not designated standards. However, the MHRA deems these latest versions best practice and we therefore strongly recommend their use over previous versions.*

3.1 EN 62366-1:2015 Medical devices, Part 1 and IEC/TR 62366-2:2016

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.

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 basic medical device safety and essential clinical performance. It 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 part 2 technical report has a broader focus and focuses not only on safety, but also on how usability relates to attributes such as task accuracy, completeness and efficiency, and user satisfaction.

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 of the user interface to assess whether any human factors issues / use errors are present. These are evaluated according to Annex C as 'User Interface of Unknown Provenance' (UOUP). However, if any modifications are made to the User Interface or its parts then only the unchanged parts of the User Interface remain UOUP and the changed parts of the User Interface are subject to the requirements of clause 5 of the standard.

It is important to note that the standard applies to all classes and types of medical devices and situations, including both devices with complex user interfaces, such as electromedical equipment and others with more basic user interfaces, for example:

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

Although differences still exist, it is also worth noting that the standard is now considered to be more consistent with FDA guidance [2] (see also [13] and [14]) and requirements, which is helpful for global product development.

3.2 Other relevant standards:

EN 60601-1:2006 3rd Ed + A1 2013 – Safety & Essential Performance [15]

- > CI 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 60601-1-8:2007 Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems [16]

- > Patient safety depends on the ability of the users to correctly discern the characteristics of alarm signals. Consequently, usability is important in the design of alarm signals that are readily discernible without being unnecessarily distracting or disturbing. Alarm signals shall be validated, e.g., by clinical or simulated clinical usability testing.

EN 60601-1-11:2010 Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment [17]

- > CI 7.1 The usability of the marking and accompanying documents intended for Lay users shall be evaluated based on an operator profile that includes a maximum of eight years of education. Home healthcare environment equipment should be designed to be simple to use and not require reference to complex documentation.

EN ISO 15223-:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements [18].

- > Using internationally recognised symbols consistently will improve usability and meet regulatory requirements.

EN 1041:2008 (and EN 1041:2008+A1:2013) Information supplied by the manufacturer of medical devices [19]

- > CI 5.1.1 requires that any means of provision of information with medical devices shall take into account the intended users, the conditions of use and any issues specific to individual device types that are necessary for the safe and effective use of the device.

EN ISO 14971:2019* Medical devices - Application of risk management to medical devices [20]

- > Risk management integrates into the usability engineering process detailed in EN 62366-1. Information or data for estimating risks can also be obtained from usability tests employing typical users;

EN ISO 13485:2016 Medical devices. Quality management systems. Requirements for regulatory purposes [21]

- > Requirements specifically for usability have been included in EN ISO 13485: 2016. 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.

**please note this is not a designated standard. However, the MHRA deems this latest version best practice and we therefore strongly recommend its use over previous versions.*

4 Summary of a usability engineering process

The aims of a usability engineering process are to deliver products that are easy to use and safe in the intended context of use, and by intended users (whether by carers or patients themselves). Users should not have to read, understand and remember complex instructions for use 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, and will have a user interface that is consistent with user experiences and expectations.

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

Figure 2 describes the stages of a typical 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 whether their particular use scenario has been taken into account. A statement of 'compliance with IEC 62366' is not sufficient without supporting evidence. Usability engineering files should be kept clear and concise and documentation should be prepared with the reviewer in mind, to make it as easy as possible for them to access all the information they require.

Table 1 summarises widely used usability engineering techniques and aligns them with the stages of the usability engineering process (Figure 2). Not all these techniques are relevant to every process, and other, complementary, techniques may be applied by people with appropriate expertise; the list of techniques is illustrative rather than mandatory. However, user testing and Failure Modes and Effect Analysis (FMEA) are normally considered the minimal requirements. In both the figure and the diagram, there are cross-references to the sections of this document where these processes are described, but it is recommended that techniques be applied by professionals with relevant expertise: this guidance does not provide a tutorial in the application of usability engineering techniques.

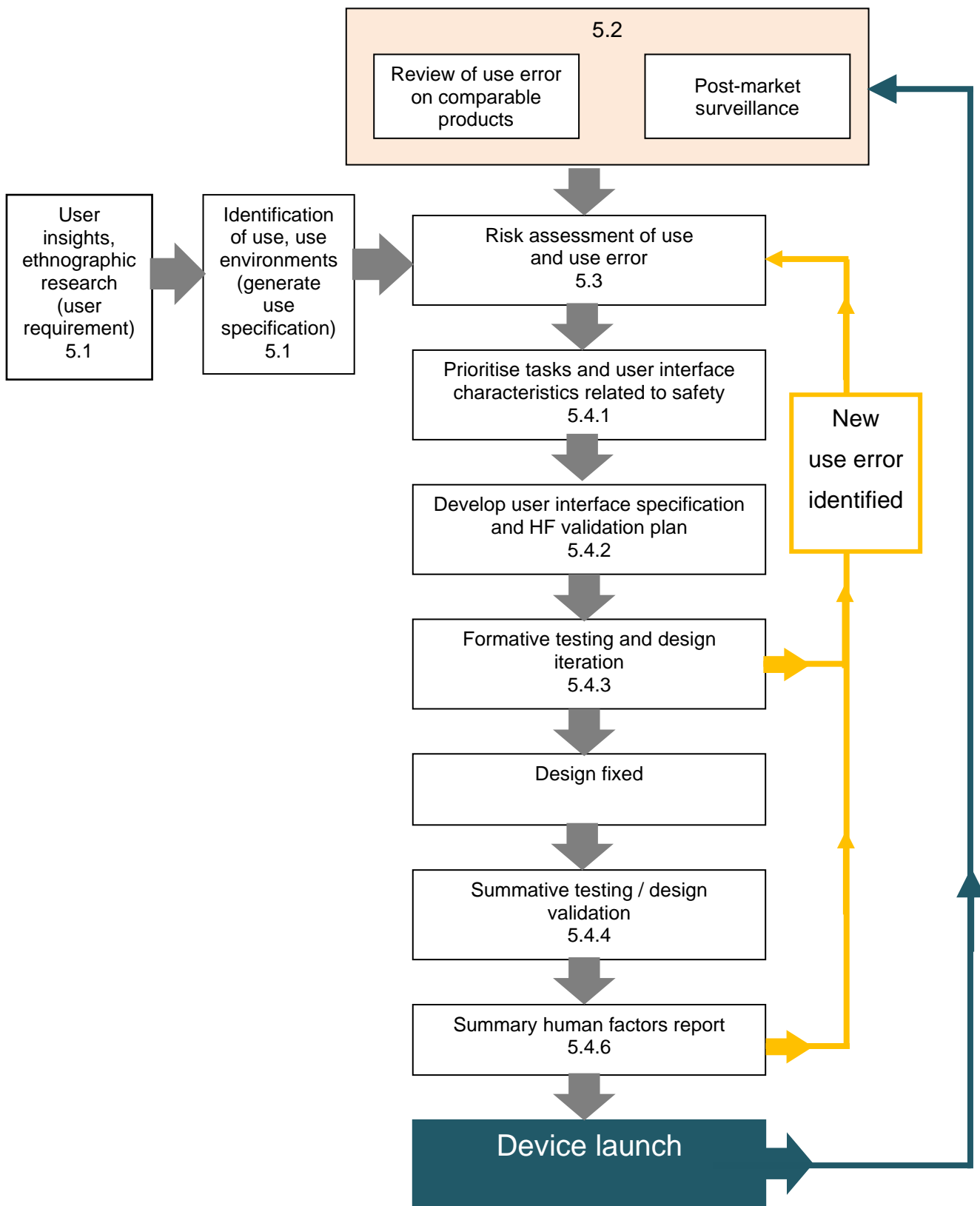


Figure 2 Example of usability engineering process (see details in section 5)

Table 1					
Usability engineering techniques	Features	Suited for	Considerations	Stages	Resources
Observation in the field (sometimes called 'ethnography' or 'field research')	Observing people working and using devices in the actual environment of use	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	[22] (p.43); [23] (p.28); [24]
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	[25] (p.16); [18] (p.56); [19] (p.44); [26]
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	[18] (p.55); [19] (p.46); [27]
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	Challenging to apply in settings where people move around (e.g. on foot) a lot. Takes place within the actual environment of use.	5.1	[21] (p.16); [18] (p.44); [28]

Table 1					
Usability engineering techniques	Features	Suited for	Considerations	Stages	Resources
Working with existing sources	Using existing sources (incident reports, academic literature, existing databases – see section 6 – 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 possible	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	[18] (p.58); [19] (p.49)
Failure Modes and Effects Analysis (FMEA)	Analysis team ‘brainstorms’ likely causes and consequences of failures, including use error. May also involve other techniques such as task analysis and user testing	Reasoning about likely causes and consequences of device failure and use error	Needs expertise in human factors to be effective; subjective; focuses on failures	5.3	[21] (p.12); [19] (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 task analysis should be based on empirical data of real user tasks (and how these should map onto device tasks)	5.4.1	[21] (p.14); [18] (p.52); [19] (p.54); [29]
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	Personas should be based on empirical evidence	5.4.1	[18] (p.50); [30]

Table 1					
Usability engineering techniques	Features	Suited for	Considerations	Stages	Resources
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	Scenarios should be based on empirical evidence. The range of scenarios can sometimes become unmanageably large	5.4.1	[18] (p.51); [31]
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)	[32]
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)	[21] (p.15); [18] (p.48); [19] (p.65); [33]
Cognitive walkthrough	An expert review approach that involves 'walking through' the steps of an interaction between user and device, reasoning about possible use errors	Early review, focusing on user cognition	Should be conducted by experts in cognitive science.	5.4.3	[21] (p.18); [18] (p.40); [34]

Table 1					
Usability engineering techniques	Features	Suited for	Considerations	Stages	Resources
User testing / usability testing	Testing the device with representative users in a simulated use environment or the actual environment of use. Often used with think-aloud and/or debrief interviews	Identifying which device features people find easy to use, and which cause problems. Determining whether the device is susceptible to use errors that could cause harm.	<p>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.</p> <p>Facilitators for evaluations in simulated use environments need appropriate training.</p>	5.4.3, 5.4.4 (formative and summative assessment)	[21] (p.21); [18] (p.46); [19] (p.77)

Table 1: Key features of principal engineering techniques for medical devices; alternative approaches could be used if justified. The stages (sections) identified for each technique are suggestions reflecting the most common uses of each.

5 Stages of a usability engineering process

5.1 Identification of uses, users, use environments, operational contexts of use and training (creation of use specification)

To design for real world use, it is important to understand who the users are, their experience, the tasks they have to perform 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. All potential users of the device should be identified and described here including occasional users such as maintenance personnel.

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, culture, any anthropometric and biomechanical considerations, disease state)
- use environment (e.g. temperature, humidity, light, noise)
- 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 (including any training decay details)
- frequency of use.

The rationale for selecting representative users, use environment and fidelity of test should be risk assessed and 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 (both internally and externally held) for potential use error for similar products and comparable competitor products (through post-market surveillance, complaints, see section 6 and 7) and include this within the product risk assessment relating to use and use error (see EN ISO 14971 [20]). Other sources of information, including interviews with and observational studies of users and those identified in section 7, should also be used to identify issues that may not have been implicated in patient harm but that nevertheless negatively affect user experience and efficiency.

5.3 Risk assessment of use and use error

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 (formative evaluation), and heuristic analysis and documenting the product risk assessment relating to use and use error (see EN ISO 14971 [20]). Reasonably foreseeable use errors associated with each step or user interface characteristic should be documented.

The tasks and associated use errors should be scored for severity of harm. This will enable prioritisation of development work to focus on areas of the user interface which could impact safe and effective use and therefore reduce risk through design. The rationale for the prioritisation of tasks should be documented.

5.4 Formative and summative evaluation

During development, any device should be subjected to formative evaluation(s) in order to assess how well it addresses user needs and to identify whether the use-related risk mitigations are effective, and to detect previously unknown errors. Towards the end of the development process, it is generally necessary to conduct summative evaluation to demonstrate that the device can be used by intended users without serious use errors or problems, for the intended uses and under the expected use conditions (also known as human factors summative testing). It is usually adequate to carry out this testing in a simulated environment. For both formative and summative evaluation, it is necessary to identify suitable tasks as a basis for evaluation.

Where human factors studies (either formative or summative) are to be done in the UK and involve the clinical use of the device on humans may constitute a 'clinical investigation' and the study would need MHRA and ethics committee approval. This applies to a device that is not UKCA or CE marked, or is UKCA or CE marked but is being used outside the approved labelling.

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 tasks/scenarios
- A subset of the hazard-related use scenarios based on severity of harm (critical tasks)

5.4.2 Develop user interface specification and human factors engineering plan

A user interface specification should be developed which describes the design characteristics identified to mitigate potential use errors. These include user interface characteristics such as: labelling, shape, colour, icons, alarms and buttons.

A plan for how the design is to be developed through formative and summative evaluation should also be written. This can describe the aspect of the user interface to be assessed, who will be tested and the environment.

5.4.3 Formative testing (iterative testing during product development)

Testing can be carried out 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 should 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 relevant characteristics of the intended users. The rationale for the numbers of users involved in testing should be documented. Advice on sample sizes is given in both IEC/TR 62366-2:2016 [11] and FDA guidance [2]. However, a manufacturer may choose other numbers and constitution of

participant groups; the rationale should take account of diversity of user population and the number of tasks supported. Use errors identified in the formative studies should be reviewed against and added to the use risk assessment for their severity as well as potential to cause harm and their acceptability determined.

Formative studies and design improvements should be carried out until confidence is gained that the design is safe and effective (that unacceptable risk has been mitigated) in order to progress to summative validation.

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

Ethics:

It is important to involve the intended users of a device as far as possible in design and evaluation. In planning all forms of user testing, it is important to consider ethics and risks of harm. For formal studies (such as clinical trials) and studies that involve recruitment via the National Health Service (in the UK), there are defined requirements for obtaining ethical clearance (<http://www.hra.nhs.uk/>). While official (and even best practice) guidance is less well defined for early-stage formative testing, risks and benefits to participants should be considered and documented. An example of an ethical dilemma in evaluating a particular health technology is provided by [by the User Experience Professionals Association \(UXPA\): "should-we-conduct-this-usability-study"](#). Participants should, where practicable, give informed consent to participating.

Organisations such as the UXPA present guidelines such as '[Do no harm and if possible provide benefits](#)'. This includes identifying risks of physical or psychological harm and other costs (e.g. time, expenses) to participants, as well as potential benefits, both immediate and longer-term, to participants.

It is the manufacturer's responsibility to ensure that they are satisfied that their proposed studies have the appropriate level of ethical consideration before commencing evaluation.

5.4.4 Summative testing

5.4.4.1 Validation of the instructions for use and accompanying documentation/ information

The instructions for use and accompanying documentation 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 should 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 be on materials representative of the final text and layout.

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 those tasks, with identified potential use error that could impact the safety and effectiveness of the design and have associated user interface (UI) risk control, including the device information for safety. This testing must be carried out on a product representative of the launch product.

The study must:

- Include representatives from all identified user groups (according to Faulkner 2003 [35] 15 of each group identifies an average 97% of all use errors)
- Include all tasks / UI characteristics with identified potential use error that could impact the safety and effectiveness of the design.
- Include tasks essential for the operation of the device.
- Be carried out in a realistic simulated environment or in the actual environment 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 during the study.
- Assess the completion of tasks and gather subjective data on safety and ease of use.

5.4.4.3 Training

In design and testing, consideration should be given to user skills and knowledge, including the nature and substance of required training; when and how this training is to be delivered; and whether or not the assumptions made about training delivery are reasonable and effective. For example, agency nurses working in an unfamiliar context might be experts in a particular diagnostic or therapy but have limited access to training on an unfamiliar device. Manufacturers should clearly state and justify their training expectations / requirements, including demonstrating that the requirements are reasonable for the intended contexts of use.

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. Close calls, use related difficulties and subjective feedback should also be considered. 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 use risk assessment and use error and residual risk assessed for acceptability.

5.4.6 Human factors summary report

A summary report can be prepared to help communicate the usability / human factors activity on a project, documenting the steps taken to mitigate risk to the user. It typically includes, but is not limited to, the following details:

- intended device users, uses, environments and training
- description of the device user interface
- summary of known use problems (device under consideration and other related devices in market)
- user task selection and prioritisation (based on the risk management file)
- summary of formative evaluations
- results of summative usability testing (including manual validation)
- the benefit-risk status of the device from the risk management file
- conclusions

6 Post-market surveillance

All medical device manufacturers who reside in the GB and/or wish to place devices on GB market are obliged under the UK MDR 2002 [5] 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 (i.e. in the pre-market area).

As part of these obligations, medical device manufacturers are obliged to inform the MHRA 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’ [36]. Feedback from the MHRA needs to be considered as part of PMS. This guidance makes a distinction between use error and abnormal use.

When companies are involved in contractual relationships (e.g. device manufacturer with the medicines market authorisation holder), comprehensive arrangements for sharing safety information and respective responsibilities for safety reporting should be clearly specified.

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. This review should include complaints data for potential use error for their own and (when available) similar products and comparable competitor products. Publicly available adverse event and product recall data should also be reviewed. Such data is made publicly available in the FDA Manufacturer and User Facility Device Experience (MAUDE) database [37], FDA’s MedSun: Medical Product Safety Network [38], EU field safety notices on competent authority websites, FDA’s CDRH Medical Device Recalls [39] and the Australian TGA Device Adverse Event Notification (DAEN) database [40].

All other relevant potential data sources should be actively reviewed where available. This can include:

- complaints data for potential use error for their own and similar products and comparable competitor products
- articles in journals
- results of publicly available clinical studies
- feedback from post market clinical follow-up studies
- device registries
- user studies and observational studies of users used to identify lower level issues that may not have been implicated in patient harm but that nevertheless negatively affect user experience and efficiency
- hospital episode statistics
- social media

This ongoing review of data should include updating the product's risk assessment relating to use and use error (see ISO 14971 [20]). The evaluation is governed by risk management, usability engineering, design validation, and corrective and preventive action processes.

7 Product life-cycle and continuous improvement

Usability engineering should be incorporated into the product design from the conception of the idea to the final validation of the device, and post-market surveillance, as part of the benefit-risk profiling of all medical devices / IVDs and combinations of medical devices used with medicines (see Figures 2 and 3). Considering the wide range of medical devices and drug-device 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. However, the approach taken should be risk-based, justified and appropriately documented throughout the life-cycle of the product.

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 UKCA/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 may not be necessary to perform formal human factors studies at this stage.

However, if minimally-trained users or lay persons are involved in the clinical investigation, or the potential for use error resulting in harm is high, usability engineering needs greater consideration at an earlier 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 UKCA/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 further design changes may be necessary following clinical studies.

It is also expected that device change management will occur throughout a product lifecycle (i.e. post pivotal clinical studies for a drug-device combination product), 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, the need for additional usability engineering studies considered with regard to the associated risks and the approach taken justified in the technical file.

Figure 3 below represents many of the same principles as those in Figure 2, but is included to emphasise:

- the importance of product iteration and improvement throughout the life-cycle
- the relationship of both post-market vigilance and surveillance of similar devices

- the role of human factors considerations to promote optimal clinical outcomes

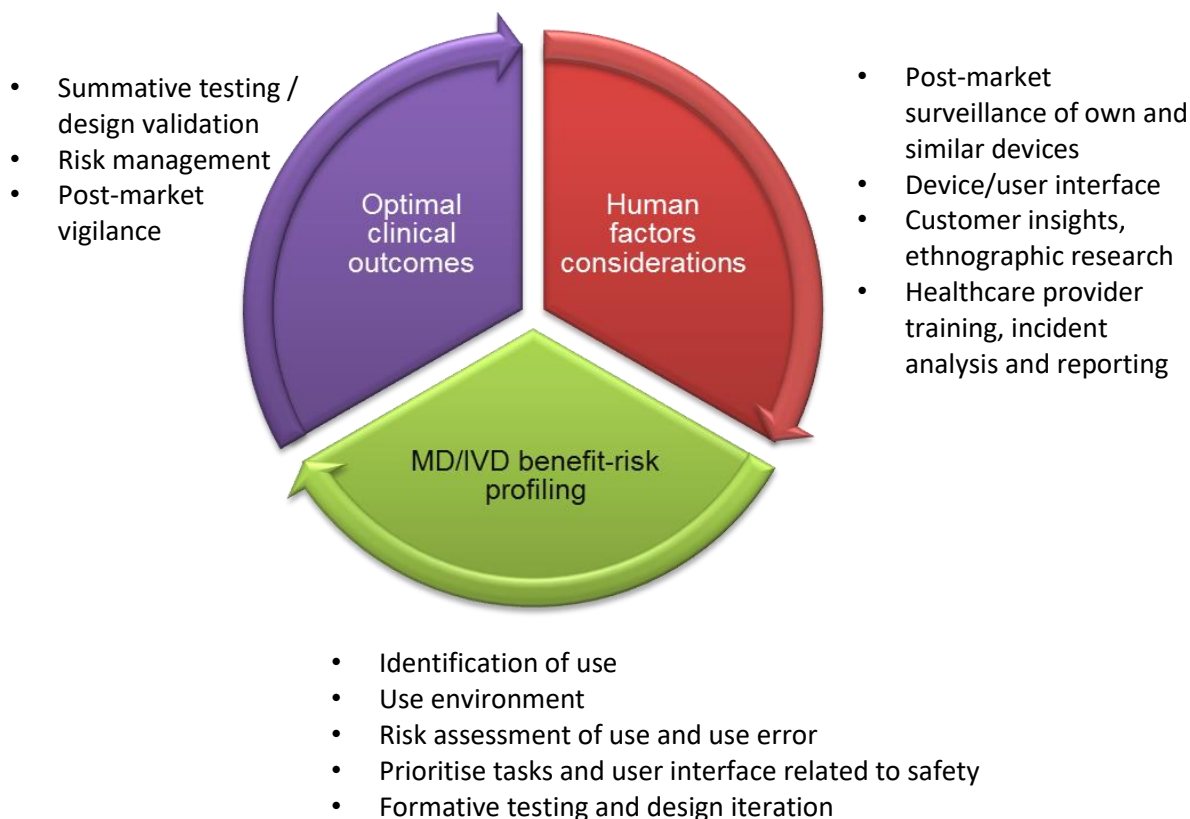


Figure 3 Human factors as part of benefit-risk management throughout the product lifecycle

For older products where summative testing may not have originally been performed, it is recommended to follow the approach described in EN 62366-1:2015 Annex C (normative) 'Requirements for user interface of unknown provenance (UOUP)'. Essentially, use-related risk analysis should be implemented for older products and informed by available post-market data to establish if adequate controls are in place.

8 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 this latter group of products, the critical characteristics and nature of the medicinal products to be delivered by the device should be considered in the risk analysis of the device. There are also medicinal products that include a significant device component, either co-packaged with, or integral to the medicinal product. The distinction between the different drug-delivery combination types is explained in MEDDEV Guidance 2.1/3 [41].

For non-integral drug-device combination products (e.g. refillable pen injectors and their cartridge of medicinal product), the UK MDR 2002 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 Part II of the UK MDR 2002, Annex I (as modified by Schedule 2A to the UK MDR 2002) still apply with regard to safe and effective use of the device component.

Therefore, for both integral and non-integral drug-device combination products, the expectations for human factors and usability engineering considerations will be similar to those for any other medical device 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 usability engineering studies may be required. Vigilance reports illustrate that the device component can be pivotal in the safe and effective use of a medicinal product. The risk of medication error due to the device component should be considered in the Risk Management Plan for medicinal products incorporating an integral medical device [42], [43]. Once marketed, any medication errors should be reported as an adverse reaction [43].

Also of note, is that integral drug-device combination products may be available in different presentations (different strengths for example) requiring the user to distinguish between presentations and identify the correct drug-device combination. Where relevant and related to risk, drug-strength differentiation should generally be considered in summative testing to demonstrate that users are able to correctly distinguish between them.

For drug delivery devices with well-established platforms where there are no unusual or novel features introduced (e.g., pressurized metered dose inhalers, pre-filled syringes) and the risks associated with the device components are well known, a simplified approach, e.g. risk-based usability assessment rather than formal usability engineering studies may be acceptable, based on the intended user group and environment of use. Robust justification for the approach taken should be documented, in particular, where additional HF studies are not considered necessary. This is an evolving area, and at the time of print, guidance for human factors requirements specifically for combination products is under discussion in the US, Europe and other regions, in particular the relationship of human factors studies to clinical studies. Human Factors studies are generally

expected to be conducted with placebo products, unless the use of active drug substance is considered necessary to assess users' handling of the product. It is also recognised that the purpose of human factors studies is different from that of clinical trials to demonstrate efficacy and safety of the medicinal product formulation, when used as intended.

Similarly, there may be an overlap in expectations for human factors testing of the device instructions for use and readability testing of the patient information leaflet for medicinal products.

In addition to the 62366 standards (Parts 1 and 2), the current EU guidance documents relating to drug-delivery devices include those for inhalation products [44], [45] and information provided in the EMA Quality of medicinal products Q and A on specific products (e.g. dry powder inhalers, measuring devices for liquid medicines and eye-drops [46]).

Manufacturers may also wish to discuss expectations for combination products regulated as medicinal products in scientific advice meetings [47].

9 Appendix 1

Organisations represented in the MHRA task and finish group producing the original 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 Medical Devices

Devices Expert Advisory Committee (DEAC)

Dexcom Inc.

Eucomed

Lloyd's Register Quality Assurance Ltd

National Institute for Health and Care Excellence (NICE)

NHS Improvement

SGS United Kingdom Ltd

Smith & Nephew

UL International (UK) Ltd

University College London

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10 Appendix 2

Essential requirements (ER) of Part II of the UK MDR 2002, Annex I (as modified by Schedule 2A to the UK MDR 2002) that may be affected to some degree by human factors 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 manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in regulation 2(1) of the UK MDR 2002 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 Part III of the UK MDR 2002, Annex 1 (as modified by Schedule 2A to the UK MDR 2002).

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.

ER 13

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.

ER 15

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 UK mark (*UKCA 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.

11 Further reading

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)

ISO 9241-210 User-Centered Design

BSI Post-market surveillance, BSI/UK/440/ST/0614/en/HL

<http://www.bsigroup.com/LocalFiles/en-GB/Medical-devices/whitepapers/WP-Post-market-surveillance.pdf>

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- [11] IEC/TR 62366-2:2016. Medical devices, Part 2: Guidance on the application of usability engineering to medical devices
- [12] EN 60601-1-6:2010+A1:2015 Medical electrical equipment, Part 1-6 General requirements for basic safety and essential performance. Collateral standard. Usability.
- [13] FDA [Draft List of Highest Priority Devices for Human Factors Review](#)
- [14] FDA [Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development](#)
- [15] EN 60601-1:2006 3rd Ed + A1 2013 – Safety & Essential Performance

- [16] EN 60601-1-8:2007+A1:2013 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
- [17] EN 60601-1-11:2010 Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- [18] EN ISO 15223-1:2016. Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.
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- [39] FDA [CDRH Medical Device Recalls](#)
- [40] Australian [TGA Device Adverse Event Notification \(DAEN\) database](#)
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- [44] [EMA Guideline on the pharmaceutical quality of inhalation and nasal products](#)
- [45] [EMA Guideline on the requirements for clinical documentation for orally inhaled products](#)
- [46] [EMA Quality of medicines Q and A on specific products](#)
- [47] [MHRA Scientific meetings](#): Medicines: get scientific advice from MHRA

Hyperlinks last checked: January 2021