chfg

clinical human factors group

the charity working to make healthcare safer

Selecting safe & easy to use products for healthcare

Using Human Factors Specification & Checklists (Version 1.0)

Contents

Written by the Clinical Human Factors Group – working with clinicians and Human Factors experts to make healthcare safer for patients and staff.

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How to use this Guide

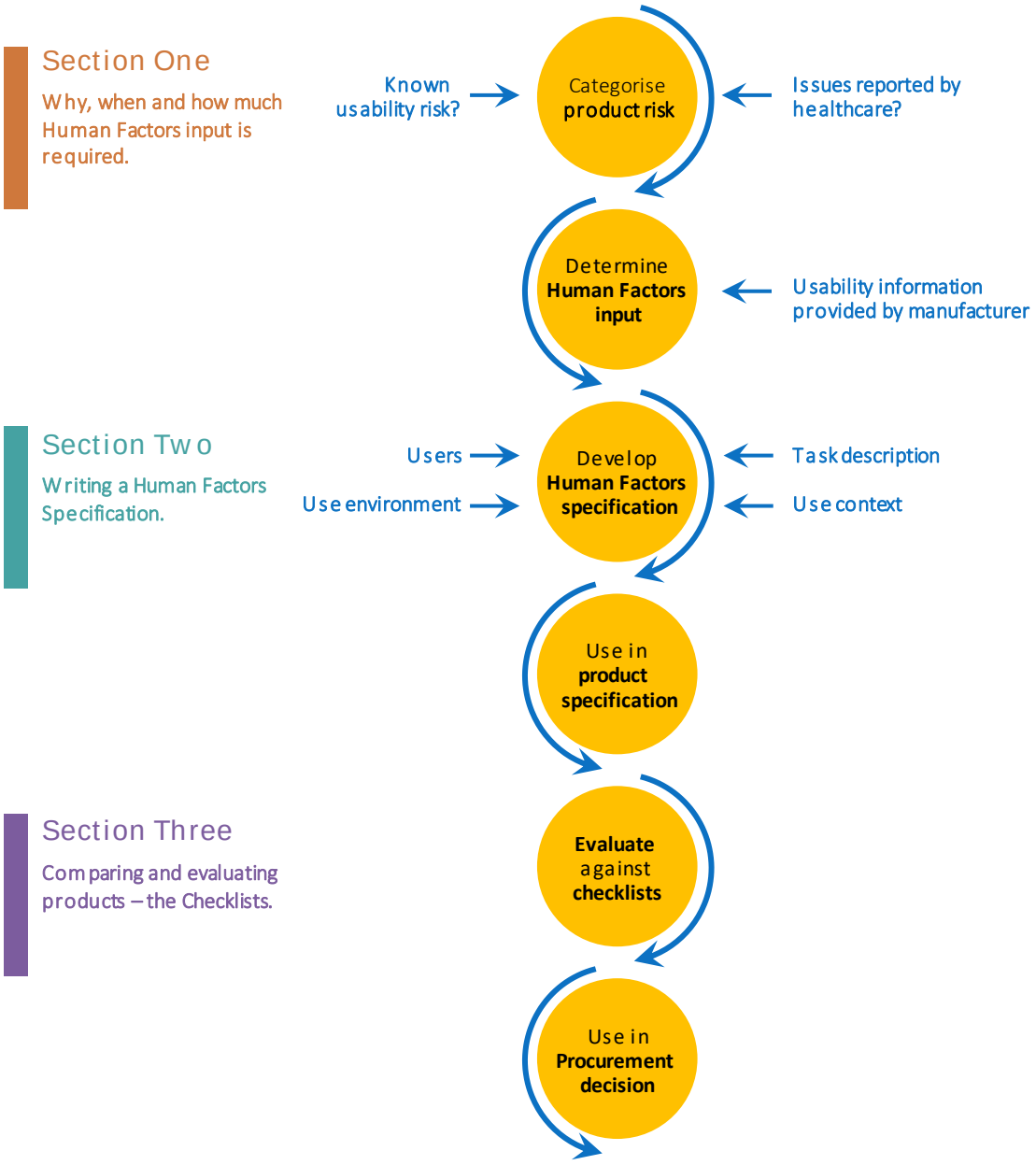
Using Human Factors science increases the likelihood of obtaining well-designed and easy to use products to deliver safe patient care. Poor designs, by contrast, can cause unintended harm to patients.

This Guide is to help staff working in procurement or with medical devices and equipment, to use Human Factors to specify and select the best and safest products to use in healthcare. This is important because conformity with Regulations and Standards does not always guarantee safe outcomes when products are used in practice.

This Guide is particularly relevant to medical devices but can be used for other healthcare products.

Figure 1 provides an overview of how Human Factors can be used within the Procurement process and provides an overview of each Section in this Guide.

Figure 1 Human Factors input to the procurement process.



Section One

Using Human Factors in Procurement

Why use Human Factors Science?

Human Factors is a body of knowledge about physical, psychological and other characteristics applied to the design of things used by humans. Using Human Factors increases the likelihood that a product will be safe, easy to use, effective, efficient and satisfying when people use it.

In healthcare this may mean safer patient care.

Poor designs that are not easy to use and increase the risk of use-error can cause unintended harm to patients. Use-error occurs when designs, for example, confuse the user or are inconsistent, fail to meet users' needs and expectations, do not do what is needed or are used in an inappropriate situation.

Examples of outcomes due to poor design:

- wrong artificial joint combinations inserted during surgery due to difficult-to-distinguish packaging[1]
- incorrect intravenous fluids doses (over 50%[2]) due to non-standardised infusion pumps
- death from anoxia due to anaesthetic machines with critical switches unguarded, unalarmed, out of view, and too easily overlooked
- patient harm caused by oxygen shortage when portable cylinders display ambiguous full and empty status[3]
- risks of bleeding, or life-threatening introduction of air into blood vessels due to the design of 3-way taps where it is not obvious if ports are open or closed
- wrong route medication due to poor use of colour coding on oral syringes[4]
- a surgeon sustained a work-related musculoskeletal injury after working repeatedly at an operating couch with insufficient adjustability.

The CE mark does not guarantee that use-errors will not occur.

The Medicines and Healthcare Products Regulatory Authority (MHRA) states that the growing number of medical devices, and errors in use are of increasing concern. "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 use environment, less skilled or even unskilled users, including patients and carers, must be able to use quite complex medical devices safely."[5]

[1] Investigation into the implantation of wrong prostheses during joint replacement surgery. Healthcare Safety Investigation Branch. 2017

[2] Incidence and prevalence of intravenous medication errors in the UK: a systematic review. *European Journal of Hospital Pharmacy* Published Online First: 23 October 2018. doi: 10.1136/ejhpharm-2018-001624. Sutherland A, Canobbio M, Clarke J, *et al*

[3] Design and Safe use of Portable Oxygen Systems. Healthcare Safety Investigation Branch. 2018

[4] Inadvertent Administration of an Oral Liquid Medication into a Vein. Healthcare Safety Investigation Branch, April 2019

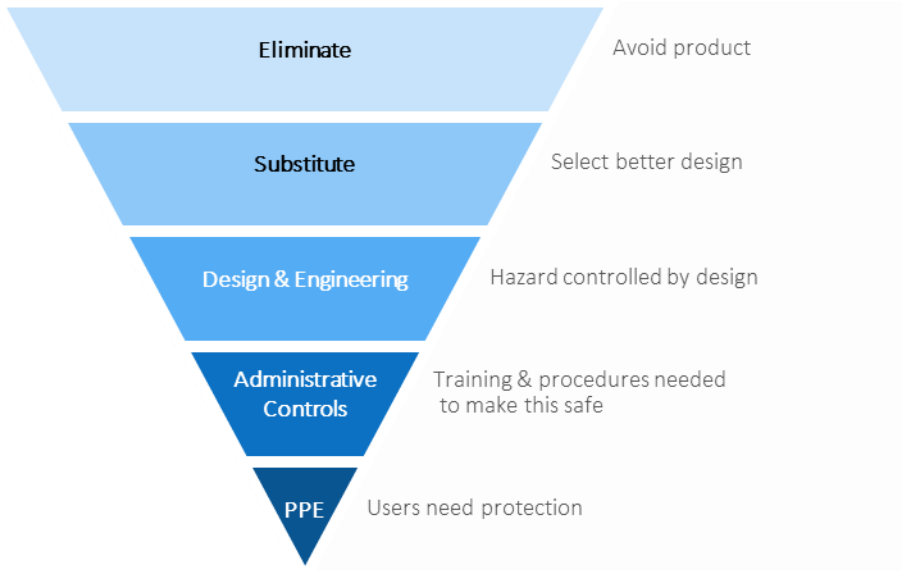
[5] Human Factors and Usability Engineering – Guidance for Medical Devices Including Drug-device Combination Products. Medicines & Healthcare Products Regulations Agency. September 2017.

Why Human Factors is important during Procurement

Procurement provides a unique opportunity to prevent the introduction of poorly designed products into healthcare before they can negatively impact staff performance and patient safety.

Figure 2 shows that given appropriate information, procurement can select products that reduce use-error by good design−the most effective form of hazard control− rather than products that rely on changing the way people work, or training and new procedures to ensure safety.

Figure 2 Hierarchy of risk control – as applied to procurement



Using Human Factors has performance and cost savings benefits, important business case drivers, but also contributing to safety by virtue of reducing waiting times, workload, and pressure on the workforce[6].

Wider benefits of using Human Factors in Procurement

- **Provides rigour to mitigate subjective influences**
- **Improves task & organisational performance (fewer errors, faster task completion)**
- **Increases satisfaction & engagement with new equipment**
- **Reduces implementation problems, troubleshooting & maintenance**
- **Reduces training as easier to use or learn to use**
- **Prevents device work-around**

[6] Purchasing for Safety: A Human Factors influenced procedure for evaluating medical products. Fuller, Lightner, Maddox, Shanawani, Bagia, Hemphill, Cassano-Piché, Cafazzo, Chagpar, and Easty (2010) Choosing Safer Medical Technologies: How Human Factors Methods Can Help in the Procurement Process. Biomedical Instrumentation & Technology: Human Factors, Vol. 44, No. s1, pp. 49-56.

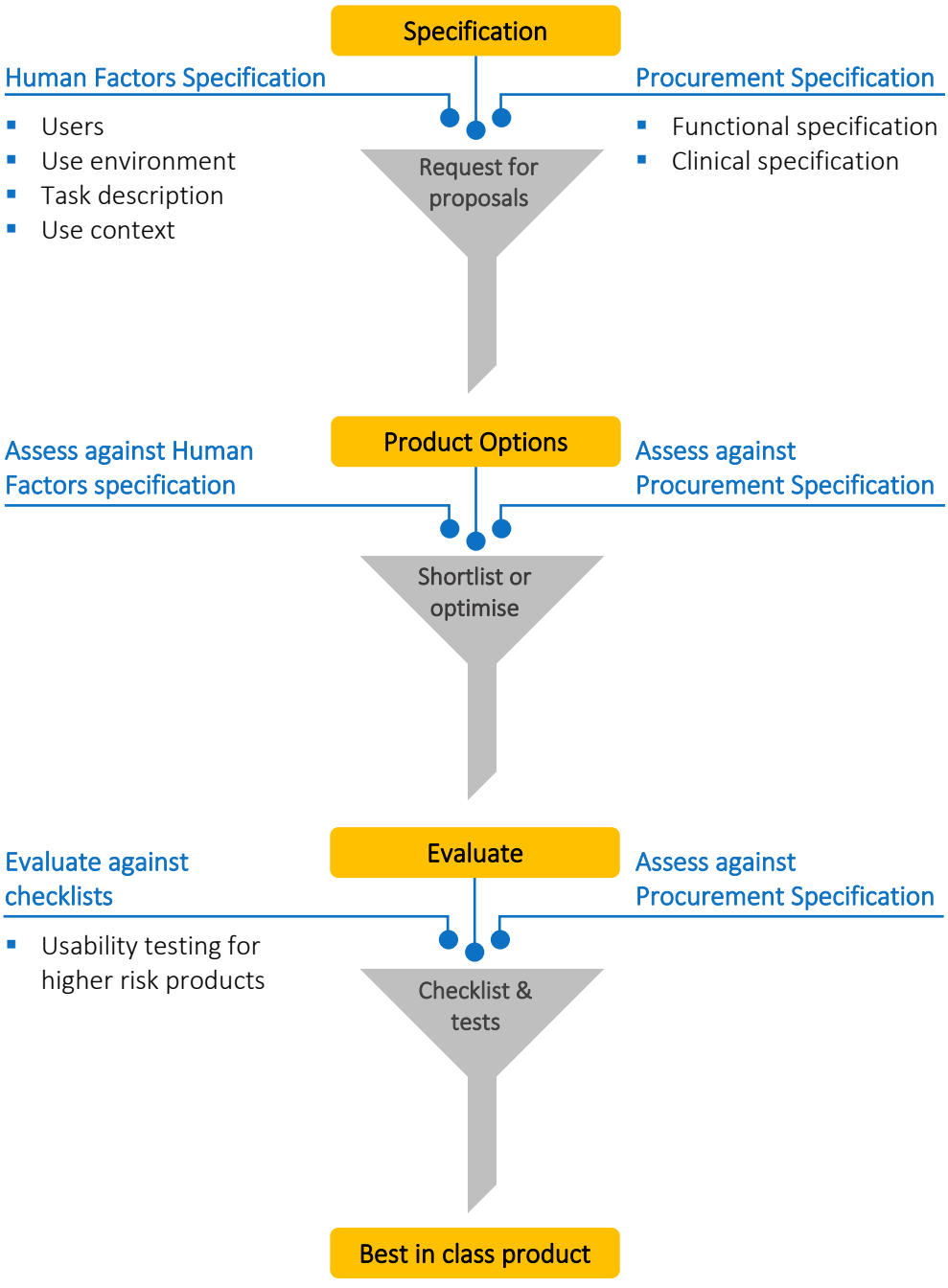
When to use Human Factors in Procurement

There are three stages where using Human Factors can support Procurement:

1. Specification
2. Short-listing or optimising
3. Evaluation

The NHS Supply Chain Clinical and Product Assurance (CaPA) Framework is committed to ensuring patient safety and using Human Factors to complement their process. Figure 2 shows the three stages where using Human Factors can support Procurement.

Figure 2. Incorporating Human Factors into existing Procurement activities



How much Human Factors input is needed?

Risk assessment determines the level of Human Factors input. The NHS Supply Chain Clinical and Product Assurance (CaPA) Framework base their risk assessment on the requirements of the Medical Devices Regulations. This could be supplemented by considering known human factors risks with particular devices, such as fluid delivery devices, life support equipment and devices with a computerised information system[7]. Also risk factors such as: products with reported issues; new to market; or new models of previous designs.

Higher risk and complex products are likely to need more detailed usability testing determined and conducted by trained Human Factors staff. The use of the Evaluation Checklists in Section Three may not identify all patient safety risks but they can be used to guide further usability testing.

What to ask manufacturers and suppliers

The amount of information provided by manufacturers and suppliers will also impact the Human Factors effort required by procurement staff.

Manufacturers of well-designed products will be able to provide evidence that they applied Human Factors and Ergonomics throughout the product design cycle in the Usability Engineering File required by Regulations and Standards.

You can request to see, for example:

- User tests conducted during design and their outcomes
- Number of participants and healthcare versus non-healthcare test participants
- Supporting evidence to demonstrate this medical device is more efficient, safer, easier to use than comparatives
- Documented test reports.

Regulations and Standards mandate that designers in the European Union and internationally must use Human Factors during the design of medical devices. In 2020 a new Medical Devices Regulation comes into force followed in May 2022 by new Regulation for in vitro diagnostic medical devices.

The International Standard ISO 62366-1:2015[8] identifies that the development of safe and usable medical devices and systems requires the application of Human Factors and Ergonomics throughout the product design cycle, as seen in Figure 3.

[7] Guidance for Human Factors Evaluations in the Procurement of Medical Devices, Equipment and Technology. Western Canada Human Factors Collaborative. May 2017

[8] 62366:2007, Medical devices–Application of usability engineering to medical devices.

Figure 3: Human Factors applied during the design process

To evidence this process, manufacturers must maintain a Usability Engineering File to demonstrate they have followed the Usability Engineering Process. The File includes usability test results, user profiles and development plans. This is not typically released for reasons of privacy and intellectual property but can be requested.

A note on definitions

Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, on human beings.[9] This includes consumables, such as, cannulas, dressings, to hospital beds and trolleys, to MRI scanners, defibrillators and anaesthetic machines.

In vitro diagnostic medical device means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body[10]. This includes: pregnancy tests, blood glucose monitors, urine test strips.

This Guide uses **the term Human Factors**, but equivalent terms include, ergonomics, usability (engineering) and user-centred design.

[9] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC . A full definition can be found in Article 2(1)

[10] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. A full definition can be found in Article 2(2)

Section Two

Writing a Human Factors Specification

The Human Factors Specification

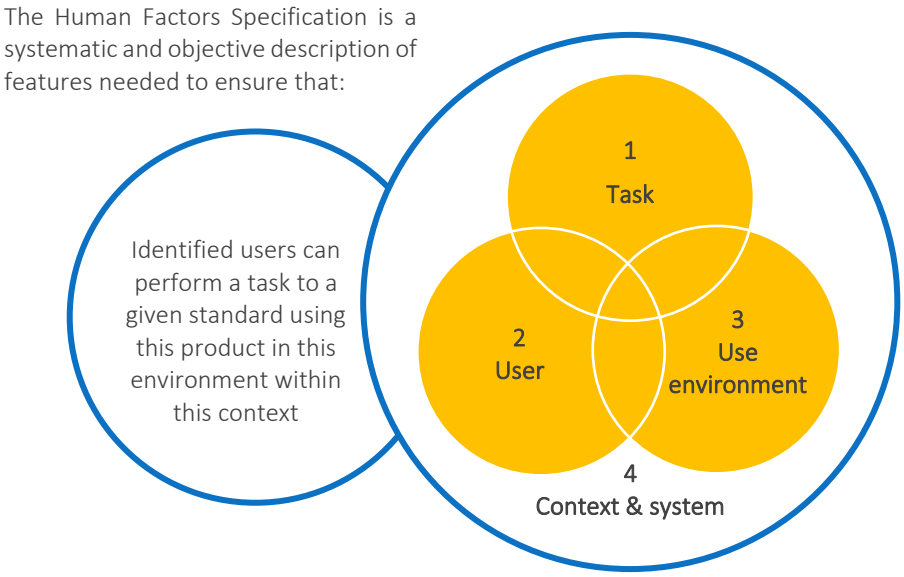
The Human Factors Specification is a list of requirements (in addition to utility and clinical requirements) used to communicate to suppliers – how your users will use the product. The more Procurement specialists know about their users and their requirements, the more likely it is that they will select the best and safest products. The Specification can be used by Procurement to shortlist from a range of products and then later to conduct a more detailed assessment.

A Human Factors Specification comprises the:

1. User specification
2. Task description
3. Use Environment
4. Context or system factors

Most of the Human Factors Specification, once developed, can be used across similar product categories, customising where needed. A task description will be needed for each product.

Figure 5: The Human Factors Specification



The more that designers and manufacturers know about who and what they are designing for, the better the products will be created and manufactured. Designers report that it is difficult to get adequate access to healthcare staff who use their products, so it is important that Healthcare specify their Human Factors requirements as accurately and comprehensively as possible.

The following guidance provides prompts and questions to assist in the development of a Human Factors Specification.

Users

The User Specification identifies who are the users and describes their characteristics.

Product designers make design decisions based on a general user specification that may reflect your user population to a greater or lesser degree. Suppliers should demonstrate and provide evidence that the product **can meet your User Specification**.

Specifies:

1. Users – patients & staff
2. Patients
3. Male to female & age ratios
4. Percentile ranges – physical characteristics
5. Cognitive characteristics

Who are your users?

List all users, remembering the secondary users also interact with the product, such as, infection prevention and control nurses and porters. Users include, for example:

Staff	Carers	Patients
cleaners	adult carers	children
clinical engineers	child carers	adults
doctors, anaesthetists, surgeons	older adult carers	older adults
healthcare assistants		
maintenance staff		Specific cohorts:
nurses		Diabetics
occupational therapists, physiotherapists		People with dementia
paramedics		The obese
pharmacists		Motor-sensory
porters, administration staff		Mobility impaired
radiographers, radiologists		etc.

Who is it used on?

Identify groups of patients, in detail, as their characteristics vary widely and since most devices or parts of devices come into contact with patients – their characteristics affect design. For example:

Patients	Patients with specific needs, such as:
Babies: premature, new born, etc	Diabetes
Toddlers: to 2 years	Memory impairment
Children: 3 to 5 years	Obesity
Children: 6 to 12 years	Motor-sensory impairment
Teenagers	Mobility impairments
Young adults	outside anthropometric range 2.5th to 97.5th %
Adults	Learning difficulties
Older adults, etc.	

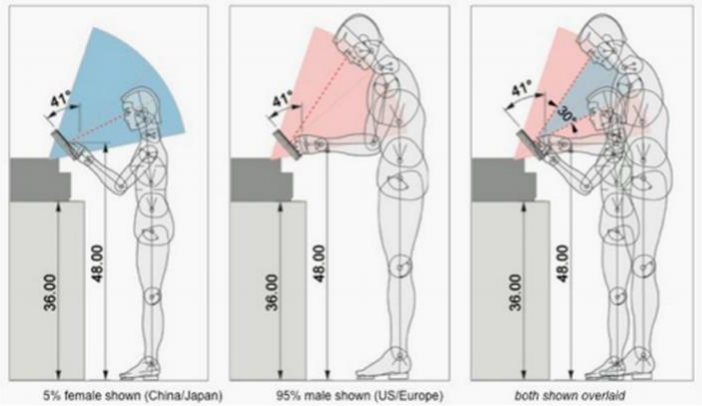
What's the male to female ratio and age profile of users?

Specify age and sex ratios to enable suppliers to explain how product features meet users' needs and overcome known differences, for example, grip strength, hand size and hip breadth. Where the product cannot meet all users' needs to the same extent, then the ratios assist procurement to prioritise otherwise difficult choices.

How this information is used

Once your users are identified, as above, designers and suppliers must provide evidence that the product meets their physical characteristics and cognitive characteristics. The supplier's Product Specification should state the percentile range that the design accommodates. This is typically 2.5th percentile – 97.5th percentile range but might be increased for safety critical features to 1st to 99th percentile range. Figure 6 illustrates percentiles used to set monitor height.

Figure 6: Physical characteristics used to determine the position of a monitor



Human Factors provides published population data on physical characteristics arranged by age and sex. Most people are near to the average (50th percentile), with proportionately fewer people towards the extremes (1st and 99th percentiles). Designers are interested in the extremes, where any given aspect of a design may not fit, or at worst, is unusable.

This data helps designers determine design features such as reach distances, body-part clearances, equipment height, manageable weights, acceptable postures, biomechanical forces and ranges of adjustment.

For example, radiology equipment must provide sufficient height adjustment and power-assist to enable smaller (2.5th percentile height) radiographers to reach and operate equipment but at the same time ensure head clearances for the taller (97.5th percentile) radiographer and patient.

Cognitive characteristics such as memory, information processing, decision-making, and attention affect the way we use devices and equipment. These are influenced by age, training, educational level, experience, expectation, awareness, alertness and wellbeing but also by the organisation and context of device and equipment use.

For example, for older adults, a device must support limited short-term memory and impaired decision-making, with instructional prompts, avoid high frequency alarms that older users tend not to hear, and require less hand strength and dexterity to hold and operate.

Example

Example of User Profiles

Your User Specification will comprise a number of User Profiles. Table 3 shows examples of different User Profiles found in healthcare. These can be used in your Specification across different products, where user populations are consistent, customising where necessary.

Colour coding helps focus the product evaluation on characteristics that are more difficult for the product to satisfy (see the red flags in Table 1 below). If the product can satisfy these then it might be that the other characteristics will be accommodated too.

Table 3: User profiles

	Profile A Untrained staff	Profile B Trained Staff	Profile C Carers	Profile D e.g. Diabetic patients
Psychological characteristics				
non-fluent English?	maybe	unlikely	maybe	maybe
reduced reading ability?	maybe	unlikely	maybe	maybe
reduced ability to understand instructions?	unlikely	unlikely	maybe	maybe
untrained?	likely	unlikely	maybe	maybe
unsupervised?	maybe	maybe	likely	maybe
memory issue?	unlikely	unlikely	maybe	maybe
used previous device?	maybe	likely	maybe	likely
List others…				
Physical characteristics				
decreased strength?	unlikely	unlikely	maybe	likely
dexterity issue?	unlikely	unlikely	maybe	likely
balance issue?	unlikely	unlikely	maybe	likely
fine motor impairment?	unlikely	unlikely	maybe	likely
gross motor impairment?	unlikely	unlikely	maybe	likely
mobility impaired?	unlikely	unlikely	maybe	likely
outside anthropometric 2.5th to 97.5th % range?	unlikely	unlikely	maybe	likely
visually impaired?	unlikely	unlikely	maybe	maybe
hearing impairment?	unlikely	unlikely	maybe	maybe
sensory motor impairment?	unlikely	unlikely	maybe	maybe
needs arising from specific pathology?	unlikely	unlikely	maybe	likely
List others…				

Example of how to use User Profiles

Your User Specification for a handheld blood glucose monitoring device needs to accommodate User Profiles A to D in Table 3 above. The product will need to be usable by users with the following red flags:

- unsupervised
- untrained
- with carry-over learning from previous devices that they have used

Features to support the above user characteristics might include a user interface that can be tested to show:

- that the novice user can be led through the task to completion
- feedback about task completion at each step
- the use of non-language standard icons and symbols
- that it has a well-developed help menu supplemented by plain English instruction sheet.

Task

Your Task Description states what you need this product to do in a way that supports how your users work. This helps avoid the risk of a product unintentionally changing behaviour in a non-desirable way, adding extra tasks, complexity or non-essential functions.

The supplier's product specification will need to provide evidence that it meets your Task Description and reflects the way your users work, their performance standards, and other contextual requirements.

Describes:

1. Task goal and steps
2. Likely interruptions
3. Concurrent tasks
4. Duration

Use observations, interview a range of users, check procedures and ask the user to talk you through the task. Observations, in a range of use settings, are important to identify how the task is actually done in practice, as procedures may not be adhered to, sometimes for good reasons.

Gather users' views (good and bad) on existing products, current issues, and review incident data and other available data.

Describe the goal the user is trying to achieve

Describe the task starting with the expected goal. A basic task description will include the:

- goal – the intended outcome.
- tasks – actions, one step at a time, to achieve the goal.
- Sub-tasks – a further break down of tasks.

What are the related and secondary tasks?

From the task description, it should be possible to identify secondary tasks (related tasks), such as:

- Replacing consumables
- Cleaning & sterilisation
- Storage
- Moving equipment between points of use
- Maintenance

For example, a patient using an analgesia syringe, needs to be moved. This involves disconnecting the driver from mains power, ensuring there is sufficient battery power to continue treatment, securing the device for transport and re-connecting to power source on arrival. The description of the secondary task highlights features required to prevent inadvertent operation, facilitate safe and easy manual handling, and error-free reconnection.

What are the likely task interruptions?

Identify parts of the task where interruptions are likely to have the greatest impact on use-error. Healthcare use environments are unpredictable and interruptions and distractions are common. Most devices will need design features that enable:

- the user to pause the device
- prompts to remind the user where they are in a task
- storage of inputted information for later
- enables another user to complete the task
- prompts to remind the user to complete the task.

How will this task interact with other tasks?

Identify what else might be happening simultaneously, what other equipment and consumables are in use, and what other devices staff or patients might be using. Individual tasks rarely happen in isolation so the design of equipment and devices must consider, for example:

- length of use (for example, 24 hours a day or extending past shift handovers)
- availability of the history of device settings
- the impact on the patient each time staff interact with the device
- impact on the patient's activities and independence when using or wearing the device

How long do tasks take?

Specify how long task completion takes currently and the target task length. These can be measured and tested.

The task length for primary and secondary tasks might vary across different user groups. New equipment should not, without very clearly defined reasons and benefits, increase the time to complete a task – yet it is not uncommon for this to be the case.

Also consider how long it will take to maintain or service a product, as this will have implications on its availability for use (as well as cost). For example, manufacturers servicing recommendations, and mandatory tests such as calibration.

Note there is usually a period of embedding – some new devices may increase time to do the task initially – but it may be a 'safer system' for the patient.

What is the frequency of the tasks?

Specify the frequency of use of this device across different user groups. The frequency of tasks impacts the user's behaviour. For example, for frequently used devices staff are more likely to: remember how it works; use shortcuts; make incorrect assumptions; and downgrade the importance of the intervention.

Example

Example of Task Description

The examples below in Table 2 and Figure 7 illustrate different methods of recording task descriptions.

Describing the task helps build a picture of users' needs, interactions with other users, related consumables and identifies the use environment. Task descriptions can be used to specify and later evaluate product features and be developed for more rigorous user testing for higher risk products conducted with Human Factors expertise.

Table 2: Tabular format of task description

Goal of task	Sub tasks	Steps	Secondary tasks
Measure blood glucose level	1. Collect finger-prick blood sample	1.1 Wash hands	
		1.2 Prepare lancet device	Using lancet device
		1.3 Get blood sample	
		1.4 Apply dry swab on puncture	
	2. Turn meter on	2.1 Locate power	
		2.2 Insert test strip	
	3. Read result	3.1 Await result	
		3.2 Safe disposal of sharp & swab	Using sharps disposal
	4. Record result		

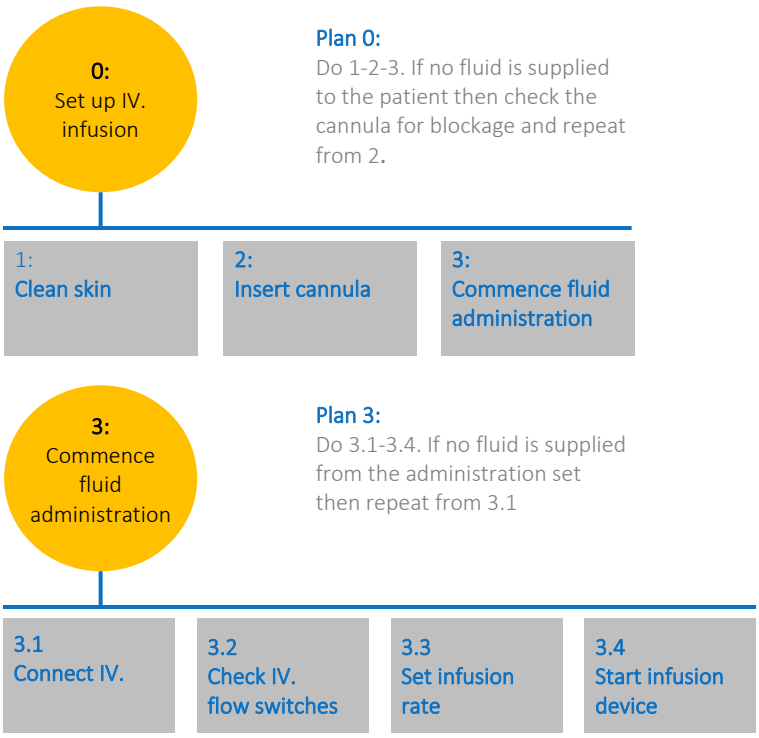


Figure 7: Hierarchical task analysis – example of setting up an intravenous infusion[11]

For more complex or high-risk tasks you may need to use or ask to see evidence of a hierarchical task analysis.

This can be used to identify and specify the behavioural or cognitive steps that need to be combined in order to achieve the goal and sub goals and it should be used during the manufacturers testing and evaluation.

With additional analyses, task descriptions can be used to identify where use-error is most likely to occur.

[11] Human factors in anaesthetic practice: insights from a task analysis. D. Phipps1*, G. H. Meakin3, P. C. W. Beatty2, C. Nsoedo2 and D. Parker. British Journal of Anaesthesia 100 (3): 333–43 (2008)

Example

Use environment

This specifies the conditions and physical features of workplaces where the product will be used. Use Environment Profiles can be used across products, customising where necessary.

The supplier's product specification will need to provide evidence that the product is designed, can be used and has been tested for your specified use environment conditions.

Describes:

1. Environmental conditions
2. Physical space
3. Indoor, outdoor or mobile features

For example, screens viewed under bright overhead lights as well as conditions of dimmed lighting must provide brightness and contrast adjustment if users are to see the screen.

Measure the Use Environment

State the range of conditions specified in Workplace Regulations for heat, light and noise (these are based on the needs of human performance and comfort). There might be additional requirements where a specific task has to be performed in a range of environments.

Check a sample of use environments and measure:

- temperature, heat and humidity
- type of and location of lighting, sources of glare and reflections
- light levels – natural and artificial and uncontrolled glare from the sun
- noise levels – ambient noise, equipment noise, and alarm noise and how these are likely to interfere with natural speech and hearing.

The device will need to perform within acceptable and environmental ranges. Where this is not the case special considerations for workforce safety and comfort will need to be considered.

For example, equipment requiring a low temperature to work efficiently had an impact on both staff and patient comfort and the ability to get clear and accurate images (as patients found it hard to hold still).

Measure and observe the physical space

Provide measurements and likely ranges for a sample of locations:

- workspace, access and egress and movement within
- work surface heights, storage heights
- range of movement between different locations (how far will this be carried?)
- type of floor covering, levels and change of level
- range of vertical movement between surfaces (manual handling implications)

Identify additional features for outdoor and mobile use

List special features required to overcome less predictable use environments, such as:

- features to enable manoeuvre across unlevel ground and weather proofing
- clear indication of battery life, back-up battery, low battery alarm
- indication if power source is battery or mains (for when the patient is static)
- the suitability of alarms and warnings to allow for time to reach a 'safe haven'
- device and equipment security.

Example of Use Environment Profiles

Table 3 shows examples of use environment profiles. These can be used across products, where use environments are likely to show some consistency customising where necessary.

Colour coding helps focus the evaluation on characteristics that are more difficult for the product to satisfy (see the red flags in Table 3 below). If the product can satisfy these then it might be that the other characteristics will be accommodated too.

Table 3: Use environment profiles

Environment		Profile 1 Theatre	Profile 2 Emergency/ Urgent care	Profile 3 Ward	Profile 4 Out-pts/GP	Profile 5 Out-pts/GP	Profile 6 Mobile/ outside
Light	poor light levels?	unlikely	unlikely	unlikely	unlikely	maybe	likely
	sources of direct glare?	likely	likely	unlikely	unlikely	maybe	likely
	sources of reflection?	maybe	maybe	maybe	maybe	maybe	likely
Temp.	sweating likely?	unlikely	unlikely	unlikely	unlikely	maybe	maybe
	cold discomfort or shivering?	unlikely	unlikely	unlikely	unlikely	maybe	maybe
	cold – issues with dexterity?	unlikely	unlikely	unlikely	unlikely	maybe	maybe
	humidity issue?	unlikely	unlikely	unlikely	unlikely	maybe	maybe
Noise	interferes hearing speech?	unlikely	maybe	unlikely	unlikely	unlikely	maybe
	other alarms?	likely	likely	likely	maybe	unlikely	maybe
	traffic noise?	unlikely	unlikely	unlikely	unlikely	unlikely	maybe
	other equipment?	maybe	maybe	maybe	maybe	unlikely	maybe
Weather	exposed to rain?	unlikely	unlikely	unlikely	unlikely	unlikely	maybe
	exposed to snow?	unlikely	unlikely	unlikely	unlikely	unlikely	maybe
	exposed to sun?	unlikely	unlikely	unlikely	unlikely	maybe	maybe
Surface	uneven?	unlikely	unlikely	unlikely	unlikely	maybe	likely
	wet?	maybe	maybe	maybe	unlikely	maybe	likely
	change of level?	unlikely	unlikely	unlikely	maybe	likely	likely
	carpet?	unlikely	unlikely	unlikely	unlikely	likely	unlikely
	non-solid ground?	unlikely	unlikely	unlikely	unlikely	unlikely	likely
PPE	gloves?	likely	likely	likely	likely	likely	likely
	face masks?	likely	maybe	maybe	maybe	maybe	maybe
	visor?	maybe	maybe	maybe	unlikely	unlikely	maybe
space	confined?	maybe	maybe	maybe	unlikely	maybe	likely
	constrained postures?	maybe	maybe	maybe	unlikely	maybe	likely
	reach above shoulder?	unlikely	unlikely	unlikely	unlikely	unlikely	likely
	reach below knee?	unlikely	unlikely	unlikely	unlikely	maybe	likely
	no worksurface to support kit?	unlikely	unlikely	unlikely	unlikely	maybe	likely

Context of Use

This requires description of the wider operational or organisational context or system that affects the way that users may perform the tasks using the product.

This description must specify all other factors that impact the use of this product and requires input from appropriate stakeholders.

Describes:
1. Organisational
2. Operational requirements
3. Situations and context

For example, new equipment in clinic has reduced the time it takes to weigh a patient by two minutes – this equates to freeing-up one hour of time for staff over a morning in a busy out-patient Clinic.

What are the organisational requirements?

Provide as much detail as possible about organisational and social contexts that affect users' abilities to perform tasks. When patient harm occurs, incident analysis often cites organisational human factors that have impacted user performance. Organisational requirements include:

- upstream and downstream circumstances – what happens before or after this task
- unintentional consequences
- staffing levels, turn-over, use of locum and agency staff, shift patterns
- staff rotation (device knowledge of new starters, access to training)
- skill mix
- time available to complete the task, appointment length, waiting times
- availability of training and refresher training
- supervision
- standard operating procedures and the use of checklists
- safety culture
- performance measures (staff and service performance)

What situations will the device be used in?

Identify the high-pressure, urgent, unplanned and time critical situations where the product design will need to provide more features to reduce the burden on staff in terms of memory, decision making and information processing.

Section Three

Checklists

Evaluating performance

The Checklists specify performance requirements for easy, safe and effective use -i.e. what good design would look like. These requirements are based on design principles, usability guidelines, and input from healthcare and published sources. The checklist is not exhaustive there may be other features that need to be assessed.

The Checklists can be used for:

- Specifying requirements for product performance – select the relevant performance requirements for your product
- Evaluating products during short listing – compare products with each other systematically
- Supporting usability testing – select the relevant performance requirements to test with users in a test situation

The checklist is not a pass or fail process. The level of acceptable device performance should be based on the level of risk. If the product does not perform favourably on items in the checklist, this may be a prompt for further consideration or usability testing.

Usability testing and Human Factors Expertise

Using the Checklists is not the same as Usability testing. This requires running systematic performance tests of the device with representative users, using objective measures, such as, time taken to complete, number of errors made, and number of times that the user asks for help or refers to instructions. Usability testing is most effectively undertaken in a test or simulated environment (to control variables) with representative users and requires Human Factors expertise.

Checklist Instructions

1. Select Checklist Sections relevant to the product you are assessing.
2. Use the Profiles developed in the Human Factors Specification to focus on the most difficult to meet needs of your users, task requirements, use environment and organisational context
3. Use more assessors to decrease the subjectivity of a single assessor
4. Set levels of acceptable device performance based on level of risk.

Using scenarios can help make evaluation - using the checklists - easier and less subjective. For example, Mary a carer (See Profile C) is helping her disabled parent at home (Profile 5) to use a handheld blood glucose monitor (See task description).

1. The Packaging – addressing errors of selection

Packaging must provide the name, size, model, and details of variations of this product. Fonts need to be large enough to see in the place of use and storage. Consider risks associated with lookalike sound-alike items stored adjacently and mistakes when verbally communicating device variations (with similar codes) in workplaces such as theatre. Packing must be easy to remove, perhaps one-handed while wearing gloves. Consider older adult patients' needs.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
1.1	Immediate naming of the device is possible because of prominent labelling with large enough fonts?						
1.2	Error-free selection of given model, or size when picking from store?						
1.3	Labels are attached to multiple sides to aid visibility when stored?						
1.4	Error-free verbal communication between users of device variations?						
1.5	Identification of: disposable/single use/single patient use?						
1.6	Identification if multiple parts packed or if other components are needed?						
1.7	Display of instructions for storage? (packaging will be sufficient)						

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
1.8	Visible CE mark?						
1.9	Recognisable and standard symbols?						
1.10	Scissor-free and easy package opening?						
1.11	Ability to open and separate packaging from device first time?						
1.12	Ability to open one handed (while wearing gloves)?						
1.13	Ability to open packaging without droppage or accidentally discarding device parts?						
1.14	Instructions for use that can be referred to when using the device?						
1.15	Easy access to unique identifying barcode?						
	Other requirements:						

2. The unpackaged device – checking at the point of use

Devices might be unpackaged by one clinician, used by another, cleaned or disposed of by someone else. Once packaging is removed, the device variations must remain identifiable to enable checking at the point of use, and information regarding re-use, single-use, and cleaning.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
2.1	Immediate naming of this device?						
2.2	Error free identification of model or size when unpackaged?						
2.3	Identification of non-disposable parts?						
2.4	Identification of: disposable/single use/single patient use?						
2.5	Visible expiry date?						
2.6	Error free recognition of which way up this is used?						
2.7	Easy access to unique identifying barcode?						
2.8	Other requirements:						

3. Handling the device – pick-up, manipulating and using

Device use in healthcare often require users to hold steady to minimise patient discomfort and to complete the task successfully. The device should enable the user to pick-up, hold securely, grip and use with a comfortable grip, manipulate and operate the device according to task needs. Test with gloves, slippery hands, and interaction with body fluids etc. plus left and right-handed users.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
3.1	First time pick – up without error or dropping?						
3.2	Secure grasp/grip in correct orientation to use?						
3.3	Holding device steady for required time period?						
3.4	Use while sitting or standing as task requires						
3.5	Use of worksurface support at the height required – i.e. sitting or standing						
3.6	Easy manipulation with device accessories attached?						
3.7	Use within normal posture range for wrists, hands and fingers?						
3.8	Use within normal posture range for arms and shoulders?						

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
3.9	Use with reasonable force and hand strength?						
3.10	Comfortable use without exerting pressure areas on the operator?						
3.11	Comfortable use without exerting pressure areas on the patient?						
3.12	Comfortable use without the need to lean over the patient?						
3.13	One handed/two hand/ need assistance?						
3.14	Fits within the workspace available						
3.15	Meets manual handling requirements?						
3.16	Enables handling in line with infection prevention expectations						
	Other requirements						

4. Connections to the device – consumables, connectors and other devices

Connections to the device gives rise to potential wrong connections and patient harm. Consider everything that should connect to the device as well as anything in the use environment that could be connected in error.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
4.1	Instructions, symbols or other identifiers of what must be connected to the device?						
4.2	Ability to make and secure connections one-handed? (wearing gloves)						
4.3	Ability to make connection with reasonable force and finger/hand strength?						
4.4	Features prevent incorrect connections to the device or parts of it?						
4.5	Connections remain intact during use, movement and accidental contact?						
4.6	Additional labels, icons or other distinguishing features alongside all colour coding.						
4.7	Identifiable sterile and non-sterile parts?						
	Other requirements:						

5. Controlling the device – how we interact

Controls, for example, buttons, switches, dials, knobs, levers, switches and pedals, should be arranged to support the task, work in a predictable way, be consistent with other easy to use devices and follow well evidenced design conventions.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
5.1	Controls immediately identifiable?	.					
5.2	Error-free selection of functions?						
5.3	Controls are distinguishable from each other?						
5.4	Logical grouping according to function or other rationale recognised by users?						
5.6	Immediate identification of high priority controls?						
5.7	Immediate pairing of controls and their displays?						
5.8	Device operation consistent with what user expects?						
5.9	Device operation consistent with other devices used previously, or devices used alongside?						
5.10	Recognisable conventions, such as knobs for turning, levers to push or pull, buttons to depress etc.						
	Other requirements						

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
5.11	Device operation is possible without instruction or prompting?						
5.12	Device provides prompts to help use it?						
5.13	Controls operated with reasonable force and finger/hand strength?						
5.14	Size, location and spacing of controls protects against inadvertent activation?						
5.15	User receives visual feedback when controls activated?						
5.16	User recognises tactile and/or auditory feedback when not looking at the device?						
5.17	Inadvertent activation not observed as controls require appropriate level of force to activate?						
5.18	Critical functions are protected from inadvertent activation?						
5.19	Protection of functions for certain users – password protected access?						
5.20	Tamper proofing of control activation is available if required?						
5.21	Device indicates power-on but not active (e.g. demo or standby mode)						
	Other requirements:						

6. Viewing the device display – position and adjustability

Information displays range from a display window to a computer monitor/s. The principles for assessment are the same in terms of users' needs. Consider the impact of lighting conditions, glare, reflections, dirty displays, reading from a distance, and eyesight capabilities of those using the device.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
6.1	Display visible from all device operating positions and distances?						
6.2	Display is visible with head and neck in neutral posture?						
6.3	Display is visible without causing visual or postural discomfort?						
6.4	Display has height, angle and tilt adjustments for range of users and light conditions?						
6.5	Adjustment of brightness and contrast enable viewing in all conditions?						
6.6	Display provides large enough fonts readable from all device operating positions?						
6.7	Massages are displayed for a sufficient period of time?						
6.8	Previous messages can be recalled?						
	Other requirements:						

7. Information input and output – timely, appropriate and easy to understand

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
7.1	Required information input follows sequence used elsewhere, e.g. name, date of birth, etc?						
7.2	Users detect where one patient's episode of care starts and ends?						
7.3	Simple and unambiguous language is understood by users?						
7.4	Language is consistent with terms used by users?						
7.5	Information provided is useful, relevant and comprehensive?						
7.6	Information provided at appropriate time to support task?						
7.7	Information is presented in a readily usable form?						
7.8	Related information is grouped together?						
7.9	Units of measurement are consistent – no conversion necessary?						
7.10	Abbreviations & acronyms avoided?						
7.11	Symbols used are standard and readily understood by users?						
	Other requirements:						

8. Correcting known mistakes – error recovery

Users need to be able to recognise and correct mistakes, such as, cancel or go back a step and restart. Well-designed interfaces will support immediate error recognition and guide the user to recover (without relying on error codes).

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
8.1	Immediate error recognition?						
8.2	User can identify & explain errors?						
8.3	Error message enables steps to recover from an error easily?						
8.4	Error messages alert users to potentially dangerous settings?						
8.5	Device prevents user from activating potentially unsafe settings?						
8.6	Cancellation of action possible and return to previous state?						
8.7	Priority and error messages are immediately recognisable as different from other information?						
8.8	Priority and error messages visible?						
8.9	Priority and error messages are consistent in form and location?						
8.10	Priority and error messages must be acknowledged before user can progress task?						
8.11	Error log makes it possible for users to check to see if an error was made?						
	Other requirements:						

9. Supporting the task sequence – device status and settings

Users require feedback and guidance to support them through the task sequence. Feedback and status information is important following power failures, task interruptions, or where tasks are completed by multiple users.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
9.1	Immediate recognition of device status? (standby, on/off, mode, etc.)						
9.2	Automatic and user-controlled settings are indicated clearly?						
9.3	Any settings held in memory are indicated on start-up?						
9.4	Default settings easy activated?						
9.5	Input does not require user to recall or refer elsewhere?						
9.6	Sequence of interactions to complete the task are succinct and predictable?						
9.7	Prompts available to guide user through the task?						
9.8	Menu levels are minimised?						
9.9	Recognisable immediately where you are within the task sequence?						
9.10	Recognisable immediately what information already entered?						
9.11	Satisfactory completion is indicated?						
9.12	Paused task can be restarted and completed by another user?						
	Other requirements						

10. Device alarms – identifying, interpreting and acting on alarms

Alarms may need adjustment to suit different use environments and users but with safeguards to ensure normal levels are returned on next user.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
10.1	Alert user to accidental activation, interference, power supply changes?						
10.2	Auditory and visual alarms accompany error messages?						
10.3	Visual alarms readily distinguished in all lighting conditions?						
10.4	Audible alarms are readily distinguished in use environments?						
10.5	Adjustable levels of alarms?						
10.6	Distinction of critical or high priority alarms and less urgent alarms?						
10.7	Alarm message enables user to identify and explain the issue?						
10.8	Alarms are easy to set and re-set?						
10. 9	Alarm activation level adjustable?						
10.10	Alarm status on/off and sensitivity?						
10.11	Protection from inadvertently silencing an alarm?						
10.12	Clear indication that the alarm has been silenced?						
10.13	Immediate activation when predetermined settings are reached?						
10.14	Feature to check and test alarms?						

11. Training for the device – training for use, not to overcome poor design

Devices designed for ease of use and to meet users' needs will require less training. Training should not be used to overcome poor design or overly complex device operation. Training has a big organisational impact, and needs to be considered within the context of staffing levels, availability for training, staff turnover, cost of training, etc.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
11.1	Users can use device without training?						
11.2	Users can use device without reference to training manual?						
11.3	Users can use device without reference to instructions on packaging?						
11.4	Users require training?						
11.5	Identifies need for staff refresher training?						
11.6	Identifies where the device is for use by specific personnel only						
	Other requirements:						

12. Batteries and power – status and warnings

The Device will need to operate for a sufficient amount of time on battery power if used in transit.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
12.1	Device provides easy to understand low battery warning?						
12.2	Device provides easy to understand battery power status?						
12.3	Device marked clearly with batteries required?						
12.4	Standard batteries used?						
12.5	Batteries easy to insert without error?						
12.6	Device operates for sufficient amount of time on battery power: consider requirements for use in transit?						
	Other requirements						

13. Cleaning the device – surface cleaning to decontamination

Assess the different cleaning tasks conducted by different user groups. Assess sterilisation or decontamination where required.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
13.1	Identifiable how to clean this?						
13.2	Cleaning instructions provided on the device or packaging?						
13.3	Easy and quick cleaning due to smooth surfaces, minimal recesses and crevices?						
13.4	Status alerts prompt when fans, air filters, and other parts need cleaning or exchange?						
13.5	Removable parts are easy to access, change and reinstall?						
13.6	Device provides lock mechanism to enable cleaning safely in situ?						
13.7	Device is compatible with common cleaning processes and chemicals?						
13.8	Cleaning can be done safely?						
13.9	Cleaning records are sufficient and consistent?						
13.10	Number of parts displayed on device to ensure complete reassembly If device is taken apart to clean/sterilise?						
	Other requirements						

14. Maintenance – servicing, mandatory and repairs

Consider manufacturer's servicing recommendations, and mandatory tests. How long maintenance tasks take have implications on its availability for use (as well as cost). When devices fail the protection of patient and staff safety is critical.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
14.1	Unique identification for product recall?						
14.2	Users can complete servicing and maintenance tasks from instructions?						
14.3	If the device fails, it fails safely?						
14.4	Self-diagnostic features useful and provide sufficient instruction to return to operation?						
14.5	Access to serviceable areas is easy?						
14.6	Serviceable parts and internal components easy to identify, access, remove and replace?						
14.7	Serviceable parts labelled clearly?						
14.8	Requires standard tools for maintenance or provides special tools?						
14.9	Maintenance can be done safely?						
	Other requirements						

15. Transporting the device – manual handling and moving when in use

Consider the product requirements for carrying by hand, transporting attached to the patient, or transporting via trolley etc.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
15.1	User can lift and carry without assistance?						
15.2	Trolley is not required?						
15.3	One person can lift and carry?						
15.4	Meets the requirements of the Manual Handling Regulations?						
15.5	Handles or grips are provided for carrying?						
15.6	Device is not an awkward shape or fragile?						
15.7	Device and power source can be transported attached to the patient?						
	Other requirements						

16. Storing the device – ease, requirements and avoiding damage

Devices need to be designed to ensure space saving where possible. Avoiding damage during storage is essential.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
16.1	Device storage is indicated on the device?						
16.2	Device design enables storage close to the point of use?						
16.3	Device can be stored conveniently with components or consumables?						
16.4	Measures ensure parts are not lost during storage?						
16.5	Difficult to damage?						
16.6	Provision to charge the device whilst in storage?						
16.7	Device is protected against drop shock?						
	Other requirements						

17. Disposal and expiry dates – avoiding use of out of date products

Out of date and end of life products need to be easy to identify so that use is avoided.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
17.1	Lifetime clearly indicated?						
17.2	Number of uses indicated?						
17.3	Number of times it has been used is indicated?						
17.4	Expiry date indicated?						
17.5	Expiry date when package open?						
17.6	Safe disposal is possible by all users?						
17.7	Means of safe disposal indicated?						
17.8	Barcode links to e-procurement system/Scan4Safety?						
	Other requirements						

18. Health and safety regulation and standards – risk assessment

Many Regulations require the completion of health and safety risk assessment. The previous Sections may provide detail useful for assessments.

	Performance Requirements	Notes	User profile?	Task/scenario?	Use environment?	Context & organisational factors?	Measures? (time, errors, help)
18.1	Conforms to electrical safety requirements?						
18.2	Conforms to chemical safety requirements?						
18.3	Requires a Manual Handling risk assessment?						
18.4	Require a Display Screen Equipment risk assessment?						
18.5	Device is protected against fluid ingress?						
18.6	Device is protected against electromagnetic and electrostatic fields?						
18.7	Device design avoids sharp edges, finger and pinch traps?						
18.8	Moving parts and entrapment hazards are guarded?						
18.9	Device design protects user from high surface temperatures and or vibrations?						
	Other requirements						