Human Factors in the Design and Operation of Ventilators for Covid-19

Guidance from the Chartered Institute of Ergonomics and Human Factors

Chartered Institute of Ergonomics & Human Factors

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Introduction

The purpose of this document is to provide designers and manufacturers of ventilators with overarching advice and guidance on the key themes for consideration and specific Human Factors and Ergonomic (HFE) issues in a period of "crisis management" requiring **rapid design and production**.

The authors are mindful that some manufacturers may not have design experience of health care or the production of ventilators. Wherever possible we have used plain language and provide illustrative examples of issues to be addressed to **"nudge thinking"** aimed at creating a safe and user-friendly product within the current frontline operating context of hospitals.

This document outlines seven key topics that designers and manufacturers of ventilators should address. Suggestions for how to address these issues and the link to the Covid-19 crisis are identified.

1. User interface
2. Users of ventilators
3. Environment of use
4. Task
5. The Risks
6. Instructions for use
7. Training

An explanation of the discipline of HFE is provided, and a list of relevant standards is included at the end of this guide.

CIEHF has assembled a list of expert advisers with relevant knowledge and practical experience who are able to work directly with designers and manufacturers. These include clinical panels (anaesthetists, ICU nurses and others), researchers and practitioners who can undertake usability testing remotely. Usability protocols are also available.

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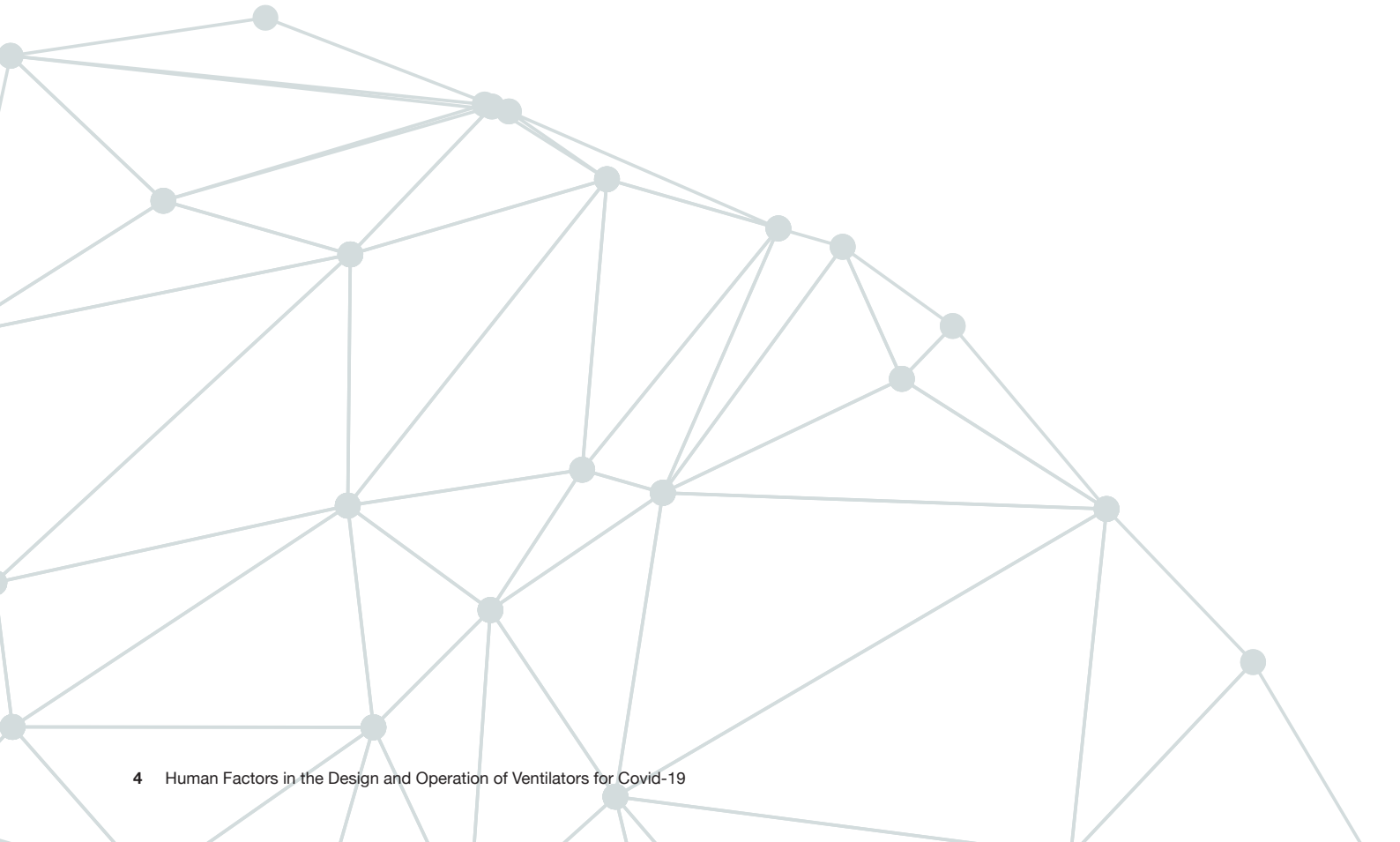
Human Factors and Ergonomics

HFE is a discipline that examines the design of individual work system components (e.g. people and technology) and the interactions with each other, taking into account human capabilities and characteristics, with the goals of **achieving optimum human safety and performance**.

HFE experts are formally trained to design and adapt/reconfigure work systems to maximize individual and team performance under high-risk, high-stakes environments, while minimizing the introduction of new significant safety risks or unintended consequences into the work system. Specialists use various conceptual approaches and methods to identify barriers and enablers to consistent compliance with any guidelines and protocols.

HFE specialists can inform the development of appropriate solutions to support individual and team performance in epidemic and pandemic situations. Some solutions can be highly practical and developed quickly with minimal resources, such as within hours or days (e.g. developing usable signage, checklists and procedures to support distributed or team cognitive work) with input from one or two HFE specialists. Other solutions may take longer and require a larger group of experts. For example, the HFE-informed web-based training development for donning/doffing personal protective equipment (PPE) during the Ebola epidemic took 10 days and required an interdisciplinary team of 40 experts.

In the context of Covid-19, CIEHF specialists are using their collective knowledge to provide designers and manufacturers with guidance for rapid production.



1. User interface

The importance of a good and intuitive user interface cannot be overstated. The user interface includes not only screens but any physical aspect of the device with which the user needs to interact. Good user interfaces can reduce use errors, increase efficiency and contribute to a better user experience (and reduce frustration). The design of the user interface builds on the previous steps, and is not something that should (or could) be left until the end. From the outset it is important to have a clear vision of how different types of users will interact with the device under different operating conditions.

HOW TO DO IT

User interface design and evaluation should be done iteratively and formatively. The design of the user interface is informed by the risk analysis. For example, the user interface might include warnings or alarms for critical steps or in situations that are unsafe. Care needs to be taken when designing alarms as alarm fatigue is a well-documented problem. The manufacturer needs to consult with users about situations that need to be alarmed and how this should take place (e.g. audible alarm), and how it needs to be dealt with. Generally, if a situation does not require a user action, then this should not be designed as an alarm, but instead displayed as an information-only indicator. There are many usability evaluation techniques available. Many of these techniques consist of (a) getting users to interact with the device on specific scenarios, and (b) eliciting their feedback after use through a structured questionnaire or interview. In addition, there are also generic heuristics that can provide indications of interface quality. Examples include consistency of the layout (e.g. consistent colour-coding), informative feedback to users and transparency about device status, and reducing the number of items a user needs to remember.

HOW IT RELATES TO THE COVID-19 CRISIS

We need to assume that the ventilators will be used by both clinicians who have used ventilators before as well as clinicians who might not have much experience with ventilators. Medical technicians will also be required to inspect and maintain devices. Experienced users will come with a set of expectations about how to interact with the ventilator. A radically new design could potentially lead to confusion. It might be useful to aim to make the interface similar to existing devices (unless there are known interface issues).

Designers and manufacturers must consider that users will be wearing personal protective equipment (PPE) while operating the ventilators safely and accurately. This will include wearing eye goggles (in addition to standard spectacles if worn), face shield, plastic apron, surgical gown, and two layers of gloves which are donned in layers and sticky taped onto sleeves of gowns in between layers.

User interface

- **Where possible align new ventilator designs to existing designs to allow rapid learning and reduce use errors.**
- **The user interface should be intuitive and provide informative feedback to users.**
- **Alarms should be included for critical situations where a user response is required.**
- **Alarms should be audible in a noisy critical care environment. Note that different alarm/tones may mean different things to users.**
- **Indication-only feedback can be provided for non-critical situations to avoid alarm fatigue.**
- **Ensure physical connectors work across settings and that they are easily recognisable.**
- **Retractable cables are ideal when being stored or when the ventilator is close to the patient and unnecessary lengths do not spill onto the floor.**
- **If the ventilator is intended to be moved it needs to be lightweight and on a base that allows easy repositioning to avoid musculoskeletal health issues for staff.**
- **Screens and displays should be adjustable for height and take account of glare.**
- **Moving between machines consider the sequencing of readouts for various parameters with similar units, for example respiratory rate or PEEP (as opposed to tidal volume with much higher figures).**
- **Buttons should be far enough apart so that two are not activated inadvertently simultaneously.**

2. Users of ventilators

Different types of users will have different skill sets, come from a range of backgrounds, and might have differing expectations and needs. At the start of the design, user profiles should be created that describe important characteristics and differences between user groups, such as their attitudes and motivations, their experience with the task, and any specific physical characteristics that might be of importance, e.g. colour-blindness and visual impairment.

- The device designer needs to understand the users and their characteristics.

HOW TO DO IT

Pre-existing categories of users can serve as a starting point, e.g. clinicians, nurses, technicians, etc. Interviews with domain experts can provide information about this. Then, interviews with individuals from each category can be carried out to further understand each user group, and to determine whether further differentiation might be necessary and useful.

- Perhaps this research is best undertaken as a single research project for all designers and manufacturers.
- Can firms who have already studied user requirements share the data?

HOW IT APPLIES TO THE COVID-19 CRISIS

Manufacturers of ventilators need to understand who will be using the devices. It has already been suggested that these will not necessarily be a uniform expert user group, but might include other clinicians.

- What assumptions can be made about their professional background and level of experience with ventilators? What care settings are the clinicians from?
- Are there other important user groups that do not provide patient care, e.g. technicians and maintenance staff?

Users of ventilators

- **Ventilators need to be usable by novices as well as experienced users.**
- **Users might not have a critical care background.**
- **Consider non-clinical users such as technicians and maintenance staff.**

3. Environment of use

The device designer needs to consider the social and physical environment within which the device will be used. In this case the environment is a stressful and highly pressurised hospital setting for treating Covid-19 patients. Clinical settings are complex systems, where many people and technologies interact.

- Do not focus on the design of the device in isolation think of the operating context.
- Think about the layout and available space where the device will be used, and ambient lighting, temperature and noise.
- Does the device need to be floor standing, wall mounted or fixed onto a hospital bed?

HOW TO DO IT

Process walks and reviews of the operational environment can provide helpful insights into operational realities. In cases where the operational environment is yet to be designed, detailed conceptual designs can be used. Reviews of existing environments can provide input, but should be accompanied by expert input about differences in the new operational environment.

HOW IT APPLIES TO THE COVID-19 CRISIS

It is anticipated that the new fleet of ventilators will be deployed in a diverse range of repurposed settings, and these are unlikely to be similar to a traditional intensive care setting. How much space will there be for clinicians to operate and walk around the ventilator? Are there designated spaces for the ventilators? Are they assumed to be static or do they need to be mobile? If they are mobile, how can people move them easily and safely within the specific clinical environment?

Environment of use

- **Consider limitations of new operational environments.**
- **Ensure appropriate connectors and power supplies are in place.**
- **Avoid obstacles in areas where ventilators need to be moved.**

4. Task

The device designer needs to scope and articulate clearly the tasks for which the device is going to be used, and how it is going to be used. It is important that this is done based on operational realities faced by sharp- end staff groups (work-as-done) rather than through an abstract view of what should be done in principle (work-as-imagined) as envisaged by designers, healthcare leaders and policy makers.

Typically, a range of operational tasks needs to be considered, such as routine tasks, exceptional or emergency response tasks, and maintenance and inspection and moving tasks. Understanding of the task includes consideration of what specifically needs to be done by what type of user, in what kind of order different task steps need to be done, what kinds of information are required to complete the task, what forms of interactions and communication take place, and what other tasks people might be engaged with at the same time.

- Can the device be used intuitively, defibrillators in public places are a good example?

HOW TO DO IT

Task analysis requires a thorough understanding of the work. Existing procedures and documentation can be helpful to generate a preliminary understanding of the tasks. This needs to be complemented by data elicited from people doing the work. This data may already be available.

HOW IT APPLIES TO THE COVID-19 CRISIS

Existing procedures for ventilator operations can form the starting point. Manufacturers unfamiliar with clinical settings and ventilators in use will benefit from visits to clinical settings where ventilators are used. Task review workshops can be done with expert clinicians and medical technicians outside in an office setting or even remotely (technology-mediated). Is operation of the ventilator going to be the same for every type of user?

Task

- **Consider a range of tasks including normal and abnormal ventilator operation, infection control and maintenance tasks.**
- **Ensure ventilators are easy to clean and to maintain to maximise their availability.**
- **Ventilators that support a narrower range of tasks might require more clinical frontline time if they need to move patients more frequently or need to make more adjustments manually.**

5. The risks

Device manufacturers need to understand the risks that come with the use of devices. This includes consideration of how users might interact with the device in ways that might differ from what is expected or prescribed in the procedure. If there are significant ways in which user interaction with the device can lead to patient harm (or other adverse consequences), then the device manufacturers need to determine whether these can be designed out, whether safeguards can be designed in, and whether there are conditions that affect human performance, which might be improved upon. These latter conditions (or performance shaping factors) include issues such as the physical layout, the usability and quality of the user interface, the clarity of procedures, and the adequacy of training.

HOW TO DO IT

Risk analysis builds on the task analysis. It requires input from people who are doing the task. It is best done in a systematic way where each task step is looked at in turn and is analysed for potential ways in which the task step might fail. To assist the analysis, it can be helpful to consider different types of human behaviour, such as actions, communication, checking, monitoring and selection. The risk analysis can then consider issues such as an action done too late, a check being omitted or the wrong item being selected. For each failure mode, the analyst needs to determine how likely the failure is and what the potential consequences of the failure are. This can be used to build a risk ranking to prioritise critical task steps. For critical task steps, the analyst then needs to consider whether there are engineering solutions that could be adopted, e.g. forcing functions or automatic safeguards.

HOW IT RELATES TO THE COVID-19 CRISIS

Identification of critical task steps in ventilator operation is crucial in order to protect patients. This is particularly relevant as the user population might be less experienced than under normal situations. When a critical task step has been identified, there might be a number of different approaches that could be taken to reduce the risk. For example, can that step be carried out by the inexperienced user with appropriately designed instructions for use or job aids? Is there are an experienced user available that could take over the task for particularly critical steps? Can we provide training to inexperienced users in getting these critical steps right? Clinician workload and stress levels might increase in situations where manufacturers do not introduce design solutions to reduce risk, but rely on people instead.

The risks

- **Learn from past experiences with existing ventilators.**
- **Risks should be designed out where possible or reduced through design solutions.**
- **Have some safeguards for number entry so errors that are dangerous are caught before they reach the patient.**
- **When a critical task step relies on a person it can increase workload and stress levels.**
- **If intended to be used during a transfer, then ability to tolerate some vibration needs to be considered along with potential dropping.**
- **The attachment of nebulisers and humidification into circuits needs to be included in any testing.**

6. Instructions for use

Designing instructions for use can be tricky, because a trade-off needs to be struck between completeness and usability. It is unrealistic to expect users to read a lengthy document during time-critical periods. It is useful to distinguish between different purposes of documentation and then design different types of documentation. The user manual can include a fairly comprehensive description of what a user might need to know, and it could be used for training purposes. A procedure should be a step-by-step description of how to do a task. A job aid can be designed to support specific aspects of the task, for example, a particularly critical step, or a step where calculations need to be done or which are demanding on memory.

HOW TO DO IT

The development of instructions for use should be based on the task analysis. The task analysis breakdown itself can form the basis for the step-by-step procedure. The risk analysis can identify high-risk task steps that require specific attention. These high-risk task steps can be highlighted in the procedure itself, and job aids might be designed as appropriate with the help of users. The level of technical detail should be proportionate to the level of experience of the user and the complexity and risk profile of the task. The layout, presentation and usability of procedures and job aids is as important as the technical detail. Procedures and job aids should be consistent and formulated in a way that is accessible to users.

HOW IT RELATES TO THE COVID-19 CRISIS

There are likely to be fairly novice users who will require clear procedures that alert them to critical task steps without overloading them with detail. The Medicines and Healthcare products Regulatory Agency (MHRA) has suggested that instructions for use should be attached to the ventilator. This might be best achieved by focusing on a job aid for the high-risk task steps rather than attempting to represent a step-by-step procedure. The procedure should include a clear rationale for task steps that might not be intuitive to non-experts or that carry high risks, to enable the users to understand why they are asked to do something in a particular way. Where appropriate, procedures and job aids should reflect existing ventilator operation to lessen training requirements and the potential for confusion of experienced users.

Instructions for use

- **Where possible the user interface should be intuitive and responsive allowing users to understand where they are in the current process of attaching and activating the ventilator.**
- **Procedures should describe the task step-by-step.**
- **High-risk task steps should be clearly marked and a rationale should be provided.**
- **Readout signs and displays need to consider visual impairments and use of PPE that will hinder vision.**
- **The design of a display is more likely to be effective and maintain high performance levels if it is meaningful and usable.**
- **Users should be able to distinguish the text from the background and surrounding materials easily.**
- **The text should be easily understood and in plain language.**
- **Careful consideration has to be given to colour combinations. The choice of foreground and background colours can affect legibility.**
- **The choice of colours should be used consistently from one screen to another.**
- **Appropriate layout of a display will increase the speed with which information is processed and the accuracy of the user's response.**
- **Overcrowding of the screen should be avoided because it takes users longer to process all of the information and they may be more susceptible to making mistakes.**
- **Active rather than passive verbs result in more efficient use of the system.**
- **Design job aids for critical task steps.**

7. Training

Training aims to build competence and confidence. Safety-critical tasks should include both formal training as well as supervised on-the-job training opportunities. Ideally, training and the resulting learning are experiential rather than the simple transfer of knowledge from one person to another. Good design can contribute to reducing training needs, but users will still need to understand the risks associated with a task, the critical steps that are involved, and how to properly interact with the device, especially during abnormal and non-routine situations. Training is minimised through good user design.

HOW TO DO IT

Simulation is an excellent form of delivering work-based training. Relevant clinical and operational scenarios need to be identified. These might include routine tasks, such as basic interaction with the device (e.g. setting up parameters and starting ventilation), critical task steps (e.g. changing ventilation modes), responding to alarms or patient deterioration, and managing device issues or problems (e.g. power failure). Additional scenarios might include maintenance activities. Non-simulation training (e.g. shadowing or online learning) should include explanation of critical task steps and why these are critical.

HOW IT RELATES TO THE COVID-19 CRISIS

With the anticipated mix of users including people with little prior experience in the operation of ventilators, adequate training is absolutely essential. This is not only to ensure patient safety, but also to lessen anxiety and stress of clinicians, and to reduce adverse impact on the wellbeing of the workforce in this critical time. The NHS has simulation centres that might provide facilities for training, but this might not be available to everyone. Training needs to include highlighting to users the critical task steps, and an explanation of the breadth of potential clinical scenarios, including how to respond to alarms, and how to spot potential device problems and malfunctions.

Training

- **Training builds competence and confidence.**
- **Training needs to include normal, high-risk and abnormal scenarios.**
- **Training should deal with staff anxieties about using the equipment.**
- **Simulation can facilitate learning.**
- **Adequate supervision during operation is essential.**

Regulations and Standards

- IEC 62366-01-2015 *Part 1 Medical devices, application of usability engineering*
- *Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff*, CDRH, Feb 2016
- AAMI HE75
- ISO 14971-2019 *Medical devices, application of risk management*
- EC Directive 2001-83-EC *Medicinal products for human use*
- ISO 15223-1-2012 *Medical device symbols*
- ISO 8317-2015 *Child resistant packaging*
- EMA 606103 *Guidance on medical error prevention*
- AAMI TIR49 *Design of training materials*

BSI Ventilator standards include

- BS EN 794-3:1998+A2:2009 *Particular requirements for emergency and transport ventilators*
- ISO 10651-3:1997 *Lung Ventilators for Medical Use - Emergency and Transport*
- BS ISO 80601-2-84:2018 *Medical electrical equipment. Part 2-84. Particular requirements for basic safety and essential performance of emergency and transport ventilators*
- BS ISO 10651-5:2006 *Gas-powered emergency resuscitators*
- BS ISO 19223:2019 *Lung ventilators and related equipment. Vocabulary and semantics*

BSI ventilator standards:
www.bsigroup.com/en-GB/topics/novel-coronavirus-covid-19/ventilators

BSI PPE; Hygiene; Risk Management and business continuity:
www.bsigroup.com/en-GB/topics/novel-coronavirus-covid-19/bsi-knowledge---uk-national-standards-body

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The CIEHF was established in 1949, with a vision to improve life, wellbeing and system performance through integrated design including science, engineering, technology and psychology. The Institute is a founder member of the International Ergonomics Association (IEA) representing over 40 professional bodies across the world.

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