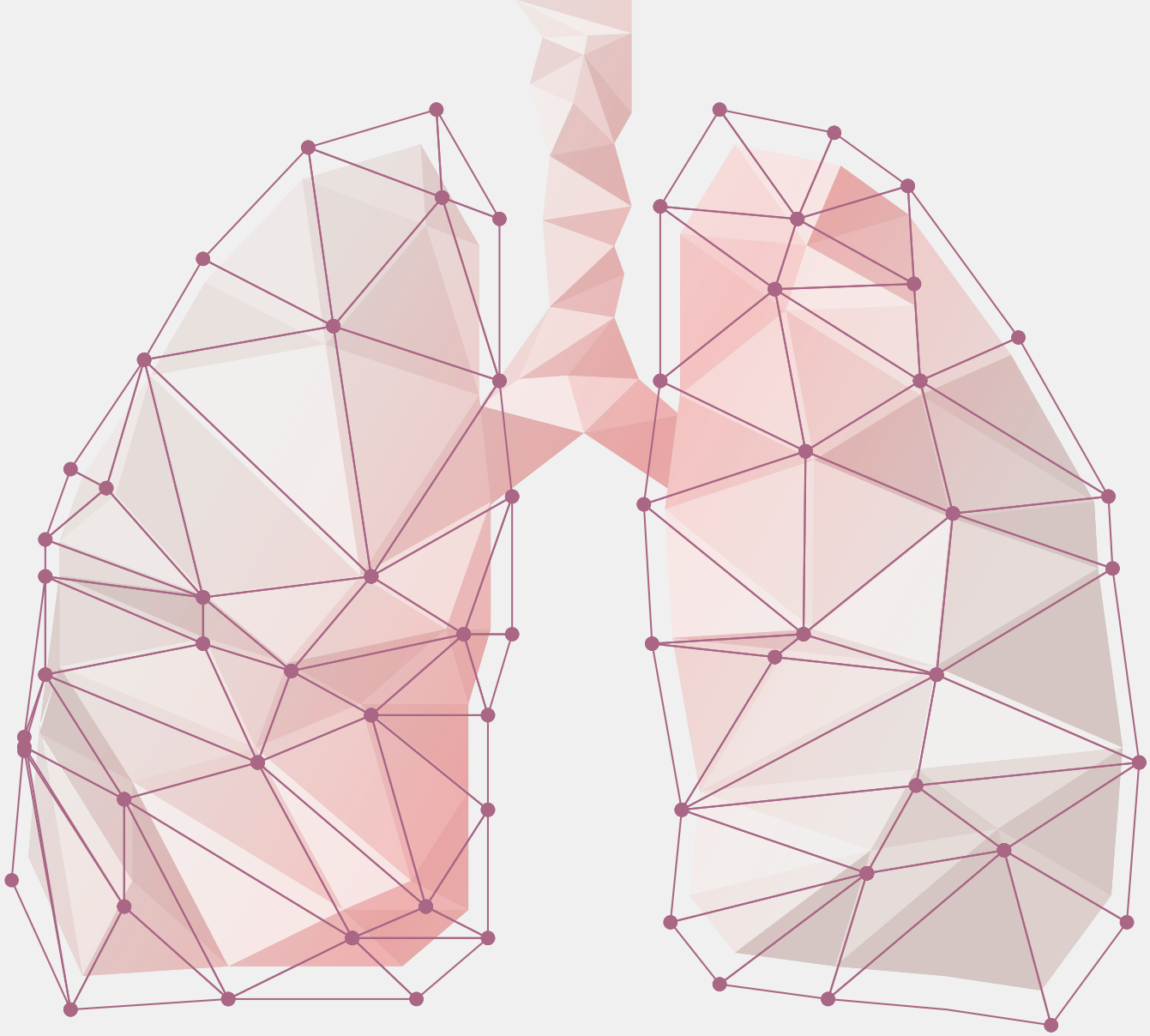

Formative Usability Testing of Rapidly Manufactured Ventilator Systems by Chartered Ergonomist and Human Factors Specialists (C.ErgHF)

Chartered Institute of Ergonomics & Human Factors

Foreword

The Chartered Institute of Ergonomics & Human Factors (CIEHF) received its Royal Charter in 2014 to recognise the uniqueness and value of the scientific discipline and the pre-eminent role of the Institute in representing both the discipline and the profession in the UK. This includes the protected status of "Chartered Ergonomist and Human Factors Specialist" with the post-nominal C.ErgHF awarded to practising Registered Members/Fellows who are among a group of elite professionals working at a world-class level.

The CIEHF is offering a rapid response to assist manufacturers with testing in line with MHRA (2020) specification requirement to ensure that the rapid production and roll out of ventilators does not present unforeseen and potentially catastrophic problems. A rapid and easy to use testing protocol will identify and assist in eliminating many of these issues.

The usual Formative Usability Testing could use a range of Human Factors/Ergonomics (HFE) methods (MHRA, 2017) but with the speed of testing required for COVID-19 we propose to use the following protocol with an **Expert Professional Panel of Clinicians, Medical Technicians and C.ErgHF.**

The CIEHF is committed to ensuring that the rapid design of ventilators contributes to saving lives and that all possible human errors are designed out by utilising expert assistance.

Dr Noorzaman Rashid
Chief Executive
Chartered Institute of Ergonomics and Human Factors

This document is intended to be used by C.ErgHF when providing advice and support for rapidly manufactured ventilator systems (RMVS).

Contents

Planning Usability Testing

The following protocol should be used to support the planning and delivery of usability testing so that the scope, timing and design of Human Factors/Ergonomics activities deliver the required benefits.

- Secure the services of a C.ErgHF qualified specialist to plan and conduct the testing.
- Plan the design and development process so that usability testing informs iterative product development.
- Specify the aims and objectives of the test.
- Describe the product (i.e. ventilator model and core functionality) being tested.
- Specify the context in which the ventilator will be used.
- Define the characteristics of the usability test participants required (how many, what clinical expertise, familiarity with existing ventilators, etc.).
- Use the CIEHF usability protocol (this document) to tailor the approach required.
- Conduct the test in representative clinical conditions (including online panel).
- Discuss the findings with multidisciplinary representatives in order to prioritise the issues to be addressed.
- Design and develop technical solutions to resolve the issues identified. Do this before considering less effective measures (such as documentation and training).
- Repeat the process as required.
- **Seek further support and advice from the CIEHF; please email: noorzaman.rashid@ergonomics.org.uk**

Scope of Usability Testing for an Adult Ventilator

The intended scope for the testing includes:

Tasks[iii]:

- Frequently occurring tasks
- Safety critical tasks
  - These may not be as frequent, but an error could be fatal
  - Consideration of different patient presentations where using the wrong mode or setting (e.g. pressure setting) could be fatal
- Tasks where novice users are most likely to make mistakes
- Tasks where user errors are known to be common
- Transporting tasks
  - Within the hospital
  - Between hospitals - interference from movement - less sophisticated ventilators need to stand up to the extra noise/vibration.

Critical incidents, e.g.:

- How easy it is to identify oxygen failure or falling supply (which may become an issue with increased demand)
- How easy it is to quickly find the information you need on the ventilator screen whilst using full PPE and double gloving and other critical moments such as disconnection of patient, high airway pressure alarms
- Managing the patient 'fighting the ventilator' by adjusting settings.

Location and/or context of use, e.g.:

- Intensive Care Units (ICU), High Dependency Units (HDU), COVID-19 wards, Emergency Departments, repurposed operating theatres, field hospitals, possibly also in community settings
- Different aspects of operational issues, e.g.:
  - exceptionally noisy / busy environment
  - moving the machines about quickly
  - absence of standardised connectors or locations for connectors / leads
  - change in lighting, different (less) space allocation
  - different and/or unfamiliar positioning / orientation.

Staff

Before any non-specialist clinical user operates a ventilator, they must have training by a skilled and experienced ventilator user, this may only be 15 - 20 minutes of instruction and practice. They should then be supervised by more experienced consultant clinicians ('Super Users').

Formative Usability Test Protocol

It is expected that the user testing (focus group) discussion would include the following general testing steps:

1. Introduction: to provide an explanation of the study, gain informed consent, undertake Non-Disclosure Agreement (NDA) signing, and provide a briefing on how the study will be undertaken.

2. Initial impressions (optional): to give users a chance to briefly talk about:
   a. What they think about the ventilator system without interacting with it
   b. What they think it looks like
   c. Whether there is anything they don't like or didn't expect.

3. Simulated use (task scenario walk-through): to provide end users with an opportunity to either undertake simulated tasks (walk-through) or to talk-through as a focus group discussion. The discussion will typically follow the pathway a patient would go through with regard to their individual requirement for ventilator use, starting from admission and initial testing of the ventilator, initiation of mechanical ventilation, mandatory modes (likely to be used in the initial phase), switching to spontaneous/triggered modes, monitoring and then managing the weaning process.

4. Feedback from users: ideally through discussion including the logging of errors/risks and probing of any error potential.

5. Overall 'user evaluation': via a rating questionnaire and subjective comments on a user's willingness to adopt the product compared to products currently/previously used.

6. Summary and close: to provide opportunity for further comments, thank users for their participation and close the testing session.

Task scenario

This scenario depicts a combined set of patient pathways to test the ventilator across a range of circumstances that would be unlikely to occur in an individual patient experience.

Tasks	Participants N= Nurse, D = Doctor	Detailed sub-tasks	Equipment/ keys/ knobs/ dials/ screen etc.
Ventilator set up and check prior to receiving patient			
Assemble circuit	N1+D1	Check for integrity of valves / diaphragms etc.	Ventilator Test equipment (e.g. test lung, flow sensor calibration equipment) Power supply
Install circuit onto ventilator		Connect to test simulator (test lung) and perform self-test	
Set up ventilator to patient specific parameters		Choose mandatory mode, set Inspiratory pressure or tidal volume (IBW based) according to mode. Respiratory rate, I:E ratio (if adjustable) FiO_2 and PEEP	
Check alarms (disconnect, high pressure, apnoea, volume alarms, O_2 supply and battery level). Change alarm parameters.		Disconnect, high pressure, apnoea, volume alarms, O_2 supply and battery level. Change alarm parameters.	
Perform leak test and test patency of circuit with all parts attached (incl. filters)			
Check integrity and function of flow sensors, Oxygen calibration			
Initiation of mechanical ventilation and adjust to initial parameters			
Intubation of patient, attach to ventilator, initiating and confirming safe ventilation	*N1 + D1 + D2 + runner*	*Complex process, separate evaluation, outside of scope of this evaluation*	Airway trolley Ventilator Monitor Sim Man/lung
Initiate ventilation and confirm safe delivery of set ventilator parameters	N1 or D1	Assess tidal volume, peak/ plateau airway pressure, PEEP, FiO_2, respiratory rate as displayed by ventilator	
Adjust respiratory rate and I:E ratio (if adjustable)	N1 or D1		
Rapidly increase or decrease FiO_2	N1		
OPTIONAL (not in MHRA specification, 2020) Identify level of intrinsic PEEP (gas trapping)	*N1 or D1*		
Optimise PEEP	N1 or D1	Sequential adjustments to improve oxygenation and titrate to compliance	

Task scenario

Tasks	Participants N= Nurse, D = Doctor	Detailed sub-tasks	Equipment/ keys/ knobs/ dials/ screen etc.
React to sudden change in status and alarms			
Respond to low supply pressure alarm		Evaluate integrity of supply pressure, look for disconnection	
Respond to high airway pressure alarm		Systematic evaluation from patient to ventilator	Monitor Ventilator Sim Man/lung
Respond to low airway pressure alarm (circuit or patient disconnection)		Systematic evaluation from patient to ventilator looking for leaks or disconnections	
Rapidly adjust FiO_2 in response to desaturation or enable suction		Single button (O_2 flush) or complex step involving adjustment of FiO_2	
Respond to volume alarms		High Vt or low Vt or MV	
Respond to apnoea alarm		Ensure backup mode initiates	
Respond to low battery or power disconnection		Identify source of power	
OPTIONAL (only single mandatory mode in MHRA 2020 specification) Changing modes of ventilation			
Switch from mandatory mode to spontaneous/triggered mode and adjust flow trigger and apnoea time		*May require multiple adjustments titrated to patient*	*Monitor* *Ventilator* *Sim Man/lung*
Switch from volume control to pressure control			
Initiate spontaneous mode with pressure support and PEEP and adjust to patient parameters as tidal volumes and respiratory rates change. Confirm backup/ apnoea ventilation enabled.			

Patient Profiles

The following patient profiles are provided to outline common issues and patient presentations.

Patient 1:

Patient: 44 years old, well controlled asthmatic admitted with increased breathlessness and confirmed as COVID-19.

Apart from mild obstructive sleep apnea and a BMI of 35, she has no significant co-morbidities. Despite High Flow Nasal Oxygen her condition deteriorates and eventually requires intubation.

Task: Intubate in a side room of ward; Transfer to ITU ventilator on ICU – changing between ventilator types; Suction ETT secretions using closed suctioning system; Change of HME filter in patient-ventilator circuit.

Equipment to be used: patient bed, transfer ventilator and circuit, ICU ventilator and circuit, intubated patient, arterial blood gases, monitoring including $ETCO_2$ trace, inline suction.

Patient 2:

Patient: 62 years old male, COVID-19 positive, assessed by ICU consultant as deteriorating and tiring. Decision has been made to transfer to ICU for intubation and ventilation and ICU care. SOP requires transfer in full PPE and intubation and stabilisation in a dedicated area on ICU before transfer to bed space.

Task: Set up ventilator, intubate patient and re-programme ventilator based on feedback once patient ventilated (e.g., changing respiratory rate, tidal volumes, PEEP according to values on ventilator, $ETCO_2$ trace, oxygen saturations and arterial blood gases).

Equipment to be used: patient bed, transfer monitor, ventilator under test and tubing, arterial and CVP transducer sets, intubation equipment including face mask, airway adjuncts, video laryngoscope, bougie, range of ETT sizes, $ETCO_2$ monitoring, tube ties, HME filter, waters' circuit, airway rescue trolley, NG tube, drip stand, full PPE for aerosol generating procedures, intubation drugs.

Patient Profiles

Patient 3:

Patient: Female patient 42 years old, day 10 on ventilator, making good progress and ready for trial of CPAP with pressure support, however, does still have apnoeic episodes.

Task: Change ventilation mode from mandatory mode to CPAP with pressure support. Managing finding the right CPAP and pressure support, which is comfortable for patient, gives adequate gas exchange and does not lead to tiring. Also, should ensure that backup settings are set to manage periods of apnoea.

Equipment to be used: patient bed, ventilator and tubing, intubated patient, arterial blood gases, monitoring including $ETCO_2$ trace.

Patient 4: OPTIONAL Non invasive ventilation.
Note – this is not part of the MHRA (2020) specification

Patient: Male patient, 55 years old with respiratory failure. Requires escalation from face mask oxygen to non-invasive ventilation.

Task: Set up non-invasive ventilator circuit, test for integrity and evaluate the adjust default settings. Activate standby until patient arrives. Fit mask to patient and check for leaks and adjust as necessary, manage changes as patient deteriorates with falling tidal volumes, increased respiratory rate, then re-programme machine in preparation to switch to invasive ventilation**.**

Equipment to be used: patient bed, NIV face mask and circuit, ventilator, patient, arterial blood gases, monitoring.

Test measures

For each task / test scenario, the following criteria should be used to define the success or failure of the end user to complete the task / task stages:

- Task stages and completion: pass/fail parameters
- Errors/difficulties to use as prompts during the walk-through task scenario
- User evaluation
- Reporting Usability issues.

Task stages and completion: pass/fail parameters

Outcome	Abbr.
Success (pass)	S
Alternate Success (not in line with IFU but no risk)	AS
Success with Observed Difficulty	SOD
Close Call (error occurred but was recovered)	CC
User Error (user does not complete task as per IFU) Fail	UE
Not Applicable (blocked by a previous task)	NA
Device Failure	DF

Test measures

Errors/difficulties to use as prompts during the walk-through task scenario

Different errors and difficulties will be emergent during testing for different ventilators. The following list is based on previous research (Jiang et al, 2018; Marjanovic & L'Her, 2016; Morita et al., 2016; Templier et al., 2007) and may provide suitable prompts for potential difficulties and errors for the ventilator(s) being tested. Further prompts gathered during forthcoming tests will be collated by CIEHF and circulated to all C.ErgHF qualified specialists using this protocol.

Type of Error	Error detail
Failure to set up correctly	Ability to use despite failure to pass self-test (e.g. Hamilton T1 can still be used despite failure of flow sensor calibration) Ability of novice to set up ventilator circuit according to on-screen instructions Inter-changeability of circuit with other types of ventilator circuitry (look similar)
Failure to find a setting site or display site	Difficulty with indirect adjustment of a requested setting, e.g. high error rate in adjusting the inspiratory flow on the Oxylog 3000 Difficulty manipulating multiple controls of different types, e.g. location of power switch (prefer on right side), not hidden behind sliding cover Difficulty making basic adjustments, similar to simple pneumatic ventilators (tidal volume, respiratory rate, maximum inspiratory pressure, and FIO_2) – due to indirect access. Critical in emergencies Confusion and error for the new or occasional user when adjusting for advanced parameters as manipulation of different types of controls is often necessary to visualise or confirm a given parameter
Setting site identified correctly but inappro-priate setting	Illogical default settings, not necessarily immediately obvious to user (e.g. Inspiratory pause on some ventilators too short) Errors in adjusting the inspiratory trigger Clear indication on the controls of the trigger sensitivity (e.g, from "very sensitive" to "least sensitive") might reduce this type of error, or a warning message to check trigger when changing modes Changing one parameter leads to change in other parameter which is not immediately recognised (e.g. Change RR will change I:E ratio by default, this may need further menu steps to change to previous I:E ratio)
Failure to confirm the settings.	Does the use of PPE (double gloving) affect the response of the touchpad? Is the display legible (size, colour and type of font)?

Test measures

Errors/difficulties to use as prompts during the walk-through task scenario

Type of Error	Error detail
Errors of interpretation	Ease of reading/interpreting display Screen size, resolution, information design and mode presentation (thresholds, config, default values, etc.)
Errors of cleaning	Ease of cleaning both during patient use and between patients; nooks and trim, etc. should be minimal; smooth and easy to wipe down Ease of preparation for next patient Ease / accuracy of reassembly if disassembled during the cleaning Errors (and risks) associated with poor cleaning or failure to replace contaminated parts
Errors of maintenance	Consider: - training/qualifications of technical support staff - basics that less skilled technicians can do to reduce workload - errors that could be introduced by non-clinical staff - common failures and failure modes - maintenance/calibration log for specific machine

Test measures

User evaluation questionnaire

This questionnaire provides a template for gathering the required feedback from end users. Complete as appropriate for the task stage under evaluation.

Some questions will not apply to all parts of the task scenario, please move to the next relevant question.

Please indicate the rating that best represents your opinion from: Strongly Agree (5) to Strongly Disagree (1). N/A Not Applicable

Strongly Agree (5) – Agree (4) - Neutral (3) - Disagree (2) - Strongly Disagree (1)							Comments / Issues
General appearance and transportation	**5**	**4**	**3**	**2**	**1**	**N/A**	
1. The ventilator system is too large and heavy to transport easily							
2. The ventilator is very fragile and can be damaged during transportation							
3. It is very easy to transport (handles, wheels, manoeuvrability etc.)							
4. It is very easy to use the ventilator system during stretcher use							
5. It is very easy to determine battery charge							
6. It is very easy to set up the circuit							

Test measures

User evaluation questionnaire

Please indicate the rating that best represents your opinion from Strongly Agree (5) to Strongly Disagree (1). N/A Not Applicable

Strongly Agree (5) – Agree (4) - Neutral (3) - Disagree (2) - Strongly Disagree (1)							Comments / Issues
Starting up and adjusting the settings	**5**	**4**	**3**	**2**	**1**	**N/A**	
7. It is very easy to set the mandatory mode							
8. It is very easy to set mandatory mode inspiratory phase (volume or pressure)							
9. It is very easy to switch from mandatory mode to spontaneous mode (e.g. PSV with PEEP)							
10. It is very easy to set the PSV with PEEP mode and apnea ventilation							
11. The time taken to set up and programme the ventilator system was reasonable							

Test measures

User evaluation questionnaire

Please indicate the rating that best represents your opinion from Strongly Agree (5) to Strongly Disagree (1). N/A Not Applicable

Strongly Agree (5) – Agree (4) - Neutral (3) - Disagree (2) - Strongly Disagree (1)							Comments / Issues
Alarms	**5**	**4**	**3**	**2**	**1**	**N/A**	
12. It is very easy to identify pre-set alarm ranges							
13. It is very easy to modify an alarm range							
14. It is very easy to identify the alarm(s), e.g. audio, visual alarms							
15. The automatic alarms are very useful							
16. It is very easy to cancel / reduce alarm sound							
17. The error messages are meaningful							

Test measures

User evaluation questionnaire

Please indicate the rating that best represents your opinion from Strongly Agree (5) to Strongly Disagree (1). N/A Not Applicable

Strongly Agree (5) – Agree (4) - Neutral (3) - Disagree (2) - Strongly Disagree (1)							Comments / Issues
Interface	**5**	**4**	**3**	**2**	**1**	**N/A**	
18. The overall interface (screen, knobs, dials) is very easy to use							
19. It is very easy to read/ interpret the display from a distance							
20. The plots are very useful							
21. It is very easy to identify patient parameters							
22. I think that I would need the support of a technical person to be able to use this system							
23. I found the various functions in this system were well integrated							
24. There are an acceptable number of menus to navigate to find what you need easily							

Test Results

User evaluation questionnaire

Please indicate the rating that best represents your opinion from Strongly Agree (5) to Strongly Disagree (1). N/A Not Applicable

Strongly Agree (5) – Agree (4) - Neutral (3) - Disagree (2) - Strongly Disagree (1)							Comments / Issues
Instructions for use and job aids	**5**	**4**	**3**	**2**	**1**	**N/A**	
25. The instructions for use are very legible and clear							
26. It is very easy to identify critical steps and required actions							
27. It is very clear what I should do if the ventilator fails							
28.I would imagine that most people would learn to use this system very quickly							
29. It is very easy to learn how to use the ventilator system without a manual (instructions for use)							

Test measures

User evaluation questionnaire

Please indicate the rating that best represents your opinion from Strongly Agree (5) to Strongly Disagree (1). N/A Not Applicable

Strongly Agree (5) – Agree (4) - Neutral (3) - Disagree (2) - Strongly Disagree (1)							Comments / Issues
Overall feedback	**5**	**4**	**3**	**2**	**1**	**N/A**	
30. I thought the system was very easy to use							
31.I think that I would like to use this system frequently							
32. I found the system unnecessarily complex							
33.I thought there was too much inconsistency in this system							
34. I felt very confident using the system							
35. I will need to learn a lot of things before I could get going with this system							
36. The number of steps required to programme the ventilator system was acceptable							
37. This ventilator system will be very safe to use on a patient							
What 3 things would be a priority to change in the design?	**1.** **2.** **3.**						

Test Results

Managing usability issues

Usability issues (that have been captured during the test process) should be assimilated during a wrap-up discussion in which feedback must be recorded and prioritised. The use of a structured issue recording format (see form below) will assist the ventilator design and development team with prioritisation and solution design. Please note that the efficiency, effectiveness and satisfaction of the design solutions will be increased through the collaborative activities of a multidisciplinary team. As such, system designers should observe usability testing and C.ErgHF should review issue mitigations and design options.

Issue ID	System Function	Issue Description	Recommendation	Priority	Status
Unique ref	*Part of the system*	*Description of the problem*	*Description of the agreed design solution*	*High, medium or low*	*Open, closed or rejected*
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

Glossary (from MHRA, 2020)

ARDS – Acute Respiratory Distress Syndrome: a life-threatening form of respiratory failure where the lungs become severely inflamed due to an infection or injury and can't provide the body's vital organs with enough oxygen.

SIMV-PC – Synchronized Intermittent Mandatory Ventilation – Pressure Controlled: a mode of ventilation where the patient is allowed to take spontaneous breaths, the machine will assist the patients breathing when a spontaneous breath is taken. If the patient does not make a pre-set number of breaths a minute (i.e. 10) the machine provides mechanical ventilation to provide the set number.

CMV – Continuous Mandatory Ventilation

PCV – Pressure Controlled Ventilation

VCV – Volume Controlled Ventilation

PRVC – Pressure Regulated Volume Controlled: A mode of ventilation where a set tidal volume is delivered to the patient while maintain the lowest pressure possible in the airway, to avoid trauma.

CPAP: Continuous Positive Airway Pressure a non-invasive ventilation mode that provides a constant steady pressure to keep the lungs expanded

BIPAP – Bilevel Positive Airway Pressure: a non-invasive ventilation mode that provides different levels of pressure when the patient inhales and exhales.

IPPV – Intermittent Positive Pressure Ventilation: a mandatory invasive ventilation mode used to replace a patient's breathing when they cannot breathe for themselves. Can be either volume controlled or pressure controlled. It does not synchronise any patient breathing efforts.

PEEP – Positive End-Expiratory Pressure: The lower pressure applied to the patient's airway to allow them to breathe out, but not too much.

EPAP – Expiratory Positive Airway Pressure: Similar to PEEP, pressure applied to the airway on patient expiration to prevent collapse of the airway.

HMEF – Heat and Moisture Exchange Filter: device fitted to the patient end of the breathing system, contains hydrophobic medium that absorbs heat and moisture from the patients exhaled breath and uses absorbed moisture to humidify inhaled gases. Can also filter bacteria and viruses, this will be used on all patients. WARNING can affect delivered pressure.

RF – Radio Frequency: Many medical devices are sensitive to RF interference. Care should be taken to ensure that this is kept to a minimum.

EM – Electro Magnetic Emissions: Many medical devices are sensitive to EM interference. Care should be taken to ensure that this is kept to a minimum.

$Fi0_2$ – Fraction of inspired oxygen: concentration of oxygen in the gas mixture that the patient inhales

AGSS – Anaesthetic gas scavenging system: where anaesthetic agents have been included in the gas mixture, this system is used to collect and remove exhaled gas to avoid exposure to health

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