The University of Birmingham

Innovative Human Interfaces for Simulation-Based Hospital Rehabilitation

by

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Abstract

The research detailed within this thesis focuses on the idea of rehabilitation within the context of an Intensive Care Unit (ICU), within two major inner city hospitals. The research has been both human (patient)-centred and stakeholder-led from the outset involving clinical and nursing specialists, patients (both current and former), and advisors from the Queen Elizabeth Hospital Birmingham (QEHB). The body of work looks at the rehabilitative practices for incentive spirometry (IS) and intensive care acquired weakness (ICW-AW), and investigates two areas, i) The ergonomic and environmental challenges associated with the design, construction, and introduction of two iterative prototype technology solutions (closely adhering to the ISO 9241-2010 standard) within the restrictive confines of an ICU bed-space. Prototypes that are capable of acting as a conduit to deliver virtual reality gameplay to either compliment or replace existing medical equipment/practices. ii) The usability of the prototypes within the ICU bed-space, by means of patient/staff feedback, and also by observational studies in the form of a link analysis to explore if the introduction of the prototype posed any hazards to both the operational environment and to patient/staff safety.

The final part of the thesis looks at an often overlooked aspect of research, the legacy and the redeployment of the prototypes into other hospital ICUs.

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To Jacklyn, wives are supposed to be annoying? mine is, she calls it motivation which I guess in hindsight was!!

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I would like to add just one final name….

During this whole academic journey, from undergraduate all the way to Ph.D., nothing has ever touched my soul more than this one particular moment, the moment in question is mentioned in the final chapter of this thesis, and it made me realise that when you do something that is used in the real world by real people and you see a moment of joy in a person's face despite all the pain and suffering they are experiencing, it is the most humbling feeling. This thesis is dedicated to the memory of Nick Richards.

List of Abbreviations

3D	Three-Dimensional
BHH	Birmingham Heartlands Hospital
BVF	Bacterial/Viral Filter
CAM-ICU	Confusion Assessment Method for the ICU
CE	Conformite´ Europe´enne
COTS	Consumer Off The Shelf
CREST	Clinical Research Tool
CRT	Continuous Rotational Therapy
CVVH	Continuous Veno-Venous Hemofiltration
EU	European Union
GI	Gastrointestinal
GPU	Graphics Processing Unit
HF	Human Factors
ICU	Intensive Care Unit
ICU-AW	Intensive Care Unit - Acquired Weakness
IED	Improvised Exploding Device
IS	Incentive Spirometry
ISO	International Organisation for Standardization
MHRA	Medicine and Healthcare Regulatory Agency
Mi-Fi	Cellular wireless router
MOF	Multi Organ Failure
N3	NHS Network
NHS	National Health Service
OOHCA	Out of hospital cardiac arrest
PPC	Post-operative pulmonary complications
QEHB	Queen Elizabeth Hospital Birmingham
RASS	Richmond Agitation Sedation Scale
RCSQ	Richard Campbell Sleep Questionnaire
REC	Research Ethics Committee
REVERE	Restorative Virtual Environments for Rehabilitation
SD	Standard Deviation
SOB	Shortness of breath
SRMRC	Surgical Reconstruction and Microbiology Research Centre
SUS	System Usability Scale
USB	Universal Serial Bus
VR	Virtual Reality
VR-I Module	Virtual Reality-Interaction Module

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1.0 Introduction



Figure 1.0: The Queen Elizabeth Hospital Birmingham (QEHB)

http://news.bbc.co.uk/media/images/48017000/jpg/_48017021_aerial1-march2010.jpg

The following body of work investigates the ergonomic, environmental, and regulatory challenges associated with the design, construction, and introduction of prototype consumer-off-the-shelf (COTS) technologies, to facilitate with the rehabilitation of vulnerable patients within the confines of an Intensive Care Unit (ICU) at two busy inner-city hospitals, the Queen Elizabeth Hospital Birmingham (QEHB) (Figure 1.0), and the Birmingham Heartlands Hospital.

The catalyst for the forthcoming research arose from work conducted by Shingari, (2015) who explored the idea of introducing a prototype Virtual Reality Interaction (VR-I) Module for use within a military designated ward within the Queen Elizabeth Hospital Birmingham. Research focused specifically on returning service personnel from front line duty in Afghanistan/Iraq who had sustained injuries ranging from gunshot to blast IED (improvised exploding device) damage. The VR-I Module prototype was designed to provide an easily re-deployable platform from which to conduct both interface and system usability evaluations at the patients' bedside.

At that stage, the VR-I Module required no design constraints with regards its size, as its intended use was at the foot of a NHS issue bed positioned within a spacious side room or sizeable multi-occupancy ward. Due to the de-escalation of military operations in 2014, there followed a sharp and thankful reduction in patient numbers, to which permission was granted by the medical stakeholders to switch focus from a military to a civilian cohort where attention focused on the hospital's intensive care unit (Figure 1.1). It was at that milestone in the research that a prototype device created for use in one medical environmental context had limitations when deployed in another. Despite a revised VR-I Module-V2 prototype being created solely for use within the ICU, and which debuted as part of the Restorative Virtual Environments for Rehabilitation (REVERE) Sleep study (Chapter 3), found that the usability of the VR-I Module-V2 was still compromised due to the unforeseen change in circumstances.



Figure 1.1: A typical ICU bed-space within the Queen Elizabeth Hospital Birmingham

The research herein remains firmly within confines of the ICU and sets out to examine how the VR-I Module-V2 performed during the REVERE-Sleep study from an ergonomic / usability perspective, and how conclusions led to an iteration of the Human-centred design for interactive systems process (Chapter 5.1, Figure 5.1) resulting in the creation of two new

prototypes to aid with respiratory and physical lower limb rehabilitation of post-operative critically ill patients. In addition, strict attention was paid to the ISO 9241-210:2010 standard (Iso.org, 2010) to provide an iterative system of design and review that ensured that at each stage of the design process both stakeholders and end users (patients, both former and current) were consulted, be that from a focus group (Chapter 5), to patient and care professional feedback (Chapter 4.5) to ensure that both hardware and software components within subsequent new prototypes could enhance human-system interaction and integrate with greater effectiveness within such a confined operational environment.

1.1 Patient Types

1.1.1 Upper (GI) Gastrointestinal

The research concentrated on the post-operative ICU patient and explored two rehabilitative contexts, firstly the patient who underwent major upper (GI) gastrointestinal surgery (Sussexsurgical.co.uk, 2017) which consisted of the oesophagus, stomach and duodenum (Figure 1.2), in particular oesophagectomy (the removal of part or the whole oesophagus) (Cancerresearchuk.org, 2018) or total gastrectomy (complete removal of the stomach) (Nhs.uk, 2017).

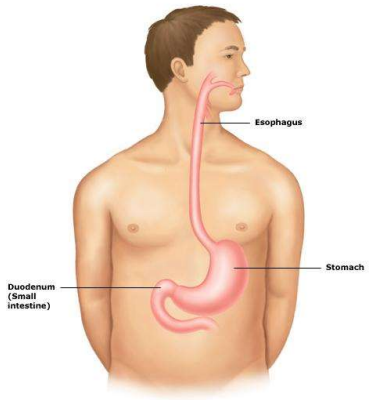


Figure 1.2: The upper gastrointestinal tract

http://www.thegiguy.com/procedures

Upper abdominal surgical procedures are associated with a greater risk of postoperative pulmonary complications. Previous studies have indicated that between 17% and 88% of patients having surgery will suffer complications relating to their lungs and that lung volume tends to fall post-operatively (do Nascimento Junior et al., 2014). Breathing after ventilated surgery or prolonged periods of bed rest can lead to the build-up of fluid and mucus (WebMD, 2017) in the lungs mainly due to the ability to only take small, shallow breaths, in an attempt to reduce the severity of these complications, post-operative care patients are encouraged to use treatments designed to encourage breathing (inspiration). Patients undertake a series of slow deep breathing exercises, termed incentive spirometry (Restrepo et al., 2011, Agostini and Singh, 2009) at regular intervals during their early recovery phase in an attempt to increase lung volume. Incentive spirometry is an intervention prescribed routinely in cases of major upper gastrointestinal surgery and aims to reduce post-operative pulmonary complications (PPCs) (Palmer, 1955; Canet and Mazo, 2010), such as pneumonia and prolonged mechanical ventilation which is a key source of morbidity and mortality (Rock et al., 2003).

1.1.2 Intensive Care Acquired Weakness (ICU-AW)

The second rehabilitative context concentrated on Intensive Care Acquired Weakness (ICU-AW) where a strong correlation exists between weakness and long-term ventilator dependence. Traditionally, the notion of a "period in bed for the treatment of illness" or bed rest is beneficial, with 6-9 hours of sleep a necessity to facilitate repair and recuperation, although little evidence suggests that prolonged periods (in excess of 24-48 hours) of bed rest provides any benefits (Brower, 2009; Slutsky, 2010).

ICU-AW is a major factor in patient outcomes after surviving acute respiratory failure and may be present for months, or indefinitely, during the rehabilitation phase of critical illness (Griffiths and Hall, 2010). It affects nearly all patients after a stay of more than seven days' in

an intensive care unit, patients will be immobile for extended periods of time, leading to pressure sores, thromboembolism, disuse atrophy and depression (Dyer, Barrow and Coakley, 2009). A study of patients by Herridge et al., 2011, suggested that patients who spent greater than 28 days in ICU reported continued levels of severe weakness following discharge, and still exhibited abnormalities after year five. Sacanella et al., 2011 saw a significant reduction in functional status in elderly survivors who presented with normal functional status during admission, yet functional capacity had not returned to bassline one year after discharge.

1.1.3 Sleep

Sleep disruption is a common problem for patients on ICU. It is characterised by disruptions of sleep architecture and circadian rhythms, its causation is likely to be multi-factorial combination of the consequences of critical illness, sedation and the ICU environment itself. During the recovery phase from critical illness while in the ICU, reductions in sleep duration and quality resulting in pathological or atypical sleep are exacerbated by environmental 'assaults' on the conscious patients (Tse et al., 2002; Gazendam et al., 2013; Gehlbach et al., 2012; Bijwadia and Ejaz, 2009). Pathological, atypical, sleep is recognised by the combination of sleep fragmentation with decreased periods of rapid eye movement (REM) and slow wave sleep (SWS) (Meriläinen et al., 2010; Bourne et al., 2007). Sleep is an essential physiological process and sleep deprivation impairs processes such as immune function and wound healing (Honkus, 2003; Cuesta and Singer, 2012; Fontaine et al., 2001; Mantz et al., 2010; Tracy and Chlan, 2011). Poor sleep may delay successful weaning from mechanical ventilation (Roche-Campo et al., 2013; Perren and Brochard, 2013). Whilst poor sleep quality has been associated with increased mortality and adverse outcomes within critical care, the causative role of this is unclear (Kamdar et al., 2013; Parthasarathy et al., 2010). Indeed, sleep disruption and delirium

may simply have the same underlying neurobiological cause and co-exist as symptoms of the same pathological process (Chellappa et al., 2013; Watson et al., 2012).

1.1.4 Medical Ergonomics

To ensure maximum compliance, medical devices are subject to highly stringent regulations whereby medical devices are divided into specific classes. It is those classes that are identified by the different regulatory bodies according to the potential risk that may occur during the devices usage. One of the most important regulations for a developer to consider is the EC Medical Device Directive 93/94/EEC, it is this set of regulations that with compliance allows for the device to obtain CE marking and indicate to governmental officials that the product may be legally placed on the market. The whole premise of medical device regulation is risk management, developers must work to eliminate, or reduce as far as possible, the risk associated with their device and where appropriate take adequate protection measures, to ensure that the device does not compromise either the clinical condition of the patient nor the health and safety of care professionals (Medical Device Directive 93/42/EEC).

1.2 Contribution of VR to rehabilitation

Computer-generated, three-dimensional “virtual” worlds have existed in the fields of gaming and, education and simulation for decades. Computer hardware such as motion-tracking head mounted displays and noise-cancelling headphones allows immersion in, and interaction with, an artificially generated “virtual” environment. This type of interactive technology, synonymous with computer gaming, virtual reality and “serious” games has been exploiting in a number of clinical fields. Explorations include modification of patient perception, performance feedback, education and assessment. Rapid progress, driven by the commercial sector, is presenting opportunities for exploration of increasing high-tech, yet relatively low-cost solutions for a plethora of healthcare related issues. Patients recovering from critical illness

and injury have complex care needs and many suffer adverse long-term outcomes related to their treatment and recovery, particularly associated with their perception of their environment. Virtual Reality (VR) provides an opportunity to bring the complexity of the physical world into a controlled environment such as an ICU. VR also allows precise control over a number of physical variables that influence behaviour whilst recording physiological and kinematic responses (Carrozzo and Lacquaniti, 1998). There are numerous strengths underlying the use of VR with rehabilitation (Rizzo et al., 2004; Rizzo and Kim, 2005). Amongst these are that VR provides the opportunity for real-time performance feedback, independent practice, stimulus, and response modification that are contingent on a user's physical abilities whilst possibly offering an element of distraction. Use of interactive technology is currently limited amongst such patient and too date, no group has investigated the use of interactive, virtual based technology to modify the ICU patient environment.

1.3 Aspects of Usability

The formal definition of usability as stated in ISO 9241-11 (Iso.org, 1998) standards is: "The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" Throughout this research the aspects of usability studied as selected from the 5Es by (Quesenbery, 2004) encompassed;

i) 'Effective' addressing whether the designed rehabilitation software was useful and allowed the user to achieve their goals accurately. If the user fails to complete the task they set out to do (or do something unnecessary), it will not matter whether the experience is short or long, easy or hard. In the end, they have failed to complete their tasks or meet their goals.

ii) ‘Engaging’ how pleasant, satisfying, or interesting an interface is to use. All software has an emotional impact on users which varies with the type of program. An engaging interface might draw someone into the work, promote confidence or increase immersion. The visual style or quality of the interaction could contribute to making software engaging or off-putting.

iii) ‘Easy to Learn’ explores how well the system supports both initial orientation and deeper learning. This can apply to both the care professional setting up and maintaining the prototypes as well as the patient who needs to use the system for rehabilitation without a steep learning curve.

1.4 Research Aims

i) Determine requirements for new interactive systems for use within the ICU.

ii) The development of interactive systems utilising COTS interface technologies.

iii) Evaluate integration of systems within the context of an ICU hospital setting.

iv) Evaluate systems with respect to Environmental and Rehabilitation ICU applications.

1.5 Research Questions

i) What are the key health recovery-related issues that define the need for an integrated interactive modular system for supporting patient rehabilitation and communication?

ii) What are the unique environmental and Human Factors qualities and features of ICU wards and bed-spaces, both in terms of patient-centred layout and the need to allow carer access/unhindered working, that define the need for and constraints of an integrated interactive modular system?

iii) Can an integrated interactive modular system improve patient wellbeing and hospital stay rating / satisfaction rating?

iv) Can an integrated interactive modular system help improve staff practices?

1.6 Thesis Structure

The remaining thesis is structured as follows:

Chapter 2: Presents a review of relevant literature that looks at the intensive care unit in terms of care levels and pathways for a mechanically ventilated patient, then on to the idea of rehabilitation from within the ICU bed-space in terms of respiratory and physical rehabilitation. The review then proceeds to look at the idea of introducing gaming hardware technology to aid with rehabilitation and the negative aspects that can present itself when using COTS technologies not designed with the needs of patients.

Chapter 3: Looks at the use of the Virtual Reality-Interaction (VR-I) Module-V2 within the REVERE-Sleep study and evaluates its usability performance and technology acceptance from both clinical professionals and patients involved in the study.

Chapter 4: Looks at the next generation of VR-I Module prototype by means of a focus group conducted within the ICU at the QEHB, the focus group looked at the REVERE-Breathe VR-I Module-V2 that led to a series of proof of concept prototypes that were presented and demonstrated to members of staff within a live ICU bed-space. The outcomes led to a completely different trolley-based concept (InspireVR) being developed. The prototype was demonstrated and met with approval, only to be discounted due to the lack of CE marking which was a requirement of the MHRA application process.

Chapter 5: Builds upon the major setback encountered with the non-CE marked InspireVR prototype and looks at the development of a new VR-I Module entitled, InspireVR-V2, designed to comply fully with the CE marking requirement, thus being granted MHRA approval to undertake participant testing. The chapter also looks at the modifications made

during the study in an attempt to cure a small number of ongoing safety issues, mainly attributed to the systems handling from bed-space to storage and vice versa.

Chapter 6: Looks at the introduction of the InspireVR-V2 in a study that seeks to evaluate the usability of the prototype by:

i) patients recovering from oesophagectomy or total gastrectomy within the critical care unit.

ii) staff members caring for the patients.

iii) Evaluation of events related to the use of the InspireVR-V2 prototype from within the ICU bed-space by means of a link analysis.

Chapter 7: Follows the prototype design and build of a new Virtual Reality Interaction (VR-I) Module prototype entitled VeloVR, and looks at a series of ICU installation tests both in a live bed-space, and mated with a commercial bed-side ergometer used during patient rehabilitation practices.

Chapter 8: Seeks to introduce the VeloVR prototype into the ICU bed-space to evaluate if the system could provide real time feedback during in-bed ergometry sessions whist also examining if the prototype is feasible and safe in an operational medical environment by both patients and care professionals.

Chapter 9: Looks at the impact and legacy of the research paying attention to the prototypes that underwent testing within the QEHB and Birmingham Heartlands hospital, and the exposure received that led to a collaboration with Torbay Hospital in South Devon. A collaboration that led to the donation and installation of both the InspireVR and VeloVR systems.

2.0 Literature Review

The following literature review looks at the hospital environment, specifically the intensive care unit (ICU), and focuses on the levels of care required for the long stay patient who displays complex medical issues, and at some stage has been mechanically ventilated. It is those patients who require extensive rehabilitation prior to discharge to general wards, which leads to the areas of sleep and delirium (2.3), incentive spirometry (2.4) and physical rehabilitation (2.5). Within the sphere of sleep and delirium, to date no group has investigated the use of interactive, virtual reality based technology to modify the ICU patient environment. Within the sphere of both respiratory and physical rehabilitation the primary outcome is to understand the current methods (2.4.1, 2.5.1) which currently provides patients with no form of performance feedback or distraction from the discomfort many experience as a consequence of exertion, and then to develop prototypes using a human centred design process to incorporate virtual reality to aid patient performance during incentive spirometry (IS) and in-bed ergometry.

2.1 The Intensive Care Unit

The intensive care unit (ICU) is a dedicated facility within a hospital that houses critically ill patients cared for by specially trained staff. A typical ICU (Torpy, 2009) consists of a varied array of care professionals, including specialist doctors (surgeons and anaesthetists), nurses, respiratory therapists, clinical nurse specialists and physical therapists. The ICU differs from other units within a hospital, primarily due to the need for constant and intense patient observation and monitoring. Nursing staff levels also differ in the ICU (Intensive Care Society. 2002); the nurse-to-patient ratio is dependent on the unique situation and condition of the patient. The following Table (Table 2.1) examines the levels of care that individual patients need.

Table 2.1: Critical care classifications	
Level 0	1 nurse to 6-8 patients. Patients whose needs can be met on a normal ward.
Level 1	1 nurse to 4 patients. Patients at risk of further complications or those who need critical care team input.
Level 2	1 nurse to 2 patients, HDU care - Single failing organ, or level of care being stepped down from high levels.
Level 3	1 nurse to 1 patient, ICU care – Failure of at least two organ systems, also patients requiring respiratory support.

Source: Williams, Schmollgruber and Alberto, 2006)

The types of equipment and devices essential for the care of critically ill and vulnerable patients make the ICU the most technologically sophisticated environment in any hospital (Almerud et al., 2007), the environment can often be a challenging and anxiety-raising experience for a seriously ill patient. The levels of equipment in any given bed space can seem overwhelming; at a minimum, the patient is connected to a heart-rate monitor, blood pressure, and respiratory rate devices. Ventilators help those in need with a method of aided breathing until such a time as they can sustain their own breathing rhythm. Novaes et al., (1999) identified the major stressors to a long stay critically ill patient as being in pain, the inability to sleep, having tubes in the nose or throat, having no control over one's own body and having no explanations regarding treatment from care professionals. A patient's lack of control over their environment has been linked to increased levels of stress and the release of stress hormones such as corticosteroids (Nursing Times, 2018; Ogden, 2007).

Several studies have indicated that prolonged periods of bed-rest have had adverse psychological effects on patients (Moffitt et al., 2008; Ishizaki et al., 2002 and (Maloni, Brezinski-Tomasi and Johnson, 2001). Notable symptoms included depression, anxiety, forgetfulness and confusion. Many of these symptoms can be attributed to the lack of personal control imposed by bed-rest. For example, one day an individual may be in full control of his or her life and environment, and the next, he or she may be suddenly confined to a single, quite frightening location almost against his or her will.

2.1.2 Pathways for a ventilated patient

An international consensus conference (Boles et al., 2007), proposed the categorisation of ventilated patients into three groups, based on the difficulty and duration of the weaning process. "Simple weaning" (Group 1) includes patients who successfully complete weaning trial (Thille, 2018), and are extubated (the removal of the breathing tube) without difficulty. "Difficult weaning" (Group 2) includes patients who fail the first weaning trial and require up to three spontaneous breathing trials or seven days to achieve successful weaning. "Prolonged weaning" (Group 3) includes patients who require more than seven days of weaning after their first weaning trial. Relevant research publications (Esteban et al., 1995; Brochard et al., 1994; Vallverdu et al., 1998) suggest that the proportion of patients in each group can be estimated at 70% for Simple weaning, 15% for Difficult weaning, and 15% for Prolonged weaning.

Critically ill patients are often exposed to prolonged immobilisation, which can lead to neuromuscular weakness and subsequent impairments in physical function, lasting from months to years following discharge from an Intensive Care Unit, (Ann Parker, 2018; Herridge et al, 2003; Fletcher et al., 2003; Needham et al., 2008). Referring to the list of potential pathways for a patient on ICU, (Table 2.2), the research focused primarily on point 3. Patients

within this grouping are classified as "prolonged weaning" and are therefore dependent on higher levels of critical care and require greater support during the rehabilitation phase.

Table 2.2: Potential pathways for a critical care patient on ICU	
1. ICU —> Home	A small minority; usually following profound intoxication with a short-acting substance, e.g. alcohol, narcotics. The majority of patients will walk off the ICU.
2. ICU (Short Stay) —> Ward—> Home	Patients who have undertaken, for example, elective surgery, severe illness in an otherwise fit patient, e.g. pneumonia, not requiring extensive rehabilitation prior to discharge.
3. ICU (Long Stay) —> Ward—> Home	Patients with complex medical issues, mixed pathologies, more severe illness or injury, elderly, requiring extensive rehabilitation prior to discharge.
4. ICU —> Ward —> Care Facility	Patients unable to live at home, discharged to nursing/residential home, or specialist facility, e.g. spinal rehabilitation unit.
5. ICU —> RIP	Patients succumbing to central nervous system and cardiovascular failure, leading to death due to multi organ failure.

In the case of patients classified as "prolonged weaning" (Group 3), early rehabilitation within the ICU may promote muscle strength and functional mobility, leading to improved quality of life (Adler and Malone, 2012; Burtin et al., 2009; Korupolu and Needham, 2009; Li et al., 2013; Needham et al., 2010). Schweickert et al., (2009) conducted a randomised trial and made comparisons to usual hospital care processes. Early physical and occupational therapies led to achieving greater functional status, less ICU-acquired weakness, and greater unassisted walking distances at hospital discharge.

The benefit to the patient in terms of accelerated discharge times also has considerable cost benefits to the NHS. In financial terms, patient care in the ICU is an expensive undertaking, due to high staff-to-patient ratios and the need for intensive monitoring and associated therapeutic requirements. The estimated average cost to the NHS per patient day across eleven UK-based ICUs amounted to £1000 (Edbrooke et al., 1999). Bennett and Bion (1999) however estimated this figure as much as £1500 per patient day.

2.2 Critical Care Rehabilitation

Rusk (1960) described rehabilitation after a critical illness as the "third phase of medicine", and that rehabilitation strategies should wait until the patient is both medically and surgically stable. Several investigations have indicated that early rehabilitation, introduced at a stage when the patient is physiologically stable and continuing his or her "Journey" through critical care, may improve functional mobility and, therefore, contribute to early discharge from ICU (Bailey et al. 2007).

Critically ill patients faced with extended periods of bed rest, ultimately leads to muscle dysfunction, due in part to inactivity but also due to the use of specialist medication (Deem 2006; De Jonghe et al., 2007; Helliwell et al., 1998; Schweickert & Hall 2007; Topp et al., 2002; Winkelman, C. 2007). This, combined with the underlying neuromuscular syndromes

associated with their illness, means that, for the patient, the initial 2 to 3 weeks in ICU leads to the highest levels of muscle wastage (Gruther et al., 2008). There exists a need for rehabilitation throughout the critical illness cycle (Chiang et al., 2006; Griffiths et al., 1995; Martin et al., 2005; Nava, S. 1998; Zanotti et al., 2003) however, levels of rehabilitation performed in ICUs are often inadequate, (Corrado et al., 2002).

Identifying rehabilitation needs early, and starting rehabilitation at an early stage may lead to a possible reduction in healthcare costs, by reducing dependencies on: nursing care, anxiety, length of stay, and may also possibly improve the patients' subsequent health-related quality of life (Evans et al., 1995; Indredvik et al., 1991; Johnston et al., 2003; Kramer et al., 1997).

2.3 The Critical Care Environment; Impact on Sleep

The critical care environment is, for many patients, highly stressful and can have a detrimental impact on sleep. In particular, high noise levels are associated with disrupted sleep architecture (Fontana and Pittiglio, 2010; Uğraş and Oztekin, 2007). Noise is attributed to equipment, alarms, oxygen masks, telephones ringing and people talking (Nicolás et al., 2008) and many critical care units have higher noise levels than the 35 decibel limit recommended by the World Health Organisation for hospitals (Meriläinen et al., 2010). Other environmental factors include lighting, ambient temperature and absence of time indicators. A Lack of a clock, reading glasses, or family members to aid orientation are associated with delirium in the elderly (McCusker et al., 2001). Patient factors which can be exacerbated by their surroundings include anxiety, immobility, pain and discomfort; all of which contribute to, and are heightened by sleep deprivation (Nicolás et al., 2008; Uğraş and Oztekin, 2007; Jones and Dawson, 2012). Patients may report pain or discomfort on exposure to the unfamiliar hospital environment (Tse et al., 2002). Encroachment of personal space, required for interventions, assessment and nursing care, cause stress, anxiety and fear (Meriläinen et al., 2010).

The critical care environment serves to provide the best conditions to undertake life-saving treatment, with high technology monitoring and physiological support systems. Where feasible, optimisation of conditions for sleep can include reduction of light levels in the patient bedspace, attention to patient comfort and temperature. These should be combined with minimisation of procedure-related disturbances at night (Honkus, 2003; Fontaine et al., 2001; Tracy and Chlan, 2011). Increasing ventilatory support to patients weaning from mechanical ventilation can improve rest and sleep quality (Roche-Campo et al., 2013). A quality improvement study completed at the Johns Hopkins Intensive Care Unit demonstrated that common sense measures to improve sleep, from avoidance of caffeine and providing a warm bath at bedtime, caused significant improvements in night time noise and delirium and. Sleep quality, as measured by RCSQ, improved but did not meet statistical significance (Kamdar et al., 2013). Efforts have been made to study the impact of environmental modification. These can be considered as adaptations of ambient sights, sounds and scents.

2.3.1 Sound

A Cochrane systematic review of the use of music interventions to reduce anxiety and distress in mechanically ventilated patients compared to standard care found eight small studies which showed a consistent reduction in heart rate and respiratory rate. This suggests that music may aid relaxation, although no studies they reviewed examined the effects of music on sleep (Rotondi et al., 2013; Bradt et al., 2010; Fontana and Pittiglio, 2010; Mistraletti et al., 2008). A subsequent multi-centre randomised controlled trial comparing cortisol levels in mechanically ventilated patients receiving self-initiated music showed no significant effect when compared to the use of noise-cancelling headphones or standard environmental conditions (Granja et al., 2005; Chlan et al., 2013a; McKinley et al., 2012). Both the music and noise cancelling headphones reduced anxiety levels compared to normal conditions, this

reduction was associated with a reduction in sedation levels (Fontana and Pittiglio, 2010; Chlan et al., 2013b; Uğraş and Oztekin, 2007).

A randomised placebo-controlled trial showed that playing nature sounds to mechanically ventilated patients reduced systolic and diastolic blood pressure, anxiety and agitation levels when compared to a control group who received the headphones without sound. Sleep was not assessed as part of this study (Nicolás et al., 2008; Saadatmand et al., 2013). The use of a combination of music and nature sounds for cardiac surgical patient caused no reduction in anxiety, pain or relaxation scores (Meriläinen et al., 2010; Cutshall et al., 2010).

2.3.2 Sight

Playing exciting computer games increases sleep latency and reduces REM sleep, although performing low mental load tasks using a bright computer display does not impede sleep structure in young males (Higuchi et al., 2005). The assumption that viewing a computer screen causes poor sleep was not borne out by the study by (Brunborg et al., 2011), who suggested that media use in the bedroom was associated with a later "lights off" time but no delay in sleep latency or subsequent architecture.

Adapting the visual environment has been studied in a variety of settings for the management of pain. The aim of such modifications is to provide distraction from the painful stimulus and to reduce anxiety. The most effective distraction techniques require high levels of patient engagement, using multi-sensory inputs and redirection of attention from the pain. These have been developed as virtual reality games, using head mounted displays to reduce the real-world environmental inputs to the patient. Such techniques have shown reductions in procedure related pain and anxiety for burns and trauma dressings, dental procedures and paediatrics (Bourne et al., 2007; Malloy and Milling, 2010; Miller et al., 2010; Li et al., 2011). No study has evaluated the use of these systems for sleep improvement.

Views of nature both real, in the form of windows onto a view, and artificial, in the form of images or computer-generated scenes, as well as sounds of nature, have been studied as variables affecting pain, anxiety, relaxation, rehabilitation and outcome from surgery in non-critical care groups (Cuesta and Singer, 2012; Diette, 2003; Mantz et al., 2010; Kline, 2009; Lechtzin et al., 2010; Ulrich, 1984; Raanaas et al., 2012; Alvarsson et al., 2010; Schneider and Hood, 2007). Contact with real nature reduces stress and improves psychological and physiological wellbeing (Perren and Brochard, 2013; Park et al., 2009; Lee et al., 2011; Ulrich et al., 1991), probably due to evolutionary benefits to habitat selection, perceived safety and comfort (Parthasarathy et al., 2010; Grinde and Patil, 2009). Nevertheless, an epidemiological analysis of over 12,000 adult critical care patient outcomes comparing those in rooms with windows or natural views showed no benefit when compared to those without (Watson et al., 2012; Kohn et al., 2013). Likewise, the presence of natural light from a window does not improve outcomes in patients admitted to critical care with subarachnoid haemorrhage (Hweidi, 2007; Wunsch et al., 2011; Biancofiore et al., 2005; Simini, 1999; Rotondi et al., 2013; Novaes et al., 1997). A local audit failed to demonstrate improved sleep quality in patients exposed to natural light during the day.

2.4 Respiratory Rehabilitation

Mechanical ventilation allows patients to recover from acute respiratory failure and major surgical procedures (Tobin 2001). As prolonged use of mechanical ventilation can be associated with complications, such as upper airway injury and ventilator-induced lung injury, it is necessary for ventilation to be discontinued as soon as the patient's autonomous respiration can be sustained. The process of reducing the patient's dependence on mechanical ventilation and onto spontaneous breathing is termed *weaning* (Caminal et al., 2010). Weaning involves reducing the patients' levels of ventilator dependence, therefore forcing him or her to breathe independently, but still aided by mechanical support. With reference to point 3 in Table 2.2,

the present research is concerned with patients who are classified as long stay and present as "prolonged weaning". Patients who fail three attempts at weaning, or who are still ventilated 7 days after the first spontaneous breathing trial, fall into a category known as prolonged weaning. The problem affects up to 25% of patients on the ICU (Caroleo et al., 2007) and is associated with increased morbidity and mortality, as well as the considerable financial implications to the NHS.

2.4.1 Current Practice



Figure 2.1: Spiro-Ball, Volumetric Exerciser

(Spiro-Ball, Volumetric Exerciser, 2018)

In the case of the post-operative upper GI patient (Section 1.1.1) current practice for incentive spirometry to facilitate in the reduction of post-operative pulmonary complications (PPCs) is to employ the use of a Spiro-Ball Volumetric Exerciser (Figure 2.1). The patient is required to breathe in (inhale) slowly and as deeply as possible through a tube attached to a hand-held plastic chamber, within the chamber sits a ball that levitates between two markers. When sufficient inspiratory volume is met, the patient then breathes out (exhale) normally. Best practice sees 10 consecutive inhalations per hour whilst the patient is awake, aiming for 10 sessions per day. The Spiro-Ball is designed to facilitate the maximum possible inspiration and

motivates the patient to take long, slow, deep breaths that increase lung inflation (AARC 1991; Chuter 1990).

2.5 Physical Rehabilitation

The idea of introducing physical activity early into the rehabilitation cycle (Thomsen et al., 2008) is that it provides a feasible and safe intervention that can be achieved after initial cardio-respiratory and neurological stabilisation. Schweickert et al., (2009) suggested that implementing early mobilisation and muscle training could positively influence cognitive and respiratory conditions in critically ill patients. Passive or active limb movements and Continuous Rotational Therapy (CRT) are deemed chief amongst strategies for patient mobilisation. CRT involves the use of a specialised bed featuring an air pocket mattress that can inflate and deflate to help roll the patient from side to side up to a rotational angle of 60 degrees (deBoisbanc et al., 1993, and Fink et al., 1990). The treatment can prevent airway closures and reduce the risk of complications such as pneumonia. In ICU, the imbalance between muscle strength, load on the respiratory system and diminished cardiovascular activity are major factors of weaning failure in ventilated patients.



Figure 2.2: A ventilated patient using a cycle ergometer in the ICU

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An alternative method to CRT is the utilisation of a bedside ergometer (commercialised as MOTOmed) to aid with early mobilisation. Bedside ergometry provides either passive, active-assisted, or active movement of lower extremities whilst the patient remains in bed. The cycle ergometer Figure 2.2) is essentially a stationary exercise bicycle adapted to fit within a bed space using built-in mechanisms that can vary the workload undertaken by the patient. The patient exercises aim to optimise joint motion to improve soft-tissue length and muscle mass (Koch et al., 1996). Ergometry can be deployed to critically ill patients who are either sedated or awake. In the case of the patient suffering from Intensive Care Acquired Weakness (Chapter 1.1.2) early treatment using a cycle ergometer has been shown to promote functional status and limited walking ability at hospital discharge, (Burtin et al., 2009).

2.5.1 Current Practice

Current practice sees patients undergo 20 minute ergometry sessions every 2-4 days until able to step transfer from bed to chair with assistance. The practice is consistent with that reported elsewhere (Kho et al., 2015). The MOTOmed device has three modes of use; passive, active-assist and active (with adjustable resistance) (Kho et al., 2015). Patients are instructed to actively pedal for as long as there are able, if fatigue sets in the system reverts to a passive mode whereby pedal rotation will continue automatically until the end of the prescribed session. The active-assist mode in not used.

2.6 Gaming in rehabilitation

The incorporation of interactive technologies especially those which promote activity have been explored in a rehabilitation context. Systems evaluated ranged from low cost gaming technologies such as the Nintendo Wii (Gil-Gómez et al., 2011; Daniel, 2012) to highly-developed robotic simulators (Merians et al., 2006). Interactive technologies have been integrated into a number of systems designed to aid rehabilitation for a variety of conditions,

many utilising different interfaces with varying levels of interactivity, complexity and cost. Many of the systems use environmentally-appropriate scenarios to increase levels of immersion in the therapy and applicability to real-world areas (Bohil, Alicea and Biocca, 2011). It is these scenarios that can be precisely controlled and tailored to match the needs of the patients (Keshner, 2004). The low cost nature of gaming technology makes for an appealing addition to the physiotherapists toolkit. Designed for ease of use in the commercial market, they have been repurposed for a variety of patient groups, including the elderly (Mirelman et al., 2010). (Kho et al., 2012) investigated the potential of using the Nintendo Wii within the ICU. It was found that the hardware was viable and safe for use, however a number of patients were not able to get to grips with the technology which was made worse by the motion tracking required by the games only working whilst standing up, a drawback as the majority of patients were unable to stand independently. Although there are interactive systems to enhance performance during wheelchair ergometry (O'Connor et al., 2001), there currently does not exist such interactive technologies to aid with ergometry in the ICU.

2.7 Medical Device Design

Human factors (HF) are a series of systems, behaviours or actions that alter human performance, and look at how an individual interacts within an environment. Employing HF engineering principles can improve human performance with medical devices and can improve patient, work place safety and reduce errors (Weinger et al., 2011). Money et al., (2011) identified that HF practice had been tarnished by an over reliance on a small number of senior healthcare staff. They also commented that there was a culture of avoidance in consulting with patients or junior members of staff, which led to the practice of making design modifications on the basis of instinct rather than the more formal approach of user testing. The outcome of which found a lack of clarity vis-à-vis as to who the end user was.

Efficient design can reduce the prospect of errors (Clarkson et al., 2004). For medical devices, several examples of redesign that could reduce error rates exist (Lin et al., 1998; Thimbleby and Cairns, 2010). In some instances, valuable opportunities have been missed once the equipment had been deployed and circumstances meant that it was near impossible to update or make modifications. In terms of medical devices, failure in communication has been identified in the wrong device being developed or purchased (Vincent et al., 2014). In a study examining requirements for a purchased medical imaging device, there proved to be a lack of interest / need for such a device when end users were surveyed (Hinrichs et al., 2010; Martin et al., 2012). Studies examining the correlation between equipment providers and healthcare professionals have found several barriers to the formation of a satisfactory outcome.

2.7.1 Medical Device Regulation

To ensure maximum compliance, medical devices are subject to highly stringent regulations whereby medical devices are divided into specific classes. It is those classes that are identified by the different regulatory bodies according to the potential risk that may occur during the devices' usage. The whole premise of medical device regulation is risk management, developers must work to eliminate, or reduce as far as possible, the risk associated with their device and where appropriate take adequate protection measures.

One of the most important regulations for a developer to consider is the Medical Device Directive (Council of the European Union 1993/42/EEC), it is this set of regulations that with compliance allows for the devices to obtain Conformite´ Europe´enne (CE) marking. Medical device regulatory approval is mandatory within the European Union (EU) and is subject to strict council directives. The directives require medical-device designers to display CE marking on their products (Council of the European Union 90/385/EEC). This stipulates that the device has been designed and manufactured for the purposed intended, and does not compromise either the clinical condition of the patient or the health and safety of care professionals. CE

categorisation for medical devices are: Class 1 (generally regarded as low-risk; Class 2 (generally regarded as medium-risk; and Class 3 (generally regarded as high-risk) (Heneghan et al., 2011). In 2003, the UK, commissioned the Medicine and Healthcare Regulatory Authority (MHRA), to ensure that the European directive is enforced (MHRA, 2016).

2.8 Hospital Bed-Space

Hospital bed-space is the largest repeated design in an acute hospital environment, defined as an area around an individual bed that offers privacy either as a single side room or as a cubical within a multi occupancy space, cordoned off using screens or curtains (Hignett & Lu, 2010). The bed-space offers a complex challenge due to the differing types of individuals who frequent the area, e.g. nursing staff, doctors, consultants, and physiotherapists etc. The overriding constant being the bed-bound patient who would form the nucleus to a wide range of task activities (Lu & Hignett., 2005). It has been suggested that hospitals are not designed with the specific goal of enhancing staff and patient safety though innovative facility design (Reiling et al., 2004) and the idea that the physical environment can have an impact on health and safety, cross contamination and travel time within the environment. Villeneuve (2000) suggested that ergonomics would complement architecture rather than compete with it, so ergonomic methodology has a lot to offer bed space designers. To produce a research-based or user-centred design, a detailed knowledge of work processes within a defined space/area is needed. A range of ergonomic methods including task analysis and user-needs analysis could be used to provide this information (Irbnet.de, 2018; Rutter, 1996).

2.9 Link Analysis

A Link analysis is a systematic ergonomic tool that is used to study interactions between human–human, human–environment (Kirwan & Ainsworth,1992). It has been employed in a wide array of industries and environments (Chapanis, 1959; Nemeth, 2003; Stanton & Young,

1999; Thomson, 1972). The idea of employing a link analysis is to study interactions in a workspace layout, formulate frequently linked elements, and to improve task efficiency by reducing overall link distances. Elements are items that represent the physical layout (or location of people), links are made between elements to record movements when there is physical change in location.

Link analysis has previously been used to analyse patient and staff in hospital environments (Ferreira & Hignett, 2005; Lu & Hignett, 2009), where data has been collected using a traditional pen and paper method, the method has three stages, i) The production of a scale drawing of the workspace, assigning all elements with a unique identifier, ii) The observation of tasks and recording of interactions by inputting a series of lines to indicate movement and, iii) Formulation of results in terms of, i) Link diagram, displaying the scale drawing with all elements and links, and ii) a link table to show the frequency of links between elements.

2.10 Discussion

Based on the literature it can be surmised that rehabilitation is a crucial part of the patient recovery process, patients often become weak and deconditioned during their stay in the ICU and for many patients is highly stressful and has a detrimental impact on sleep which is a common problem. Sleep is an essential physiological process and sleep deprivation impairs processes such as immune function and wound healing (Honkus, 2003; Cuesta and Singer, 2012; Fontaine et al., 2001; Mantz et al., 2010; Tracy and Chlan, 2011). Poor sleep may delay successful weaning from mechanical ventilation (Roche-Campo et al., 2013; Perren and Brochard, 2013).

ICU-AW is associated with increased durations of mechanical ventilation and weaning, longer ICU and hospital stay, and increased mortality. The physical impairments may last for years after discharge which gives rise to the notion that early rehabilitation may be beneficial to the patient and may prevent or remove some of the physical deficiencies. It can also be suggested

that the idea of evolving existing practices for both incentive spirometry, and bed-cycle ergometry to provide an element of gamification may improve patient performance, motivation, distraction, and even add a layer of self-competition all with the aim of leading to an earlier discharge from ICU.

To facilitate with the idea of introducing virtual reality within an ICU bed-space three physical prototypes would need to be designed, based on close input from medical stakeholders. The need for stakeholder involvement from the outset would be crucial to ensure that the final prototypes are fit for purpose from the perspective of patients (both former and current), and care professionals' whist also being sympathetic to the intense operational environment of the ICU. The prototypes would act as a platform to interface either as a stand-alone system (REVERE Sleep, Chapter 3; InspireVR, Chapter 6), or with existing medical technologies (VeloVR, Chapter 8), that would strictly adhere to the Ergonomics of human-system interaction – Part 2010: Human-centred design for interactive systems standard (Iso.org, 2010), to ensure that the prototypes that enter patient testing are viable in terms of technology acceptance and usability.

The following chapter (3) looks at the use of the Virtual Reality-Interaction (VR-I) Module within the REVERE-Sleep study and evaluates its usability performance and technology acceptance from both clinical professionals and patients involved in the study.

3. Study 1 - Restorative Virtual Environments for Rehabilitation (REVERE) Sleep



Figure 3.1: VR-I Module undergoing patient testing

The following chapter looks at the introduction of a new prototype Virtual Reality Interaction (VR-I) Module (Figure 3.1) that was created adhering to the human-centre design process ISO 9241-210:2010 (Iso.org, 2010) to ensure that the interactive technologies matched the needs and capabilities of each patient, the majority being bed-bound and having limited data input capabilities. The VR-I Module was created as a self-contained unit that was easy manoeuvrable between bed-spaces, featuring audio, and a number of interfaces (Figure 3.4. It acted as a physical platform in which to incorporate a 3D virtual environment (Figure 3.2) (Qian, C. 2015) of a costal seaside scene based on a real-world location of outstanding natural beauty. The combined system entered into the REVERE Sleep study, which led to a new question. Do virtual scenes of nature enhance sleep in the ICU?



Figure 3.2: Screen captures of Virtual Wembury at two different times of day

The idea for the research was inspired as a result of studies conducted in the 1980s by Ulrich, R. (1984) that suggested that exposing patients to views of real-world scenes of nature (Figure 3.3) from their hospital beds (trees, gardens, etc.) positively influenced their recovery periods, reduced the need for analgesia and increased perceived satisfaction of their hospital stay when compared to those patients with no such views.

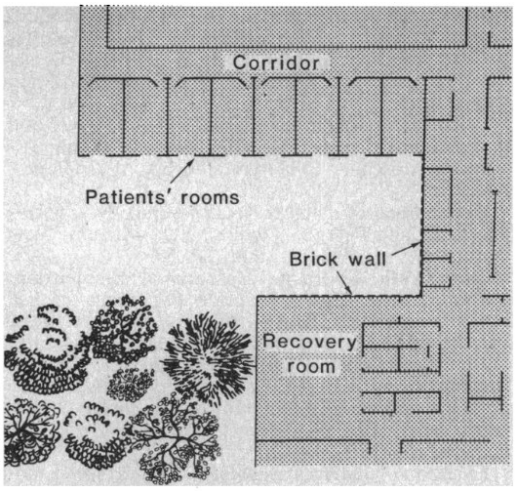


Figure 3.3: Patients view of either trees or a brick wall

Ulrich, R. (1984)

3.1 Background

Sleep disruption is a common problem that patients encounter during their stay in the intensive care unit. It is characterised by disruptions of sleep architecture and its causation is likely to be a combination of the consequences of critical illness, sedation and the ICU environment. Whilst on ICU and during the recovery phase from critical illness, reductions in sleep duration and quality resulting in pathological or abnormal sleep are aggravated by environmental 'assaults' on the conscious patients (Tse et al., 2002; Gazendam et al., 2013; Gehlbach et al., 2012; Bijwadia and Ejaz, 2009). Sleep is a crucial physiological process and sleep deprivation impairs such processes as wound healing and immune functionality (Honkus, 2003; Cuesta and Singer, 2012; Fontaine et al., 2001; Mantz et al., 2010; Tracy and Chlan, 2011). Successful weaning from mechanical ventilation may be delayed due poor sleep quality (Roche-Campo et

al., 2013; Perren and Brochard, 2013). Whilst it can be said that poor sleep quality is linked to increased mortality and adverse outcomes with the ICU, the causative role is unclear (Kamdar et al., 2013; Parthasarathy et al., 2010). However, disturbed sleep patterns are one of the greatest perceived stressors for patients (Jones and Dawson, 2012; Hweidi, 2007; Richardson et al., 2007; Biancofiore et al., 2005; Scotto et al., 2009; Simini, 1999; Rotondi et al., 2013; Novaes et al., 1997), and are associated with other potentially avoidable symptoms, such as delirium, anxiety and low mood (Higuchi et al., 2005; Rotondi et al., 2002; Fontana and Pittiglio, 2010; Mistraletti et al., 2008). Post ICU recollections, including sleep disruption can have long term damaging consequences to the mental health and quality of life for survivors (Granja et al., 2005; McKinley et al., 2012).

3.1.1 The ICU environment and impact on sleep

For many patients, the critical care environment is highly stressful and has a detrimental impact on sleep, high noise levels are associated with disrupted sleep architecture (Fontana and Pittiglio, 2010; Uğraş and Oztekin, 2007). Noise is attributed to equipment, alarms, oxygen masks, telephone ringing and people talking (Nicolás et al., 2008) and many critical care units have higher noise levels than the 35-decibel limit recommended by the World Health Organisation for hospitals (Meriläinen et al., 2010). Other environmental factors include lighting, ambient temperature and absence of time indicators. A lack of a clock, reading glasses, or family members to aid orientation are associated with delirium in the elderly (McCusker et al., 2001). Patient factors which can be exacerbated by their surroundings include anxiety, immobility, pain and discomfort; all of which contribute to, and are heightened by sleep deprivation (Nicolás et al., 2008; Uğraş and Oztekin, 2007; Jones and Dawson, 2012). Patients may report pain or discomfort on exposure to the unfamiliar hospital environment (Tse et al., 2002). Encroachment of personal space, required for interventions, assessment and nursing care, cause stress, anxiety and fear (Meriläinen et al., 2010).

The critical care environment serves, primarily, to provide the best conditions to undertake life-saving treatment, with high technology monitoring and physiological support systems. Where feasible, optimisation of conditions for sleep can include the reduction of light levels in the patient bedspace and the attention to patient comfort and temperature. These should be combined with minimisation of procedure-related disturbances at night (Honkus, 2003; Fontaine et al., 2001; Tracy and Chlan, 2011). Increasing ventilatory support to patients weaning from mechanical ventilation can improve rest and sleep quality (Roche-Campo et al., 2013). A quality improvement study completed at the Johns Hopkins Intensive Care Unit demonstrated that common sense measures to improve sleep, from avoidance of caffeine and providing a warm bath at bedtime, caused significant improvements in night time noise, delirium and coma. Sleep quality, as measured by Richard Campbell Sleep Questionnaire (RCSQ), improved but did not meet statistical significance (Kamdar et al., 2013).

3.2 Research Questions

i) Is the VR-I Module prototype system appropriate for use by patients within a critical care environment?

ii) What are the patients' perceptions of the VR-I Module prototype?

iii) What are the optimal qualities for the VR-I Module display and interaction technology hardware?

iv) What are the staff opinions of the acceptability and the utility of the VR-I Module?

v) What modifications are recommended by critical care staff and patients to improve the feasibility of using the VR-I Module?

3.3 Methodology

The study was a clinical investigation of a novel class 1 Medical device. All researchers had adhered to the protocol and investigation material submitted to the Research Ethics Committee

(REC) and Medicines and Healthcare Products Regulatory Agency (MHRA). All of the researchers working on the study have signed the delegation of duties log and have a current certificate of Good Clinical Practice.

3.3.1 Study Setting

The study was conducted at the Queen Elizabeth Hospitals (QEHB) critical care unit. It was an 86-bed mixed level 2 and 3 adult teaching hospital unit that admitted medical, surgical, trauma, burns, liver, cardiac and neurosurgical patients.

3.3.2 Recruitment, Consent and Withdrawal

Patients were informed of the study by their clinical team and were be approached by the chief investigator (CI), accompanied by a ward nurse as chaperone. The patients were reminded of the study and provided with an information sheet. Patient family members were also invited to ask questions of the research team if agreed to by the patient. Patient would have up to 24 hours to decide if they wished to enrol in the study, at which point written informed consent would be taken. Patients were informed of their right to withdraw from the study at any time and that they will not be required to give a reason for doing so. Participants were advised that they may request that their data be withdrawn from the study, but would need to make this request within 14 days of the data collection occurring.

3.3.3 Inclusion and Exclusion Criteria

For the patient to be approached and recruited onto the study, they were required to meet the inclusion criterion:

i) The patient must be a resident of the critical care unit

ii) Conscious and able to communicate

iii) Aged over 18 years old (for informed consent)

iv) Richmond Agitation Sedation Scale (RASS) score -1 to +1

v) Considered unlikely to be discharged from critical care for 5 days

The patient would not be approached based on the following exclusion criteria:

i) Bilateral upper limb paralysis or limb loss preventing ability to use the hand interfaces

ii) Severe visual or hearing loss

iii) Active delirium or psychosis at screening from RASS and Confusion Assessment Method for the ICU (CAM-ICU) score

iv) Severe cognitive impairment including dementia or hepatic encephalopathy

v) Active infection or colonisation with multi-drug resistant organism

3.3.4 Participants

15 participants were recruited onto the REVERE Sleep study over a 6-month period.

3.3.5 Ethics

South Birmingham Research Ethics Committee were approached and granted NHS ethical approval.

3.3.6 Data Management

The team followed guidelines set out in the Data Protection Act 1998. Data captured was anonymised with all forms stored securely, via an encrypted hard drive, at DMACCP facilities at the Birmingham Research Park.

3.3.7 Conditions

Three conditions were used in sequence -

A. Static image. Patient unable to navigate or alter their position within Virtual Wembury but objects within Virtual Wembury will move; including sun setting, water effects and animal movements.

B. Toggle view with 180 degree viewing motion. Patients will be able to toggle between different viewpoints and look around from a static position.

C. Interactive version of VR-I Module, whereby patients can navigate Virtual Wembury freely.

3.3.8 Interfaces

The interfaces employed during the study consisted of 5 hand controllers (Figure 3.4), mostly standard PC/gaming technologies with the exception of a Genius ring mouse (last image in Figure 3.4) that provided a single-handed method of toggling pre-defined viewpoints to allow for a 180 degree change in viewpoint by stroking the surface of the mouse.

Keyboard and Mouse



Single handed thumb controller (Motion XS controller)



Two-handed gaming controller (Xbox 360 controller)



Micro-switch joystick



Genius ring mouse



Figure 3.4: Interfaces employed during participant testing

3.3.9 Procedure

Exposure to the VR-I Module comprised of:

i. Viewing the virtual reality scene (Virtual Wembury – a virtual reality reconstruction of the South Devon coastal path) on a 32in display.
ii. Listening to the sounds using noise cancelling headphones (noise cancelling function can be switched off at the patient's request).

Trial day 1: The patient received control conditions (no VR-I Module), and undertook usual clinical care.

Trial day 2: Condition A – Static image. Patient were unable to navigate or alter their position within Virtual Wembury but objects within Virtual Wembury will move; including sun setting, water effects and animal movement.

Trial day 3: Condition B – Toggle view with 180 degree viewing motion. Patients were able to toggle between different viewpoints and look around from a static position.

Trial day 4: Condition C – Interactive version of VR-I Module, whereby patients were able to navigate the virtual environment freely.

Trial day 5: The patient received control conditions (no VR-I Module), and undertook usual clinical care.

Each condition represented increasing complexity of, and potential engagement with VR-I Module. Patients offered condition B or C were able to revert to condition A by not using their hand controllers if they so desired.

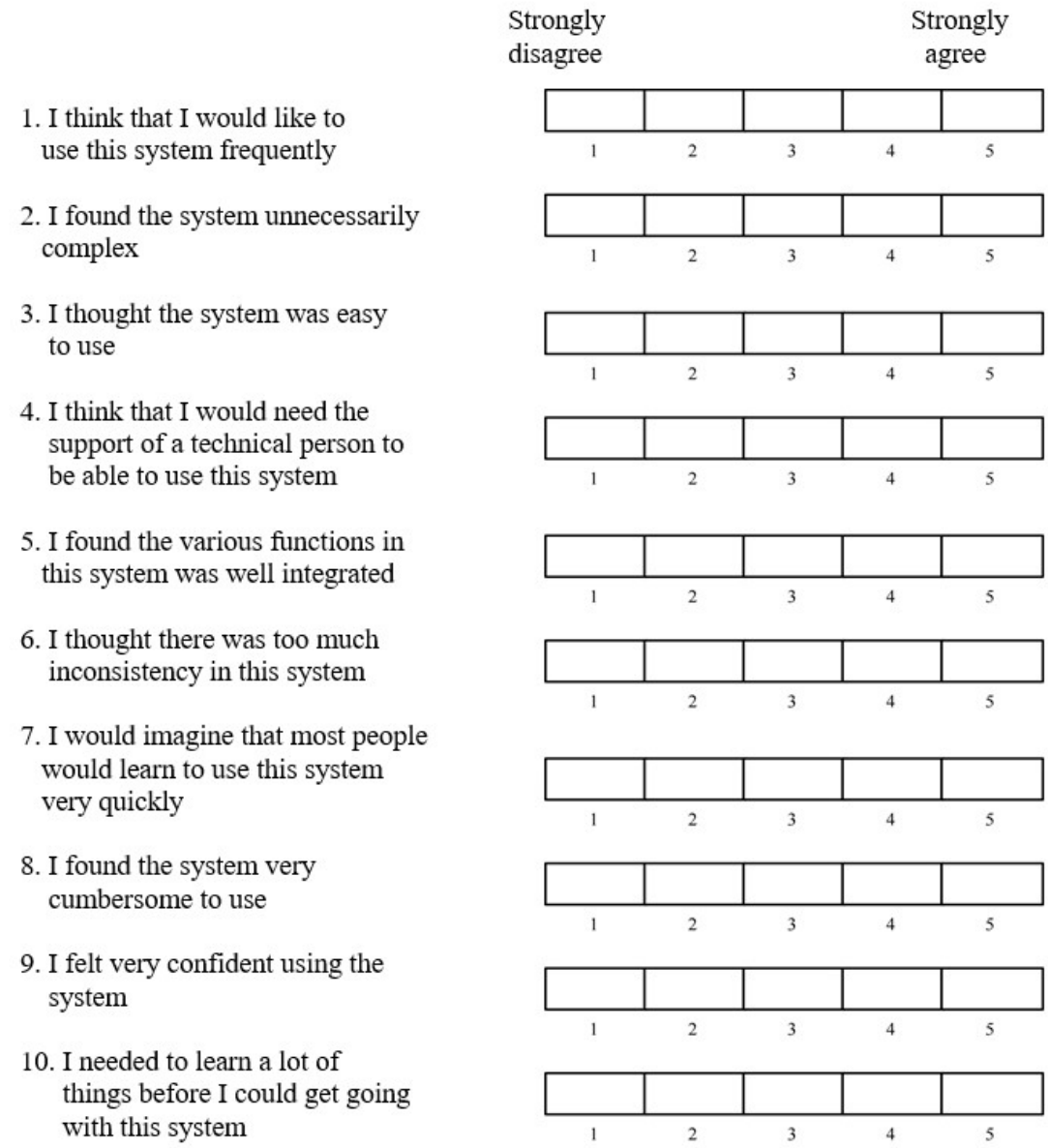
The intervention comprised of up to one-hour access to the VR-I Module before they went to sleep. This would usually be following the 22:00 drug round prior to their sleep time, however if patients wished to go to sleep earlier, they may receive the VR-I Module any time after 20:00. Patients were not woken up to receive a condition. Should the patient fall asleep before

receiving the VR-I Module and wake before 04:00, they were offered the VR-I Module if they wished to try to go back to sleep. Timings of sleep and offering of the VR-I Module were documented by the nurse caring for the patient.

3.4 Measures

3.4.1 System Usability Scale – (SUS) STAFF / PATIENT

The System Usability Scale (SUS) was developed in response to the lack of cost effective or practical solutions for a complete contextual analysis of usability (Brooke, 1996). The SUS is a method to measure perceived usability in a quantitative manner, minimising both effort and expense. It comprises of ten items on a Likert scale of strong disagreement (1) to strong agreement (5). The scale alternates between positive and negative items to account for biases from lack of attention while completing it (Brooke, 1996). The results of 2,324 SUS surveys of many different types of interfaces were found to be reliable and useful (Bangor et al, 2008). The benefits of not creating a new form of usability questionnaire is that results from SUS can be compared with other peoples results from SUS to establish whether a system is more or less usable, it is valid, the SUS does measure approximately whether or not the users perceive a system to be useable or not.



A full copy of the SUS can be found in Appendix 3.1

3.4.2 Patient follow up questionnaire

This took place between day 9 – 12 following condition testing.

What is your feedback on the process of taking part in the REVERE Sleep study?
Do you have any further comments you'd like to make about the VR-I Module system?
Would you recommend participation in this study to others in your position?
Do you consent to being contacted in the future by the research team? Patient signature and name Date Witness (sign and name)

3.4.3 Staff feedback

Did the patient seem relaxed whilst using the VR-I Module? Please discuss -
Did the patient seem uncomfortable whilst using the VR-I Module? Please discuss -
Was the VR-I Module easy to use? Please discuss -
Did the VR-I Module cause you or the patient any problems, side effects or adverse events? Please discuss -
Did you feel the patient benefitted from using the VR-I Module? Please discuss -
Would you recommend the VR-I Module for other patients? Please discuss -

3.5 Results

3.5.1 System Usability Scale (SUS)

Due to the nature of the sleep study, testing commenced at any time after 20:00 which was dependent on the patient's needs. The SUS data collection therefore took place the following morning as soon as the patient was awake. If possible the same member of the research team (senior physiotherapist or nurse) who were present during the testing phase would obtain the data either verbally, if the patient was not able to self-complete. If the same member of staff was not available at the time of SUS collection (due to shift change, or emergency), another member of staff would be on hand to collect the data as long as they had been briefed as to the study in advance (Chapter 3.3).

Important note:

It must be noted that while each of the participants can be identified by their ID number and repeated measures, analysis can be performed on their data with respect to the three VR-I Module conditions (A, B, C), this is not the case with staff data associated with the participant. No background information was collected on the members of staff who completed the SUS questionnaires. In addition, it is not clear if the same member of staff completed the SUS for each of the VR-I Module conditions with respect to the associated participant. Indeed, a single member of staff may have completed the SUS questionnaire for all three VR-I Module conditions but following supervision of different participants or different members of staff may have completed subsequent SUS questionnaires for a given participant. This was not noted nor recorded.

As such, the staff SUS data must at the very least be treated as independent sample data across the three VR-I Module conditions, where repeated measures analysis should not be undertaken.

With no record or control of which staff member completed which SUS questionnaire with which participant, the staff SUS data should be treated with caution.

3.5.2 SUS reliability analysis

Table 3.1 shows SUS data collected from the participants following exposure to the VR-I Module conditions and Table 3.2 shows corresponding staff data. A comparison of mean SUS scores for the participant and staff groups across the three VR-I Modules is shown in Figure 3.5.

Based on a review of 50 studies, Tullis & Albert (2008) suggested that an average score of less than 60 is relatively poor while one above 80 is relatively good. The overall mean SUS score across both participant and staff groups and for all VR-I Module conditions was 77.9 ± 14.0. Between the participant and staff groups there was no difference in SUS ratings ($p>0.05$). There was also no difference in SUS ratings between the three VR-I Module conditions ($p>0.05$).

A frequency distribution of SUS scores (Figure 3.6) shows that the mode score for staff responses was in the 81-90 range and for participants it was between 71-80 and 81-90 ranges. This suggests that the majority of users rated the usability of the VR-I Module as relatively good. For the participant group there were 4 relatively poor ratings of less than 60. However, two of these were from the same participant (#14), while another participant (#8) initially rated VR-I Module-A low yet subsequently improved the rating to high by the VR-I Module-C condition.

This suggests a possible learning effect. For the staff group there were 3 relatively low SUS scores, and while these are associated with different participant IDs and conditions (i.e. #8 VR-I Module-B, #11 VR-I Module-A, #14 VR-I Module-A), as there was no recording of staff details (refer to Important note box above) it is not possible to tell if these ratings improved with subsequent usage or indeed if it was the same person each time.

Table 3.1: Participant SUS data

	Total SUS Score			
ID	VR-I Module-A	VR-I Module-B	VR-I Module-C	Ave
1	80.0	82.5	75.0	**79.17**
2	-	82.5	-	**82.50**
3	95.0	-	-	**95.00**
4	87.5	77.5	80.0	**81.67**
5	90.0	90.0	87.5	**89.17**
6	77.5	-	-	**77.50**
7	-	-	-	**-**
8	60.0	75.0	80.0	**71.67**
9	97.5	100.0	-	**98.75**
10	-	-	-	**-**
11	65.0	82.5	-	**73.75**
12	-	-	-	**-**
13	-	95.0	50.0	**72.50**
14	55.0	50.0	-	**52.50**
15	65.0	-	-	**65.00**
16	-	-	-	**-**
17	-	-	-	**-**
Mean	**77.25**	**81.67**	**74.50**	**78.26**
SD	**15.25**	**14.36**	**14.40**	**12.74**
N	**10**	**9**	**5**	**12**

Table 3.2: Staff SUS data

	Total SUS Score			
ID	VR-I Module-A	VR-I Module-B	VR-I Module-C	Ave
1	82.5	85.0	97.5	**88.33**
2	70.0	62.5	85.0	**72.50**
3	-	-	-	**-**
4	95.0	75.0	67.5	**79.17**
5	90.0	80.0	85.0	**85.00**
6	85.0	-	-	**85.00**
7	82.5	-	-	**82.50**
8	90.0	45.0	67.5	**67.50**
9	97.5	-	-	**97.50**
10	-	-	-	**-**
11	60.0	-	-	**60.00**
12	-	-	-	**-**
13	75.0	77.5		**76.25**
14	52.5	-	-	**52.50**
15	-	-	-	**-**
16	-	-	-	**-**
17	72.5	-	-	**72.50**
Mean	**79.38**	**70.83**	**80.50**	**76.56**
SD	**13.82**	**14.72**	**12.92**	**12.54**
N	**12**	**6**	**5**	**12**

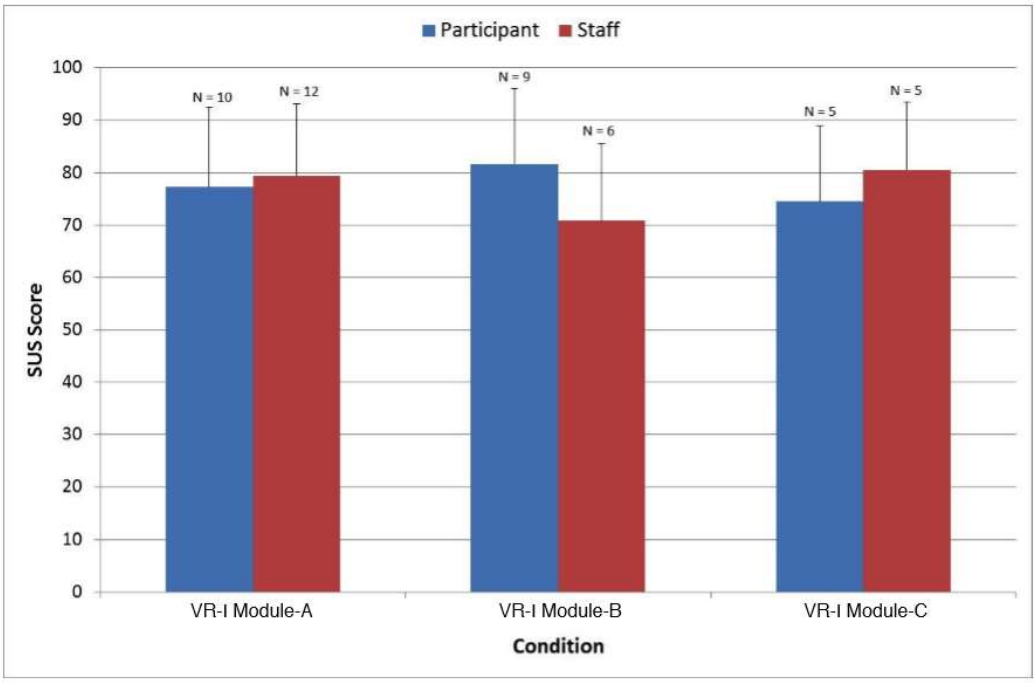


Figure 3.5: Mean SUS scores for the three VR-I Module conditions, the error bars indicate the standard deviation from the average values

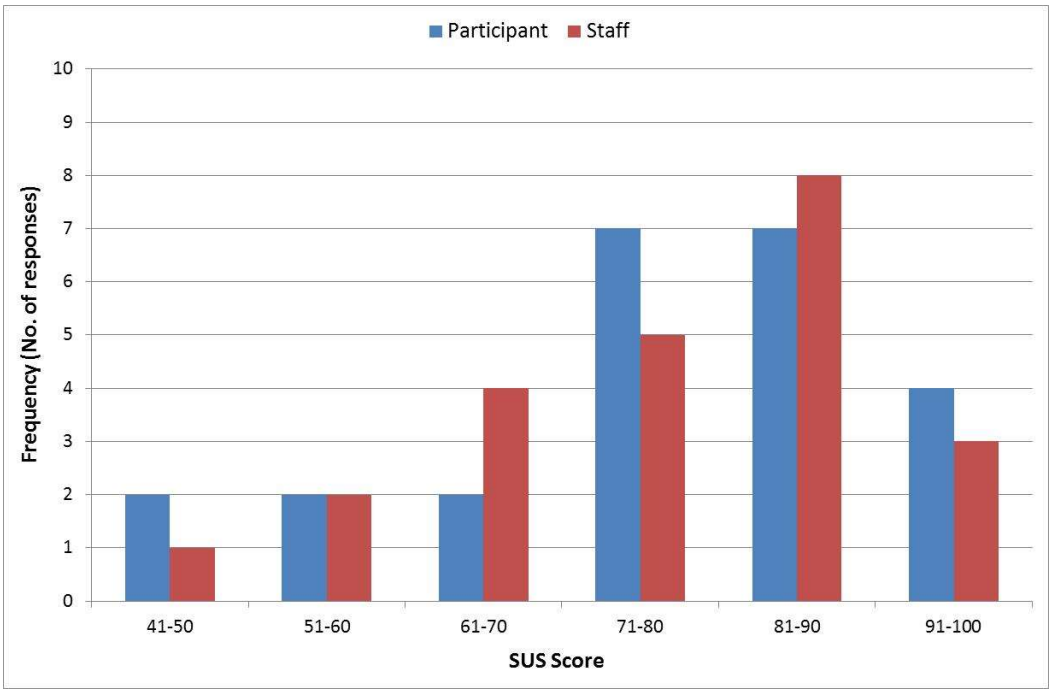


Figure 3.6: Frequency distribution of SUS ratings

3.5.3 Participant feedback

3.5.4 Estimated usage times

Estimated VR-I Module usage times are shown in Table 3.3. Values for estimated times spent watching the VR-I Module as opposed to listening to the VR-I Module were exactly the same for all participants and for all conditions. It suggested that the values may be an estimation of the duration of time that the VR-I Module system was simply on rather than being consciously engaged with.

Mean values suggested an increase in usage time from the VR-I Module Conditions A-C. However, conditions B and C mean values were greatly inflated by large values by single individual participant data (participants #14, VR-I Module-B and participant #5, VR-I Module-C). Adjusting for these anomalous values (by exchanging it for a value equal to the participant's mean across the other two conditions) reduced the VR-I Module-B and C group mean values to similar to the condition A. As such, the data suggested that there was no change in average estimated usage times between the three VR-I Module conditions.

Table 3.3: Participant estimated usage times

	Watching time (mins)			**Listening time (mins)**		
ID	**VR-I Module-A**	**VR-I Module-B**	**VR-I Module-C**	**VR-I Module-A**	**VR-I Module-B**	**VR-I Module-C**
1	60	120	90	60	120	90
2	-	60	-	-	60	-
3	120	-	-	120	-	-
4	30	60	120	30	60	120
5	30	60	240	30	60	240
6	75	-	-	75	-	-
7	-	-	-	-	-	-
8	60	30	60	60	30	60
9	120	120	-	120	120	-
10	-	-	-	-	-	-
11	120	120	-	120	120	-
12	-	-	-	-	-	-

13	90	60	15	90	60	15
14	120	360	-	120	360	-
15	30	-	-	30	-	-
16	-	-	-	-	-	-
17	120	-	-	120	-	-
Ave	**81**	**110**	**105**	**81**	**110**	**105**
SD	**39**	**99**	**85**	**39**	**99**	**85**

Table 3.4 shows a frequency count of participants estimated usage times within 30-minute duration groups. Overall, for the 26 recorded usages there was a fairly even distribution of counts across the different time duration groups. The modal usage duration was up to 120 minutes with a count of 9, though this was not significantly greater than any other duration group. Between the different VR-I Module groups the distribution of counts did not significantly change. It must be noted that the number of usage counts for each condition (N) reduced with each subsequent condition. While this includes instances of participants being unable to continue in the study, it also includes instances where participants voluntarily withdrew as they no longer wished to take part, which could be argued to equate to a usage duration of 0.

Table 3.4: Frequency count of estimated usage times

Duration (mins)	**VR-I Module-A**	**VR-I Module-B**	**VR-I Module-C**	**Total count**
up to 30	3	1	1	**5**
up to 60	2	4	1	**7**
up to 90	2	0	1	**3**
up to 120	5	3	1	**9**
over 120	0	1	1	**2**
N	12	9	5	**26**

3.5.5 Participant feedback comments

Table 3.5 displays the patient feedback captured during the use of the VR-I Module. The comments have been assigned a colour code based on Negative, Neutral or Positive responses (Figure 3.7). The raw comments were captured by research physiotherapy / nursing staff who were part of the study and carried a current certificate of good clinical practice. The data was reviewed and assigned a colour code independently by two assessors, the researcher, and chief medical investigator. The coded data was compared, with any differences discussed to formulate a complete and consistent table.

	Negative or critical comments indicating improvements required
	Neutral or mixed with some positive and some negative comments
	Positive comment

Figure 3.7: Colour coding of participant feedback comments

The negative comments predominantly revolved around participants feeling bored, specifically in the VR-I Module condition A whereby the participant has no active interaction with the prototype. There were two critical comments on realism of the graphics and two critical of the control interface (Genius ring mouse). There were also another two reports of the system not working or crashing. The positive comments included, easy to use, interesting, relaxing, and comments that visitors also liked the systems. Some participants also recommended that the VR-I Module should be used by others.

Table 3.5: Participant feedback comments

ID	VR-I Module-A	VR-I Module-B	VR-I Module-C
1	Found it a bit boring. Was sleepy so fell asleep using VR-I Module.	Ring mouse was too tight. Thumb-stick would be better. Patient should be able to control the time of day.	Too much shrubbery hampered the view. Went dark too quickly. Hand ached after use. Parts of the path are too long. Could use different flowers. Parts of the path were too dark. By headland seaview I went off the edge of the cliff on the way to minehead. Map would be useful too.
2	-	Nice to watch, easy to use.	-
3	Very relaxing and pleasant.	-	-
4	Nothing to add. Not too intrusive.	Was able to use the thumb mouse easily. Was able to change views easily but liked the view from the beach by the sea the best. No problems with sound.	Would recommend to others. Would have it again. Could make it more interesting.
5	I liked watching the VR-I Module as it made me fall asleep quickly and nothing to worry about.	I think the prototype should be used more often because it helps with sleeping.	Good idea for relaxing and to help with sleep.
6	Needs to be a video which is more realistic. Graphics were poor – not very realistic. Rubbish. Doesn't want to use it again.	-	-
7	-	-	-
8	Remembers it being on. Easy and nice to watch. Was a bit disorientating when I woke up and it was on.	Boring. Easy to use thumb controller. Fell asleep easily.	Easy to use. Enjoyed being able to explore Wembury. A bit boring thought. Woke up when the system crashed and desktop came on., increasing light levels in the bed space.
9	Relaxing to watch. Nice change from watching TV. Friends like it.	Loved the ring mouse. Better than the video version. Would like activities to do.	-
10	-	-	-
11	Boring after 5 minutes. Not high enough.	Patient is disappointed she can't use it tonight as being transferred to ward.	-

12	-	-	-
13	Interesting.	Good – quite like it.	Programme froze, just stopped working.
14	Didn't work.	Didn't think controller was very good, didn't work reliably.	-
15	No feeling towards equipment, when asked if it would work "possibly".	-	-
16	-	-	-
17	Quite boring.	-	-

3.5.6 Patient follow up

Feedback from medical staff (Table 3.6) supervising the patient was gathered with respect to three questions (Figure 3.4.2); data was captured between day 9 – 12 following condition testing.

Table 3.6: Patient follow up feedback

ID	Feedback on process	Further comments	Recommend participation	Further contact
1	RIP			
2	PATIENT TOO UNWELL			
3	RIP			
4	Enjoyed taking part	None	Yes	Yes
5	Enjoyed taking part. Not intrusive. Interested in hearing about results	Continue developing VNT system	Yes	Yes
6	WITHDREW FROM STUDY – PATIENT REQUEST			
7	WITHDREW FROM STUDY - DELIRIUM			
8	DISCHARGED HOME			
9	No problems. Something to do as was bored on the ward (ICU)	More interactive activities	Yes	No
10	-	-	-	-
11	DISCHARGED HOME			
12	-	-	-	-
13	DISCHARGED HOME			
14	Did enjoy, first video made me relax, but for second night worked intermittently only	It was difficult but cool	Yes, if they are willing to try	Yes
15	WITHDREW FROM STUDY – PATIENT REQUEST			
16	WITHDREW FROM STUDY – PATIENT DETERIORATED			
17	WITHDREW FROM STUDY – PATIENT REQUEST			

Based on the 17 participants who entered the REVERE-sleep study, there were 4 positive responses, 2 passed away, 3 exercised their right to withdraw from the study, 3 withdrew due to illness, 3 discharged home and there were 2 non-responses.

3.5.7 Staff feedback

Feedback from medical staff (3.4.3) supervising the patient was gathered with respect to six questions. As with the SUS data (3.4.1) there was a concern that no details have been recorded regarding the authors of these comments (staff members), so as to be able to cross reference between conditions. Staff feedback comments generated from these questions are shown in tables 3.7 - 3.12. As with the participants' feedback, the comments have been colour coded (Figure 3.8).

	Negative comment with regards the VR-I Module prototype
	Neutral comment where the member of staff maybe unsure. It may also highlight a mixed comment with both positive and negative opinions if the VR-I Module prototype
	Positive comment with regards the VR-I Module prototype

Figure 3.8: Colour coding of staff feedback comments

Did the patient seem relaxed whilst using the VR-I Module? (Table 3.7)

Responses were mostly positive with only two giving a negative comment, one of which (participant 15, condition A) was probably independent of the VR-I Module.

Did the patient seen uncomfortable whilst using the VR-I Module? (Table 3.8)

Responses were mostly positive. One participant had issues with the controller and the positioning of the display. There were two other reports of discomfort, but no specifics as to the cause.

Was the VR-I Module easy to use? (Table 3.9)

There was only one negative comment with regards the control interface and the position of the display being too close. This corresponded with the discomfort reported in the previous question (Table 3.8).

Did the VR-I Module cause you or the patient any problems, side effects or adverse events? (Table 3.10)

The question generated 5 comments addressing concerns regarding the size and bulk of the VR-I Module. There was one instance of a change in display lighting waking a patient. There was also an instance of motion sickness and hand fatigue reported by the participant – and this was related to discomfort and ease of use as highlighted in Tables 3.8 and 3.9.

Did you feel the patient benefited from using the VR-I Module? (Table 3.11)

The response to this question was met with the most varied answer. There were 10 negative responses by which the staff member thought the system was not of benefit to the patient. Conversely there were 8 comments that suggested a positive benefit and a further 5 were unsure. It may be that this question was difficult for staff to reply to, more so if they are not monitoring the patient at all times.

Would you recommend the VR-I Module for other patients? (Table 3.12)

Only 1 comment suggested that the staff member would not recommend the VR-I Module, as they were unsure of its benefit. Though the response was for the condition-A (static viewpoint) and subsequent (more interactive) conditions produced positive recommendations from staff for the same patient. Interestingly, of the 10 negative comments with regards the benefits of the VR-I Module (see Table 3.11) only one remained negative with regards recommending it for other patients. The 8 that were negative on the benefits were positive in recommending it for other patients, whilst 1 was unsure.

Table 3.7: Staff feedback on perceptions of patient relaxation

Did the patient seem relaxed whilst using the VR-I Module?			
ID	VR-I Module – A	VR-I Module – B	VR-I Module - C
1	Yes, asleep. Waking on and off.	Yes, was managing to pan around and flick between views without stress or frustration. Although initially saying it was boring, he appeared to be captivated with the views and panning around for quite some time. Patient preferred to watch daytime rather than dusk.	Sort of. Liked the views/nice colour but when we navigated – started to feel seasick but liked the colour and graphics. Became more lively if anything discussing the VR-I Module and reasons for it.
2	Yes, but some factors Caused disruption, such as suctioning.	Yes, he was relaxed when watching it and said it was nice.	Unable to assess as the patient appears uninterested.
3	---	---	---
4	The patient was usual self with the VR-I Module in the back-ground. Patient was doing his routine, watching TV, occasional glances at the monitor. A shame he can't hear the birds because the TV is too loud.	Relatively. I think it has provided distraction from his current situation and surroundings for a short period of time.	Yes, the patient appeared very relaxed and said he quite enjoyed the experience.
5	---	Yes, however was already sleeping prior to use.	---
6	Yes, calm and settled whilst video was playing.	---	---
7	Yes.	---	---
8	She slept throughout.	I think so.	Was not interested in the system.
9	Yes.	---	---
10	---	---	---

11	Yes.	She was calm in bed and dozing on and off whilst this was on. Not really sure to say this was from the effect of this. Asking the patient she states that it did not make her relax.	---
12	---	---	---
13	Yes.	Yes, (see other comments).	
14	No, she wasn't	---	---
15	watching/looking at it. The patient was aggravated by his tracheostomy.	No change.	---

Table 3.8: Staff feedback of perceptions of patient discomfort using the VR-I Module

Did the patient seem uncomfortable whilst using the VR-I Module?			
ID	VR-I Module – A	VR-I Module - B	VR- I Module - C
1	No	No. Said that the finger clicker was a bit tight on his finger, patient does have large hands and initially his thumb got tired but this was resolved by swapping hands. He said he got eye strain from looking at the screen. Overall though, appeared comfortable.	Felt screen too close. Perhaps have a different handset – thought a steering wheel might be easier and a longer lead.
2	Not sure as patient also had a sleeping tablet to calm him down.	No, he didn't.	Unable to assess.
3	---	---	---
4	No, patient is comfortable, still doing his routine, not bothered by the monitor.	No.	No.

5	---	No.	---
6	No.	---	---
7	Yes.	---	---
8	No.	No.	Was offered the control to move around but did not use.
9	No.	---	---
10	---	---	---
11	No, not at all. She said it had gotten boring towards the end.	No.	---
12	---	---	---
13	No.	No signs of discomfort.	---
14	She was uncomfortable,	---	---
15	Only due to his tracheostomy.	Yes.	---

Table 3.9: Staff feedback on VR-I Module ease of use

Was the VR-I Module easy to use?			
ID	VR-I Module – A	VR-I Module – B	VR-I Module - C
1	Yes.	Patient stated he liked the "stroking motion" used with the finger clicker to pan around and was able to do this quite well. Was easy for me to turn on, load and operate the system and turn off. Patient asked for me to change the time between day and dusk and it was easy to discover how to do this.	Found remote easy but needs a longer lead as the screen too close and large (felt sea sick) if longer lead/wireless could move further away. Hand ached after use. Found it easy to use as a system.
2	Yes, it is easy to use and there is a guideline at bedside.	Yes, it was very easy to use and navigate through it as I did this for the patient and involved him.	Yes.
3	---	---	---

4	Yes, the instruction given by the researcher was very simple and there is written instruction.	Yes, it's essentially turning on a laptop and running a programme which most of us are familiar with these days.	The patient seemed to find it easy to use. Unfortunately I didn't have time to use it myself so am unable to comment.
5	---	Yes.	---
6	Yes.	---	---
7	Yes.	---	---
8	Yes.	I haven't tried playing with the system i'm too busy.	---
9	Yes.	---	---
10	---	---	---
11	Didn't have to use it, just unplugged it at the end.	Patient states it is easy to use but still unsure of what it is all about.	---
12	---	---	---
13	Yes.	I merely had to switch it off and move to a discrete location – not difficult.	---
14	It was on when arrived and it turned itself off – so yes.	---	---
15	Yes.	Yes.	---

Table 3.10: Staff feedback on the problems, side effects or adverse events using the VR-I Module

Did the VR-I Module cause you or the patient any problems, side effects or adverse events?			
ID	VR-I Module – A	VR-I Module – B	VR-I Module – C
1	None.	None.	Made him feel sea sick, initially and occasionally throughout – spent probably 1.5hours watching happily and navigating routes. Hand aching

			after use – felt he would like a steering wheel.
2	None.	No problems. The patient himself couldn't use the navigator but was engaging the screen.	None.
3	---	---	---
4	None for both patient and nurse.	None.	The only issue was the size of the system, as the room is already full of other equipment - also, not that easy to manoeuvre with the large base.
5	---	None.	---
6	None.	---	---
7	None, it was very positive, patient felt sleepy.	---	---
8	None.	No, just space consuming especially as patient is on cvvh and RO and watching TV.	Screen went off in the middle of night and the computer screen – bright light – woke patient up. Quite big for bedspace.
9	None.	---	---
10	---	---	---
11	No not really, other than being a bit bulky.	None.	---
12	---	---	---
13	None.	None.	---
14	Found it to be in the way, very large piece of equipment.	---	---
15	None.	None.	---

Table 3.11: Staff feedback on patient benefits of using the VR-I Module

Did you feel the patient benefitted from using the VR-I Module?			
ID	VR-I Module – A	VR-I Module – B	VR-I Module - C
1	No – sleepy started video at 20:00.	Yes, patient seemed actively interested in the views and talking about places the views reminded him of and places he had visited. He particularly was impressed with the sky and cloud formations. Fell asleep 1.5 hours into using it.	Yes, even though he felt sea sick/need a longer lead. He enjoyed the interactivity – wide awake throughout discussing the VR-I Module. Didn't fall asleep as night fell whilst using the VR-I Module but slept well afterwards.
2	I think it will benefit somehow, patient 2 seems to have calmed a bit after putting on the VR-I Module. Like instead of talking about his NIBP cuff, he was looking at the screen.	He engaged in the system but unsure whether he benefitted as he was unable to use the navigator.	Not on this shift as the patient appears to be uninterested. But i'm sure in time it will benefit the patient.
3	---	---	---
4	I think it will be beneficial for the patient in the long run. At present it was only the 1st night that the patient used the VR-I Module so I can't say the benefit at present.	Patient doesn't think he does. However, I believe having some form of outdoor interaction is beneficial for this type of patient especially. Having been isolated in a room with very little to see must be affecting him negatively, he clearly liked some of the scenes he could choose from.	He seemed to quite enjoy using it and certainly slept better than previous night.
5	---	Patient fell asleep prior to using the VR-I Module therefore no benefit was seen.	---
6	No, patient slept easily.	---	---
7	Yes, patient asleep in 30mins from starting.	---	---

8	No, she slept the whole time it was on.	I'm not sure, she slept most of the night. Not even aware of VR-I Module at bedside.	Patient stated she found it boring and would rather watch TV.
9	Not interested, wanted to watch films on ipad.	---	---
10	---	---	---
11	Yes, she seemed to be interested in watching it.	I do not think so. Patient was not concentrating on it at all. Talking to the patient she does not see any benefit to her. She is not a TV person, may benefit someone who has interest in watching such programmes. As for me a staff I do not really know what I am watching for.	---
12	---	---	---
13	Yes, patient claims that the VR-I Module have helped him to relax.	He went to sleep whilst watching it. When awake patient seemed engaged; changed scene from time to time.	---
14	No, patient restless. VR-I Module did not calm patient.	---	---
15	Patient didn't look at the screen much.	The patient found it boring.	---

Table 3.12: Staff feedback on recommending future use of the VR-I Module

Would you recommend the VR-I Module prototypes for other patients?			
ID	VR-I Module – A	VR-I Module - B	VR-I Module – C
1	Unsure of what benefit it would have.	Although the patient was alert and orientated, he seemed to forget it was a computer generated programme and was convinced he was looking at Glastonbury. Commented that "some parts of this are painted" and needed reminding it was computer generated. Therefore, might Cause some confusion in other patients. I definitely think VR-I Module will improve patient experience, reduce sensory deprivation and distract patients from their clinical environment in a positive way.	Yes, although it needs to be used selectively. I don't think it would suit all e.g. not all connect with interactive /computer technology. It has been such a positive response for this patient – as he seemed brighter when using this and talking to staff – I also felt that he enjoyed taking part in this trial and really wanted to give positive feedback. So on that basis I would.
2	Yes, especially long term patients in the side rooms.	Yes, I would recommend this as the scenery is very relaxing but may not be to everyone's taste.	Yes. I am sure some of the patients will benefit from this system, specifically patients who are being nursed in the side rooms.
3	---	---	---
4	Yes, especially for long term patients. Videos are so relaxing and realistic.	Yes, as mentioned I think this would be useful for long term patients who have had long periods of isolation, along with the use of other conventional methods.	Yes – I think it could be very beneficial especially for patients in side rooms or in parts of the unit that lack natural daylight.
5	---	Yes, very interesting to see results of this.	---
6	Yes.	---	---

7	Yes, but it is a bit bulky and can get in the view of the patient.	---	---
8	Yes, if they were awake when it was started/stayed awake when told it was being put on.	I don't know, probably for the patients who are in the side room.	Some patients may like it, may get boring though after a day or so.
9	Yes.	---	---
10	---	---	---
11	Yes, I think it's a good idea.	As this is new I would recommend it to other patients so we get different views. The more patients we get with different views the more precise our data will be and enable us to make a comprehensive result and outcome.	---
12	---	---	---
13	Yes.	Have no issues with its use but from brief exposure here unable to comment on its effectiveness.	---
14	It may work, yes I would recommend it.	---	---
15	Yes, might be more useful if there was sound to accompany the pictures.	Yes.	---

3.6 Discussion

The current chapter introduced the VR-I Module prototype into an ICU bed-space and into the REVERE Sleep study. The aim of the study from an ergonomic/usability perspective was to determine if the developmental modifications made based on feedback from critical care staff and patients performed favourably or generated negative feedback. The SUS data suggested that both participants and staff rated the VR-I Module prototype as having relatively good

levels of usability, where the majority of participants felt that the prototype was easy to use, interesting, relaxing, and had a positive effect on mood. A question could be asked as to the reliability of that data collection, firstly in terms of the level of trust in staff members collecting data without bias, and secondly the accuracy in the patient's responses the following morning, due possible levels of medications, mental capacity etc. Only staff members who had direct knowledge of the study (consultants, senior physiotherapists, nurses) and who had been briefed fully on how to use the prototype (software and hardware) were allowed to collect the relevant data. In terms of the patient, screening during recruitment (3.3.2) looked for active delirium, severe cognitive impairment, and for active infections requiring high levels of medication, one or more would fit the exclusion criteria and therefore non approach. Patient who were conscious and able to communicate and scored -1 to +1 on the Richmond Agitation scale (-1 Drowsy; 0 Alert and Calm; +1 Restless) met the inclusion criteria.

A large proportion of participants experienced no adverse effects whilst using the system, however there were two instances of adverse effects recorded by participants concerning motion sickness and disorientation whist navigating through the virtual environment. There was a minor element of participants who found the interaction levels boring, this was mainly being targeted towards the VR-I Module, Condition A, which was the single static view with no interface input. There were reports based on staff feedback that the VR-I module was too bulky of the ICU bed-space, but in contrast most of the staff members would recommend the prototype for future patient use.

An issue arose as to the validity of the data collection techniques. The raw data was captured by research physiotherapists and nurses who were overseen by both the chief clinical and principal investigator at the QEHB. The data was then independently colour coded by both the researcher and clinical investigator, and then compared, any discrepancies were looked at an

amended based on the researcher's judgement. The weakness of this method was that the data can be miscoded or coded to reflect a subjective outcome. A possible solution would be to employ grounded theory. Grounded theory (Glaser & Strauss, 2017) comprises of the collection and analysis of data, the theory is 'grounded' in actual data, meaning the analysis and development of theories happen after data collection. To initiate the grounded theory process, the area of interest must be identified, any preconceived theories must be avoided with attention focused only on the data. Theoretical sensitivity must be applied, together with an awareness of subtle messages and meanings within data. Data collection may take the form of both qualitative or quantitative or a combination of both. Data collection often includes participant interviews, with open ended questions and observational studies / focus groups.

The methodology for data collection employed during the REVERE-Sleep study consisted of SUS (3.4.1), patient feedback (3.4.2) captured 9 – 12 days' following testing, and staff feedback questionnaires (3.4.3) that gauged both patient and staff reaction to the prototype. The subsequent studies InspireVR (Chapter 6) and VeloVR (Chapter 8) evolved the data collection to incorporate series of non-validated questionnaires exploring patient demographics, device familiarity / experience, and perceived technology acceptance prior to any exposure to the prototypes. A modified version of the SUS (6.4.5) was distributed upon completion of the testing, together with the capture of qualitative feedback, this time taken on the last day of the trial reducing the time delay as stated above.

The study sought from an ergonomic perspective to determine if the developmental modifications based the feedback gathered from critical care staff and patients could form the basis of a new series of prototypes also to be used within the ICU. The following chapter (4) reviews the usage of the VR-I Module V2 by means of a focus group consisting of care professionals who had be exposed to the prototype during the REVERE Sleep study.

4. Prototype Design Conceptualisation – Next Generation VR-I Module

4.1 ICU Focus Group

The VR-I Module-V2 prototype that underwent ICU testing during the REVERE-Sleep study (Chapter 3) was designed and built adhering to the ISO 9241-210:2010 (Iso.org, 2010) standard for Human-centered design processes for interactive systems (Figure 4.1). The end of the study fell between the "Evaluate design against requirements" and "Understand and specify the context of use" phases.

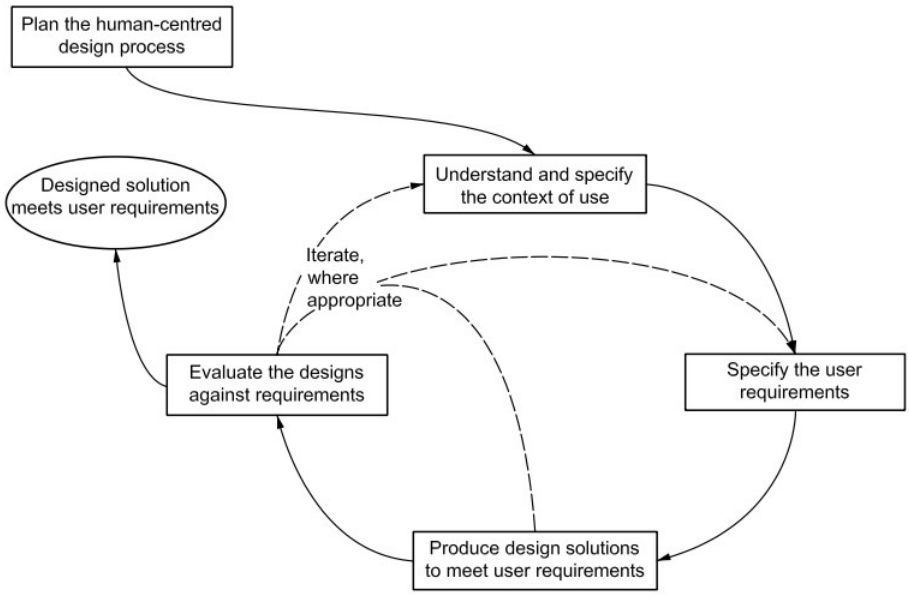


Figure 4.1: Human-centered design processes for interactive systems

(ISO 9241-210:2010)

ISO (International Standards Organisation). BS EN ISO 9241-210:2010 – Ergonomics of Human-System Interaction; Part 210: Human-Centred Design for Interactive Systems. BSI Group, 2010.

In order to evaluate the system and formulate a strategy for the next iteration of prototype VR-I Modules (Sections 5 and 7), a focus group was conducted within the ICU. The focus group was made up of eleven participants consisting of consultants, nursing staff, and physiotherapists that had all been in contact with, or at least had observed the REVERE-Sleep prototype at some point during the testing period.

The focus group set out to identify from an ergonomic perspective if the current REVERE-Sleep prototype was fit for purpose within the operational environment of an ICU bed-space and fit for purpose from a patient-system interaction viewpoint. A number of possible hardware and mounting solutions together with display technologies were examined with the aim of narrowing down the design for the next iteration of the prototype system. A copy of the focus group literature can be found in Appendix 4.1.

4.1.2 Focus Group Summary



Figure 4.2: Example of bed-side mounted computer mount

https://www.dhresource.com/0x0s/f2-albu-g3-M01-FD-13-rBVaHVZDWAiAMfDqAAExM6tSAwo388.jpg/laptop-360-portable-stand-adjustable-

The consensus found that the current REVERE system performed well in terms of its ability to be wheeled in and wheeled out of a patients' bed-space as a self-contained unit, however issues were raised as to the prototype's physical size and manoeuvrability during emergency situations, therefore a system smaller in stature was deemed a positive step. A number of mounting options were presented, some represented ideal world solutions and others were actual real-world solutions. Overall, the leading real-world solution for a possible next

generation of REVERE prototype was a rig that that could be retrofitted to the side of standard issue ICU bed frame (Figure 4.2), the second option was a bolt on addition to the existing hospital tray table (Figure 4.3).



Figure 4.3: Example of hospital tray table

http://www.hospitaldirectmedical.com/wp-content/uploads/2014/04/1-Hill-Rom-Patient-Mate-Overbed-Table-Model-634-2.jpg

An integral part of the iterative design process for the next generation of REVERE prototypes was the need for early proof of concept systems to be developed to identify if conclusions drawn in the focus group correlated to real world implementation and validation.

4.2 Early Prototype Proof of Concept Designs

Following on from the focus group a series of prototypes designs were worked through, with the aim of narrowing down on a final viable option for use within the ICU. The overriding requirement for all of the prototypes, both proof of concept and final build was that it followed the idea of using Commercial off-the-self (COTS) technologies. The use of COTS technologies allowed for components to be sourced without the need to commission custom made solutions, which proved advantageous as it allowed for a rapid and more cost effective design/build cycle.

4.2.1 Spirometry Proof of Concept, Prototype A

The idea of creating a prototype that was self-contained and easily mountable to a hospital tray table led to the modification of a clamp based angle pose mount (Figure 4.4) that featured a magnetically mounted digital spirometer. The major failure identified was that the display was too small (9.7inch) and in order to increase the size would increase the overall weight which in turn would cause the mount to fail.

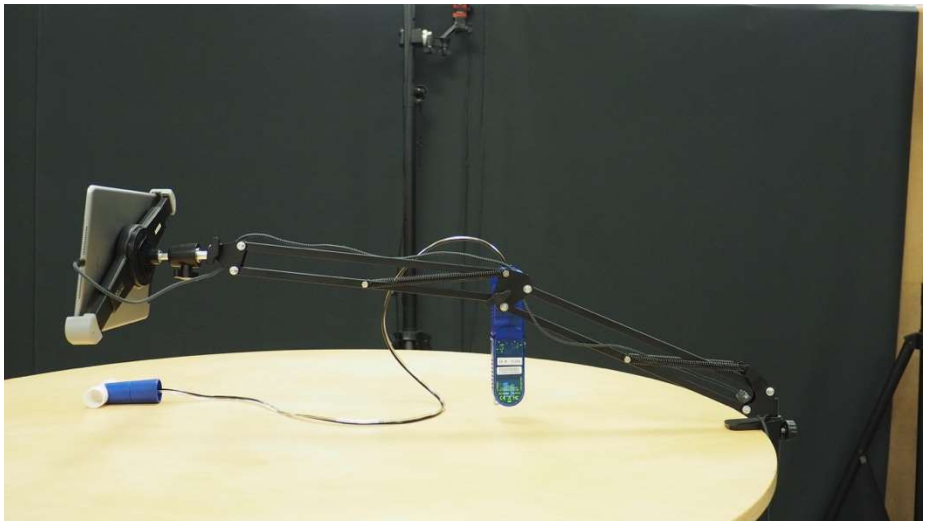


Figure 4.4: Proof of concept, angle pose mount

4.2.2 Spirometry Proof of Concept, Prototype B

A second idea was to employ a goose neck (Figure 4.5) floor mounted solution, this fared well but had the same issues with the display size. The base plate was also excessively heavy which could lead to health and safety implications whist being manoeuvred between patients.

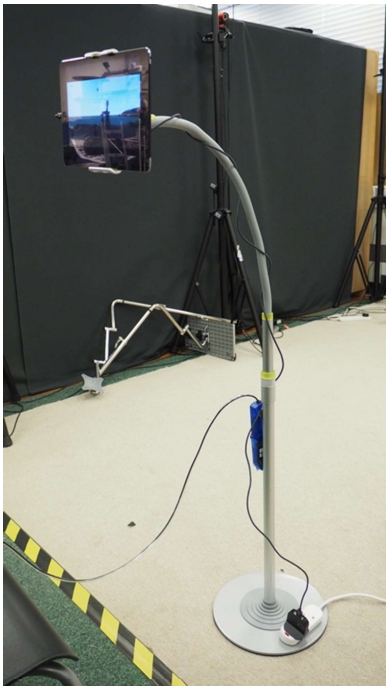


Figure 4.5: Proof of concept, goose neck floor mount

4.2.3 Spirometry Proof of Concept, Prototype C

The third design, was an evolution of Prototype A, whereby a stronger table mounted solution was created that would be able to support the required larger display. The test for the prototype took place (Figures 4.6 and 4.7) within the ICU at the Queen Elizabeth Hospital and was designed to evaluate the findings of the focus group.



Figure 4.6: Spirometer Prototype C being evaluated within the ICU, QEHB

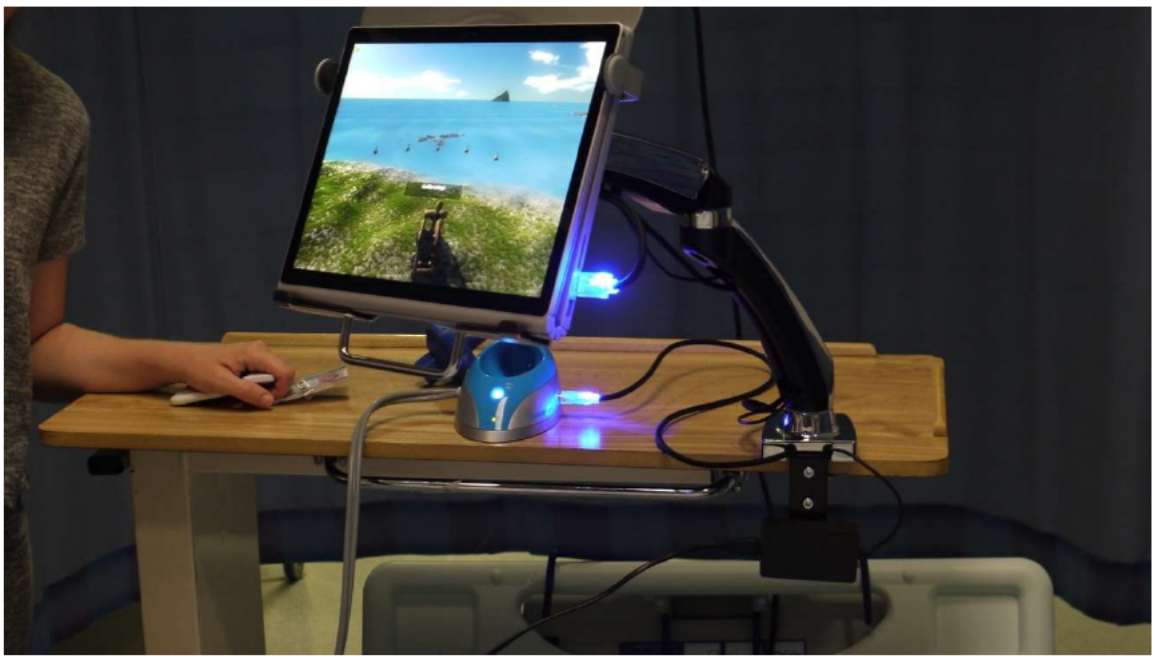


Figure 4.7: Spirometer Prototype C mounted on to a standard NHS issue hospital tray table

The prototype met all the requirements for a table mounted solution as concluded in the focus group feedback, although when presented to clinical staff they were hesitant to adopt due to the amount of space taken away from the patient and that they often have drinks or personal effects that could interfere with the operation of the system.

4.3 Summary

Based on the development of the proof of concept prototypes it became apparent that a self-contained trolley mounted system would need to be developed that could be wheeled in and out of the bed space and adjusted to fit the patient in either a seated (Figure 4.16) or bed bound position (Figure 4.17). During the evaluation of Prototype C, a throwaway idea (Figure 4.8) based on an evolution of Prototype B was brought along to see how it might integrate within the bed-space and to act as an alternative option from the clamp based mounts.



Figure 4.8: Trolley mount system within a bed-space, ICU QEHB

4.4 InspireVR Prototype Design

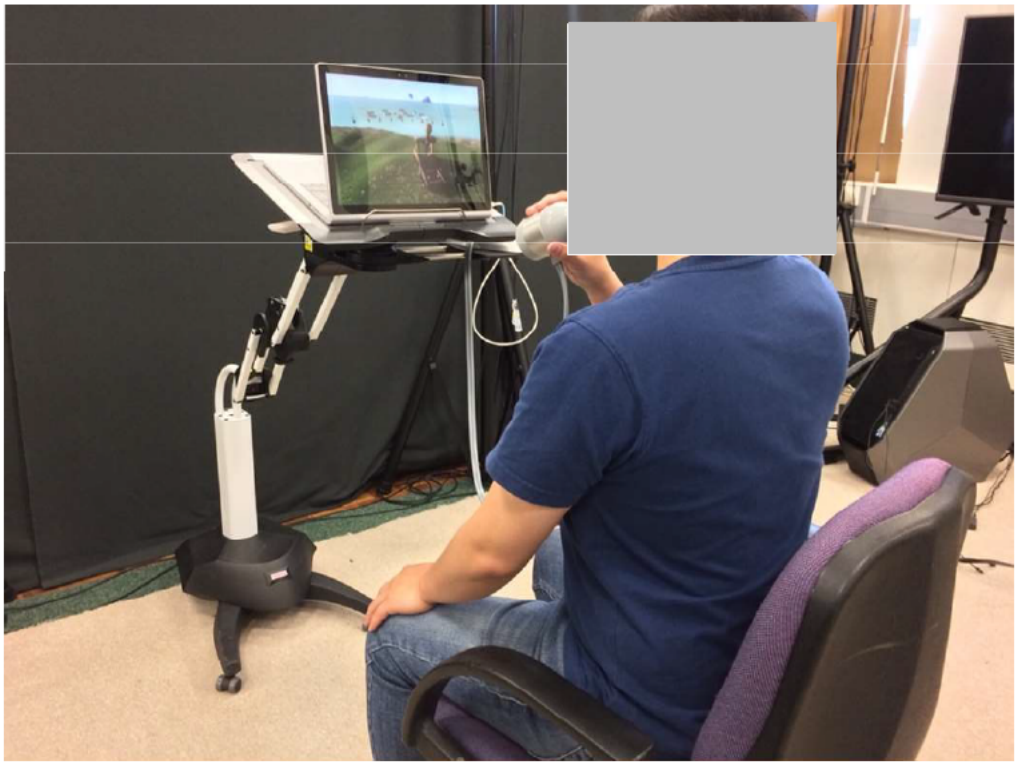


Figure 4.9: Basic InspireVR prototype undergoing early in-house testing

The new idea for the spirometry prototype also came with a new name for the study it was to enter into, InspireVR was chosen. The basis for the new prototype started out as a simple domestic laptop (Figure 4.9) stand, a number of modifications were added to make it suitable for use within a medical environment.

One of the main issues with regards making the system ICU friendly was the need for cable management, the system was designed to function via a single power plug, to achieve this, cable glands and a 3D printed internal laptop power adapter mount was installed internally in

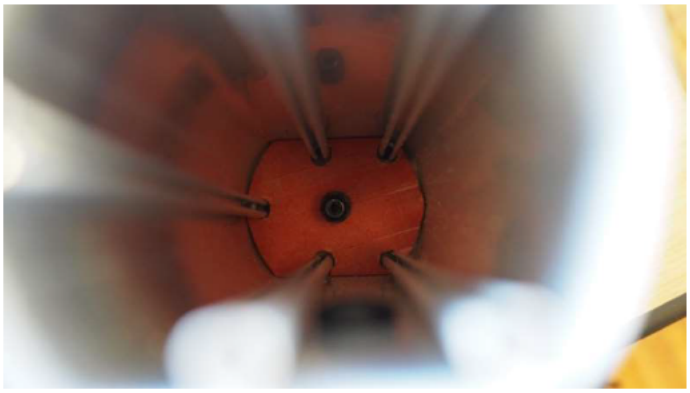


Figure 4.10: 3D printed bracket to support a laptop power supply

the main vertical frame of the stand (Figure 4.10, 4.11). Dry ballast (Figure 4.12) and uprated locking casters were also added to the lower section of the frame to provide greater stability when the stand was at maximum reach.

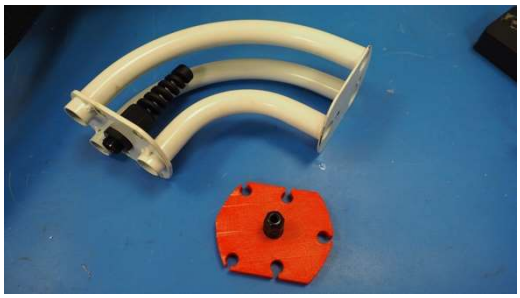


Figure 4.11: Cable modifications were added to provide safe passage for cabling



Figure 4.12: Uprated locking casters were added to provide greater stability and better traction on polished hospital floors

The laptop used for the prototype was a 2017 Microsoft Surface Book 2 (Figure 4.13). It was selected as (at the time of testing) it was the only 2in1 system that provided a dedicated NVidia

GPU that was necessary to run the complex virtual spirometry software and 3D runtime. The display was able to be detached, flipped and re-docked so that the patient would benefit from an unobstructed view of the display.



Figure 4.13: Microsoft Surface Book PC with display flipped

The system featured a Vitalograph Pneumotrac (Model 6800) digital spirometer (Figure 4.14), the spirometer was a medically certified device that was autoclave compatible for hygiene and featured a single use bacterial viral filter, documentation for hygiene and cleaning of the Pneumotrac is located in Appendix 4.2.

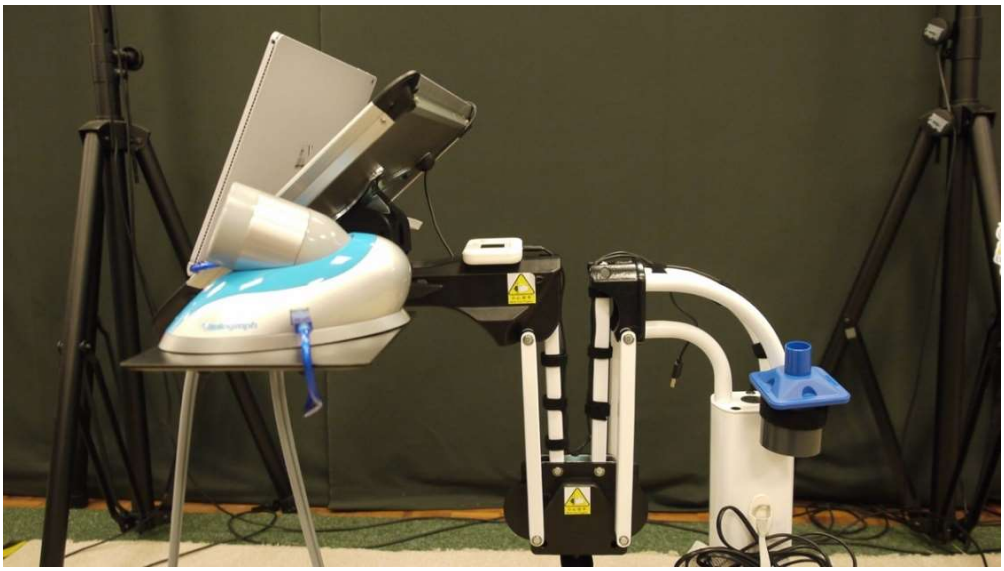


Figure 4.14: Image of the Vitalograth Pneumotrac digital spirometer and disposable filter holder mount on the REVERE Breathe Prototype

The InspireVR prototype required an internet connection during the start-up / authentication phase of the software, the hospital employed a secured network for medical equipment but it was deemed unwise to utilise this, a Mi-Fi dongle (Figure 4.15) was installed with a cellular data sim to provide a stand-alone approach.



Figure 4.15: Mi-Fi dongle installed on the InspireVR prototype

The advantage of the InspireVR prototype was that it was able to be adjusted for either a seated (Figure 4.16) or a bed bound (Figure 4.17) patient which would provide an element of flexibility not seen with clamp mounted solutions.

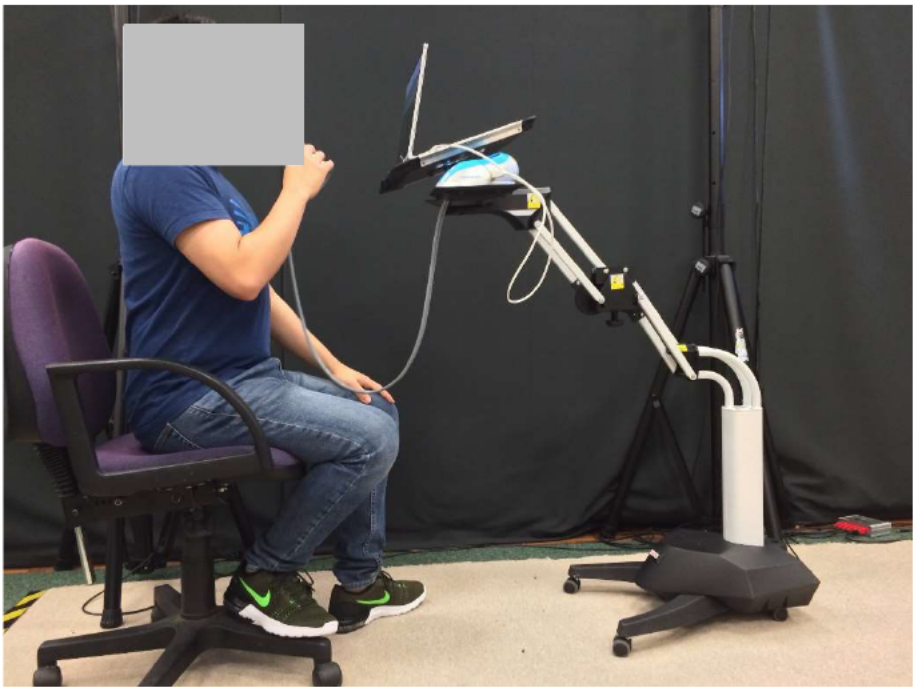


Figure 4.16: The InspireVR prototype adjusted for seated use

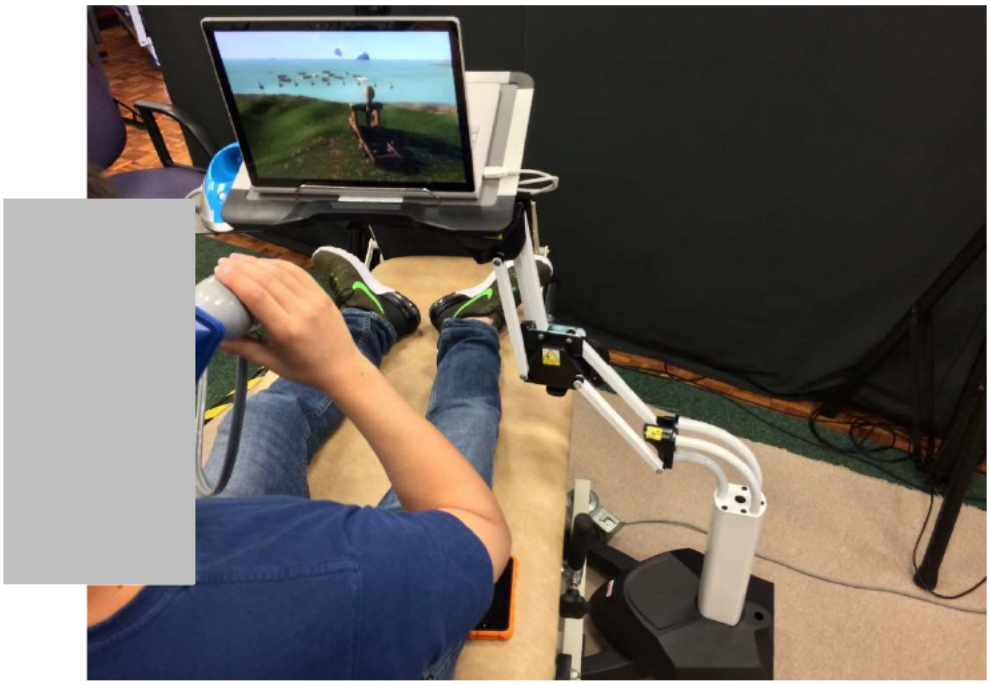


Figure 4.17: The InspireVR prototype adjusted for a bed bound patient

The completed InspireVR prototype underwent an installation test at the QEHB (Figure 4.18) and met with approval by physiotherapists and the senior ward sister.



Figure 4.18: InspireVR system during the final installation test within the ICU, QEHB

The user guide generated for the completed InspireVR prototype (Figure 4.19) that was provided to care professionals at the QEHB can be found in Appendix 4.3.



Figure 4.19: Fully assembled InspireVR prototype

4.5 Medicines & Healthcare products Regulatory Agency approval

Running in parallel to the build of the InspireVR prototype, Medicines & Healthcare products Regulatory Agency (MHRA) approval was sought (MHRA, 2016) with the aim of obtaining an overall CE marking to form a Class 1 medical device. The reason for applying for the MHRA approval in addition to the mandatory ethical approval was the potential of running a nationwide clinical investigation should InspireVR prove successful. A mandatory but overlooked requirement in the application process was to ensure that every component of the system carried a valid CE marking from each manufacturer, and that combination form an overall CE marked device. A major issue arose as the basic stand that was core to the InspireVR

prototype was sourced from a China, and although it met the equivalent standards for use within China its certification was not valid for use within the UK and therefore was not admissible in the MHRA application procedure.

A copy of the InspireVR Device Description can be located in Appendix 4.4
A copy of the MHRA Non CE Mark objection can be located in Appendix 4.5

4.6 Summary

The failure to obtain MHRA approval for the InspireVR prototype was a major setback in the research timeline, all the preliminary proof of concept and final prototype builds were supposed to lead up to the start point of the participant study (Chapter 6). The only course of action was to completely redesign the InspireVR prototype from the ground up by sourcing a CE marked stand that would satisfy all the technological and safety requirements necessary (risk assessment for the InspireVR can be located in Appendix 4.6). A new prototype had to be hastily built, and to ease with the participant testing time frame a second system was also constructed which was to be deployed in another location, the ICU at Birmingham Heartlands Hospital.

The following Chapter (5) details the build of the InspireVR-V2 prototype constructed to satisfied the MHRA requirements and in turn gain approval and permission to debut the system in the InspireVR study. The chapter also looks at a number of minor incidents that occurred during the study period and the modifications made to rectify them.

5. Revised Prototype Design – InspireVR-V2

The failure to obtain MHRA approval (Chapter 4.5) was a major setback in the build phase of the InspireVR system, a new solution was required that embraced the CE marking requirement by the MHRA in order to obtain the much-needed Class 1 Medical Device certification (MHRA, 2016). The following chapter details the rapid ground up redesign of the InspireVR-V2 (Figure 5.6) prototype built as a second attempt to introduce the system to the ICU and to enter into the InspireVR study (Chapter 6).



Figure 5.1: Component form of the revised InspireVR-V2 prototype prior to modification

A number of modifications were made to adapt the basic stand in preparation for operational life within the ICU. The casters were exchanged from non-locking plastic to a locking rubberised set (Figure 5.2) that would provide a stable platform when installed in a bed space especially when the display arm was at maximum reach (Figure 5.9).



Figure 5.2: Uprated locking casters

To accommodate the Vitalograth Pneumotrac digital spirometer a shelf (Figure 5.3) was attached to the main vertical section of the stand via a 3D printed collar, the shelf itself was extendable and was able to hold a Bluetooth keyboard used as a method of data input by physiotherapists.



Figure 5.3: Shelf mounted to accommodate both the digital spirometer and wireless keyboard

The basic mount had no method of accommodating the PC (Figure 5.1) in a vertical orientation, a wall bracket for an LCD display was modified to hold the PC whilst configured as a tablet (Figure 5.4). The power supply was fixed to the rear (Figure 5.5) of the mounting plate to keep the front facing profile as clean possible. The cabling was attached in such a way that if any damage occurred during testing it would be able to be replaced with minimal disruption. Also affixed to the rear of the mounting plate was a Mi-Fi dongle (Figure 5.5) that provided the system with its own internet connection independent of the hospital's Wi-Fi, it was used during the start-up phase of the systems software.



Figure 5.4: Vertical positioning of tablet PC



Figure 5.5: Location of PC power supply and Mi-Fi dongle

5.1 Completed InspireVR-V2 prototype

The following images (Figures 5.6 – 5.9) detailed the completed InspireVR-V2 prototype. Two identical systems were built and deployed, one to the Queen Elizabeth Hospital and the other to Birmingham Heartlands Hospital in preparation for the InspireVR (REVERE Breathe) study.



Figure 5.6: (right) Completed Inspire VR-V2 undergoing soak testing before deployment



Figure 5.7: (above) top view of InspireVR-V2 that illustrates the fitment of the PC equipment



Figure 5.8: (above) Fitment of the Vitalograph Pneumotrac digital spirometer



Figure 5.9: (above) InspireVR-V2 display mount at maximum reach

5.2 Bench Testing

The newly constructed InspireVR-V2 prototype was designed to spend its life undergoing patient testing (Chapter 6) and beyond (Chapter 9). It was imperative the system's integrity was tested to cover all eventualities ensuring that any failures were observed and rectified. The prototype was tested both in-house and by medical subject experts at a series of demonstrations at the QEHB. The demonstrations provided a hands-on opportunity to elicit comments as to usability and technology acceptance as well as to fine tune the system's operational procedures.

Modifications and improvements to the InspireVR-V2 prototype developed to present the spirometer technologies effectively and safely to the bedspace and patient, accommodating a range of patient on-bed postures (with each refinement being verified using standard ergonomics/anthropometric texts, such as the hospital design space components of Panero, J. & Zelnik, M. (1979).

In–house testing saw both software and electronic component testing consisting of sessions that took place every two days for two weeks, with 5 sessions held per day, the procedure included:

- Repeated power-on (boot-up) procedures,
- Repeated power-off (shut-down) procedures,
- Performance and stability during system set-up procedures,
- Performance and stability during periods of active use,
- Performance and stability during a 12-hour period of non-use (i.e. standing idle with the software running),
- Review of fault detection logs (an integral component of the run-time software used in this project).

During the bench testing, the integral logging system reported zero crashes, zero faults, a copy the Internal performance/fault test log can be located at Appendix 5.1.

Following on from the bench testing a detailed Risk Analysis was drawn up to categorise the levels of risk associated with various tasks and their potential hazards.

A full copy of the Risk Analysis can be located in Appendix 5.2

A mandatory requirement of the InspireVR study (Chapter 6) was the need to generate a detailed user guide. The guide covered many aspects of the system, from moving and handling, cold boot up procedure for hardware and software, troubleshooting basic issues, to hygiene and infection control of the various components.

A full copy of the user guide can be found in Appendix 5.3.

A copy of the MHRA no objection is located in Appendix 5.4.

5.3 Safety Modifications

During the study, a number of modifications were made to the InspireVR-V2 in an attempt to cure several repeated incidents. The main requirement for any work undertaken was that it had to be conducted within the ICU, the prototype was designed and built so any failure could be repaired without any tools therefore causing minimal disruption.

5.4 Summary

Based on the major setback encountered during the build of the InspireVR system (Chapter 4.6) two new prototypes were rapidly constructed in order to satisfy the MHRA requirement for CE marking therefore allowing for clinical investigations to be conducted across two intensive care units. The following Chapter (6) sees the debut of the completed InspireVR-V2 prototype in an incentive spirometry study entitled InspireVR.

6. Study 2 – InspireVR

6.1 Background

Patients who undergo major upper gastrointestinal surgery (oesophagectomy or total gastrectomy) are encouraged during their early recovery phase on the ICU to complete regular deep breathing exercises, termed incentive spirometry (IS). Incentive spirometry can reduce the risk of post-operative pulmonary complications, such as lung infections (do Nascimento Junior et al., 2014, Zingg et al., 2010). Current practice sees the use of non-electronic devices such as the Spiro-Ball, (Chapter 2.4.1) which are administered by physiotherapists with the aim of guiding patient technique. The patient is encouraged to breathe in slowly and as deeply as possible, then to hold his/her breath for 2-6 seconds before exhaling, with the exercise being repeated 10 times an hour, aiming for a maximum of 10 hours.

A floating indicator on the Spiro-Ball (Figure 2.1) provides visual feedback as to how well the patient's lungs are functioning. To date, such devices are non-electrical and does not record how well or how often the patient uses them, nor does it offer any performance feedback.



Figure 6.1: InspireVR prototype

InspireVR (Figure 6.1) was a pilot feasibility study evaluating the usability of a novel prototype interactive device developed closely adhering to the human centred design process, ISO 9241-210:2010 (Iso.org, 2010) to aid patient performance during IS. Commercial-off-the-shelf (COTS) technologies such as stand, display, PC, and interface technologies, combined with novel purpose-built software that provided IS-based "gameplay". The primary outcome of the study was to evaluate the usability of the InspireVR prototype against the current administered device, Spiro-Ball (Chapter 2.4.1, Figure 2.1).

The trial was carried out to satisfy the requirements of the Medicines and Healthcare products Regulations Agency (MHRA, 2016) in order to apply for the InspireVR prototype to be awarded an overall CE marking and to obtain a class 1 medical device certification.

6.2 Aims

The study sort to establish the feasibility of such a trial and, therefore, its aims were to:

i) Evaluate the usability of the InspireVR prototype by patients recovering from oesophagectomy or total gastrectomy on the critical care unit.

ii) Evaluate the usability of the InspireVR prototype by staff caring for patients recovering from oesophagectomy or total gastrectomy on the critical care unit.

iii) Evaluate adverse events related to the usage of the InspireVR prototype.

6.3 Methodology

6.3.1 Study Setting

The study was split over two hospitals, the Queen Elizabeth Hospital Birmingham (QEHB) and Birmingham Heartlands Hospital (BHH) critical care units.

6.3.2 Recruitment, Consent and Withdrawal

Patients participated in the trial during their first three postoperative days in critical care. Day one of the trial was the day after surgery. All patients undergoing oesophagectomy or total gastrectomy for cancer treatment were eligible. Patients undergoing emergency procedures, such as following a traumatic injury, were not included in the trial. Most patients were eligible to participate. Severe cognitive or visual impairment prevented patients from interacting with InspireVR, these were the only patients' groups that were excluded. Routine care for upper gastrointestinal cancer patients included regular visits to outpatient clinics, before, during and after neoadjuvant chemotherapy. Following chemotherapy, a multidisciplinary team meeting decided if the surgical removal of the tumour was indicated. Patients attended a pre-operative assessment clinic approximately seven days prior to surgery. All patients received an InspireVR patient information leaflet during one of their outpatient clinic visits, where surgery was discussed. Patients met with a member of the research team at their outpatient preoperative assessment. At this point, they were reminded of the study, invited to participate and given the opportunity to ask questions and discuss potential issues. They were shown both a portable version of the InspireVR and the Spiro-Ball system. Written consent was repeated following their operation and active participation in the study provided sufficient evidence of willingness to take part. Following consent, a study identification number was assigned. Randomisation was carried out at this point to determine whether the patient starts on condition A or B (Table 6.1). The randomisation sequence was stored on the Clinical Trials Administration (CREST) system at QEHB. A copy of the sequence will be stored in each research unit. Figure 6.2 illustrates the patient pathway from recruitment to follow up.

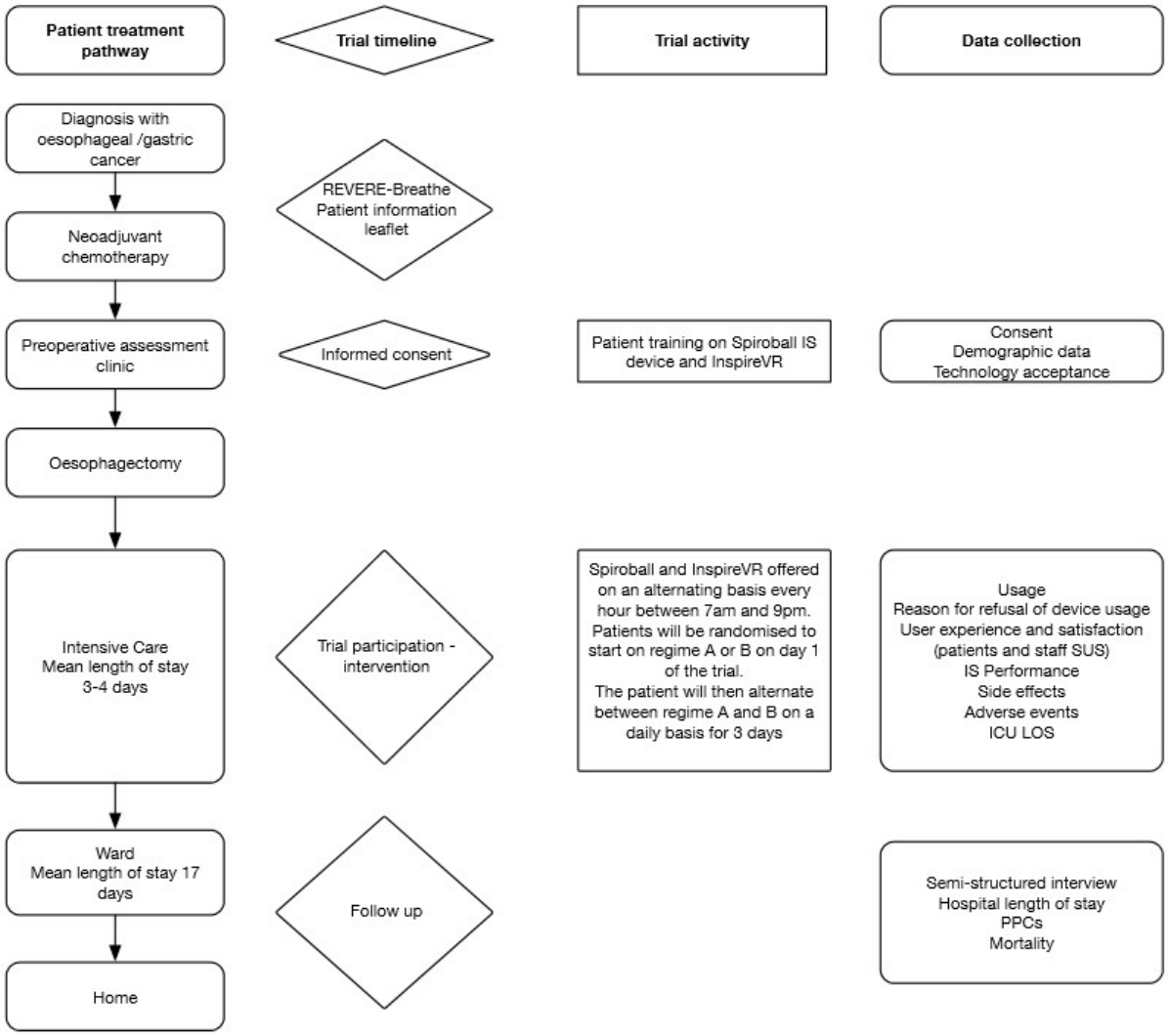


Figure 6.2: InspireVR study pathway

Should the patient become unable to continue in the study, such as in the event of delirium, reintubation or re-sedation, the patient was withdrawn from the study. If the patient became unwilling to participate in the study and if there was no resolution, a member of the physiotherapy team would be allowed early review and intervention if required. Should the patient be discharged to a surgical ward before the end of their third postoperative day, the patient would be withdrawn from the study.

6.3.3 Inclusion and Exclusion Criteria

The inclusion criteria for entry onto the InspireVR study extended to all patients who underwent elective oesophagectomy and total gastrectomy for cancer treatment on their first post-operative admission to the critical care units at QEHB or BHH.

The exclusion criteria were based on a number of factors:

i) Cognitive impairment

ii) Known multi-drug resistant chest infection

iii) Tracheostomy

iv) Patients intubated for more than 24 hours

v) Reintubation

vi) Readmission to the critical care units for any cause following discharge to ward

6.3.4 Participants

20 patients were recruited onto the InspireVR study over a 6-month period. 10 from QEHB and 10 from Birmingham Heartlands Hospital. N=20, 14 males, 6 females, age range between 46-81, mean age = 67.95, SD 9.72. Significantly more patients at the QEHB were consented to participate in the trial then were rendered ineligible due to cancellation of surgery due to, cancer progress, failure to recover adequately post op, and surgery being undertaken on a Friday with no physiotherapist available to administer on the Saturday/Sunday.

6.3.5 Ethics

South Birmingham Research Ethics Committee was approached and granted NHS ethical approval.

6.3.6 Data Collection and Tools

Written data was collected using paper case report forms. The data was then entered into the Clinical Research Tool (CREST), held on the secure QEHB trust and N3 (NHS network)

servers. Data from QEHB was entered into CREST using data capture software (FORMIC). Data from BHH was entered manually into CREST.

6.3.7 Data Management

The data management followed guidelines set out in the Data Protection Act 1998. Data collection forms and video recording (stored on recording device) were stored securely at the Trauma/Critical Care Research Office, Surgical Reconstruction and Microbiology Research Centre (SRMRC), 4th Floor, Institute of Translational Medicine, Queen Elizabeth Hospital Birmingham. A coding key was used to link the research data set with NHS patient records. Case report forms will be archived for the period of three years at the Surgical Reconstruction and Microbiology Research Centre) SRMRC.

6.3.8 Conditions

The two conditions administered during the experiment were either, InspireVR or the Spiroball device. Patients were randomised to start on condition A or B on the first day of the trial (Table 6.1) A free randomisation tool was used to generate the sequence (www.randomization.com). The patients alternated between condition A and B on a daily basis.

Table 6.1: Randomised sequence of conditions

Condition	A	B
07:00	Spiroball	InspireVR
08:00	InspireVR	Spiroball
09:00	Spiroball	InspireVR
10:00	InspireVR	Spiroball
11:00	Spiroball	InspireVR
12:00	InspireVR	Spiroball
13:00	Spiroball	InspireVR
14:00	InspireVR	Spiroball
15:00	Spiroball	InspireVR
16:00	InspireVR	Spiroball
17:00	Spiroball	InspireVR
18:00	InspireVR	Spiroball

19:00	Spiroball	InspireVR
20:00	InspireVR	Spiroball
21:00	Spiroball	InspireVR

If the patient was unable or unwilling to use the InspireVR system, they were offered the use of the Spiro-Ball which was the current therapy offered.

6.3.9 Procedure

Prior to undertaking condition testing the patient would have received training on the use of InspireVR during a preoperative assessment clinic and then on admission to the critical care unit. Physiotherapy and nursing staff were provided with training in device usage and issued with trouble-shooting documentation. If the patient was unable to use InspireVR, they were offered the use of the Spiroball, maintaining standard care.

Trial days 1 - 3

Provided the patient had been extubated (the removal of a tube from the airway), and was alert and cooperative, they would commence their incentive spirometry breathing exercises using, alternately, Spiro-Ball and InspireVR (Table 6.1). A member of the research team would visit at 08:00 to ensure both devices were in the bed-space and ready for use. The patient and nurse caring for them would be reminded by a physiotherapist on how to use each device and shown the data collection form for the day. During the day a member of the research team visited the patient at least once to check for any issues.

Trial Day 4

Once the patient had completed the experimental phase of the trial, the patient was asked if they were happy to participate in a semi-structured interview.

The InspireVR prototype was withdrawn from the patient bed-space, inspected for damage, cleaned and placed into storage in the critical care research offices.

6.4 Measures

Data was collected during patient pre-admission clinics by means of a series of questionnaires that looked at patient demographic, device familiarity / experience, and technology acceptance, copies of which are detailed below (6.4.2 – 6.4.4). A system usability scale (SUS) was distributed at the end of the daily test session (6.4.5). Following on from discharge to general wards a semi-structured interview was conducted that sought to gain feedback on a number of InspireVR related topics, relating to device usability, system ergonomics, errors encountered during its use and levels of motivation elicited during rehabilitation sessions.

6.4.1 Harms

Sickness related to motion-tracking systems "cyber-sickness" occurs in 3-5% of the general population, but has never been studied in the critical care population. The risk may be increased by the use of medication. Cyber-sickness is self-limiting following cessation of exposure to virtual reality based games. Patients and staff were warned about cyber-sickness. A review of rates of sickness; assessed via patient and nursing reports and use of anti-emetics, were undertaken after every 10 completed accruals. The study would have been suspended if the rate of sickness during exposure rose to 20% above baseline. Previous research on patients exposed to the same virtual environment as that used in the current trial (Shingari, 2015) reported no episodes of cyber-sickness in the 30 participants, all of whom were critical care patients.

Transmission of infection - the device was decontaminated and cleaned between participants using 70% alcohol wipes, in the same manner as all patient-contact medical devices, as advised by the University Hospitals Birmingham Infection Control Team.

6.4.2 Demographic data

Non-validated demographic data was captured during the patient's pre-operative assessment clinic visit by a member of the research team who administered the questionnaire which was self-completed by the patient.

Male/Female	Ethnicity	Main language	
Diagnosis		Operation: Oesophagectomy/Total Gastrectomy	
Occupation (previous if retired/currently unemployed)	Education level O level/A level/Degree /Higher degree		Hobbies
Age of children resident at home	Child 1	Child 2	Child 3

6.4.3 Device familiarity / Computer experience

A non-validated device familiarly / computer experience questionnaire was administered during the patient's pre-operative assessment clinic visit by a member of the research team, the questionnaire was self-completed by the patient.

Device familiarity/ Computer experience	Ownership	Confidence using (1 not at all, 5 very)
Computer/laptop	Y/N	1 2 3 4 5
Tablet device, e.g. iPad	Y/N	1 2 3 4 5
Smart/Interactive TV	Y/N	1 2 3 4 5
Mobile phone	Y/N	1 2 3 4 5
Smart phone	Y/N	1 2 3 4 5
Wearable monitoring device e.g. Fitbit	Y/N	1 2 3 4 5

Computer games console e.g. Xbox	Y/N	1 2 3 4 5
Other (list)	-	1 2 3 4 5

6.4.4 Technology Acceptance

A non-validated technology acceptance questionnaire was administered during the patient's pre-operative assessment clinic visit by a member of the research team, the patient was given a brief demonstration of a portable version of the InspireVR system and was then presented with a questionnaire that was self-completed, therefore there was no bias as to how the data was collected.

Technology Acceptance	Strongly disagree 1, Strongly agree 5
InspireVR will help remind me to do my deep breathing exercises	1 2 3 4 5
InspireVR will help me to do my deep breathing exercises more effectively	1 2 3 4 5
I could easily learn how to use InspireVR	1 2 3 4 5
Learning to use new electronic devices makes me feel apprehensive	1 2 3 4 5
I feel confident I will be able to follow the instructions for using the InspireVR	1 2 3 4 5
Use of InspireVR will help with deep breathing exercises	1 2 3 4 5
I am looking forward to using InspireVR	1 2 3 4 5
I am worried that InspireVR will cause me harm	1 2 3 4 5
I use computers and electronic gadgets in my everyday life	1 2 3 4 5

I feel confident using computers and electronic gadgets	1 2 3 4 5
I expect to be using electronic devices to help with my rehabilitation after surgery	1 2 3 4 5
I intend to use other electronic devices during my rehabilitation after surgery	1 2 3 4 5
I will have enough support to use InspireVR in hospital	1 2 3 4 5
I have a disability/impairment which will prevent me from using InspireVR properly	1 2 3 4 5

6.4.5 Modified System Usability Scale (SUS)

The language used for the items has caused comprehension problems. The word "very" was present in three items. A respondent stated that he felt conflicted by the word since he felt "confident" but not "very confident" (Finstad, 2006). Some studies have shown that the "cumbersome" was not clear enough for non-native English speakers. The alteration to the word "awkward" improved comprehension (Finstad, 2006); Lewis & Sauro, 2009; Bangor et al, 2009). Small changes may help the participant not to dwell on any one item and help them complete the SUS. The SUS was modified in an attempt to add clarity and tailor the questions directly towards the usability of the InspireVR prototype in order to help the patients better understand what was being asked of them. The SUS was distributed to the patient at the end of each test session by senior physiotherapists who were involved in the study, and was self-completed by the patient who had been screened during pre-admission (6.3.3).

Item		Strongly disagree 1 – strongly agree 5
1	I would recommend using InspireVR to others	1 2 3 4 5
2	I found InspireVR too complicated to use	1 2 3 4 5
3	I thought InspireVR was easy to use	1 2 3 4 5
4	I needed someone to help me use InspireVR	1 2 3 4 5
5	InspireVR helped me to do deep breathing exercises more effectively	1 2 3 4 5
6	I found InspireVR confusing to use	1 2 3 4 5
7	I think others would learn to use InspireVR quickly	1 2 3 4 5
8	I felt that InspireVR was too awkward to use	1 2 3 4 5
9	I felt confident using InspireVR	1 2 3 4 5
10	It took me a long time to learn how to use InspireVR	1 2 3 4 5

A copy of the unmodified SUS can be found in Appendix 3.1

6.4.6 Qualitative feedback of patient experience of InspireVR

On day four of the trial the patient was invited to participant in a semi structured interview that was administered by the chief medical investigator, the questions were presented in paper form and responses gathered followed the data handling procedure set out in 7.3.4.

Topic	Questions	Probes
6.4.6.1 Device Usability	What difficulties did you have using the InspireVR? How long did it take you to feel confident using the InspireVR? Which device was easier to use, the InspireVR or the Spiroball? How would you suggest we make it easier to use?	What made it easy/not easy to use? Was the system easy to set up? Was the game easy to follow? Did you understand what you needed to do?
6.4.6.2 System Ergonomics	How did you feel about having the InspireVR device in your bedspace all the time? Was the device difficult to move around?	Did you find it intrusive? Did it get in your/your visitors' way?
6.4.6.3 Errors	Did you make any mistakes whilst you were using the InspireVR?	What do you think caused these mistakes?
6.4.6.4 Motivation	How did the InspireVR affect your motivation during the breathing exercises? Did you understand the scores and levels and why they were important?	Did you look forward to getting to the next level?

	How did seeing your game results/scores make you feel?	

6.5 Results

The following section details the results gathered during the InspireVR study. Due to the nature of participant testing and in particular the recruitment of critically ill patients, it should be noted that data for certain patients are omitted. The omitted data can be attributed to patients being successfully consented on to the study only to have delays in surgery, complications post-surgery, referred back to general wards, discharged home, or passing away.

6.5.1 Demographic data taken at pre-admission clinic

The following data refers to the questionnaire located at 6.4.2. Table 6.2 illustrates the participant cohort consisting of n=20, of which 14 were male and 6 were female, age ranged between 41-81, with a mean age of 68, SD 9.72.

Table 6.2: Patient age range

Age	45 – 50	51 – 55	56 – 60	61 – 65	66 – 70	71 – 75	76 – 80	80 – 85
Male		2		3	3	3	2	1
Female	1			1	1	2	1	

The following Figure (6.3) looked at patient occupation which was categorised into worker groups; white- collar being primarily those in professional, managerial or administrative fields, blue-collar, whose work would entail some aspect of manual labour. The remainder of the grouping consisted of retired and unemployed. Patient education (Figure 6.4) was categorised in to qualification groups, the majority of respondents had no education, with the remainder of qualification levels evenly spread.

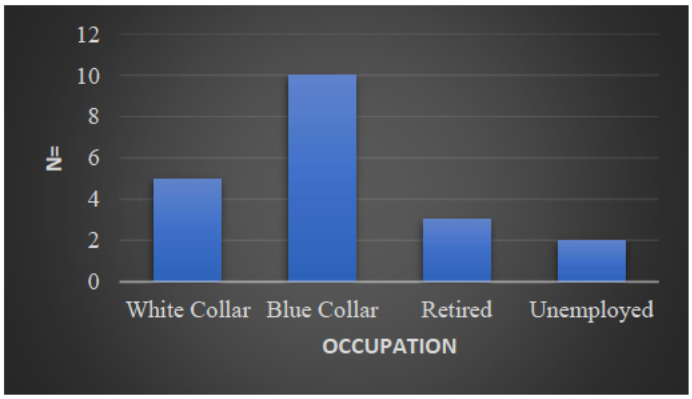


Figure 6.3: Patient Occupation

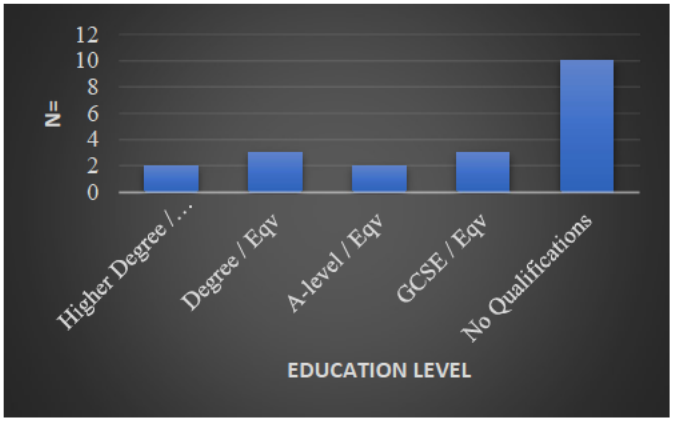


Figure 6.4: Patient Education

6.5.2 Device familiarity/experience

The following data in this section corresponds to responses gathered during the distribution of a device familiarity/experience questionnaire (6.4.3) at a pre-admission clinic. The questionnaire asks about device ownership, and a rating of confidence ranging from not at all, to very confident.

Table 6.3 Device familiarity / computer experience

	Device familiarity / computer experience						
Question	Usage		Not at all confident	Least confident	Neutral	Confident	Very confident
1. Computer/laptop	Yes	14		2	5	5	2
	No	6					
2. Tablet Device	Yes	12	1	1	3	2	5
	No	8					
3. Smart TV	Yes	15	1	3	3	3	5
	No	5					
4. Mobile Phone	Yes	15		1	6	3	5
	No	5					
5. Smart Phone	Yes	12		1	4	2	5
	No	8					
6. Wearable device	Yes	1				1	
	No	19					
7. Computer games console	Yes	3			1	1	1
	No	17					
8. Other	Yes	0					
	No	20					

Table 6.3, Question 1, relates to the question of tablet usage and confidence. From the 20 responses of ownership, 40% answer no. In terms of usage, 25% felt most confident, 10% felt confident, 15% neutral, 5% less than confident and a further 5% were not at all confident.

Table 6.3, Question 2, relates to computer/laptop ownership and levels of confidence with its usage. The idea of the question was to try and correlate patient adaptability to InspireVR by looking into background technology habits and abilities. From the 20 participants who replied, 10% showed high confidence, 25% showed confidence, 25% showed neutral confidence and 10% were less than confident. The remaining 30% answered no to ownership.

Table 6.3, Question 3, relates to the ownership of a smart TV and levels of confidence in its usage, out of the 20 participants asked, 25% answered no to ownership, 25% were most confident, 15% were confident, 15% were neutral, 15% were less than confident, and 5% were not at all confident.

Table 6.3, Question 4, relates to mobile phone ownership and levels of confidence, out of the 20 participants who were asked, 25% responded no to ownership, 25% felt very confident, 15% confident, 30% neutral and 5% less than confident.

Table 6.3, Question 5, relates to smart phone ownership and confidence, 40% said no to ownership, 25% felt most confident, 10% felt confident, 20% were neutral and 5% felt less than confident.

Table 6.3, Question 6, relates to wearable monitoring devices and confidence, this only garnered one response, therefore 95% responded no to ownership and 5% showed as confident in its use.

Table 6.3, Question 7, relates to game console ownership and confidence (table 7.9), 85% answered no to ownership, 5% rated at very confident, 5% at confident and 5% neutral.

With regards the question as to other devices and confidence (Table 7.3, Question 8), there were no responses.

6.5.3 Technology Acceptance

The following technology acceptance data (Table 6.4) refers to the questionnaire (located at 6.4.4) that was distributed to 20 consenting patients at a pre-admission clinic. The questionnaire looked at the perceived technology acceptance before any rehabilitative sessions took place using InspireVR. The rationale for the distribution of the demographic and technology acceptance questionnaires was to identify if any of the patients had any experience and / or displayed confidence in using technology, the idea being that those who had, would adapt better to using the InspireVR system and would be more inclined to accept InspireVR as an acceptable method of rehabilitation more than those who were technology phobic. A large proportion of respondents felt that InspireVR was easy to use (Q3) and that the instructions (Q5) together with the support from hospital staff would allow them to perform in terms of deep breathing exercises (Q6). Patients felt that InspireVR would help to remind them to do their deep breathing exercises (Q1), which was partly due to the on-screen countdown timer that was present between rehabilitation sessions. There was a largest proportion of neutral response (40%) towards InspireVR actually helping the patient to conduct deep breathing exercises effectively Q2). In contrast there was a greater combined proportion of respondents who agreed and strongly agreed (55%) to the system aiding with respiratory exercise.

The majority of patients with a combined 90% strongly disagreed and disagreed that InspireVR would cause them harm, in contrast less strongly agreed or agreed (50% combined) to looking forward to using the prototype with (45%) having neutral feelings towards it. This could be directed either to the InspireVR itself or the rehabilitation process as a whole. There was a mixed response to the question (9) that looked at computer use and electronic gadgets in everyday life, which was asked to gauge patient acceptance levels with respect to using a PC based rehabilitation system with a handheld digital spirometer. It saw mixed results most (40%) strongly agreed but in contrast 25% strongly disagreed, the question had similarities to question

(1) in the device familiarity / experience questionnaire (6.5.2), and therefore could be omitted without impacting the data.

Table 6.4: Technology Acceptance

Question	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. InspireVR will help remind me to do my deep breathing exercises	5%		20%	55%	20%
2. InspireVR will help me to do my deep breathing exercises more effectively	5%		40%	30%	25%
3. I could easily learn how to use InspireVR	5%		10%	35%	50%
4. Learning to use new electronic devices makes me feel apprehensive	25%	35%	5%	25%	10%
5. I feel confident I will be able to follow the instructions for using InspireVR			5%	35%	60%
6. Use of InspireVR will help with deep breathing exercises	5%		20%	40%	35%
7. I am looking forward to using InspireVR		5%	45%	30%	20%
8. I am worried that InspireVR will cause me harm	60%	30%	5%	5%	
9. I use computers and electronic gadgets in my everyday life	25%	5%	15%	15%	40%
10. I feel confident using computers and electronic gadgets	15%	5%	30%	25%	25%
11. I expect to be using electronic devices to help with my rehabilitation after surgery	35%	20%	15%	15%	15%
12. I intend to use other electronic devices during my rehabilitation after surgery	40%	20%	20%	10%	10%
13. I will have enough support to use InspireVR in hospital			20%	35%	45%

14. I have a disability/impairment which will prevent me from using InspireVR properly	75%	20%	5%		

6.6 SUS Reliability Analysis

SUS data was collected from the patients (6.4.5) following exposure to the InspireVR condition testing, data was captured for N=12 participants owing to a number of factors ranging from the patient wanting to use the Spiro-ball over in InspireVR, system software/hardware failure or the patient withdrawal from the study.

Table 6.5 shows SUS data collected from the participants following exposure to InspireVR. A comparison of mean SUS scores for the participant grouping from Birmingham Heartlands Hospital (BHH) and Queen Elizabeth Hospital (QEHB) is shown in Figure 6.5.

Table 6.5: Patient SUS data

Total SUS Score			
Heartlands		QEHB	
ID	InspireVR	ID	InspireVR
1	82.5	11	67.5
2	-	12	62.5
3	50.0	13	-
4	65.0	14	100
5	-	15	10
6	-	16	85
7	-	17	95
8	100	18	-
9	75	19	-
10	-	20	92.5
Mean 74.5 SD 18.74 N=5		Mean 73.21 SD 31.22 N=7	

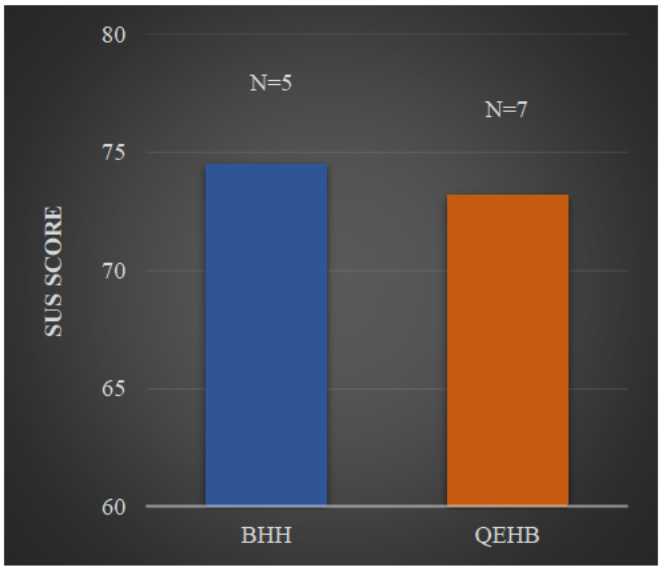


Figure 6.5: Mean SUS scores for BHH and QEHB

Based on a review of 50 studies, Tullis & Albert (2008) suggested that an average score of less than 60 is relatively poor while one above 80 is relatively good. The overall mean SUS score across both participant hospital groups for the InspireVR condition was N=12, 73.8±25.7, between both groups there was no difference in SUS ratings ($p>0.05$).

6.7 Qualitative feedback

Upon discharge from critical care to general ward, patients were invited to undertake a semi-structured interview (6.4.6) that sought to gain feedback on key topics such as, device usability (6.4.6.1), system ergonomics (6.4.6.2), errors encountered (6.4.6.3), and motivation levels (6.4.6.4). The questions asked were followed by prompts to help guide feedback, the comments were tabulated and assigned a colour code indicating, positive, negative and neutral aspects of the InspireVR.

	Positive comment
	Negative or critical comments indicating improvements required
	Neutral or mixed with some positive and some negative comments

6.7.1 InspireVR - Device Usability

Feedback (Table 6.6) saw the InspireVR system as easy to use, comments were made as to the better fitment of the digital spirometer mouth piece over the Spiro-Ball, one commented on wanting to use the system at home, whilst another felt the system was easier to use than the traditional method.

The negative comments were aimed at both the software and hardware elements, one comment was made as to the prototype's size and difficulty of setup, one mentioned that the system kept falling apart and that it had too much of a prototype feel to it. One of the issues that was identified saw how the InspireVR system was stored between test sessions, multiple instances of damage occurred outside of the bed-space and within equipment storage areas. Comments made towards the software were aimed towards the freezing game play and the system exiting and restarting at will. Detailed user documentation (Appendix 6.1) was distributed to the research staff and provided a step by step cold boot-up procedure and also trouble shooting the system should a software failure occur; on several occasions the researcher was called out to provide support only to find that certain steps were overlooked and could have been avoided with better training.

Table 6.6: Device Usability

Positive	Negative	Neutral
Felt confident using after first go	Game kept freezing	At the beginning I wasn't using it properly and kept breathing into it, I asked my daughter to write a reminder which said "MOUTHPIECE IN, REMOVE, BREATH OUT"
InspireVR mouthpiece was easier to use	Kept resetting itself	Device was hard to use post op than pre op
Understood what I needed to do	Device was too big and too hard to set up	
Game was easy when worked	More time for tuition is needed	

Understood the game well	Power saving function was a problem – kept turning off and resetting	
Apart from the technical issues it was easy to use	Not useable in the ICU setting	
Would like to use at home	Too much of a 'prototype' feel to it	
Easy to use but did not interest me	Too early to use in the device's development	
When the system wasn't crashing it was quite easy to use	Visual element was not useful as it provided no data	
Easy to use once I got used to it	I wanted to throw the InspireVR out of the window	
Good as I only need to breathe in gently to make it work	System was hopeless	
The InspireVR is easier to use that the Spiroball	The software was not user friendly	
I felt confident using it as I had support from the nurses	Software was too sensitive – goes in and out of the programme – so not ideal for unwell people	
Could get a better seal on the InspireVR mouthpiece than the Spiroball	System kept falling apart	
A good concept but needs a few tweaks	Too many engineering design flaws to use it properly	
No difficulties using InspireVR	Issues when the InspireVR froze	
Both systems equally easy to use		
Easy to use, smiling faces helped		

6.7.2 System Ergonomics

Based on the system ergonomic feedback it can be said that InspireVR met with mixed results (Table 6.7), some patients stated that the system was not intrusive, easy to adjust and integrated well within the bed-space. Other responses stated that the system was still too bulky and could have benefited from being mounted to an existing stand. This was always an option during the design of the underlying VR-I Module but due to the nature of participant testing and the need

to switch between bed-spaces it was left as a discussion point for a future evolution of the system. More pressing were the failures that occurred such as the digital spirometer mouth piece and secondary keyboard being knocked off by staff whilst actively being used in the bed-space, the failures when identified were addressed during the study as it was deemed a safety concern.

Table 6.7: System Ergonomics

Positive	Negative	Neutral
Not intrusive, didn't get in the way	Device was in the way	Patient felt guilty that device was in the staff's way
No problem having the machine in the bed-space	Intrusive and cumbersome	Spirometer was heavier than the Spiroball but not to heavy
Not in the way of patients or staff	Too big and bulky – should be more compact	
Easy to adjust, comfortable to use	Not well presented	
It was not intrusive	Needs to be fixed to one of the stands already in the bed-space as it's already quite crowded	
InspireVR didn't get in the way	Accessing the device from the stand was quite difficult	
It was easier to use the InspireVR once sat out	The shape of the mouthpiece on the InspireVR made it harder to use that the Spiroball	
It didn't get in the way	Filter kept falling off the InspireVR	
Difficult to get a good grip on the Spiroball	Keyboard not secure	
	InspireVR Spirometer kept falling off its holder	
	Spiroball was easier to pick up	
	Difficult to manoeuvre the stand – the keyboard fell off	

6.7.3 Errors (noted by physiotherapist team)

During the study, physiotherapists were encouraged to capture any notable errors during the prototype's usage. The majority of errors came primarily from human error or software issues; patients were not using the digital spirometer as advised whereby they would blow into the

mouth piece or breathe in as advised but then exhale partially leading to the system crashing. In one instance it transpired to be the patient becoming aware that she had been taught how to the Spiroball incorrectly so was doing the exercises wrong during pre-op. Other issues related to errors generated from the system often resulting in the InspireVR system freezing or turning off leading to a complete reset.

6.7.4 Motivation

The feedback responses (Table 6.8) were mostly positive, the majority of respondents commented on sensing improved performance, and using the on-screen visuals as a guide to motivation. Negative aspects came from the lack of understanding of the system and what was required of them, and also already feeling motivated to recover due to the health benefits. One patient in particular saw it as a gimmick, another was unmotivated by the smiley faces. Some comments made comparisons to the Spiroball and not being able to go beyond the recommended 10 deep breaths per session.

Table 6.8: Motivation

Positive	Negative	Neutral
Improved my motivation, understood the scores and why they were important and looked forward to getting to the next level.	Did not affect motivation to do exercises	Feedback was useful but game kept resetting so unable to progress through levels
Good incentive – wanted to improve	No help with motivation	Understood the levels but wanted more numerical feedback, felt the face Emojis were a bit childish
Felt more motivated to do the exercises	Didn't really understand how to go up a level	Better feedback on Spiroball which gave numbers rather than faces
Provided good motivation	Already motivated by wanting to recover from surgery knowing the health benefits, game design did not help	Would be useful to see progress – spreadsheet/graphics and a report

I was disappointed on the last evening when the device was removed as I was just getting into it.	Game was a gimmick, I dreaded using I, the lack of practicality meant I that I was less motivated	I found the feedback helpful but didn't it improved my performance
Encourages improved performance to get through levels but probably needs better feedback visual to show you've reached each level	I don't think the smiley faces improved my motivation	I was already motivated
The smiling faces helped to keep a record of what I have done, I liked the feedback		I felt more motivated with the Spiroball
InspireVR helped to remind me of the importance of doing the exercises		InspireVR was a good distraction but I didn't think it was beneficial
I was already motivated to recover but the game made it more interesting		I wanted to do more than 10 deep breaths, which I could only do using the Spiroball
Sinking ships helped egg me on		
I looked forward to using the InspireVR		

6.7.5 Feedback - Research Physiotherapist Staff

Feedback captured (Table 6.9) was mainly targeted at software failure, in some instances (ID1) the system functioned as expected but then on subsequent days presented errors that when rectified left the patient reluctant to use it. Several instances (ID2, ID4, ID9, ID12, ID13, ID15, ID16) saw software failure at some point throughout the three days, and in some cases the issues were addressed with a reboot/reset of the system, others (ID2) preferred the use of only the Spiroball. ID3 and ID7 saw damage to the InspireVR stand prevent its usage, both coming from Birmingham Heartlands Hospital which occurring whilst in storage and before entry into the ICU bed-space. ID11 encountered software issues on day two but on day three preferred the use of InspireVR. With reference to the device familiarity / experience questionnaire (6.4.3), it can be said that those who displayed confidence or greater in a range of technologies had no control over the system failures that led to negative experiences, and a loss of

motivation, evident by the reluctance to use the system when it was rebooted opting instead to use the Spiroball.

Table 6.9: Feedback from Research Staff

ID	Day 1	Day 2	Day 3
1	Patient requested more frequent use of VR, therefore "spacebar" pressed to allow further use. Patient reported that device froze yesterday afternoon and that it said 'ready' he took a breath, catapult did not draw back.	Whilst on countdown, screen returned to desktop with Vitalograph program open then spontaneously shut down. After resetting a few times, the game restored on level 1 but is progressing automatically without patient use. Restarted level 1 – appears to be working. Patient not taking very effective breaths so encouraged to inhale deeper.	Patient reported device had frozen overnight. Restarted this morning and after some troubleshooting is not working. Patient reports device froze this afternoon. Screen states 'ready' but patient declined using it again at present.
2	InspireVR would not function. Could not be used. Patient reverted to Spiroball use for the day. Use was not recorded. InspireVR game would not load despite rebooting. Physio had documented in notes that the patient is using Spiroball hourly.	InspireVR not used 'see day one'	Patient did not wish to use InspireVR device as she has been using Spiroball over weekend as is happy with this, despite InspireVR functioning again.
3	InspireVR device not working – USB connection to handheld device had snapped. Call from HDU staff. Patient does not wish to continue use with InspireVR as it has required rebooting twice and would prefer to just use Spiroball.	Copy of CRF left with HDU staff over the weekend but unable to find record of device use.	
4	Some difficulty experienced when trying to use/switch on InspireVR.	Unable to use InspireVR. Message saying 'prepare to fire' but wouldn't go ahead. Hourly Spiroball instead.	
5	Patient states he only wishes to use Spiroball today.	Clinical deterioration in patient.	Patient re-intubated, withdrawn from trial.

6	Patient declined any spirometry for most of the day.	Pain limiting exercise, patient reluctant to carry out incentive spirometry.	Patient encouraged to deep breath without spirometer.
7	Equipment stand not safe to use to allow use of InspireVR		
8	Documented "pain on spirometry" during day. Breathing exercises worse due to pain.	InspireVR not turning on. Reverted to Spiroball	
9	InspireVR keyboard not connecting to device. Programme not starting up correctly. Reverted to Spiroball.	InspireVR used but patient did not keen and kept stating he preferred the Spiroball. Also appears confused.	Does not wish to use InspireVR today.
10	Patient confused and unable to use InspireVR.		Device removed from bed-space – post operative delirium, withdrawn from trial.
11	Spiroball lost for 2 hours.	InspireVR failed to load.	Patient preferred InspireVR today.
12	InspireVR froze during use. Needed restarting/rebooting.		InspireVR froze and needed restarting.
13	Monitor froze for about 5 minutes, keyboard stopped working.		Patient refused further use of InspireVR/Spiroball
14	Patient nauseated.	Error message on screen, unable to troubleshoot.	InspireVR crashed, needed restarting,
15	Patient does not like mouthpiece on InspireVR, prefers Spiroball. InspireVR stopped working today.	Patient declined further participation, withdrew from trial.	
16	Patient declined Spiroball, InspireVR crashed on start-up and needed rebooting.		
17	Patient falling asleep. InspireVR turned itself off.	Delirium and clinical deterioration,	Patient re-intubated. Withdrawn from trail.
18	Patient sleeping.		
19	-	-	-
20	Needed physio assistance with InspireVR	InspireVR calibrated faster. Early discharge to ward,	

6.8 Discussion

The InspireVR study set out to examine the current established rehabilitative practice of incentive spirometry using non-electric devices (Chapter 2.4.1), and to introduce a novel prototype interactive device to be used as a method to guide patient deep breathing technique. The prototype (InspireVR) was developed adhering to the human centred design process, ISO 9241-210:2010 (Iso.org, 2010), and two identical InspireVR modules were constructed and distributed to the Queen Elizabeth Hospital and Birmingham Heartlands Hospital, where they underwent patient testing within active ICU bed-spaces. Testing saw InspireVR installed in a bed-space for the duration of a day shift and for patients to alternate hourly between InspireVR and Spiro-ball.

Throughout the study, feedback was gathered as a precursor to the exposure of InspireVR that was used to gauge device familiarity across a range of interactive technologies, and levels of confidence, to evaluative if the those who displayed higher levels of confidence would adapt better to using novel interactive technologies as opposed to technologically inexperienced or phobic participants. There was a large percentage of non-ownership in computer / tablet usage, with those who did displaying equal proportions of neutral, and at best, average confidence. Tablet usage faired a little better, with a higher percentage displaying confidence in usage but in contrast a higher percentage came from no ownership. Computer games consoles familiarity scored low with 85% answering no to ownership and just 5% at showing as very confident. A series of questions relating to perceived technology acceptance was asked before any rehabilitation took place, the idea was to gauge the potential reaction to using InspireVR during rehabilitation sessions to analyse if poor responses would lead to lower performance levels during usage. The majority of patients felt that they would have enough support to use InspireVR and that it would be easy to learn and use. Patients were also not expecting to encounter electronic devices to help with rehabilitation after surgery but felt confident that it

would help with deep breathing exercises. Upon completion of the days testing a system usability scale (SUS) was distributed in order to gauge the usability of InspireVR, as a rule of thumb a SUS score of below 60 would be considered poor whilst one above 80 would be considered good (Tullis & Albert, 2008). A combined SUS score across both hospitals provided a mean SUS score of 73.80, SD 25.7 which was based on N=12 responses suggested that despite the incidents of minor damage to InspireVR rig, and minor software issues the system proved to be relatively usable.

Following patient discharge to general ward, a semi-structured interview was conducted that sought to gain feedback on several topics such as, device usability, system ergonomics, and motivation levels. Patients saw InspireVR as easy to use and not overly intrusive, but saw some mixed reactions to the digital spirometer, some suggested the mouth piece provided a better fit over its non-electronic counterpart. Others commented that the spirometer kept falling of its cradle, which was due to the digital spirometer being stored backwards in its cradle with its bacterial / viral filter attached throughout the daily test period to prevent the patient from having to remember the extra step of attaching the filter before rehab sessions. The issue was addressed with the use of rubberised self-amalgamating tape. Ergonomic feedback was balanced between InspireVR being too cumbersome in the bed-space to "no problem having the machine in the bed-space", the issues that did present itself was down to the handheld digital spirometer being heavier than the Spiro-ball. At the time of the study the only option for a medically certified digital spirometer available was the Vitalograth Pneumotrac to which four were purchased, two used during the ICU study and two during pre-admission clinics (and as backups) to provide the patient with a live demo. Future studies could explore other alternatives that offer a smaller form factor that could be integrated better within a further iteration of VR-I Module prototype. For the majority of patients who were exposed to InspireVR felt improved motivation and enjoyed the game play elements, others felt the visual feedback was helpful but had little effect

on personal performance, some were disappointed at not being able to use it after the study session. Negative comments came from a lack of understanding of the concept or poor device familiarity / technology acceptance levels.

Physiotherapist staff who were in direct contact with InspireVR throughout the study were also requested to provide feedback, to which software failure (6.7.1, 6.7.5) was a prevalent issue, some of the failures was traced back to the InspireVR software system not connecting to the internet via its on board Mi-Fi cellular dongle in order to authenticate the mid-ware necessary to interface the Vitalograth Pneumotrac spirometer with the VR game play software. A future consideration would be to apply to utilise the NHS secure Wi-Fi network to help manage a consistent network connection. In addition, a method to prevent issues from arising would be to conduct a failure mode effects analysis (FMEA), which is a systemised group of activities to recognise and evaluate the potential failure of a product or process and its effects, identify actions that could eliminate or reduce the occurrence of the potential failure and document the process. Conducting a full site survey to assess Wi-Fi availability within each bed-space in an attempt to isolate suitable known areas in which the study can be undertaken, an issue with this method is being at the mercy of the ICU staff who may be reluctant to move consented long term patients from bed-space to bed-space. The InspireVR rig itself proved to be reliable and only received one comment of sustaining damage, citing “Equipment stand not safe to use, to allow use of InspireVR”, which was traced back to poor storage and handling practices at Birmingham Heartlands Hospital.

6.9 InspireVR, Link Analysis

6.9.1 Introduction

Feedback from the REVERE-Sleep study (Chapter 3.5.7) indicated some concerns from hospital staff about the size and bulk of the Virtual Reality Interactive (VR-I) Module and the risk of it interfering or inhibiting nursing activities given its location by the bedside of the patient. The aim of the study was to determine and evaluate the risks associated with the introduction of a trolley mounted incentive spirometry system within the confines of an ICU bed-space.

6.9.2 Background

Villeneuve 2000; Irbnet.de, 2018, suggested that ergonomics would complement architecture rather than compete with it. In order to produce a research-based or user-centred design, a detailed knowledge of work processes within a defined space/area was needed. A range of ergonomic methods including task analysis and user-needs analysis could be used to provide this information (Rutter, 1996). As Stanton (1983) stated “badly positioned equipment in theoretically adequate overall space would prevent the room from being used as intended”, a limitation of simulation was obviously that the simulations were carried out within mock-ups, which were taken from the site visits and might not have been optimal.

Bed space mock-ups constructed to same layout and size as a standard NHS ICU bed-space will never be equal to the real world, for example, nurses may do a real resuscitation task with some emotional stress (Kozer et al, 2004), but as participants they may have performed the task without any pressure. This could lead to the loss of some procedures or actions which may affect the physical environment. Ideally, mock-ups should be built in a real clinical environment with the real equipment / elements to give the participating nurses a more realistic setting.

6.9.3 Link Analysis

Prototype development and evaluation must consider the environmental context into which the device is to be used (Iso.org, 2010; Zhao, Hignett and Mansfield, 2012). It is important to determine the impact of adding the InspireVR system into the critical care environment to ensure that there is no detrimental impact on efficiency of care or safety. A link analysis is an ergonomic tool which measures, and provides illustration of, interactions between components (persons or equipment) within a system (Lester and Chui, 2016). The system under evaluation in this part of the study is the care of the patient on the critical care unit. A link analysis was conducted to determine the impact of the InspireVR device on the activity of the caregivers within the critical care bed-space. Due to the extremely sensitive nature of a) filming within an ICU and b) filming a critically ill patient it was deemed appropriate to conduct movement observations and link analysis on the first consenting participant within the critical care unit at the Queen Elizabeth Hospital Birmingham.

6.9.4 Aims

1. Determine a set of bed-side activities carried out by doctors, nurses and physiotherapists and analyse activities with respect to the positioning, movement and actions of personnel around the bed-side.

2. Determine likely impact on performance of these activities if the InspireVR prototype system was introduced into the bed-space environment.

6.9.5 Methodology

Link Analysis

The study consisted primarily of a link analyses. The analysis comprised of:

1. An observations of tasks/activities by doctors/nurses/physiotherapists.

2. The creation of link analysis diagram detailing the positioning and movements around the bed-space for each task/activity.

3. A heat map overlaid onto the link analysis diagram to determine high and low activity zones around the bed-space for each task/activity.

4. A Risk analysis/assessment for inclusion of the prototype system within the bed-space environment.

The observation lasted a total of nine hours (single day shift) and was completed by observing tasks within the bed-space.

6.9.6 Location of Study

ICU, Queen Elizabeth Hospital Birmingham.

6.9.7 Participants

A total of 5 participants consented to being videoed for the duration of a complete day shift, with 1 to act as a baseline to evaluate the bedspace without the InspireVR installed.

6.9.8 Data Collection

1. Data collection took the form of a video positioned at the head of the ICU bedspace.

2. Study time frame would be over a single day shift (08-00 – 18:00)

6.9.9 Data Handling/Storage

Staff and patients would have their faces pixelated.

Video data was stored on an encrypted hard drive in a secured cupboard within the Department of Electronic, Electrical and Systems Engineering, University of Birmingham.

All data was held only for the purpose of data analysis and was destroyed upon completion of the study.

6.9.10 Equipment Used

An array of video equipment was used to facilitate the video capture / evaluation of data required to formulate the link analysis, the equipment used included:

GoPro Hero 4 + display

3D printed GoPro mount

Slim profile tripod

Mini USB extension cable 3metres

USB power adapter

2TB external hard drive (for video storage)

Laptop for video analysis

6.9.11 Procedure

A GoPro camera was placed at the head of the ICU bed-space and angled 45degrees to the right encapsulating the operational area of the InspireVR, the camera was focused on the right side of the bed and also the patient's bed-side chair (Figure 6.6).



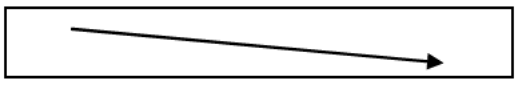
Figure 6.6: ICU camera placement during link analysis at the QEHB

The observation looked at the movements and tasks performed from within the bed-space with in the InspireVR prototype in situ and being used by the patient from the both the bed-side chair and bed. The observation lasted a total of 10 hours which equated to a single day shift. The link analysis was only undertaken at QEHB.

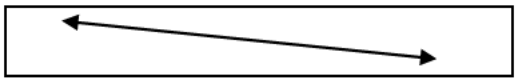
6.10 Results

The following link analysis diagram (Figure 6.8) was based upon a review of 10 hours of ICU bed-space footage. Every nurse, physiotherapist, and consultant was assigned an individual colour code and each line in the bed-space detailed any given movement between any object / location within the bed space. Three different variations of lines were used to indicate volume of traffic and repeated locations.

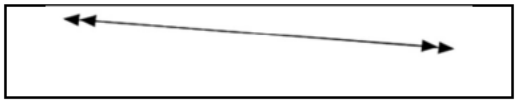
The first line with a single arrow represented a single direction travelled with no return along the same path.



The second line with arrows at each end represented a return journey to either the patient, equipment, or too any part of the bed-space.



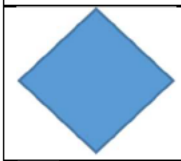
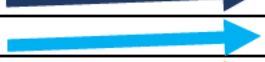
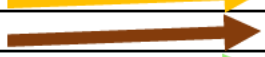
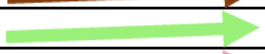
The third line with multiple return arrows indicated multiple return journeys, the greater the number of arrows alone a line, the greater the number of times the path was travelled.



6.10.1 Link Analysis – Key Assignment

For each physical element within the bed-space, or for each position change an indicator was assigned, the indicators would help construct a map of both care professionals and equipment movement, including the InspireVR prototype. Table 6.10, provides an index of the indicators used to differentiate between the types of care professionals, and also provide different colour assignments for equipment, equipment re-positioning and start locations.

Table 6.10: Key assignment for ICU bed-space analysis

Physical bed-space Element	Description
	Drug cart
	Doctor – starting location
	Nurse 1 – starting location
	Nurse 2 – starting location
	Nurse 3
	Ward sister
	Pharmacist
	Nurse 4
	Consultant

	Bin
	Bed side table original position
	Bed side table moved position 1
	Bed side table moved position 2
	Visitor chair original position
	Visitor chair moved position 1
	Visitor chair moved position 2
	VRI-I Module original position
	VRI-I Module moved position 1
	VRI-I Module moved position 2
P	Physiotherapist
	Patient side chair
	Patient
	Medical infusion stand original position
	Medical infusion stand position 1
	Camera and direction
	Ceiling mounted stanchion
	Supply trolley
	Sink
==========	Wall
----------	Bed-space operating area
	Bed

6.10.2 Link Analysis – Equipment Movement

During the link analysis the majority of wheeled equipment found themselves repositioned at some point, often to help clear the path whilst moving the patient in and out of bed, or simply to gain access to the patient for treatment. Figure 6.7 provides a look at the bed-space without the link paths but with the equipment in place in order to gain an understanding of the original start position of equipment and all the position changes made during the 10-hour shift.

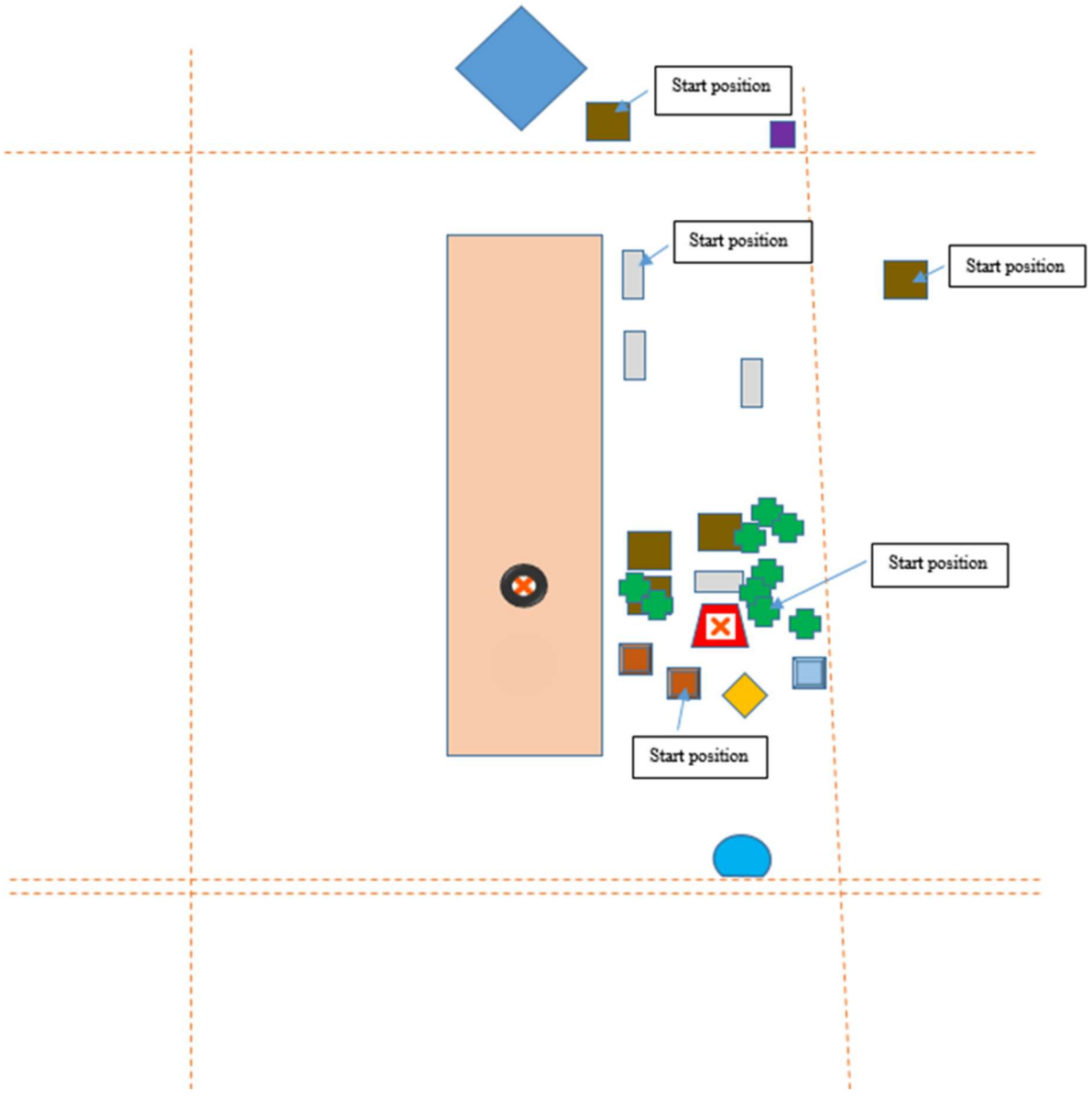


Figure 6.7: Start position and movement of equipment throughout link analysis

6.10.3 Link Analysis – Flow Diagram

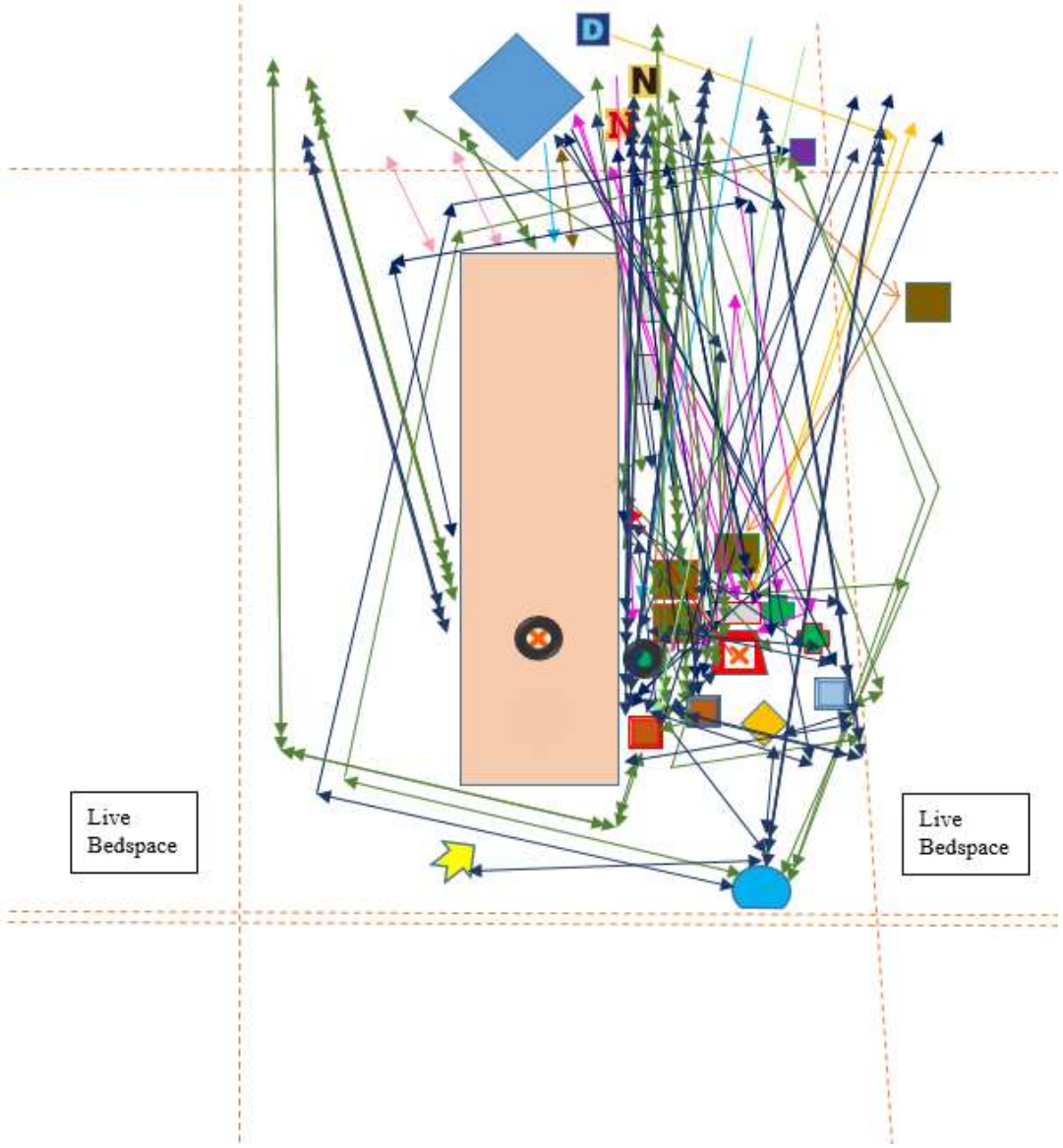


Figure 6.8: Link analysis diagram of a live QEHB ICU bed-space

The above diagram (Figure 6.8) details the outcome of the link analysis. Every person who entered the bed-space was assigned a colour code (Table 6.10) and was tracked by means of a flow line to indicate route travelled. Section 6.10 details the type of indicators used to identify if single or multiple paths were travelled and in turn tallied by means of a link table (Table 6.12) to gauge both the task and the frequency they occurred. The link table was used to note if any instances of the InspireVR being in the bed-space caused a hazard or hindered the

movement of normal medical routines or interventions with the patient. Based on the link analysis flow diagram and the link table a series of coloured overlays (Table 6.11) were applied to the analysis diagram (Figure 6.9).

Table 6.11: Hotspot overlay key

	Least of amount of traffic within the bedspace
	Moderate traffic within the bedspace
	Heavy traffic within the bedspace

Each colour represented the density of traffic in certain areas; green represented the least amount of traffic within the bed-space which indicates the safe areas for InspireVR to be located; yellow represented moderate traffic within the bed-space, InspireVR would be able to operate but would require frequent repositioning; and finally red which represented the heaviest areas of traffic, primarily due to the fact the patient is the nucleus for all activity, InspireVR would need to be moved often and could hinder care professionals' movements during certain tasks.

Table 6.12: Link Table

Task	Frequency with InspireVR	Impact of InspireVR on task completion
Hand washing	12	No impact
Observation / documentation	6	No impact
Moving of patient from chair to bed	1	InspireVR was moved to one side to allow for staff to step transfer patient into chair
Moving of patient from bed to chair	1	InspireVR was moved to one side to allow for staff to step transfer patient into bed
Hand washing	12	No impact
Visit to the waste bin	7	No impact

Task	Frequency with InspireVR	Impact of InspireVR on task completion
Adjustment of infusion pumps (stand mounted)	36	InspireVR needed to be moved to allow access to pumps, damage to digital spirometer occurred on one instance (Figure 7.9)
Movement of tray table (seated patient)	3	InspireVR was moved to one side to allow for reposition of tray table to and from the patient
Physiotherapist sessions / visits with patient	7	InspireVR was moved into reach of the patient to allow for teaching and initial rehabilitation session
Doctor consultation	2	No impact
Patient pressure sore roll in bed	1	No impact

6.10.4 Heat map

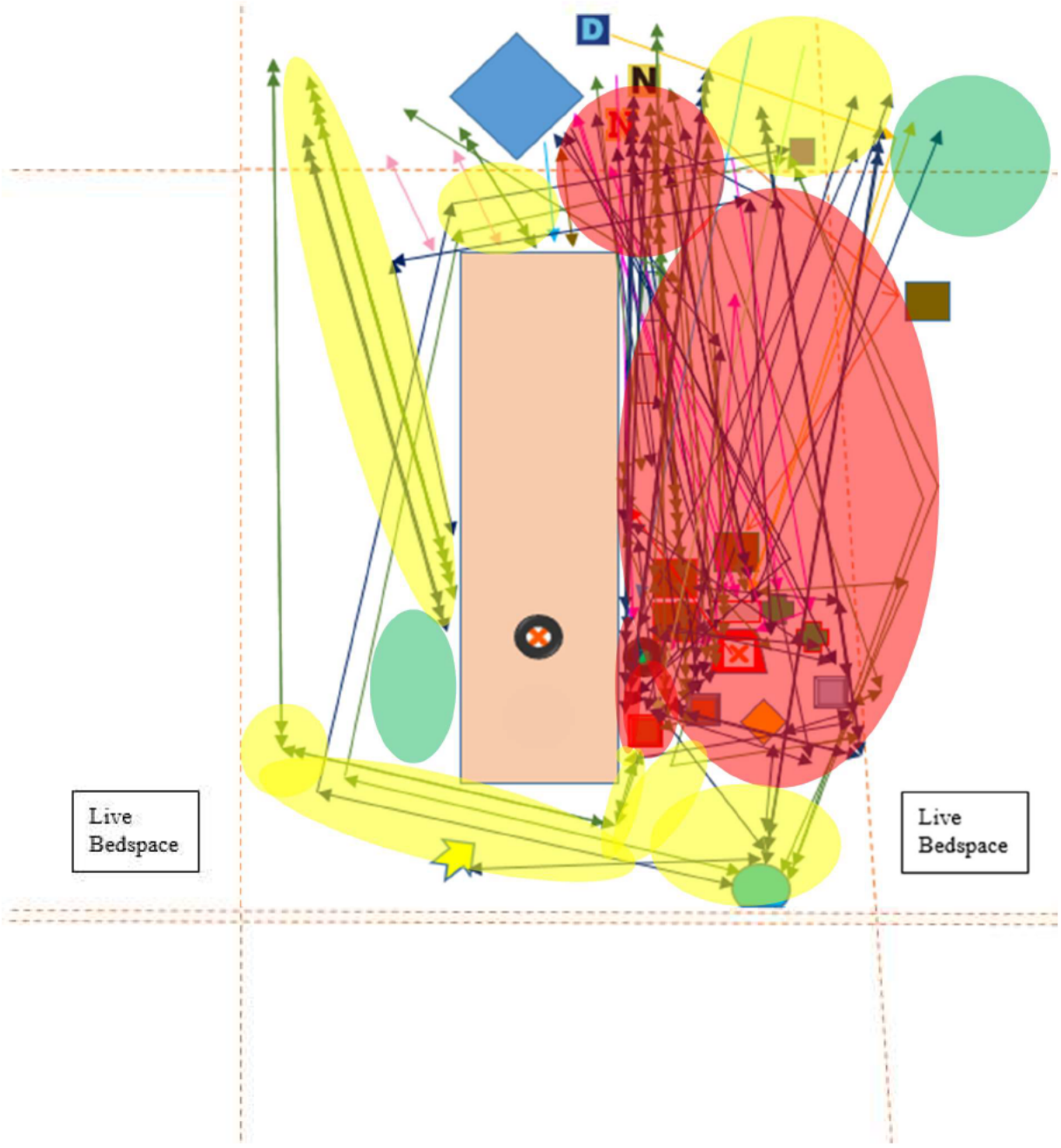


Figure 6.9: Link Analysis with heat map

6.10.5 InspireVR Usage and damage to equipment



Figure 6.10: Patient use of InspireVR whist bed-bound

The InspireVR prototype was designed to accommodate both seated (Figure 6.6) and bed-bound (6.10) patients during rehabilitation sessions. During the time the patient was in bed and whilst in between sessions a nurse who was acting on an alarm from one of the infusion pumps had to squeeze between InspireVR and the bed during which the stand was knocked leading to the digital spirometer mouth piece falling causing damage. Figure 6.11 illustrates the moment the damage occurred.



Figure 6.11: Damage to InspireVR captured during link analysis

6.11 Discussion

The rational for conducting the link analysis was to view the InspireVR prototype within the operational environment it was designed for, namely the intensive care unit. Due to the many restrictions in terms of allowing a non-medically trained outsider into such a high risk and controlled environment, a small camera was used as a valid substitute. The camera was trained on both the InspireVR and the patient (with full consent) who would be undergoing rehabilitation sessions. In between these sessions InspireVR was required to co-exist within the bed-space for the full duration of the patients' rehabilitation cycle (1 complete day shift).

The ethical approval allowed for the first five consenting patients to be used in the study (only at the QEHB), one to act as a control with no InspireVR, and the remaining four with the prototype in the bedspace. Unfortunately, there was a loss of data due to the theft of a GoPro from a secure area within the ICU itself. Therefore, the data (7.10.3) refers to only one bedspace analysis. The captured footage spanned 10 hours and was used to formulate both a link table

(Table 6.12) and link analysis (Figure 6.8) that looked at the movement of equipment and traffic flow of care professionals. Upon completion of the analysis a heat map overlay (Figure 7.9) was applied to the link diagram to highlight areas of most and least activity.

The areas highlighted in red indicated the highest volume of activity which at the time of the link analysis was where InspireVR was placed, to validate the findings during this period damage occurred to the digital spirometer (Figure 6.11) indicating that the system caused a hazard albeit due to the unfamiliarity of having a new piece of equipment in that location. The ideal solution would be to position the system within the green zone on the left side of the bed (Figure 6.9), the main restriction being the placement of patient lines and sensing equipment. Currently the infusion stand is placed centrally between the bed and the side-chair, to have InspireVR in that location would need the infusion stand to be re-positioned behind the head of the bed, this would prove to be unfeasible as during serious interventions medical professionals would require rapid access to the patient, would be faced with a sea of medical equipment.

There were issues with the link analysis whereby certain critical situations were not captured due to not being necessary for the patient, an example of which might have been a crash scenario (both seated and bed bound) whereby the InspireVR would have needed to be hastily repositioned or removed from the area. Further investigation would need to be conducted to capture and identify long term usage and positioning of the InspireVR to establish a safe operating environment that would not compromise the integrity of the prototype, but above all ensure patient and care professional safety.

The following Chapter (7) looks at the design and construction of the VeloVR prototype in preparation for its debut in the VeloVR study within the ICU at QEHB.

7. Prototype Design – VeloVR (REVERE Move)

The VeloVR prototype was designed to complement the Reck MOTOmed Letto (Appendix 7.1) in a non-intrusive manor. The MOTOmed was a medically certified piece of equipment, therefore it was not feasible to mount or retrofit anything onto it for fear of voiding both the warranty and compromising the devices medical certification. Based on this it was necessary to construct a prototype that needed to be:

a) compact enough to fit between the patient (in a bed-back raised position) and the MOTOmed.

b) able to offer multiple ergonomic adjustment points for height, reach, and angle to offer the maximum comfort to the patient.

c) be constructed to a high standard in order to cope with the operational and hygienic demands of the intensive care unit.



Figure 7.1: Original component breakdown of VeloVR prototype (with anodised base plate)



Figure 7.2: First basic assembly of VeloVR prototype

The new prototype, entitled VeloVR (to align with the pending study, chapter 8) was constructed (Figures 7.18 and 7.19) utilising elements from a basic laptop stand (Figure 7.1). The remainder of the current chapter details the stages of the build from the initial ICU bedspace and ergonomic fitment evaluation to final pre-study deployment test to medical stakeholders and physiotherapists.

7.1 Initial ICU Bedspace and Ergonomic Installation Test

Once the basic VeloVR rig was assembled (Figure 7.2) it was taken to the Queen Elizabeth Hospital where it was placed within an active ICU bed-space and evaluated to identify if any ergonomic issues arose, the installation test looked at:

i) The clearance of the wheeled base plate under a standard NHS issue ICU bed (Figure 7.3) proved to be sufficient to allow the rig to slide fully without interfering with the motorised height adjustment mechanism of the bed.



Figure 7.3: View of the base frame on the VeloVR whilst fully docked under a ICU bed

ii) The ability of the display mount to be lined up centrally along mid-line of the bed (Figure 7.4), therefore in line with the MOTOmed and the patient, failure to achieve this would have caused the patient using the MOTOmed to have an off angle view of the gameplay and potentially compromise patient comfort and study outcomes.



Figure 7.4: VeloVR prototype display mount centrally positioned over the bed

iii) The maximum adjustment of the display mount would be required to suspend a 24" pc display in such a manner that when raised would clear a patients' legs and torso when considering a 95th percentile user, i.e. for the largest possible user. The first (Figure 7.4) test demonstrated that the maximum vertical placement was too low (Figure 7.5).



Figure 7.5: Lack of vertical display clearance

The vertical arm was modified and re-installed (Figure 7.6) which vastly improved height clearance in contrast to Figure 7.5, the image also showed the MOTOmed placed at the foot of the bed.



Figure 7.6: Improved vertical mount positioning

7.1.1 Display Adjustment

The display mount featured a quick release mechanism that allowed the display to be angled backwards (Figure 7.7) or forwards (Figure 7.8) to a maximum angle of +/- 40-degrees. The levels of adjustably would ensure that the patient would be able to get the best possible viewing angle whilst bedbound.

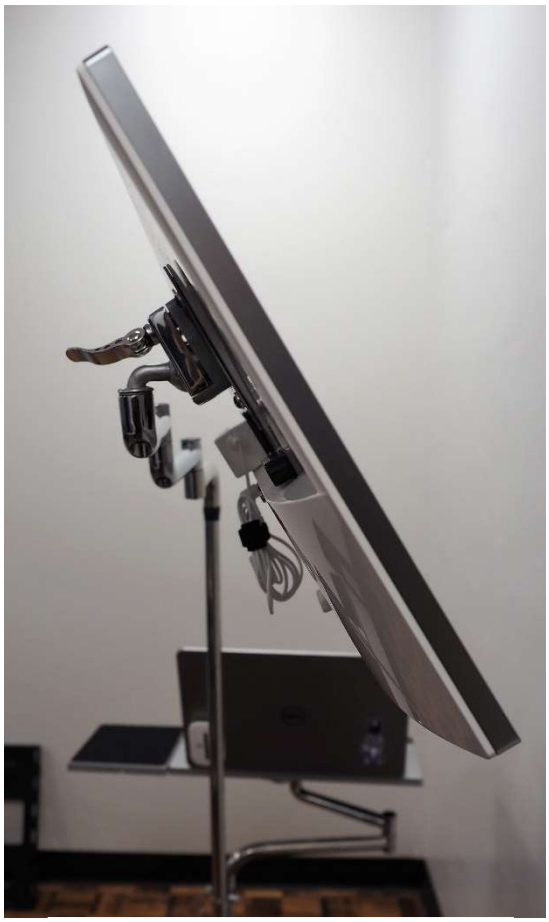


Figure 7.7: Display at 40-degree backward tilt

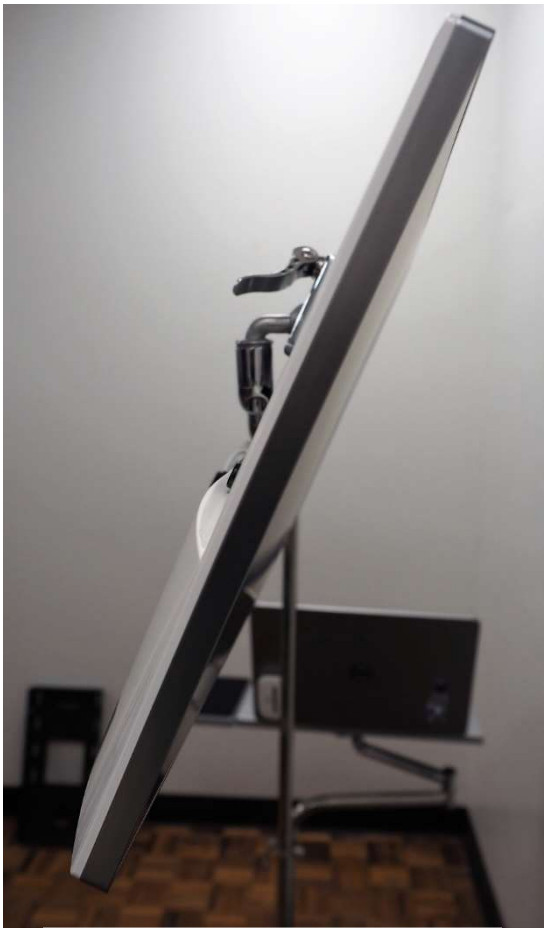


Figure 7.8: Display at 40-degree forward tilt

7.1.2 Display Arm Adjustability

The display mount arm was designed to concertina in (Figure 7.9) to help with the manoeuvrability and storage footprint of the VeloVR prototype.



Figure 7.9: VeloVR display mount in the stowed position

When at maximum reach (Figure 7.10) the VeloVR was examined to identify and stability issues of prototype, the reworked aluminium base plate functioned a satisfactory counterweight.



Figure 7.10: VeloVR display mount at full extension

7.1.3 Cadence Sensor Installation

The interface between the pedal rotation of the MOTOmed and the VeloVR PC came from the fitment of a Garmin GSC10 cadence sensor (a Bion CX-320 sensor was substituted at a later date due to loss) that transmitted pedalling rate (cadence) and transmitted the signal via Bluetooth to a USB ANT+ receiver. The cadence sensor was mounted on the frame of the MOTOmed (Figure 7.11) and a small magnet was placed on the pedal crank (Figure 7.11) in a way that with each pedal rotation it passed the arm of the sensor.

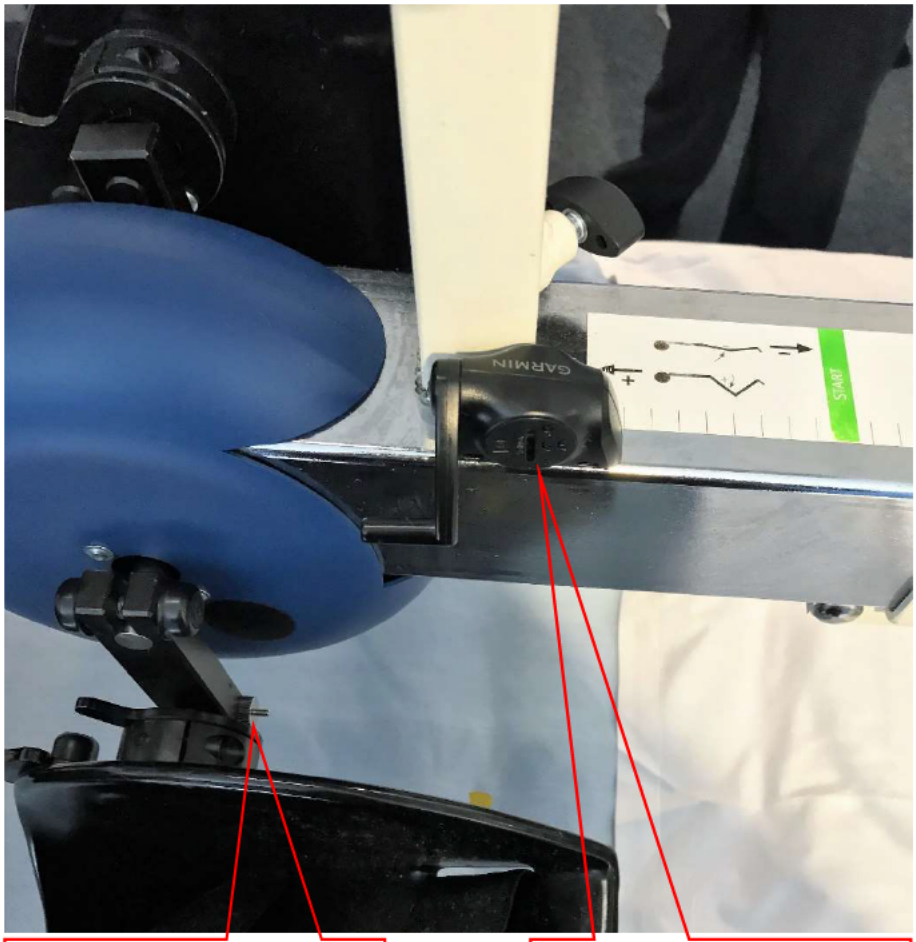


Figure 7.11: Placement of cadence sensor and magnet on the MOTOmed

7.2 Second ICU Installation Test

Following the completion of the build stage of the VeloVR prototype a second installation test was conducted to check if the issues encountered (7.1) had been addressed. The prototype was close to the pre-deployment stage and the second installation test was the first opportunity for clinical professionals to view and demo the system (Figure 7.12 – 7.15).

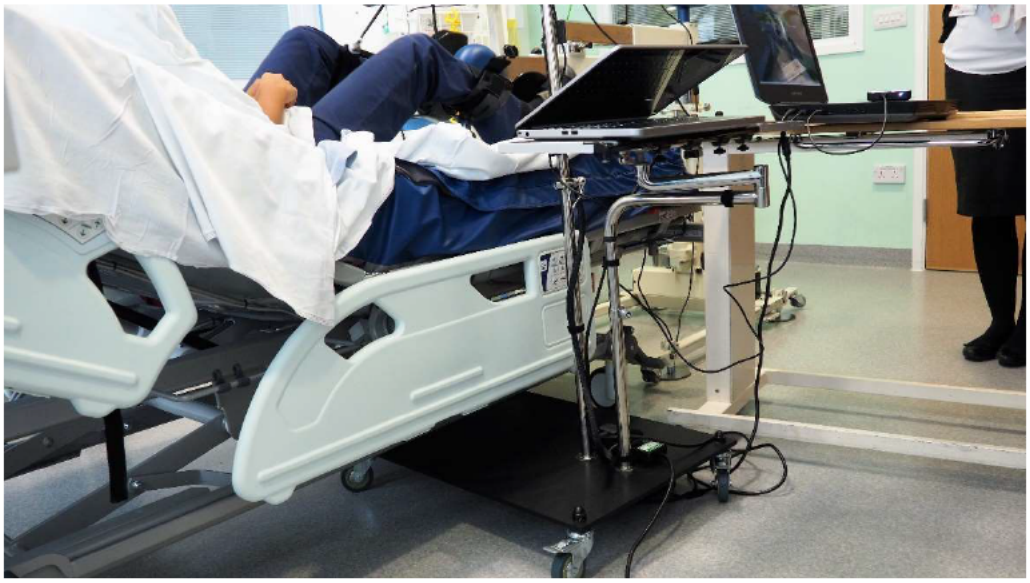


Figure 7.12: VeloVR prototype installed at the side of an NHS ICU bed



Figure 7.13: Demonstration of the VeloVR prototype to clinical care professionals and former ICU patients



Figure 7.14: Demonstration of the VeloVR prototype to clinical care professionals and former ICU patients



Figure 7.15: square on side-view of the VeloVR display mounted above the MOTOmed

7.3 Final Pre-Deployment Test

The final stage in the design cycle of the VeloVR prototype was to install it in an active ICU bedspace to check its fitment, adjustability, and safety. Figure 7.16 demonstrated how the system would fit from a patient perspective, and Figure 7.17 illustrated how the prototype integrated with other ICU equipment.

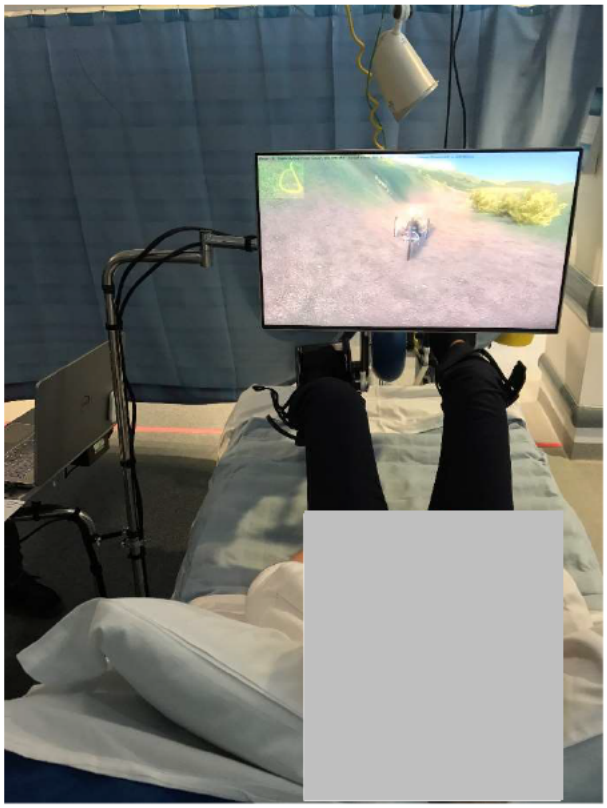


Figure 7.16: VeloVR being trailed by and ICU physiotherapist in a live ICU bedspace at the QEHB

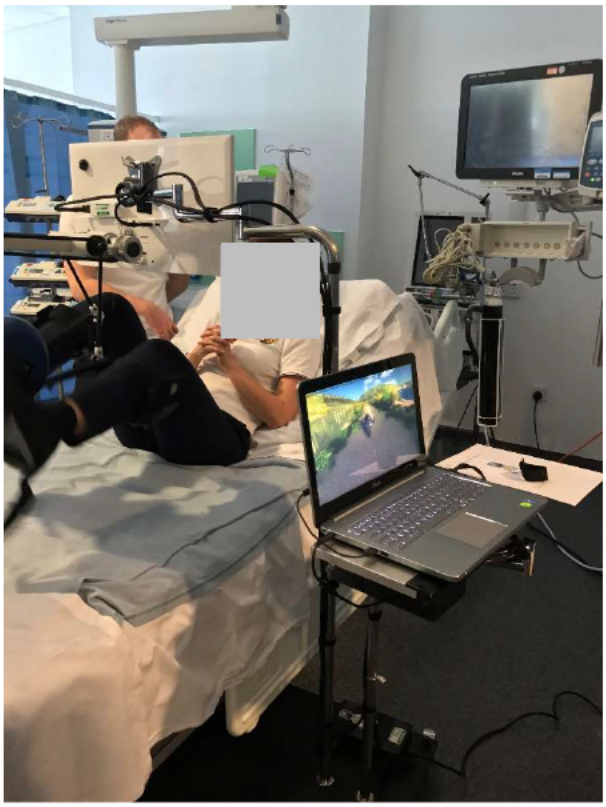


Figure 7.17: Final installation check of the VeloVR prototype in a live ICU bedspace at QEHB

A full copy of the VeloVR user guide that was distributed with the prototype can be located at Appendix 7.2.

A copy of the favourable opinion from the West Midlands – Edgbaston Research Ethics Committee can be found located at Appendix 7.3.

7.4 Deployment

The VeloVR prototype system was installed with the ICU at the QEHB in early March 2017 and was ready for patient recruitment, until this point the system had only seen design and informal testing. Figure 7.18 and 7.19 shows the VeloVR prototype within the ICU and being used by a critically ill patient.





Figure 7.18 and 7.19: images of VeloVR undergoing patient trails with the QEHB

The following Chapter (8) will determine the safely and performance of the VeloVR prototype in a study conducted within the ICU at the QEHB. The study aimed to satisfy the requirements of a clinical investigation as required by the directives of the MHRA in the category of novel medical devices in order to obtain CE marking as a class 1 medical device (Medicines and Healthcare Regulatory Agency (2016).

8. Study 3 - VeloVR

8.1 Background

Many patients who pass through the ICU system recover from critical illness with few adverse consequences, others develop a condition called “Intensive Care Acquired Weakness (ICU-AW)”. The condition leads to profound muscle wastage resulting in severe and incapacitating weakness. A recommended therapy used to aid recovery and rehabilitation is the use of in-bed cycling, in contrast to the majority of exercise equipment found in commercial gyms, the in-bed cycle provides the patient with no form of performance feedback or distraction from the discomfort felt as a consequence of exertion.

The study sought to evaluate if a new Virtual Reality Interaction (VR-I) Module prototype named VeloVR (Chapter 7), could integrate effectively within an ICU bed-space whilst being respectful as to not interfere with an existing piece of commercial rehabilitative equipment, as well as compromise the patient’s safety, nor their ability to perform rehabilitative tasks safely and unrestricted. The prototype was designed to offer a platform to provide real-time feedback during a patient’s in-bed cycle session whilst also examining if the prototype was feasible and safe to use with stable patients diagnosed with ICU-AW on the ICU. VeloVR was a novel interactive technology-based system using commercial-off-the-shelf (COTS) interface devices, custom built rig combined with custom-designed gaming software designed to interface to the Reck MOTOmed Letto (Figure 8.2) (hereafter referred to as “MOTOmed”) in–bed cycle ergometer. The study will determine the safety and performance of VeloVR in order to meet the necessary requirements of a clinical investigation as mandated by directives of the MHRA for novel medical devices in order to obtain a CE mark as a class 1 medical device (MHRA, 2016).

The VeloVR system offered two incentive gameplay modes, the first being distraction-based and the second competition-based. The modes were designed to improve patient experience and performance sessions of in-bed cycle ergometry, by those diagnosed with ICU-AW on the Intensive Care Unit (ICU). As the MOTOmed was a commercial medically certified device it was not feasible to interface with the systems electronics in order to extract a usable signal, a far simpler and cost effective solution came from incorporating a cadence sensor (Figure 8.1) to track the crank rotation of the MOTOmed, with the signal being translated into the game movement of a virtual cyclist on a rig mounted (Chapter 7, Figure 7.16) patient display that was in sync with the patients' effort. The faster the patient would pedal on the MOTOmed the faster the virtual cyclist would travel.

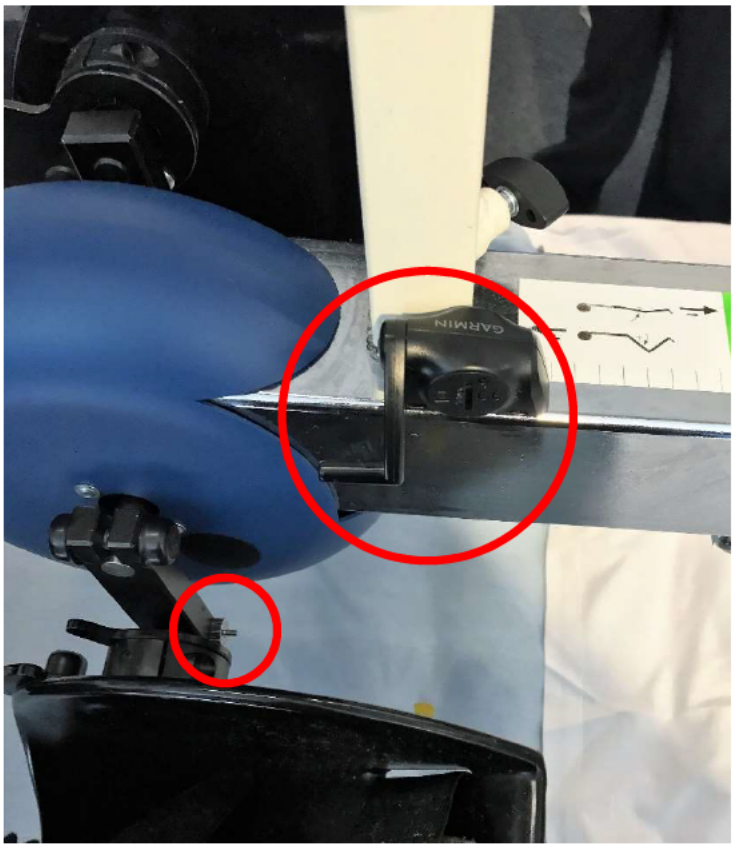


Figure 8.1: Placement of cadence sensor on a MOTOmed at the QEHB

8.1.1 Intensive Care Unit-Acquired Weakness

A large proportion of ICU survivors requiring treatment in the ICU suffer significant long-term physical and psychological trauma, reducing their health-related quality of life (Dowdy et al., 2005, Pearman and Herridge, 2013, Needham et al., 2013. One of the most prevalent of these complications is intensive care unit-acquired weakness (ICU-AW), which is evident in 50% of patients who are mechanically ventilated for greater than five days (Puthucheary, Harridge and Hart, 2010).

A series of pharmacological and non-pharmacological interventions have been investigated for the prevention and treatment of ICU-AW. Early mobilisation in ICU reduces the dependency of mechanical ventilation (Hermans et al., 2014), improves the patients' functional abilities and muscle strength in preparation for discharge to ward care (Early mobilisation and recovery in mechanically ventilated patients in the ICU: a bi-national, multi-centre, prospective cohort study, 2015) and can contribute to improvements in physical performance ad capabilities on discharge home (Kayambu, Boots and Paratz, 2013).

8.1.2 Rehabilitation for ICU-AW

For those diagnosed with ICU-AW, rehabilitation focuses on whole-body muscle and cardiorespiratory training (Ambrosino, Janah and Vagheggini, 2011), aimed at improving functional status, reducing time to independent ambulation and accomplishment of activities of daily living prior to discharge to a general ward (Gosselink, Needham and Hermans, 2012). There are a small number of technologies evaluated to aid rehabilitation on ICU (Needham, Truong and Fan, 2009). Those who are too weak to attempt walking or step transfer out of bed undergo sessions of recumbent cycle ergometry, which has been demonstrated to improve peripheral muscle strength, functional status and subjective wellbeing at hospital discharge in patients with prolonged ICU stay (Burtin et al., 2009).



Figure 8.2: Reck MOTOmed Letto cycle ergometer

https://www.motomed.com/en/products/motomed-letto2/ [Accessed 18 Jul. 2018].

Recumbent cycle ergometry is utilised at the QEHB for patients with ICU-AW by means of a MOTOmed Letto (Figure 8.2). Patients diagnosed with ICW-AW are referred to the ICU Supportive Rehabilitation Team (SRT), a multidisciplinary team led by physiotherapists with expertise in the management of complex and long-stay ICU patients. It is those patients who undergo ergometry sessions of up to 20 minutes every 2-4 days (Figure 8.3) until capable enough to step transfer with assistance. The practice is consistent with that reported elsewhere (Kho et al., 2015). The MOTOmed device is equipped with three modes; passive, active-assist and active (with adjustable pedal resistance). Patients are instructed to actively pedal for as long as they are able, after which the MOTOmed reverts to a passive mode whereby the pedals continue to rotate slowly until the end of the prescribed session. The active-assist mode was not utilised.

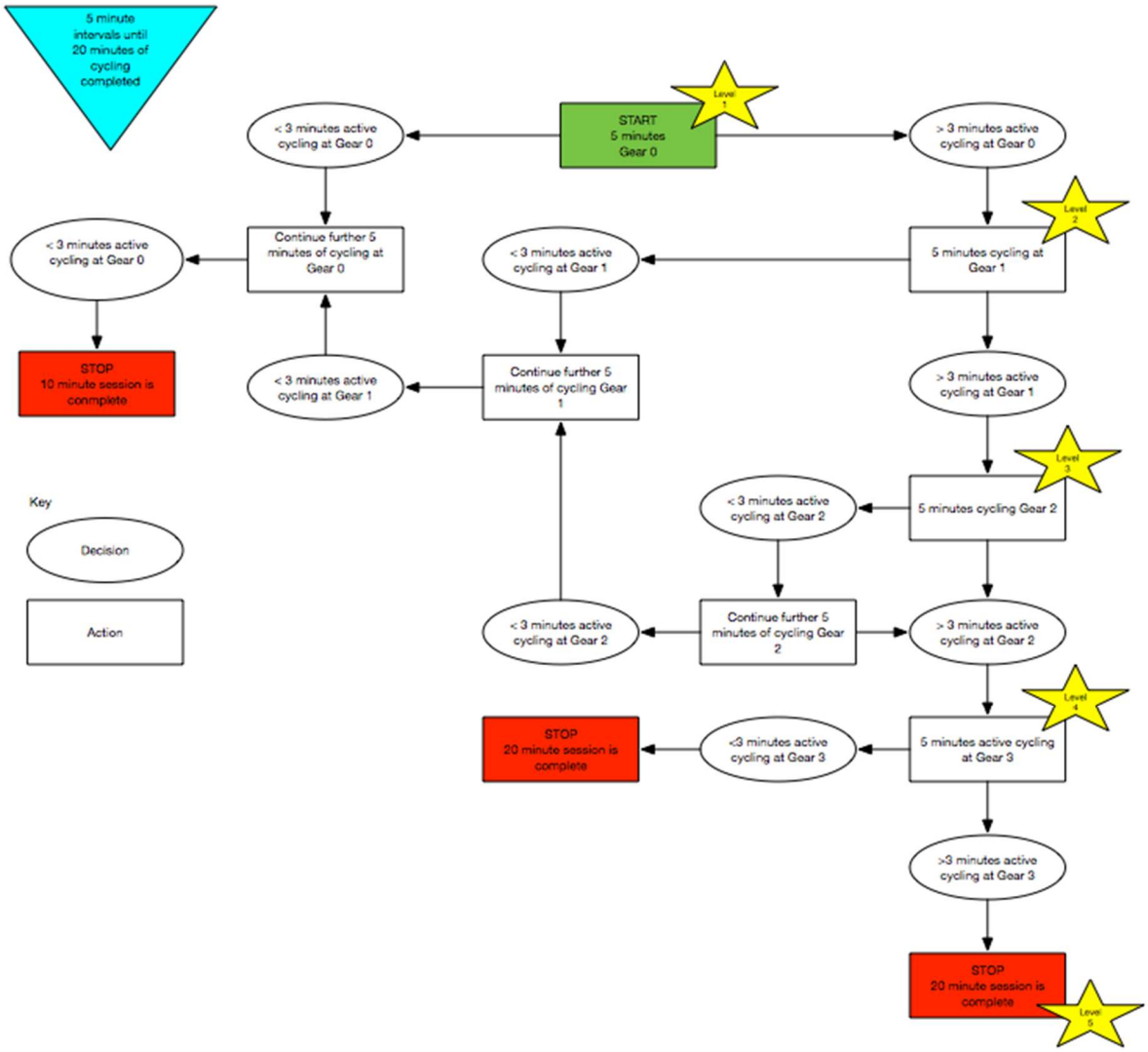


Figure 8.3: Standard QEHB protocol for recumbent ergometry (MOTOmed)

8.2 Aims

The aims of the VeloVR study was to:

i) Evaluate the usability and user acceptance of the VeloVR device by patients on ICU.

ii) Evaluate the usability and user acceptance of VeloVR by staff providing rehabilitation to patients on ICU.

iii) Evaluate the safety of, and adverse events related to the use of VeloVR

8.3 Methodology

8.3.1 Study Setting

The study was undertaken on the critical care unit of Queen Elizabeth Hospital Birmingham (QEHB). The unit was an 86 bed mixed level 2 and 3 adult teaching hospital unit that admits medical, surgical, trauma, burns, liver, cardiac and neurosurgical patients.

8.3.2 Recruitment, Consent and Withdrawal

8.3.2.1 Recruitment

All patients invasively mechanically ventilated for five days or more will be identified by the research physiotherapist via the hospital Patient Information and Communication System (PICS). Each of these patients will be reviewed daily until they can be tested for ICU-AW. As the diagnosis of ICU-AW requires some patient cooperation, this is usually after cessation of intravenous sedation. Once ICU-AW weakness is diagnosed and there are no contraindications to the use of the recumbent cycle, the patents will then be reviewed daily until they are cognitively able to receive information on the study. A letter of invitation and patient information leaflet will be provided by the research physiotherapist, with opportunity given for the patient, their friends and family to discuss the trial with a member of the research team.

8.3.2.2 Consent

At least 24 hours will be given prior written informed consent being taken. In the context of ICU-AW, some patients will be unable to write and provide a signature. In this event, signed witness to consent will be requested from a member of the patient's clinical team.

Staff members will be invited to participate in the study. The physiotherapist supervising the recumbent cycle session will be invited to complete a questionnaire following each intervention. All members of the ICU physiotherapy team will be given invitation letters and information forms prior to the trial opening. Members of the research team will be available to

discuss the study with staff members. Written consent will be taken from all staff participants prior to commencement of the ergometry session.

8.3.2.3 Withdrawal from the study

Participants will be informed of their right to withdraw from the study at any time and that they will not be required to give a reason for doing so. Participants will be advised that they may request their data be withdrawn from the study, but that they will need to make this request within 14 days of the data collection occurring.

8.3.3 Inclusion and Exclusion Criteria

For the patient to be approached and recruited onto the study, they were required to meet the following inclusion criterion:

i) Must be a patient within ICU

ii) Conscious and able to communicate

iii) Aged over 18 years old (for informed consent)

iv) Richmond Agitation Sedation Scale (RASS) score -1 to +1

v) Diagnosed with ICU-AW as defined by the presence of 1,2,5, and either 3 or 4 from:

1. Weakness developing after the onset of critical illness
2. The weakness being generalized (involving both proximal and distal muscles), symmetrical, flaccid, and generally sparing the cranial nerves (e.g. facial grimace is intact)
3. Muscle power assessed by the Medical Research Council (MRC) sum score of ,48 (or a mean score of ,4 in all testable muscle groups) noted on .2 occasions separated by .24h
4. Dependence on mechanical ventilation
5. Causes of weakness other than ICU-AW have been excluded.

The patient would not be approached based on the following exclusion criteria:

i) Severe visual loss

ii) Active delirium or psychosis at screening from the Richmond Agitation Sedation Score (RASS) and the Confusion Assessment Method for the ICU (CAM-ICU) score.

iii) Severe cognitive impairment or encephalopathy

iv) Profound neurological deficit

v) Orthopaedic patients with contraindications to mobilise (e.g. pelvic / spinal fractures)

vi) Poor level of mobility (<10yds)

vii) Neuromuscular disease (e.g. Motor Neurone Disease

viii) Expected withdrawal of treatment within the next 24 hours

ix) Patients with already established rehabilitation pathways (e.g. amputees)

x) Previous participation in the study

8.3.4 Participants

20 patients were recruited onto the VeloVR study over a 6-month period.

15 males; 5 female; mean age = 51.41 (based on 17 recorded age values); age range 26 – 74.

8.3.5 Funding

Joint Medical Command Medical Directorate, Ministry of Defence. Ref:

20140312_DMSRSG

8.3.6 Ethics

South Birmingham Research Ethics Committee was approached and granted NHS ethical approval.

8.3.7 Conditions

The trial was not randomised; therefore, each participant was exposed to all conditions in the same order:

Session 1: NoVR - Standard MOTOmed, VeloVR in place but system off.

Session 2: SoloVR - VeloVR system running in Distraction mode (solo play).

Session 3: CompVR - system running in Competition mode (playing against solo effort from session 2).

8.3.8 Procedure

The in-game setting for VeloVR was Virtual Wembury (Chapter 3, Figure 3.2), a virtual reality-based simulation of a real world natural environment, developed by the Human Interface Technologies Team at the University of Birmingham. It was based on a South West coastal path around Wembury Bay (Depledge, Stone and Bird, 2011). The system had been adapted for use by patients in the ICU, with a selection of appropriate interface systems and consideration of bed-space and working environment ergonomics for staff.

The duration of each intervention was a maximum of 20 minutes. Patients followed the standard QEHB recumbent ergometry protocol (Figure 8.3).

A cadence tracking sensor (Figure 8.1) tracked the MOTOmed crank rotation. The rotational data was then converted via a custom mid-ware into key-presses that progressed the VeloVR avatar forward. The game play was displayed on PC display mounted between the patient and the MOTOmed, adjusted to patient eye level allowing for a comfortable viewing position (Figure 8.4).

The MOTOmed ergometer was set to "Active" for each intervention

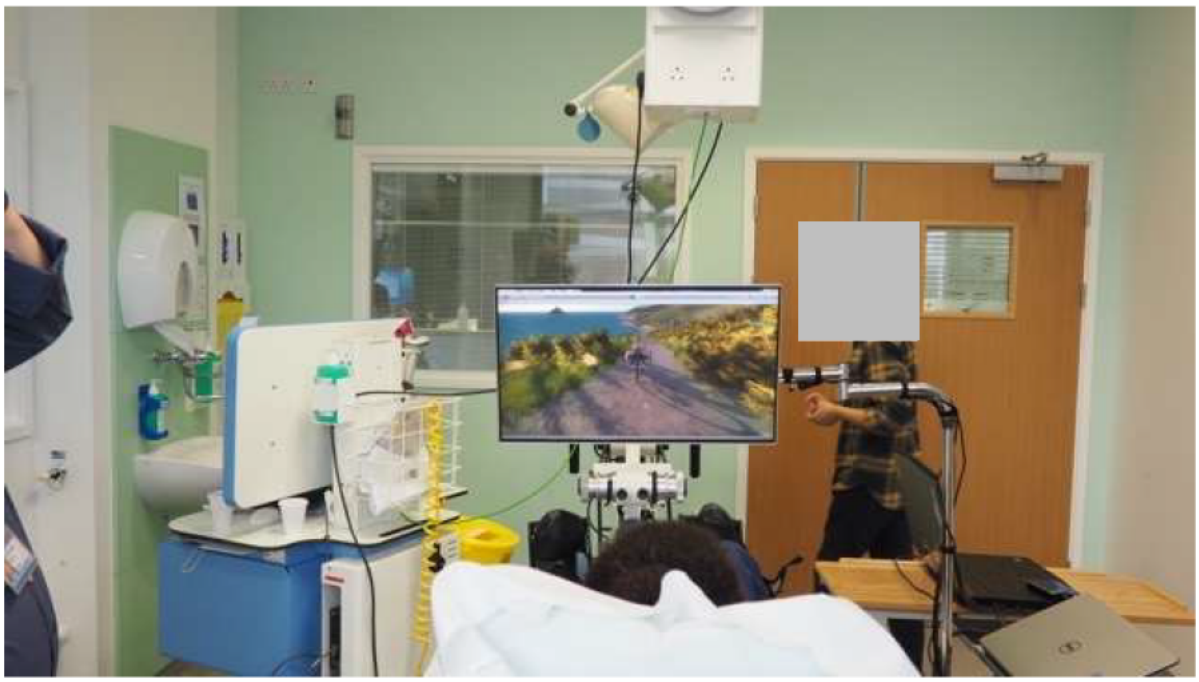


Figure 8.4: VeloVR prototype undergoing final pre-deployment testing on the ICU, QEHB

The game play featured two modes:

1. Distraction (solo) mode - patients pedal along the coastal path of Virtual Wembury. Speed along the path is determined by cadence speed.
2. Competition mode - patients pedal and compete against a cycling avatar, attempting to move faster than them along the coastal path. The avatar speed and progress is that achieved by the patient during their previous session. Thus, they are aiming to perform better than during the previous session.

As the MOTOmed gearing is increased in line with the standard QEHB protocol for recumbent ergometry (Figure 8.3), the change in effect was represented within the VeloVR game by an increase in speed. Each participant completed four sessions of MOTOmed, two using VeloVR, Figure 8.5 illustrates the participant flow diagram.

The flow diagram on the following page (Figure 8.5) illustrates the flow of the study, from the initial selection criteria of the patient being mechanically ventilated for a minimum of 5 days, before becoming eligible for assessment to diagnose for ICU-AW, to the flow of the 4 conditions and capturing of questionnaire data.

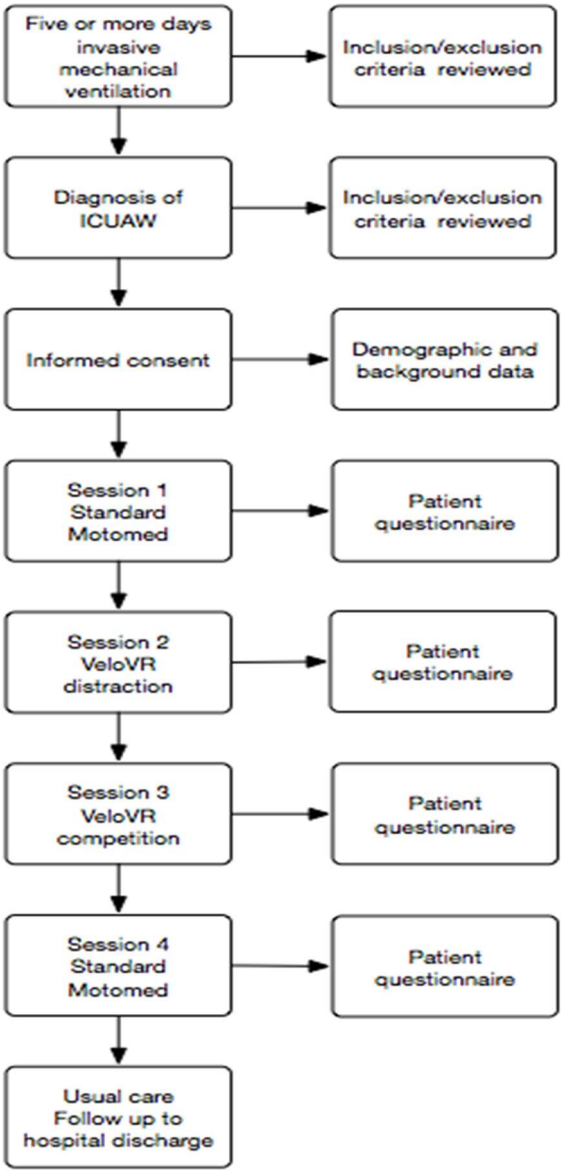


Figure 8.5: Participant testing flow diagram

8.4 Measures

The following questionnaires were distributed during pre-admission clinics in order to consent suitable participants on to the study

8.4.1 Demographic data taken at pre-admission clinic

<table>
<tr><td>Male ☐
Female ☐</td><td colspan="2"></td><td>Main language
English ☐
Other TEXT</td></tr>
<tr><td colspan="2"></td><td colspan="2">Pre-admission functional status
TEXT</td></tr>
<tr><td>Occupation
TEXT</td><td colspan="2">Highest education level
No qualifications ☐
O level/GCSE/Equiv ☐
A level/Equiv ☐
Degree/Equiv ☐
Higher degree ☐</td><td>Hobbies and interests
TEXT</td></tr>
<tr><td>Would you consider yourself to be competitive?
Yes ☐
No ☐</td><td colspan="2">How often do you exercise recreationally?
Never ☐
Every day ☐
1-5 times a week ☐
Less than once a week ☐
Have you exercised more frequently in the past?
Yes ☐
No ☐</td><td>Have you ever played competitive sport?
Yes ☐
No ☐
To what level?
Local ☐
Regional ☐
National ☐
International ☐</td></tr>
<tr><td colspan="4">Member of the armed forces: Current/Previous
Details:</td></tr>
<tr><td>Age of children resident at home</td><td>Child 1
NUMBER</td><td>Child 2
NUMBER</td><td>Child 3
NUMBER</td></tr>
<tr><td colspan="2">MRC Sum score
NUMBER 1-2 digits</td><td colspan="2">MMS at consent
NUMBER 1 digit</td></tr>
</table>

8.4.2 Device familiarity / Computer experience

Device familiarity/ Computer experience	At home	Confidence using (1 not at all, 5 very) 1 2 3 4 5
Computer/laptop	Y ☐ N ☐	☐☐☐☐☐
Tablet device, eg iPad	Y ☐ N ☐	☐☐☐☐☐
Smart/Interactive TV	Y ☐ N ☐	☐☐☐☐☐
Mobile phone	Y ☐ N ☐	☐☐☐☐☐
Smart phone	Y ☐ N ☐	☐☐☐☐☐
Wearable monitoring device e.g. Fitbit	Y ☐ N ☐	☐☐☐☐☐
Computer games console e.g. Xbox	Y ☐ N ☐	☐☐☐☐☐
Other (list)	TEXT	☐☐☐☐☐

8.4.3 Technology Acceptance

Technology acceptance	Strongly disagree 1, Strongly agree 5 1 2 3 4 5
VeloVR will help me to perform my best during the cycling session	
I could easily learn how to use VeloVR	
Learning to use new electronic devices makes me feel apprehensive	
I feel confident I will be able to follow the instructions for using the VeloVR	
Use of VeloVR will help with cycling exercises	
I am looking forward to using VeloVR	
I am worried that VeloVR will cause me harm	

I use computers and electronic gadgets in my everyday life	
I feel confident using computers and electronic gadgets	
I expect to be using electronic devices to help with my rehabilitation after my illness/injiry/operation	
I intend to use other electronic devices during my rehabilitation after my illness/injury/operation	
I will have enough support to use VeloVR in hospital	
I have a disability/impairment which will prevent me from using VeloVR properly (please describe)	TEXT

8.5 Daily Recumbent Ergometry Records

The same daily recumbent ergometry record was administered after each of the 4 rehab sessions, the sessions were run in the same order: Session 1: Standard MOTOmed**,** Session 2: VeloVR (Distraction, Session 3: VeloVR (Distraction) and Session 4: Standard MOTOmed.

Date NUMBER	CAM ICU Positive ☐ Negative ☐	RASS NUMBER (-3 to +3)	MMS NUMBER	Vent mode TM ☐ CPAP ☐ PS ☐ PCV ☐	PS NUMBER 1-2 digits
Session duration (minutes): NUMBER	Level Achieved: NUMBER	Highest gear: NUMBER	Distance covered: NUMBER	Minutes of active: NUMBER	Active: Passive ratio NUMBER: NUMBER
Reason for discontinuing session: TEXT		Nausea: Yes ☐ No ☐	Other side effects: TEXT		
Worst pain/discomfort experienced: 0 1 2 3				IMI NUMBER 1-2 DIGITS	
Average pain/discomfort experienced: 0 1 2 3					
Breathlessness: 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20					
Perceived exertion: 0 1 2 3 4 5 6 7 8 9 10					

8.6 Borg Scales

8.6.1 Modified Borg Dyspnoea Scale



(Modified Borg Dyspnoea Scale, 2018)

https://healthunlocked.com/blf/posts/130484665/modified-borg-scale-for-breathlessness

8.6.2 Borg Rating of Perceived Exertion Scale

6	No exertion
7	
8	
9	
10	
11	Light
12	
13	Somewhat hard
14	
15	Hard (heavy)
16	
17	Very hard
18	
19	
20	Maximal exertion

(Borg Rating of Perceived Exertion scale, 2018)

https://pilates1901.com/cardio-routine-making-fat/rpe/

A full copy of the Borg Ratings of Perceived Exertion (RPE) and Dyspnoea Scale can be located in Appendix 8.1

8.6.4 Staff Interview

8.6.5: Device Usability

Topic	Questions	Probes
Usability	What difficulties did you have using VeloVR? How long did it take you to feel confident using VeloVR? How would you suggest we make it easier to use?	What made it easy/not easy to use? Was the system easy to set up? Was the game easy to follow? Did you understand what you needed to do?

System Ergonomics	How did you feel about having the VeloVR device in the patient bedspace? Was the device difficult to move around?	Did it get in your way?
Errors	Did you make any mistakes whilst you were using VeloVR?	What do you think caused these mistakes?

8.6.6: Performance feedback and appraisal

Topic	Question	Probes
Motivation	How did VeloVR affect the patients' motivation during the cycling exercises?	Did they prefer the competition or the distraction game?
Study Experience	How did you find being in this study? Would you recommend participating in this study to other staff members?	Did you feel that everything was explained clearly to you?
Other	Do you have any other comments?	

8.7 Participant details

The following section details the results gathered during the VeloVR study. Due to the nature of participant testing and in particular the recruitment of critically ill patients, it should be noted that data for certain patients are omitted. The omissions can be attributed to patients being successfully consented on to the study only to have delays in surgery, complications post-surgery, referred back to general wards, discharged, or passing away.

8.7.1 Demographic data taken at pre-admission clinic

The following data refers to the questionnaire located at 8.4.1. Table 8.1 illustrates the participant group that consisted of n=20, of which 15 were male and 5 were female, 3

participants failed to supply ages, therefore adjusted grouping consisted of n=17, of which 13 were male and 4 were female, age ranged between 26-74, with a mean age of 51, SD 16.54.

Table 8.1: Participant age range

Age	20 - 30	31 – 40	41 – 50	51 – 60	61 – 70	71 – 80
Male	3	3	1	2	3	1
Female				1	2	1

Figure 8.7 looked at the patient's stay (measured in days) within the ICU before consenting to the VeloVR study. Out of the days in ICU captured for n=13 of the 20 patients, each spent an average stay of 20.46 days (2.92 weeks), SD 11.65 (chapter 1.1.2).

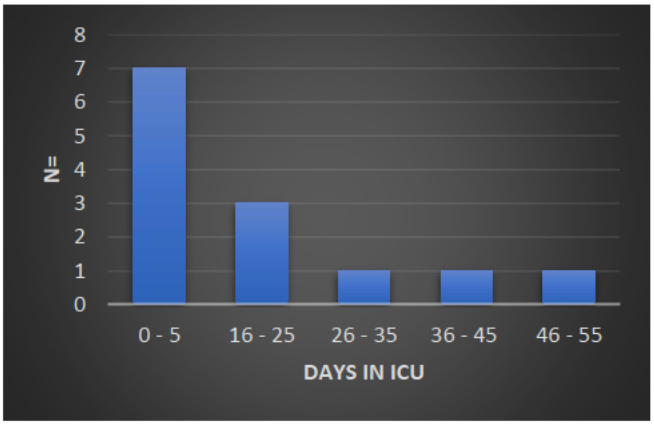


Figure 8.7: Days spent in ICU prior to VeloVR study

The largest proportion of patients within the VeloVR (Figure 8.8) cohort were undergoing a transplant of sorts, be it, heart, liver or lung. Other patients were being treated for Whipples, which is a major surgical operation performed to remove cancerous tumours from the pancreas, chronic obstructive pulmonary disease (COPD), endocarditis (inflammation of the inner heart lining, or laparotomy (abdominal surgery).

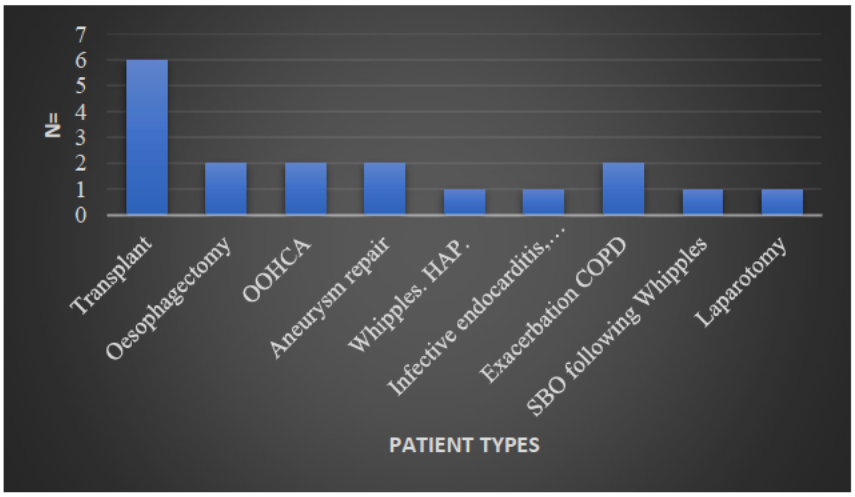


Figure 8.8: Patient types within the VeloVR cohort

8.7.2 Technology self-efficacy

A Pre-test questionnaire was distributed during pre-admission clinics to measure device familiarity/experience and technology acceptance.

8.7.2.1 Device familiarity/experience

The following data in Table 8.2 corresponds to responses gathered during the distribution of a device familiarity/experience questionnaire (8.4.2) at a patient pre-admission clinic. The idea for the questions was to try and correlate patient adaptability to VeloVR by looking into background technology habits and abilities. It can be said that a large proportion of the 18 respondents felt very confident towards the most common forms of technologies (Questions 1, 2, 3, 4, 5 and 7). With regards to question 1, there was also a large percentage of respondents displaying both neutral and least confidence, whereas more people displayed better confidence using tablet/smart phone systems. Smart TV users (who would typically use a remote control to interact with their experience) saw a greatest percentage of very confident with the remainder seeing neutral. Wearable devices (Question 6) such smart watches, Fitbits, etc. and other devices scored no response, this appeared to be due to the lack of uptake with respondents. A

question (8) asked about other technologies owned and a single response to ownership came for a head-mounted display that was typically used for computer game consoles (Question 7).

Table 8.2: Device familiarity / computer experience

	Device familiarity / computer experience						
Question	Usage		Not at all confident	Least confident	Neutral	Confident	Very confident
1. Computer/laptop	Yes	14		28.57%	21.43%	7.14%	42.86%
	No	4					
2. Tablet Device	Yes	12		8.33%	8.34%	33.33%	50%
	No	6					
3. Smart TV	Yes	7			28.57%		71.43%
	No	11					
4. Mobile Phone	Yes	16		6.25%	25%	31.25%	37.50%
	No	2					
5. Smart Phone	Yes	11			18.18%	36.36%	45.45%
	No	7					
6. Wearable device	Yes	0					
	No	18					
7. Computer games console	Yes	5					28.78%
	No	13					
8. Other	Yes	1					5.55%
	No	17					

8.7.2.2 Technology Acceptance

The following technology acceptance data refers to the questionnaire (located at 8.4.3) that was distributed at a pre-admission clinic, the questionnaire looked at the perceived technology acceptance before any rehabilitative sessions took place on VeloVR. From the data in Table 8.3 it can be said that a large proportion did not expect to be using electronic devices to aid with rehabilitation (Question 10) but patients agreed that VeloVR may have a positive impact

on their rehabilitative sessions (Question 1), and that they were less apprehensive about learning how to use a new electronic device (Question 3), trusting that there would be enough support from hospital staff (Question 12) in order to learn how to use VeloVR (Question 2). In contrast a high percentage of patients used computers and electronic gadgets in everyday life (Question 8) but offered mixed responses in terms of confidence in using computers and electronic gadgets (Question 9) although were not worried about VeloVR causing any harm (Question 7).

Table 8.3: Technology Acceptance

Question	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. VeloVR will help me to perform my best during the cycling sessions			12.5%	31.25%	56.25%
2. I could easily learn how to use VeloVR		6.25%	12.50%	37.50%	43.75%
3. Learning to use new electronic devices makes me feel apprehensive	43.75%	12.50%	12.50%	25%	6.25%
4. I feel confident I will able to follow the instructions for using VeloVR		43.75%	12.50%	25%	43.75%
5. Using VeloVR will help with cycling exercises		6.25%	12.50%	37.50%	43.75%
6. I am looking forward to using VeloVR		6.25%	12.50%	31.25%	50%
7. I am worried that VeloVR will cause me harm	75%	18.75%	6.25%		
8. I use computers and electronic gadgets in my everyday life	6.25%	31.25%		12.50%	50%
9. I feel confident using computers and electronic gadgets	6.25%	25%	6.25%	25%	37.50%
10. I expect to be using electronic devices to help with my rehabilitation after my illness / injury / operation	18.75%	37.50%	25%	12.50%	6.25%

11. I intend to use other electronic devices to help with rehabilitation after my illness/injury/operation	12.50%	43.75%	25%	12.50%	6.25%
12. I will have enough support to use VeloVR in hospital		6.25%	6.25%	31.25%	56.25%
13. I have a disability/impairment which will prevent me from using VeloVR	75%	12.50%	6.25%	6.25%	

8.7.2.3 Summary

It can be said that although patients were familiar with the more basic types of technology, experience and confidence was mid to low in terms of computer and gaming usage. Patients displayed higher acceptance levels in the belief that VeloVR would be easy to learn, would help them to perform to their best, and that it would help with cycling. Overall it could be said that a high proportion of patients were not gamers but those who were displayed highest confidence.

8.8 Data Analysis

8.8.1 Statistical Analysis

Patients saw a dropout rate from N=20 in condition 1 (NoVR) to N=11 by condition 3 (CompVR) that affected statistical analysis of the Borg data collected for RPE and Dyspnoea. The dropout rate was due to patients being discharged to general wards, with-drawing from the study due to pain, anxiety, or having to return to theatre due to further complications. Normal practice would be to perform an ANOVA to determine the significance of the data across the 3 test conditions. However, if an ANOVA were applied across all conditions 9 of the participants would be excluded as they did not complete all conditions. Therefore, analysis was based on a series of paired comparisons between conditions (i.e. NoVR x SoloVR; NoVR x CompVR; SoloVR x CompVR) using within subjects repeated measures analysis. Due to the small sample size non-parametric tests were applied. Specifically, Wilcoxon tests for

differences between two dependent samples (McCormick et al., 2017). Figure 8.9 illustrates the types of statistical analysis methods depending on the types of data captured, the highlighted pathway denotes the Wilcoxon test. Because of multiple paired comparisons, the P value was adjusted to 0.016 using the Bonferroni correction. Feedback from the staff and participants/patients collected via interview and questionnaires were analysed qualitatively.

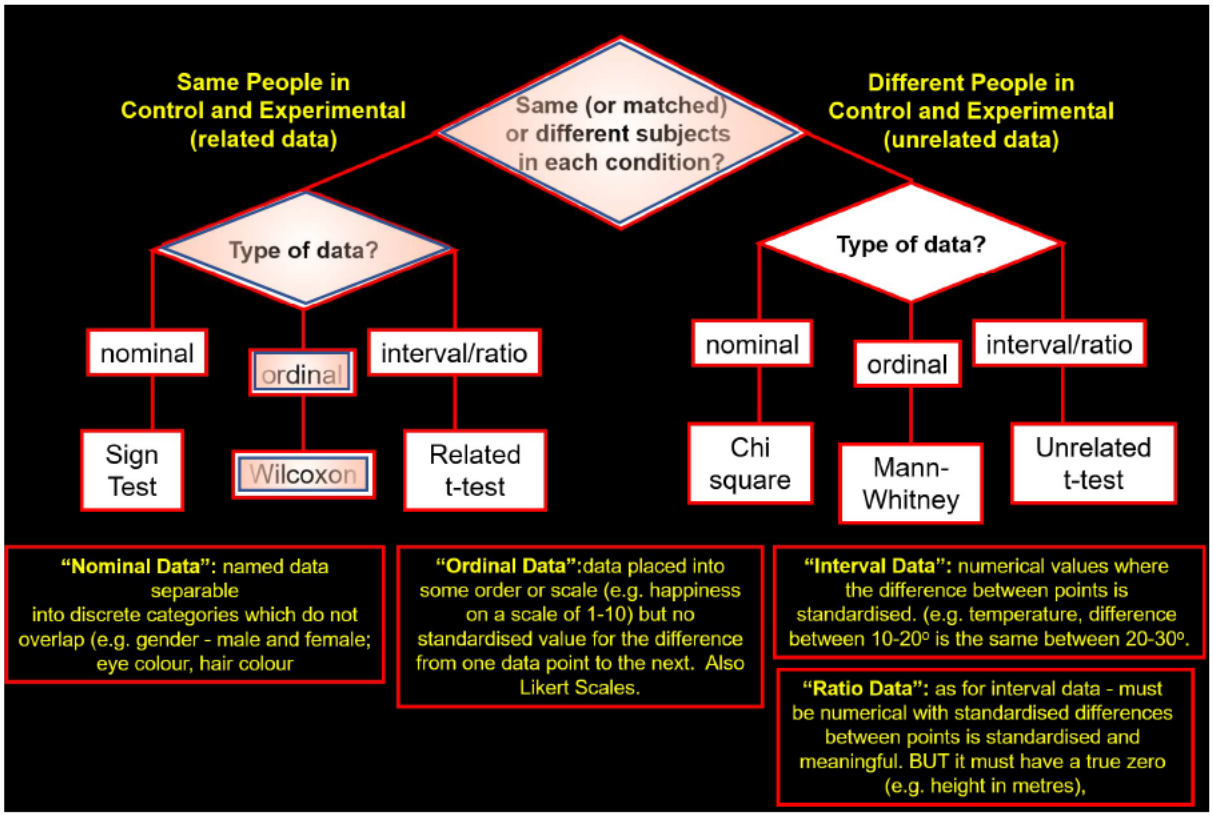


Figure 8.9: Flow diagram of statistical analysis methods

8.9. Results

8.9.1 Breathlessness and Perceived Exertion

8.9.1.1 Dyspnoea

The Borg Dyspnoea Scale (Borg, G. 1982) (Section 8.6.1) illustrates the value of patients' symptomatic breathlessness whilst using the MOTOmed / VeloVR, a value of 0 relates to the least difficulty in breathing and 10 relates to the maximum. Results for the mean Dyspnoea

data are shown in Table 8.4, and details of the statistical analysis can be found in Appendix 8.2.

Table 8.4: Borg Dyspnoea

NoVR vs SoloVR	(N=11)		
		NoVR	SoloVR
	Mean	4.91	5.55
	SD	2.12	1.92
	Sig	Z(11)=1.051, P=0.293	
NoVR vs CompVR	(N=10)		
		NoVR	SoloVR
	Mean	4.90	6.70
	SD	2.23	2.36
	Sig	Z(10)=1.637, P=0.102	
SoloVR vs CompVR	(N=11)		
		SoloVR	CompVR
	Mean	5.73	6.36
	SD	1.85	2.50
	Sig	Z(11)=0.838, P=0.402	

8.9.1.1.1 Dyspnoea for NoVR v SoloVR

Between the NoVR and SoloVR conditions 4 patients withdrew from the study. Therefore, analysis was carried out on data from N=11 patients. The data showed a slight increase in mean rating from 4.91±2.12 to 5.55±1.92, but this increase was not significant ($p>0.016$).

8.9.1.1.2 Dyspnoea for NoVR v CompVR

Between the NoVR and CompVR conditions 6 patients withdrew from the study. Therefore, analysis was carried out on data from N=10 patients. The data showed a slight increase in mean rating from 4.90±2.23 to 6.70±2.36, but this increase was not significant ($p>0.016$).

8.9.1.1.3 Dyspnoea for SoloVR v CompVR

Between the SoloVR and CompVR conditions 3 patients withdrew from the study. Therefore, analysis was carried out on data from N=11 patients. The data showed a slight increase in mean rating from 5.73±1.85 to 6.36±2.50, but this increase was not significant ($p>0.016$).

8.9.1.2 Perceived exertion

The Rating of Perceived Exertion Scale (Borg, G. 1982) (Section 9.6.2) is a widely used indicator to monitor levels of physical exertion. The scale allows individuals to subjectively rate their levels of exertion during exercise, ranging from a level of 6=No exertion to 20=Maximum exertion. Results for the mean RPE data are shown in Table 8.5, and details of the statistical analysis can be found in Appendix 8.3.

Table 8.5: Borg RPE

NoVR vs SoloVR	(N=16)		
		NoVR	SoloVR
	Mean	10.38	10.63
	SD	3.27	2.98
	Sig	Z(16)=0.372, P=0.710	
NoVR vs CompVR	(N=11)		
		NoVR	SoloVR
	Mean	10.91	9.55
	SD	3.27	2.98

	Sig	Z(11)=0.952, P=0.341	
SoloVR vs CompVR	(N=11)		
		SoloVR	CompVR
	Mean	11.64	9.55
	SD	2.77	2.98
	Sig	Z(11)=1.610, P=0.107	

8.9.1.2.1 RPE for NoVR v SoloVR

Between the NoVR and SoloVR conditions 4 patients withdrew from the study. Therefore, analysis was carried out on data from N=16 patients. The data showed a slight increase in mean rating from 10.38±3.27 to 10.63±2.98, but this increase was not significant (p>0.016).

8.9.1.2.2 RPE for NoVR v CompVR

Between the NoVR and CompVR conditions 9 patients withdrew from the study. Therefore, analysis was carried out on data from N=11 patients. The data showed a slight decrease in mean rating from 10.91±3.27 to 9.55±2.98, but this decrease was not significant (p>0.016).

8.9.1.2.3 RPE for SoloVR v CompVR

Between the SoloVR and CompVR conditions 5 patients withdrew from the study. Therefore, analysis was carried out on data from N=11 patients. The data showed a slight decrease in mean rating from 11.64±2.77 to 9.55±2.98, but this decrease was not significant (p>0.016).

8.9.1.3 Distance travelled

The distance travelled by patients across the three conditions highlighted a trend that showed that from NoVR to SoloVR and then to CompVR the "distance travelled" by patients increased

significantly. Results for the mean distance travelled data are shown in Table 8.6, and details of the statistical analysis can be found in Appendix 8.4.

Table 8.6: Distance travelled (metres)

NoVR vs SoloVR	(N=15)		
		NoVR	SoloVR
	Mean	67.71	101.93
	SD	61.38	97.39
	Sig	Z(14)=2.955, P=0.003	
NoVR vs CompVR	(N=11)		
		NoVR	SoloVR
	Mean	77.45	149.55
	SD	66.13	154.03
	Sig	Z(11)=2.669 P=0.008	
SoloVR vs CompVR	(N=11)		
		SoloVR	CompVR
	Mean	108.35	149.89
	SD	97.47	140.62
	Sig	Z(11)=2.095, P=0.036	

8.9.1.3.1 Distance travelled for NoVR v SoloVR

Between the NoVR and SoloVR conditions 5 patients withdrew from the study. Therefore, analysis was carried out on data from N=15 patients. The data showed an increase in mean distance travelled from the NoVR condition (67.71±61.38) to the SoloVR condition (101.93±97.39), which Wilcoxen Signed-Ranked test showed to be significant (p=0.003) (table 9.6).

8.9.1.3.2 Distance travelled for NoVR v CompVR

Between the NoVR and CompVR conditions 9 patients withdrew from the study. Therefore, analysis was carried out on data from N=11 patients. The data showed a significant increase in mean distance travelled between the NoVR (77.45.71±66.13) and the CompVR (149.55±154.03) conditions (p=0.008) (table 9.6).

8.9.1.3.3 Distance travelled for SoloVR v CompVR

Between the SoloVR and CompVR conditions 4 patients withdrew from the study. Therefore, analysis was carried out on data from N=11 patients. This analysis showed that the increase in distance travelled between the SoloVR (108.35±97.47) and the CompVR (149.89±140.62) conditions was significant (p=0.036, not significant using Bonferroni correction p.0.016) (table 9.6).

8.10 Staff Interview

Following on from VeloVR condition testing, staff interviews (Chapter 9.6.4) were conducted in order to gauge feedback as to the prototypes operational life within the ICU. The interview took the form of a series of structured questions together with a series of guided prompts to help focus feedback.

8.10.1 Device Usability (8.6.5)

8.10.2 What difficulties did you have using VeloVR?

Staff occasionally encountered difficulty in picking up a signal from the monitoring device (cadence sensor) on the MOTOmed, therefore the patient would be cycling but on the screen the VR avatar would be stationary; a period of re-adjustment and resetting would be required which would be off putting for the patient as they would be strapped in and ready to being their rehabilitation session.

8.10.3 How long did it take you to feel confident using VeloVR?

Staff reported that it only took a couple of sessions to build confidence in each setting (solo and competition mode). VeloVR was often used in pairs so was able to have one person monitoring the patient and the MOTOmed and the other monitor the use of the VeloVR.

8.10.4 How would you suggest we make it easier to use?

To make the system easier to use it was suggested that an all-inclusive system that incorporated both the MOTOmed and VeloVR be created to help reduce the bulk and to help reduce the setup time. This was always a consideration, but due to the MOTOmed being a medical grade device it was deemed unwise to make any modifications to its design in the fear of voiding its certification.

8.10.5 What made it easy/not easy to use?

Feedback suggested that it was easy to setup VeloVR and load the VR gameplay, whereas the tracking device (cadence sensor) wasn't very reliable and the stand was a little bulky. From a practicality viewpoint it was difficult to get into the right position within the bed-space.

8.11 System Ergonomics

8.11.1 How did you feel about having the VeloVR device in the patient bed-space?

For the most part having VeloVR in the bed-space was met with enthusiasm from patients, nursing staff and relatives. The system attracted attention from other staff members on critical care and was seen as a positive addition to rehab and other doctors were enquiring about using it with patients outside of the study.

VeloVR was only ever in the bedspace during rehab sessions and accompanied the MOTOmed, therefore was not left in the bed-space for long periods of time.

8.11.2 Was the device difficult to move around?

VeloVR proved not to be the easiest piece of kit to manoeuvre, it was difficult to push as the stand as the wheeled base would rotate which would make it unstable and difficult to guide it under the bed especially when the ventilator was installed. Other difficulties were the physical size of VeloVR which was at times cumbersome in the bed-space, more so of the patient had other attachments such as ventilator or CVVH (Continuous Veno-Venous Hemofiltration). Figure 8.10 illustrated VeloVR installed in an equipment rich ICU side room, the patient is undergoing rehabilitation with ventilator support.



Figure 8.10: Patient using VeloVR with ventilator support

8.11.3 Did it get in your way?

VeloVR was only ever in the bed-space for the duration of MOTOmed treatment sessions, so did not get in the way of patient care, once treatment was completed by the physio the MOTOmed and VeloVR was stored away to minimise disruption, the stand was too big to leave in the bed-space for extended periods of time. The physiotherapy department does not have a lot of space so something smaller would be needed if it was to be used long term.

8.12 Performance and feedback appraisal (9.6.6)

8.12.1 Motivation

Staff stated that patients were interested in VeloVR and thought it was a great idea, there was positive feedback and patients seemed who were already motivated to get better saw the trial as a great opportunity for extra physiotherapy.

8.12.2 Study Experience

Overall all staff enjoyed being in the VeloVR study and were happy to be part of the research process that saw first-hand the difference it could make to patient care. Staff were all happy to recommend other staff members in participating in VeloVR.

8.12.3 Other comments

Other comments mentioned that it might be good to implement other game play concepts into rehab – possibly by changing the MOTOmed configuration from leg to arm (chapter 9, Figure 9.3). The system was not appropriate for all the patients in ICU, due to medication, fatigue, poor concentration or delirium. However, for those patients it is relevant for, it would be a great addition to rehab and care. The ICU is a frightening environment for patients, so a positive distraction through VR or game-play would be a rally worthwhile investment. It would also be a great adjunct to rehab for therapists in the ICU, to make rehab more varied and enjoyable. Further comments stated that it was great to see enthusiasm amongst the wider members of the Multi-Discipline Team (MDT) during the trial, not just physiotherapists but nurses and doctors.

8.13 VeloVR feedback – Patient Comments

The following section looks at patient feedback across all 4 sessions, it was captured verbally and noted by members of the QEHB, ICU research team physiotherapists, other issues relating to the systems usage were also noted.

8.13.1 Session 1 – No VR

As this would have been the first time the patient would have encountered the MOTOmed there was a period of adjustment particularity to the leg straps where padding was frequently added to help aid comfort (Figure 8.11). Other issues related to patients displaying difficulty achieving a full pedal rotation due to hip/knee weakness, which led to nursing staff administering drugs mid-session.



Figure 8.11: Patient undergoing MOTOmed rehabilitation with additional leg support

8.13.2 Session 2 – VeloVR solo mode

The patient requested that the display be tilted and brought closer, causing his knees to hit the bottom of the display which led to the patient becoming conscious of this and appeared to focus on his legs rather than the game play. Another patient opted to use VeloVR reclined (Figure 8.12) as he commented on the display being to close and too bright, the patient also required the use of handles on the side of the bed to help remain stable whilst peddling.

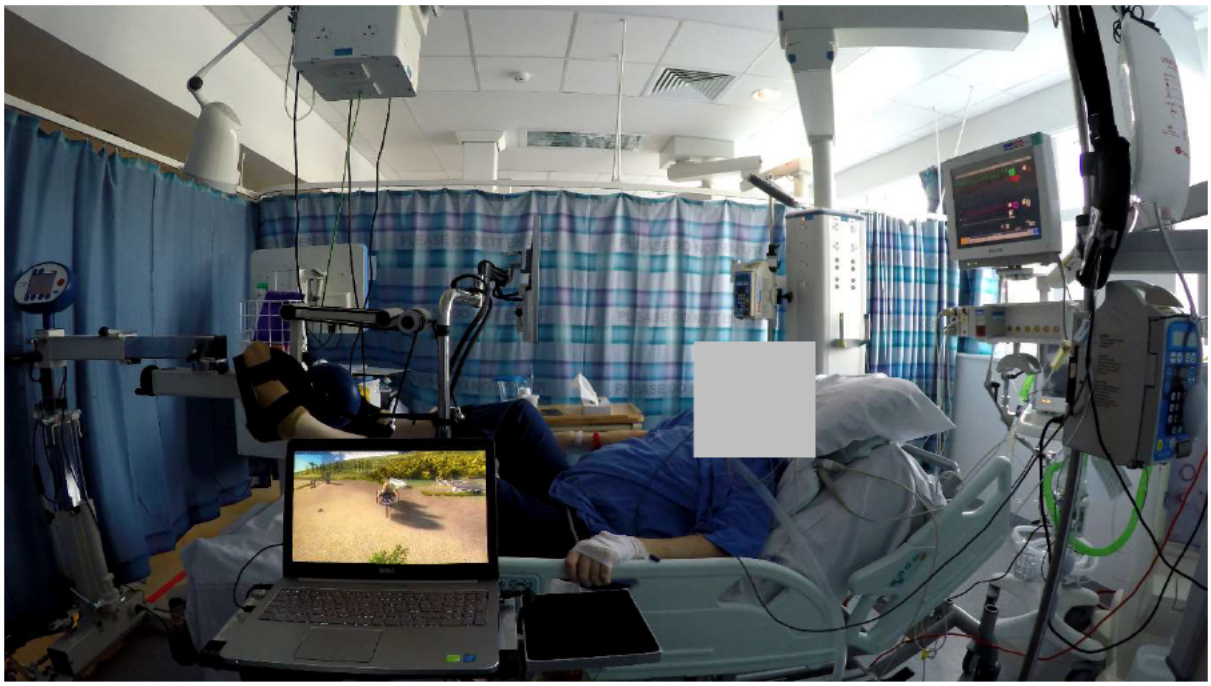


Figure 8.12: Patient using VeloVR in a reclined position

An issue with the last comment was that patient was suffering from Marfan syndrome and so was very tall. There were two instances of the sound failing at the 7 and 10-minute mark, with the patients opting to continue their sessions.

8.13.3 Session 3 – VeloVR Competition mode

There were several issues that hindered patients progress throughout session 3, for the most part setup issues both to the VeloVR software and the cadence sensor were identified. In order for the software to work a valid internet connection was required to authenticate the software enabling the cadence sensor to work with the game play, without authentication the software would crash requiring a pc re-boot. The provided Mi-Fi dongle had issues connecting to a stable cellular signal due to the location of the VeloVR system at certain points within ICU. One patient had issues with glare on the display leading to the closing of the curtains, another again had issues with the sound stopping at certain periods.

8.14 Comments from members of the QEHB, ICU research team, Physiotherapists

The following section looks at comments from physiotherapists relating to patient experience whilst being exposed to the MOTOmed / VeloVR during the 4 rehabilitative sessions.

8.14.1 Session 1 – No VR

Overall patients enjoyed the cycling session, many seeing the benefits. One patient who usually finds rehab increases SOB (shortness of breath) and anxiety, found it relaxing throughout. Another patient looked forward to the next session as felt the VR interaction would be beneficial. Some patients felt embarrassed and silly using the cycling kit, stating that they didn't expect to be exercising on ICU, but overall found it beneficial as he wanted to increase strength levels to improve walking.

8.14.2 Session 2 – VeloVR Solo mode

The following feedback has been broken down and categorised into positive, negative and neutral comments:

Positive		
Patients enjoyed being able to see themselves peddling. In the future might be better to have more landscape to explore rather than going round in circles, but overall the VR made it more interesting.	Patient enjoyed the session more than the one without VR. Felt it is a good idea and concept. Enjoyed the coastal setting, preferred with sound. Screen felt quite close initially, better once reclined. Feels screen not needed for motivation recovery/walking is enough motivation.	Found VR more fun and interesting, happy to do anything to help and thinks VR is a good idea. Good distraction from pedalling and helps the time to pass. Initially felt confused and distracted as unable to steer/direct movement on screen as expected, but thought the screen was a good idea and enjoyable.
Really enjoyed VR, though it was a great idea. Much better than no VR yesterday, enjoyed the coastal path and would have liked a controller to be able to steer.	Enjoyed the session. Focussed on the screen throughout – enjoyed the concept and scenery. Doesn't feel the need to steer or over complicate the game.	Likes the mechanics of the bike. Felt like I was engaging with outside of the hospital. Great technology. Should be built on, lots of scope for improvements and other uses.

Thought VR was good, made it more interesting, Liked the view.		
Negative	**Neutral**	
Would rather watch the football or TV. Found the screen a distraction. "Not my thing really" but cycling "not too bad", "more for kids"	Would be useful to do different activities.	

8.14.3 Session 3 – VR Competition mode

The following feedback has been broken down and categorised into positive, negative, neutral and future improvements:

Positive		
Enjoyed much more with the competition mode, more interesting and motivating	Patient enjoyed the session. Finds VR interesting - a good distraction while in hospital to lift mood, particularly as feels low in a side room and NBM. Likes sound and views of the sea.	Found competition mode more engaging than solo. Enjoys the coastal path. Feels this will help him.
Patient thoroughly enjoyed the trial - found it really helpful - looked forward to it, found VR more enjoyable than standard. However, first session of MOTOmed "standard" helped to build confidence. Initially patient thought "I can't do this" until had a go. Loved "the coast" with sounds of waves and birds. Thought perhaps if could just see the legs on screen and have something to hold would be more realistic rather than seeing full body cycling. Felt interactive technologies/games were fun and distracting in ICU and helped recovery, improved confidence.		Enjoyed cycling. Would like handles to stabilise upper body. Screen needs to be more adjustable. Helped while on the ICU, breaks up the day, gives goals.
Negative	Neutral	Future Improvements
Competitor (avatar) kept disappearing and didn't seem consistent. Like the idea though.	Patient fatigued, had had a busy day and walked 40m prior to MOTOmed but wanted to have a go as enjoys cycling as "it's good for you"	Would be good to compete against someone else. Liked competing against himself. The was the best session enjoyed the competition.
		Would like to be able to see lap times. Would like a touch screen with the system

		Would like to steer and change direction when VR cycles through bushes, maybe with steering wheel or pushing R or L leg harder. Would like more control of bike and more feedback - mainly on speed, e.g. more like a racing car, feedback to "pick up the pace" or MPH.
		Would like to have different views - would find more varied scenery interesting

8.15 Discussion

The research conducted within this study looked at the idea of ICU rehabilitation to treat ICU-AW, brought on by extended periods on ICU which can cause muscle atrophy and extreme weakness. A prototype system that interfaced unobtrusively with an existing medically certified in-bed cycle ergometer (MOTOmed) was created (chapter 8). The prototype (VeloVR) was designed as a catalyst for the addition of real time Virtual Reality gameplay to help motivate and encourage patients to overcome the boredom of cycling with no means of feedback nor distraction from physical exertion. The testing took the form of three sessions over as many days, with the first acting as a baseline, the second exposing patients to VeloVR and a solo cycle effort for the duration of their rehabilitative stint. Session three built upon session two and allowed the patient again to use VeloVR but this time racing a ghost representation of their first effort with the aim of motivating to better that performance. Throughout the study, feedback was gathered as a precursor to the exposure of VeloVR that was used to gauge device familiarity across a range of interactive technologies, and levels of experience to evaluative if the those who possessed higher levels of confidence would adapt better to using novel interactive technologies as opposed to technologically inexperienced or phobic participants. Overall patients' displayed confidence with a whole array of devices, ranging from, PC/tablets, to smart phones and smart TVs. There was lower confidence in

wearables and other devices, this was mainly due to the low adoption of these technologies, for example, Fitbit or VR headsets. A series of questions relating to perceived technology acceptance was asked before any rehabilitation took place, the idea was to gauge the potential reaction to using VeloVR during rehabilitation sessions and to analyse if poor responses would lead to lower performance levels during VeloVR sessions. The majority of respondents were confident that VeloVR would be easy to learn and they would receive enough support from physiotherapists which in turn will allow them to perform to their best during rehabilitation sessions.

Upon completion of each of the 3 test conditions, performance was measured using the Borg Dyspnoea Scale (Borg, G. 1982) in which the patient was asked to rate breathlessness from 0 (minimal) to 10 (maximum) during MOTOmed sessions. The data suggested that there was a slight increase in mean breathlessness between NoVR and SoloVR; NoVR and CompVR and SoloVR and CompVR, however across all conditions the increases were not significant.
The Borg Rating of Perceived Exertion (RPE) Scale (Borg, G. 1982) was also used to identify levels of exertion, scores ranged from 6 (no exertion) to 20 (maximum exertion). The data suggested that there was a slight increase in mean rating for both NoVR vs SoloVR and NoVR vs CompVR, however this was not significant. There was a slight decrease in mean ratings for SoloVR vs CompVR but again this was not significant. It must be noted that at the point of each of the 3 conditions the RPE for each patient was dependant on levels of medication, wellbeing and pain management. Although there was no change in the ratings of Dyspnoea or RPE from the data it can be said that there was a noticeable increase in the distance covered by patients; both VR conditions were higher than without VR and CompVR was greater than SoloVR. It could suggest that from sessions 1 to 3 a slight learning effect could have taken place and that after the unfamiliarity of using the MOTOmed in session 1 to using VeloVR in sessions 2 and 3, patients would have been able to engage fully with the gameplay in both VR

sessions, therefore cover increased distances whilst both Dyspnoea and RPE scores remaining stable.

From a staff perspective VeloVR proved to be easy to setup both in terms of the physical rig and VR game play, there were instances of cadence sensor failure that was traced back to the mid-ware software not receiving a stable internet connection at the point of software authentication to bridge the gameplay software and sensor, possibly due a signal weak spot within the ICU. Other issues related to the bulk of the prototype which was necessary in order to counter balance the display once fully extended over the bed (Figure 8.13).



Figure 8.13: VeloVR display arm at full extension

Negative remarks were aimed at the difficulty of getting the cadence sensor to initially start tracking, which was traced to the software needing internet access to authenticate but in certain areas of the ICU cellular signals were intermittent.

The final chapter (9) looks at impact, legacy and future, of the VeloVR study following the conclusion of the study at QEHB.

9. Impact, Legacy and Future Research

The final chapter looks at the life of the InspireVR, and VeloVR prototypes following completion of both their respective studies at the Queen Elizabeth Hospital Birmingham and Birmingham Heartlands Hospital. Throughout the research, a strong human centred approach had been adopted which, through close engagement with a range of stakeholders, from medical consultants, pain control specialists, physiotherapists, and nursing staff, to patients (past and present), and even on occasions, their relatives, has helped to ensure the evolutionary design of both the InspireVR and VeloVR together with their component interactive technologies had been undertaken both scientifically and sensitively. The greatest issue faced when developing bespoke prototype hardware solutions that are geared towards one specific research area, and as seen with the first two iterations of VR-I Modules (Chapter 3, Figure 3.1, Chapter 5, Figure 5.6 and Chapter 7, Figure 7.14) is that once they have met their data gathering objectives necessary to evolve the study, they are left without any further purpose and often retired into storage or at best salvaged for components.

9.1 Impact

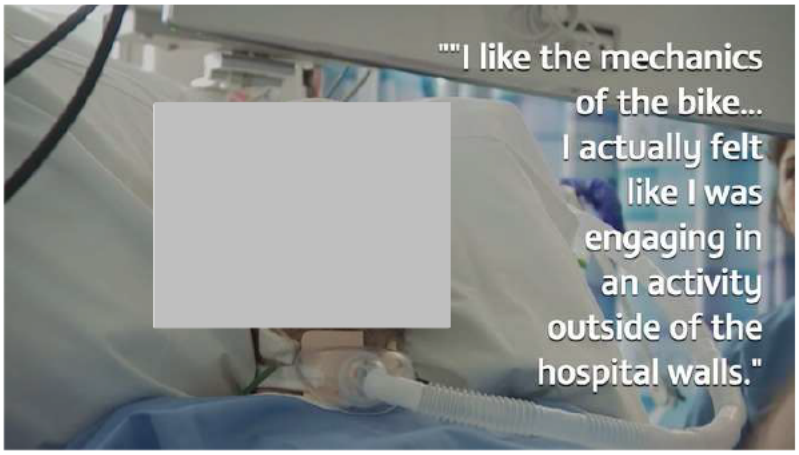


Figure 9.1: VeloVR patient who had recently had a double-lung transplant

Credit: ITV News Central. https://www.itv.com/news/central/2017-07-13/virtual-reality-project-helping-patients-to-cycle-the-coast-path/

During the VeloVR study, local regional news made contact and ran a story in July 2017. The news piece saw a patient who had undergone a dual-lung transplant using VeloVR (Figure 9.1), which was met with excellent feedback from both the patient and the patient's family, one quote from the patient stated "I like the mechanics of the bike, I actually felt like was engaging in an activity outside of the hospital walls."

Following the news item, interest was received from care professionals outside the two study locations who were interested in the use of the technology to help with rehabilitation, an approach was made from Torbay Hospital in South Devon who were interested in the VeloVR and InspireVR studies and were looking into the viability of adopting a similar rehabilitative strategy for their ICU patients. The timing was fortunate as the conclusions of both the VeloVR, and InspireVR studies were fast approaching with no thought as to the legacy of the work that had been detailed in this thesis.



Figure 9.2: Typical ICU bed-space within the ICU at Torbay Hospital

The decision was taken to undertake a site visit to the ICU at Torbay (Figure 9.2) to assess if rather than the systems being retired at the University they could be refurbished and donated taking into account the lessons learned from the installation and rigors of ICU testing, whilst also using the outcomes of the studies to add validity to the prototypes usability. The idea for the donation was not to engage in a formal study, but to have the two systems used by patients with the aim of improving rehabilitation sessions, and to gather any informal comments that could help steer the direction of ICU rehabilitation and possible future iterations of the VR-I Module family.

The visit saw the use again of a Reck MOTOmed, but not the Letto (Chapter 8, Figure 8.2) as used at the QEHB but a more compact leg and arm trainer version called the Viva 2 (Figure 9.3) which was used solely whilst seated either in a wheelchair or side-chair.



Figure 9.3: Reck MOTOmed Viva 2 leg and arm trainer

9.2 Legacy

VeloVR was delivered, setup, and installed within an ICU bed-space and was put straight to work. Nick Richards (Figure 9.4), who had suffered a broken his neck several years ago which had left him a tetraplegic (all four limbs affected) and unable to walk nor grip anything with his hands. Nick had been admitted to the ICU with breathing difficulty and was diagnosed with pneumonia and was intubated before having a tracheostomy, he was now beginning his slow rehabilitation path in an attempt to wean from his tracheostomy. Rehabilitation took place using the upper limb element of the MOTOmed, this was a completely new approach of using VeloVR and the system adapted well to the change. Permission was granted to use the hospital's Wi-Fi to help eliminate the authentication issues that plagued the software/cadence sensor failures noted in Chapter 8.13.3.



Figure 9.4: Patient undergoing upper limb rehabilitation using VeloVR, Torbay Hospital

9.3 Feedback

After using the VR device, Nick commented: “This was so much better than I expected. I found it fun chasing my own tail, catching myself and passing my own ghost! It was a very good diversion from just peddling the bike which can be rather monotonous at times. The time flew by and instead of achieving the usual 5 minutes on the bike, I actually managed to cycle for at least 20 minutes!

“I enjoyed the terrain. I had a sense of leaning and tipping and going downhill. I love the beach and the scenery suited me very well - I could lose myself in this programme. I’m looking forward to using it again and seeing how it develops.”

Nick’s wife, Sandra Richards, noticed a difference in Nick’s attitude straight away: “At the time of taking part Nick had been in the intensive care unit for a long nine weeks and his discharge was not imminent. So it was wonderful to see Nick taking part. He clearly enjoyed himself and was happy to feed back to the team whilst cycling. There’s no doubt that this helped his mood and the fact that he was able to cycle further than he expected left him feeling optimistic about his potential and his future. A super experience and we both believe this has an important part to play in Nick’s rehabilitation and those with similar conditions.”

The coincidental element to this story was that pinned to the window in his ICU cubical was a photo (Figure 9.5) of Nick in his specially adapted wheel chair hand cycle on a beach.



Figure 9.5: Nick Richards in his specially adapted wheel chair hand cycle

Sadly, shortly a week after participating so enthusiastically in the first trial of VeloVR at Torbay Hospital, Nick passed away. Sandra said: "He was so proud to be a part of this and just before he passed he read the press release and again mentioned how proud he was of being a part of it".

9.4 Clinical feedback

The following informal remarks came from (i). an ICU Specialist Occupational Therapist and (ii). a patient who had exposure to VeloVR -

(i). Specialist Occupational Therapist

Our ICU Rehab team has invested in two static upper and lower limb MOTOmed bikes. We use the bikes during patients' ICU and ward based rehabilitation. We run a post ICU exercise group which we use the bikes in to promote cardiovascular fitness. The bikes have been a

success to give our patients a different tool and experience to support their ongoing recovery. We were asked to trial a VR system which linked to the moto med. This VR system allowed the patient to be emerged within an outdoor environment. The feedback we have had is that the patients liked the experience of being outside and via basic observations the patient produce longer sessions of exercise as they were distracted. The system is a great tool but obviously could be improved. As a team we would like to thank you for the opportunity to trial the device and hope you would consider use for version 2 as a pilot site?

James Bruce, Intensive Care Rehabilitation Co-ordinator / Specialist Occupational Therapist

Intensive Care Unit

Torbay and South Devon NHS Foundation Trust

(ii). Patient feedback

The patient commented on the frustration of being strapped in ready for his rehabilitation session but having to wait for the longer setup times needed by the therapist to get the cadence sensor re-attached to the MOTOmed, cold booting the PC and software before commencement of VeloVR game play.

Comments as to improvements that could made came from patients wanting to explore the Virtual Wembury environment rather than be on a fixed pathway, as well as having the choice of different environments. The idea of the study at the QEHB was to evaluate if the use of VeloVR over standard MOTOmed usage could have an impact on patient performance, in the case of Torbay the idea of free roam could offer more of a performance incentive and perhaps the idea of linking to google maps road side view so that the patient could cycle around familiar areas may also have an increased effect.

9.5 InspireVR

The InspireVR prototype was delivered and installed in much the same vein as VeloVR, but sadly at the time of writing the system had been used but no images had been taken, feedback however was generated and is detailed in Section 9.6.

9.6 Feedback

The following informal feedback came from a consultant in Intensive Care Medicines and Anaesthetics: -

Those times I have witnessed the VR assisted physical exercise interventions, the patients say they feel much more engaged and certainly appear to really be enjoying the intervention. There is no replacement in my view for the role of compassionate staff in any aspect of patient care, but the value of integrating technology with care, delivered compassionately and enthusiastically cannot be overstated.

Clinical staff have recognised a serious problem with engaging patients with often tedious, unpleasant and repetitive physical rehabilitation interventions (particularly long stay patients with poor nutritional status and muscle wasting). Technologies that increase the appeal and novelty and therefore greater ongoing engagement with rehabilitation interventions are self-evidently beneficial, and virtual Wembury and the incentive spirometer are breaking new ground in that regard.

I have seen real excitement and enthusiasm from patients and also staff caring for patients as a result of working with Virtual Wembury, and personally I am now convinced of its value. As the technology continues to evolve, I look forward to new ways to engage, support and motivate faster and greater recovery for patients needing re-ablement and rehabilitation.

The main difficulty with the kit, is its ease of transporting between areas in the hospital - corridors with bumpy bits, lifts etc. better wheels, cart etc. would help.

9.7 Future Research

Based on the research and lessons learned throughout this thesis, it could be said that at each iteration of the human-centred design process (Chapter 5, Figure 5.1) and through the close engagement with stakeholders, each VR-I Module created offered something new in terms of its approach to the rehabilitative needs of the patient and the environment it saw exposure in. The main constant with the use of each of the prototypes, be it for sleep and delirium, incentive spirometry, or physical rehabilitation was that it took place within the confines of the ICU. Before any approach can be made to the patient a strict inclusion and exclusion criteria would need to be followed that is dependent on the rehabilitative context and patient suitability based on their admittance to ICU. Sections 3.3.3, 6.3.2 and 8.3.3 details both the inclusion and exclusion criteria for accepting or rejecting a patient on to the study. In addition, factors such as ergonomics, physical and cognitive ability, no adverse effects to using VR and user acceptance (consent) are all important considerations when designing for a target population.

The VR-I Modules were prototypes designed using COTS technologies that were cost effective in terms of financial outlay, reparability, and reproducibility, something that would be key if other hospitals would want to consider adopting such systems. Any future prototype system that would see use in an ICU context would need to be once again refined taking the lessons learned from patient and staff usability, feedback, and the prototypes integration within the ICU bed-space to formulate a strategy for re-introducing a VR-I Module.

In terms of the InpireVR and VeloVR studies, a number of key elements would need to be addressed to increase the systems reliability, chief of which would be the need to work to remove dependence on the mid-ware software that would often be the cause of hardware /

software failures that would put both systems out of action and hold up testing. Refinements would need to be made to both prototype rigs and associated hardware technologies to take on board comments in terms of stability vs size in the case of VeloVR, and durability in the case of InspireVR.

9.8 Recommendations for introducing prototype technologies into ICU

Based on the research undertaken and lessons learned throughout this thesis a series of guidelines was created that highlights the important stages necessary in order to create and deploy innovative novel prototype for use within the operational environments of an intensive care unit. Table 9.1 details the stages-:

Table 9.1: Recommendations for the introduction of prototype technologies

Stakeholder Involvement	A crucial element before any prototype solution is designed is to engage with stakeholders with the aim of understanding the full scope and requirements from those who operate and work within the environment in question.
User involvement	Throughout the all stages of the prototype life cycle, attention must also be paid to actual user of the system, a user can be classed as a clinical professional who facilitates the system behind the scenes or during testing, or the patient who the system was designed for.
Environment	The prototype may be designed for use within a sterile controlled environment, but considerations must be made as to how the prototype is handled outside of this area, for example, rough terrain, slopes, rough handling of equipment can cause severe damage to the system.
Storage	Considerations must be made as to how the prototype is stored. A prototype is a work in progress and not a ready for market product and as such is susceptible to sustaining damage when held with larger items of medical grade equipment.
Technology acceptance	With the consultation of both stakeholders and users from outset, the prototype system will stand a greater chance of being accepted and used, as it is relevant to the needs of the patient and the environment.

Adhere to the relevant ISO standards	During all stages of the prototype life cycle, from design, to build, to implementation, and review, attention must be paid to the relevant ISO standards to ensure that what is created is safe and relevant for use within the context it was designed for.
Usability	Continual feedback must be gathered during the prototypes usage in order to validate or refute the initial design choices and to help formulate a strategy for an iteration in the prototype design cycle.
Prototype observation	The prototype must be viewed within the operational area it was designed for to ensure that it integrates well with other medical equipment and poses no threat to patient/care professional safety.
Evolution of design	During the prototypes deployment the design must continually be evolved to eliminate any unforeseen safety issues that can only been identified during real world implementation, other evolutionary choices would need to be addressed in future iterations of prototype design, especially if undergoing participant testing.
Repairable / Cost effectiveness	To ensure the prototype is cost effective and easy to repair (especially in the field) the design of the system must employ the idea of using Consumer off the shelf technologies (COTS). The use of which can be of benefit when the need to replace damaged or worn out items is required. The use of exotic or heavily over engineered components cannot just increase costs but more importantly can add time delays to the system.
Reproducible / Re-deployable	The prototype must be cost effective so that if the need arises additional system can be component sourced, constructed and deployed in a short time.
Cyber-sickness	Any display technology employed must consider sickness related to motion-tracking systems "cyber-sickness" occurs in 3-5% of the general population, but has never been studied in an ICU population. The risk may be increased by the use of medication. Cyber-sickness is self-limiting following cessation of VR exposure.
Use of Virtual Reality head mounted displays (HMD)	Any use of Head mounted display technologies must take into account patient welfare with regards, levels of medication, delirium., cyber-sickness and the need for patient observations, i.e. eye movement.

	HMD Hygiene must also be considered, many off the COTS head mount displays are not designed for multi person use and are not currently medically certified for use within an ICU.
Levels of immersion	Levels of immersion are dependent on the task at hand, if the VR experience is engaging then the possibility of smaller display technologies can be employed.

9.9 What happened to InspireVR – Version 1?

The aim of the InspireVR study was to seek and obtain class 1 medical certification to which qualification required that each and every component carried its own CE marking, sadly the main component of the system, the trolley mount (Chapter 5, Figure 5.19) was sourced from China and was therefore void. It led to the sourcing and hasty re-adaption of a new stand to create the InspireVR V2 prototype that saw participation in the InspireVR study (Chapter 7). The non CE marked prototype was re-purposed together with hardware and software integration, and donated to help with a pilot study, again within the ICU at QEHB looking at the concept of non-verbal patient to care-professional communication.

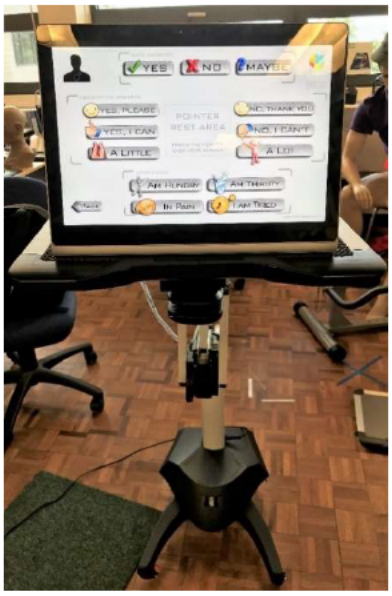


Figure 9.6: InspireVR-V1 prototype re-purposed for ICU chat pilot study

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Appendix 3.1

SUS - A quick and dirty usability scale

John Brooke



Abstract

Usability does not exist in any absolute sense; it can only be defined with reference to particular contexts. This, in turn, means that there are no absolute measures of usability, since, if the usability of an artefact is defined by the context in which that artefact is used, measures of usability must of necessity be defined by that context too. Despite this, there is a need for broad general measures which can be used to compare usability across a range of contexts. In addition, there is a need for "quick and dirty" methods to allow low cost assessments of usability in industrial systems evaluation. This chapter describes the System Usability Scale (SUS) a reliable, low-cost usability scale that can be used for global assessments of systems usability.

Usability and context

Usability is not a quality that exists in any real or absolute sense. Perhaps it can be best summed up as being a general quality of the ***appropriateness to a purpose*** of any particular artefact. This notion is neatly summed up by Terry Pratchett in his novel "Moving Pictures":

> " 'Well, at least he keeps himself fit,' said the Archchancellor nastily. 'Not like the rest of you fellows. I went into the Uncommon Room this morning and it was full of chaps snoring!'
> 'That would be the senior masters, Master,' said the Bursar. 'I would say they are supremely fit, myself.'
> '*Fit?* The Dean looks like a man who's swallered a bed!'
> 'Ah, but Master,' said the Bursar, smiling indulgently, 'the word "fit",as I understand it, means "appropriate to a purpose", and I would say that the body of the Dean is supremely appropriate to the purpose of sitting around all day and eating big heavy meals.' The Dean permitted himself a little smile. " (Pratchett, 1990)

In just the same way, the usability of any tool or system has to be viewed in terms of the context in which it is used, and its appropriateness to that context. With particular reference to information systems, this view of usability is reflected in the current draft international standard ISO 9241-11 and in the European Community ESPRIT project MUSiC (Measuring Usability of Systems in Context) (e.g., Bevan, Kirakowski and Maissel, 1991). In general, it is impossible to specify the usability of a system (i.e., its fitness for purpose) without first defining who are the intended users of the system, the tasks those users will perform with it, and the characteristics of the physical, organisational and social environment in which it will be used.

Since usability is itself a moveable feast, it follows that measures of usability must themselves be dependent on the way in which usability is defined. It is possible to talk of some general classes of usability measure; ISO 9241-11 suggests that measures of usability should cover

- effectiveness (the ability of users to complete tasks using the system, and the quality of the output of those tasks),
- efficiency (the level of resource consumed in performing tasks)
- satisfaction (users' subjective reactions to using the system).

However, the precise measures to be used within each of these classes of metric can vary widely. For example, measures of effectiveness are very obviously determined by the types of task that are carried out with the system; a measure of effectiveness of a word processing system might be the number of letters written, and whether the letters produced are free of spelling mistakes. If the system supports the task of controlling an industrial process producing chemicals, on the other hand, the measures of task completion and quality are obviously going to reflect that process.

A consequence of the context-specificity of usability and measures of usability is that it is very difficult to make comparisons of usability across different systems. Comparing usability of different systems intended for different purposes is a clear case of "comparing apples and oranges" and should be avoided wherever possible. It is also difficult and potentially misleading to generalise design features and experience across systems; for example, just because a particular design feature has proved to be very useful in making one system usable does not necessarily mean that it will do so for another system with a different group of users doing different tasks in other environments.

If there is an area in which it is possible to make more generalised assessments of usability, which could bear cross-system comparison, it is the area of subjective assessments of usability. Subjective measures of usability are usually obtained through the use of questionnaires and attitude scales, and examples exist of general attitude scales which are not specific to any particular system (for example, CUSI (Kirakowski and Corbett, 1988)).

Industrial usability evaluation

The demands of evaluating usability of systems within an industrial context mean that often it is neither cost-effective nor practical to perform a full-blown context analysis and selection of suitable metrics. Often, all that is needed is a general indication of the overall level of usability of a system compared to its competitors or its predecessors. Equally, when selecting metrics, it is often desirable to have measures which do not require vast effort and expense to collect and analyse data.

These sorts of considerations were very important when, while setting up a usability engineering programme for integrated office systems engineering with Digital Equipment Co. Ltd, a need was identified for a subjective usability measure. The measure had to be capable of being administered quickly and simply, but also had to be reliable enough to be used to make comparisons of user performance changes from version to version of a software product.

The need for simplicity and speed came from the evaluation methods being used; users from customer sites would either visit a human factors laboratory, or a travelling laboratory would be set up at the customer site. The users would then work through evaluation exercises lasting between 20 minutes and an hour, at the end of which a subjective measure of system usability would be collected. As can be imagined, after this period of time, users could be very frustrated, especially if they had encountered problems, since no assistance was given. If they were then presented with a long questionnaire, containing in excess of 25 questions it was very likely that they would not complete it and there would be insufficient data to assess subjective reactions to system usability.

SUS - the System Usability Scale

In response to these requirements, a simple usability scale was developed. The System Usability Scale (SUS) is a simple, ten-item scale giving a global view of subjective assessments of usability.

SUS is a *Likert scale*. It is often assumed that a Likert scale is simply one based on forced-choice questions, where a statement is made and the respondent then indicates the degree of agreement or disagreement with the statement on a 5 (or 7) point scale. However, the construction of a Likert scale is somewhat more subtle than this. Whilst Likert scales are presented in this form, the statements with which the respondent indicates agreement and disagreement have to be selected carefully.

The technique used for selecting items for a Likert scale is to identify examples of things which lead to extreme expressions of the attitude being captured. For instance, if one was interested in attitudes to crimes and misdemeanours, one might use serial murder and parking offences as examples of the extreme ends of the spectrum. When these examples have been selected, then a sample of respondents is asked to give ratings to these examples across a wide pool of potential questionnaire items. For instance, respondents might be asked to respond to statements such as “hanging’s too good for them”, or “I can imagine myself doing something like this”.

Given a large pool of such statements, there will generally be some where there is a lot of agreement between respondents. In addition, some of these will be ones where the statements provoke extreme statements of agreement or disagreement among all respondents. It is these latter statements which one tries to identify for inclusion in a Likert scale, since, we would hope that, if we have selected suitable examples, there would be general agreement of extreme attitudes to them. Items where there is ambiguity are not good discriminators of attitudes. For instance, while one hopes that there would be a general, extreme disagreement that “hanging’s too good” for those who perpetrate parking offences, there may well be less agreement about applying this statement to serial killers, since opinions differ widely about the ethics and efficacy of capital punishment.

SUS was constructed using this technique. A pool of 50 potential questionnaire items was assembled. Two examples of software systems were then selected (one a linguistic tool aimed at end users, the other a tool for systems programmers) on the basis of general agreement that one was “really easy to use” and one was almost impossible to use, even for highly technically skilled users. 20 people from the office systems engineering group, with occupations ranging from secretary through to systems programmer then rated both systems against all 50 potential questionnaire items on a 5 point scale ranging from “strongly agree” to “strongly disagree”.

The items leading to the most extreme responses from the original pool were then selected. There were very close intercorrelations between all of the selected items (± 0.7 to ± 0.9). In addition, items were selected so that the common response to half of them was strong agreement, and to the other half, strong disagreement. This was done in order to prevent response biases caused by respondents not having to think about each statement; by alternating positive and negative items, the respondent has to read each statement and make an effort to think whether they agree or disagree with it.

The System Usability Scale is shown in the next section of this chapter. It can be seen that the selected statements actually cover a variety of aspects of system usability, such as the need for support, training, and complexity, and thus have a high level of face validity for measuring usability of a system.

System Usability Scale

© Digital Equipment Corporation, 1986.

	Strongly disagree				Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

Using SUS

The SU scale is generally used after the respondent has had an opportunity to use the system being evaluated, but before any debriefing or discussion takes place. Respondents should be asked to record their immediate response to each item, rather than thinking about items for a long time.

All items should be checked. If a respondent feels that they cannot respond to a particular item, they should mark the centre point of the scale.

Scoring SUS

SUS yields a single number representing a composite measure of the overall usability of the system being studied. Note that scores for individual items are not meaningful on their own.

To calculate the SUS score, first sum the score contributions from each item. Each item's score contribution will range from 0 to 4. For items 1,3,5,7,and 9 the score contribution is the scale position minus 1. For items 2,4,6,8 and 10, the contribution is 5 minus the scale position. Multiply the sum of the scores by 2.5 to obtain the overall value of SU.

SUS scores have a range of 0 to 100.

The following section gives an example of a scored SU scale.

System Usability Scale

© Digital Equipment Corporation, 1986.

	Strongly disagree				Strongly agree	
1. I think that I would like to use this system frequently					☒	4
	1	2	3	4	5	
2. I found the system unnecessarily complex				☒		1
	1	2	3	4	5	
3. I thought the system was easy to use		☒				1
	1	2	3	4	5	
4. I think that I would need the support of a technical person to be able to use this system	☒					4
	1	2	3	4	5	
5. I found the various functions in this system were well integrated		☒				1
	1	2	3	4	5	
6. I thought there was too much inconsistency in this system			☒			2
	1	2	3	4	5	
7. I would imagine that most people would learn to use this system very quickly		☒				1
	1	2	3	4	5	
8. I found the system very cumbersome to use				☒		1
	1	2	3	4	5	
9. I felt very confident using the system					☒	4
	1	2	3	4	5	
10. I needed to learn a lot of things before I could get going with this system		☒				3
	1	2	3	4	5	

Total score = 22

SUS Score = 22 *22.5 = 55

Conclusion

SUS has proved to be a valuable evaluation tool, being robust and reliable. It correlates well with other subjectives measures of usability (eg., the general usability subscale of the SUMI inventory developed in the MUSiC project (Kirakowski, personal communication)). SUS has been made freely available for use in usability assessment, and has been used for a variety of research projects and industrial evaluations; the only prerequisite for its use is that any published report should acknowledge the source of the measure.

Acknowledgements

SUS was developed as part of the usability engineering programme in integrated office systems development at Digital Equipment Co Ltd., Reading, United Kingdom.

References

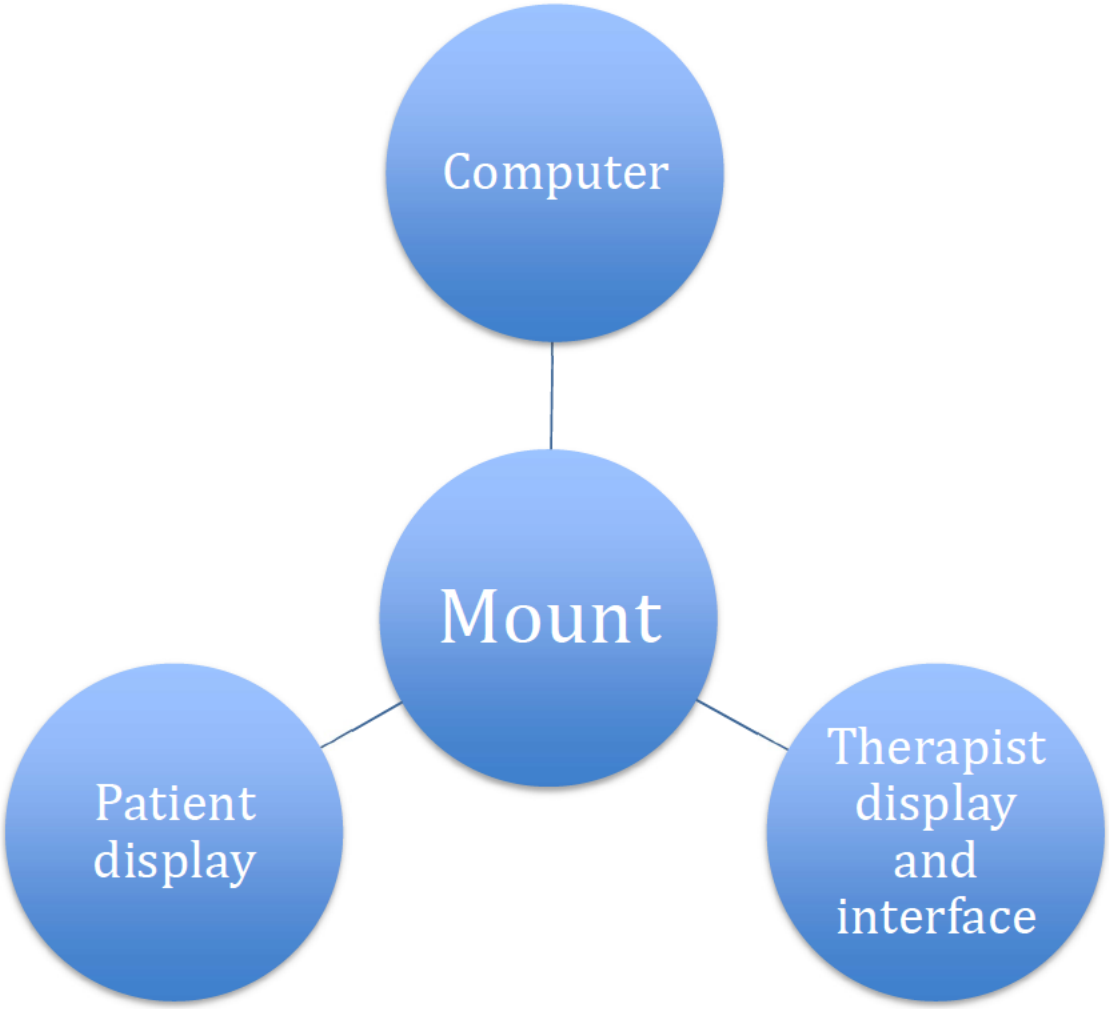
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Pratchett, T., 1990 *Moving Pictures*. London: Gollancz

Appendix 4.1

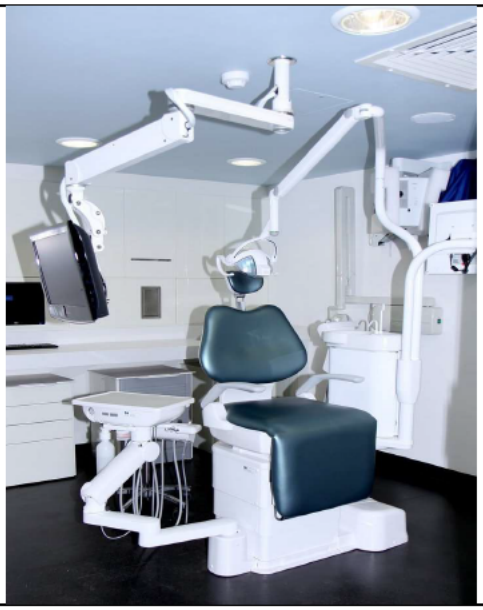
REVERE 2.0 Prototype: Design conceptualisation

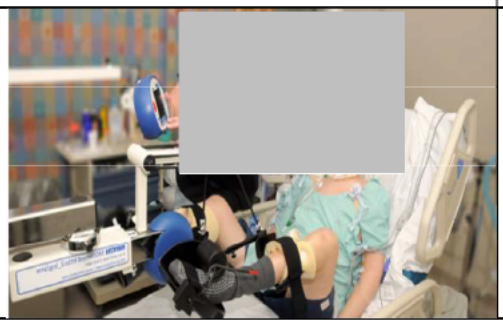


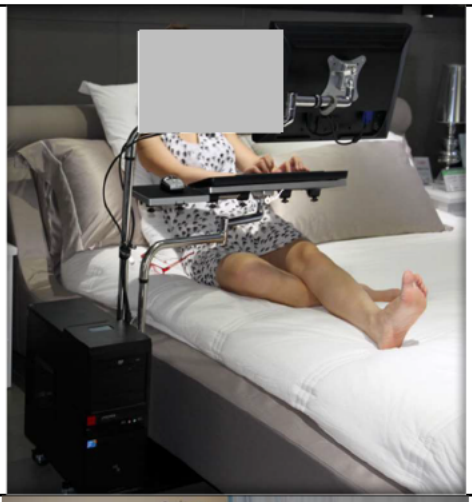
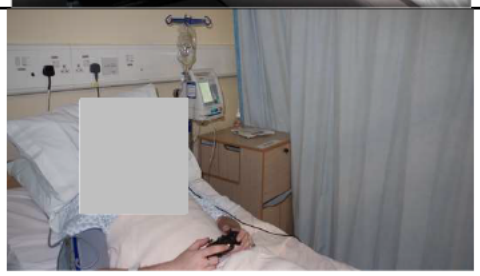


Possible mounting solutions / options for REVERE 2.0 prototype

Mount

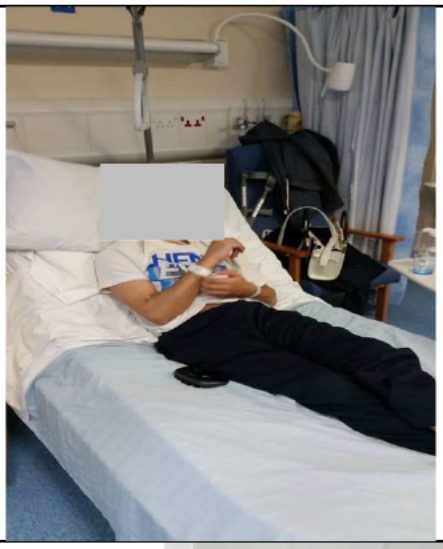
	Mount type	Image	Comments
1	**Floor** Table (semi-static)		Bulky, installation may be problematic due to moving and handling (M&H) and wiring
	Trolley (wheeled)		Good flexibility – equipment can move to patient Self contained Bulky to store and move
2	**Ceiling** Fixed		Inflexible – patient comes to the equipment. Could be integrated/piggy backed with current bed space entertainment systems where available Minimal storage/installation issues

	Track/rail		Limited flexibility - patient has to come to equipment, unless entire unit tracked Can only serve one patient at a time (unable to have multiple systems on one track) As above
3	**Wall**		Limited flexibility – patient has to come to equipment As above
4	**Stanchion/infusion stand (device designed to be "load-bearing")**		Equipment come to patient Need to consider load/weight and limitations of the stand. System will need to be "small scale", hence ease of installation/ storage
5	**Equipment mounted (retro-fitting) – device not necessarily designed to carry "load"**		Will need manufacturer permission As above

6	**Bed frame**		May restrict access to patient As above
7	**Person (wearable's devices)**		Eg HMD "mounted" directly onto the patient Infection control Skin integrity Comfort Cybersickness

NOTES

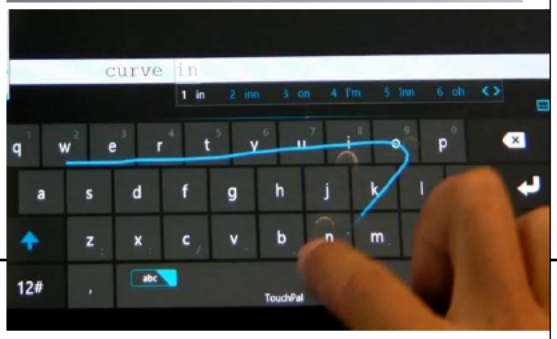
Patient display

	Display type	Image	Comments
1.	**Head mounted**		Not appropriate for the voiceless, weak ICU patient – unable to remove independently Infection control Skin integrity Comfort Cybersickness
2.	**LCD** **Small** **Medium** **Large**		Screen size will determine balance between immersion/quality of image/image scaling and bulk/portability
3.	**Projection**		Requires adequate levels of ambient lighting / appropriate structure to project on to, i.e wall / screen.

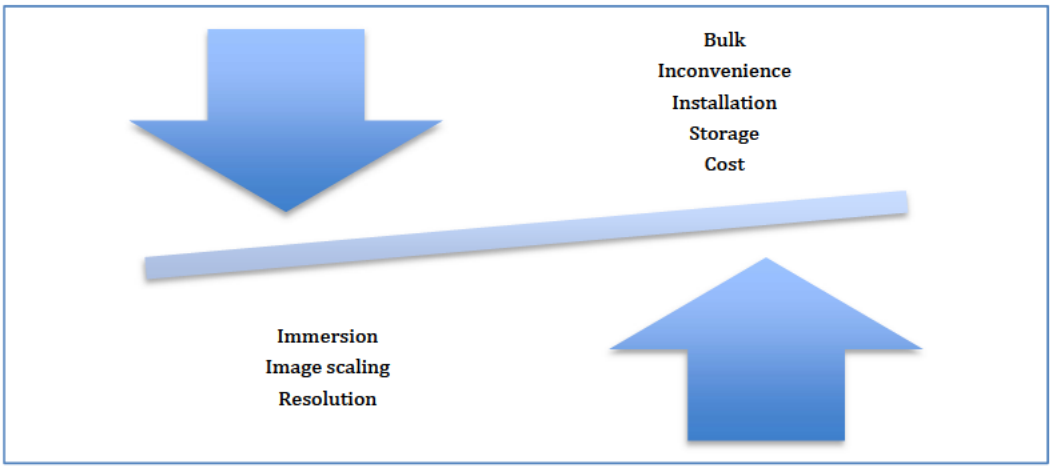
NOTES

Therapist interface/display

	Components	Image	Comments

1.	**Display size/shape**		Secondary wireless display to aid with remote monitoring
2.	**Control** Touch screen Keyboard		Integrated touch interface for hygiene control
3.	**Wired/wireless**		Possible interference with exist in medical / sensing equipment

Weighing up the screen size



NOTES

Appendix 4.2

Cleaning Instructions

1. Cleaning and Low Level Disinfection of the Vitalograph Pneumotrac

The parts of the Vitalograph Pneumotrac that make up the flowhead, which comes into contact with subjects being tested, require **low level disinfection.** The body of the device may be **cleaned** with an alcohol wipe.

A spirometer is not designed as a 'sterile' device.

A new BVF should be used with each subject to prevent cross contamination, the BVF protects both the subject and the device.

One cleaning cycle should be performed weekly.

It is recommended that the complete flowhead and flowhead connection tube be replaced annually.

Table of Cleaning/Disinfection Methods

Part	Clean/Low Level Disinfection	Recommended Cleaning/Low Level Disinfection
Case Exterior	Clean	Wiping with a 70% isopropyl alcohol impregnated cloth.
Flowhead Tube	Clean	
Fleisch Element	Clean	See section 2 for disassembling and cleaning of flow head. See section 3 for reassembling and low level disinfection of the flowhead
Flow Conditioning Meshes	Clean	
Flowhead Body	Clean & Low Level Disinfection	
Flowhead Cone	Clean & Low Level Disinfection	
Flowhead End Cap	Clean & Low Level Disinfection	

2. Disassembling and Cleaning of the Fleisch Flowhead

1. Remove the cone and the end cap from the flowhead.
2. Remove the flow conditioning meshes from inside the cone and the end cap, and examine them for damage or contamination. If they are damaged or blocked, discard and replace with new parts.
3. To remove the flowhead body from the fleisch element, place the fleisch element on a hard, flat surface with blue tapping /ribbed connector side of the flowhead body furthest away from the flat surface. Push down on the flowhead body with thumbs and forefingers until it reaches the flat surface. A final pulling and twisting action will separate the parts.

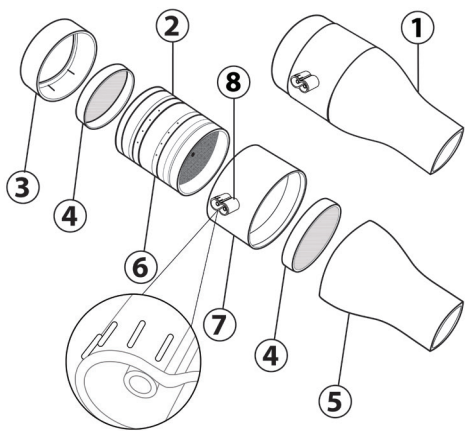


Fig 1: Flowhead Assembly

1. Flowhead Complete
2. 'O' rings
3. Flowhead End Cap
4. Flow Conditioning Meshes
5. Flowhead Cone
6. Fleisch Element
7. Flowhead Body
8. Port Pressure Tappings

Lubrication: Silicone Grease

4. To clean the fleisch element, swill vigorously in warm soapy water. Do not attempt to "rub" or "scrub" at capillaries.
5. To clean the flowhead end cap, flowhead body, flow conditioning meshes and flowhead cone, wash in warm soapy water. Rub surfaces to remove any visible soiling.
6. Examine all parts to ensure they are visibly clean. If not visibly clean repeat the cleaning process.
7. Rinse all parts in distilled water.
8. Leave to dry completely before reassembling. Drying the fleisch element components may require placing them in a warm place overnight. A drying cabinet is ideal.

Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.

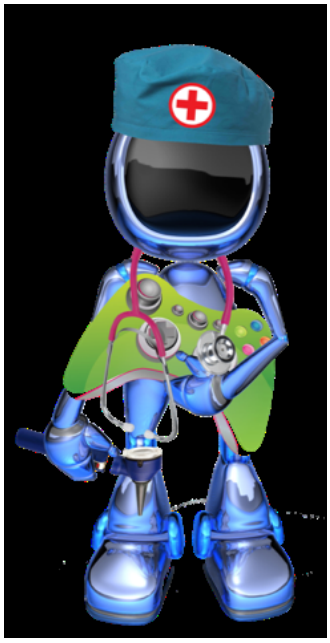
3. Reassembling and Low Level Disinfection of the Fleisch Flowhead

1. Examine the fleisch element to ensure that no liquid or particles remain in the holes, grooves or pressure tappings.
2. Check the 'O' rings for damage and ensure that they are correctly positioned within the grooves.
3. Apply a very small amount of silicone grease to 'O' Rings and inside the surfaces of the flowhead body. Wipe off any visible amounts of grease. Ensure that the tiny annular holes on the outside of the fleisch element are not blocked.
4. When re-assembling the flowhead, fit the flow head element assembly into the flow head body ensuring that it is inserted at the blue tapping /ribbed connector side of the body.
5. Ensure that the flowhead body is pushed fully home and rotate it so that the pressure ports are approximately 180° opposite the end of the fleisch element coil.
6. Fit flow conditioning meshes to both the flowhead cone and the flowhead end cap. (See Fig 1, Flowhead Assembly.)
7. Push the flowhead end cap onto the fleisch element at the blue tapping /ribbed connector side of the flowhead body and push the flowhead cone onto the opposite side.
8. Wipe all external surfaces of the flowhead with a 70% isopropyl alcohol impregnated cloth.
9. When attaching the flowhead connection tube, ensure that the matching ribbed port pressure tappings on the flowhead and the Vitalograph Pneumotrac are connected to each other.

It is recommended that an accuracy check is carried out following reassembly to verify correct operation and accuracy.

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InspireVR Instructions for Use



Problems or questions: Please contact the research team on:	

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1.Quick start Guide

PC Password PIN -

WIFI Modem Password -

Game Controls -

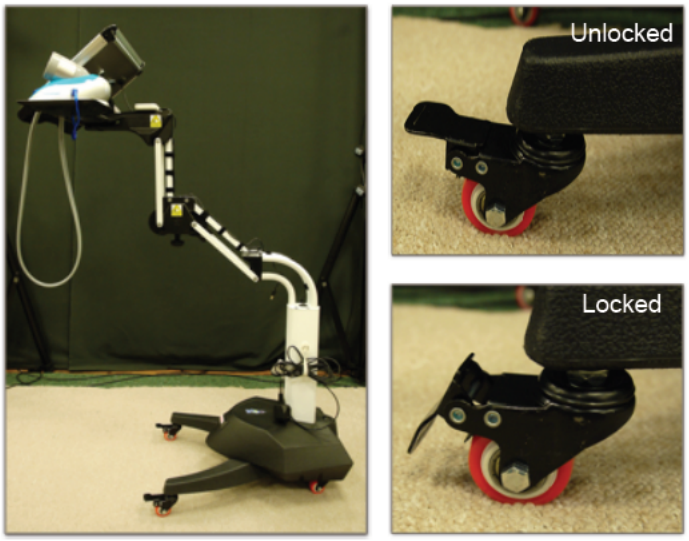
Press “F6” to start the game,

Press “R” to restart the current level

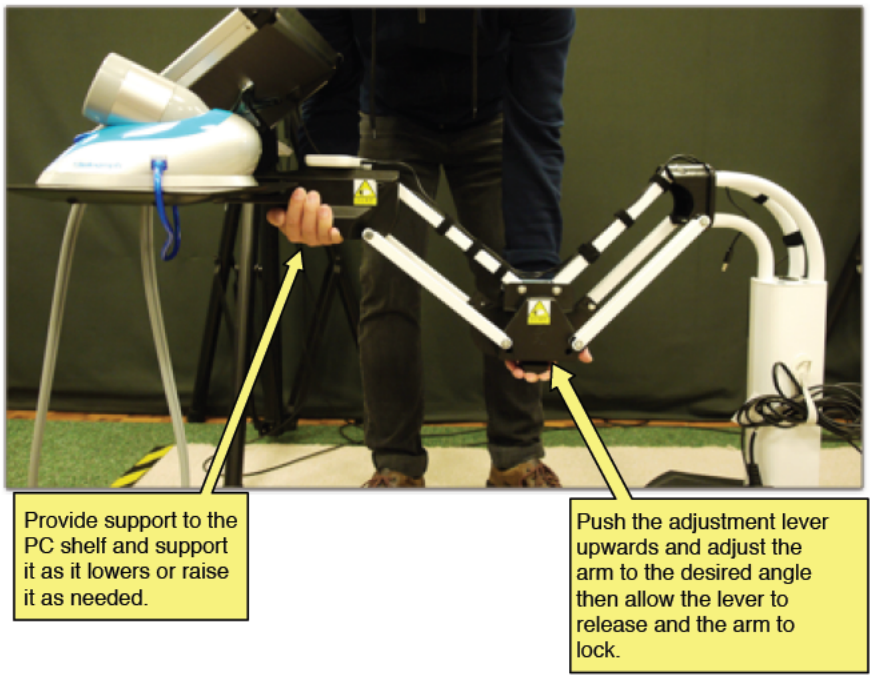
Press “F12” to exit to desktop

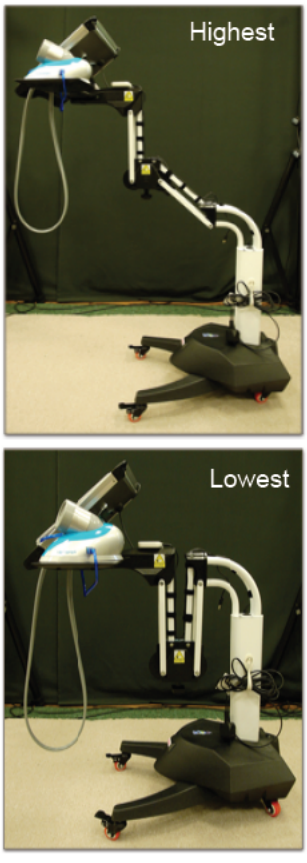
2.Moving and handling

The InspireVR trolley mount features locking rubberised castors and a sand-filled base to provide stability during transportation. The Personal Computer (PC) and the spirometer mouthpiece are secured to the trolley. The castors feature a locking mechanism that can be activated or released by depressing the tab with your foot.2. Height and Reach Adjustment



3. Height and reach adjustment





4. Tray adjustment

Raise the white handle to allow for tilt adjustment of the PC shelf, release the handle when you reach the desired angle and allow the shelf to lock in place.





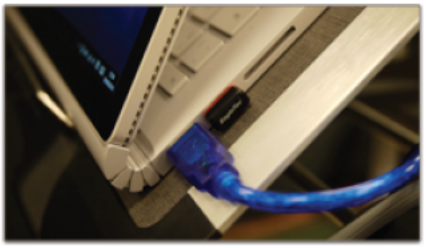
5. Power

InspireVR runs via a single mains plug, during transportation please stow it using the cable tidy located on the frame.

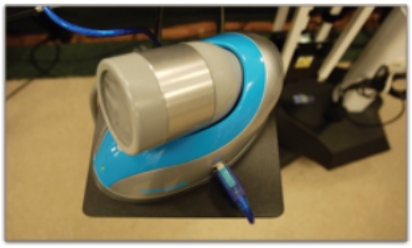
6. Cabling

InspireVR has been designed to remain as a complete unit, this section describes the cables and how they are connected to the PC.

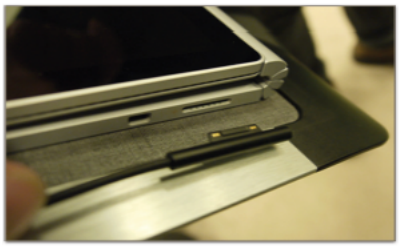
The blue USB cable connects to the spirometer mouthpiece, the black USB dongle connects to a wireless keyboard.



The other end of the blue USB cable connects to the spirometer's base unit.



The power cable for the PC is held on magnetically, if it detaches simply push it back in place.



7. Laptop

To start the laptop press the power button (located on top of the display) and wait for the system to boot up.







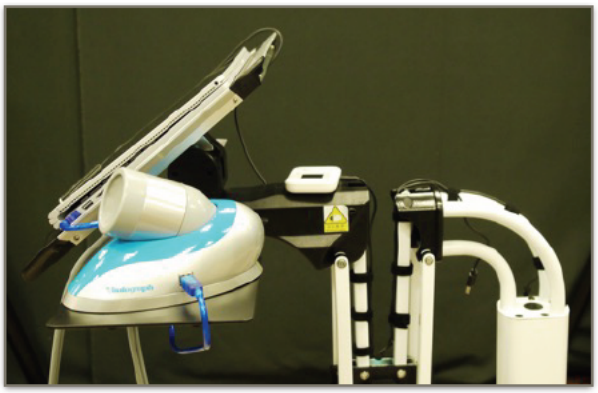
When the laptop screen illuminates, swipe up on the display

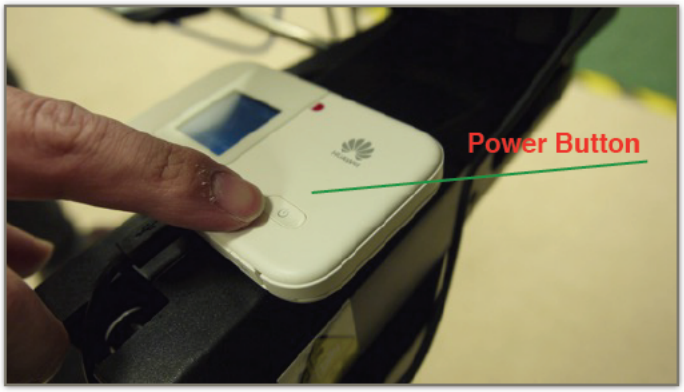
Touch on sign in and the laptop will load up the desktop

The password pin for the PC is "**3091**"

8. WIFI Modem

In order for the system to function correctly, the spirometer software requires a brief internet connection to authenticate the software upon start up.





To power up the modem press and briefly hold the power button until the display lights up, after a period of inactivity the modem may go to sleep to wake it up simply press the power button and the display should light up.

9. WIFI Setup laptop





The WiFi modem should automatically connect to the laptop, if not you will need to manually select the WIFI modem.

Touch the Wireless manage icon. This located on the lower right side of the display.
The connection named [redacted] is the WIFI modem so please connect to this.

10. Laptop Volume

To increase the sound volume press the + side of the button and to reduce the sound press the - button.





11. Charging

When the laptop is being stored either overnight or between participants please plug it into a mains outlet, this will ensure that both the laptop and the Wifi modem are fully charged, so that in the event of temporary mains failure the testing can still continue.

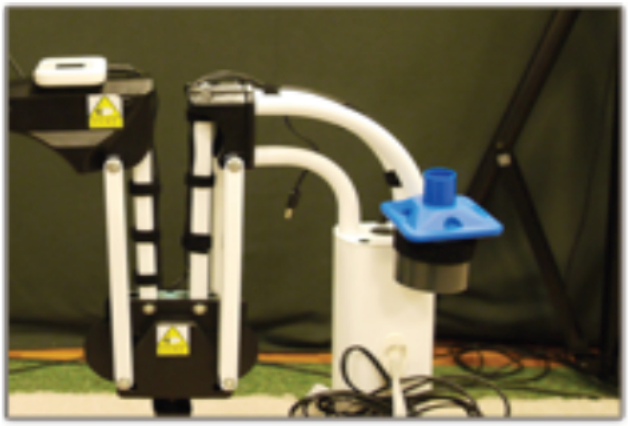
12. Spirometer



The Spirometer uses a single-patient bacterial-viral filter (BVF) that the participant uses throughout their time in the study.



The mouthpiece pushes onto the spirometer body



When the mouth piece is not in use please store it in the holder mounted on the frame.

13. Software

Once logged in (see section 6) you will be presented with the desktop. There is single “start” button visible, the patient touches the start each morning to set up the system for the day.

14. Game Controls

Using the supplied wireless keyboard

Press “F6” to start the game,

Press “R” to restart the current level

Press “F12” to exit to desktop



15. Game walkthrough

At the start of each day the user will be prompted to set their breath volume targets for the day (calibration). This is done by taking three deep breaths, using the spirometer mouthpiece. At each successful attempt a smiling face will appear. This would signify that the participant will need to repeat the process until three smiling faces are achieved. The highest breath volume achieved will be used to set the target volumes for the rest of that day.



Successful attempt



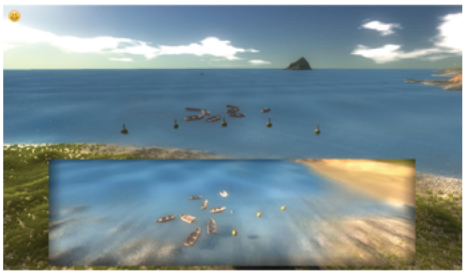
Following on from calibration a countdown timer will appear to signify the start of level 1.



When the game is loaded, the screen you will see the screen below.



The participant should then place the spirometer mouthpiece in their mouth, creating a tight seal. They then take a long, deep, steady breath, then hold their breath for three seconds.When the participant breathes in on they will see the trebuchet pull back and then fire the boulder into the sea. The distance the boulder is fired depends on how deep a breath they take (inspiratory capacity). As the boulder fires, a separate game window appears showing the trajectory the boulder is taking.

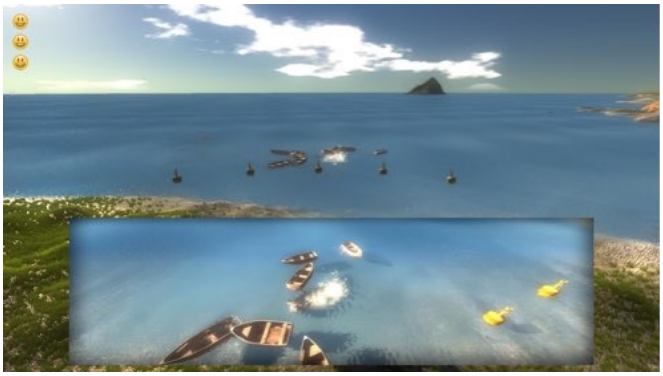




If the breath does not meet their target volume for that level, the participant will be shown a sad face. If the breath is sufficient then the participant will be presented with a smiling face.



The patient repeats this process ten times (ten deep breaths)

When a smiling face appears, the patients has met their target breath volume (inspiratory capacity). There will be a water splash near to the boats, or a direct hit of a boat. When the sad face appears, the patient has not met their target breath volume. The boulder will land somewhere between the buoys and the trebuchet.



The line of buoys represents the distance to the calibration volume at the start of the day. If seven or more smiling faces are achieved during a session, the patient “wins” that level and will start on the next level up at their next session in using the InspireVR. Each level represents a 5% increase in breath volume (inspiratory capacity). If the achieve less that seven smiling faces, the patient will re-try the same level at the next session using InspireVR.



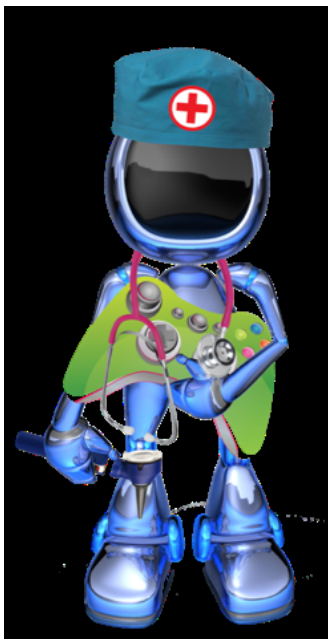
Upon successful completion of each a timer will appear to signify the time to the start of the next session of InspireVR (two hours later). During this time, please leave the laptop on and store the spirometer mouthpiece.Upon successful completion of all levels the participant will be presented with the message “Well done, all levels complete!.”.

16. Hygiene

Please use a single patient-use bacterial-viral filter for each patient.

InspireVR can be cleaned using 70% alcohol wipes, if alcohol free wipes are to be used please avoid using them on the touch display as it will leave a white residue which, once dry, will create glare on the display and impact on the quality of game play.

The spirometer itself can be sterilised if exposed to pathogens of concern. Please contact the research team for information.



InspireVR Device Description

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2. Device Identification 3
3. Brief Description 4
4. Prototype Design Process 5
5. Standards 8
6. Stakeholder Group 8
7. Inspire VR system components 9
8. Inspire VR Software 10

1. Applicant Details

Name	[redacted]
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Work address	Department of Anaesthesia and Critical Care Queen Elizabeth Hospital Birmingham Mindelsohn Way Edgbaston Birmingham B15 2WB
Home address	[redacted]
Email	[redacted]
Phone Number	[redacted]

2. Device Identification

Generic Name	InspireVR
Model Name	InspireVR
Model number	1
MHRA Classification	Class 1
Manufacturer	Professor Bob Stone Human Interface Technologies Team School of Electrical, Electronic and Systems Engineering University of Birmingham B15 2TT
Email	
Phone Number	

3. Brief Description

The InspireVR system has been designed as a bedside device for use in patients required to undertake incentive spirometry. Incentive spirometry is the term used to describe the process of taking a deep breath to maximum inspiratory capacity (MIC) followed by a non-forced exhalation. Incentive spirometry is recommended as a therapy to reduce the risk of pulmonary complications, such as lung infection or basal atelectasis, following severe illness, trauma or major surgery. Patients who have undergone oesophegectomy or total gastrectomy for cancer treatment are at high risk of developing postoperative pulmonary complications (PPCs) due to intra-operative lung deflation, post-operative pain inhibiting deep breathing and cough, and poor physical state following neoadjuvanrt chemotherapy. The purpose of incentive spirometry is to recruit collapsed small airways, reinflate the lung bases and encourage expectoration of airway secretions. InspireVR has been designed to meet the user requirements of patients in their early phase of recovery from elective major upper gastrointestinal surgery (oesophagectomy or total gastrectomy) for cancer treatment, whilst on critical care. The aim of the manufacturers is to produce a device which is superior to the current alternative, non-electronic, visual feedback devices, such as the Leventon Spiroball Incentive Volumetric Exerciser (Image 1). These devices do not record patient activity, preventing objective usage or performance data collection when incentive spirometry is carried out independently. The absence of such capabilities has contributed to the methodological limitations of studies evaluating the efficacy of regular post operative incentive spirometry.(1)



Image 1: Spiroball Incentive Volumetric Exercises.

4. Prototype Design Process

InspireVR has been developed using a human centred design process, combining the requirements described in BS EN ISO 9241-210, Ergonomics of human-system interaction (Part 210: Human-centred design for interactive systems)(2) and IEC 62366-2007, Medial Devices - Application of Usability Engineering to Medical Devices.(3) Given the impact of the context of the device, the usability engineering processes described by these directives have been combined with strategies recommended by the Medical Research Council for the Development and Evaluation of Complex Medical Interventions (4) to create a framework for system development (Figure 2).

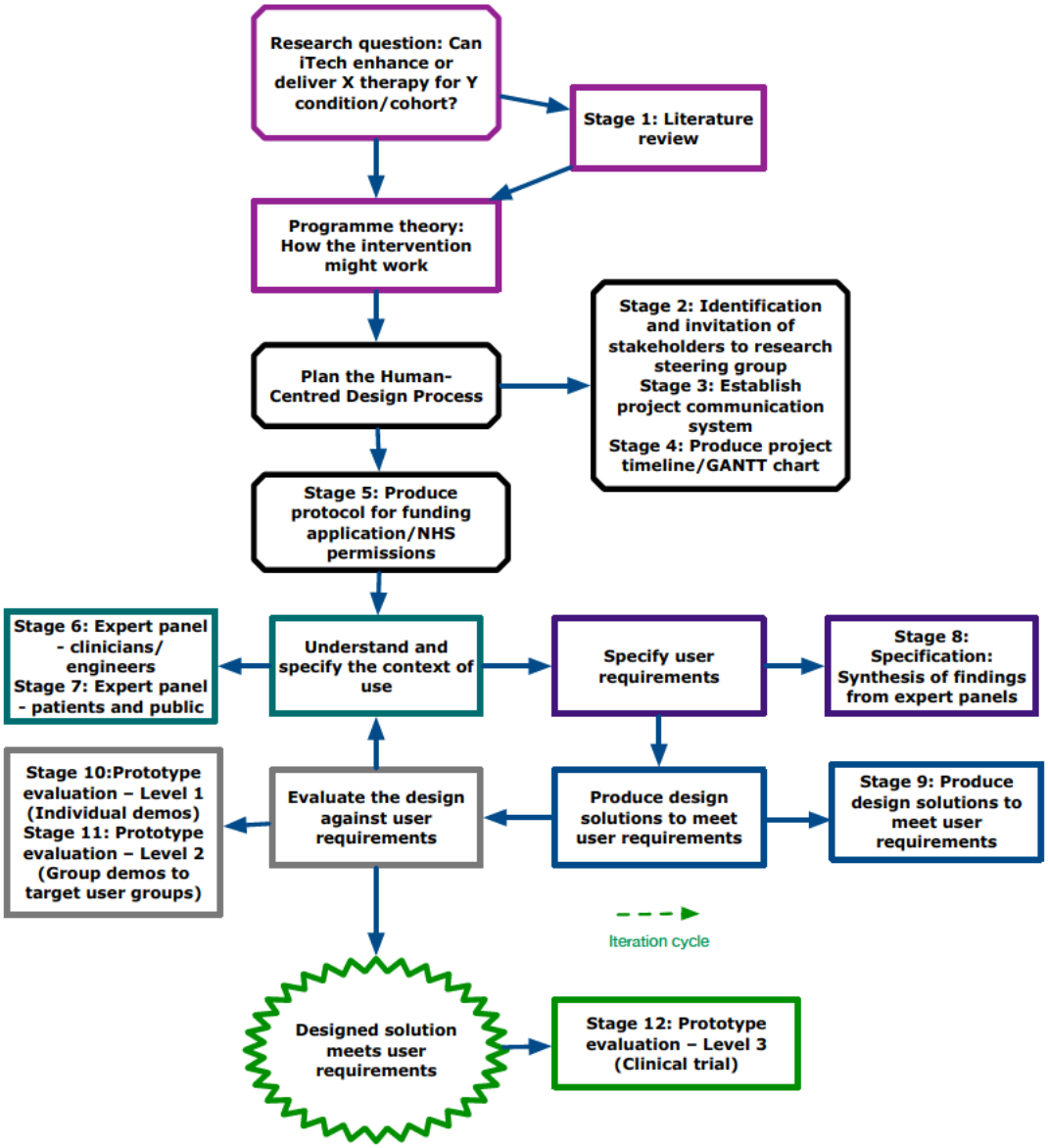


Figure 2: Human Centred Design process adopted for the development of the InspireVR prototype (adapted from ISO 9241-201)

Stages 1-12 have been completed, producing a product ready for clinical investigation/feasibility study in a clinical setting.

The specification of requirements has been developed by compiling a detailed description of the required task and goals, combined with evaluation of user capabilities and the context of use (Figure 3)

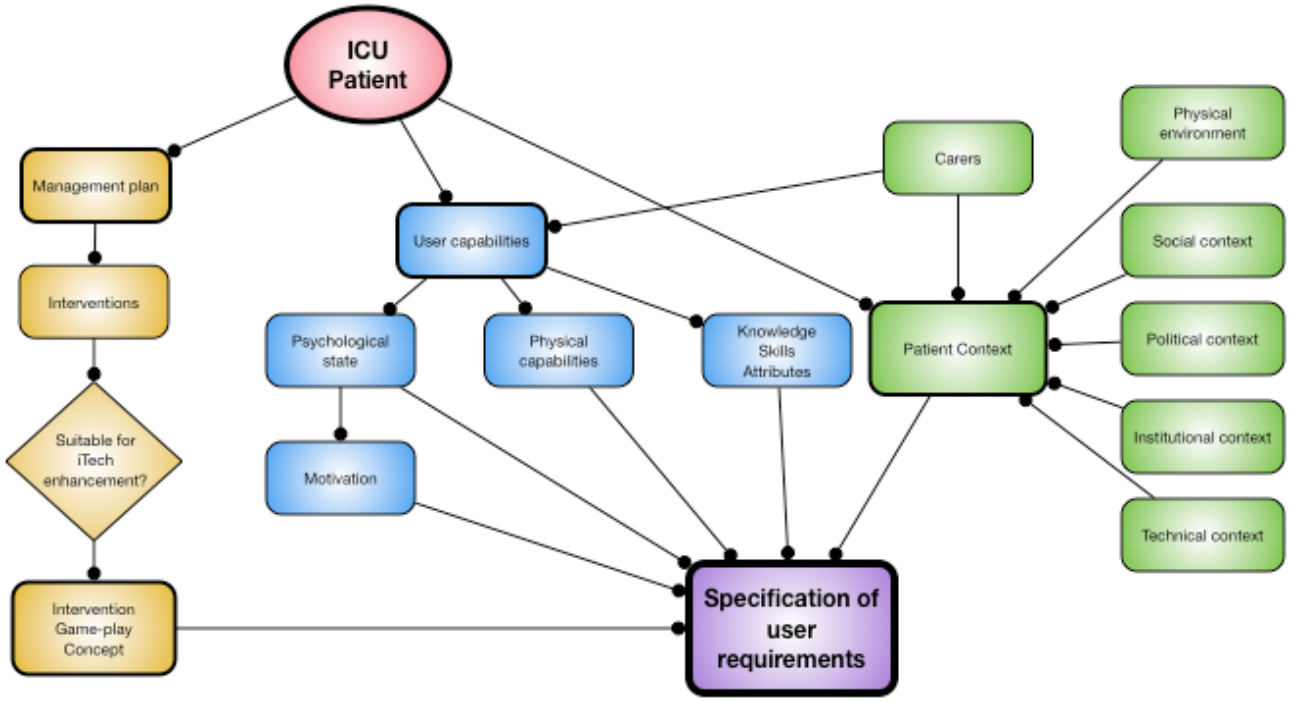


Figure 3: Framework for specification of user requirements

Development of the gameplay concept has been informed by a literature review of recommendations for breathing exercises in patients recovering on critical care. This has established that incentive spirometry is practised as a standard of care in a large number of institutions, ensuring relevance of the device. The precision of the gameplay has been informed by instructions provided by the physiotherapists to ensure the game intuitively encourages the correct breathing action and rewards when the correct action has been completed. Synthesis of user acceptability and user knowledge/skills/attitudes (KSA) from previous research by the group, alongside recommendation by the PPI representatives has informed the description of user requirements. Understanding of the patient context by the Human Interface Technologies (HIT) Team has been developed by regular site visits of the HIT Team to the Critical Care Unit at Queen Elizabeth Hospital Birmingham (QEHB), alongside input from the infection control, medical device and critical care management teams.

In line with the recommendations of the MRC, a programme theory has been developed to identify the theoretical plausibility for efficacy of action (Figure 4). From this, a framework has been produces to enable evaluation of individual components within the trial design.

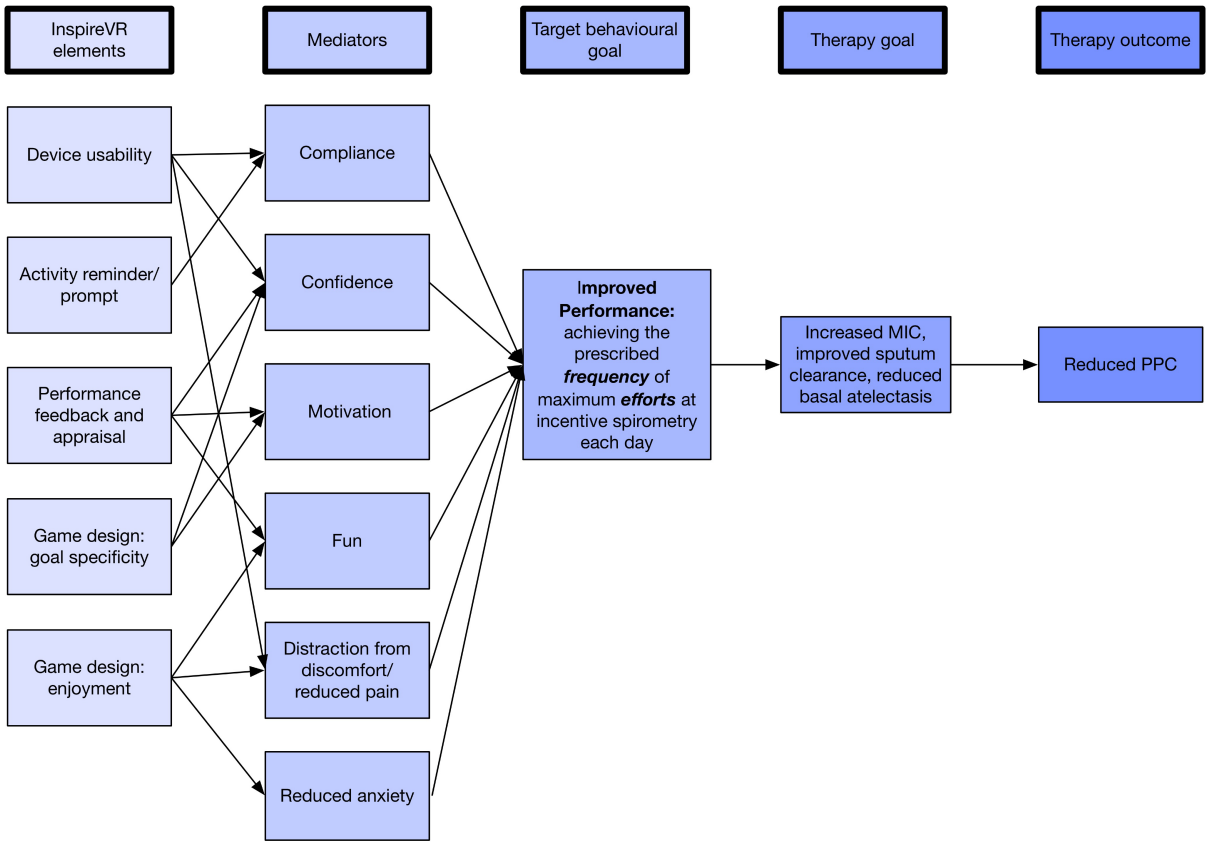


Figure 4: Causal Model to illustrate the theoretical process whereby the use of InspireVR will enhance the target behaviour goals, increasing the likelihood of accomplishing the therapy goals and achieving the therapy outcome.

5. Standards

The development process of InspireVR has been conducted to meet the standards set out by:

1. University Hospitals Birmingham NHS Foundation Trust and Heart of England Foundation Trust policies on:
   A. Use of medical devices
   B. Infection control

2. Medicale Devices Directive 92/43/EEC.

3. British Standard ISO 9241:210 - Ergonomics of Human System Interaction, Human-Centred Design for Interactive Systems.

4. IEC 62366_2007: Medical devices – Application of usability engineering to medical devices (International Electrotechnical Commission).

5. ISO 14971 Risk management for medical devices.

6. Stakeholder Group

Chief Investigator: Dr Charlotte Small

Lead expert patient: Duncan Buckley

Lead expert relative: Lisa Buckley

PPI Groups:

QEHB Oesophagectomy Survivors Group,

QEHB Critical Care Survivors Group (Pathfinder)

Human Factors & Simulation Lead: Prof Bob Stone

Technology Development, Integration and Evaluation: University of Birmingham Human Interface Technologies Team: Dr Cheng Qian, Mr Vish Shingari

Principal Investigator (Queen Elizabeth Hospital Birmingham): Dr Catherine Snelson

Principle Investigator (Birmingham Heartlands Hospital): Miss Olga Tucker

Lead physiotherapist: Jonathan Weblin

Research Physiotherapist: Charlotte Wilson

Nursing advisor: Sister Jennifer Williams, QEHB Critical Care and Follow up

Consultants Upper GI surgery: Mr John Whiting QEHB), Ms Olga Tucker (BHH).

Academic supervisors: Prof Bob Stone, Prof Julian Bion, University of Birmingham

Sponsor: Dr Sean Jennings, University of Birmingham.

The research team would like to acknowledge the assistance of Dr Tom Clutton-Brock, NIHR Trauma Management Healthcare Technology Cooperative.

7. Inspire VR system components

The InspireVR system (Image 2) is the combination of a commercially available spirometer (Vitalograph Pneumotrac 6800) and new software delivered via a personal computer (Microsoft Notebook).

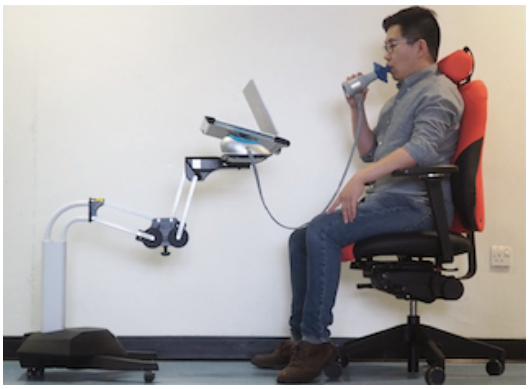


Image 2: InspireVR system

The Vitalograph Pneumotrac 6800 is a class 2a medical device, manufactured in accordance with the European Medical Device Directive 92/43/EEC (MDD) and conforms to ISO 13485-2003, the safety standard IEC 60601-1:2005 and the performance standard ISO 23747.



Image 3: Vitalograph Pneumotrac

The Vitalograph Pneumotrac 6800, when combined with Spirotrac software, has been designed for bedside, clinic or home use, for the measurement of pulmonary function. The main component parts of the Pneumotrac 6800 are the mouthpiece, fleisch-type pneumotachograph flowhead, twin tubing flow sampling and USB data output cable.

8. Inspire VR Software

The novel software for the InspireVR has been designed to facilitate patient performance of incentive spirometry (Figure 1). The software has the following core features:

1. Reminders to the patient to complete incentive spirometry. The frequency of the reminders is determined by the clinical setting and indication.
2. Intuitive gameplay to encourage accurate MIC efforts at each session of incentive spirometry.
3. Performance feedback of each incentive spirometry session to provide the patient and clinicians with information on MIC achieved and the number of MIC efforts.

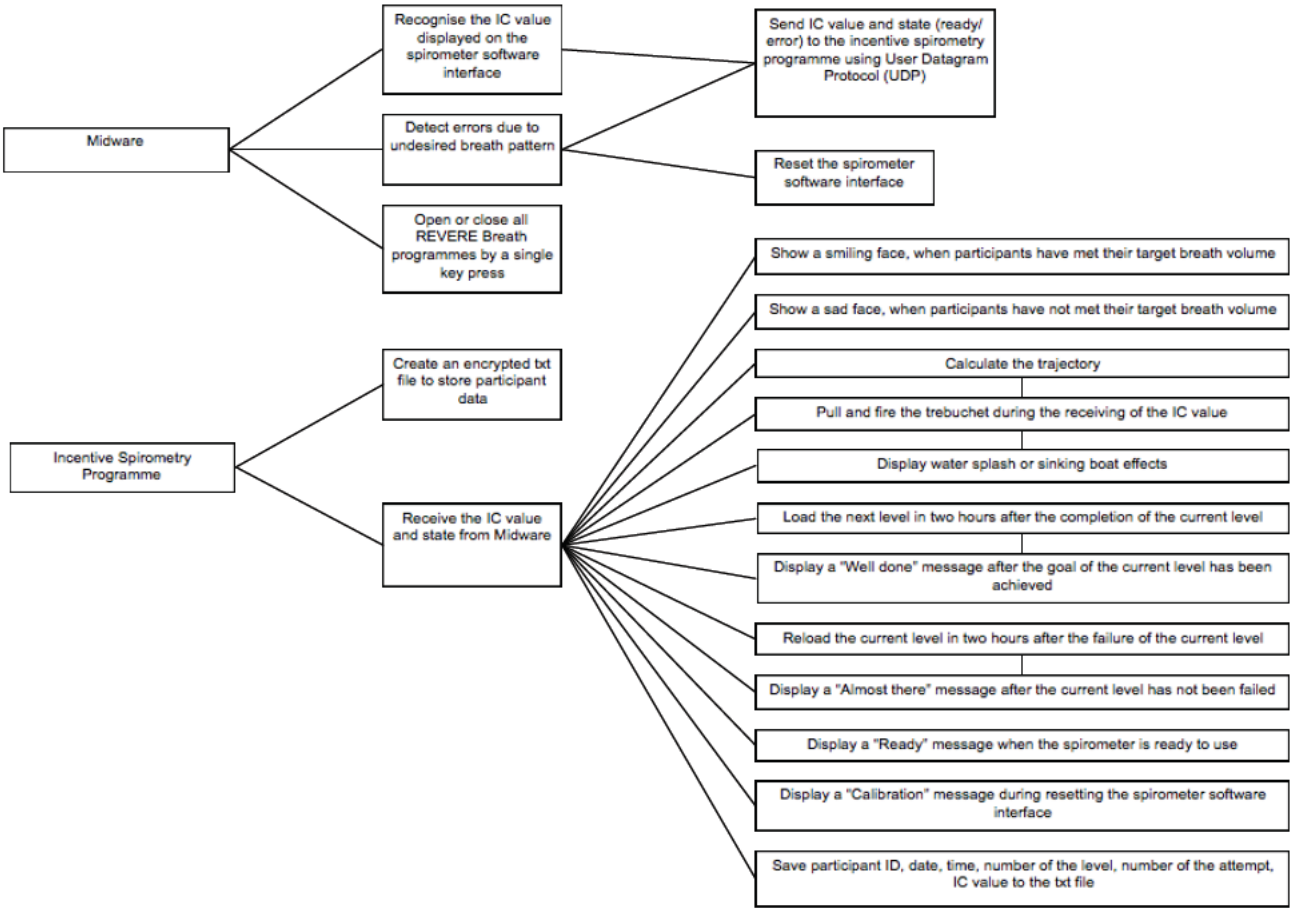


Figure 1: InspireVR software flowchart

The setting for the InspireVR game is Virtual Wembury, a three-dimensional virtual reconstruction of Wembury Bay, part of the South Devon Coastal Path. Virtual Wembury has been constructed by the Human Interface Technologies Team at the University of Birmingham and exploited in two previous clinical trials delivered by the research team . The incentive spirometry gameplay concept is a representation of a trebuchet (medieval catapult) which retracts on patient inspiration, firing a boulder into the sea at the end of maximal inspiration (Image 4) . The larger the MIC, the further the boulder will travel. Large MIC efforts will be rewarded with boats sinking.



Image 4: Screenshot of InspireVR game

The InspireVR game includes the following features:

1. Usability: Game play that is usable and achievable by the patients recovering from oesophagectomy or total gastrectomy on the critical care unit. Game play has been informed by early developmental work by the research group.
2. Applicability: Game play that replicates, exactly, the manoeuvre required during incentive spirometry. The patients' ability to score points during the game will be dependent only on their ability to take a deep breath (aiming to increase their maximum inspiratory capacity with each effort), rather than requiring additional cognitive abilities or other skills.
3. Personalisation: All patients will have the potential to progress through the levels of the game. This allows tolerance for inter-user and daily variability in patient status. Success will be measured by meeting a target MIC above baseline. Once a target is met, the patient will proceed to the next level for the next session, with an associated higher target capacity. The target MIC will be set for each patient at the start of each day (calibration). The patient will be prompted to provide three best effort MIC breaths. The targets for each level will be calculated based on the highest volume achieved over the three attempts during morning calibration (Figure 2)
4. Feedback for clinicians. Patient MIC values are stored in an excel file and can be reviewed periodically to assess compliance and performance.

Currently, there is no published data of serial MIC values following major upper gastrointestinal surgery. Local data suggests that patients with preoperative values of approximately 2000ml only achieve MIC values of 500ml in the first day postoperatively. There is no data to inform likely progress of MIC increase during early postoperative recovery Hence, a pragmatic, consensus opinion-based approach has been taken when defining each level of progress within the game The proposed clinical investigation will collect data from each participant to inform modification of the game algorithm as appropriate.

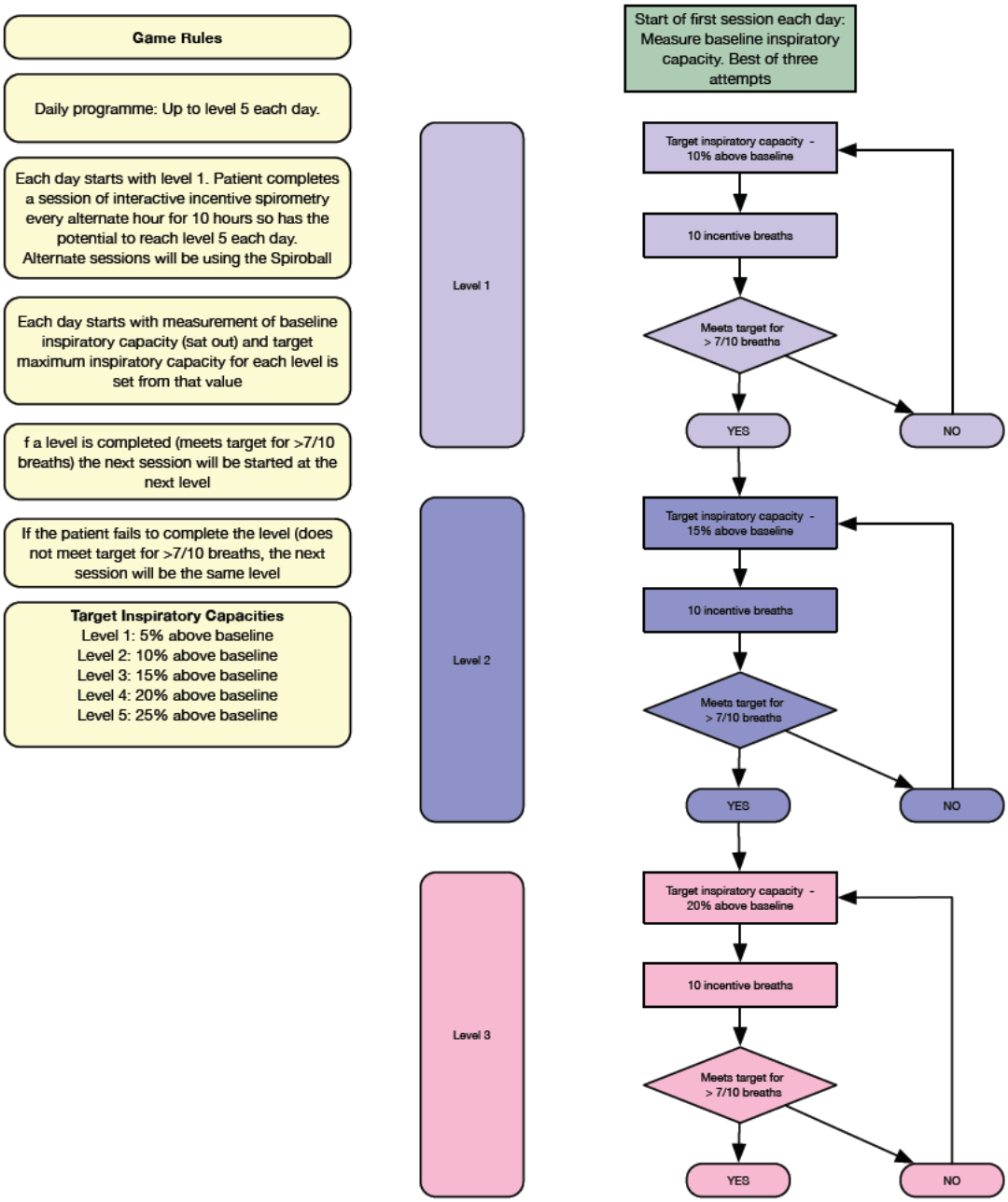


Figure 2: InspireVR game rules

Appendix 4.5

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Professor Robert Stone
School of Electronic, Electrical and Systems Engineering
University of Birmingham
B15 2TT
United Kingdom

PRE-CLINICAL ASSESSMENT REQUEST FOR ADDITIONAL INFORMATION

Investigational device: InspireVR system

MHRA REF: CI/2016/0064

MHRA

151 Buckingham Palace Road
London
SW1W 9SZ
United Kingdom

www.gov.uk/mhra

Information request letter: 01

18 January 2017

Dear Professor Stone

I am writing to advise you that additional information is required before a full assessment of your notification can be performed.

More details about the information manufacturers should make available upon request by the Competent Authority are given in the guidance for manufacturers on the MHRA website. (https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device)

Please provide the following additional information:-

1. You state in section 6 of the protocol that '*The trial is being carried out to meet the requirements of the MHRA in order to apply as CE mark as a class 1 medical device.*' and in section 8 that '*This study will determine the safety and performance of the Inspire VR to meet the requirements of a clinical investigation as mandated by directives of the MHRA for novel medical devices in order to obtain a CE mark as a class 1 medical device.*' Please be advised that MHRA does not CE mark medical devices and the directives which apply to medical devices are European directives. You can find further information on the MHRA website at https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements. Please amend the protocol accordingly.

2. Please confirm whether the subjects will also receive standard chest physiotherapy if required.

3. According to page 8 of the instructions for use, when the mouthpiece is not in use it should be stored in the holder mounted on the frame. Please advise whether it would be more appropriate for the mouthpiece to be stored with the patient to reduce the risk of cross infection.

The mouthpiece has been allocated a small air tight storage container that is to be mounted on to the frame of the system using dust free Dual Lock Velcro. It can however be detached and stored with the patient for the purpose of hygiene and infection control.

4. Whilst the investigator brochure describes the stand's function, it appears to have been excluded from other documentation such as the device description and the risk analysis. For this device to be eventually CE marked, the stand would need to be included and considered if it is part of the whole 'system'.

5. Which product standards were used in the development of the stand's design?

6. Was the risk of finger/hand entrapment considered?

   Yes, the stand has been designed to be operated using two hands, one to hold the release/adjustment mechanism and the other to support the laptop shelf during height/ reach adjustment

   Please refer to section 3 of the InspireVR user guide.

   In addition, there are a number of warning labels to highlight any potential trap hazard points.



7. In document MHRA InspireVR Software Compliance V2.0, you do not specify any standards used in the development of the software. Were any standards used?

8. If IEC 62304 was used what is the safety classification of the software according to that standard?

9. Is the "Virtual Wembury" program CE marked?

10. Please provide the software development plan, software requirements specifications and the results of any verification and validation performed on the investigational software.

11. Pages 8-12 in the document MHRA InspireVR Software Compliance V2.0 are blank. Is this intentional?

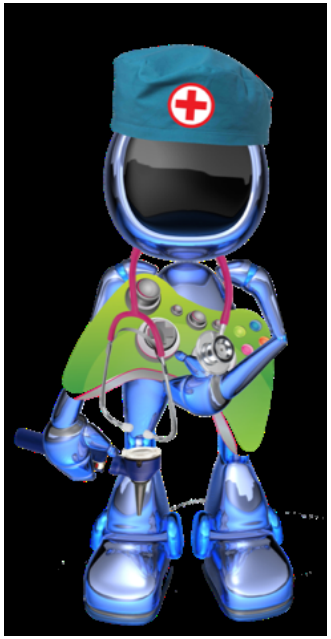
I will be grateful if you could please provide the additional information as soon as possible or in any event by **Wednesday 25 January 2017**. Failure to do so could mean that the Competent Authority may be unable to assess your notification within the statutory time limit of 60 days. This may result in the Secretary of State having to reject the notification. An acknowledgement of receipt of this letter would also be appreciated.

If you have any enquiries about this letter, please contact myself at the number below, or in my absence Mrs Daniella Smolenska on 020 3080 7363.

Yours sincerely

Shaleenah Ramjan
(on behalf of the Competent Authority, UK)

Tel:
Ema



Inspire VR Risk Analysis

Task	Hazard	Foreseeable sequence of events	Hazardous situation"	Persons P Patient PC Patient Carer, V Visitor/ Others	Occurence	Severity	Risk level	Method of control	Risk level with control
InspireVR placed into patient bedspace	Moving and handling	Patient carer, patient or visitor moves device in such a manner that requires lifting and excessive use of force	Musculo-skeletal injury to patient carer or visitor. Injury to patient	P, PC, V	Probable	Serious	12	InspireVR has been designed to minimise user load during moving and handling. Device training on moving and handling will be provided to patient carers. Moving and handling instructions will be provided with each InspireVR system.	3
	Damaged components	System receives structural damage on movement	Sharp edges of broken device cause personal injury	P, PC, V	Remote	Minor	4	Patient under constant supervision from nursing staff who can remove system from the bedspace should it become damaged. Trial participation is contingent on adequate patient cognition and cooperation - patients will be able to inform carers should damage occur. A member of the research team will inspect the system on a daily basis.	2
	Electro-magnetic energy	InspireVR becomes contaminated with water/other liquid	Electric shock	P, PC, V	Remote	Critical	8	Surge protection incorporated to mains power lead, to trip in the event of short circuit.	4

Task	Hazard	Foreseeable sequence of events	Hazardous situation"	Persons P Patient PC Patient Carer, V Visitor/ Others	Occurence	Severity	Risk level	Method of control	Risk level with control
	Power loss/ not charged	Device not placed onto charge during previous storage period			Occasional	Minor	6	Laptop is to be run on mains power to provide full graphical and processor power. User guide check list to include section on charging of laptop during down time.	2
InspireVR set up by user	System fault	InspireVR fails to switch on due to software malfunction - Microsoft Windows update, Operatig system crash, Midware failure	Patient failure to complete Incentive Spirometry (IS)	P	Occasional	Minor	6	1. Spiroball provided at all times to allow alternative method of delivering IS. 2. Second InspireVR system available for use. 3. User instructions provided to guide reboot. 4. Over the phone/on site technical support available for duration of the study	2
	System fault	System unable to connect to MiFi (WiFi)	Patient failure to complete Incentive Spirometry (IS)	P	Occasional	Minor	6	1. Spiroball provided at all times to allow alternative method of delivering IS. 2. Second InspireVR system available for use. 3. User instructions provided to guide reboot. 4. Over the phone/on site technical support available for duration of the study	2

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	Electro-magnetic energy	Electric shock from power adapter	Electric shock	PC	Improbable	Serious	12	Cease use of power adapter and call technical support for a replacement to be installed.	3
	System function	Failure to connect to MODEM	Patient failure to complete IS	P	Occasional	Minor	6	1. Spiroball provided at all times to allow alternative method of delivering IS. 2. Second InspireVR system available for use. 3. User instructions provided to guide reboot the WiFi Modem 4. Check the signal strength of the WiFi Modem in the bed-space. 5. Over the phone/on site technical support available for duration of the study	2

Task	Hazard	Foreseeable sequence of events	Hazardous situation"	Persons P Patient PC Patient Carer, V Visitor/ Others	Occurence	Severity	Risk level	Method of control	Risk level with control
Incentive spirometry carried out by patient	Poor device usability	Patient unable to complete IS using InspireVR. Patient physically or mentally unable to use device.	Patient failure to complete IS	P	Probable	Minor	12	1. InspireVR has been developed using a human centred design process. 2. Spiroball provided at all times to allow alternative method of delivering IS. 3. Second InspireVR system available for use. 4. User instructions provided to guide reboot. 5. Over the phone/on site technical support available for duration of the study	2
	No output from spirometer	Patient unable to complete IS using InspireVR	Patient failure to complete IS	P	Occasional	Minor	6	1. Spiroball provided at all times to allow alternative method of delivering IS. 2. Second InspireVR system available for use. 3. User instructions provided to guide reboot. 4. Over the phone/on site technical support available for duration of the study	2

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InspireVR in bedspace when not being used for IS	Data Security	Theft/loss of laptop	Patient data stored on laptop compromised	P	Improbable	Serious	12	Secure laptop to stand by means of physical lock. Encryption of patient data (.txt files) on laptop.	3

Task	Hazard	Foreseeable sequence of events	Hazardous situation"	Persons P Patient PC Patient Carer, V Visitor/ Others	Occurence	Severity	Risk level	Method of control	Risk level with control
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Task	Hazard	Foreseeable sequence of events	Hazardous situation"	Persons P Patient PC Patient Carer, V Visitor/ Others	Occurence	Severity	Risk level	Method of control	Risk level with control
InspireVR moved into new bedspace / placed into storage	Biological contaminant	InspireVR incorrectly decontaminated between patient use	Transfer ot biological pathogen between patient/ other user	P, PC, V	Occasional	Serious	9	External surfaces of system components can be decontaminated using 70% isopropyl alcohol wipes, in line with manufacturer instructions and NHS infection control guidelines. In the unlikely event of contamination of the spirometer by serious respiratory pathogen* (e.g mycobacterium tuberculosis), the spirometer can be sterilised as per manufacturer instructions. *Know active respiratory infection, or other infection with multi-agent resistant organism is a contraindication to major surgery	3
	Storage conditions	Device stored at extremes of temperature - too hot/too cold	Device failure	P	Improbable	Minor	2	Device to be stored on the critical care units, within bedspace or in medical device storage facility in controlled environmental conditions.	2

Occurence					
Frequent 5	Low 5	Medium 10	High 15	High 20	High 40
Probable 4	Low 4	Medium 8	Medium 12	High 16	High 32
Occasional 3	Low 3	Low 6	Medium 9	Medium 12	High 24
Remote 2	Low 2	Low 4	Low 6	Medium 8	High 16
Improbable 1	Low 1	Low 2	Low 3	Low 4	Medium 8
Severity	Negligible 1	Minor 2	Serious 3	Critical 4	Catastrophic 8

Occurence/Severity table: From http://www.greenlight.guru/hubfs/Sales_Material/gg_guide_to_risk_management.pdf

Severity level	**Description**
Critical	Loss of limb, life-threatening injury
Major	Severe, long-term injury, potential disability
Serious	Short-term injury or impairment requiring additional medical intervention to correct. Includes psychological sequelae of personal data loss.
Minor	Slight inconvenience to user, little to no effect on product performance, non-vital fault
Negligible	No or negligible risk to patient

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Appendix 6.1

REVERE Breathe – Internal Performance/Fault Test Log
01/08/2016 to 30/09/2016

Dates >	01 Aug	03 Aug	05 Aug	08 Aug	10 Aug	12 Aug	15 Aug	17 Aug	19 Aug	22 Aug	24 Aug	26 Aug	29 Aug	31 Aug	02 Sept	05 Sept	07 Sept	09 Sept	12 Sept	14 Sept	16 Sept	19 Sept	21 Sept	23 Sept	26 Sept	28 Sept	30 Sept	Tech Sign-Off	Sup Sign-Off
Power On	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Power Off	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
System Set-Up Performance and Stability	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Active Use Performance and Stability	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
12-Hour **Non-Use** Performance and Stability	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Review of Fault Detection Logs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Inspire VR Risk Analysis

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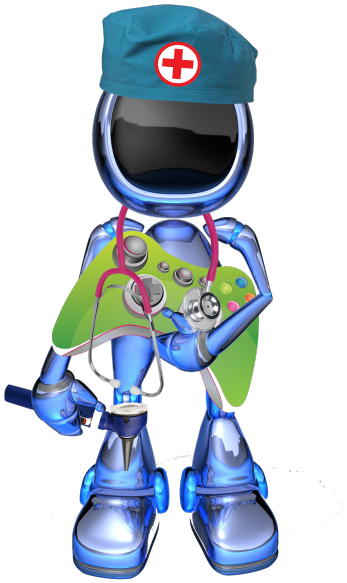
Occurence					
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Occurence/Severity table: From http://www.greenlight.guru/hubfs/Sales_Material/gg_guide_to_risk_management.pdf

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Severity level	**Description**
Critical	Loss of limb, life-threatening injury
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Negligible	No or negligible risk to patient

InspireVR-V2 Instructions for Use



Problems or questions: Please contact the research team on:	

Contents

1. Quick Start Guide
2. Moving and Handling
3. Reach adjustment
4. Laptop adjustment
5. Power
6. Cabling
7. Laptop
8. Bluetooth Keyboard
9. WiFI Modem
10. WiFi Setup with PC
11. PC Volume
12. Charging
13. Spirometer
14. Software
15. Game Walkthrough
16. Hygiene

1. Quick Start Guide

PC Password Login PIN:

WIFI Modem - Network Name:

Password:

Game Controls -

Double click the "REVERE BREATHE" icon to start the mid-ware

Press " - " to start the game,

Press " = " to exit to desktop

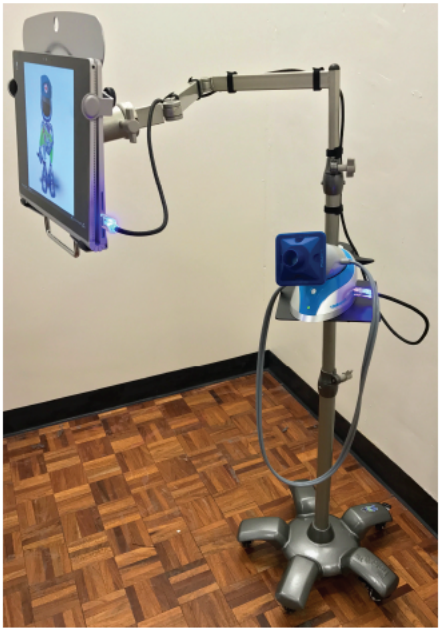
Troubleshooting

If the game does not reach the home screen (player ID screen), press escape/esc on the keyboard and the program will reset.

If any error show up during use press stop key "=", then press ok on any popup windows. After the program stop, press "-" to start over.

2. Moving and Handling

The InspireVR trolley mount features rubberised castors to provide stability during both use and transportation. The Personal Computer (PC) and the Spirometer unit are secured to the trolley. The casters feature a locking mechanism that can be activated or released by depressing or raising the tab with your foot.







3. Reach adjustment



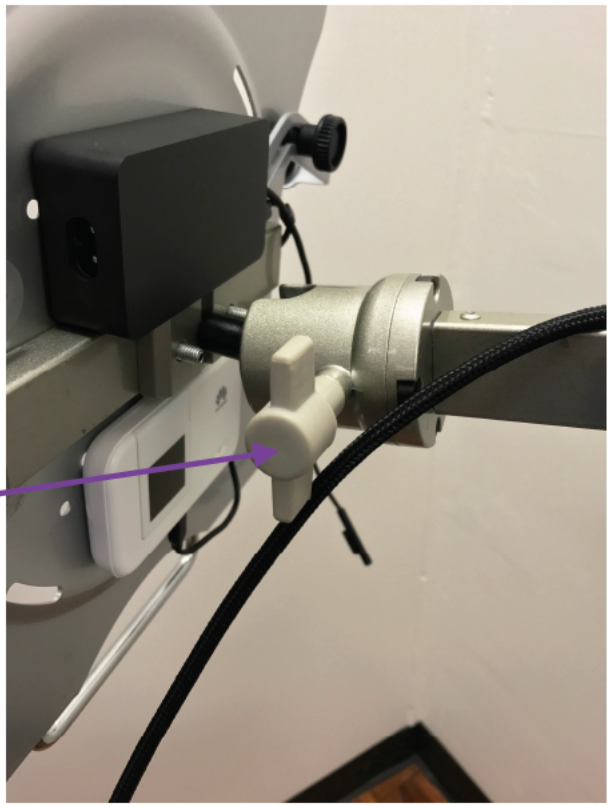


The stand has a hinged adjustment system, so can be simply unfolded and folded.

When moving the InspireVR system please fold the arm as tightly as possible to prevent tipping whilst in transit.

4. Laptop adjustment

To adjust the rotation and the angle of the PC, simply turn the handle to the left and adjust, be sure to tighten it back up when complete.



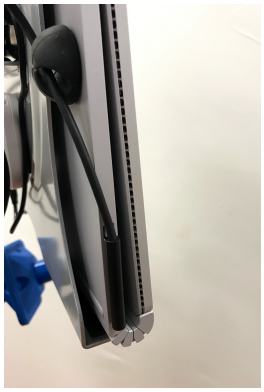
5. Power

InspireVR runs via a simple mains plug, during transportation please stow it using the cable tidy located on the frame.

image of cable tidy

6. Cabling

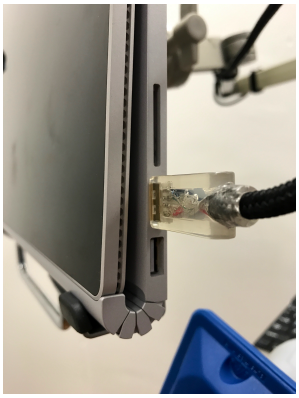
The InspireVR system is pre-wired but should any cables become detached the images below illustrate how they connect.



The power cable for the PC is held on magnetically, if it detaches simply push it back in place.



The USB cable from the PC connects to the digital spirometer, when powered up the plug will emit a blue light.



The USB cable with the transparent plug connects to the spirometer, when the system is on it will light up blue.

7. Laptop

To start/shut down the laptop press the power button (located on the top of the display) and wait for the system to boot up/shut down.



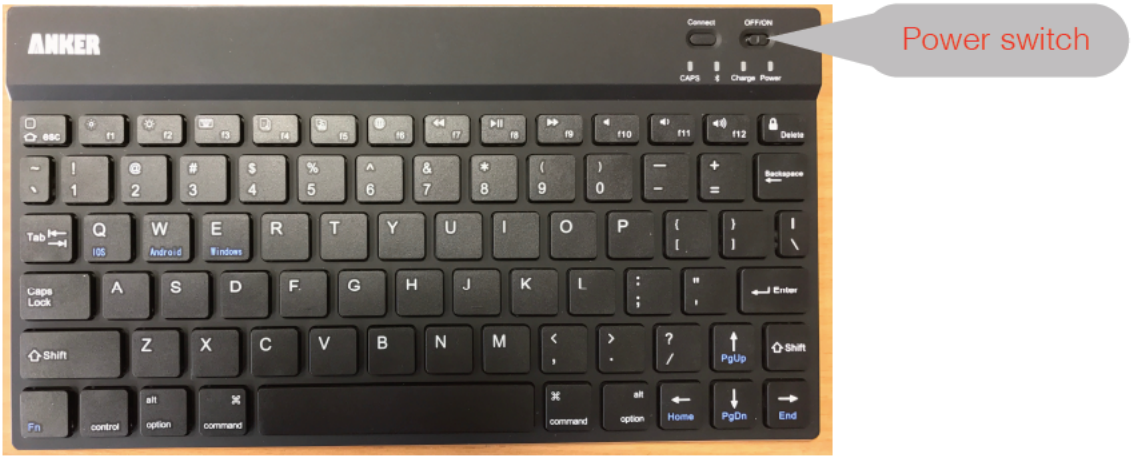
Laptop on / off button.



When the PC boots up, swipe up on the screen and enter the login

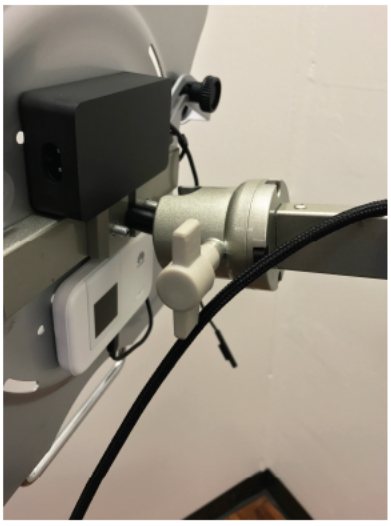
8. Bluetooth Keyboard

The InspireVR systems requires the use of a bluetooth wireless keyboard, the keyboard as be pre-paired with the tablet PC. The keyboard after a period of inactivity will go to sleep, to wake it simply press any key to wake it.



9. WiFI Modem

In order for the system to function correctly, the Spirometer software requires a brief internet connection to authenticate the software upon start up.



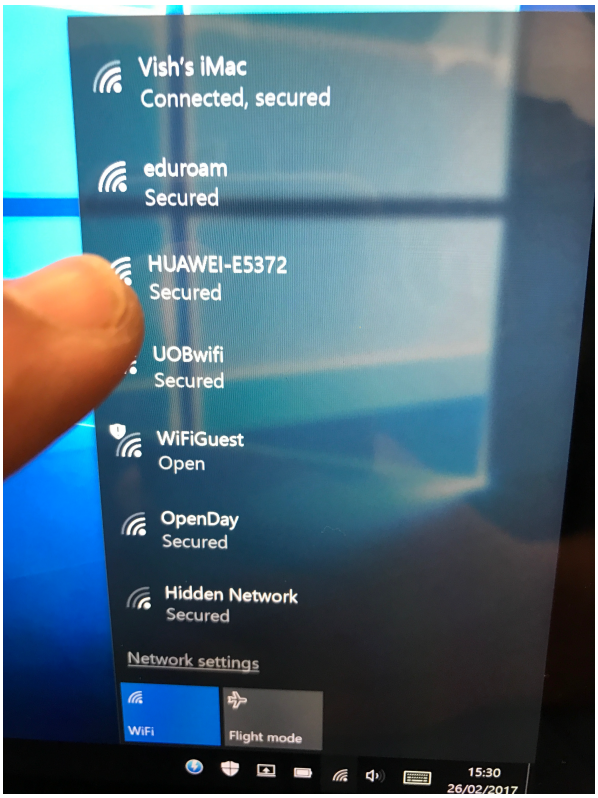


To power up the modem press and briefly hold the power button until the display lights up, after a period of inactivity the modem may go to sleep, to wake it simply press the power button and the display should light up.

10. WiFi Setup with PC



The Modem should connect to the laptop automatically, if not please press on the signal icon located at the bottom right of the screen.



The Modem is called, [redacted] please press to select and connect to it.

11. PC Volume

To adjust the volume on the PC simply press the rocker switch, you will get both an audible and visual indication.



12. Charging

The InspireVR system is design to be used on mains power, the only exception is the Bluetooth keyboard that may periodically need charging, there is a MicroUSB socket on the right side of the keyboard, you can connect the supplied MicroUSB cable to a free USB socket on the side of the PC.



13. Spirometer



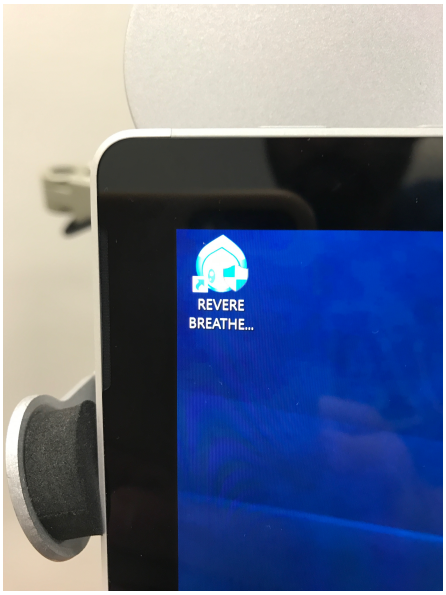
The Spirometer uses a single-patient bacterial-viral filter (BVF) that the participant uses throughout their time in the study.



The mouthpiece is design to stay attached and the spirometer body can sit in its cradle between sessions.

14. Software

To start the InspireVR software, you will need to double tap on the REVERE Breathe icon which will be on the top left of the screen, this will load up the Spirometer software.



Press the " - " key on the wireless keyboard, you should hear a beeping sound, this will indicate that the InspireVR software is starting up. During this stage please do not press anything on the PC nor the wireless keyboard.

To exit the game you will need to follow these steps:

1. Press the " = " key on the keyboard to shut the software down, this is important as this will allow the data to be saved.

2. Press the power button on the laptop to shut it down.

15. Game Walkthrough

At the start of each day the user will be prompted to set their breath volume targets for the day (calibration). This is done by taking three deep breaths, using the spirometer mouthpiece. At each successful attempt a smiling face will appear. This would signify that the participant will need to repeat the process until three smiling faces are achieved. The highest breath volume achieved will be used to set the target volumes for the rest of that day.



Successful attempt



Following on from the calibration a countdown timer will appear to signify the start of level 1.



When the game is loaded, you will see the screen show below.



The participant should then place the spirometer mouthpiece in their mouth, creating a tight seal. They then take a long, deep, steady breath, then hold their breath for three seconds.When the participant breathes in on they will see the trebuchet pull back and then fire the boulder into the sea. The distance the boulder is fired depends on how deep a breath they take (inspiratory capacity). As the boulder fires, a separate game window appears showing the trajectory the boulder is taking.



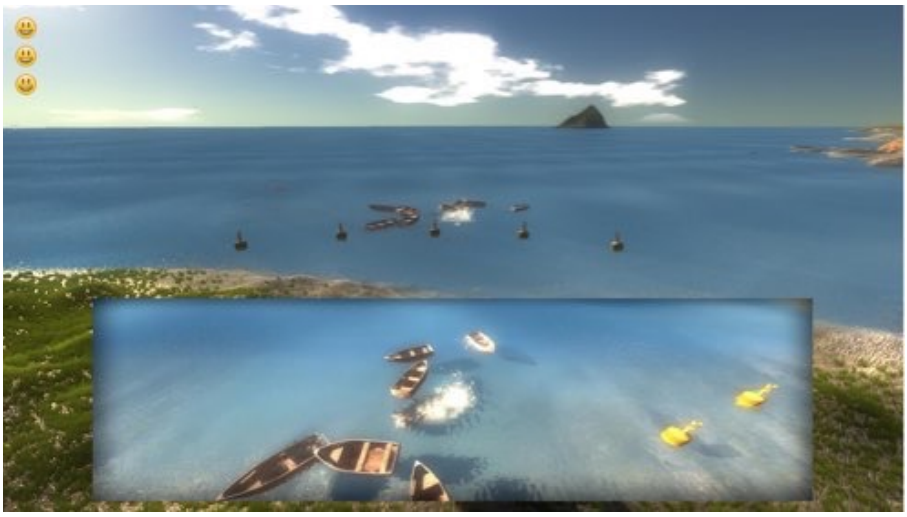


If the breath does not meet their target volume for that level, the participant will be shown a sad face. If the breath is sufficient then the participant will be presented with a smiling face.



The patient repeats this process ten times (ten deep breaths)

When a smiling face appears, the patients has met their target breath volume (inspiratory capacity). There will be a water splash near to the boats, or a direct hit of a boat. When the sad face appears, the patient has not met their target breath volume. The boulder will land somewhere between the buoys and the trebuchet.



The line of buoys represents the distance to the calibration volume at the start of the day. If seven or more smiling faces are achieved during a session, the patient “wins” that level and will start on the next level up at their next session in using the InspireVR. Each level represents a 5% increase in breath volume (inspiratory capacity). If the achieve less that seven smiling faces, the patient will re-try the same level at the next session using InspireVR.



Upon successful completion of each a timer will appear to signify the time to the start of the next session of InspireVR (1 hour later). During this time, please leave the laptop on and

store the spirometer mouthpiece.Upon successful completion of all levels the participant will be presented with the message “Well done, all levels complete!.”.

17. Hygiene

Please use a single patient-use bacterial-viral filter for each patient.

InspireVR can be cleaned using 70% alcohol wipes, if alcohol free wipes are to be used please avoid using them on the touch display as it will leave a white residue which, once dry, will create glare on the display and impact on the quality of game play.

The spirometer itself can be sterilised if exposed to pathogens of concern. Please contact the research team for information.

Appendix 5.4

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Professor Robert Stone
School of Electronic
Electrical and Systems Engineering
University of Birmingham
B15 2TT
United Kingdom

MHRA

151 Buckingham Palace Road
London
SW1W 9SZ
United Kingdom

www.gov.uk/mhra

15 February 2017

MHRA REF: CI/2016/0064

Dear Professor Stone

CLINICAL INVESTIGATION: NO OBJECTION

Manufacturer	: University of Birmingham
Investigational device	: InspireVR
Your notification dated	: 17 November 2016
Protocol version number	: 3.3
Number of patients	: 25 (anticipated)

I hereby notify you that the UK Competent Authority has no grounds for objection to making available the above medical device for the purposes of a clinical investigation as declared in the above notification.

Competent Authority Comments

1. Please ensure that you note and understand the requirements set out below for reporting adverse events to the UK Competent Authority. In addition to the below reporting requirements, please submit summary SAE reports after the first 5 patients have been treated and then monthly thereafter.

2. This was a very weak submission with little objective evidence to support a finding that the investigational software had been developed in a planned manner according to a defined software development process. Any further software development would benefit from the application of the software standard such as BS EN 62304:2006+A1:2015 or its equivalent.

While descriptive documentation in the submission is helpful, it is important to provide objective evidence that a software development process has been followed. This should include as a minimum the software development plan, software requirements specification together with any software verification and validation planning and results produced during the development. Any further submission will be expected to contain this information.

3. The device(s) must be labelled "*exclusively for clinical investigation*".

4. Please ensure that all requirements listed in the appendix to this letter are understood and adhered to.

Yours [redacted]

Shaleenan Ramjan
(on behalf of the Competent Authority, UK)

Tel: [redacted]
Em:

Appendix

Before commencing the clinical investigation

You should ensure that you have the following in place before commencing the study in the UK:

- Favourable REC opinion letter (required for all studies)
- Signed contract/agreement with participating NHS organisation(s)
- NHS Permission Letter (for studies conducted in the NHS in Northern Ireland, Scotland and Wales)
- HRA Approval letter (for studies conducted in the NHS in England)

	Studies conducted in England	Studies conducted in Northern Ireland, Scotland and Wales	Provide to MHRA when available	Keep available for MHRA
Favourable REC opinion letter	x	x	x	
Signed contract/ agreement with participating NHS organisation(s)	x	x		x
NHS Permission Letter		x		x
HRA approval letter	x			x

If not already provided as part of the notification to MHRA, please provide us with a copy of the ethics committee favourable opinion letter as soon as it becomes available. The clinical investigation must not commence at any UK centre until the relevant ethics committee favourable opinion is obtained.

Each individual site in this clinical investigation must have confirmed management permission. NHS organisations in England provide this by confirming that they have the capacity and capability to take part in the study. In Northern Ireland, Scotland and Wales NHS organisations provide a letter of NHS Permission. Non-NHS organisations should confirm their management permission and receive a favourable Site-Specific Assessment from the Research Ethics Committee. Please note that this clinical investigation must not commence in any UK site until you have received the relevant confirmation for that individual site.

In addition, this clinical investigation must not commence in any NHS site in England until it has received HRA Approval.

Full details can be obtained from the Health Research Authority website (http://www.hra.nhs.uk/) or by emailing hra.queries@nhs.net. When seeking advice from the Health Research Authority you should make it clear that the investigation involves a non-CE marked medical device.

Following commencement of this clinical investigation:

Adverse Event Reporting

You are reminded that Regulation 16(10)(a) of the Medical Devices Regulations 2002 (SI 618) and Annex X of the Medical Devices Directive 93/42 require you to record fully all adverse events and report all serious adverse events occurring in all participating centres to the Competent Authority.

Such reports should be made to the MHRA (devices) Adverse Incident Centre and should include all serious adverse events, whether initially considered to be device related or not, that have occurred in all participating centres, whether European or non-European.

A "serious adverse event" is an adverse event that:

a) led to a death, injury or permanent impairment to a body structure or a body function.
b) led to a serious deterioration in health of the subject, that either resulted in:
- a life-threatening illness or injury, or
- a permanent impairment of a body structure or a body function, or
- in-patient hospitalization or prolongation of existing hospitalization, or
- in medical or surgical intervention to prevent life threatening illness
c) led to foetal distress, foetal death or a congenital abnormality or birth defect.
NOTE 1: Planned hospitalization for pre-existing condition, or a procedure required by the Clinical Investigation Plan, without a serious deterioration in health, is not considered a serious adverse event.

NOTE Device deficiencies that might have led to a serious adverse event where a suitable action had not been taken or an intervention had not been made or if circumstances had been less fortunate are handled under the serious adverse event reporting system.

Such adverse events should be reported as soon as possible. When reporting these events please include the total number of patients treated in the UK at the time of reporting.

MEDDEV 2.7/3 provides guidance on the requirements for reporting serious adverse events with timelines and provides a template form to use for this purpose. This document can be downloaded from: http://ec.europa.eu/growth/sectors/medical-devices/guidance/

In the case of a blinded control clinical investigation using a CE marked device as control, all adverse events should be reported to MHRA in line with the requirements above.

Where an un-blinded controlled clinical investigation is being carried out using a CE marked device as the control, adverse events involving the CE marked devices should be reported to the competent authority in line with vigilance guidelines.

Please use the MEDDEV 2.7/3 reporting Excel spreadsheet to report serious adverse events. Please email the complete spreadsheet to aic@mhra.gsi.gov.uk quoting MHRA's CI reference number or upload through MORE https://aic.mhra.gov.uk/ including the MHRA's CI reference number in the 'incident description' field. **Please ensure that sufficient information is included in the table to allow MHRA to understand what happened in each incident and that all fields are complete.** Failure to do so will result in further requests for additional information on each individual case, therefore please ensure the following:

a. ALL sections are completed in FULL, especially sections where a decision is required as to whether or not the event is device / procedure related.

b. Any deaths reported should have the cause of death recorded.
c. Reports should be made in a timely manner as per regulatory requirements.

Please note that adverse events involving a medicinal product should also be reported to MHRA Medicines by the manufacturer of the medicine or sponsor of the study. Information on the requirements for reporting of such events can be found here https://yellowcard.mhra.gov.uk/

Summary reports

In addition to the reporting of individual serious adverse events as detailed above, please provide summary reports of all serious adverse events. Please refer to the Competent Auhtority Comments section at the top of this letter for details of the frequency required.

When providing these summaries please include in tabular format the following information broken down by event type:

- number of serious adverse events
- number of participants affected by those events
- percentage of the total number of enrolled participants affected by those events

Event type	Number of events	Number of participants affected	% of participants affected
e.g. Stroke			
e.g. Heart Failure			

Please also include a summary analysis of the serious events together with the manufacturer's conclusions. Please also ensure the following when submitting a table of adverse events:

- ALL sections are completed in FULL, especially sections where a decision is required as to whether or not the event is device / procedure related.
- Any deaths reported should have the cause of death recorded.
- Reports should be made in a timely manner as per regulatory requirements.
- Incomplete tables will not be assessed and will be returned to you.

Amendments

You must notify the Competent Authority of all proposed changes to this investigation and await our letter of no objection before you implement them. This includes changes relating to the device, study documentation including the clinical investigation plan, investigators or investigating institutions, and changes made upon the request of an ethics committee. Failure to notify us of proposed changes could result in the manufacturer being liable to prosecution.

When notifying changes, please provide the following information:

- the reference number shown at the top of this letter.
- In tabular format - a summary of each proposed change with the rationale and justification for each change.
- red lined and clean copies of all amended study documentation.
- a signed statement by or on behalf of the manufacturer that the proposed change(s) do not predictably increase the risk to the patient, user or third party.

Study deviations

You must notify the Competent Authority of all deviations to the study as soon as you have been made aware of them. Please provide details about the nature of the deviation, when it occurred, where it occurred, and any proposed corrective actions.

Final Report

Under Regulation 16(11) and 29(10) of the Medical Devices Regulations 2002 (SI 618), as amended by the Medical Devices (Amendment) Regulations 2008 (SI 2936), you are required to notify MHRA of the end of this clinical investigation. In the case of premature termination a justification for the premature termination is also required. A letter informing the Competent Authority of when the trial has been completed would be appreciated.

Under Regulation 16(10) and 29(9) of the Medical Devices Regulations 2002 (SI 618) the written report of a completed clinical investigation must be kept available for the Secretary of State if required. MHRA request that a copy of the written report is provided when available.

CE Marking

MHRA would be interested to know when the device under investigation is CE marked and would be most grateful for notification of this once completed.

We request that at the same time MHRA are also provided with a summary report of the clinical data from this clinical investigation that was used to support the CE mark.

MHRA actions

The assessors who assisted with the evaluation of your notification will be sent a copy of this decision, for information only and strictly "in confidence". Our decision will also be notified to the relevant ethics committee(s) and HRA if you have confirmed that you are happy for us to do this. If you have not then you may wish to advise them of this decision yourself.

We will retain all the documentation provided by you for one month from the date of this letter. After this time the documentation (except for one copy, retained for record purposes only) will be destroyed, unless you request its return.

MOTOmed®
move differently



Movement Therapy in Supine Position

MOTOmed® letto2



Active and passive safety
MOTOmed® Safety Concept

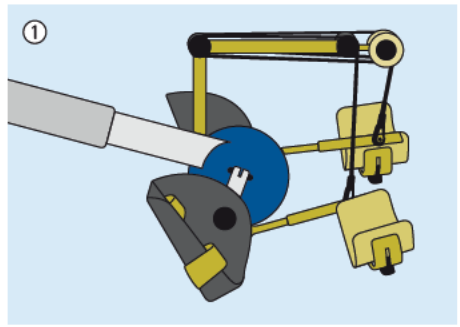
MOTOmed MovementProtector with SpasmControl

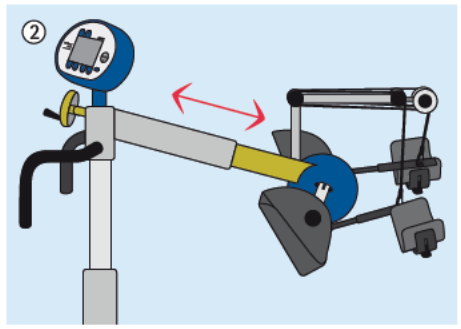
The *MOTOmed MovementProtector* monitors the muscle condition throughout the training session and stops the pedals once a sudden cramp occurs (spasticity), preventing injury to the lower and upper extremities. After a brief pause, the *MOTOmed SpasmControl* will change the cycling direction. This process is repeated multiple times until the cramping has been relieved.

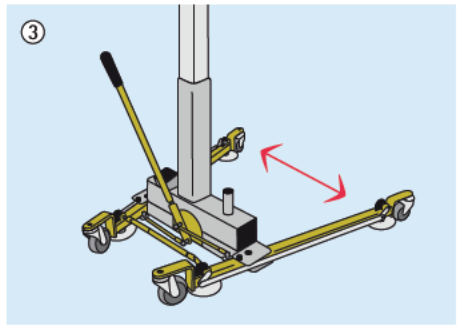
Unique and empowering
MOTOmed® ServoCycling

The MOTOmed can recognize even the slightest muscle impulse. When minimal muscle impulses are detected, the ServoCycling feature then assists with the pedalling. Thereby, it enables individuals to train actively even with minimal residual muscle strength. Residual muscle strength that may not be sufficient for a fully active movement can be discovered, applied and strengthened.









Individual adaptation
MOTOmed® Equipment and Accessories

① **»TrainCare Comfort« including adjustable knee support**

Recommended for paralyzed, unconscious and weak patients. Safe hold and secure guidance of the legs with knee protection. Each leg's position can be independently adjusted. The legs are secured with elastic Velcro straps.

② **Knee bending adjustment including adjustment wheel**

Enables the range of motion of the knee or elbow joints to be easily adjusted even during the training session.

③ **Expandable chassis**

Avoid obstracles under the bed by simply adjusting the width (wider/narrower) of the tracks with a lever. Suitable for all common bed or therapy chair constructions.

④ **Hygiene solutions**

For areas requiring strict hygiene control fully disinfectable plastic-coated foot shells, leg guides and handes are standard feature. Disinfectable rubber securing straps are also available as an accessary.

Increased safety with the **patient remote stop button**





Legs

Leg training made easy
MOTOmed® letto2

Everyday Flexibility

The four big transport castors give the MOTOmed letto2 the mobility that is required in a daily hospital routine. Different MOTOmed letto2 chassis options and the spring supported height adjustment assure optimal adaption to different bed or chair constructions.

With the flexible *floor fixation (also called the 4-Brake-Stop)* the unit can be easily secured in place, without having to attach it directly to the bed. The position of the knee joints is easily adjustable with the *knee bending adjustment*, either after inserting the legs or even during the training.



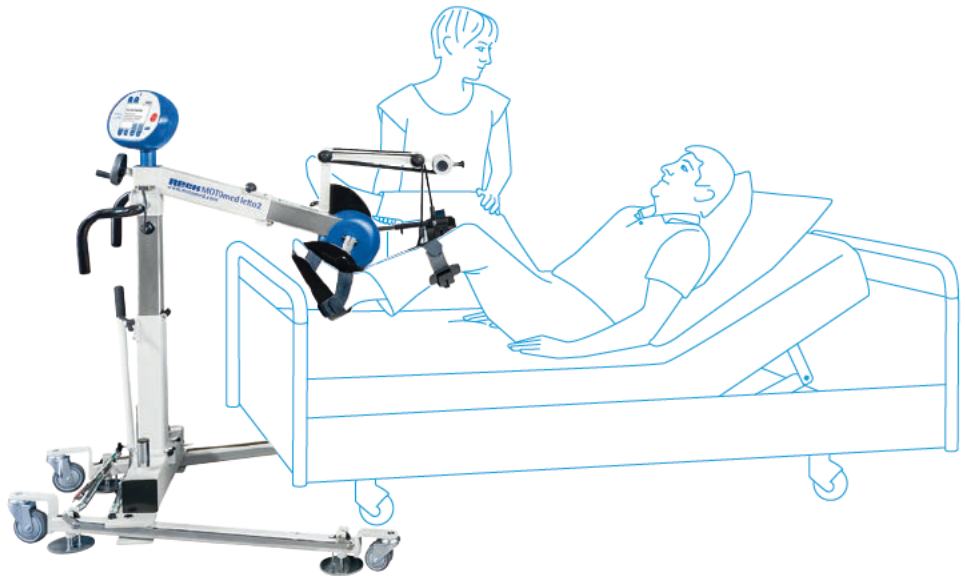


Handling

306



Use the 4-Brake-Stop floor fixation to securely position the MOTOmed letto2 unit



Simple foot insertion before the training

Simple start and finish of the training with the user-friendly operating panel

MOTOmed letto2 **Technical specifications of the basic model:**
measurements: 126 – 156 cm / 49 – 61 in. (h) x 55 – 85 cm / 21.7 – 33.5 in. (w) x 117 cm / 46 in. (d); weight: approx. 63 kg / 139 Lbs.,
chassis inside: 43 – 73 cm / 16.9 – 28.7 in.; height adjustment (max bed height): from approx. 72 cm – 102 cm / 28.3 – 40.2 in.;
chassis height (ground clearance for bed units): 14 cm / 5.5 in.
mains Voltage: according to country specifications; *frequency:* 50 Hertz; *construction:* all-metal construction, medical device class MPG IIa

Standard Configuration
MOTOmed letto2

① **Safety foot shells**
For a safe foot hold. Also available with optional disinfecting plastic coating.

② **Big transport castors**
For more mobility and flexibility.

③ **Floor fixation**
Stable position during the training.

Patient remote stop button (see pg. 9)
For a better user safety.

Recommended accessories

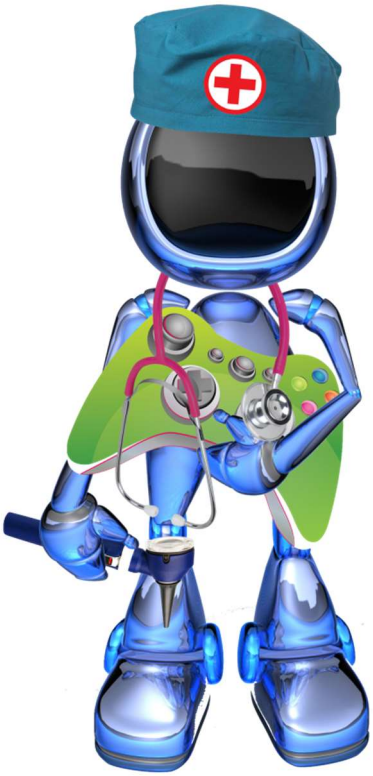
④ **Knee bending adjustment including adjustment wheel**

⑤ Detailed adjustment of the leg and arm bending angle.

⑥ **»TrainCare Comfort«**
Safe and secure guidance of the legs.

Expandable chassis
Chassis adjustment for the optimal positioning to the bed or therapy chair.

Velo-VR Instructions for Use



Problems or questions: Please contact the research team on:	

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1. Quick Start Guide

PC Password -

WIFI Modem ID -

Password -

Game Controls -

Press " - " to start the game

Press cursor "up arrow" to move up a level

Press " = " to exit to desktop

2. Moving and Handling

The Velo-VR trolley mount features locking rubberised casters and a solid cast aluminium base to provide stability both during transportation and patient use. The castors feature a locking mechanism that can be activated (Figure 1) or released (Figure 2) by adjusting the tab with one's foot.

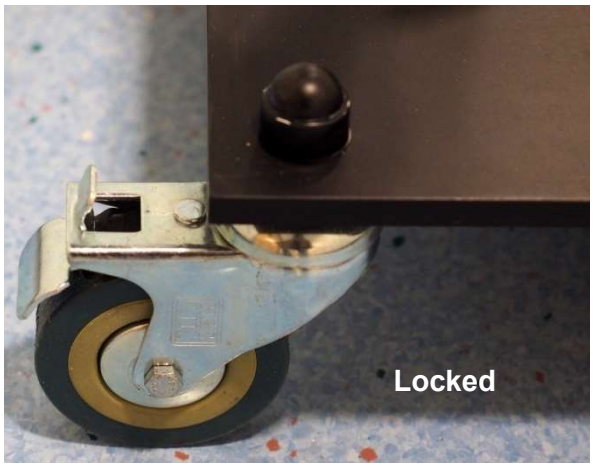


Figure 1 - Wheels in Locked Position

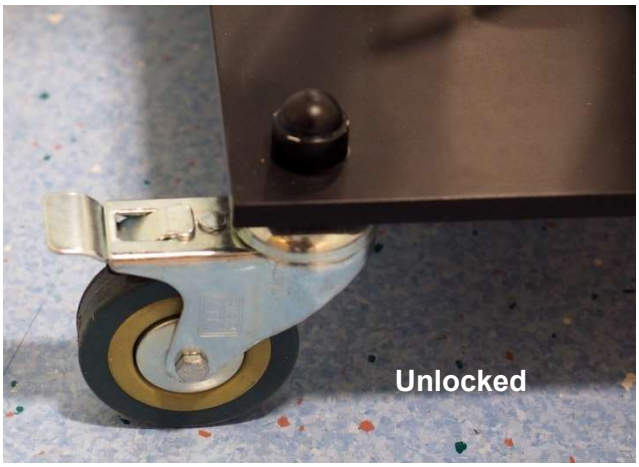


Figure 2 - Wheels in Unlocked Position.

Figures 3 and 4 illustrate the Velo-VR system in its stowage / travel position. Notice how the display arm behind the display is folded. Extension details for this arm are provided later.



Figure 3 - Velo-VR Front View



Figure 4 - Velo-VR Rear View

3. Height and Display Adjustment

Velo-VR is designed to fit above and interface with a standard MOTOmed (Figure 5).



Figure 5 - Velo-VR working with the MOTOmed

Velo-VR has three thumb release mechanisms for adjustability, one for display angle or rotation and two for height adjustability. Each thumb release is marked with "open" and "closed" (Figure 6). After any period of adjustment, ensure that the thumb release is pushed back to the closed position.

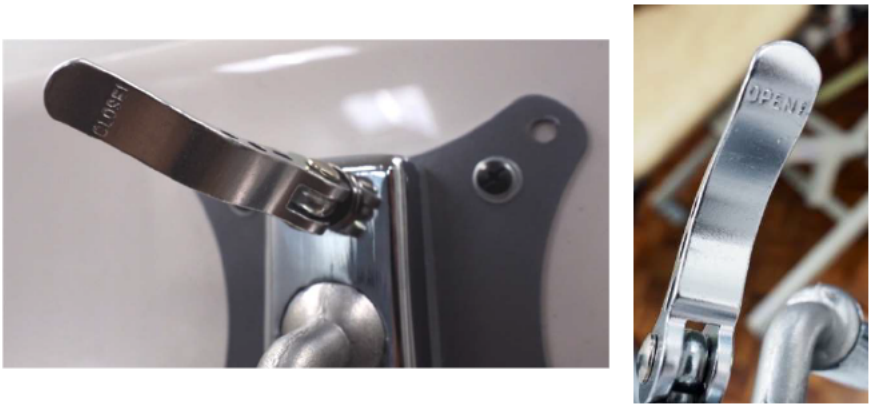


Figure 6 - Thumb Release Open and Closed

The three thumb release mechanisms that offer adjustability are highlighted on Figure 7 below.



Figure 7 – Thumb Release Mechanism Locations to Adjust Velo-VR (See Key Below)

This thumb release allows the display mount to be lowered a minimum height of 102cm and raised to a maximum height of 139cm, with the heights taken from the floor to the bottom of the display.

This thumb release allows the laptop tray to be lowered to a minimum height of 62cm and raised to a maximum height of 91cm.

The thumb release on the display (also shown in Figure 8) allows it to be centered in-line with the patient and also square-on with the top of the Moto-Med (Figure 5). To help align the display, a spirit level is mounted on the rear of the display, to be adjusted until the bubble is in the centre of the level.



Figure 8 - Thumb Release for Velo-VR Display and Spirit Level Location

4. Display Arm Adjustment

Figures 3 and 4 in Section 1 illustrate the Velo-VR in travel / storage configuration. In order to prepare it for patient use, the display arm needs to be extended to look similar to Figure 5. The following series of images (Figures 9 -12) provides visual details on how to extend the Velo-VR arm.



Figure 9 – Velo-VR Display Arm in Stowed Position



Figure 10 – Arm Partially Extended (1)



Figure 11 – Arm Partially Extended (2)



Figure 12 - Fully Extended Arm, Ready for Use

5. Velo-VR at the Bedside

Velo-VR has been designed to fit under a range of hospital bed types (Figures 13 and 14). It is important to remember to activate the locks on the casters once under the bed (see Figure 1).



Figure 13 - Velo-VR Under-Bed Location

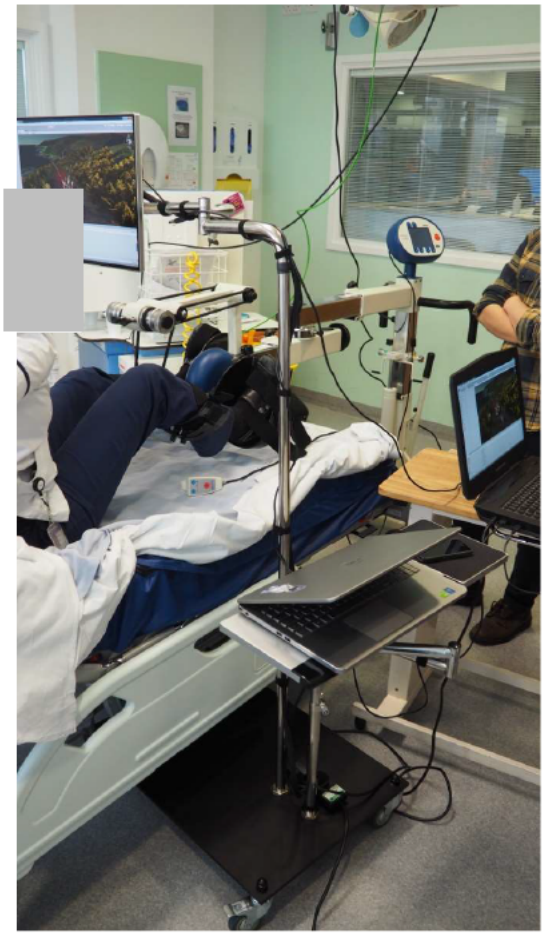


Figure 14 - Velo-VR Located Correctly Under and Alongside a Bed

6. Power

Velo-VR is already pre-wired for use and has been designed to run off a single 13amp mains plug. A 3-metre cable (Figure 15) has been incorporated to aid with flexibility.



Figure 15 - Velo-VR Mains Cable

As with other components of the Velo-VR system, this mains cable has passed Portable Appliance Testing (PAT) and is safe for use (Figure 16).

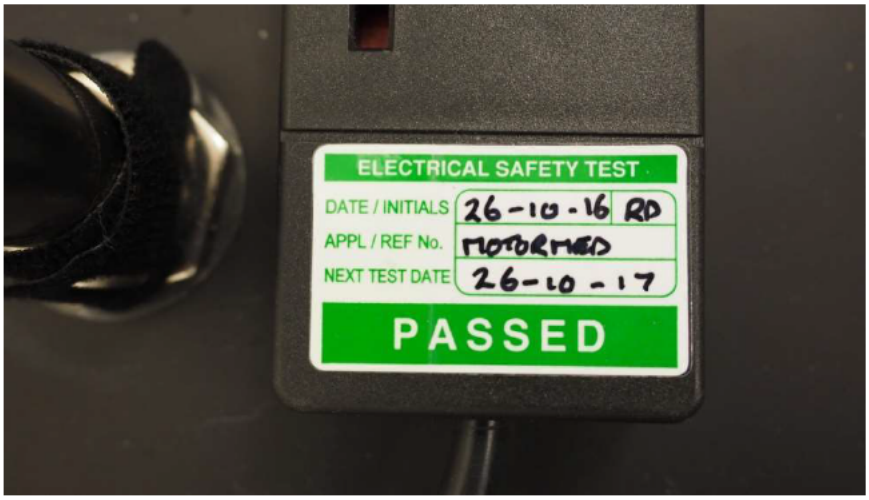


Figure 16 – Mains Cable PAT Certificate

7. Laptop Computer

The Laptop Computer (Figure 17) is mounted to the adjustable tray using high-strength 3M Velcro to prevent it from being knocked over during use, or falling during transportation. To start the system, press the power button and wait for the screen image shown in Figure 17 to appear. Once this has occurred, press any key and enter the password "apple". The laptop will now boot to the desktop.

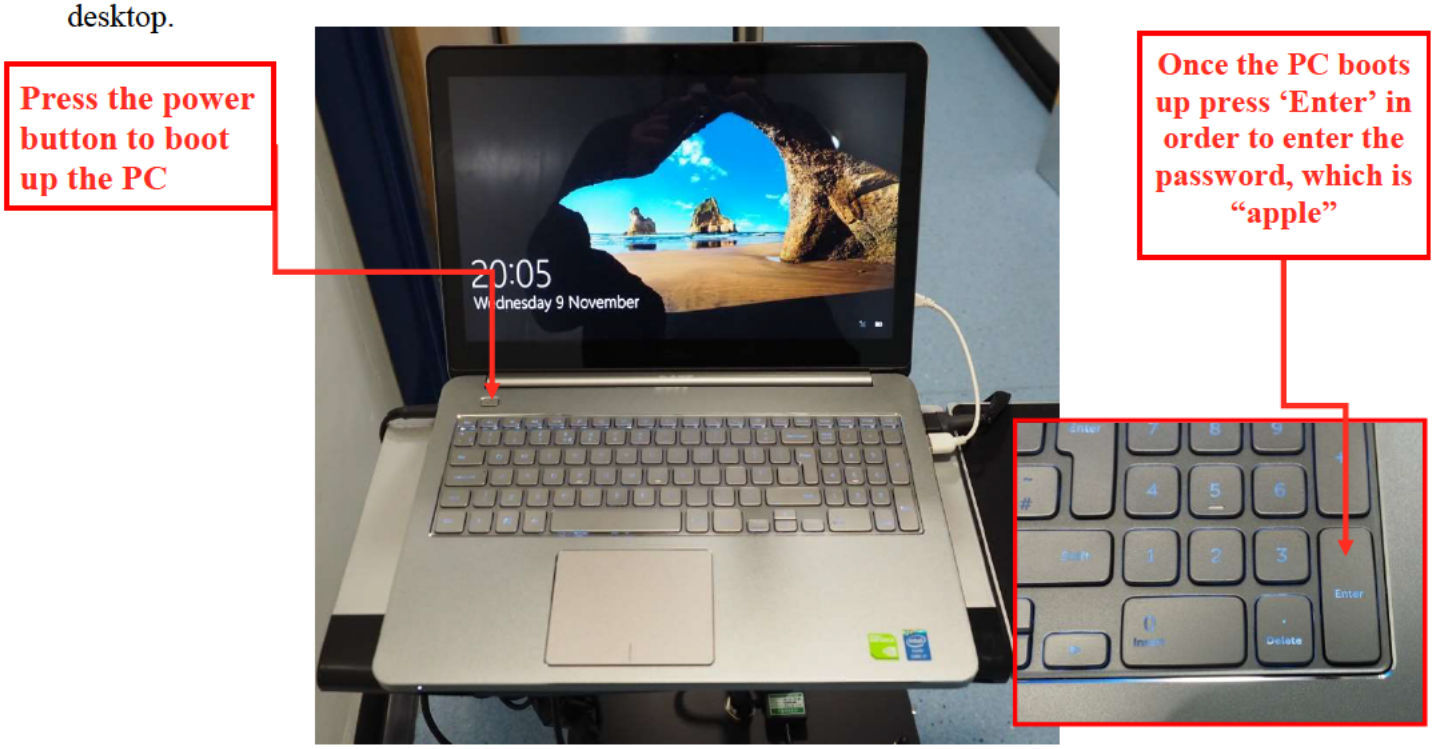


Figure 17 – Laptop Start-Up Keys

Once the laptop computer is running, it will be necessary to check a number of key components before starting the Velo-VR session. These are detailed in Sections 8, 9, 10 and 11. Once these checks have been completed satisfactorily, then the Velo-VR software can be started (Section 12).

8. Display

Velo-VR features a 24-inch display (Figure 18) for presentation of images to the patient. The display should automatically power on when the laptop boots up, but if it fails to do so, press the power button located on the **underside** of the base of the display. Once pressed, it will then search for the laptop and should mirror the image displayed on the laptop screen.



Figure 18 - Patient Display (Upper Images Show Location of Power Button)

9. Laptop Connections

There are several cables pre-connected to the PC but in the event of disconnection they can be re-attached by reference to the following images and descriptions.



Figure 19 - Cables Attached to the Right-Hand Edge of the Laptop.

Figure 19 is an image of the bank of connections on the laptop's right-hand edge. From left to right they are: Garmin cadence sensor data receiver, USB charging lead for Modem and HDMI cable for patient display. The only connection on the left-hand edge of the laptop is the power cable (Figure 20).

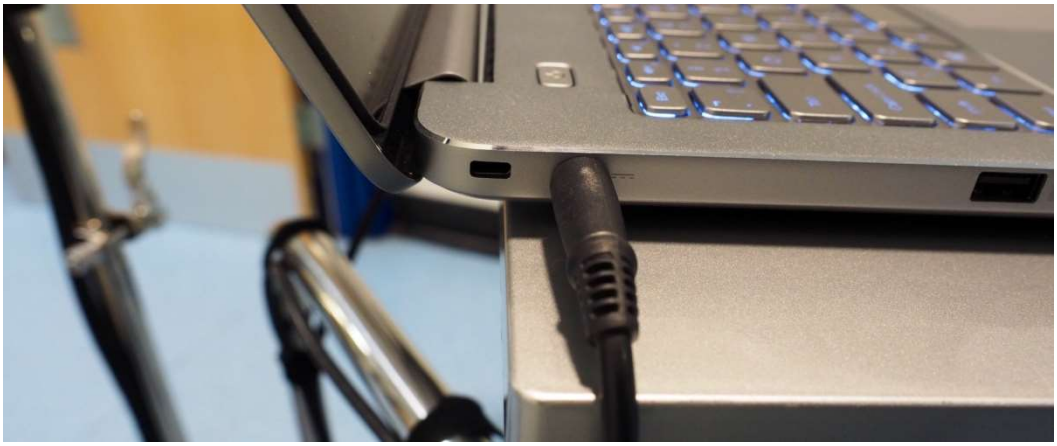


Figure 20 – Power Cable on the Left-Hand Edge of the Laptop.

10. Cadence Sensor

The cadence sensor (Figure 21) is a device that measures the rotational speed of the pedals on the MOTOmed and translates this into movement and speed within the game. The sensor itself is permanently mounted to the frame of the MOTOmed and a small magnet is mounted onto the rotating crank.

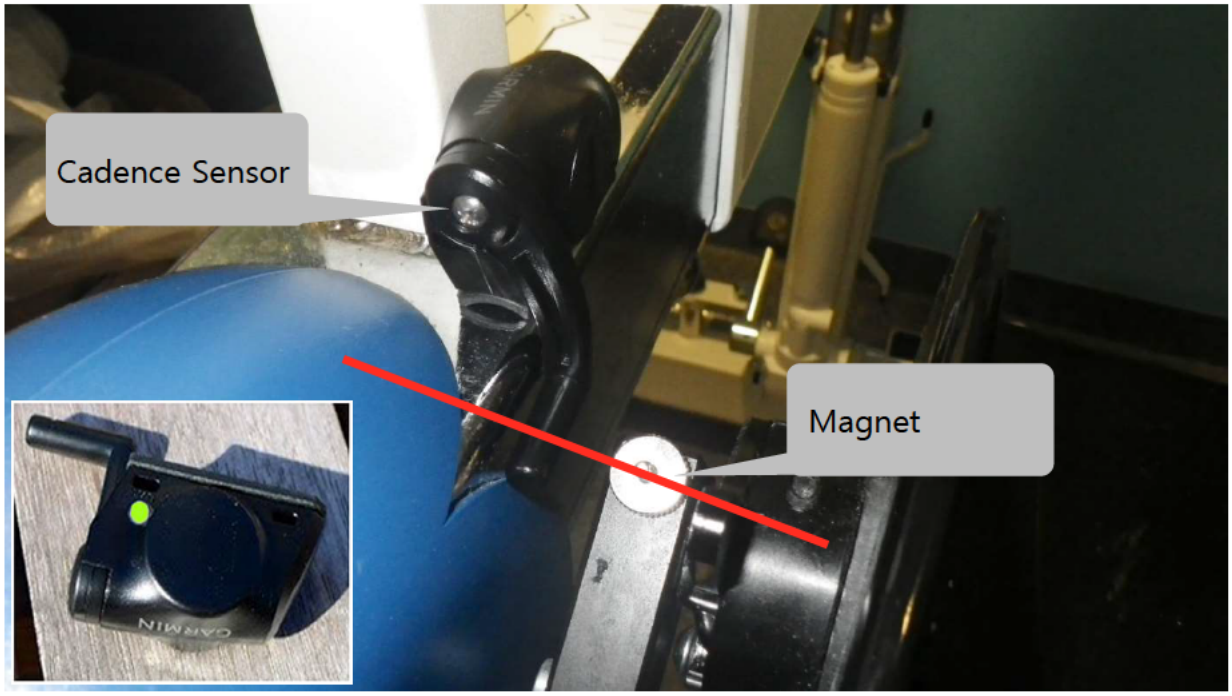


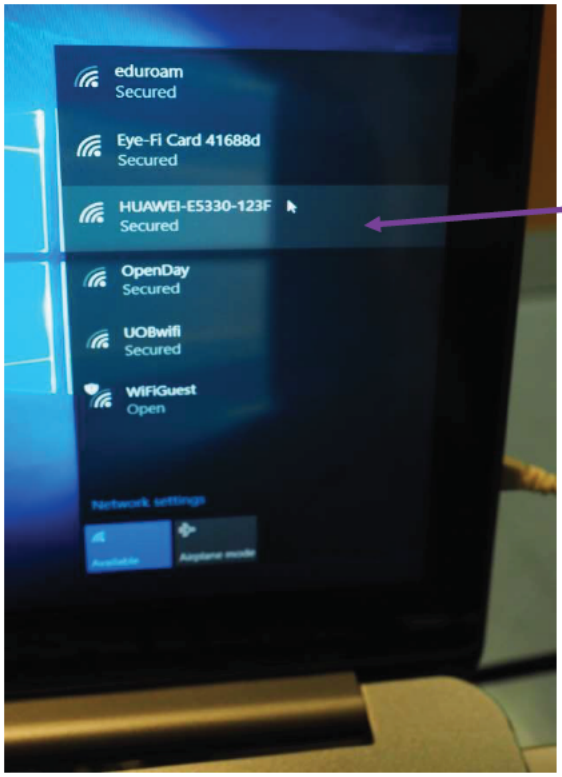
Figure 21 - Cadence Sensor Mounted to the MOTOmed

Notice how the magnet is in-line with the cadence sensor arm as the pedals rotate travels round. If it is out of line, it will produce erratic results. The cadence sensor itself has a white multi-function button. Following a period of inactivity, press the white button for a couple of seconds until it flashes green (shown in the insert in Figure 21). Now, whenever the magnet passes across the sensor, this button will flash green, signifying that it is working correctly. If this does not happen, inform one of the technical support team as soon as possible.

11. Mi-FI Modem

The system requires a brief period of access to the internet in order to run properly. To do this, a small modem (Figure 22) has been attached to the back of the laptop display. To use it, press the power button until the icons light up. The laptop should automatically find the modem and connect to it. However if this does not happen, it will be necessary to search for the modem manually by selecting the internet signal icon on the right of the task bar located on the bottom of the desktop screen.





If the modem does not connect to the internet automatically, select:

If the system asks for a password, enter:

Figure 22 - MiFi Dongle and Manual Activation

12. Game Controls

Once at the desktop, and with all pre-game checks having been completed (see Sections 8 to 11), press " - " to begin the game. Once the game is running the screen will display a simple game character on a recumbent tricycle (Figure 23).

As soon as the MOTOmed session starts, movement of the in-game character will also commence. The character and recumbent tricycle is designed to follow a set path through the computer-generated representation of the coastline, much like a "roller coaster track". Steering is not activated in this game, so all that is required is pedal input.

If, during the session, it is decided that the patient requires greater resistance to be applied to the MOTOmed pedalling mechanism, pressing the "up arrow" on the keyboard (↑) will also change the in-game resistance to match.

Once the session has been completed or abandoned, press " = " to return to the desktop.



Figure 23 – In-Game Character and Recumbent Tricycle

13. Velo-VR Game

The patient is required to complete 4 sessions on Velo-VR. These are:

i) No VR - This is essentially using the Moto-Med with Velo-VR in situ but not functioning as a game.

ii) Distraction VR - The patient takes part in the game and completes a 10-minute period of pedalling.

iii) "Ghost VR" - The patient takes part in the game and completes a 10-minute session of pedalling. On completing a lap, a "ghost version" of their character (Figure 24) joins to compete against the patient, based on the timing of their most recent session).

iv) No VR (again, this is essentially using the Moto-Med with Velo-VR in situ but not functioning as a game).

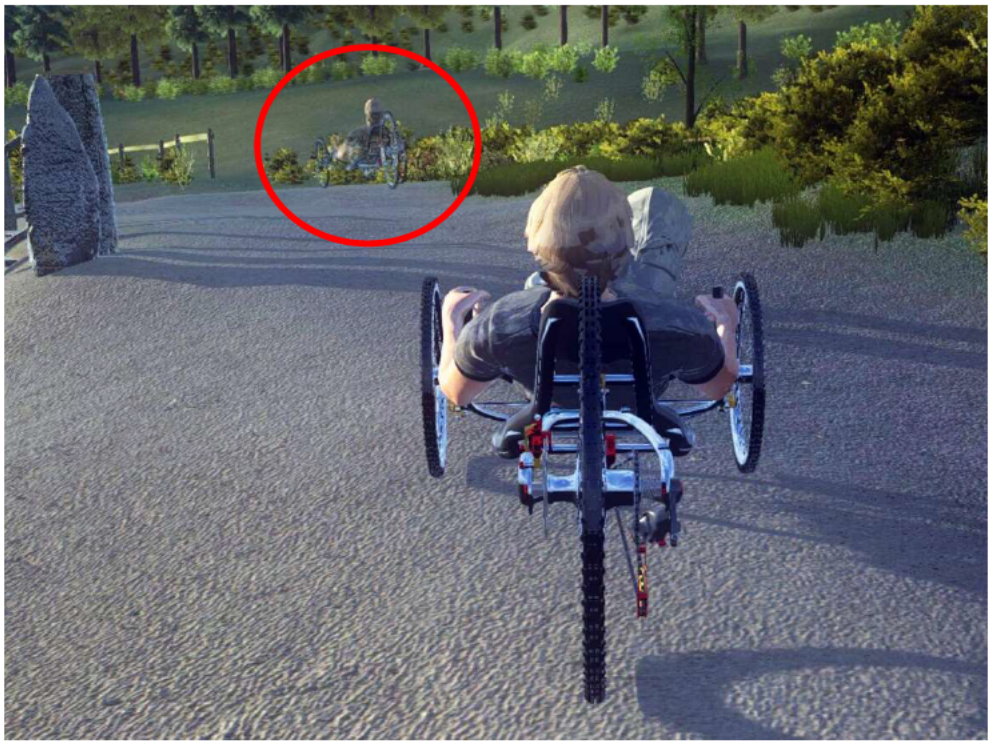


Figure 24 - Ghost VR in Game Session

14. Hygiene

Velo-VR can be cleaned using 70% alcohol wipes. If alcohol-free wipes are to be used, avoid using them on the laptop's touch display, as this will leave a white residue which, once dry, will create glare on the display and impact on the quality of gameplay.

Appendix 7.3

Health Research Authority

West Midlands - Edgbaston Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0207 104 8115

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

26 January 2017



Study title:	**Restorative Virtual Environments for Rehabilitation: Feasibility of the use of interactive technology-enhanced recumbent cycling to aid (VeloVR) mobilisation on the Intensive Care Unit**
REC reference:	**17/WM/0007**
Protocol number:	**ERN_16-1458**
IRAS project ID:	**219440**

The Research Ethics Committee reviewed the above application at the meeting held on 18 January 2017. Thank you for attending to discuss the application along with Charlotte Jones.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1. The following changes to the consent forms are required:
    a) The consent point seeking permission to contact participants after the study end must be removed if not relevant. Alternatively, the consent point must read 'I agree to being contacted by the research team after the study has been completed about participation in any future ethically approved research studies'.

2. The following changes to the patient information sheet are required:
    a) The following sentence must be added 'If you would like to participate but feel you will be unable to sign the form yourself, we can arrange for someone independent of the research study to sign as a witness to confirm you would like to take part'.

3. The following changes to the staff information sheet are required:
    a) Reference to the Birmingham Heartlands Hospital must be removed.
    b) The sentence 'Once you give your consent to us, you are able to withdraw this consent at any time with no adverse consequences to your medical care.' Must be changed to 'Once you give your consent to us, you are able to withdraw this consent at any time with no adverse consequences.'.
    c) The last paragraph in the 'Further Information and Contact Details' section with regard to contacting PALS must be removed.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

Notice of no objection must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming no objection or giving grounds for objection, as soon as this is available.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet completed any site-specific assessment(s) (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Summary of discussion at the meeting

Social or scientific value; scientific design and conduct of the study

The Committee welcomed the applicants and were pleased to note they had reviewed two related applications previously for this team. Members commended the applicants for the involvement of patients in the design of the study, and stated it showed in the quality of the application. They queried what PhD the Chief Investigator was undertaking for this research. *The applicants informed it was a PhD in Clinical and Experimental Medicine, but would be co-supervised by the Engineering Department at the university due to the nature of the research.*

Members queried whether patient feedback would be one of the key considerations in deciding whether the approach was feasible. *The applicants confirmed this was one of the secondary outcomes and was vital to feasibility. The primary outcome would be whether the system was usable, and the secondary was patient experience.*

Recruitment arrangements and access to health information, and fair participant selection

The Committee noted the application indicated patients would be screened by the physiotherapy team and initially approached by a research physiotherapist or a research nurse. They sought to clarify whether all individuals accessing data and approaching the patients prior to consent had a legitimate right to do so as part of their usual role. *The applicants informed the Chief Investigator was the research physiotherapist referred to; she was also a part of the long term patient rehabilitation team in her usual role. They confirmed, therefore, that only those who were part of the patient's care team would have access to them and their data at this time. Others outside the care team would not be involved in screening.*

The Committee queried whether it was possible participants could be discharged to a general ward during their study participation, and if so what would happen. *The applicants informed this would not happen because patients had to be able to mobilise before they were discharged to another ward. All patients using the motor-med would be doing so because they were immobile, and therefore no one currently using the motor-med would be in a position to be discharged.*

Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)

Members queried whether it was possible the video recording of the intervention could impact on visiting hours, and whether there was a risk of those who had not consented therefore appearing on the recording. *The applicants informed the physiotherapy sessions would only take place with the curtains pulled and it was not standard practice to have relatives or friends present in the bed space at such times. There was therefore very little risk of others appearing in the video.*

The Committee commented this could be a very good use of the technology, but acknowledged virtual reality systems could be unfamiliar and challenging to use for some. Members asked what arrangements were in place to talk each participant through the system. *The applicants explained their previous studies had looked at how participants handled exposure to new technology. This study was different in that there was no requirement to interact with the technology; participants would be passive in a game and would only need to pedal, as per standard care. They added they would discuss the game with all participants in order to explain what it all meant and what the avatar was for. They*

had tried very hard to make the graphics on screen as clear as possible based on feedback from previous studies. They had worked with a patient group of ICU survivors who as a group had very little capacity to learn new technology, and had used their feedback to inform the design of the game. The applicants added the only addition from a patient perspective would be a TV screen, which they would all be familiar with. In general the approach had been kept as simple as was possible in order that there was no need for participants to learn any new skills. The Committee noted this.

The Committee sought to clarify the risk assessment arrangements that were in place for use of the system on these units. *The applicants informed full risk assessments were already in place for the cycle machine, as this was used regularly in standard care. There was no need for an additional risk assessment for the addition of a screen for this study.* Members asked whether the system would require any technical expertise to set up. *The applicants informed it had been designed not to require any sort of technical or engineering support as this would have made it impractical. The system was very simple and did not require specific technical expertise to run.*

It was noted the applicants had considered the possible side effect of cyber sickness, and set a maximum participants occurrence rate of 20% above baseline at which point they would stop the study. *The applicants confirmed this. They added they would be assessing every five patients and if it appeared that more than one in five or those were experiencing cyber sickness it would trigger a safety review. They further explained, however, that they had used similar systems in two previous studies and had experienced no occurrences of cyber sickness. In this study the screen was much farther away from the participants' eyes which should mean the tracking issues associated with previous technology would not occur.*

Informed consent process and the adequacy and completeness of participant information

The Committee commented given the consent point seeking permission to contact participants again for future research was optional, it required both 'yes' and 'no' boxes alongside it to make it clear participants could decline if they wished. In addition, it was not clear why permission was sought to do so. Members commented this would need to be specified in the consent form. *The applicants explained there would be no additional visits required after the study interventions, but they had felt for completeness they should obtain consent as they would be continuing to collect data for the study from the routine care investigations.* The committee sought to clarify whether there would be any reason to contact participants again following the end of the study. *The applicants confirmed there would not be any reason to do so, over and above contact for usual clinical care.*

Members noted there were arrangements for a witness to sign the consent form if the patient was physically unable to do so. They commented this should be stated in the information sheet so that those reading were not discouraged from attending if they felt they would not be able to sign. *The applicants noted this.* The Committee sought to clarify any witness would be an advocate for the patient, and not a researcher. *The applicants confirmed it would be the clinician responsible for the patient on the day, and not a researcher. They would know the patient best and all were GCP trained.*

The Committee noted there was reference to the Birmingham Heartlands Hospital in the staff information sheet. *The committee commented this was an error.* In addition, there were some statements not relevant to staff that should be removed. For example, reference to withdrawing not affecting the medical care they receive, and the statement that they, their

family or friends can contact the Patient Advice Liaison Service (PALS) should they have any concerns. *The applicants noted this.*

Please contact the REC Manager if you feel that the above summary is not an accurate reflection of the discussion at the meeting.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance]	1	13 December 2016
GP/consultant information sheets or letters [REVERE Move Consultant/GP letter]	1.0	11 November 2016
Instructions for use of medical device [Instructions for use]	1.1	10 November 2016
Interview schedules or topic guides for participants [REVERE Move Case Report Form]	2.0	16 November 2016
IRAS Application Form [IRAS_Form_13122016]		13 December 2016
Letter from funder [Letter from funder]	201611	16 November 2016
Letter from sponsor [Sponsor letter]	1	13 December 2016
Letters of invitation to participant [REVERE Move PIL]	1.1	14 November 2016
Letters of invitation to participant [REVERE Move Letter to staff participants]	1.0	01 January 2017
MHRA Notice of No Objection Letter (Medical Devices) and relevant correspondence [Letter of no objection]	1	11 November 2016
Non-validated questionnaire [REVERE Move Case Report Form]	2.0	16 November 2016
Other [VeloVR Images]	1.0	01 January 2017
Participant consent form [REVERE Move patient consent]	1.2	12 December 2016
Participant consent form [REVERE Move staff consent]	1.0	11 November 2016
Participant information sheet (PIS) [REVERE Move PIS]	2.1	12 December 2016
Participant information sheet (PIS) [REVERE Move staff PIS]	1.0	16 November 2016
Research protocol or project proposal [REVERE Move protocol]	4.4	12 December 2016
Summary CV for Chief Investigator (CI) [C Small CV]	1	11 November 2016
Summary CV for student [C small CV]	1	14 November 2016
Summary CV for student [V Shingari CV]	1	11 November 2016
Summary CV for student [V Shingari CV]	1	01 January 2017
Summary CV for supervisor (student research) [R Stone CV]	1	01 November 2016
Summary CV for supervisor (student research) [J Bion CV]	1	01 October 2015
Summary CV for supervisor (student research) [R Stone short CV]	1	01 January 2017
Summary CV for supervisor (student research) [J Bion Short CV]	1	01 September 2016

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

17/WM/0007	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely



Mr Paul Hamilton
Chair

E-mail: NRESCommittee.WestMidlands-Edgbaston@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
"After ethical review – guidance for researchers"

Copy to: *Mr Sean Jennings*
Dr Chris Counsell, University Hospitals Birmingham (UHB) NHS Foundation Trust

Rating of perceived exertion: Borg scales

Rating of perceived exertion (RPE) is a widely used and reliable indicator to monitor and guide exercise intensity. The scale allows individuals to subjectively rate their level of exertion during exercise or exercise testing (American College of Sports Medicine, 2010). Developed by Gunnar Borg, it is often also referred to as the Borg Scale.

Two RPE scales are commonly used:

1. the original Borg scale or category scale (6 to 20 scale), and
2. the revised category-ratio scale (0 to 10 scale).

The original scale was developed in healthy individuals to correlate with exercise heart rates (e.g., RPE 15 would approximate a HR of 150 bpm), and to enable subjects to better understand terminology (Borg, 1982). The category ratio scale was later developed and has since also been modified to more specifically record symptomatic breathlessness (Modified Borg Dyspnoea Scale).

RPE scales are particularly valuable when HR measures of exercise intensity are inaccurate or dampened, such as in patients on beta blocker medication. This is due to the scale's ability to capture the perceived exertion from central cardiovascular, respiratory and central nervous system functions (Borg, 1982).

Both the 6-20 and 0-10 scales are used in clinical practice to measure perceived exertion; no current recommendations exist regarding use of one scale in preference to another. The Modified Borg Dyspnoea Scale is most commonly used to assess symptoms of breathlessness.

Despite being a subjective measure of exercise intensity, RPE scales provide valuable information when used correctly. It is therefore important that clinicians take sufficient time to educate the patient and ensure appropriate understanding prior to use (Whaley et al., 1997; Borg 1998,).

Rating of Perceived Exertion (RPE) Category Scale

6

7 Very, very light

8

9 Very light

10

11 Fairly light

12

13 Somewhat hard

14

15 Hard

16

17 Very hard

18

19 Very, very hard

20

Borg G. Borg's Perceived Exertion and Pan Scales. *Champaign, IL: Human Kinetics, 1998.*

Rating of Perceived Exertion (RPE) Category-Ratio Scale

0	Nothing at all	
0.3		
0.5	Extremely weak	Just noticeable
0. 7		
1	Very weak	
1.5		
2	Weak	Light
2. 5		
3	Moderate	
4		
5	Strong	Heavy
6		
7	Very strong	
8		
9		
10	Extremely strong “Maximal”	
11		
•	Absolute maximum	Highest Possible

Borg G. Borg’s Perceived Exertion and Pan Scales. Champaign, IL: Human Kinetics, 1998

Modified Borg Dyspnoea Scale

0	Nothing at all
0.5	Very, very slight (just noticeable)
1	Very slight
2	Slight
3	Moderate
4	Somewhat severe
5	Severe
6	
7	Very severe
8	
9	Very, very severe (almost maximal)
10	Maximal

Patient Instructions for Borg Dyspnoea Scale

"This is a scale that asks you to rate the difficulty of your breathing. It starts at number 0 where your breathing is causing you no difficulty at all and progresses through to number 10 where your breathing difficulty is maximal. How much difficulty is your breathing causing you right now?"

Appendix 8.2

Wilcoxon Test for Borg Dyspnoea

Ranks

		N	Mean Rank	Sum of Ranks
So oVR - NoVR	Negat ve Ranks	5[a]	6.10	30.50
	Pos t ve Ranks	8[b]	7.56	60.50
	T es	3[c]		
	Tota	16		
CompVR - NoVR	Negat ve Ranks	2[d]	5.75	11.50
	Pos t ve Ranks	8[e]	5.44	43.50
	T es	1		
	Tota	11		
CompVR - So oVR	Negat ve Ranks	3[g]	5.17	15.50
	Pos t ve Ranks	6[h]	4.92	29.50
	T es	2[i]		
	Tota	11		

a. So oVR < NoVR

b. So oVR > NoVR

c. So oVR = NoVR

d. CompVR < NoVR

e. CompVR > NoVR

f. CompVR = NoVR

g. CompVR < So oVR

h. CompVR > So oVR

. CompVR = So oVR

Test Statistics[a]

	So oVR - NoVR	CompVR - NoVR	CompVR - So oVR
Z	-1.051[b]	-1.637[b]	-.838[b]
Asymp. S g. (2-ta ed)	.293	.102	.402

a. W coxon S gned Ranks Test

b. Based on negat ve ranks.

Appendix 8.3

Wilcoxon Test for Borg RPE

Ranks

		N	Mean Rank	Sum of Ranks
So oVR - NoVR	Negat ve Ranks	7[a]	7.64	53.50
	Pos t ve Ranks	8[b]	8.31	66.50
	T es	1[c]		
	Tota	16		
CompVR - NoVR	Negat ve Ranks	6[d]	5.08	30.50
	Pos t ve Ranks	3[e]	4.83	14.50
	T es	2		
	Tota	11		
CompVR - So oVR	Negat ve Ranks	8[g]	6.38	51.00
	Pos t ve Ranks	3[h]	5.00	15.00
	T es	0[i]		
	Tota	11		

a. So oVR < NoVR

b. So oVR > NoVR

c. So oVR = NoVR

d. CompVR < NoVR

e. CompVR > NoVR

f. CompVR = NoVR

g. CompVR < So oVR

h. CompVR > So oVR

. CompVR = So oVR

Test Statistics[a]

	So oVR - NoVR	CompVR - NoVR	CompVR - So oVR
Z	-.372[b]	-.952[c]	-1.610[c]
Asymp. S g. (2-ta ed)	.710	.341	.107

a. W coxon S gned Ranks Test

b. Based on negat ve ranks.

c. Based on pos t ve ranks.

Appendix 8.4

Wilcoxon Test for Distance Travelled

Ranks

		N	Mean Rank	Sum of Ranks
So oVR - NoVR	Negat ve Ranks	1[a]	8.00	8.00
	Pos t ve Ranks	14[b]	8.00	112.00
	T es	0[c]		
	Tota	15		
CompVR - NoVR	Negat ve Ranks	2[d]	1.50	3.00
	Pos t ve Ranks	9[e]	7.00	63.00
	T es	0		
	Tota	11		
CompVR - So oVR	Negat ve Ranks	3[g]	2.33	7.00
	Pos t ve Ranks	7[h]	6.86	48.00
	T es	1[i]		
	Tota	11		

a. So oVR < NoVR

b. So oVR > NoVR

c. So oVR = NoVR

d. CompVR < NoVR

e. CompVR > NoVR

f. CompVR = NoVR

g. CompVR < So oVR

h. CompVR > So oVR

. CompVR = So oVR

Test Statistics[a]

	So oVR - NoVR	CompVR - NoVR	CompVR - So oVR
Z	-2.955[b]	-2.669[b]	-2.095[b]
Asymp. S g. (2-ta ed)	.003	.008	.036

a. W coxon S gned Ranks Test

b. Based on negat ve ranks.