Medical Devices Testing and Evaluation Centre

Usability Testing

July 27
2018

Company Name: Uvamed Limited

Unique Beneficiary Number: TEC 009

Type of Report: Formative usability study

Date of Report: 13/09/2018

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Contents:

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1. Introduction

1.1. About MD-TEC

The MD-TEC project is funded by the European Regional Development Fund (ERDF) as part of the European Structural and Investment Funds (ESIF) Programme 2014-2020 – Priority Axis1: Promoting Research and Development. University Hospitals Birmingham (UHB) is the lead organisation for MD-TEC project, in partnership with the University of Birmingham and Aston University. The project supports the accelerated translation of novel innovations in the laboratory through to the clinic and commercial exploitation. In doing so, this will aid the development of existing markets and stimulate new ones for companies within the Life Sciences market, enabling them to bring products to market quickly, at less cost and with reduced risk.

The MD-TEC team members cover broad areas of expertise ranging from scientific lab-based services to usability studies / human factors engineering, clinical trials consultancy, standards and commercialisation: routes market, CE marking. MD-TEC is a state-of-the-art facility designed to support medical technology and Life Sciences businesses across the region.

1.2. Product description

Uvamed's Rainbow Trays™ are compartmented, colour coded anaesthetic syringe trays designed to reduce medication error by assisting anaesthetists in the medication preparation process, as well as during surgery. The colour coding is compliant with ISO 26825:2008 for "Anaesthetic and respiratory equipment -- User-applied labels for syringes containing drugs used during anaesthesia -- Colours, design and performance" which is widely adopted in the UK, but also in other European and non-European countries. Figure 1 presents the Rainbow Trays™; having a simple design, the product targets specific uses and hospital departments, the trays come in product versions as: main, emergency and local anaesthetics trays.

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Figure 1. Rainbow Trays™.

The product is not intended to replace current practices for drug labelling i.e. on syringes, but to provide a visual check of the required drug, as the trays are compartmented and colour-coded following the logical progression from induction of anaesthesia to reversal. It is acknowledged that errors related to drugs administration are more frequent, especially in anaesthesia: wrong dose, wrong route and wrong order errors [1]. Rainbow Trays™ contain a base tray which is re-usable (must be cleaned between uses e.g. antibacterial wipes, Ethylene Oxide) and an insert single-use tray which is 100% recyclable (see Figure 2). Both trays are made of bacteriostatic PET (Polyethylene terephthalate). According to Uvamed Ltd., Rainbow Trays™ have been through the European and United States regulatory approval process since the device is CE marked (Conformité Européenne / European Confirmity) and FDA (Food and Drug Administration) approved.

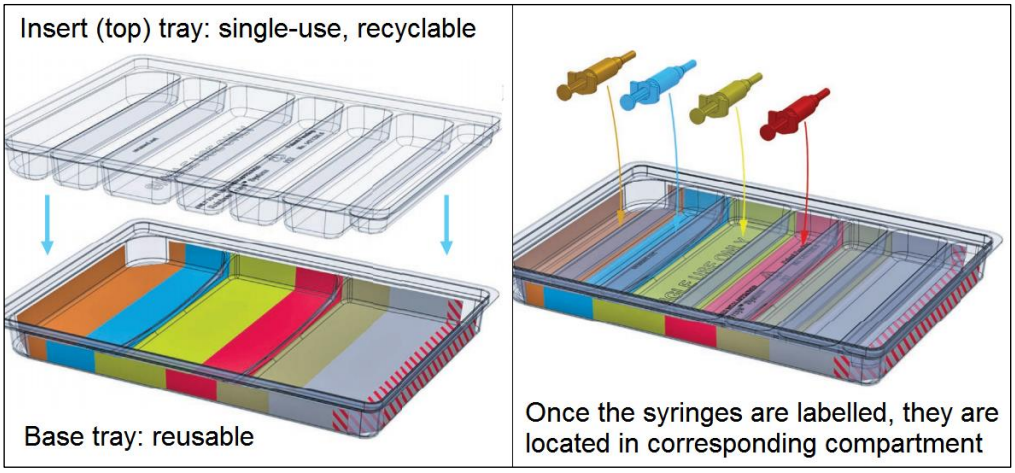

Figure 2. Rainbow Trays™ components and utilisation principle.

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1.3. Test objectives

The aim of this formative usability study was to assess the efficiency of Rainbow Trays™ for drug labelling and storage over current practices. A formative usability study is part of the iterative product development process and it is different than a summative usability study, conducted for validation purposes [2].

Uvamed Ltd. has previously collaborated with Nottingham University and East Midlands hospitals. Almghairbi et al. [3] conducted an observational feasibility study of Rainbow Trays™ across two NHS Trusts in 2017 which revealed a good acceptance of the medical device due to its ease of use compatibility with current practices, but it identified some concerns around the size of the trays and reusability of the insert trays. In addition to the comparative focus, the usability study conducted at MD-TEC addressed these concerns and acquired feedback regarding product introduction at department level and training needs.

In spite of realistically replicating the use scenario, there are some well acknowledged limitations of usability studies, such as "testing is always an artificial situation" and personal preferences of the participants, not representative of the entire user population [4].

2. Executive summary

MD-TEC conducted a formative usability test in two sessions on the 27th of June and 27th of July 2018 using MD-TEC Simulation Suite facilities i.e. operating theatre. The purpose of this test was to assess the usability, acceptability and training needs for Uvamed's Rainbow Trays™. Part of the usability study, MD-TEC put together a package for Uvamed Ltd. comprising: the current report, a summary of test results as per used assessment forms and usability videos (hands-on session) of all targeted participants (available at: https://vimeo.com/289257829/4109a46ecc).

Seven healthcare professionals participated in the usability study: session 1 (held on the 27th of June 2018) – two anaesthetists and one surgeon; session 2 (held on the 27th of July 2018) – four anaesthetists. The usability test was organised in two sessions simply for recruitment reasons, using the same protocol and tools in both sessions. Each individual session lasted approximately 40 minutes and it involved: Audio/Video (A/V) consent, hands-on session using current solution, followed by a brief break (approximately 10 minutes) and a second hands-on session using Rainbow Trays™, participant questionnaire and semi-structured interview.

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All participants found Rainbow Trays™ easy to use as the device is compliant with in-use drug colour coding standard i.e. ISO 26825:2008 “Anaesthetic and respiratory equipment -- User-applied labels for syringes containing drugs used during anaesthesia -- Colours, design and performance”. Rainbow Trays™ main advantage relies on the fact that it does not interfere with anaesthetists’ clinical routine, while offering an additional safety mechanism during drug preparation and administration. The conducted formative usability study indicate a reduction in the procedure time (in the given scenario) by an average of 9.8% (equivalent of 6.16 [s]).

The study has not identified any significant issues related to either the design, functionality / ergonomics, labelling or instructions for use (IFU). However, during the study we witnessed a medication error when using the usual disposable, cardboard kidney bowl: one of the anaesthetists accidentally dropped a syringe (neuromuscular blocking agent) and picked an incorrect / unintended one (muscle relaxant); in this particular case, the error was prevented when using Rainbow Trays™ since the participant could more comfortably handle the drugs, he double-checked the label when picking the syringe from tray compartment and corrected his actions (timed at 06:45 in the video).

The participants had a positive attitude towards Rainbow Trays™, being satisfied with the current design, but they made some valuable design recommendations based on their clinical practice and personal preferences, as summarised below:

- Base or insert tray to include labels for drug categories as well for more clarity
- Holes to be punctured in the (top) insert tray in case of any spillages
- Improve tray’s edge grip to facilitate handling Rainbow Trays™ while wearing gloves
- Consider including a compartment for flushing or bungs without increasing tray size if possible
- Attach lid for short-term storage and ensure that Rainbow Trays™ fit in hospital fridges
- Improve visibility of reusable (base tray) and disposable (insert tray) components via stamped labels
- Use coloured labels on syringes rather than coloured syringes in IFU diagrams to avoid confusion.

This document contains the participant feedback and satisfaction ratings, information on ease or difficulty of task completion, as well as recommendations and access information for the hands-on session recordings. A copy of the questionnaires is included in the Appendices section (Appendix I, II).

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3. Method

3.1. Participants

The study was advertised to the Anaesthesia Department and a total of seven volunteers participated in this study, among which six were fully trained and experienced anaesthetists – see Table 1. However, one participant (RT3) had a surgical specialty and limited exposure to the usability scenario (described in 3.2). The relevant participants had broad varying experience levels between 3 years and 17 years and currently work for Queen Elizabeth Hospital Birmingham (4x) and Worcestershire Acute Hospitals NHS Trust (2x).

Table 1. Table of participants, roles and relevant professional experience.

Participant number	Job title	Experience level
RT1	Registrar, Anaesthetics department	17 years
RT3	Surgical Rotation (Trainee)	N/A
RT4	Anaesthetist	3 years
RT5	Intensive Care & Anaesthetic Consultant	15 years
RT6	International Fellow, Cardiac Anaesthesia & Critical Care	16 years
RT7	International Fellow, General Anaesthesia	3 years
RT8	Senior Anaesthetist	13 years

3.2. Tasks and test scenario

The study procedure was defined based on company's objectives and built around the three core elements: users, use environment and user interface [5]. Rainbow Trays™ pose minimum direct risk to end users as they aim to assist healthcare professionals during anaesthetic procedures. The device does not introduce a new function or application and is not targeted at replacing current medication labelling standards and procedures. Hence, the utilisation of Rainbow Trays™ is highly similar with any currently used drug storage / containers during operations e.g. disposable cardboard pulp bowls, kidney dishes. The tasks involved for drug preparation are:

1. Collect the drugs / ampoules.
2. Determine the amount of drug required.
3. Transfer dose to syringe.
4. Label syringe and ampoules.
5. Place drugs in a suitable tray.

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The targeted end users of Rainbow Trays™ are anaesthetists and as previously mentioned, this medical device is aimed at assisting them for easier and accurate drug preparation, handling and administration during surgeries. The conducted usability study was structured around a task-based scenario: the administration of readily labelled drugs to SimMan® in order to perform Rapid Sequence Induction / Intubation (RSI) on SimMan® (step 5), in the following order:

1. Fentanyl (opiod, blue-labelled)
2. Propofol (induction agent, yellow-labelled)
3. Suxamethonium (neuromuscular blocking agent, red and black-labelled).

3.3. Test facility

The usability study was conducted in the operating theatre at MD-TEC in a setup as presented in Figure *3*. An Operating Department Practitioner (ODP) volunteer assisted the anaesthetist during the RSI procedure in order to replicate realistic working conditions for the end user. A high-definition (HD) camera on a tripod and a GoPro camera attached to participant's chest have been used to record participant's actions and to focus on the assessed medical device. The final interview session with the participant was recorded using a voice recorder.

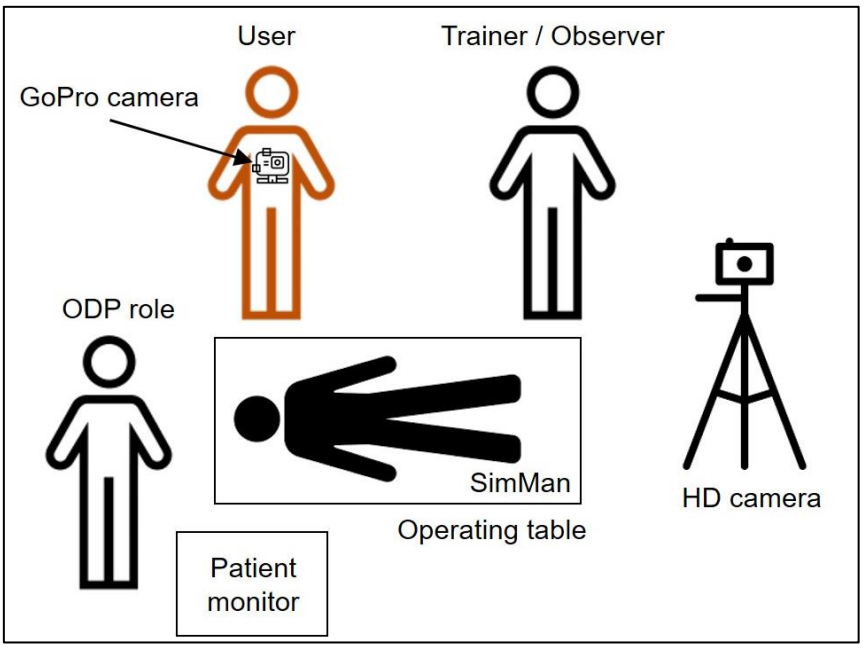

Figure 3. Usability study set-up at MD-TEC.

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3.4. Test administrator tools

After completing the hands-on session, the participants were required to complete a Likert scale ranking questionnaire (Appendix I). This addressed their confidence level during RSI using Rainbow Trays™, ease of use and possible added value in their daily role. This was followed by a semi-structured interview including the packaged medical device and instructions for use (IFU). The guidance questions are included in Appendix II. Uvamed Ltd. expressed their particular concerns regarding the size of Rainbow Trays™ based on mix feedback received in the past, hence we focused on this in the design characteristics discussion.

4. Experimental design

4.1. Procedure

The test procedure was established under the guidance of our clinical staff from MD-TEC. The study volunteers were recruited via the Anaesthesia Departments and Learning Centre (University Hospitals Birmingham NHS Foundation Trust) and professional contacts. Due to the simplicity of the medical device, as well as the current practices using standardised drug colour coding, information on Rainbow Trays™ (device to-be-assessed) was not revealed prior to the study. The advertising email mentioned the task i.e. Rapid Sequence Induction (RSI) for the assessment of a new medical device for anaesthesia. A team of four (MD-TEC) planned and moderated the usability study, in the sequence shown in Figure 4: administrator (welcoming the participants and A/V consent form), test facilitator (instructed the participant), ODP role (briefly trained) and interviewer.

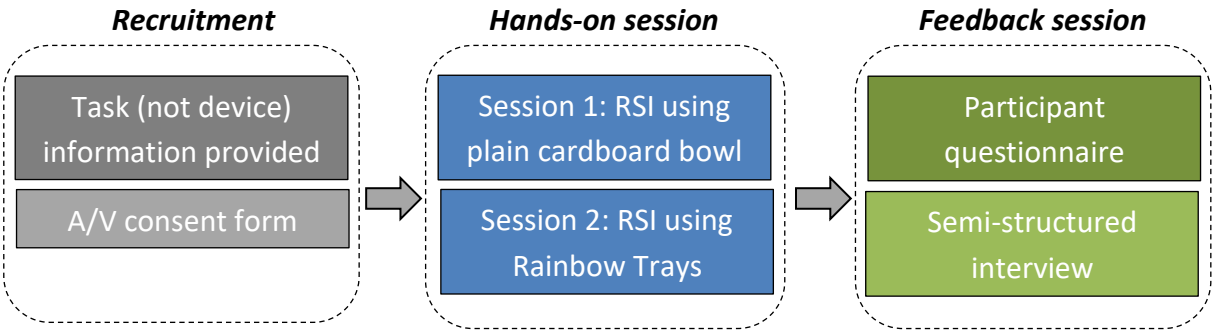

Figure 4. Usability study structure and assessment methods.

Uvamed Ltd. assisted on the day, participating in the semi-structured interview and having the chance to exchange contact details with the volunteers. After the study, the company provided some of the

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participants with Rainbow Trays™ samples and the participants consented to be contacted by the company for further feedback, design issues, etc.

5. Results

5.1. Rainbow Trays™ usability overview

Figure 5 shows participants ranking of Rainbow Trays™ ease of use and their confidence levels during its utilisation in the study, with a mean value of 4.71 (std. deviation 0.49) and 4.57 (std. deviation 0.53) respectively. While no correlation was found between the experience level and the overall questionnaire score, the ranked mean of the two features increases to 4.83 and 4.66 if not considering participant RT3 who is not a targeted end user.

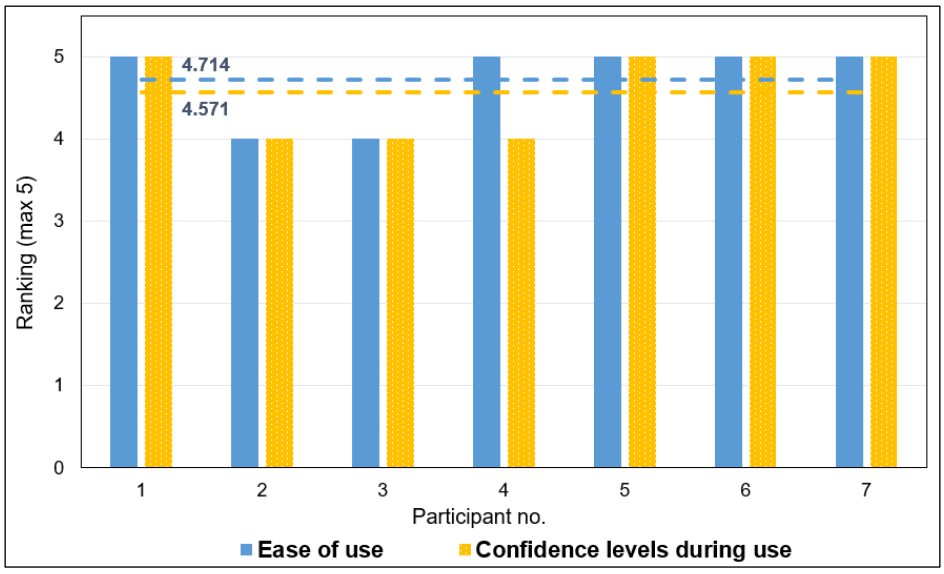

Figure 5. Rainbow Trays™ rankings of ease of use and participant confidence levels during its utilisation.

The participants were overall satisfied with their performance in the study (average of 4.71), which was also reflected in their confidence levels. Interestingly, the participants used different techniques to locate and handle the syringes during the RSI procedure. The participants identified the potential of the medical device in enhancing drug labelling (mean value of 4.14, std. deviation 0.69) and to assist them during anaesthetic procedures (mean value of 4.29, std. deviation 0.76). The participants ranked the current design of Rainbow Trays™ as satisfactory, with a mean ranking of 3.28 (std. deviation 0.76), close to neutral. Figure 6 shows participant ranking of medical device design readiness and fitness for purpose.

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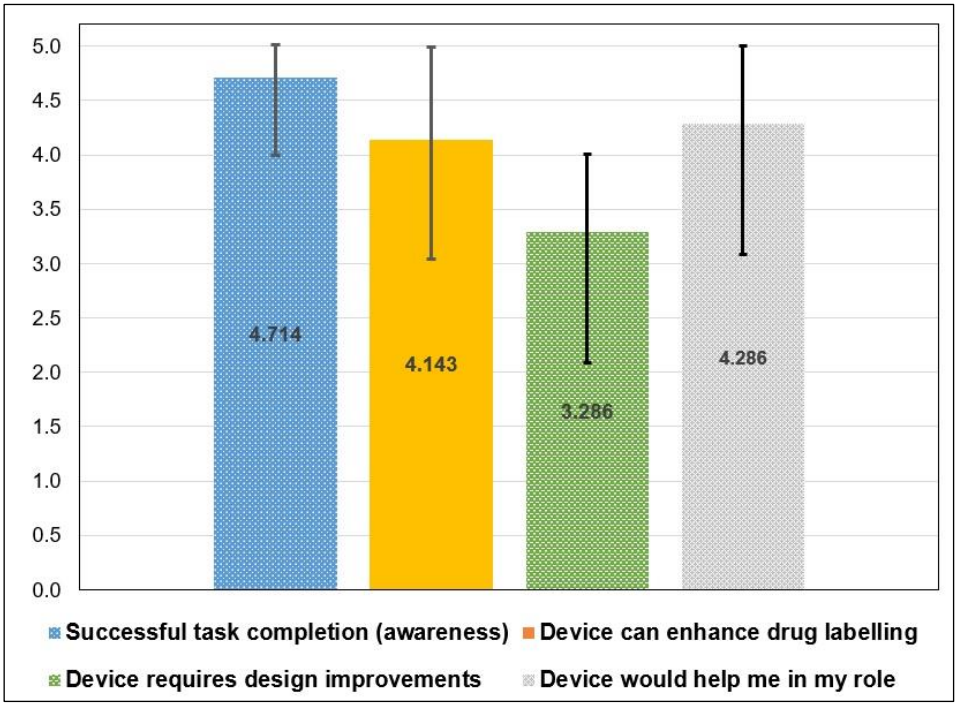

Figure 6. Rainbow Trays™ design readiness ranking.

One of the participants made a significant error when using the cardboard kidney bowl as he dropped the Suxamethonium syringe (neuromuscular blocking agent, labelled with red and black) in the gap between the surgical trolley and the anaesthesia machine, recorded at approximately 06:45 on the video, and he injected Atracurium (muscle relaxant, labelled in red) instead – see Figure 7. He also initially selected Atracurium from the Rainbow tray, but the participant corrected his mistake prior to the injection ("closes call" in FDA usability terminology) - see Figure 8. Both drugs belong to the same class of muscle relaxants, but they are employed depending on patient's clinical situation; Atracurium is slower than Suxamethonium in paralysis induction [6].

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Figure 7. Participant drops the Suxamethonium, neuromuscular blocking agent (left) and picks Atracurium, a muscle relaxant, instead.

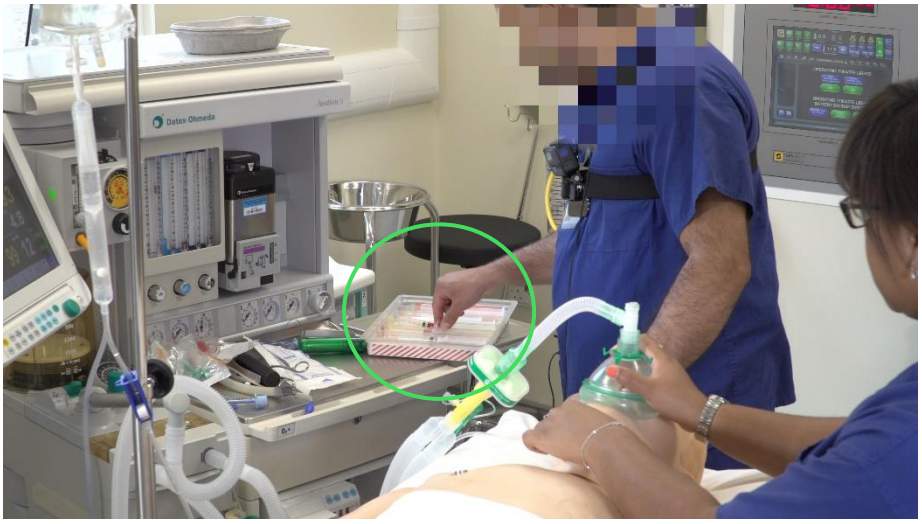

Figure 8. Participant double checks label and corrects himself, collecting the intended Suxamethonium (neuromuscular blocking agent) and not Atracurium (muscle relaxant).

A practical limitation of the study might be the labelled, readily prepared syringes; anaesthetists might have different personal preferences in this respect. Our method was to attach the drug label round the syringe barrel, whereas some users might prefer it along the length of the barrel. However, this was not reported by any of the participants and still, the label colours were clearly visible.

5.2. Usability metrics

All participants were able to perform the RSI procedure using both the cardboard pulp disposable kidney bowl and Rainbow Trays™, hence a success rate of 100% for the representative end users (6/6). It should be noted that RT3 required assistance throughout the procedure since not working as an anaesthetist

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(see Table 1). The user interface of Rainbow Trays™ is effective as leading to an increase in user confidence while performing routine anaesthetic procedures.

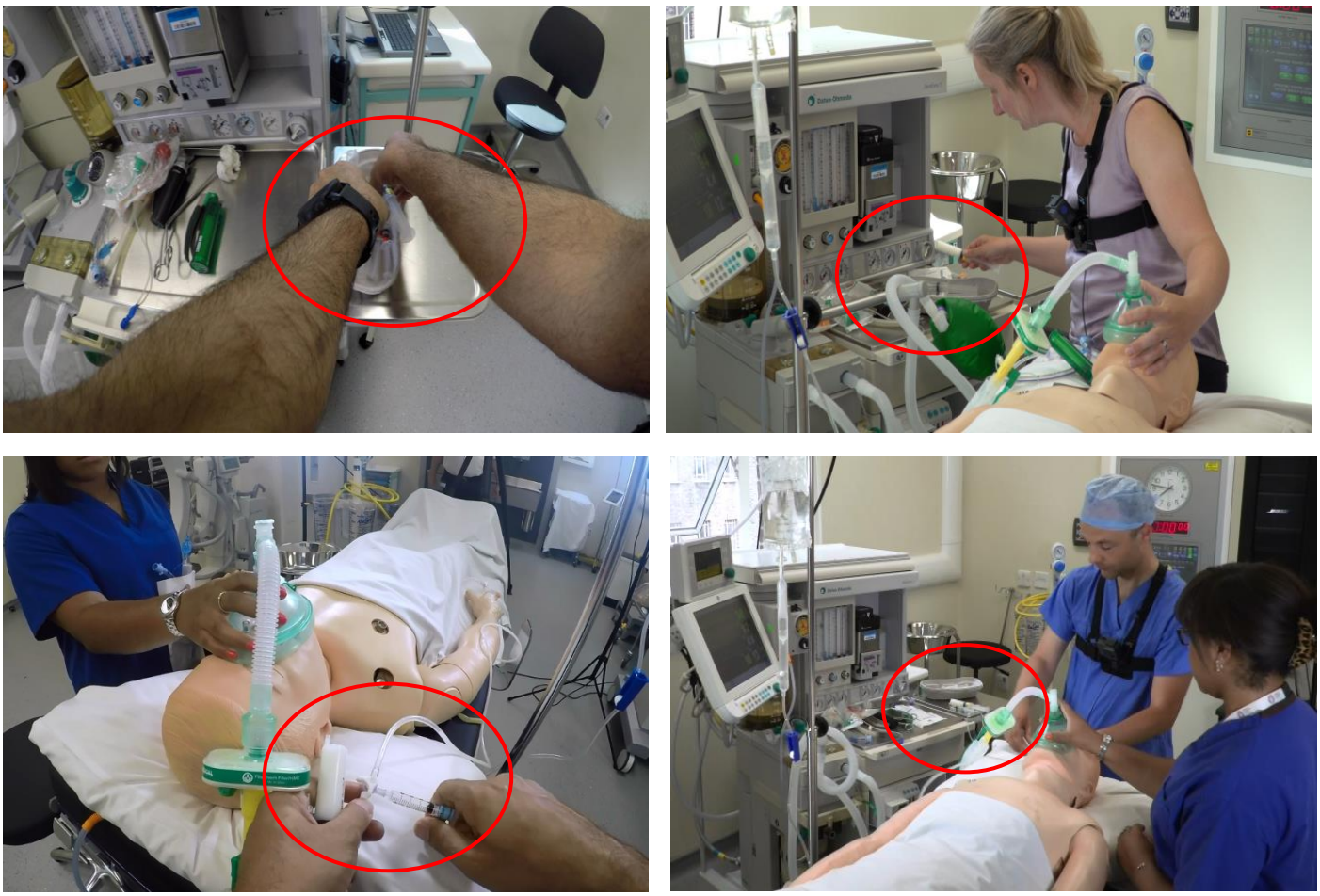

Figure 9. Difficulties encountered for syringe selection from cardboard kidney bowl: two hands (top left); difficulties in accessing it and reading the label (top right); holding several syringes during drug administration (bottom left); participant lays required drugs on the trolley (bottom right).

100% of participants (7/7) reported an increase in efficiency when using Rainbow Trays™ compared to the non-compartmented bowl. We quantified the time-on-task i.e. completion time, from the moment when the ventilation mask was attached to the SimMan® until complete drug administration for the given scenario. The average completion time across six participants when using the pulp cardboard trays was 62.33 [s] compared to 56.16 [s] when using Rainbow Trays™. Hence, the average improvement was 6.16 [s], which is equivalent to approximately 9.8% required time for this RSI procedure. It is worth mentioning participants RT1 whose efficiency increased by 31 [s] when using the compartmented colour-coded tray. Interestingly, the time-on-task for participant RT4 increased by approximately 23 [s] when using Rainbow Trays™, however it can be noticed that he selected and arranged the medication out of the standard kidney cardboard bowl and placed the syringes in administration order on the surgical trolley (see Figure 9).

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Moreover, Figure 9 exemplifies some of the standard practices and difficulties encountered in identifying the required syringe and its label when using the usual kidney bowl. This was also reflected by the score given in the questionnaire (Q3d; subjective / preference measure), with a mean value of 4.286 (std. deviation 0.76), with a minimum ranked value of 3 (Neutral) and maximum of 5 (Highly Agree). The improvement is evident in the video (https://vimeo.com/289257829/4109a46ecc) for RT5 at 08:28 vs 09:19, and RT8 at 09:48 vs 11:35 respectively.

In regards to user satisfaction, all participants (7/7) showed overall interest and positive feedback on Rainbow Trays™ driven by the need for consistency across hospitals, as well as opportunity for assistance/ double-checking mechanism during anaesthetic procedures. More specific design aspects are discussed in the following section (5.3). Figure 10 shows the ease of access to drugs and syringe labels when using Rainbow Trays™.

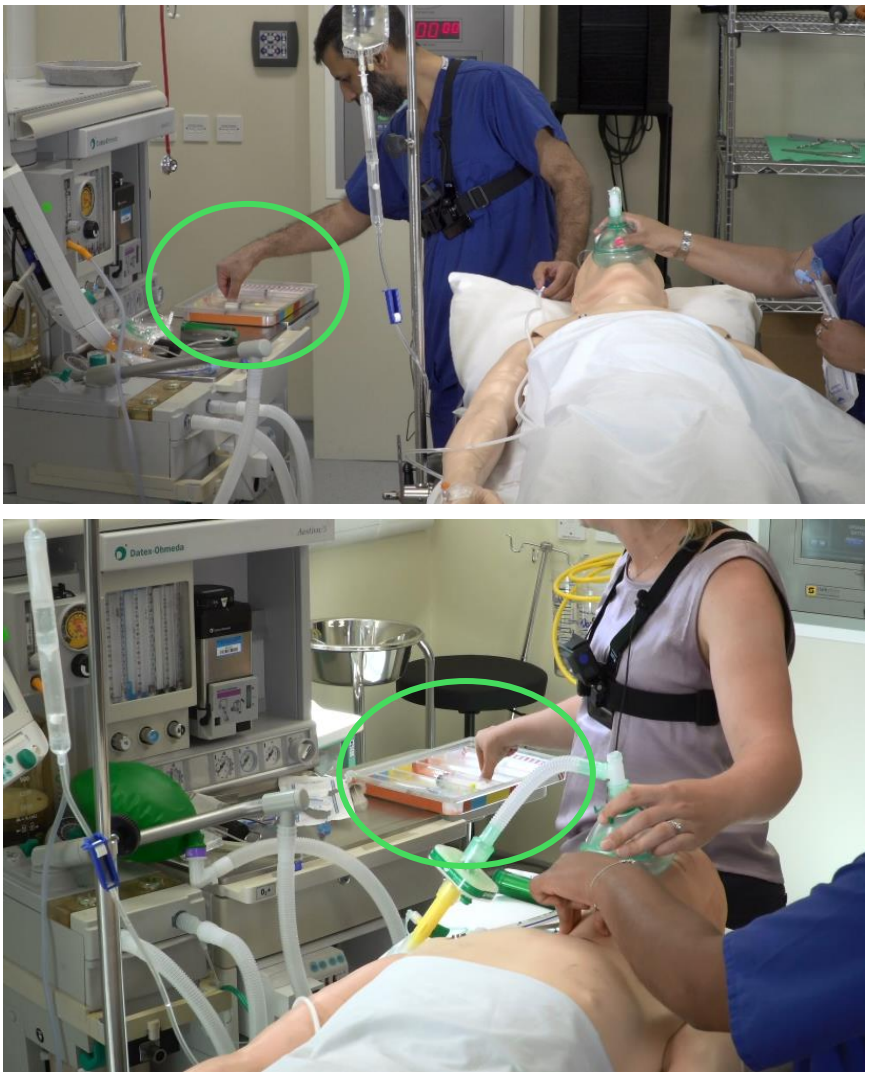

Figure 10. Example of syringe selection when using Rainbow Trays™.

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5.3. Design feedback

As part of the semi-structured interview (Appendix II), the participants were required to name likes and dislikes of the Rainbow Trays™ design. Table 2 summarises participant feedback that captures impressions on design functionality and ergonomics, but also personal preferences. The participants appreciated the ordered sequence and compartments of the Rainbow Trays™, as well as its compliance with existing standard and practices around drug labelling. A main advantage of Rainbow Trays™ is that it does not interfere with the anaesthetists' clinical routine, while offering an additional safety mechanism during drug preparation and administration.

Six out of seven participants (85.7%) were satisfied with the size of Rainbow Trays™. While there was no clear correlation between the participant experience and their acceptance levels, the more experienced anaesthetists provided an overall more positive feedback. One of the participants found the Rainbow Trays™ too colourful, but he admitted that this was purely due to personal preference.

In terms of training, all participants (100%) agreed that there are no particular training needs as the drug colour coding system is adopted in the UK, so Rainbow Trays™ introduction at department level would rely on an intuitive transition. The addition of labels as per drug categories to the insert tray for example (RT3, RT4, RT6) would potentially make the medication administration process even more error-proof; the medical device should be introduced at department level (RT2) and in order to facilitate its introduction, a simple schematic can be displayed in the drug room (RT4). One participant (RT1) highlighted a slightly confusing representation of the labels on syringes in the instructions for use (IFU), as being shown as coloured syringes rather than colour-labelled.

Three out of seven participants (42.8%) expressed their concerns around the (re)uses of base-tray and insert tray, especially in terms of limited recycling habits in hospitals; there is a risk that either both (top and base) trays will be disposed after a single-use or reused as long as possible, in which case cleaning is critical. These limitations can be addressed via labels and packaging; RT8 recommended the addition of a cleaning label on the base tray e.g. "To be cleaned and re-used", while RT5 suggested the use of a "more robust" plastic for the manufacturing of the base tray. Based on participants' points, recycling facilities and reusability practises vary at departmental and Trust level, however, in response to their concern, the participants were advised that Rainbow Trays™ are 100% recyclable.

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Table 2. Rainbow Trays™ design pros and cons.

Participant	Likes	Dislikes
RT1	Drugs well arranged, easy to use	-
	"Less delay and less chances for mistakes" during RSI	
	Good size for required syringes and ampoules	
RT3	Clearly coloured, "less hassle especially in emergency situations"	Drug compartments should also be labelled with drug categories
	Can be helpful for junior doctors and nurses	
	Appropriate size, easy to transport	
RT4	Useful as a compartmented tray for drug storage	Too colourful
		A bit oversized
RT5	It is a prompt to make sure all the drugs are prepared and labelled	It seems a bit big, however, you can fit a fully drawn syringe
	It follows the standardised colour code system for drug labelling	
	"I am going to know without looking too much where to pick the drug from"	
RT6	Clearly arranged drugs	Smaller size ideal for more workspace e.g. A&E
	"It helps managing the thinking process"	One syringe per tray compartment might be sufficient
	The product satisfies the need for consistency in hospitals	
RT7	"Colours follow pretty much anaesthesia drug administration sequence"	-
	It allows to double check the drug administration process with tray colour-coding; "additional safety factor"	
	Good size for its purpose	
RT8	Easier to separate and pick syringes	The main tray should have a purple compartment i.e. vasopressors
	Good size as it can sit nicely on the anaesthetic machine	
	Good aide-memoire to check that all the required drugs have been prepared	
	The tray is "really good for novices and emergencies in the middle of the night"	

Last but not least, the participants were encouraged to make usability recommendations and some proposed interesting design and marketability ideas, as listed below:

- Holes to be punctured in the (top) insert tray "would help in case of spillage" (RT1)

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- Inclusion of labels for drug categories for improved (RT3, RT4, RT6)
- Improve grip at the edges of the tray in case it is handled with gloves (RT6)
- Can include a small compartment for flushing or bungs e.g. possibility to slightly reduce space on the emergency tray (RT6)
- Attach lid for short-term storage (must fit in a fridge) and handling (RT8)
- Provision of a "complete" tray version: main tray + emergency tray (RT8).

6. Conclusions

The formative usability study conducted by MD-TEC revealed a high acceptance rate of Uvamed Rainbow Trays™ including its concept and current size. The six anaesthetists who participated in this study perceived the device as an additional checking tool with a direct positive impact on their usual clinical practice with a potential to reduce medication error and implicitly improving patient safety. Based on the study, as well as participant feedback, Rainbow Trays™ current design is suitable for the intended purpose and its targeted end users.

While the product offers the required medication space in a simple, compatible design with current drug colour-labelling standards, the results of this formative usability study indicate a reduction in the procedure time (in the given scenario) by an average of 9.8%. The usability study participants showed interest in trialling and introducing Rainbow Trays™ in their clinical duties.

7. Recommendations

The following table lists recommendations for further development based on the conducted study:

1	Uvamed Ltd. to liaise with participants (they have already consented to be contacted) and provide them with Rainbow Trays™ samples to be introduced in their clinical practice / acquire further feedback.
2	Uvamed Ltd. to perform a value/feasibility analysis of design recommendations made by participants (e.g. MoSCoW – Must have, Should have, Could have, Would have). Further feedback from (1) can highlight added value, etc.

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References:

[1] – R. P. Mahajan, “Medication errors: can we prevent them?”, BJA: British Journal of Anaesthesia, Volume 107, Issue 1, 2011

[2] – FDA, Applying Human Factors and Usability Engineering to Medical Devices, “Guidance for Industry and Food and Drug Administration Staff”, Feb 2016

[3] – D. S. Almghairbi et al, “An observational feasibility study of a new anaesthesia drug storage tray”, Anaesthesia, Volume 73, Issue 3, 2018

[4] – R. Stanley Dicks, Mis-Usability: On the Uses and Misuses of Usability Testing, 2002

[5] – Bob North, “The growing role of human factors and usability engineering for medical devices – What’s required in the new regulatory landscape”, BSI, ©BSI/UK/565/ST/0215/en/HL, 2015

[6] – R.P.F Scott and V.A Goat, “Atracurium: a comparison with Suxamethonium”, British Journal of Anaesthesia, Volume 54, Issue 909, 1982

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Appendix I: Questionnaire – form

Questionnaire: post-usability study

Participant ID:

Please indicate your feedback by ticking or encircling the corresponding answer.

Feel free to comment on specific points using the Comments section.

1. How easy did you find the overall interaction with Rainbow Trays?

1	2	3	4	5
Very difficult	*Difficult*	*Neutral*	*Easy*	*Very easy*

2. How confident did you feel during the utilisation of Rainbow Trays?

1	2	3	4	5
Very unconfident	*Unconfident*	*Neutral*	*Confident*	*Highly confident*

Comments:

_____

_____

_____

_____

3. Please rate the following statements:

a. I was successful in accomplishing what I was asked to do part of this study.

1	2	3	4	5
Strongly disagree	*Disagree*	*Neutral*	*Agree*	*Strongly agree*

b. Rainbow Trays can enhance drugs labelling (compared to current plain, standard trays).

1	2	3	4	5
Strongly disagree	*Disagree*	*Neutral*	*Agree*	*Strongly agree*

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c. Rainbow Trays requires further design improvements *by design, we mean size, shape and colour, but also labels, marks, etc.

1	2	3	4	5
Strongly disagree	*Disagree*	*Neutral*	*Agree*	*Strongly agree*

d. The utilisation of Rainbow Trays would help me to perform my job more efficiently.

1	2	3	4	5
Strongly disagree	*Disagree*	*Neutral*	*Agree*	*Strongly agree*

3. Do you have any other comments / suggestions regarding Rainbow Trays' design and applications?

Comments:

_____

_____

_____

_____

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Appendix II: Semi-structured interview – form

Semi-structured interview: post-usability study

UVAMED: Rainbow Trays

Participant ID: **Reviewer name:**

1. Have you noticed any differences when using the plain tray and the Rainbow Trays to perform the Rapid Sequence Induction?

2. Now moving into specific design aspects: What are the two things about the design that you liked?

3. What are the two things about the system that you didn't like? What are your thoughts on the size of the tray?

4. Feedback on instructions for use (IFU) and training needs: show IFU print; what type of training do you think it will be required to train anaesthetists to use Rainbow Trays?

5. Any product / design recommendations?

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8. Further support

MD-TEC aims to support business competitiveness and profitability while at the same time, improving the success of your medical device product/service/process via this project. Therefore, we are committed to assisting you engage with all business supports functions available to you.

The Business helpline covering the Greater Birmingham and Solihull Local Enterprise Partnership (GBS-LEP) provides support for business in all areas, and is on hand to help your business grow by simplifying the process businesses go through when seeking advice. Contact them on 0800 032 3488.

This work was undertaken by Dr Tom Clutton-Brock and Dr Sinziana Popescu on the 27th of June and the 27th of July 2018.

9. Company details

Name	Company website	Post code
Contact Name	Telephone	e-mail

Project contact details

Name	Telephone	e-mail
Contact Name		

Confirmation of support provided

Name of clinician/research fellow	Date	Hours worked	Activity description
Sinziana Popescu, Blair Davis	31/05/2018	1.5	Usability scoping meeting
Tom Clutton-Brock, Sinziana Popescu, Blair Davis	06/06/2018	0.5	Established usability testing plan & protocol
Sinziana Popescu	11/06/2018	2	Usability study forms

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Tom Clutton-Brock, Sinziana Popescu, Blair Davis	27/06/2018	4.5	Usability study session 1
Tom Clutton-Brock, Sinziana Popescu, Blair Davis	27/07/2018	4.5	Usability study session 2
Sinziana Popescu	06/08/2018	3	Usability test results analysis
Tom Clutton-Brock	12/09/2018	3.5	Video editing
Tom Clutton-Brock, Sinziana Popescu	10/08/2018 13/08/2018 17/08/2018 20/08/2018 23/08/2018 13/09/2018 22/09/2018 12/10/2018	16	Report writing Company feedback actions

Workshops attended

Title	Date	Workshop hours	Sign in sheet
-	-	-	-

Clinician/Academic Signature		Print name		Date	
Project manager signature		Print name		Date	

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10. Declaration to be completed by the beneficiary (SME)

- I confirm that the company has received at least 12 hours support from the MD-TEC project and that this support does not automatically qualify the company for additional funding within the MD-TEC project
- I agree that any information provided relating to the support received may be used for marketing and impact assessment purposes, excluding your confidential information and projects covered by non-disclosure agreements, which shall not be disclosed to third parties without your written consent.
- I understand that the information within this report will be disclosed to the Ministry of Housing, Communities and Local Government for ERDF monitoring purposes.
- I declare that the details on this form are true to the best of my knowledge
- I understand that if deliberate false information is given I may be liable to prosecution and any assistance received will be recovered.

Beneficiary signature		Name (printed	
Position in the Company		Date of Signature	

The MD-TEC project is receiving £3,527,205 of funding from the European Regional Development Fund as part of the European Structural Investment Funds programme 2014-2020- Priority Axis 1: Promoting Research & Development. The Department for Communities and Local Government is the Managing Authority for the European Regional Development Fund (ERDF). Established by the European Union, the ERDF helps local areas stimulate their economic development by investing in projects which will support innovation, businesses, create jobs and local community regenerations. For more information visit https://www.gov.uk/european-structural-investment-funds