An IEC 62366-Based Case Study of a User Interface Design Process for a Rehabilitation Device

Agnes Jihae Kim, Devision of Design & Art in Yonsei University, Wonju, Republic of Korea, agnesk@yonsei.ac.kr
O Seong Kweon, Devision of Design & Art in Yonsei University, Wonju, Republic of Korea, kosg@yonsei.ac.kr
Byeong-Jong Lee, Devision of Design & Art in Yonsei University, Wonju, Republic of Korea, i@yonsei.ac.kr

Abstract

The authors performed a usability improvement study for a shoulder continuous passive motion (CPM) rehabilitation device based on the usability engineering process of IEC 62366, a mandatory standard for the development of medical devices. To enhance the usability of the entire development process for a shoulder CPM device, the authors 1) performed user research to determine design requirements and 2) evaluated the usability of the device. Requirements for a shoulder CPM device were derived through rehabilitation device comparisons, functional analysis, context inquiry and observation, and interviews. The authors used expert reviews and comparison usability evaluation methods for shoulder CPM prototyping. The methods and techniques of these design researches were declared in IEC 62366, but IEC 62366 does not include any guideline in detail. The results of this study can be used to guide the development of a user interface that meets the level of usability standards required for medical devices.

Keywords: IEC 62366, Usability, Usability Engineering Process, User Interface Design, Rehabilitation Device, Shoulder CPM

Literature review

In the version 3 revision of IEC 60601-1, an international standard for electrical devices, usability was introduced as a supplementary standard. The IEC 60601-1-6 specifications describe how to create devices that conform to the IEC 62366 standard. This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors (Chae, 2015; IEC62366, 2014). According to international standard IEC 62366(2014), use errors caused by inadequate medical device usability have therefore become an increasing cause for concern. Many medical devices developed without applying a usability engineering process are non-intuitive, difficult to learn and use, and cause errors. As healthcare evolves, less skilled users, including patients themselves, are now using medical devices, while medical devices are becoming more complicated. Design of the user interface to achieve adequate usability requires a very different skill set than technical implementation of the interface (IEC62366, 2014).
This study is a follow-up study to ‘A Study on Shoulder CPM Design Guideline Considering Body Size of Korean, (Kweon et al., 2016)' and ‘A Study on the Usability Evaluation of Shoulder CPM for Patients Who Need Upper Rehabilitation, (Lee et al., 2017)'. The design process and

improvements in usability were carried out in collaboration with a medical device company and a design specializing company according to the IEC 62366 framework.

Methods and Scope

'Annex D: Guidance on the usability engineering process' in IEC 62366 includes an overview of usability engineering, a review of the usability engineering process, and associated analysis and design techniques. Figure 1 in Annex D maps the elements in the design cycle based on subclauses of international standard IEC 62366.
Our study to enhance the usability of a shoulder CPM device involved two components: 1) research into user design requirements and 2) usability evaluation of the design. This is the development process corresponding to Figure 1 above. The 'User research/conceptual design' and 'Requirement and criteria development' (gray) in Figure 1 correspond to 'Research into user design requirements (gray circle) in Figure 2. These elements also correspond to 'Detailed design and specifications' and 'Evalutation' (blue) in Figure 1 and 'Usability evaluation of design' (blue circle) in Figure 2.

Design cycle element	Subclause of this International Standard
USER research /Conceptual design	5.1 Application specification 5.2 Frequently used functions 5.3.1 Identification of characteristics related to SAFETY 5.3.2 Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS
Requirement and criteria development	5.4 PRIMARY OPERATING FUNCTIONS 5.5 USABILITY SPECIFICATION 5.6 USABILITY VALIDATION plan
Detailed design and specification	5.7 USER INTERFACE design and implementation
Evaluation	5.8 USABILITY VERIFICATION 5.9 USABILITY VALIDATION 5.3.2 Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS

Figure 1 : Mapping of Design Cycle Elements to the Subclauses of IEC 62366.

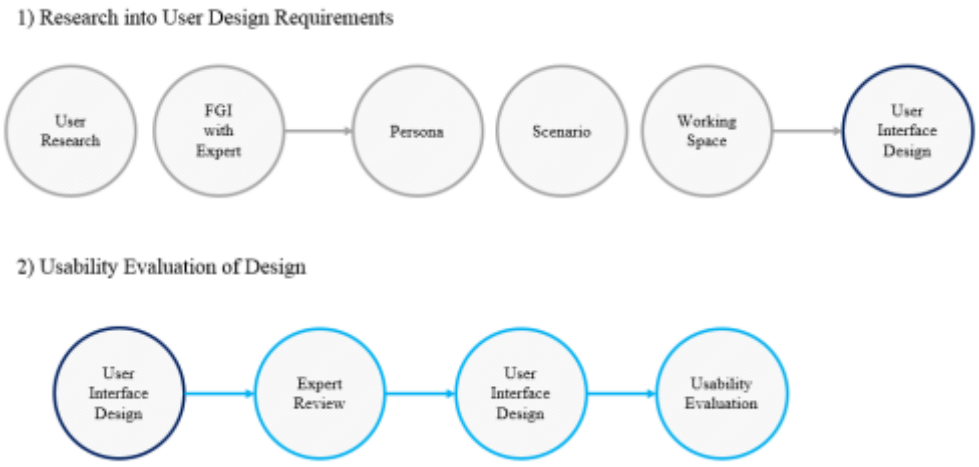


Figure 2 : Design process for a shoulder CPM device.

The authors focused on the usability of engineering process elements related to the desired

characteristics of a shoulder CPM device (work space optimized for three rehabilitation exercises and how to use them at home without specialist help). In this study, the requirements for a shoulder CPM device were derived through rehabilitation device comparison and functional analysis, context inquiry and observation, and interview. The authors used expert reviews and comparison usability evaluations for shoulder CPM device prototyping.

Research into User Design Requirements corresponding to IEC 62366 –Usability Specification

In IEC 62366: 2007 + A1: 2014, '5.5 Usability Specification' of ' Usability Engineering Process' specifies the following:

> *The usability specification shall describe at least:*
> *- Use scenarios related to the primary operating functions, including;*
> *- Frequent use scenarios; and*
> *- Reasonably foreseeable worst case use scenarios;*
> *- User interface requirements for the primary operating functions, including those to mitigate risk;*
> *- Requirements for determining whether primary operating functions are easily recognizable by the user.*

'Requirements by Use Process,' 'Work Space,' and 'Usage Method' correspond to the above 'Usability Specifications.'

Requirements by Use Process

The rehabilitation device is a continuous passive motion (CPM) device for the shoulder for patients who have difficulty exercising independently. Repeated and continuous manual exercise conferred by this type of device helps functional recovery. The main application of CPM is to increase joint mobilization and to induce smooth circulation, thereby improving muscle strength (Jeong et al., 2014).

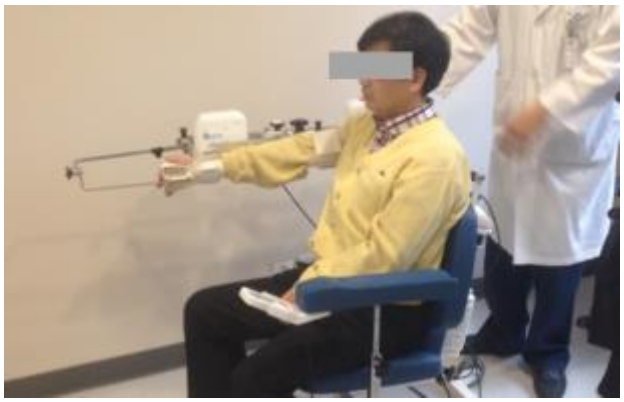
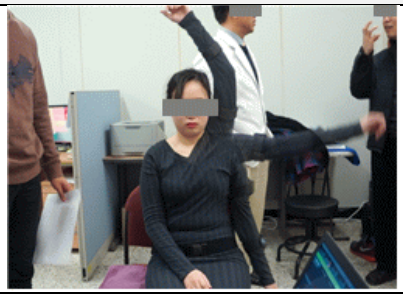
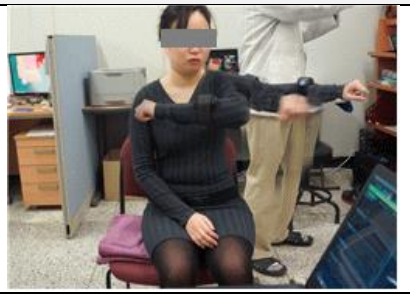


Figure 3 : Actual use of ARTUS-701S

The leading CPM products are the OptiFlex shoulder CPM device, the Kinetec Centura

Anatomical shoulder CPM machine, and the Artromot S3 shoulder CPM device. Eugene Medicare ARTUS-701S is the dominant product in Korea, and ARTUS-701S and 701ES are used as standard devices in university general hospitals in Korea(see Figure 3). Four products except ARTUS-701ES are all-in-one products that attach to a chair. The ARTUS-701ES is a stand-separated product that is separate from the chair. The CPM's program supports two or three detailed movements such as elbow, wrist combined movements in addition to shoulder movements.
To examine the use of upper CPM products in Korea, the authors visited a general hospital of a national university that uses upper CPM products and a national rehabilitation center that uses upper extremity rehabilitation robots. Patients were mainly exercised in the order of flexion - extension, adduction - abduction, horizontal adduction – abduction. In the hospital, CPM devices were available for both the shoulder and the elbow, but only the shoulder CPM was used because of the many patients who undergo shoulder surgery. Patients require CPM treatment for 2-3 weeks or 2-3 months, and devices have to be rented for use at home after hospital discharge. The authors reasoned that shoulder CPM devices should be able to be used both in the hospital and at home, and the authors argue that it is necessary to develop middle- and low-cost shoulder CPM devices that support the three types of exercises that are predominantly used for shoulder treatment (see Table 1): flexion-extension, adduction-abduction, and horizontal adduction-abduction.

Table 1 : Three types of exercises widely used for shoulder treatment.

Flexion-extension	**Adduction-abduction**	**Horizontal adduction-abduction**
		
Flexion and extension are movements that occur in the sagittal plane. (Muscolino, 2011)	Abduction and adduction are movements that moves a structure away from or towards the centre of the body. (Muscolino, 2011)	Horizontal abduction is abduction in the horizontal plane.

Because the shoulder is a sensitive and unstable joint, the shoulder CPM device should have firm body fixation to maintain a stable posture and take into account natural biomechanics (shoulder, arm, and wrist movement). In a previous study that investigated shoulder rehabilitation robots, the existing center of rotation of the shoulder rehabilitation robot was fixed; if the distance between the rotation center of the product and the center of rotation of the shoulder is not properly corrected for, shoulder impingement syndrome can occur after treatment (Kim et al., 2013). Therefore, the development of a shoulder CPM device for hospital and home use should fulfill the following safety criteria: 1) the patient should be able to maintain a stable posture during the exercise and the device should allow shoulder movement; 2) the shoulder CPM device should have a structure and form that take into account a patient's natural biomechanics during exercise, and 3) the shoulder CPM device should facilitate CPM with the correct posture without the help of a specialist. These usabillity criteria are based on expert reviews of existing products. 1) A shoulder CPM device is required for patients who need to continue shoulder treatment at home. 2) It should be

able to perform three movements: flexion - extension, adduction - abduction, and horizontal adduction - abduction. Natural biomechanics should be incorporated into the device actions when performing these three movements. 3) The user interface should enable the patient to use the device intuitively and stably without the help of a physiotherapist. Unlike other medical devices, rehabilitation devices are less likely to pose a serious danger to users during use, but users are more likely to be ordinary people than experts, so ease of use for novice users is important. Table 2 shows the requirements for a shoulder CPM device derived from analysis of existing products, a field survey, and interviews of experts.

Table 2 : Requirements for use corresponding to IEC 62366 usability specifications.

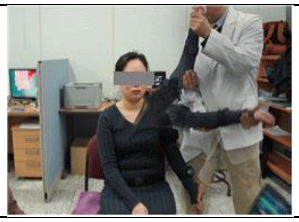
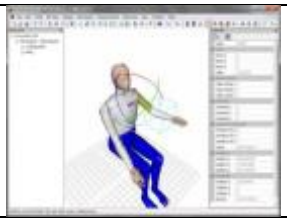
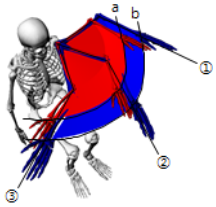
Use Process	Requirements for using a shoulder CPM device
Power on	- Power switch on main unit that is separate from receptacle power connection. - Location of the power switch should be easy to find. - The switch should be located in a position where it will not be pressed by mistake during exercise. - User should be able to check the power status.
↓	
Changing and fixing the positions of hands, arms, and shoulders	- Subject must be seated in the correct position. - Subject must be in the correct exercise position. - The device must be easily adjustable by non-powered users. - The user should be intuitively aware of the control method.
	- It should be easy to change the device to work on the left or right shoulders based on the user's requirements. - The device should be securely fixed to the body after the left and right shoulders are changed. - Arms and hand supports should be left-right compatible.
	- The user's shoulder and torso must be in close contact with the device. - It should be adjustable so that the shoulder axis height of the device and the shoulder axis height of the user are the same.
	- The length, position, and angle of the product must be adjustable to fit the user's dimensions such as arm length and hand size. - The user's arm and hand must be able to be stably mounted. - The device should be easy to mount and detach when fixing the mounted arm and hand.
↓	
Changing exercise settings	- The remote control should be positioned to allow easy movement in a seated position. - The user should be able to intuitively recognize the exercise setting method. - User should be able to set the exercise with one hand. - The user must be able to adjust the desired exercise settings.
↓	
Exercise	- User should be able to maintain correct posture during exercise. - Device should be fixed so that the user does not move the body parts not targeted while exercising. - The arms and hands of users with no arm or hand strength should be reliably held during exercise. - The user should be able to intuitively recognize how to start and stop the exercise. - The user should be able to easily start and stop the exercise. - The user should be able to understand current exercise settings.
↓	
Dismantling the device	- The user should be able to easily dismantle the fixture without hand power. - The user should be intuitively aware of the method of dismantling.
↓	

Power off	- Same as 'Power on' above

Work Space

Existing integral-type domestic shoulder CPM devices are designed to move arms completely forward or laterally (0°). A professor of physical therapy advised that, when exercising the arm, the arm should be able to move to + 30° forward and -30° lateral. According to a domestic hospital physiotherapist, detachable-type CPM devices allow adjustment of the angle of the arm during exercise, but the patient can change their body position. Thus, existing Korean shoulder CPM devices have limitations in achieving optimized and stable movement of a user's hands, arms, and shoulders during flexion-extension, adduction-abduction, and horizontal adduction-abduction exercises. To design a shoulder CPM device that overcomes these limitations, the authors considered the user's natural biomechanics (hand, arm, shoulder movement) in the work space.
Standard shoulder treatment exercises were recorded by MyoMotion using Noraxon's IMU sensor, as shown in Table 3. The data are reported in 'SizeKorea' which provides Korean body size data, arm length, upper arm length, and shoulder length data from the female 5th to the male 95th percentile of the Korean population (20 - 60 years). A human CAD simulation program and a 3D modeling program were used to simulate the motions associated with the three types of exercises using human body dimension data. Based on the simulation results, the authors derived length, angle, and range data for the hand, arm, and shoulder during these exercises (Kweon et. al., 2016).

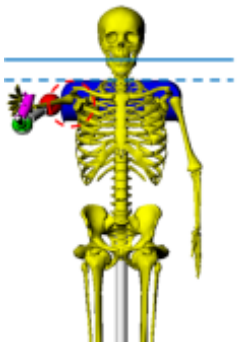
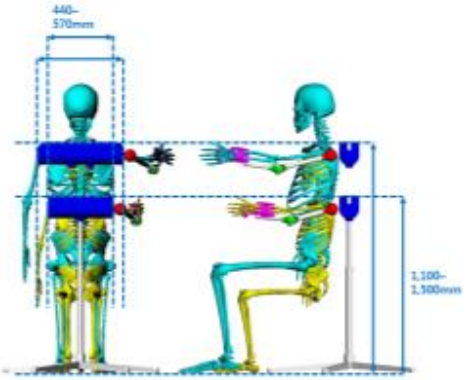
Table 3 : Three exercise simulations considering Korean body size

Procedure	1	2	3
Scenario			
Explanation	Record movement of hand, arm, and shoulder during active/ passive exercise using MyoMotion.	Human CAD simulation using Korean size data.	Simulation results: Simulation of angles, ranges, and lengths for three different exercises.

Based on the simulation results, a specialist review by a physiotherapy specialist was performed on the developed shoulder CPM prototype. The position, height, and length of the components of the shoulder CPM device that will allow for natural biomechanics are described below. The position of the shoulder CPM body should match the shoulder height of the user so that the user can lean against the CPM body, as shown in Table 4. This will ensure the correct posture and increase stability during exercises. The shoulder axis of the shoulder CPM should match the shoulder axis of the user. In flexion - extension and adduction - abduction exercises, the shoulder axis of the CPM should be located beside and behind the user's shoulders. For horizontal adduction - horizontal abduction exercises, the CPM device should be located above the shoulder.

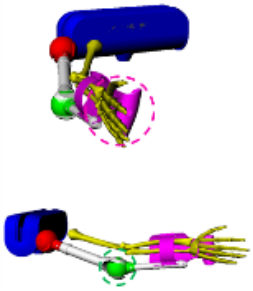
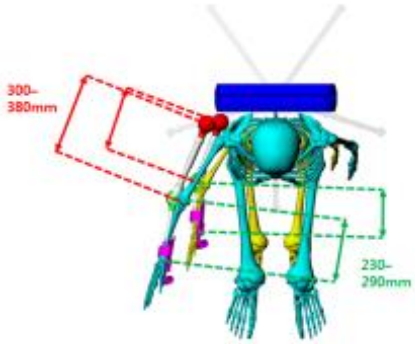
Table 4 : Position and height of the shoulder CPM device's body(Kweon et. al., 2016).

Position of shoulder CPM device body	**Height of shoulder CPM device body**

The user should position the arm to be exercised so that the arm and hand are placed on the shoulder CPM device, leaving the arm at + 30° from the front and -30° from the side, rather than completely at the front and side (0°), as shown in Table 5. The lower arm of the shoulder CPM device should be able to support the user's arm from underneath so that the user can mount his/her arm. The hand portion of the shoulder CPM device should be able to support the hand so that the user's palm direction is inside the user's body.

Table 5 : Arm and hand rest positions and lengths(Kweon et. al., 2016).

Position at rest	Length at rest
	

Usage Method

Consultation with a clinical specialist revealed that it is difficult for the user to assume the correct posture and operate the CPM device if the user has an unstable shoulder. At the hospital, a therapist is present for assistance, while at home, the help of a caregiver is required for correct posture and device settings for CPM device use. Table 6 below shows how to adjust the CPM device to ensure the correct posture and positioning.

Table 6 : How to fit shoulder CPM to user body size.

Adjustment portion	Adjust shoulder left and right positions	Adjust shoulder height	Adjust shoulder and elbow angles	Adjust arm and hand lengths

Picture				
Explanation	Turn hand and arm rest to left / right relative to the center axis	Electrically-powered height adjustment of CPM body	Adjust angle by rotating shoulder axis and elbow axis	1) Rotate the pipe connected to the hand and arm rest to unscrew 2) Pull to adjust the length

Exercise type, angle, time, and speed of our prototype shoulder CPM device can be set using the remote controller attached to the shoulder CPM device. In a hospital setting, a therapist will often use several exercise settings to accommodate a variety of patients. At home, one exercise setting can be used for the patient. Thus, 12 lists of 12 basic setting values are provided so that the user can select one to start the exercise or change the setting value. The function of the shoulder CPM remote control is shown in Table 7. Functions included in the remote control are based on review of the recommendations of a physical therapist and physical therapy professor.

Table 7 : Shoulder CPM device remote control function.

Title	Contents
Exercise	Provide 12 lists, start with 12 initial defaults 1) Display of exercise type: Display current exercise type 2) Display of exercise time: Display set time and current exercise time 3) Display of exercise speed: Display current exercise speed 4) Display the lowest angle of motion and wait time: Display the current angle to the lowest angle, display the set waiting time and current time at the lowest angle 5) Display the maximum angle of motion and waiting time: Current angle display to the highest angle, display setting waiting time and current time at the maximum angle
Setting the exercises	Provide 12 lists, choose one of the 12 factory defaults to change your workout settings 1) Selection of exercise type: Front, Side, Horizontal 2) Choice of exercise time: 1 - 90 minutes, 5 minutes can be selected, the default is 30 minutes 3) Select the speed of motion: Select 1 - 5 steps, default is 1 step (speed is 40 - 140 degrees per minute) 4) Minimum angle and waiting time selection: 0 - 180 degrees, 1 - 5 seconds (default value is 0 degrees, change by 5 degrees) 5) Select the maximum angle and waiting time: 0 - 180 degrees, 1 - 5 seconds (default is 120 degrees, change by 5 degrees)

The remote control, which provides a list of 12 preset values, is efficient in that the user does not have to change the type of exercise, time, speed, angle, and wait time each time they use it. This can be done once the user is in position to exercise; they then select the stored item.

Usability Evaluation of a Design Corresponding to IEC 62366 – Usability Validation

This chapter corresponds to the '5.9 Usability Validation' process of IEC 62366: 2007 + A1: 2014, Usability Engineering Process. The final phase of the usability engineering process is usability validation. Usability validation is performed to ensure that the right product is built. Validation is important for the user interface because unexpected interactions between the device and the user might occur that can only be discovered by validation.

User Interface Comparison

Usability evaluation of shoulder CPM devices was conducted using a standard product developed and used in Korea (hereinafter referred to as the E product) and a product developed by a medical device company and design specialization company in this study (hereinafter referred to as the J product). The purpose of the comparability usability evaluation was to investigate the learnability, effectiveness, efficiency, and satisfaction of the user interface of the shoulder CPM device (J product) under development compared with the existing shoulder CPM device (E product). As an off-the-shelf product, ARTUS-701ES, which is used as a standard device in university general hospitals in Korea and has a function similar to that of our device under development, was selected. A comparison of the characteristics of the user interfaces of the two products is provided in Table 8.

Table 8 : User Interface Comparison by Usage

	E product's user interface	**J product's user interface**
Use Process		
Power On	- Power on, located on the bottom right of the main body	- Power on, located on the back of the product.
↓		
Changing and fixing hands, arms, and shoulders	- To adjust the shoulder position, the user can 1) rotate the fixture and 2) move height of the body.	- Adjust the shoulder position by 1) pressing the upper and lower buttons on the back of the body
	- Elbow angle adjustment can be adjusted 1) lifting the fixing device, 2) adjusting the angle, and 3) lowering the fixing part	- Elbow angle adjustment can be adjected 1) releasing the fixing by rotating the fixing device, 2) adjusting the angle of the elbow, and 3) rotationg the fixing part
	- Upper arm lifts the fixing device, adjusts its length, and lowers the fixing part	- Adjustable length of the upper arm can adjust the length of the pipe after rotating.
	- Adjustable length of lower arm and hand fixation by rotating the fixing device	- Length of the lower arm can be adjusted by adjusting the length of the pipe after rotating.
	- Fix the hand and arm using Velcro attached to the pedestal	
↓		
Changing exercise settings	- It is possible to set exercise time, angle, speed, load, upper limit standby, and	- Using the remote control, the user can set the exercise mode, time, angle, speed, and

	lower limit standby by touching the screen of the remote controller (touch each item and change setting values by touching the arrow button)	upper/lower standby times. Twelve programs with default time, angle, and speed settings for the different exercise types are available. The user can select one of the 12 programs and edit it if desired
↓		
Exercise	- Start and stop motion by pressing the 'START' and 'STOP' buttons on the remote control, respectively.	
↓		
Dismantling of hands and arms	- Loosen and unfasten the Velcro attached to the pedestal.	
↓		
Power off	- Power off button located at the lower right of the main body	- Power off button positioned on the back of the main body

The overall process of use was the same for the two products. However, there were differences in the user interface between the two products with regard to location of the power source, how exercises are set with the remote control (in the E product, settings are changed by touching each item; in the J product, default setting values are selected and changed if desired), and how to adjust the shoulder, arm, and hand positions of the CPM device (E is adjusted by lifting or rotating the fixing part, while J is adjusted by rotating the fixing part).

Usability Evaluation Plan and Results

IEC 62366 defines usability as a characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction. In this study, the authors performed usability evaluation of effectiveness, efficiency, learnability, and satisfaction of shoulder CPM devices based on this definition. A summary of the usability evaluation is provided in Table 9.

Table 9 : Usability evaluation summary

Title	Contents
Object	Two shoulder CPM devices
Purpose	How do the learnability, effectiveness, efficiency and satisfaction with the user interface of the under-development CPM device (J product) compare to those of the existing shoulder CPM device (E product)?
Participants	20 people, 10 people per unit (10 men/10 women)
Items	- Experience in using similar products (rehabilitation devices) - Time required to learn how to use the product before the assignment - Success/failure of task: Success (100 points), partial success (75 points, 50 points), failure (0 points) (Tom Tullis, 2008; Jeon, 2011) - Evaluation of task error level: Identify the extent to which participants are affected by error factors in performing the task and list the error factors found during the task - Product satisfaction assessment: Satisfaction assessment using the System Usability Scale (SUS, Usability.gov)
Procedure	- Pre-interview with orientation - Explanation of shoulder CPM product - Learn how to use the product - Perform the task - Determine task error evaluation level and evaluate product satisfaction - Post-interview

Analysis method	- Independent sample T-test of learning time, success, and satisfaction - Analysis of project error level evaluation

The results of usability evaluation performed according to the above usability evaluation plan are shown in Tables 10 and 11.

Table 10 : Comparison of learning time, success score, and satisfaction between the two CPM devices.

Time required to learn to use the product(secconds)		**E product**	**J product**
Collective statistics	Mean	789.777	436.876
	SD	234.6257	193.4409
	N	10	10
Independent sample t-test for calculation of the mean	Df		18
	t-statistics		-3.66991
	P(T<=t) two-sided test		0.001752
	two-sided t set by t critical value		2.100922
Task success score		**E product**	**J product**
Collective statistics	Mean	91.87500	83.75000
	SD	7.246886	11.85854
	N	10	10
Independent sample t-test for calculation of the mean	Df		18
	t-statistics		-1.84878
	P(T<=t) two-sided test		0.080985
	two-sided t set by t critical value		2.100922
Satisfaction		**E product**	**J product**
Collective statistics	Mean	62	65.5
	SD	11.89071	19.78355
	N	10	10
Independent sample t-test for calculation of the mean	Df		18
	t-statistics		0.479507
	P(T<=t) two-sided test		0.637352
	two-sided t set by t critical value		2.100922

There was a statistically significant difference in learning time for the E and J products (p <.05); users learned how to use the J product faster than the E product. The difference in learning time between the two groups is likely due to the learnability of the control method for position, angle, and length in the J product. The E product needed a longer average learning time because the majority of subjects did not intuitively know how to adjust height, length, and angle, and the control method was not consistent. Furthermore, even knowing how to use the product, it was often not possible to produce a smooth adjustment. Therefore, the control method of J product is more intuitive, easy to understand, and consistent than that of the E product.

There was no statistically significant difference in the task success of the two products (p> .05). This suggests that there is no difference in the ability of existing product E and the developed product J to perform their basic functions. This can be interpreted to mean that there is no difference between the two products in basic power on, off, and device adjustment according to body dimensions or change of motion set-up to drive shoulder CPM.

There was also no statistically significant difference in user satisfaction between the two products ($p > .05$). Subjects were unfamiliar with the rehabilitation equipment that they were using, and neither of the products received high satisfaction scores.
The extent to which error factors affected the performance of the task was assessed. The authors did not set a limit on the number of errors and measured the error level from a low of 0.2 points to a high of 1 point according to Jeon(2011). Table 11 shows the factors that had the highest redundancies among the error factors listed for each product.
Common errors in both E and J products included difficulty in adjusting and manipulating shoulder height. The E product required a lot of power to adjust the shoulder height. The J product required that the shoulder position be ascertained while the operating part was positioned behind the device, and that the shoulder height be adjusted when in a standing position.

Table 11 : List of two product use error factors * Low: 0.2 points to high: 1 point.

E Product	Duplicate count	Average	J Product	Duplicate count	Average
Inconvenient shoulder height manipulation (forceful)	9	0.73	Inconvenient shoulder elevation manipulation (operating part is located behind the machine)	6	0.70
Device and chair interference	9	0.73	Difficult to judge proper posture and setting for treatment	6	0.57
Discomfort of elbow angle adjustment	9	0.69	Discomfort of arm fixation device	6	0.57

For the J product, it was difficult to judge the proper posture and settings for treatment, and the inconvenience of the upper arm/lower arm fixing device had reported. In the case of the J product, length and angle should be adjusted freely, not on a step-wise basis. This is difficult for novice users who do not have enough information about suitable positions for treatment; setting the correct value is therefore difficult. In the case of product E, the value can be set within a range as shown in steps 3 and 4. This appeared to be easier for novice users. However, to satisfy both novice users and professional users who might require a more nuanced configuration, the set-value step should be taken into account. Furthermore, for the J product, to adjust the lengths of the upper and lower arms, two pipes must be fixed by turning them. Several users found that this was inconvenient because fixation between the two pipes was not ensured.
For the E product, interference with the device's work space by the chair and an inconvenient elbow angle adjustment method caused many errors. For the elbow angle adjustment, difficulty was encountered because users were not familiar with how to lift the adjustment device. Finer angle adjustment is also required; the adjustable elbow angle did not provide the proper angle for treatment.

Conclusions

This study used the usability engineering process of IEC 62366 to evaluate the usability of a prototype shoulder CPM device. The authors found that the usability of the developed product was better or equivalent as that of a commercially-available standard product. Our study findings and recommendations can be summarized as follows.

(1) The authors developed a shoulder CPM device by collaboration with a medical device company, design company, and university. In general, the level of usability of an end product relies on all parties involved in development recognizing the importance of usability. Based on the usability engineering process in IEC 62366, the importance of usability should be kept in mind throughout the whole development process, from planning to design and manufacturing.
(2) The authors defined the workspace as a design study method, which is not mentioned in IEC 62366. Through this process, the authors were able to optimize the device to perform rehabilitation exercises. There were fewer errors associated with the severity (frequency of reporting and severity score) of interference with the device's work space and chair during exercise after using optimized exercise settings for the prototype product than the reference product. This means that the designer must consider the context of use based on the use scenarios.
(3) In addition, because the prototype product is designed to be used both in a clinical setting and at home, users will range from experts users to novice. Medical devices are usually used by medical personnel, but this product can be used by the general public who do not have rehabilitation knowledge. Therefore, consideration of use by novices is an important for user interface design. It is also important that the device is able to be operated quickly and accurately, but it is critical that the user interface is designed using easy-to-understand terminology that it is intuitive to use with a consistent operation method. Also, the device should be adjustable without the much power.

In IEC 62366 declare the methods and process of design researches for enhacing usability related safety. But IEC 62366 does not include guideline in detail for designer and design researcher. Therefore this study can be used as an example to guide for development of medical device, especially rehabilitation device.

References

[1] Chae, H. (2015). Understand medical device usability standards and analyze domestic countermeasures. *Korea Health Industry Development Institute Brief, 4.*
[2] IEC(International Electrotechnical Commission). (2014). IEC 62366:2007+AMD1:2014, Medical devices - Application of usability engineering to medical devices.
[3] Jeon, M. (2011). UI Usability Test Practice, Korea:Mentor.
[4] Jung, I. (2014). The Effects of CPM(Continuous Passive Motion) on Hand Function and Muscular Strength for Patients with Stroke. *Therapeutic Science for Neurorehabilitation, 3(2).*
[5] Kim. C., Woo. H., Kwon. O., & Cho. J. (2013). Shoulder Motion Analysis for Design of Upper Rehabilitation Robot. *RESKO Technical Conference 2013,* 232-233.
[6] Kweon, O., Lee, B., Kim, A., & Kim, S. (2016). A Study on Shoulder CPM Design Guideline Considering Body Size of Korean. *The Journal of Korean Society of Design Culture, 22(2),* 39-49.
[7] Lee, B., Kweon, O., Kim, A., & Kim, S. (2017). A Case Study on the Usability Evaluation of Shoulder CPM for Patients Who Need Upper Rehabilitation. *The Journal of Korean Society of Design Culture, 23(1).*
[8] Muscolino, J. E. (2011). Know the Body: Muscle, Bone, and Palpation Essentials 1st Edition, USA:Mosby.
[9] Tullis, T., Bill, A. (2008). Measuring the User Experience, USA: Elsevier Science Ltd.
[10] Usability.gov. Retrieved from http://www.usability.gov/how-to-and-tools/method/system-usability-scale.html.

Author Biography

Agnes Jihae Kim

Agnes Jihae Kim is a second-year Ph.D. student with particular interests in usability, user interface design of products for people with physical disability. She is supported by Global Ph.D. Fellowship from NRF(National Research Foundation of Korea) Grant funded by the Korean Government. She holds a Masters degree in industrial design from Yonsei University(2016), Bachelor of Science degree in industrial design and Bachelor of Interdisciplinary Studies degree in interdisciplinary major of cognitive science from Yonsei University(2014).

Prof. O Seong Kweon

O Seong Kweon is a professor and Head of design and arts at Yonsei University in Korea. He received his Bachelor of Science degree in Industrial Engineering from Hanyang University (1988) in Korea and his Master (1992) and Ph.D. (1994) in Ergonomics from University of Oklahoma, USA. He worked at the LG Electronics Engineering Institute and the Design Research Center, and was the Director of human interface group of the mobile phone division. His research interests are ergonomics, user interface, and universal design.

Prof. Byeong-Jong Lee

Lee, Byeong-Jong is a professor at division of design and art, Yonsei University. He received his Bachelor of Science degree in Mechanical Design from Seoul National University (1988) and his Diplom-Designer from Hochschule fuer Bildende Kuenste(HBK) Braunschweig (1995). Since 1996 he had worked as a professor at Korean Advanced Institute of Science and Technology(KAIST). Since 2003 he has set up a department of Industrial Design at Yonsei University. His research interests are Design Engineering, Social Design and Design History.