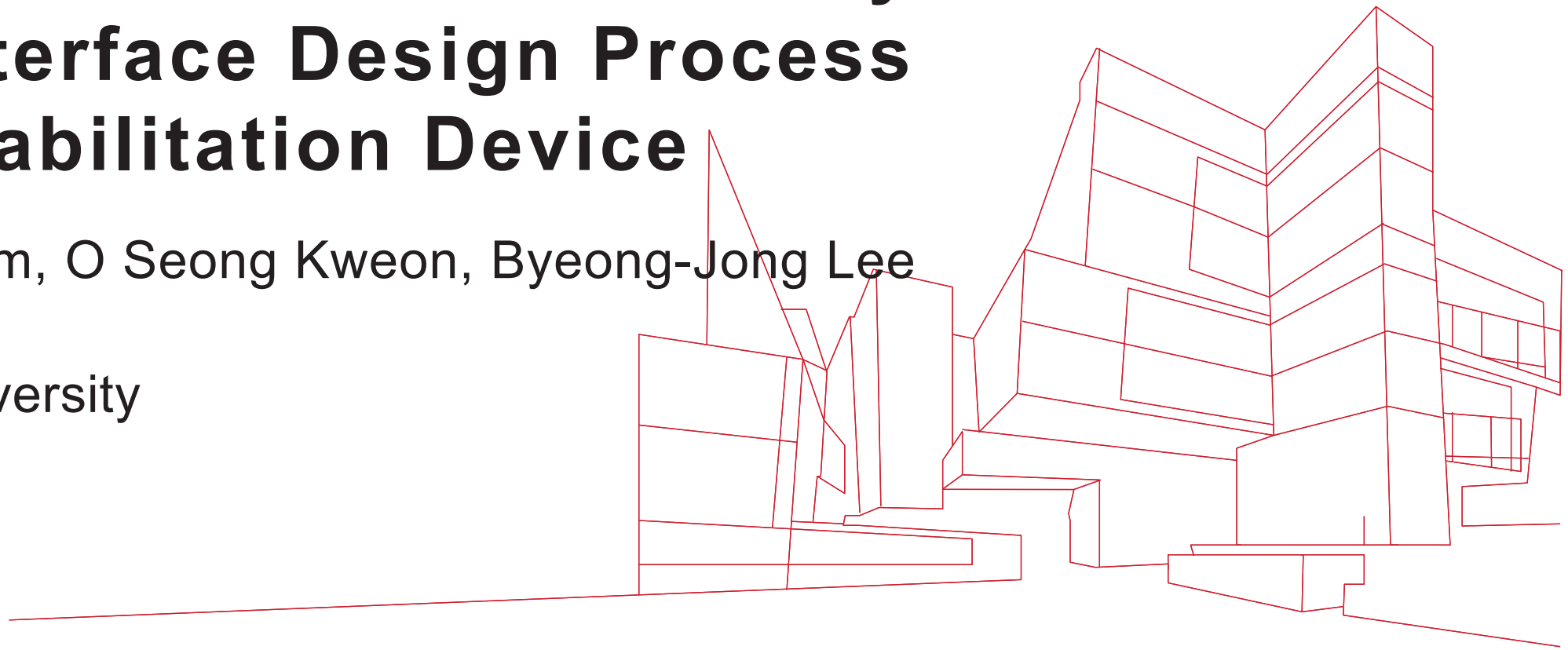
Wonju, Republic of Korea

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

Agnes Jihae Kim, O Seong Kweon, Byeong-Jong Lee

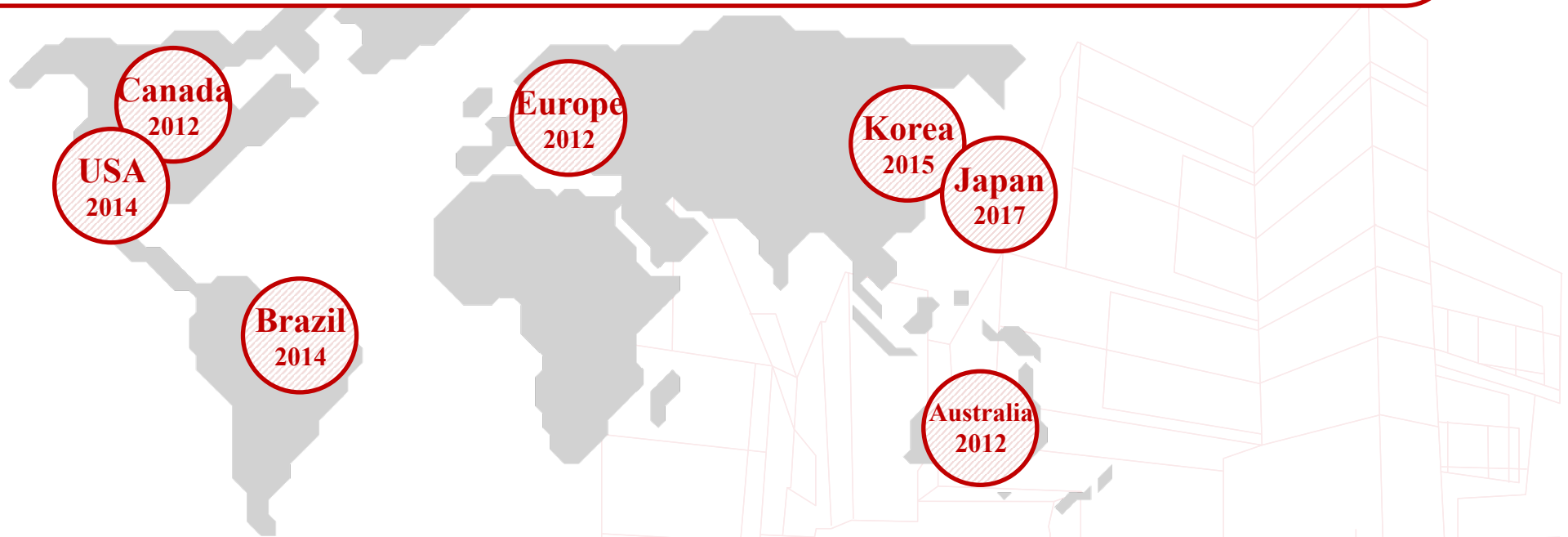
Yonsei University



Introduction

IEC 60601-1, 3rd Edition for Medical Electrical Equipment

The **manufacturer** shall address in a usability engineering process **the risk of poor usability**, including those associated with identification, marking and documents.*



Mandatory Adoption

* IEC60601-1

Introduction

IEC 62366

‘IEC (International Electronical Committee) 62366:2007+AMD1:2014,
Medical devices – Application of usability engineering to medical devices.’

Usability Engineering Process

assesses and mitigates risks caused by usability problems associated with correct use and use errors.
The usability engineering process is intended to achieve reasonable usability, which in turn is intended to minimize use error and to minimize use-associated risks.

Introduction

Shoulder CPM

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.

OptiFlex Sholuder CPM

Kintec Centura Anatomical Shoulder CPM Machine

Eugene Medical ARTUS-701S

Chattanooga Artomot S3 Shoulder CPM

Introduction

"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."

Methods and Scopes

To enhance the usability of the entire development process for a shoulder CPM device, the authors

1) performed user research to determine design requirements
   - Requirements by Use Process
   - Work Space
   - Usage method

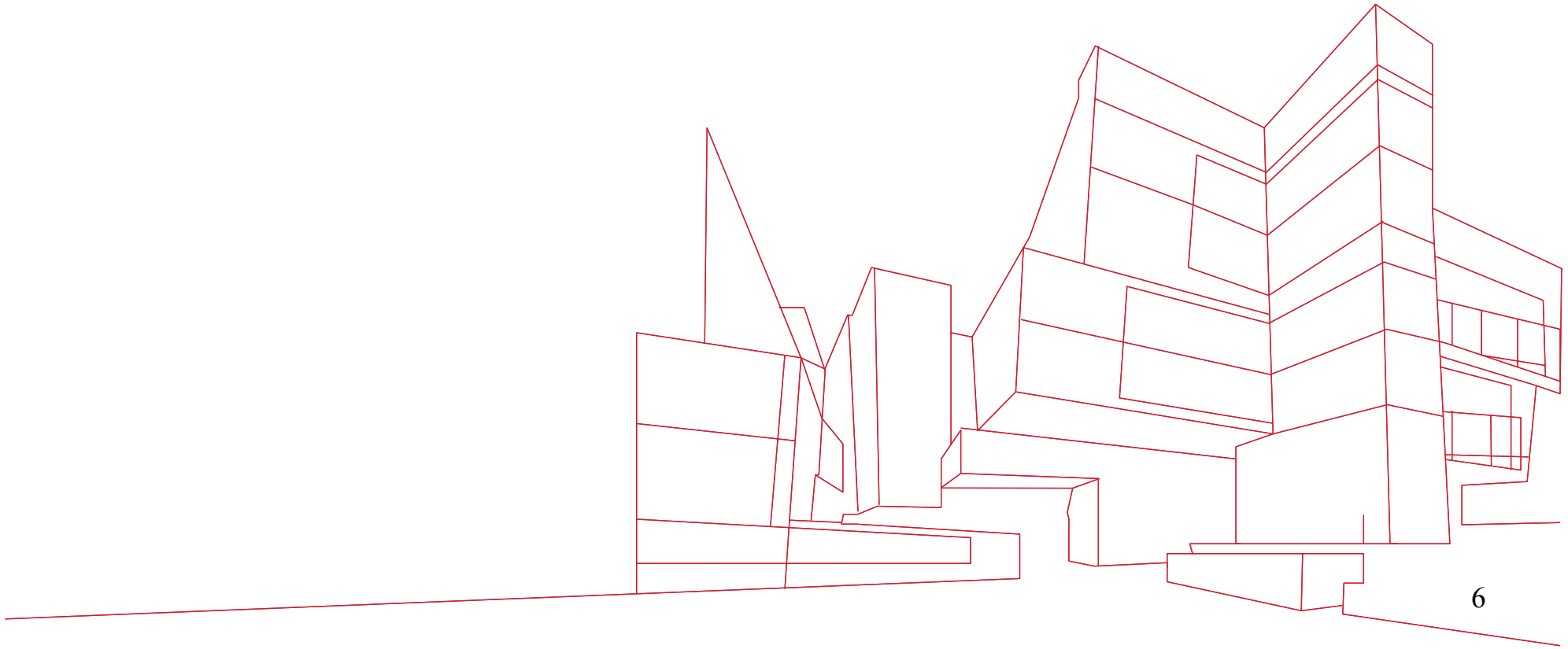
2) evaluated the usability of the device
   - Usability evaluation

Table D.2 – Mapping of Figure D.1 to the subclauses of this International Standard

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 **1**	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 **2**	5.8 USABILITY VERIFICATION 5.9 USABILITY VALIDATION 5.3.2 Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS

Table from IEC 62366

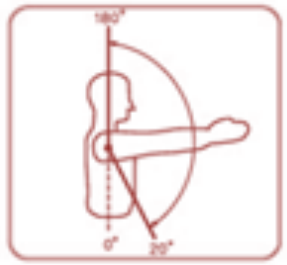
User Research into Design Requirements corresponding to IEC 62366 – Usability Specification



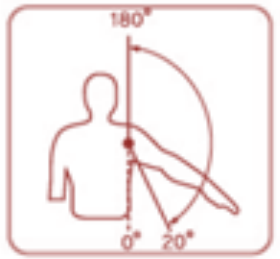
‘Requirements by Use Process’ correspond to ‘Usability Specifications’ in IEC 62366

the development of a shoulder CPM device **for hospital and home use** should fulfill the following safety and usability criteria

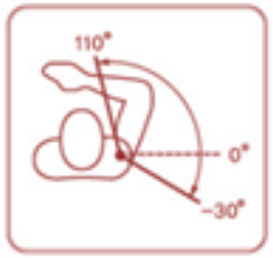
1) For patients who need to continue passive shoulder treatment at home
2) Maintain **a stable posture** during the exercise
3) Perform three movements: flexion - extension, adduction - abduction, and horizontal adduction - abduction



Flexion - extension



Adduction-abduction



Horizontal adduction-abduction

4) Take into account a patient's **natural biomechanics** during exercise
5) The **correct posture** without the help of a specialist
6) Use the device **intuitively and stably** without the help of a physiotherapist

‘Requirements by Use Process’ correspond to ‘Usability Specifications’ in IEC 62366

1. Power On → 2. Changing and Fixing → 3. Setting → 4. Exercise → 5. Dismantling → 6. Power Off

Subject must be seated in the correct position
The user’s shoulder and torso must be in close contact with the device

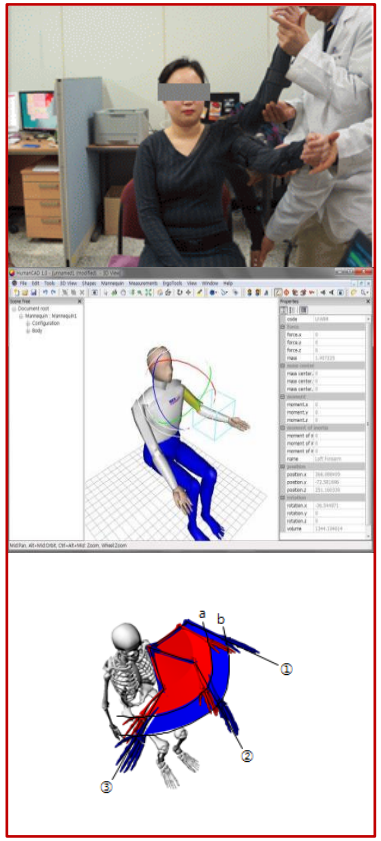
Arms and hand supports should be left-right compatible
It should be easy to change the device to work on the left or right

The arm and the hand must be fixed

Must be adjustable to fit user’s body size
The device must be easily adjustable by non-powered users
The user should be intuitively aware of the control method

‘Work Space’ correspond to ‘Usability Specifications’ in IEC 62366

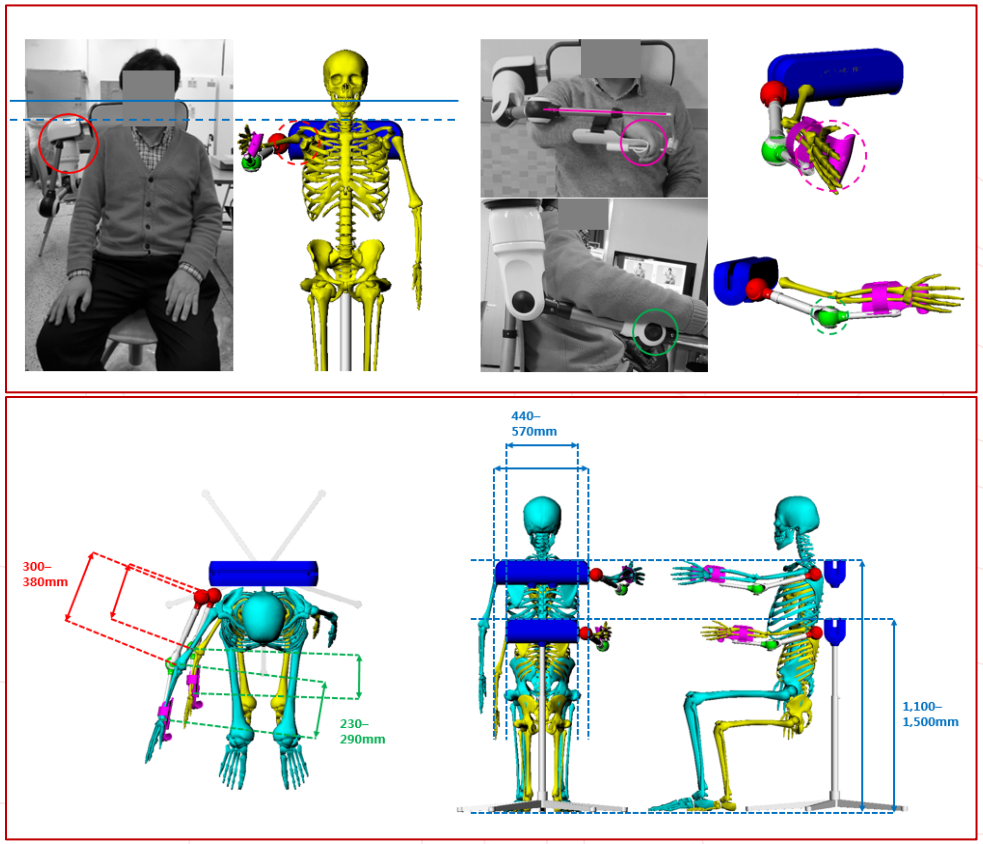
Existing Standard shoulder CPM devices have limitations in achieving optimized and stable movement of a user’s hands, arms, and shoulder.



1 Record movement during active/ passive exercise using MyoMotion.

2 HumanCAD simulation using Korean size data

3 Simulation of angles, ranges, and lengths for three different exercise.



‘Usage Method’ correspond to ‘Usability Specifications’ in IEC 62366

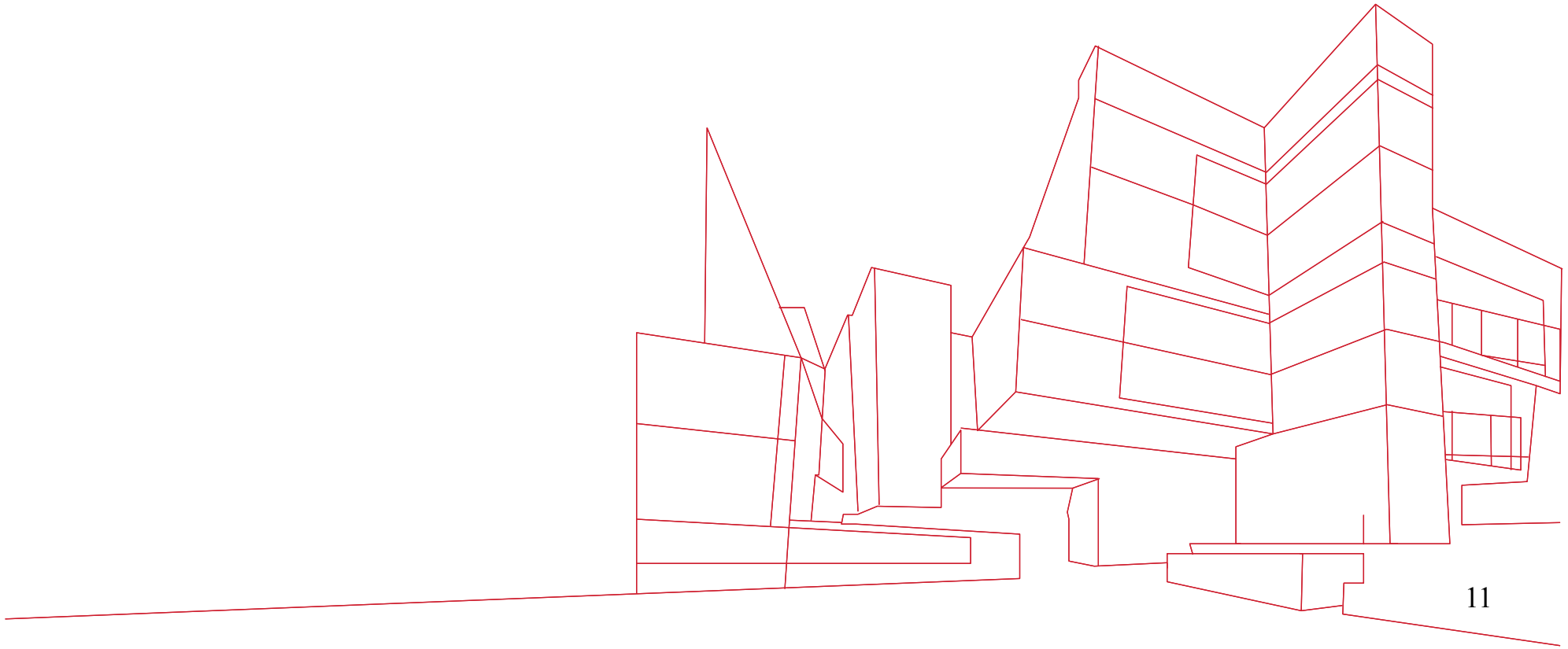
Shoulder CPM devices

Adjustment portion	Shoulder left and right positions	Shoulder height
Picture		
Explanation	**Turn** hand and arm rest to left/ right relative to the center axis	**Electrically**-powered height adjustment of CPM body
Adjustment portion	**Shoulder and elbow angles**	**Arm and hand lengths**
Picture		
Explanation	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

Remote control

Title	Contents
Exercise	Provide 12 lists, start with 12 initial defaults 1) Display current exercise **type** 2) Display set time and current exercise **time** 3) Display current exercise **speed** 4) Display the current angle to **the lowest angle**, display the set waiting time and current time at the lowest angle 5) Display current angle 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)

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



Usability Evaluation Plan

Before

After

Usability Evaluation Plan

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 (after) compare to those of the existing standard shoulder CPM device (before)?
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

Result

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

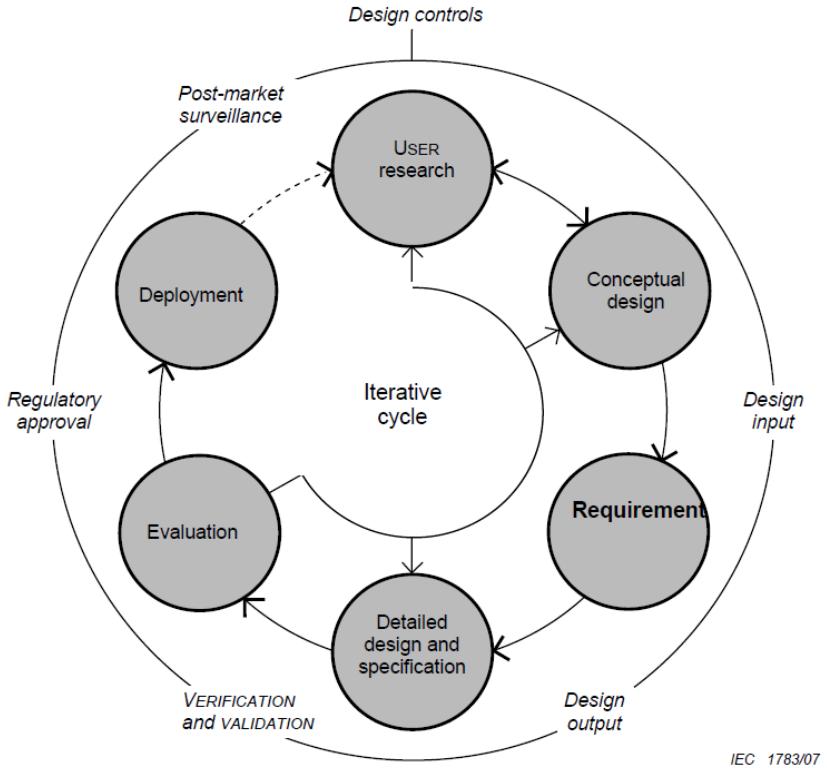
Time required to learn to use the product(seconds)		Before	After
Collective statistics	Mean	789.777	436.876
	SD	234.6257	193.4409
	N	10	10
Independent sample t-test for calculation of the mean	Df		18
	t-statistics		-3.66991
	P(T<=t) two-sided test		**0.001752**
	two-sided t set by t critical value		2.100922
Task success score		**Before**	**After**
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		**Before**	**After**
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

Result

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

Before	Duplicate count	Average	After	Duplicate count	Average
Inconvenient shoulder heigh t 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

Conclusion



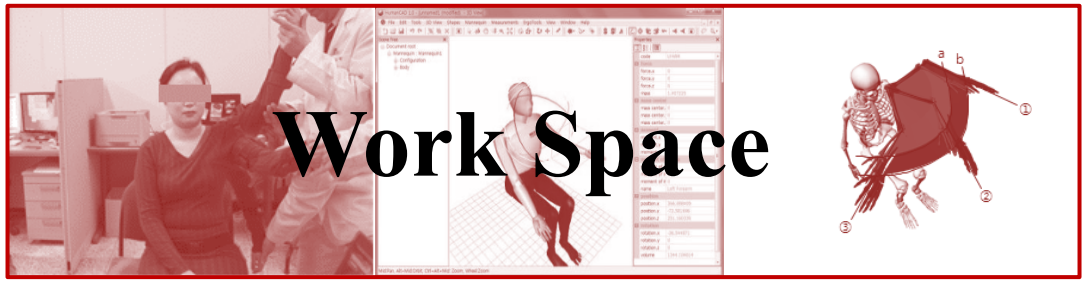
A user interface design cycle in IEC 62366

IEC 62366

Organizations participating in the project

"The level of usability of an end product relies on all parties involved in development recognizing the importance of usability. "

Conclusion



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

Conclusion

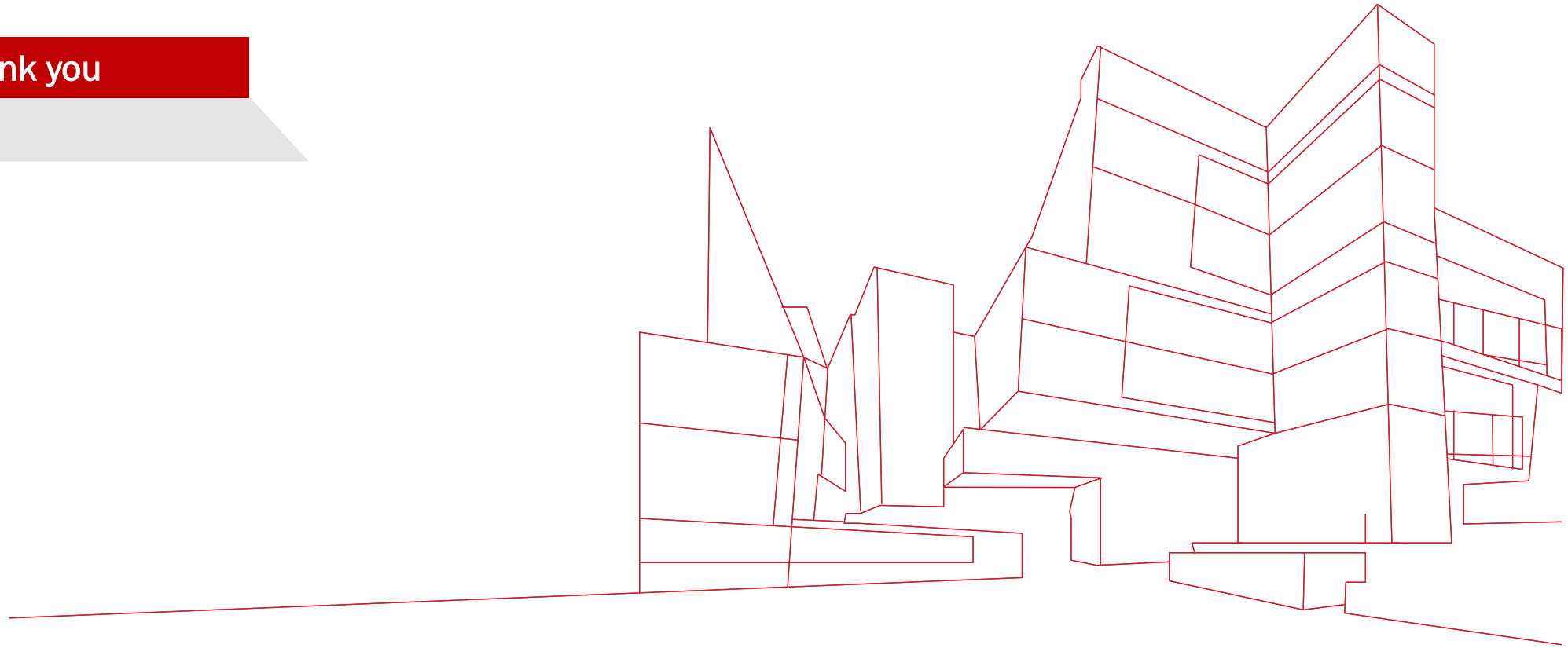
Novice

Expert

Easy to understand & Intuitive use with consistency

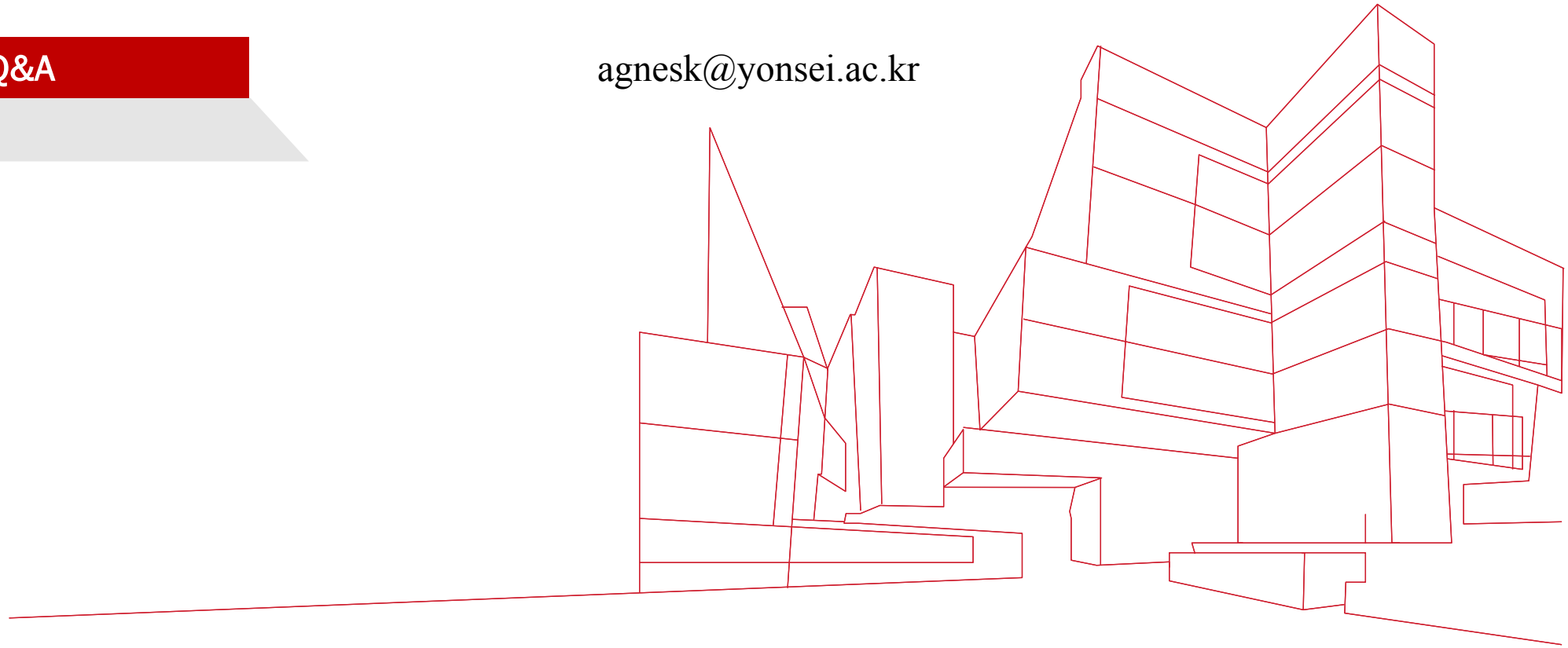
In IEC 62366 declare the methods and process of design researches for enhancing usability related safety.
But IEC 62366 does not include guideline in detail for designer and design researcher.
Therefore this study can be used as an example to guide for development of medical device, especially rehabilitation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

Thank you



Q&A

agnesk@yonsei.ac.kr



Usability

Usability is characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction*.

Effectiveness is describe as the accuracy and completeness with which users of a particular product accomplish specified goals in a particular environment**.

Efficiency signifies the accuracy and completeness of goals accomplished in relation to the cost expended with regard to the user's effort and time**.

Satisfaction is the consumer perceived comfort and acceptability with use of the product**.

* - International Electrotechnical Commission. (2014). IEC 62366: 2007+A1:2014 Medical devices–Application of usability engineering to medical devices. Geneva.
** ISO9241-11. Ergonomics Requirements for Office Work with Visual Display Terminals (VDTs) – Part II Guidance on Usability, International Organization for Standardization, 1998, Geneva.