Usability testing on developed FES device according to the operator perspective

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Abstract. The post-paralysis due to stroke, spinal cord injury or musculoskeletal disorder can be restored by rehabilitation. A popular rehabilitation method used today are physiotherapy and therapy using electrical stimulation. Functional Electrical Stimulation (FES) is one of the methods of rehabilitation using electrical stimuli, and has been proven to be effective enough to restore muscle function that is weakened due to paralysis. Nowadays, FES devices on the market are designed to rehabilitate only one type of movement and not yet applied wearable and ergonomics design. Meanwhile, the FES devices developed by the laboratory has applied a wearable design and has been able to rehabilitate several movements at once, but not yet for ergonomics design. This study developed a usability instrument and do the usability evaluation for the FES medical devices which is rehabilitate multiple movements on the upper limb. The usability variables chosen for the usability evaluation are simplicity, learnability, memorability, informativeness, and trust ability. Usability evaluation is carried out by distributing questionnaires. Data obtained from the propagation of the questionnaire are processed by statistic method such as average value and standard deviation. The results indicate that the simplicity, learnability, and memorability variables were well applied to the developed FES devices. While the variables informativeness and trust ability dimension are still not properly applied to developed FES devices.

1. Introduction

Stroke is a disease that affects many people in the world, especially in large urban areas. This disease is characterized by brain tissue death caused by reduced blood flow and oxygen to the brain due to blockages, narrowing, or rupture of blood vessels [1]. After the patient recovered from stroke, the joints in the paralyzed limbs become more rigid. Spinal cord injury or spinal cord damage can cause sufferers to experience stiffness in some parts of the body due to pain caused by spinal cord damage. Through research that has been done, one way to rehabilitate patients after stroke and spinal cord injury is the Physiotherapy method. Nowadays, technology has developed so rapidly that physiotherapy no longer has to be done with the help of other humans, but instead uses a method called Functional Electrical Stimulation (FES). The FES rehabilitation method is carried out by providing electrical stimulation to the muscles through the skin, so that the stimulated muscles can contract and cause movement of the joints.

Some of the consequences of a stroke that attacks the upper limb of the human body cause weakness or paralysis that occurs in wrist movements such as twisting and swinging, finger movements, elbow joint movements, and also in the shoulder joints [2]. Rehabilitation using the FES method in several previous studies has been proven to reduce joint stiffness and increase muscle strength of limbs in post stroke patients [2].

There are several researches about FES devices that are conducted by researcher from Institut Teknologi Sepuluh Nopember Surabaya, Indonesia. First research started by Arifin which make a low cost joint angle sensor for measurement movement using gyroscope sensor, accelerometer sensor, and Kalman filter. [3] At 2015, that research developed by Fauzan to redesign the device produce from the Arifin research [3] using wearable design [4]. At 2016, The research was continues by Erwin, which...
did an experimental study to use the wearable design to rehabilitate elbow joint, and wrist joint using PID controller [5], and Stanley, which did an experimental study to use the wearable design to rehabilitate knee joint using fuzzy logic with cycle to cycle controller [6]. Latest the research developed by Kevin by redesign of the wearable device by applying the ergonomics design [7].

Usability is a science related to human interaction with technology, both computers and machines, or it can be said that knowledge is related to the user interface and user experience. Usability also is an important factor to make a successful product [8]. Evaluation of usability in the field of medical equipment itself has not been done much as a result, there are many of the medical equipment that can give bad perception in patients who want to use it and also caused unconfident on operators while operating the medical device, especially FES device.

2. Methodology

This research aims to design a usability instrument and make a measurement tools that can be used to evaluate the FES medical devices and also conduct a usability evaluation for the FES device that used to rehabilitate multiple movement on the upper limb that were designed by Kevin [7] as shown on Figure 1 until Figure 6. Figure 1 and Figure 2 shown the Position Module (PM) which is place on both left and right side on palm, lower arm, and upper arm as shown in Figure 5. This module has a function to read the movement of the arm. Figure 3 shown the Central Processing Module (CPM) main unit of this device, function to process the data read by PM and combine with the parameters input from the Remote Module (RM) to calculate the right coefficient of the controller used. Figure 4 shown the RM which is the operator use to input the parameter for the rehabilitation session. Both CPM and RM place on the back of the jacket shown in Figure 6.

![Figure 1. Position module upper side.](image1)

![Figure 2. Position module lower side.](image2)

![Figure 3. Central processing module place on the back of the jacket.](image3)

![Figure 4. Remote module for input the parameters of the rehabilitation.](image4)
Figure 5. Front of the device when put on.  
Figure 6. Back of the device when put on.

2.1. Literature Study
Literature study conducted by find out what is usability, what is the function, how to conduct the research, how to do data retrieval, and also how to process the data and make the conclusion. This phase help to make a way of thinking to make the initial dimension and criteria. The subject was the student of the biomedical engineering from Institut Teknologi Sepuluh Nopember Surabaya, which concentration is the rehabilitation, so the student has the basic to become an engineer to design a medical device, and also to operate it.

2.2. Design of Usability Measurement
The design of the usability measurement tool is done by sampling the example of the usability dimension used in the previous journal which performs the usability evaluation on electronic equipment, and medical equipment to determine the dimension of suitable usability to evaluate the FES medical device.

2.3 Design a Questionnaire and Data Retrieval
Questionnaire question design was conducted by taking references from several previous journals on questionnaire questions that could be proposed for medical devices in both hospital, operator, and patient perspectives. The questionnaire on this study was intended for medical equipment operators, so that it could support the purpose of this research to evaluate the usability of the medical equipment made against the operator's perspective.

Data retrieval for the evaluation of usability is done by requesting the respondent to operate the created FES device. Once the respondent has finished operating the created FES device, the respondent will be asked to fill out the questionnaire sheet that was created in the previous step.

2.4 Data Analysis
The data obtained is then analysis to be processed and evaluated with statistical tools on every aspect of the usability used. The processing of data used to process the data of the questionnaire obtained is the average and standard deviation on the respective variable of the usability dimension that is used to produce an evaluation of the usability that can be used to assess the FES device developed by Kevin [7].

3. Result
3.1 Usability Tool Measurement
Usability dimension in this study, determined by consideration of several aspects, including aspects of medical devices, medical, and electronic equipment. On a journal written by Marko Yilikulju [9], the standard of medical devices is for the evaluation of the ability, requiring at least 5 major dimensions.
According to specialist Jeff Rubin and the Chisnell Fund on the journal, a product that can be used has a dimension of efficient (efficiency), effective (effectiveness), satisfaction (satisfaction), can be learned (learnability), and accessible (accessibility). While according to the specialist Jakob Nielsen, also on the same source of journal, defines five dimensions of the most important usability, among them can be learned (learnability), efficient (efficiency), can remember (memorability), errors (and satisfaction). On other journal written by Whitney Quesenberry [10], determination of the dimension of usability for a medical product, also used the dimension mentioned by Jeff Rubin, and the Chisnell fund. Meanwhile, on the journal written by Jongseo Kim, and Sung H. Han [8], a good electronic product, has a dimension of simplicity, consistency, accessibility, error prevention, learnability, and efficiency. In a book titled "Usability Testing of Medical devices" written by Michael Wiklund, Jonathan Kendler, and Allison Strochlic [11], it is mentioned that the most important criterion of a medical device is informative and trustworthy (trustable).

Based on the reference, the selected dimension of the usability in this study are simplicity, learnability, memorability, informativeness, and trust ability. Determining the dimension of this usability is based on a number of considerations, such as an efficient and effective product is a simple product, so the chosen dimension of simplicity as an alternative, then dimension of learnability and memorability in the select as it reflects the resulting device. Because the FES device is an electronic device and also a medical device, it is mandatory to be trusted and has clear and easy to understand information, so that the dimension informativeness in select. While the dimension of confidence in the evaluation of usability is still not found, so this research proposes the name trust ability as a new dimension of usability reflecting an evaluation for medical devices that is very important. In the Table 1 are outlined the five dimensions of the usability used along with their respective definitions.

### Table 1. Usability dimension used with its definition.

| No | Usability Dimension | Description |
|----|---------------------|-------------|
| 1  | Simplicity          | User interface and method of interaction of a product should be simple, clear, and identifiable intuitively |
| 2  | Learnability        | The effort required to learn the user interface and interaction methods should be small |
| 3  | Memorability        | User interface and interaction methods should be easy to remember |
| 4  | Informativeness      | User interface presented to the user should be easy and clear to understand |
| 5  | Trustability        | User's ability to trust and want to use products that have been made |

### 3.2 Usability Dimension Variable

Usability dimension variables are a development of the usability dimension used so that a bullet point can be used as an indicator to determine the questionnaire question. The main purpose of variable dimension is to find out if each of the selected dimension that is selected has an attachment to the usability evaluation.

The first dimension is simplicity, with three pieces of variable of usability dimension, i.e. the number of cables, the number of buttons, and the ease to wear. The simplicity dimension variable can be seen in Table 2. In the number of cables variable, it is selected to explain whether the number of cable connections used complicate the operator in the device installation. In the variable number of buttons, explain whether the number of buttons used already represents all the functions contained in the device and has made it easier for operators to operate. While the variables are easy to apply, explain the level of ease of device to wear to the patient by the operator.
### Table 2. Usability dimension of simplicity variable.

| Usability Dimension | Code | Usability Dimension Variable | Description |
|---------------------|------|------------------------------|-------------|
| Simplicity          | B1   | Number of cables             | The number of cable connections used on the device |
|                     | B2   | Number of buttons            | Number of buttons already represent function |
|                     | B3   | Ease to use                  | Easy device to be worn by the operator to the patient |

The second dimension of usability is learnability, with variables of usability dimension are two pieces, i.e. operator duration to recognize the function and operator duration to recognize the placement. Both variables are selected to determine how easily the FES device was studied by the operator, both from the function side and on the laying side. This dimension represents the convenience of the device to learn. The learnability dimension usability can be seen in Table 3.

### Table 3. Usability dimension of the learnability variable.

| Usability Dimension | Code | Usability Dimension Variable | Description |
|---------------------|------|------------------------------|-------------|
| Learnability        | C1   | Operator duration to recognize the function | Duration required by the operator to recognize the function and button of each module |
|                     | C2   | Operator duration to recognize placements | Duration required by the operator to recognize the placement of each module |

The third variable of usability dimension is memorability, with two pieces variables, i.e. how often the operator sees the manual book to find an explanation of the function, and how often the operator sees the manual book to find an explanation of the placement and installation steps of the device to the patient's body. This dimension represents that the resulting device is easy to remember, so it does not make it difficult for the operator to operate and pair the device. Usability dimension variable memorability can be seen in Table 4.

The fourth variable of usability dimension is informativeness with variables of the ease of UI to understand, and the feedback from the UI. This variable is more directed towards the UI, where the UI is focused to facilitate the operator while operating the device. Informativeness dimension variables can be seen in Table 5.

The fifth variable of usability dimension is trust ability with variable of two pieces, i.e. the operator’s trust to try the device for first time, and the operator's desire to operate the device again. These two variables are chosen to meet the trust ability dimension criteria, where trust is the main benchmark in the use of medical devices. Both variables also represent the research objectives at the patient's confidence level of the FES device. Trust ability dimension variables can be seen in Table 6.

### Table 4. Usability dimension of memorability variable.

| Usability Dimension | Code | Usability Dimension Variable | Description |
|---------------------|------|------------------------------|-------------|
| Memorability        | D1   | How often the operator sees the manual book to find an explanation of the function | How often the operator opens the manual book to learn the function of buttons and function modules |
|                     | D2   | How often the operator sees the manual book to find an explanation of the placement and installation steps of the device to the patient's body | How often an operator opens a manual book to learn placements and how to install devices |
Table 5. Usability dimension of informativeness variable.

| Usability Dimension | Code | Usability Dimension Variable | Description |
|---------------------|------|------------------------------|-------------|
| Informativeness     | E1   | Ease of UI to understand     | Ease of use of UI to be understood by the operator |
|                     | E2   | Feedback from the UI         | The UI used has good feedback, making it easier for operators to operate the device |

Table 6. Usability dimension of trust ability variable.

| Usability Dimension | Code | Usability Dimension Variable | Description |
|---------------------|------|------------------------------|-------------|
| Trustability        | F1   | Operator’s trust to try the device for first time | Operator’s trust to operate the FES device on first-time trial |
|                     | F2   | Operator’s desire to operate the device again | Operator's desire to operate the FES device again in the future |

3.3 Questionnaire Design
The question drafting for the evaluation questionnaire is done by developing a variable of the usability dimension that has been determined, so that it becomes a form of question with a scaling method of 1 to 5 that is presented with a highly disagreed, disagreed, normal, agreed, and highly agreed.

3.4 Usability Analysis
3.4.1 Validity and Reliability Test Methods
Validity is a measure that indicates the level or validity of an instrument. Validity in data collection testing can be differentiated into two, i.e. the validity of the factor and the validity of the item. The validity factor is measured when an item is used using more than one factor. The validity measurement of this factor is performed by correlate between the factor values with the total factor value. Item validity measurements are performed by correlate between item values with the total value of the item. The testing used in this research is the validity of the item. The validity test result for all query items can be seen in Table 7. In the table there is a variable B1, B2, and B3 representing each variable of usability dimension of the simplicity, the C1 and C2 variables represent each variable of usability dimension of the learnability, variables D1 and D2 represent each variable of usability dimension of memorability, the E1 and E2 variables represent each variable of usability dimension of the informativeness, and the F1 and F2 variables represent each of usability dimension of the trust ability.

Table 7. Validity test results.

| Variable | Correlation Coefficient | Significance | Decision |
|----------|-------------------------|--------------|----------|
| B1       | 0.698                   | 0.004        | valid    |
| B2       | 0.784                   | 0.001        | valid    |
| B3       | 0.737                   | 0.002        | valid    |
| C1       | 0.776                   | 0.001        | valid    |
| C2       | 0.867                   | 0.000        | valid    |
| D1       | 0.959                   | 0.000        | valid    |
| D2       | 0.917                   | 0.000        | valid    |
| E1       | 0.740                   | 0.002        | valid    |
| E2       | 0.780                   | 0.001        | valid    |
| F1       | 0.835                   | 0.000        | valid    |
| F2       | 0.702                   | 0.004        | valid    |
Based on the correlation calculation result will be obtained a correlation coefficient. These coefficients are used to measure the validity level of an item and determine if an item is worth using. The significance limit used in this validity test is $\alpha = 0.05$. These significance limits determine whether an item deserves to be used. If the value of significance is less than the limit, it can be concluded that the question item can be used to measure a predefined variable (valid).

Reliability testing is a test to determine whether a questionnaire is used to collect reliable research data. The reliability in question is that when the measurement tool is reused to make the measurement, the results will not be much different from the results that have been obtained before. One of the commonly used methods in research is Cronbach's Alpha. The reliability level determination criteria can be seen in the Table 8. As for the calculation result of Cronbach's Alpha value for each dimension can be seen in Table 9. According to Table 9, it can be concluded that the questions in the B, C, and D dimensions have been able to provide precise and consistent results on every measurement performed (reliable). While the question on the dimensions of E and F are less capable of delivering reliable results.

**Table 8. Criteria for determining reliability levels.**

| Criteria    | Interval    |
|-------------|-------------|
| Very low    | 0.00 - 0.19 |
| Low         | 0.20 - 0.39 |
| Middle      | 0.40 - 0.59 |
| High        | 0.60 - 0.79 |
| Very High   | 0.80 - 1.00 |

**Table 9. Reliability test results.**

| Dimension    | Cronbach's Alpha | Numbers of N | Conclusion     |
|--------------|------------------|--------------|----------------|
| Simplicity   | 0.580            | 3            | Middle         |
| Learnability | 0.518            | 2            | Middle         |
| Memorability | 0.839            | 2            | Very high      |
| Informativeness | 0.268         | 2            | Low            |
| Trustability | 0.315            | 2            | Low            |

3.4.2 Data Processing Questionnaire using Descriptive Statistical Methods

The results of the questionnaire obtained were processed using the descriptive statistic method. The simplicity, learnability, and memorability usability dimension have a good value, meaning that the dimension had been well applied in the device development. Thus, the informativeness and trust ability dimension has a fair value, meaning that the dimension was not well applied. Table 10 shows the result for the calculation result of the data obtained.
Table 10. Calculated result obtained from the questionnaire.

| No | Dimension | Variable | Code | Mean | Total Mean | Standard Deviation | Total Standard Deviation |
|----|-----------|----------|------|------|------------|--------------------|--------------------------|
| 1  | Simplicity| Cable amount | B1   | 2.32 | 2.30       | 1.54               |                          |
| 2  |           | Button amount | B2   | 2.25 | 2.30       | 1.48               | 1.55                     |
| 3  |           | Easy to use   | B3   | 2.31 | 2.30       | 1.63               |                          |
| 4  | Learnability | Operator’s duration recognizes the function | C1   | 2.18 | 2.18       | 1.43               | 1.39                     |
| 5  |           | Operator’s duration recognizes the placement | C2   | 2.18 | 2.18       | 1.29               |                          |
| 6  | Memorability | Frequency operators see manual book related functions | D1   | 2.25 | 2.25       | 1.34               | 1.44                     |
| 7  |           | Operator frequency see manual book related installation | D2   | 2.31 | 2.30       | 1.63               |                          |
| 8  | Informativeness | UI easy to understand | E1   | 1.81 | 1.81       | 1.17               | 1.16                     |
| 9  |           | UI gives a good feedback | E2   | 1.81 | 1.81       | 1.13               | 1.16                     |
| 10 | Trust ability | Operator confidence for the first time using the device | F1   | 1.86 | 1.86       | 1.11               | 1.09                     |
| 11 |           | Operator willing to operates the device in the future | F2   | 1.63 | 1.78       | 1.09               |                          |

4. Conclusion
This research has been developed a measurement evaluation measuring instrument that consists of the dimension of simplicity, learnability, memorability, informativeness, and trust ability. FES devices have been tested using the usability measuring instrument developed in this research. The result of the validity test on a shared probability questionnaire indicates that the proposed question has been valid to meet the chosen usability variable. While the reliability test results show that the simplicity and learnability dimension are at moderate reliability, the memorability dimension is at a very reliable level, and the informativeness and trust ability dimension are at a low reliability level. From the results of data processing by looking for average and standard deviation, the results of the variables B1, B2, B3, C1, C2, D1, and D2 were well applied to the FES devices designed on this research. While the variables E1, E2, F1, and F2 are still not properly applied to FES devices designed on this research.

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