

HUMAN FACTORS ENGINEERING AND TESTING FOR A WEARABLE, LONG DURATION ULTRASOUND SYSTEM SELF-APPLIED BY AN END USER

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ABSTRACT

One of the major challenges in the design of a new class of medical device is ensuring that the device will be usable by a broad range of its intended users. Human Factors Engineering addresses these concerns through direct study of how a user interacts with newly designed devices with unique features. In this study, a novel, long duration, low intensity therapeutic ultrasound device is tested by 20 end users representative of the intended user population. Over 90% of users were able to operate the device successfully. The therapeutic ultrasound device was found to be safe and effective for the intended users, uses, and use environments.

INTRODUCTION

Therapeutic ultrasound has been used to treat pain associated with musculoskeletal conditions and increase local blood flow in soft tissues for the past 80 years. The skill required to apply the treatment properly, along with the cost and size of the equipment, has previously confined ultrasound to the practitioner's office. As a result, treatments are typically applied once or twice a week for 5-15 minutes [1, 2]. Advances in piezoelectric technology have enabled a miniaturization of therapeutic ultrasound technology. As a result, it is now possible for an ultrasound therapy system to be wearable and self-applied by an end user.



Figure 1: sam® Ultrasonic Diathermy Device, the medical device assessed in this study.

Human Factors Engineering (HFE) is a significant step in designing a new medical device and ensuring it is optimally designed for the intended users and use case scenarios, pursuant to FDA guidance and IEC standards 60601 and 62366.

The sam® Ultrasonic Diathermy device (Fig. 1) is approved for sale with a prescription in the U.S.A. (21 CFR part 1050.10), but is available to users in Canada and Europe over-the-counter (OTC). Therefore, a human factors validation study was performed to evaluate the device usability from the perspective of the end user who self-administered the device away from the healthcare practitioner's office.

- Relief of pain
- Relief of muscle spasm
- Treatment of joint contracture
- Increase of local circulation

METHODS

Purpose

To ascertain the degree of usability of the sam® device in an IRB-approved clinical study

Subject selection and enrollment

Sample size was selected based on FDA guidance on human factors research citing Faulkner (2003) for the demonstration that a sample of 15 people was sufficient to find a minimum of 90% and an average of 97% of all problems related to the product

Inclusion criteria

- End users who self-administered the device during their normal daily activity
- No prior experience using the device
- 18-100 in age
- Ability to speak, read, and write in English
- Not pregnant

Protocol

• Subjects were trained on using sam and then self-applied the device 3 times within a 7-day time period, each time for a 4-hour treatment duration

- Treatment locations (Fig. 2):

shoulder, elbow, bicep, upper back, lower back, knee, quadriceps, ankle



Figure 2: sam® applied to treatment locations: a) upper back trapezius muscle, b) Achilles tendon, c) elbow tendon (epicondylitis).

After each treatment, subjects completed a usability questionnaire

- Sample questionnaire questions:

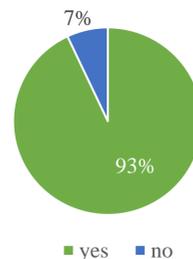
- 1.) Did you have any difficulty using the device?
- 2.) Was anything confusing?
- 3.) What might make the device (or instructions) better?
- 4.) After a few days between treatments, do you remember how to use the device?
- 5.) Are you satisfied with the device?
- 6.) Were there any design limitations that prevented you from successfully using the device?

METHODS CONT'D

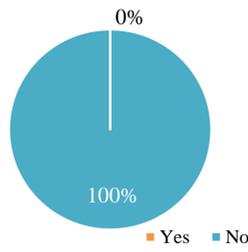
Data analysis:

- Data from the questionnaires was entered and analyzed using standard data analysis tools.
- Objective data and anecdotal data were analyzed separately.
- Data was analyzed for device usability and safety against the success criteria:
 - 90% of subjects can successfully operate and apply the device
 - 0% of subjects experience adverse events

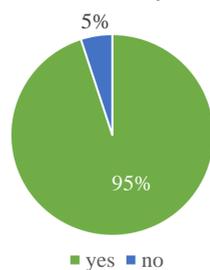
Thought sam® is easy to use



Percent of subjects that completed the study without experiencing an adverse event



Able to operate sam® successfully



RESULTS

20 subjects completed the study successfully, each used the device 3 times, indicating 60 completed use cases

- 0% of subjects reported an adverse event or experienced any skin damage from 4-hour treatments with the device.

- Nearly all subjects were able to successfully operate the device (95%) and thought the device was easy to use (93%).

- The primary constructive feedback related to the device was that the coupling medium was messy, and that there were difficulties with the interlock between the ultrasound transducer and the bandage containing the coupling medium, both in making the connection and in breaking the connection post-use.

- The reported causes of discomfort were that the bandage was irritating to the skin (3%) and that the device vibrated too much (5%), which indicates the activation of a safety feature.

CONCLUSION

The sample size of this study, 20 subjects, with each subject using the device 3 times, means that at a minimum, 95% of all user problems should be found, and the mean percentage is between 98.4% and 99.0% [3]. This demonstrates that the study captured the potential usability issues of this device with a high degree of confidence, and therefore, this feedback is sufficient to assess usability and any residual risk associated with the device.

The device was successfully used by 20 subjects over 60 treatments with no negative effects or adverse events. The overall lessons taken from this study are that the device was usable for a layperson, that the vast majority of user experiences were positive, and the majority of user feedback involved making the applicator interface with the bandage easier to handle.

The device was successful in providing treatments, and nearly 9 in 10 subjects who tried the device would use it again. The therapeutic ultrasound device was found to be safe and effective for the intended users, uses, and use environments. The 95% success rate of usage and the methods for collecting data support this conclusion. Any residual risk that remains would not be reduced by modification of the design of the user interface, and is outweighed by the therapeutic benefit derived from the use of the device.



Figure 3: sam® applied to the knee.

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