WHITE PAPER

The Importance of Human Factors Engineering and Infusion Pump Usability in Patient-Controlled Analgesia

Report of a study commissioned by ICU Medical Inc. and conducted by AAIPharma Services Corp.

Abstract

BACKGROUND

As a component of risk management, the FDA recommends manufacturers follow human factors and usability engineering processes to reduce risks associated with medical device use by minimizing potential use errors.[1]

OBJECTIVE

In this white paper, we seek to understand how clinicians utilize patient-controlled analgesia (PCA) pumps, especially as it relates to human factors and usability engineering, and apply those learnings to ICU Medical's development activities.

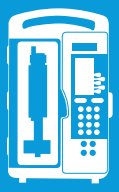
RESULTS

Data from the study ranked LifeCare PCA™ first in the following:

- Overall average score
- Ease of use
- Total first place rankings by respondents

CONCLUSION

Although the results were not generated to create statistical significance, the clinician responses suggest the LifeCare PCA may have advantages over competing pumps in a number of usability categories and further study is warranted.



Overview

In this white paper, the science of human factors and usability engineering is discussed in the context of medical devices. U.S. Food and Drug Administration (FDA) guidance and International Electrotechnical Commission (IEC) standard documents applying human factors engineering to medical devices are reviewed. An example of usability testing on PCA pumps is presented.

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Introduction

In today's healthcare environment, it is increasingly important that devices be intuitive and easy to use as less experienced providers are utilizing medical devices, and healthcare facilities may experience significant personnel turnover and less staff familiarity with equipment.[1,2,3,4] Human Factors and Usability Engineering are intended to reduce use-related errors and are applicable to a broad range of products, services, and systems, including medical devices.[1,5,6]

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The FDA has produced a guidance document entitled, "Applying Human Factors and Usability Engineering to Medical Devices," which is intended to maximize the probability that medical devices will be safe and effective for users in their use environments.[5] The IEC has similarly produced the IEC 62366-1 standard, which addresses the need for medical device manufacturers to evaluate usability as it relates to device safety.[1] Both documents aim to minimize medical device-associated risk to people, property, and the environment by providing a rigorous process to identify and mitigate failure modes that arise from user device interaction.

Human factors and usability engineering are applied to medical device development through a number of mechanisms, including usability testing. In this white paper, we review and summarize the results of an observational study that applies these concepts to three PCA pumps.

Background

The application of human factors to medical device manufacturing is analogous to other industries. The International Ergonomics Association defines human factors as:

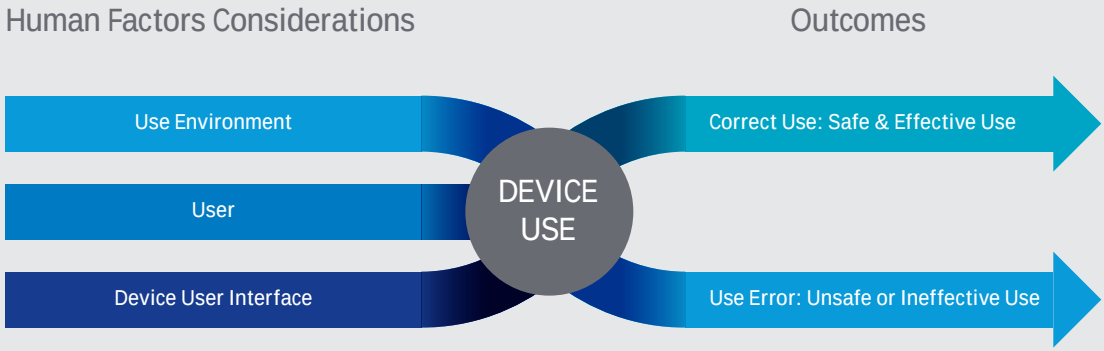
> "Ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance."[7]

ISO 14971, Medical Devices – Application of risk management to medical devices, defines risk as the probability of occurrence and severity of a potential harm.[8] As a component of risk management, the FDA recommends manufacturers follow human factors and usability engineering processes to reduce risks associated with medical device use by minimizing potential use errors. IEC 62366-1 further specifies that user-related risks arise from correct use and from use error but do not include the intentional misuse of a device.[1]

Human factors engineering in medical device development focuses on the user and device as a system. This system is comprised of three components, represented in the Figure 1[5] as (1) use environment, (2) user, and (3) device user interface.

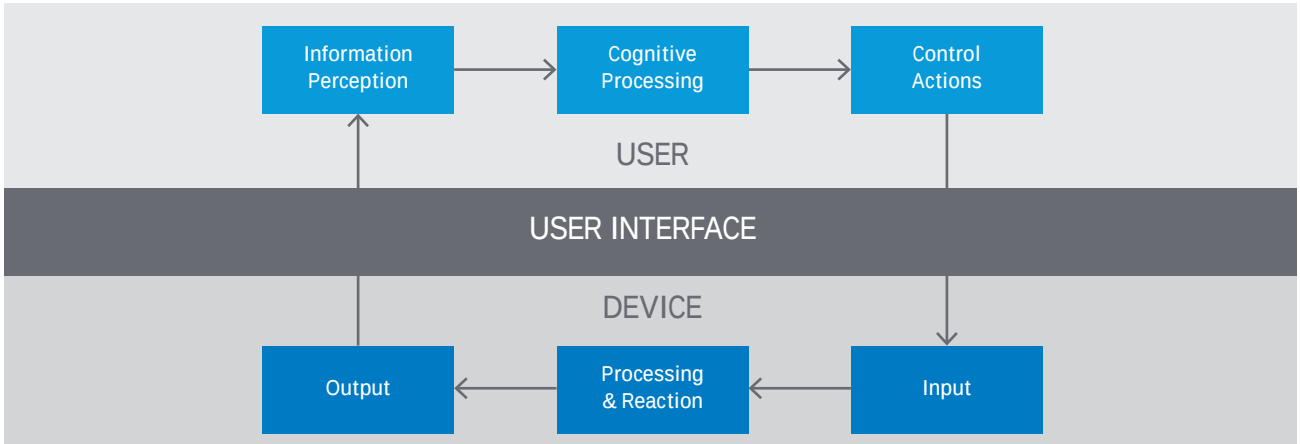
The user further engages in the processes of perception, cognition, and action to interact with the user interface and produce an output from the device (Figure 2).[5]

FIGURE 1: APPLICATION OF HUMAN FACTORS ENGINEERING



Interactions among HFE/UE considerations result in either safe and effective use or unsafe or ineffective use.

FIGURE 2: DEVICE USER INTERFACE



Device User Interface in Operational Context (adapted from Redmill and Rajan, 1997) from FDA[5]

HUMAN FACTORS ENGINEERING APPLIED TO MEDICAL DEVICE RISK MANAGEMENT

The incorporation of human factors engineering to medical device design includes accounting for the user and the device-use environment. The effectiveness of the previously mentioned user processes depend on an individual user's physical and mental capabilities. The user and the device itself are further influenced by the use setting, which ranges from medical facilities to private homes. Environmental factors to consider in use settings include lighting, noise levels, the potential presence of similar devices, temperature, and humidity.

> The user interface "should be logical and intuitive to use" and will optimally facilitate correct user actions and discourage incorrect actions that could result in harm.[5]

The device user interface affects all user interaction with the device in each potential environment. The interface includes the display, buttons, knobs, and alarms, along with the packaging, labeling, training materials, and operating instructions.[5] Per the FDA guidance document, the user interface "should be logical and intuitive to use" and will optimally facilitate correct user actions and discourage incorrect actions (use errors) that could result in harm.[5]

PCA OBSERVATIONAL RESEARCH — COMPETITIVE BENCHMARKING

Usability studies are an effective mechanism to assess the effectiveness of human factors engineering efforts in medical device design. According to IEC 62366-1, a usability test is a "method for exploring or evaluating a user interface with intended users within a specified user environment."[1] As an example of human factors engineering in medical device development, ICU Medical (Hospira at the time of the study) contracted with a third party to conduct an observational study with the LifeCare PCA infusion system.[9]

Objectives

There were two primary study objectives.

1. To better understand how a group of clinicians performed at completing a series of tasks with three PCA pumps, including the LifeCare PCA pump and two alternative infusion devices.
2. To incorporate the learnings from this study into the continuous improvement and device development activities of ICU Medical.

The study was observational without the objective of achieving statistical significance of results.

Methodology

PCA PUMPS

The LifeCare PCA 7.0 pump (ICU Medical) was compared with two alternative PCA pumps (Pump #2 and Pump #3) approved for use and available in the United States.

PARTICIPANT PROFILES

The participants were four actively practicing nurses with 7–25 years of clinical experience and familiarity with PCA pump use (Figure 3). All four nurses were current users of Pump #2. None of the nurses were current users of the LifeCare PCA, although one nurse had used it in the past. None of the nurses had used Pump #3. The participants received no study-specific training. While pump identity was not concealed, participants did not know who sponsored the study.

STUDY DESIGN

Participants took part in a two-hour laboratory study, followed by device evaluation and ranking through completion of a survey.

USE CASE DESCRIPTION

The study participants were asked to complete a series of eight clinically relevant tasks (Figure 4) with each of the three pumps.

The LifeCare PCA pump had the highest overall average score.

FIGURE 3: PARTICIPANT PCA EXPERIENCE

	Participant PCA Experience		
	LifeCare PCA	Pump #2	Pump #3
Current use	0	4	0
Past use	1	0	0

Nurses participating in the study were current users of Pump #2 in their clinical practices but had little to no experience with Pump #3 or the LifeCare PCA infusion system.

FIGURE 4: PCA TASKS

	Description
1	Program pump to deliver analgesic 1 mg/mL with 1 mg PCA doses, 6 minute lockout, 2 mg/hr continuous infusion, and dose limit of 5 mg/hr
2	Increase PCA dose to 1.5 mg
3	Deliver clinician-activated 2 mg bolus
4	Clear occlusion alarm
5	Change concentration to analgesic 5 mg/mL and continuous infusion to 500 mg/hr
6	Change continuous infusion to 5 mg/hr and dose limit to 5 mg/hr
7	Find shift and patient totals, including total dose and patient demands
8	Clear shift totals

Results

After completing the eight PCA tasks, the participants took part in a survey-based review of each pump. Participants scored the pumps on a one-to-five scale using questions from eight categories (Figure 5).

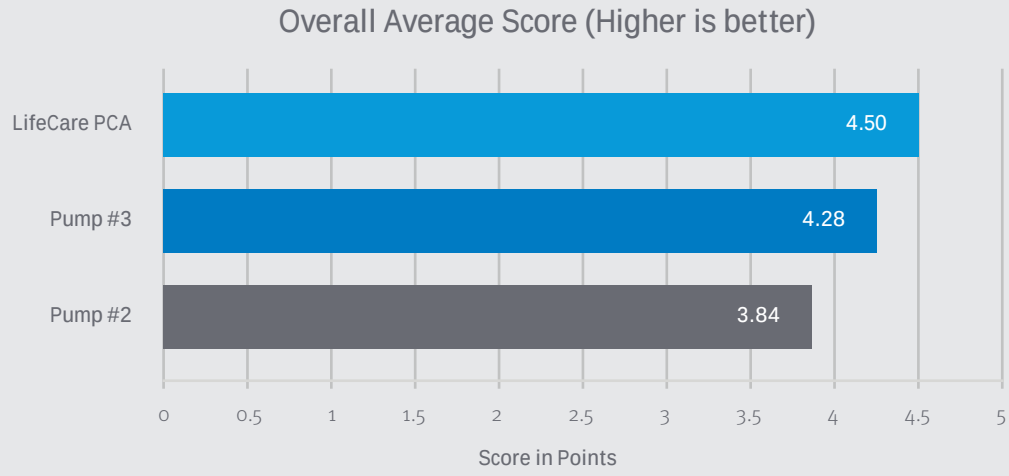
The responses for all categories were combined as an overall average score with five being the best/highest score and one being the worst/lowest.

The LifeCare PCA pump had the highest overall average score, followed by Pump #3 and Pump #2 (Figure 6).

FIGURE 5: SURVEY QUESTION CATEGORIES

	Categories
1	Setup and configuration
2	Perception
3	Information interpretation
4	User control
5	Feedback to user
6	Error correction
7	Instructions
8	Training

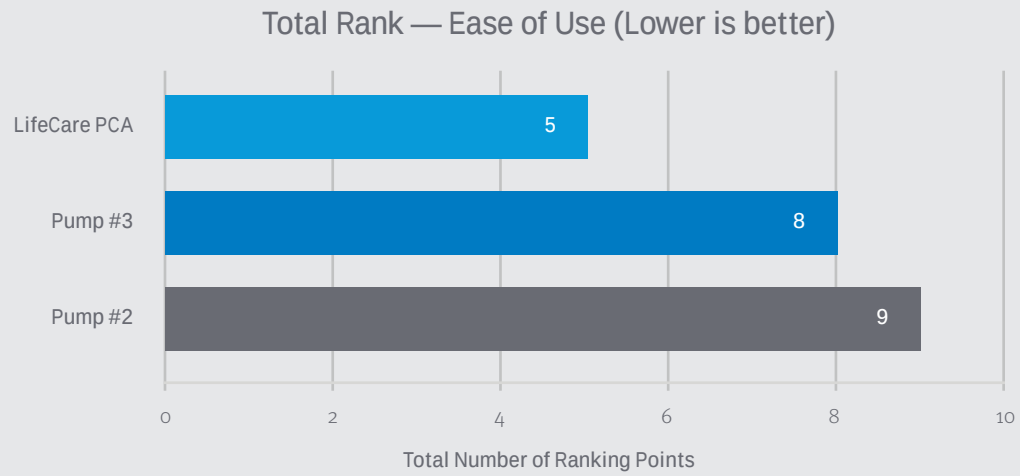
FIGURE 6: OVERALL AVERAGE SCORE



The LifeCare PCA infusion system received the highest overall score of 4.5, followed by alternative Pump #3 and Pump #2.

The participants were also asked to rank the attributes of each pump in the following categories: ease of use, design/functionality, appearance, safety, time to program, and overall performance as compared to the other pumps. A score of one indicates the nurse believes the pump leads the attribute category, while a three indicates the nurse believes the pump falls into last place in the category. For these responses, a lower score is more favorable. The results of the rankings in the ease-of-use category are shown in Figure 7. The ease-of-use results are especially notable considering none of the participants were current users of the LifeCare PCA pump and all participants were current users of Pump #2. It is also significant in that the ease-of-use category may correlate best with the FDA guidance indicating that the user interface "should be logical and intuitive to use."[5]

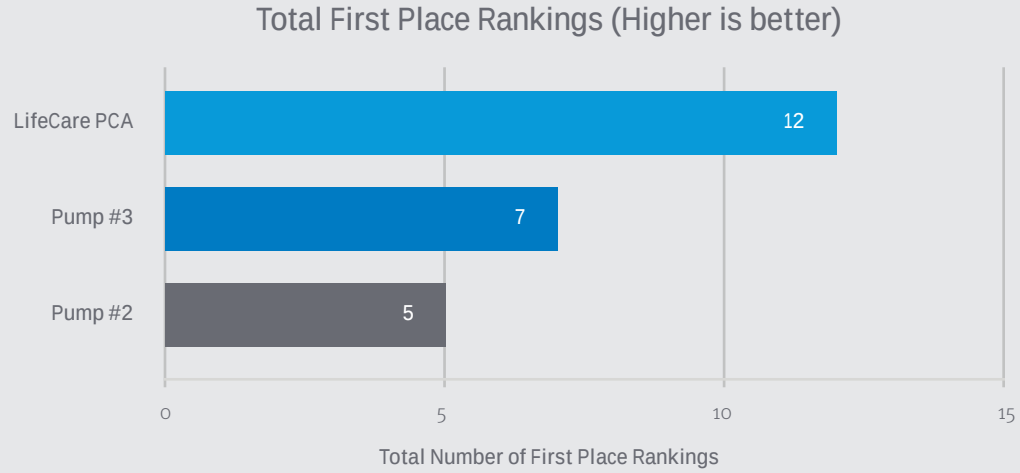
FIGURE 7: TOTAL RANK — EASE OF USE



Despite relatively little user experience with the LifeCare PCA™ infusion system, nurses consider it easier to use in comparison to Pump #2 and Pump #3.

The attribute analysis also counted the number of first place votes received across all categories for each pump (Figure 8). In this case, a higher score is better, and the LifeCare PCA pump received the largest number of first place responses.

FIGURE 8: TOTAL FIRST PLACE RANKINGS



The LifeCare PCA infusion system received the most first place responses across all categories, followed by Pump #3 and Pump #2.

Summary

Medical devices should be optimally designed with features and a user interface "that will facilitate correct user actions and will prevent or discourage actions that could result in harm."[5] This white paper presents a study demonstrating the application of human factors engineering for PCA infusion pumps. The primary objectives of this study were met and included gaining a better understanding of how clinicians utilize PCA pumps. These learnings have been incorporated into the continuous improvement and device development activities of ICU Medical. Although the results were not generated to create statistical significance, the clinician responses suggest the LifeCare PCA may have advantages over competing pumps in a number of usability categories and further study is warranted.

The clinician responses suggest the LifeCare PCA may have advantages over competing pumps in a number of usability categories.

Research Team

ICU Medical worked with ORC International and a team led by Dr. Todd Johnson of The University of Texas Health Services. The study was conducted at The University of Texas Health Services usability lab with support and funding from ICU Medical.

References

1. International Electrotechnical Commission (IEC). IEC 62366-1 International Standard Medical Devices – Part 1: Application of usability engineering to medical devices. 2015.
2. 2016 National healthcare retention & RN staffing report. East Petersburg (PA): NSI Nursing Solutions, Inc.; 2016.
3. Marcora SM, Staiano W, Manning V. Mental fatigue impairs physical performance in humans. J Appl Physiol. 2009;106(3):857-864.
4. Wagner K. Temporary nurse staffing: Taking a closer look. Healthcare Cost Containment. 2013;6(1):10.
5. U.S. Department of Health and Human Services (HHS). Applying human factors and usability engineering to medical devices: Guidance for industry and Food and Drug Administration staff. Issued February 3, 2016.
6. Human Factors and Ergonomics Society (HFES). Mission statement. Available at https://www.hfes.org/web/AboutHFES/about.html. Accessed July 27, 2017.
7. International Ergonomics Association (IEA). Ergonomics (human factors definition). Available at http://www.iea.cc/whats/index.html. Accessed July 27, 2017.
8. ANSI/AAMI/ISO 14971:2007/(R)2010. Medical Devices – Application of risk management to medical devices.
9. ICU Medical Inc. Data on File. 2015.

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