

# Proceedings of the Human Factors and Ergonomics Society Annual Meeting

<http://pro.sagepub.com/>

---

## Applying Human Factors to the Procurement of Electrosurgical Medical Devices: A Case Study

Andrea L. Cassano

*Proceedings of the Human Factors and Ergonomics Society Annual Meeting 2003* 47: 1815

DOI: 10.1177/154193120304701508

The online version of this article can be found at:

<http://pro.sagepub.com/content/47/15/1815>

---

Published by:



<http://www.sagepublications.com>

On behalf of:



Human Factors and Ergonomics Society

Additional services and information for *Proceedings of the Human Factors and Ergonomics Society Annual Meeting* can be found at:

**Email Alerts:** <http://pro.sagepub.com/cgi/alerts>

**Subscriptions:** <http://pro.sagepub.com/subscriptions>

**Reprints:** <http://www.sagepub.com/journalsReprints.nav>

**Permissions:** <http://www.sagepub.com/journalsPermissions.nav>

**Citations:** <http://pro.sagepub.com/content/47/15/1815.refs.html>

>> [Version of Record](#) - Oct 1, 2003

[What is This?](#)

## APPLYING HUMAN FACTORS TO THE PROCUREMENT OF ELECTROSURGICAL MEDICAL DEVICES: A CASE STUDY

Andrea L. Cassano  
Cognitive Engineering Laboratory  
University of Toronto  
University Health Network  
Toronto, Canada

### ABSTRACT

Human factors evaluations are currently not conducted as part of the procurement process for medical devices in most hospitals. The complexity of medical devices and interactions between those devices, the working environment and the people who use them can create a high potential for errors. This study reports on the methods used to integrate human factors usability testing into the product evaluation of electrosurgical units (ESU's) prior to procurement. It also comments on the results of the various testing methods and the impact of the results on the final purchasing decision.

The results of the human factors evaluations were used to make a purchasing decision for a major metropolitan hospital in Canada. A new purchase was necessary because the manufacturer was no longer supporting the product in use. Surprisingly, the product of choice was the oldest on the market with few new features. It was preferred and chosen based on usability and clinical acceptance by all users.

### INTRODUCTION

Operating rooms (OR's) are among the most technology-intense environments in any hospital. Medical devices are approaching saturation with the number of functions and features available to clinicians, to the point that using these devices may actually be counter-productive to an institution's goal of providing direct, safe care at the highest level possible. (Fisher, 2002)

Incorporating usability methods into the procurement process may prevent healthcare institutions from introducing preventable errors stemming from device complexity (Gosbee and Lin, 2001). Proper device selection can ensure compatibility between the work environment and the device functions, thus facilitating a reduction in the mental workload of clinicians. (Kohn, 2000; Wiklund, 2002; Kushniruk et al, 1997; CDHR, 1996)

### THESIS

This study compares the performance of three Electrosurgical Units (ESU's), manufactured by 3 vendors (A, B, and C), during clinical trials at a major metropolitan hospital in Canada. The trials were conducted with OR surgeons and nurses from the Cardiac, Gynecology, Ear-nose-throat (ENT), Plastics, Vascular, Thoracic and General-Surgery disciplines.

An ESU is a surgical device that is used to cut tissue (using the CUT modality) as well as coagulate bleeding vessels (using the COAG modality). Improper set up and use of this device can result in: increased blood loss, increased scar tissue development, unwanted tissue damage, increased Healing time, electric shock to the user, and unwanted

outcomes generating case delays.

Human factors methods such as simulation, interviews, and questionnaire-based feedback were implemented to evaluate the nature and severity of potential errors associated with each product. Errors were observed in both simulated and real surgery environments during the clinical trial period.

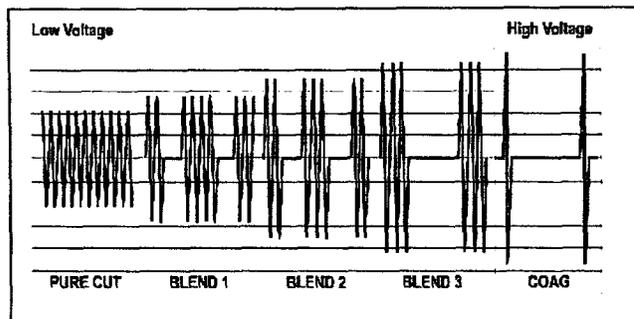
The purpose of this research was to assist the purchasing team in selecting an ESU that would function safely, reduce the potential for errors, and meet the clinical needs of all users.

### ESU BACKGROUND

An ESU uses high frequency electrical energy to thermally destroy tissue. By varying the amplitude of the voltage and the duty cycle of the electrical energy, different tissue effects are produced (Figure 1). A cutting effect is achieved using a pure sinusoid wave. This causes intense heating and the cells vaporize to create an incision. The coagulation effect is achieved by increasing the duty cycle of the wave, rapidly turning on and off the sinusoid. This type of current only dries out the tissue and coagulates blood. ESU's also have blend modes. Blend modes are literally a blend of cut and coagulation waveforms causing both cut and coagulation tissue effects simultaneously.

The ESU is one of the most frequently used tools by all surgeons in almost all types of surgery. For many surgeons it replaces the use of a scalpel for cutting. The coagulation function prevents surgeons from having to tie off bleeding vessels as they dissect tissue.

Figure 1: Typical Relationship Between Voltage and Surgical Effect (Valleylab, n.d.)



All ESU's have patient and user safety risks because they transmit electrical current through the patient's body. ESU's have two methods of delivering current to the patient. One is called monopolar, the other is bipolar. The monopolar ESU circuit (Figure 2) consists of current being produced in the ESU, leaving the generator at the tip of an active electrode where the tissue effect is created, spreading out as it travels through the patient's body, and then returning to the generator via a dispersive electrode adhered to the patient. The bipolar ESU circuit (Figure 3) uses two active electrodes at the tip of surgical instrument (called forceps). One electrode supplies the current and the other returns it back to the generator eliminating the travel of current through the patient and the need for a dispersive electrode.

Figure 2: Monopolar ESU Circuit (Valleylab, n.d.)

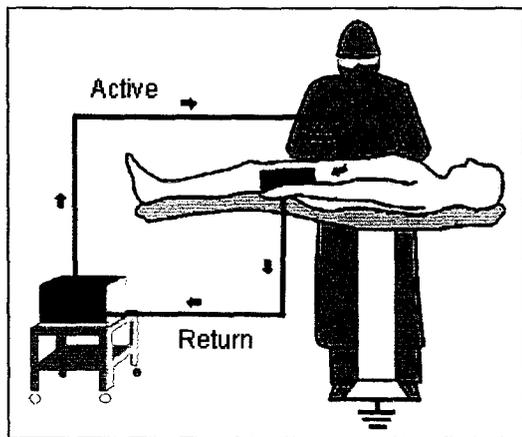
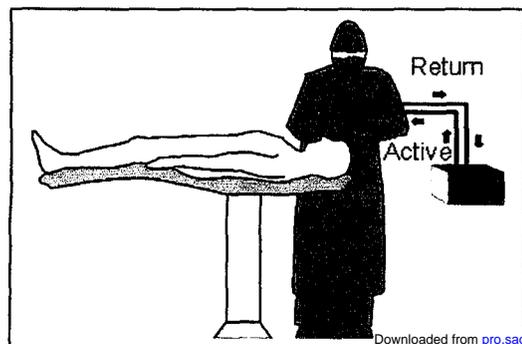


Figure 3: Bipolar ESU Circuit (Valleylab, n.d.)



Current leakage, capacitive and direct coupling, and dispersive electrode burns are all dangerous events that have the potential to injure patients when using ESU's. Recent products, however, are designed to protect patients against such adverse events.

Other types of adverse events caused by user error are not so thoroughly addressed by manufacturers. Proper mode and power selections are not always easily understood based on the interface design and are not consistent across products. A surgeon's ability to understand and use various settings plays a factor in their ability to prevent charring of healthy tissue, excessive blood loss, and increased scar tissue.

New ESU features strive to automate as many tasks as possible. However, some of the automated features could be dangerous if they are activated inadvertently. Proper human factors design needs to exist in order to allow users to efficiently set up, use, and understand various settings that allow for a desired surgical effect while keeping a patient out of harms way. By performing usability testing design flaws that prevented these goals from being achieved, and enhanced opportunities for error, were identified.

## METHOD

The three ESU products were each evaluated for a four-week period. Each four-week evaluation is referred to as a clinical trial. During the first week of each clinical trial the vendors provided training for O.R. nurses and surgeons on how to set up and use their device. The vendors were available for one-on-one or small-group training sessions approximately six hours a day for three of the five days during the allocated training week. A majority of nurses attended, however only one surgeon chose to attend any of the vendor training sessions.

During the following three weeks surgeons and nurses used the product during surgery as it rotated through the six aforementioned surgical disciplines. Both nurses and surgeons provided evaluation feedback via a questionnaire. The questionnaire consisted of nursing specific and surgeon specific questions that were answered by members of each profession respectively using a five-point Likert scale (1=poor to 5=excellent or N/A=not applicable). The questions addressed both performance and usability issues as well as the quality of training provided, specific features on the ESU, and any unanticipated responses they may have encountered.

Interviews and simulations were conducted with O.R. nursing staff only. Surgeon participation was difficult to recruit, and less relevant because they do not set up the device or manipulate it during surgery.

During the interviews, demographic information was recorded along with: years of experience; information about how well the participant understood the fundamental principles behind electrosurgery; their perceptions about their level of understanding of how ESU's work from a clinical perspective.

Simulations were conducted with 13-16 staff nurses on each product. Nurses were selected randomly but based on availability over three months in order to facilitate within-

participant testing. Testing consisted of asking participants to complete interview questions, perform scenarios that involved setting up for various surgical cases, and answer questions related to the unique features of each product. This took place, without a patient present, in an operating room.

An independent Human Factors Expert (HFE) Analysis was conducted using Heuristic Criteria (Nielsen and Molich, 1990). The chosen heuristics outline the principles of usability in interface design. Each device was inspected by the HFE to see how it violated the heuristics and what the impact of each violation could be on patient safety, case time, and ease of use.

**RESULTS**

**Training**

Each vendor conducted three days of informal training in the hallway outside the Nurse’s Lounge. During training sessions, the following three main observations were made:

1. Demonstrators tried to rush through the training to keep nurses from leaving. Many nurses would catch bits and pieces of the training session at different times but could not commit to standing through the entire session.
2. The snacks provided by the trainers were a major distraction to the training. Although they provided an incentive to get staff to attend the training, they interfered with the effectiveness of the training.
3. When a demonstrator used technical language (such as “impedance”, “thermal artifact”, “voltage”) nurses were observed to: stop listening, stop asking questions, leave the training session, or form a general opinion (heard in conversations between nurses) that the device was overly complicated. The result was that some nurses were nervous and unenthusiastic about having to interact with the ESU during the trials when it was in their room.

**Questionnaires**

Table 1: Number of participants

Product	Total Participants	Surgeons	Nurses	Resident/Fellows
A	56	25	22	8
B	49	23	21	5
C	43	18	21	4

Products A, B and C are the three products that were evaluated. The current ESU owned by the hospital was not included in the evaluation because the manufacturer is no longer supporting this product.

**Surgeon Results.** The results of the surveys (Figure 4) completed by surgeons indicated that there was no single

preference from all surgeons (See Table 1 for sample sizes). Product A appeared to be the least favoured. Numeric results from Products B and C were very close based on average values (4.13 and 4.05 respectively). Some trends were observed within surgical disciplines based on qualitative questionnaire responses (Table 2).

Figure 4: Surgeon Overall Performance Scores

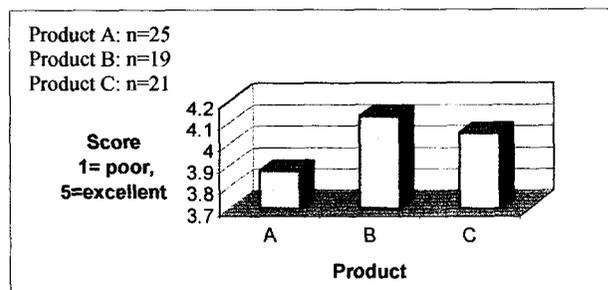


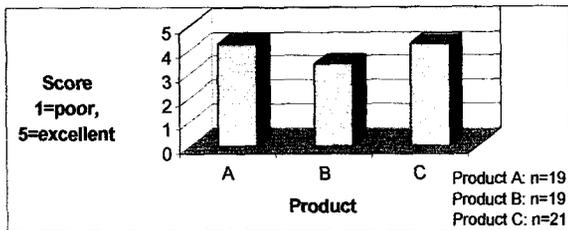
Table 2: Preferences by Surgical Discipline

Surgical Discipline	N *	Preference	Reason
ENT/ Plastics	8	Product C	<ul style="list-style-type: none"> <li>• Ability to achieve fine dissection.</li> <li>• Good bipolar mode effects (unlike product A)</li> <li>• Easy to read display (unlike product B)</li> <li>• Remote power control</li> </ul>
Vascular	2	Product C over Product B	<ul style="list-style-type: none"> <li>• Better levels of cutting and coagulation</li> <li>• Overall less damage of healthy tissue</li> </ul>
Gyne-cology	1	Product B over Product A	<ul style="list-style-type: none"> <li>• Preferred tissue effect</li> <li>• All other gynecology surgeons indicated no preference</li> </ul>
Thoracic	3	No favored	<ul style="list-style-type: none"> <li>• Similar ratings and responses for all products</li> </ul>
Cardiac	10	Various	<ul style="list-style-type: none"> <li>• Preference varied widely across products</li> </ul>

\* Number of surgeons who communicated a preference

**Nurse Results.** Based on quantitative results of the nursing questionnaires (Figure 5) for “overall comfort level” with each product, Product B was the least preferred ESU (average = 3.42). Products A and C ranked approximately equally (4.26 and 4.24).

Figure 5: Nurses Overall Comfort Level Scores



When reviewing the qualitative results of the questionnaires, the responses indicated a preference for Product C over Product A. One possible reason for the similarity in quantitative responses, despite differences in qualitative responses may have been because Product A was evaluated first and is made by the same manufacturer as the current product used. Being the first product assessed, no comparison was possible. Scores may have been inflated because the users were familiar with that particular vendors' product. Only a few comments were given for Product A. This could indicate that there was no strong support for the preference of Product A other than familiarity. Product C, however, was completely unfamiliar and still garnered high numeric ratings and positive comments about specific features that they liked.

Some specific preferences for Product C included:

- Large buttons that were easy to press, allowing for quick scrolling of power values
- Ability for surgeons to increase and decrease the power setting remotely using the hand piece
- Less noise produced by the ESU
- Easier to troubleshoot
- Ability to store programmed settings

### Interviews

The interviews were conducted prior to, but during the same session as, Product A simulations. The following four results were found:

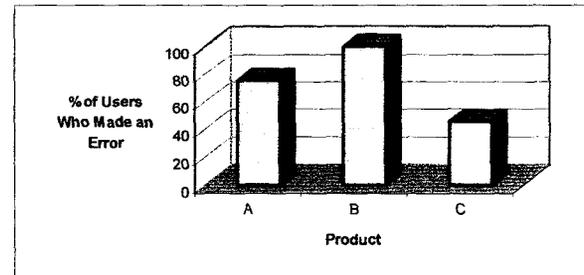
1. 87% of participants indicated that they have not received any formal training on electrosurgery in the past 2 years.
2. 62.5% of participants rated themselves a 4 or 5 (1=worst and 5=best) in response to how well they thought they understand how ESU's work from a clinical perspective. Interestingly, 70% of these participants could not explain the differences in tissue effect achieved by the various cut or coagulation modes.
3. 37.5% of users rated themselves a 3.5 or lower. Of these participants 67% had 3 or less years of experience.
4. 87.5% of users indicated that they would like to know more about electrosurgery.

From these results three major inferences can be drawn:

1. Experienced workers are less likely to admit to what they are unsure about.
2. O.R. nurses are unaware that they have a lack of knowledge about how ESU's function.
3. There is a general lack of understanding about how ESU's work, which may also imply that there is a lack of understanding about how to protect patients from the risks of electrosurgery.

### Simulations

Figure 6: User Errors During Simulations



During the two set-up scenarios, 75% of users made at least one error setting up Product A, 100% of users setting up Product B, and 45% of users setting up Product C (Figure 3).

Although error rates are high with all three products, the consequences of each error vary widely from non-hazardous to potentially very hazardous. The consequences associated with a Product B error were the most severe with the potential to char excess healthy tissue or in the worst case set the surgical drapes on fire. The consequences associated with Product A were less severe than Product B but could also impact on patient safety. Product A was susceptible to plugging the foot pedal in the wrong port, with the potential consequence of activating the wrong instrument. The consequences associated with a Product C error were the least severe, potentially resulting in a delay in total case time, and had no negative impact on patient safety.

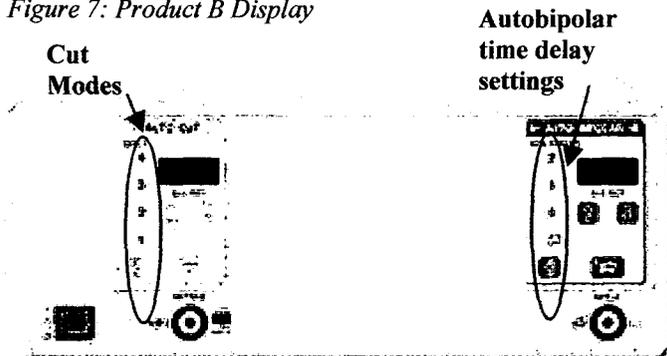
### Human Factors Expert Analysis

A heuristic analysis was conducted using Jacob Nielsen's Usability Heuristics (Nielsen and Molich, 1990).

A full description of how each product violated these heuristics is too lengthy to include here, however one major design feature in Product B should be highlighted because it appears to be sub-optimal with respect to patient safety. Product B's display (Figure 6) in the AUTOCUT section has buttons labeled numerically (1, 2, 3, and 4) indicating different cutting settings. The settings in the AUTOBIPOLAR section were also labeled numerically (0, 1, and 2). These buttons, however, did not represent different bipolar settings as the

numbers in the AUTOCUT section did. They indicated specific time delays for the activation of the AUTOBIPOLAR (automatic activation of the bipolar as soon as resistance is sensed) feature where 0 means the feature is off, 1 means there is a 0.5 second delay and 2 means there is a 1 second delay before the generator activates. This was a violation of the heuristics “Consistency of Standards” and “Error Prevention”. The consequence of this design flaw error was observed during a case when a nurse, who had not attended the training, accidentally set the autobipolar feature on with a 0.5 second delay thinking she had set a bipolar tissue effect. The surgeon was alarmed when the ESU activated without pressing the foot pedal (normally used to activate the ESU in this mode). Had the surgeon been using the instrument to move healthy tissue out of the way or pick up a saline soaked sponge the consequences would have produced unnecessary scarring and damaged tissue, or the sponge would have been set on fire, respectively.

Figure 7: Product B Display



## DISCUSSION

The ESU selected for purchase was Product C. It was chosen based on clinical preference and its ability to provide patient and user safety. Other decision factors were price and the vendor's maintenance contract, however all three vendor prices were within the hospital's budget.

Selecting Product C illustrated the decision team's confidence in the human factors component of the evaluation. Prior to the trial, the decision team did not want to include Product C because of the team's lack of confidence in the company providing service and support in Canada. However, they were included at the company's request based on upcoming changes in their corporate structure. Medical Engineering participants on the decision team felt that Product C was technologically inferior. It was viewed as being an antiquated product with limited features in comparison to the other two products evaluated. It was thought that Product C would not compliment the other leading-edge technologies purchased for the new state of the art operating rooms. However, due to overwhelming clinical support and the high performance assessment garnered in the usability testing the argument was dropped and the product was purchased.

Each vendor has been sent a copy of the simulation results and heuristic analysis for their product. The objective is to provide them with product feedback to improve their next

generation of product. If manufacturers use our feedback, it may also raise the quality of future products purchased.

Given the positive response from both users and O.R. management staff, the Director of Medical Engineering is continuing to include human factors analysis of medical devices in future procurement decisions.

## ACKNOWLEDGEMENTS

This research was completed at the University Health Network in Toronto, Canada. Thanks to, Dr. Tony Easty Ph.D., Dr. Kim Vicente Ph.D., Gillian Gravely R.N., Evelyn Fan B.A.Sc., and the UHN operating room staff for their support.

## REFERENCES

- Fisher, J. (2002). *A comparison of the opinions of nurses and emergency medical Workers regarding medical device usability*. In Proceedings of the Human Factors and Ergonomics Society 46<sup>th</sup> Annual Meeting, (pp.1477-1481). Santa Monica, CA: HFES.
- Gosbee, J., Lin, L. (2001). *The Role of Human Factors Engineering in Medical Devices And Medical Systems Errors*. In: Vincent, C. (Ed), *Clinical Risk Management: Enhancing Patients Safety*. London: BMJ Press, pp. 301-317.
- Kohn, L.T., Corrigan, J.M., Donaldson, M.S., Eds. (1999). *To Err is Human: Building a Safer Health System*. (pp.140-149) Washington, DC: National Academy Press.
- Kushniruk, A.W., Patel, V.L., Cimino, J.J. (1997). *Usability Testing in Medical Informatics: Cognitive Approaches to Evaluation of Information Systems and User Interfaces*. In Proceedings AMIA Annual Fall Symposium, (pp. 218-222). Bethesda, MD: AMIA
- Wicklund, M. (2002). *Pilot Comparison Usability Test of Intravenous Infusion Pumps*. National Center for Patient Safety Department of Veteran Affairs. Ann Arbor, MI.
- Centre for Devices and Radiological Health (CDRH). (1996). *Do it by Design: An Introduction to Human Factors*. Retrieved June 17, 2003, from <http://www.fda.gov/cdrh/humfac/doitpdf.pdf>
- Nielsen, J., and Molich, R. (1990). *Heuristic evaluation of user interfaces*. In Proceedings ACM CHI'90 Conference. (pp. 249-256). Seattle, WA
- Valleylab. Principles of Electrosurgery online. (n.d.). Retrieved June 10, 2003, from <http://66.45.30.237/static/pofe/pofes.htm>