13 The Mobile Usability Lab Tool for Accessibility Analysis of Medical Devices: Design Strategy and Use Experiences

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CONTENTS

ABSTRACT

This chapter describes the Mobile Usability Lab (MU-Lab), a structured tool for performing systematic analysis of the accessibility of a targeted medical product or class of products. MU-Lab

helps guide a research team through the assessment process. The system consists of Web-based Protocol Manager (PM) software, plus hardware that can be transported within a customized suitcase. The process starts with preliminary steps such as an initial heuristic analysis guided by universal design principles, plus the important step of determining an appropriate population of users with disabilities and documenting their abilities. This is followed by video-based usability data collection sessions that also include a structured postactivity analysis questionnaire. Data analysis includes a special focus on task analysis of events related to accessibility barriers.

13.1 INTRODUCTION

The Rehabilitation Engineering Research Center on Accessible Medical Instrumentation (RERC-AMI), to fulfill its mission, has needed to develop and then use an effective tool for cross-disability evaluation of how medical products are used. A key objective has been to understand access barriers that limit effective use of a medical device. For instance, needs assessment research by the RERC-AMI may identify a given medical product or class of products where there is a high-priority need to better understand problematic or exemplary features associated with product use. A usability analysis is then performed that systematically documents use strategies, difficulties, and access barriers. Data collection involves recruiting a sample of volunteers with a diversity of abilities, including individuals who represent subpopulations with known functional limitations. It also requires, for ecological validity, that the tool be mobile in order to enable data collection in the field, whether the site is within, for example, a hospital, home, or clinic. Often the on-site researcher is alone and must multitask under time pressures, having to both interact with the subjects and collect sensor-based and observational data. Thus a key practical consideration is that the system be easy to use in the field and indeed serve as an "enabler" for the researcher. Finally, it must support data analysis by a team of experts that, at least for some analyses, may be located at different sites (e.g., Wisconsin and California).

The obvious first step toward addressing these needs is to build on past knowledge and work, specifically in the interrelated fields of usability engineering, human factors engineering, and ergonomics. After all, these relatively mature fields have developed a rich variety of approaches and tools [1–3; see also many chapters in Parts 2 and 3 of this book]. Other resources include the Principles of Universal Design [4], accessibility guidelines for certain types of products [5,6], and a rich variety of approaches for human performance analysis tools. But based on the aims identified in the previous paragraph, none of these existing approaches have been found to completely satisfy the identified need.

In developing an approach, one important observation is that the use of most medical technologies is procedural and goal-directed. The focus of the device use evaluation can be on activities and tasks that are performed when using devices that have clearly identifiable performance goals. Thus, a task analysis of product use is viable, albeit challenging, as humans will often adapt their strategy based on their abilities. Often each activity can be broken into a sequence of subtasks (e.g., stages related to positioning, mobility, reaching, manipulation, and communication). Each of these subtasks can be broken down further, and many such classification schemes exist (see Chapter 11 and Chapter 9).

Building on these considerations, a process evolved to create a novel approach that, as appropriate, extracted useful ideas and approaches from a number of fields. The result of a collaborative effort of over 2 years is a new technology called the Mobile Usability Lab, or MU-Lab. This mobile system is specifically designed to study the accessibility and usability of targeted medical devices for individuals with diverse functional impairments and disabilities.

This chapter shares some of the internal decision-making behind its design (especially in contrast to conventional human factors and usability approaches) and describes how this system integrates a comprehensive Web-based evaluation procedure with data collection hardware and software, and a structured data analysis methodology. Finally, it describes experiences using the MU-Lab technology for a number of completed and ongoing pilot studies involving human subjects with disabilities.

13.2 BACKGROUND

A key challenge was to determine which of the many alternative approaches and methods to include in the MU-Lab. This section provides the motivation behind the selection of the components of this tool and may serve as a resource for groups interested in integrating considerations of accessibility or universal usability into a usability analysis activity.

13.2.1 Insights from Usability Analysis

Usability refers to the extent to which a product can be used by specified users to achieve specified goals in an effective and efficient manner, to the satisfaction of these users. In our case, the specified users included individuals with a diversity of abilities. Indeed, often individuals were recruited with disabilities that were known, based on our national surveys and focus groups, to have experienced difficulties with or lack of access to the device [7; Chapter 2 of this book]. The specified goals relate to roles played by a device to support and enable access by an individual to medical procedures and services. And finally, satisfaction includes both an indication of whether the procedure associated with device use was successful (e.g., collecting useful medical information) and opinions of the users (e.g., patient or health care provider).

Usability testing encompasses a number of evaluation methods that range from those typically used early in the design process that do not require a usability lab (e.g., cognitive walkthrough of the goals of and steps involved in using the interface and heuristic evaluation of whether a user interface follows established usability principles), to operational evaluations and human performance testing. Universal usability has a focus on designing products so that they are usable by the widest range of people operating in the widest range of situations as is commercially practical [8].

13.2.2 Insights from Universal Design

Universal design aims to design products (and environments) to be usable by people with a wide range of abilities, to the greatest extent possible, without the need for adaptation or specialized design [4; Chapter 6 of this book]. Universal design overlaps substantially with (and is sometimes considered a synonym for) the concepts of "design for all" (a term popular in Europe) and "inclusive design" [9,10; Chapter 7 and Chapter 8 of this book]. Seven consensus principles were developed that articulate universal design [see Chapter 6], and they are quite relevant to design and analysis of medical devices [4]: equitable use; flexibility in use, simple and intuitive use, perceptible information, tolerance for error, low physical effort, and size and space for approach and use.

Of note is that there is overlap between these and the usability approach called "heuristic evaluation." There is also overlap with accessibility (covered in subsequent pages), and indeed the Council of Europe's consensus definition of Universal Design includes the phrase: "... *products accessible and understandable to as well as usable by everyone* ... ."[11] But there are distinctions, as will be seen below. Device-oriented, more pragmatic performance measures have been developed [12], and evaluation method development is ongoing [13]; Chapter 18 and Chapter 9 of this book].)

13.2.3 Insights from Accessible Design

Accessibility addresses access to the intended use of a product (or service) by all for whom there is benefit, including any person with disability. There are degrees of this ability to access, both at the level of the individual (e.g., device use may be difficult or impossible; inaccessible device components or features may be optional or essential) and at the level of the population (e.g., more difficult or impossible for certain groups of users, integration of design features known to benefit people with similar functional capabilities). One important distinction between universal design and accessible design is that the former strives to satisfy the needs of all users concurrently, as far

as practicable, whereas the latter may add features specifically intended to accommodate the access needs of some groups of users who would otherwise lack access by providing approaches that might not be accessible (or even of interest) to other users (see Chapter 8 and Chapter 25).

We suggest that the MU-Lab tool provides a cross-disability *accessibility evaluation* rather than a universal usability evaluation in that our focus is on performing a usability analysis primarily for the parts of an activity (or task sequence) where access is difficult or impossible for any user. In other words, we prioritize the task analysis based on identification of difficult or impossible access barriers. We further consider the importance of the subtask or design feature associated with the access barrier. From this perspective, universal usability is a subset of the accessibility domain because it considers the needs of *all users,* with accessibility considering the role of assistive technologies in helping provide access, and also access through device options or multimodal interfaces.

Note that at times, making an interface more fully accessible for some people may lower the degree of usability for others. For instance, an interface may become more complex when multimodal options are added or as the number of options grow, but these may be the very features that make it accessible to groups of people with certain functional limitations. Thus while we call our technology the MU-Lab, the desired form of the usability analysis actually needs to be based on accessibility analysis considerations. A task analysis should be performed that targets understanding the nature and extent of barriers to use of the device. Thus the nature of this tool differs in some key ways from those used in conventional usability analysis.

For this project we avoid the use of the term "accessible design." *Accessible design* includes two classes of definitions:

1. It is a legal term that mandates for accessible products in certain categories where standards and guidelines exist, such as Access Board [5] guidelines, which were developed to help implement certain laws including the Americans with Disabilities Act of 1990 (ADA, [14]) and Section 508 of the Rehabilitation Act of 1973 as amended in 1998 [Rehab Act, [15]].
2. It describes the more general design methodology of maximizing accessibility and minimizing barriers that prevent individuals from using a product and participating in activities associated with it. Degrees of accessibility have been proposed to be captured by the words "difficult" [6] and "handicap" [16], each capable of describing a continuum while also having natural qualifiers (e.g., somewhat difficult and partially handicapped).

There are two basic design strategies for enhancing access:

1. Direct access - Modify a product to significantly improve its accessibility as related to the intended use of the product.
2. Assistive access — Make product interfaces compatible with add-on assistive technologies to provide the user with full access, or support other reasonable accommodations.

Legislation such as Section 508 of the Rehab Act allows either strategy [6]. Unfortunately, the legal definition of accessible design is not particularly beneficial to the aims of the RERC-AMI because, as far as we have been able to ascertain based on review of existing laws and discussions with federal experts, most medical instrumentation is currently not considered to fall under the scope of the guidelines. In contrast, regulations for implementing the ADA include a broad set of building design specifications called the "Americans with Disabilities Act Standards for Accessible Design" that hold facilities providing health care to an even higher standard than other businesses. Also, Section 504 of the Rehab Act requires that any program or service receiving federal financial assistance, either directly or indirectly, be accessible to everyone. This includes some health care facilities. Thus in terms of the universal ability to access, the laws are considerably stronger for health care facilities than for health care devices.

13.2.4 Insights from Human Factors, Ergonomics and FDA

The fields of human factors and ergonomics offer additional analysis tools and approaches from which the MU-Lab technology could potentially benefit. Often defined as the "science of work," human factors or ergonomics removes barriers to safe human performance, productivity, and quality by fitting products, tasks, and environments to people. Notice that this definition mentions barriers, but the barriers relate to safety and productivity rather than accessibility. Often human factors is considered to have more of a base in cognitive performance while ergonomics has more of a base in biomechanics ([2]; see also Chapter 11 of this book). Both matter. Notice also that, by definition, human factors and ergonomics professionals are concerned primarily with the safety and productivity of the worker, in this case the health care provider, and less so with the product, in our case, the patient.

There are two key points to make. First, the human factors or ergonomics field has a longer history than the aforementioned fields. For this reason, many more approaches and tools exist, some with roots in biomechanics and others originating in psychology. The second key point is that one strong proponent of the use of human factors methodology is the U.S. Food and Drug Administration (FDA) and its Center for Devices and Radiological Health (CDRH), which has the responsibility for regulating medical devices (including "durable medical equipment"). Product "safety" (for health care provider and patient) and "efficacy" (for the patient) are the key criteria for the FDA, and the CDRH has developed a strong interest in encouraging the use of human factors principles and processes in the design of medical products [17–19]. The FDA's Human Factors Branch has produced documents and supported standards activities that emphasize a systems perspective to help companies minimize user risks and maximize error tolerance (see also Chapter 17). One example is the current ANSI/AAMI/ISO HE74 standard (Human factors design process for medical devices) [20], and even more importantly, the emerging HE75 standard that is discussed in Chapter 15 and Chapter 16. Both involved active FDA participation. These FDA efforts are not surprising, given that medical error is said to be the eighth leading cause of death in the U.S., [21] and that many medical products initially approved for use by health professionals in controlled settings have migrated to home use. Often these products are used by persons with functional limitations, and indeed there is reason to believe that there is synergy between accessibility and safety. The FDA also attributes a significant proportion of injuries to what it classifies as use errors. Therefore, the MU Lab technology should address safety as part of its analysis, including identification of both unsafe activities and use errors.

Risk management frequently mentions the importance of understanding user abilities and limitations, often in the context of identifying "use scenarios." Kaye and Crowley [18] provide a useful distinction:

- Analytic approaches — Heuristics that involve systematic decomposition and analysis of device use (e.g., use scenarios and descriptions, descriptive functional and task analysis, heuristic analysis, and expert review).
- Empirical approaches — Use studies that involve evaluation of data from actual or simulated use of the device by a representative sample of test participants (e.g., walkthroughs and full usability testing).

Taken in the context of the aims for the MU-Lab technology, the analytical component of MU-Lab should be structured into the early part of the analysis, whereas the empirical component should be the heart of MU-Lab system.

13.2.5 Practical Considerations and Key Specifications

Prior work in the relevant fields described in sections 13.2.1–13.2.4 provided a foundation for the design of the MU-Lab system, summarized as follows:

1. From practical considerations related to RERC, the MU-Lab needs contextual field evaluations that meet certain criteria:
   - For high ecological validity, feasible evaluations should be done at a representative health care or home site.
   - The system should be mobile and modular, with wireless components used when feasible.
   - All hardware must fit within a rugged suitcase that meets airline requirements for carry-on luggage.
   - The system should enable the field researcher to effectively multitask, and include instructional documents.

2. From practical considerations related to the logistics of a multisite RERC team:
   - A password-protected Web site should be used as the primary mode for protocol planning, data collection and storage, and data analysis.
   - The cost of the MU-Lab technology must not be prohibitive, and must integrate commercial products whenever possible.
   - The technology will be developed and evaluated by the multisite team, communicating through e-mail and videoconferencing sessions.

3. From considerations and insights of usability analysis, we recognize that
   - Usability involves specified users who may have disability.
   - Specified goals normally relate to the role that the device plays in the context of goal-directed procedures.
   - One important approach is to solicit measures of user satisfaction.
   - Usability analysis is best done in stages, and use of multiple methods that extract information from different sources (e.g., experts, audio–video, and users) is often advantageous.

4. From considerations and insights of universal design:
   - Take advantage of project team member Molly Story's long history of leadership in universal design to heuristically integrate these concepts into the device evaluation protocol.
   - Apply the Principles of Universal Design at an early stage of the evaluation process to identify what difficulties users may have.

5. From considerations and insights of accessible design:
   - Carefully identify the intended use of the device.
   - Craft the analysis in terms of identifying barriers to use, and classify these barriers as "difficult" and "impossible."
   - Identify device features that affect accessibility, and study task procedures that may require use of these features, at least for some potential users.
   - Identify device features and access barrier events related to the use of assistive technologies (assistive access).
   - Consider involving test subjects who have a diversity of affected disabilities.

6. From considerations and insights related to human factors, ergonomics, and the FDA:
   - Take advantage of the experience of project team members at the University of California Ergonomics Lab, led by David Rempel, and at Marquette University, particularly Jack Winters's experience in neuromechanical performance assessment, to refine task analysis breakdown categories.
   - Take advantage of existing ergonomics software packages for event-based task analysis.
   - In addition to an accessibility-oriented task analysis, include identification of use error, unsafe activities, and exemplary positive features within the analysis.
   - Build on the foundation provided by existing FDA documents [17–19] that support and guide the inclusion of a human factors process in the design of medical instrumentation.

13.3 METHODS

The MU-Lab system development process attempted to synthesize the diversity of requirements and specifications, identified in Section 13.2.

13.3.1 General Framework

The MU-Lab system includes:

1. A Web-based Protocol Manager (PM) that helps guide the multisite research team and on-site experimenters through all the stages involved in performing accessibility and usability analyses, including preactivity preparation and postactivity data evaluation tools and procedures.
2. A portable usability lab consisting of a collection of hardware and software that can be transported within a suitcase for on-site task analysis.
3. A task analysis procedure that is event-based and focuses primarily on identification and analysis of access barriers and also documents unsafe activities and use errors.

Although it is possible to use the first two of these technologies separately, the package is designed as an integrated system.

The PM is an integral part of MU-Lab when it is used as a comprehensive accessibility analysis tool:

- It helps manage a multipart research study involving many devices because it is organized hierarchically with the IRB approval code for a study at the highest level.
- It helps coordinate, implement, and document data and filenames associated with a study, as it structures and guides data collection and documentation.
- It provides a structured way to screen potential subjects and to determine if any accommodations are needed for their participation.
- It provides structured methods to conduct universal design analyses of medical instrumentation and user pre- and postactivity scoring instruments that complement the task-based analysis tools.
- It supports integrated analysis of a single device or classes of devices with a "parent–child" structure that facilitates grouping and comparison of similar devices within the same class for a population of users.
- It supports multisite data sharing for approved members of the team, with an additional password protection beyond the initial user login that supports sharing of large files by uploading and downloading mechanisms among the researcher team.

The PM, developed by the team over the course of more than a year of meetings, guides the research team through various procedures that constitute the device evaluation process, including: formation of a research problem statement, understanding all aspects of instrument usage, universal design analyses, prescreening and tracking of subjects (both health care patients and practitioners),

activity performance observations during data collection, postactivity interviews of subjects, postactivity data analysis and documentation, and data tracking for each targeted medical device. The PM also includes tools to summarize the preactivity and postactivity questionnaire data, which are selectable by either instrument name or anonymous patient and provider codes. It is implemented in ASP.NET, C#, and XML in the Microsoft Video Studio.NET environment.

The PM has several choices for site navigation and data saving, including a "save and lock" mechanism to protect data from being accidentally overwritten once a form has been completed. It can be implemented on a single computer with the help of Internet Information Server on the computer's localhost Web site, in a standalone mode (where the data is stored on the computer's hard drive) or online whenever an Internet connection is available (where the data is stored directly to the network database).

13.3.2 Preactivity Preparation Protocol

13.3.2.1 Use of the Protocol Manager

The team recognized early on that efficient collection of the most relevant and useful data would benefit substantially from diligent and thorough preparatory work to describe the problem and plan usability testing in the field. Before collecting any data in the field with the MU-Lab, the research team takes advantage of the PM to develop and organize the details surrounding a particular research study.

The advance preparation portion of the PM is discussed within this section, which contains all of the PM sections that are completed prior to bringing in subjects to collect data. These forms include:

1. Section I: Problem statement page — This PM form is used to identify the specific device class (parent) and device model (child) of the medical instrumentation under investigation, as well as to describe the key access problems or concerns to be investigated.
2. Section II — Planning and preparation for usability testing.
   - Section IIA: Instrumentation usage page — This PM form documents practical aspects of the medical devices under investigation (e.g., medical facilities to be used for field testing, the manufacturer's intended and expected uses of the device (class), estimates of the intended and actual conditions of use at the test facilities, and the range of potential device users).
   - Section IIB: Universal design analysis of device (patient and provider perspectives) pages — These PM sections are motivated by the Principles of Universal Design [6, 9, Chapter 6], and are used to collect data on:
     - Sensory usability (e.g., ease of use for a patient or provider who is hard of hearing, deaf, or blind)
     - Cognitive usability (e.g., ease of understanding of how to use a device)
     - Physical usability (e.g., ease of use for a person who is very tall or short, has large or small hands, or can use only one hand)
     - Assistive technology accommodation (e.g., ease of use for a person using a cane, crutches, walker, or manual or powered wheelchair)
     - Error tolerance (e.g., device safety from damage, user safety from injury, and device tolerance of mistakes)
     - Equitable use (e.g., whether every user finds at least one way to use the device without stigma)

     Note that this approach bears some similarity to the usability approach of heuristic evaluation, which is also usually employed at an early stage of the process.
   - Section IIC: General requirements for test subject performance page — This PM form is used to document desired types of test participants (e.g., quantity, ability characteristics, and experience level), pilot testing needs, tasks and number of repetitions to be conducted, and data collection tools needed for the data collection sessions. It supports a team-based, interactive (either synchronous or asynchronous) approach to developing the field testing protocol.
3. Section III: Prescreening subject interview pages (patient and provider) — These PM forms are used to document interview responses from potential subjects and include sections on:
   - Demographic data (e.g., gender, race, and education)
   - Disabilities (e.g., vision, hearing, and paralysis)
   - Functional difficulties (e.g., reaching, grasping, and tremor)
   - Previous experience with this type of device
   - Provider experience level, treating patients with specific conditions (e.g., vision impairment, hearing impairment, or arthritis), if relevant
   - Assistive technology use (e.g., cane, walker, or wheelchair)

All of the above data are entered directly into the PM, using the software version on either the Web (www.rerc-ami.org/DiTwo/UserLogin.aspx) or the local computer. The user must first have a username and password, which are allocated and managed by the RERC-AMI. If an Internet connection is available, the PM can be accessed directly on the Internet, in which case the subject data collected during the research session can be stored directly on the remote server. Otherwise, the information is stored locally and the MU-Lab computer acts as the server until the data is uploaded to the network database.

13.3.2.2 Preparation of Hardware

The following steps were adopted:

- Preparation for multimedia data acquisition: Figure 13.1 displays a hardware schematic of the core MU-Lab technologies that are available for a usability analysis involving a targeted medical device or class of devices. The first step is to gather the appropriate technologies prior to travel to the field site. For some studies or locations alternative cameras, camera stands, or specialized sensors may be needed. The MU-Lab supports a variety of audio and video components, so the researcher can optimize the system for a particular device and research setting.
- Suitcase and components: All the MU-Lab hardware components fit within a standard carry-on suitcase (approximately 9" × 14" × 22"), as shown in Figure 13.2. The laptop computer is carried in a separate case that can be stored in the larger suitcase, if desired. The suitcase is protected with hard plastic shielding and contains a customized foam insert to secure the hardware components during travel. All of the hardware has specific locations within the suitcase that are labeled and several pockets within the case are used to house the cables and remote controls. Laminated copies of the informational documents included in electronic format in the PM (i.e., Quick Start, System Diagram, and Pocket Inventory) are also included as hard copies in the suitcase.
- Color quad processor: Because data collection software (i.e., Synchronized Video Data Acquisition — SVDA) currently supports only one video input for data collection, a color quad processor is used to compile up to four video streams into one output (to the laptop computer). Several display modes are available with the quad processor, depending on the number of cameras in use and different research requirements, including modes to view a single video feed, two video feeds via picture-in-picture (PIP), or up to four video feeds with a quadrant display. Either the remote control or the buttons on the front of the quad processor can be used to switch between the different modes, and more settings can be used to display the time, date and separate channel names.

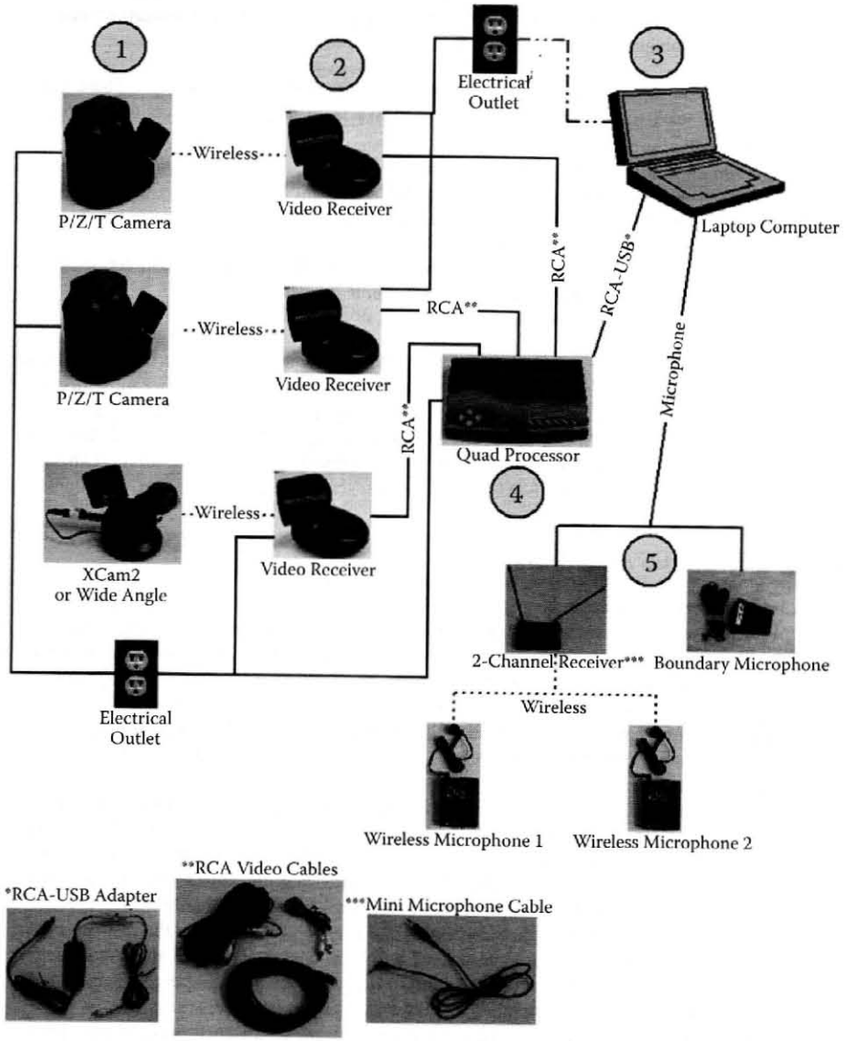

FIGURE 13.1 Schematic of the hardware technologies of the MU-Lab.

- Cameras: Several remote-controlled wireless video cameras were evaluated prior to selecting the models for inclusion in the MU-Lab, and it was desired to maximize signal quality while minimizing size and weight. Three different models were selected for inclusion in the MU-Lab, including higher-cost digital video cameras that can be automatically panned, tilted, and zoomed (Vanguard), and lower-cost digital video cameras that have 60° (XCam2) and 120° (WideEye) fields of view.

FIGURE 13.2 Photograph of the MU-Lab hardware components stored within the roll-aboard suitcase.

- Wireless video receivers: If multiple wireless video cameras are used for testing, a separate video receiver must be used for each camera. Each camera and receiver pair is tuned to the same unique channel (A, B, C, or D). Camera and receiver pairs can transmit signals up to 100 ft, although the highest quality signal is obtained when the receiver is placed near the corresponding camera.
- Microphone system: A discrete two-channel wireless microphone transmitter–receiver system and a boundary microphone are included in the MU-Lab to enable audio collection, if desired. The wireless (169–172 MHz transmission) microphones may be clipped directly onto a subject or a researcher, which is helpful in noisier environments. The protocol includes a process for checking for the amount of interference within the research environment before collecting data. A boundary microphone is available to enable audio collection inside a room without having to attach the microphone transmitter to subjects. The omnidirectional microphone can pick up audio in the hemisphere above and in front of the mesh area, but not below or behind it, and the protocol includes a process for checking the quality of the audio signal.
- Camera stands: Several camera stands can be included in the MU-Lab, and all of them have the necessary fittings for attachment to the stands. The carrying case has space for up to three camera stands (or they can be carried separately). The height ranges for the current camera stands are 7.5 in., 12.7 to 47.7 in., and 6 to 64.1 in. A ceiling amount is also available.

13.3.3 On- Site Usability Testing

This section describes the technical data collection process that occurs during usability testing with human subjects. Normally two components of usability testing data are collected from subjects: data collected with the PM, if used (e.g., subject questionnaires and recording of observations), and data collected using Synchronized Video Data Acquisition (SVDA) software (e.g., audio, video, and possibly sensor data files).

13.3.3.1 Use of the Protocol Manager for Preparation for Data Acquisition

The PM supports collection of field data only to guide the process and document activities. The PM software is available on a password-protected site on the Internet whenever there is web access at the field facility, and this is the preferred method for PM data collection since the subject interview data collected during the research session is stored directly online. Otherwise, if the information

is stored locally, the MU-Lab computer acts as the server until the data is uploaded to the remote server. Data is automatically stored within a folder structure (as XML files), which are readily available for further review in the field. Normally the field researcher will run both the PM and SVDA software (see Section 13.3.3.2) simultaneously on the same laptop computer.

Assuming the PM was used during the advance preparation phase (see Subsection 13.3.2.1), all of the collected data is available to the field researcher to help implement the sequence of tasks in the testing protocol. The PM can be used to record on-site observations and document file names, and then after data collection, to collect postactivity interview data.

13.3.3.2 Using SVDA to Collect Data

Synchronized Video Data Acquisition (SVDA, NexGen Ergonomics) software, developed by the authors of Chapter 12 (Yen and Radwin), is used to simultaneously collect video, audio, and sensor data. It supports a wide range of compression algorithms. Several other software tools are available for subsequent data reduction and analysis.

Steps required to use SVDA in the field are outlined in the MU-Lab manual, available to the on-site research both in hard copy stored within the suitcase and electronically on the laptop. The MU-Lab User's Manual also provides a suite of troubleshooting capabilities.

13.3.3.3 Use of the Protocol Manager to Administer Postactivity Questionnaire

After a subject conducts the specified sequence of tasks to use a medical device, the researcher has the option of using the PM to conduct a structured interview. The postactivity questionnaire complements video-based data collection of subject performance by systematically assessing the subject's opinion of the accessibility and usability of the devices.

The postactivity questionnaire covers the following areas: sensory usability, cognitive usability, physical usability, error tolerance, safety and comfort, and AT accommodation. Open-ended comments are also recorded at the end of each area. Many of the questions within the postactivity questionnaire are similar to the preliminary universal design analysis (in Section IIB of the PM; see Subsection 13.3.2), with an emphasis here placed on the subjects' impressions of their experiences during the testing session and their satisfaction with the device.

While the core set of questions are designed to apply to any type of medical instrumentation, the researcher can also add up to eight customized instrumentation-specific questions. This ability to add questions directly to the Web-based PM postactivity questionnaire is an important feature that has been used for every IRB-approved study conducted to date.

13.3.4 Postactivity Evaluation Tools and Procedures

13.3.4.1 Accessibility-Centered Task Analysis

The team evaluated a range of commercial products for video-based data analysis. One viable approach is to use video editing cards (i.e., Canopus DVStorm2 and Matrox RT.X100) that use Adobe Premiere for enhanced video editing capabilities. However, after evaluating many approaches, it became apparent that an event-oriented ergonomics package adapted for barrier oriented accessibility analysis, was most suited to our needs.

Multimedia Video Task Analysis (MVTA, NexGen Ergonomics, developed at the University of Wisconsin–Madison) is used for data and task analysis procedures, specifically interactive time and motion analyses of video recorded activities by researchers (Chapter 12). In general, MVTA is used to identify events with terminal break points during a timed activity for usability analyses. Multiple video and sensor data streams are synchronized so they can all be viewed on the same timeline during video playback, and video files may be viewed at any speed (i.e., real time, slow motion, fast motion or frame by frame) in both forward and reverse directions. Optionally, an event

may be replayed in a continuous loop or an arbitrary event or point in time may be displayed. MVTA can also be used to produce conventional time study reports or to study the frequency of occurrence of any particular event, which may be helpful in usability analyses but has not been used with the MU-Lab thus far.

A standard protocol and template were created for conducting medical device usability analyses with MU-Lab and MVTA. The default set of MVTA records for all usability analyses, based on an evolutionary internal development process, consists of the following:

1. *Orienting and positioning body or device barrier* — Consider: dynamic support needs, such as at setup or beginning and end of device use, e.g., transferring, body balance or stability, physical obstruction, movement requirements, reaching, strength requirements, etc.
2. *Body support barrier* — Consider: static support needs for body or extremities without which there is loss of stability or fatigue, e.g., seat, back, leg, arm, and head support.
3. *Physical interaction, manipulation, and operation of controls barrier* — Consider: physical interactions with controls (e.g., switches and levers), reaching, handling, strength, dexterity, motor control, physical obstructions to hands (or other appropriate body part), etc., during use.
4. *Sensory barrier with communication or display* — Consider: device exceeds sensory capabilities for vision, hearing, touch, etc. (e.g., sightlines, letter size, sound volume, ambient noise, and tactile features).
5. *Cognitive barrier* – Consider: misunderstanding device, misinterpreting visual cues, memory demands, cuing, and language (often difficult to interpret).
6. *Use error* — Consider: misuse from manufacturer's intended manner of use.
7. *Unsafe activity* — Consider: activity that may put subject or other person at risk of injury. Note that this is a very important record and special attention should be paid to accurate identification and classification.
8. *Environmental barrier with device* — Consider: architectural elements, auxiliary furniture, or equipment other than device.
9. *Unable to use assistive technology effectively with device* — Consider: device impedes effective use of assistive technologies.
10. *Assistance from another person required with device* — Consider: must directly affect subject's normal, intended, and expected use of device; may be physical (does not include device use tasks normally performed by someone else) or verbal (does not including subject prompting needed for task performance).
11. *Exemplary positive device features* — Consider: device features that enable or facilitate use (does not include environmental features).
12. *Flag for review* — Consider: need for further review or discussion.
13. *Context-awareness comments.*

Notice that records 1 to 5 classify accessibility barriers. For each of these, three possible events may be marked:

- Impossible — a critical barrier that makes intended device use impossible for this person.
- Difficult — a substantial barrier that makes device use difficult but still possible.
- Mildly difficult — a very minor barrier to device use or inconvenience (use of this category is optional).

Of note is that this approach diverges from the conventional "task analysis" that is common in usability engineering and human factors and ergonomics. Rather, the focus here is on accessibility barriers, scored using the "impossible" and "difficult" terminology that is common for accessibility guidelines such as the Web Accessibility Initiative Guidelines, Priority Levels 1–3 ([22]; see chapter 23). This is an important point, and perhaps more than any other helps us distinguish between

usability analysis (where the focus is on task performance) and accessibility analysis (where the focus is on identifying and then trying to understand barriers). In essence, the focus of accessibility analysis, as developed here, is on using barrier analysis as a form of "triage" for targeted (and detailed) analysis of strategic subtasks.

Notice also that records 6 and 7 identify use error and unsafe activity, events of interest to the FDA that are clearly worth documenting. Of particular interest to the RERC-AMI and others is a better understanding of when these events correlate with accessibility barriers.

Finally, records 8, 9, and 10 identify barriers or support provided by other objects and people that may be in the vicinity and affect use of the device. The project team decided that no barrier should be marked if subjects use an assistive technology (e.g., glasses, prosthesis, or wheelchair), and they are successful in using the device.

Importantly, custom MVTA records and events can also be added for more specific data analyses. This is an important feature, one that was used, for instance, for the study reported in Chapter 14. Examples of custom records include:

- Active device interaction (consider: device features that the subject actively engages for use).
- Shoulders or arms supporting body weight.*
- Contact pressure on hands or arms.

Examples of custom events include:

- Wrist range of motion — Moderate and Extreme**
- Reaching AND grasping — Moderate and Extreme***

13.3.4.2 Integrated Analysis of Subject Populations and Devices

A hierarchical "parent-child" structure with summary reporting capabilities of the PM enable a researcher to easily compare data from different subjects for any given device or class of devices. The researcher can generate reports for a group of subjects who use the same device, for one subject who uses a class of multiple devices, and for the comparative rating and ranking survey for several devices within the same class. For instance, if a researcher collects data for a group of individuals, who use several different examination tables, pre- and postactivity survey data can be summarized (1) for several subjects and one examination table, (2) for a group of subjects and several examination tables, (3) and for a subject's rating and ranking comparison of the examination tables. These summary tools within the PM automate much of the data reduction process, so the data is presented in an organized, tabulated manner with the total number of respondents for a given response summed.

13.4 RESULTS AND DISCUSSION

Two sets of the core components of the MU-Lab technology were first successfully transported in suitcases and demonstrated at an RERC-AMI Advisory Council meeting in February 2004 in Oakland, CA. At this stage the PM software was still being refined, and an aim was to solicit input from the project's advisors.

* Custom records can be added as custom events if they can be categorized within a default record. For example, "Shoulders or arms supporting body weight" could become an event under the "Body support barrier" record.

** We can always assume a custom window-event is an instance of the default window-event. So if custom events are used in place of the default events, the default information still exists, as well as more detailed information for those who are interested.

*** "AND" events can be used when there is more than one barrier (event) occurring simultaneously.

The first human subjects studies started in the summer of 2004. To date, MU-Lab has been used or is in use for eight IRB-approved human subjects studies. Of note is that several of these studies were designed specifically to evaluate MU-Lab as part of the development process [23] and were performed by graduate students from Marquette University as part of their master's projects. For these projects, a wide range of medical devices were purposely selected to be evaluated by samples of subjects with diverse abilities. Part of one of these is highlighted in Chapter 14. In all, these evaluations involved five to twelve subjects using one to three sample products for each of the following types of devices:

- Exam table, hospital beds, and weight scales
- Dental chairs, dental monitor, and portable (dental) x-ray
- Cycle ergometers, heart rate monitors, blood pressure monitors, and pulse oxymeter

These evaluations served multiple purposes. First, because these studies were performed by members of the team developing MU-Lab (and coauthors on this chapter), feedback from these experiences has been used to considerably refine the MU-Lab technology, especially as related to the PM. For instance, two versions of the PM were developed, versions 1.0 and 1.1, with the latter including a refined reporting structure and more capabilities for comparative data analysis. Second, these studies helped establish a secure database of examples of accessibility barriers for a range of device–disability conditions. The database has been critical to a reliability study of the barrier data analysis protocol used within MVTA, in which a collection of members of the California–Wisconsin team have independently scored videotape segments in MVTA using the core categories of records from Subsection 13.3.4.1. This internal study, which is especially focused on examining reliability of identifying "impossible" and "difficult" events, is nearing completion. Third, these studies have refined instructional materials such as the MU-Lab manual [24].

The other studies that have used MU-Lab are varied in nature. One study targeted videoconferencing technologies where the participants on either side of goal-directed tele-encounters had differing disabilities and was performed at the Telerehabilitation and Performance Assessment Lab at Marquette University. Several studies have targeted analysis of innovative technologies designed for use in stroke neurorehabilitation, including one study at the Veterans Affairs Medical Center in Milwaukee. Two recently approved studies relate to use of MU-Lab for projects associated with the RERC-AMI's Development Program D3 — Emerging and Accessible Health care Technologies (see http://www.rerc-ami.org/ami/projects/d/3). Both relate to usability evaluation of innovative interface technologies.

Several human subjects studies related to Research Program R2 — Usability Analysis (see http://www.rerc-ami.org/ami/projects/r/2), such as examination tables, imaging equipment, home monitors, and infusion devices are in preparation. Recently started is a study related to Development Program D2 Design Projects (see http://www.rerc-ami.org/ami/projects/d/2) that will evaluate, for a diversity of users, an exercise ergometer. This will include an integrated collection of potentially exemplary accessibility features that are largely based on the work of student design teams from around the country. Their work targeted lower-cost accessible ergometers in the RERC-AMI national design competition (see also Chapter 8). The titles and principal investigator for all of the RERC-AMI sponsored human subjects studies that use MU-Lab are posted at http://www.rerc-ami. org/ami/projects/human/, a site that is updated as new projects are approved.

Notably, a side benefit of MU-Lab use is that it serves as a natural training tool for learning about accessibility analysis, usability analysis, universal design, and human factors and ergonomics. MU-Lab provides a structured process for integrated accessibility and usability evaluation. This is not a self-evident process, and indeed MU-Lab is the consequence of an evolutionary process that, upon reflection, differs from what any member of this team could have conceptualized two years

ago. This is, in many ways, its added value. It is both a procedural tool for protocol development and implementation, and an educational tool.

Finally, MU-Lab complements the MED-AUDIT tool that is being developed for Research Program R3 — Accessible Metrics (see Chapter 22). The key distinction is that for MED-AUDIT there are no human subjects. Recent insights gained from the expert survey compared MU-Lab and MED-AUDIT approaches that are reported in Chapter 14. Based on these insights, it is becoming clear that these two alternative approaches are, in fact, quite complementary as we strive to establish excellence in performing systematic accessibility analysis of medical instrumentation.

13.5 FUTURE DIRECTIONS

The integrated collection of technologies called MU-Lab that is described in this chapter will continue to be a critical vehicle in the RERC-AMI's quest to better understand barriers to accessible medical instrumentation and to identify strategies for removing such barriers. From the initiation of this project in 2003, the aim of this tool has been to serve other RERC-AMI activities, in particular projects within Research Program R2 (for detailed usability analysis of specific, targeted problematic and potentially exemplary medical products), Development Programs D2 and D3 (for evaluation of accessibility and usability of innovative medical technologies), and Research Program R3 (as a complementary approach to the MED-AUDIT accessibility metric described in Chapter 22). Because a MED-AUDIT accessibility analysis requires less investment of time and resources than a comprehensive MU-Lab human subjects study, it makes sense that MED AUDIT eventually be integrated into the preactivity component of the PM, where it can be used as a sort of accessibility triage filter that helps identify strategic types of users who may be predicted to have use barriers as well as suggest task procedures that should be part of the testing protocol for the device.

Use of MU-Lab is gradually becoming habitual for staff members of the RERC-AMI. This is important. A considerable advantage of such habitual use is that it influences how we approach research and design evaluation activities. Based on planned use, the main improvements will relate to refining the PM so that it better supports advanced statistical analysis. This is a challenge because unlike for conventional studies with highly controlled subpopulations, we proactively desire subjects with disabilities and indeed comorbidities because our national consumer survey has found this to be the norm (Chapter 2). Thus we are looking into advanced methods for statistically correlating assessment scales made at the preactivity stage (e.g., impairment and independence) with postactivity metrics related to performance and identification of barriers. We will also continue ongoing activities related to assessing and improving reliability.

Against the advice of several members of the RERC-AMI Advisory Council, we have chosen not to patent or sell this technology. Information on and about this technology is freely disseminated, and RERC-AMI staff is available to provide technical assistance to teams that may want to implement the hardware at their site or use aspects of the software. The core PM web software, written in C# and hosted on a password-protected site, is only available by way of first building a collaborative relationship with the RERC-AMI at some level. The main criteria for collaboration with an entity outside of the RERC-AMI is that they have interest in accessibility and usability analysis, and that they agree to provide periodic feedback on their experiences with MU-Lab. This in turn may help improve MU-Lab, which is our intent.

We would like nothing better than to have the MU-Lab technology used by dozens of groups interested in usability or ergonomic or accessibility analysis; because of the nature of the package, such users will likely find that they end up employing an integrated accessibility–usability approach to conduct their research, which benefits all.

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14 Comparison of Accessibility Tools for Biomechanical Analysis of Medical Devices: What Experts Think

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CONTENTS

ABSTRACT

Accessibility analysis tools can be used to better understand the nature and extent of access barriers related to medical devices so better designs can be implemented. Expert comparisons of the utility