HeartSense Electrocardiography System
Concept Development

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Phase One

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Project Introduction

Context

Hospitals are competing for patients in an environment of intense scrutiny by consumers, insurers, and investors. Mobile medical technicians help hospitals work, by providing the essential patient interaction required for many diagnostic tests.

Electrocardiogram (ECG or EKG) technicians gather information about the electrical function of patients' hearts, and then deliver that information to those who make diagnoses. Throughout the process, they must keep track of appointments, and keep themselves supplied with all the things they need to do their jobs.

Physical Issues

ECG technicians take necessary procedures to the patient, instead of making patients move to the equipment. They do their work in dynamic environments with limited space. The equipment is often heavy or fragile, and obstacles such as ramps, wall-mounted items, and gaps in the floor can cause delay and damage.

Technicians need to use this equipment while interacting with patients, families, nurses, doctors, and other technicians, who could all be at the scene during procedures.

Designers must balance issues of durability, maneuverability, and usability in product designs. ECG equipment needs electrical power for use. The primary consumables for ECG are electrical contact patches and paper for printouts.

Data Issues

ECG technicians generally follow set protocols to operate the equipment, but must apply some measure of interpretation to assure that their data are relevant, reliable, and complete.

Assigning diagnostic data to the right patient's record is extremely important for proper health care. Mistakes can lead to unnecessary charges, delayed test results, and even death.

Information captured during EKG testing must be shared with other health professionals, and is often also stored in hospital information systems. Test results are commonly compared to previous results for diagnosis of trends.

Test results are susceptible to loss or accidental erasure, if they are ever stored on physical media.

ECG technicians are usually supported by administrative employees. These associates dispatch orders, facilitate communications, and sometimes transfer data to those who need to evaluate it.

Project Scope

HeartSense is a product concept for electrocardiography. The system provides the following benefits:

- Increased portability
- Increased equipment hygiene
- Simplified ECG readings
- Increased patient comfort
- Connectivity with wireless networks for fast, accurate data transfer and powerful dispatching

Observation and analysis revealed insights and design criteria in the following opportunity areas:

- **Interaction**: between technicians, equipment, and patients;
- **Mobility**: transport, parking, and restocking that occurs when the equipment is in use;
- **Information**: keeping orders and data moving smoothly; and
- **Equipment Management**: setting up equipment, maintaining it, keeping track of where it is, and storing it.

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1 Herzlinger, Regina. *Market-Driven Health Care* (Reading: Addison-Wesley, 1997), 16-17, 47-57, 99-104, and 117-121. Consumers are demanding more from health care, in areas of convenience, empowerment by knowledge and control, and quality of care. Insurance companies and other payers seek all of these, at lower costs!
The product concepts illustrated in the first part this paper can be classified by the opportunity areas they address. The concepts can bring improvements in more than one area at a time.

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Observation:
ECG machines must be moved close to patients because of the wire between the main chassis and the acquisition module. Printouts are not used in the room; they are used by people outside the room.

Design Criteria:
• Maneuverable in patient room.
• Minimize intrusion in patient space.
• Make data transfer fast/automatic.
• Reduce chances of switching cords and leads.
• Navigate within patient rooms.

**Interaction**

**Observation:**
Rolling the entire EKG cart into patient rooms can be challenging because space is usually limited. Laying equipment down on patients can add unnecessary discomfort to procedures.

**Design Criteria:**
- Minimize patient discomfort during procedures.
- Minimize intrusion in patient space.
- Make data transfer fast/automatic.
- Reduce chances of switching cords and leads.
- Navigate within patient rooms.

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**User Interface**
A central hub for the leads connects wirelessly to the main cart for printing and data storage.

This portable piece slips under the mattress, to avoid touching the patient. This may reduce

Leg leads are farthest from the central hub, and are good candidates for wireless transmitters. However, the leg leads must be electrically connected to the arm leads for certain readings.

ECG acquisition modules are electronic devices that connect EKG machines to a group of lead wires. They are often balanced on top of patients, somewhere in the area between the sternum and the groin. If the lead wires could emanate from something that does not touch the patient, discomfort may be reduced, and hygiene is easier to maintain.
Interaction

Observation:
The lead wires on ECG machines emanate from a central acquisition module. This module is sometimes placed on or near a patient's groin in order to reach all necessary contact points.

Design Criteria:
• Minimize patient discomfort during procedures.
• Minimize intrusion in patient space.
• Reduce chances of switching cords and leads.

The two sections of this acquisition module are held together for transport. They can be used together, or the limb leads can be separated from the chest leads for easier placement.

Part of the reason lead wires need to be as long as they are is that they must all come from a central piece of equipment. By separating the chest leads from the limb leads, the required lengths can be reduced.

Using two parts allows shorter lead lengths. Short range wireless networking would allow the modules to communicate with a data consolidation station.
Interaction / Mobility

Observation:
The lead wires on ECG machines are given extra length to reach the limbs of all people. As a result, lead wires get tangled easily, and can touch the floor.

Design Criteria:
- Minimize patient discomfort during procedures.
- Minimize intrusion in patient space.
- Make data transfer fast/automatic.
- Reduce chances of switching cords and leads.
- Navigate within patient rooms.

Retractable ECG Leads

A common complaint about current ECG technology is that the long wires get tangled. Their ends also occasionally hit the floor when acquisition modules are carried. If the leads could retract into the acquisition module, they could be carried and stowed more easily.

Leads are pulled out from the acquisition module for use. Spring-loaded wheels draw the lead wires back into the compartment with the press of a button.

It may be possible to consolidate multiple lead wires on each spring loaded wheel.
Interaction / Mobility

Observation:
Rolling an ECG cart into patient rooms can be challenging because space is usually limited.

Design Criteria:
• Move easily through hallways and elevators.
• Provide storage space and organization for an adequate storage of supplies.
• Navigate within patient rooms.

Vertical-Mount ECG Station

Hospitals often mount vital signs monitors on poles, with a wheelbase that looks like the sketch on the far left.

The first five sketches below explore a design without a keyboard. They use card readers and dispatcher programming for most data entry, and the touch screen for the rest.

Printer door open for changing paper.
Printer, touch screen display, and storage for electrode stickers and wireless acquisition module.
Wheelcovering.
Larger wheels increase mobility. Hydraulic pump allows height adjustment.
If a cover is added, chambers in the base provide a place to capture ECG leads, when the acquisition module is stored on the shelf.
Smaller offering with text messaging communication, via small keyboard.
Interaction / Mobility

Observation:
Space in hospitals is limited, and shared by many people and much equipment. Some medical equipment changes form depending on whether it is in use, in transit, or in storage.

Design Criteria:
• Navigate ramps, elevators, and hallways.
• Minimize patient discomfort during procedures.
• Survive collisions.

Lifting the extension bar gets the leads off of the patient without letting them hit the floor.

Stow-Away Lead Arm

A solid bar that extends from the cart-mounted instrument can be stowed into the cart, allowing for easier maneuverability. Collisions are reduced because there are fewer parts extending past the perimeter of the cart.

For transport or storage, most of the bar can be stowed within the cart.
Interaction / Information / Management

Observation:
Whenever mobile medical technicians need to capture data, they also need to attach information to the data that identifies the patient (and themselves.)

Design Criteria:
• Confirm that the right procedure is being done on the right person.
• Reduce data loss.
• Use consistent data coding to assist retrieval.
• Standardize interface design.
• Facilitate patient/technician data entry.

Identification Coding

By adding certain information to the patient’s wristband and the technician’s ID badge, a new system could reduce the time and error rate of data entry, vs. typing on a keyboard. As a result, typing is greatly reduced. Therefore, alphanumeric entry technology can be optimized for other factors besides typing speed, such as resistance to bacteria and ease of cleaning.

- Barcodes and radio-frequency tags are two ways that identification details can be stored. Scanning would simplify data entry of patient and technician data.

- Scanning wristbands to enter patient data could reduce errors and help tie data to centralized systems.

- The acquisition module for ECG leads could incorporate the code reader, since it is usually placed near (or on) the patient.
Observation:
Technicians must keep track of orders. Most orders are assigned by dispatchers, whether scheduled or "stat" (an emergency). Doctors often request a reading by asking technicians directly. It is possible to lose track of orders. Knowing which data have been archived is not easy to determine. Existing order management features are not always used.

Design Criteria:
• Confirm that the right procedure is being done on the right person.
• Reduce data loss.
• Standardize interface design.
• Facilitate cross-departmental coordination of ordering.

Order Consolidator
Order management means keeping track of all the requests for procedures, assigning orders, and getting the data archived. If orders are not tracked, a painful or fatal delay of treatment can occur. The Order Consolidator uses touch screen technology and wireless communications to simplify order management.

The active record is shown in detail above the list.

Whether orders are added by the dispatcher or by the technician, this screen helps technicians fill orders in the best sequence.

Soft keys allow users to navigate through the history of tests, add a new order, or delete an order.

Status of orders and urgency of requests are coded in the “Data” column. The “Archive” column indicates whether or not data has been downloaded to the archive system.
Conclusions from Phase One

There are promising opportunities for product design in this category of medical equipment. The ECG machine can benefit from human-centered design in the areas of physical form, communications links, and electronic user interface.

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<th>Communications</th>
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Phase Two
There are many times when the current method for data transfer, floppy diskette, is susceptible to loss or damage.

Hospitals that invest in wireless networks will be able to eliminate this danger, because ECG data can be sent directly to the archive system.
A wireless ECG system can be much smaller than existing equipment. Inexpensive wireless printers can be stationed anywhere printouts are needed. Centralized order entry and dispatching can eliminate much of the data entry requirements of technicians.
System Definition

Overview of Components

Limb Lead Unit
- 4 retracting leads
- Touchscreen user interface
- Stores scheduling data
- Receives data from the chest unit
- Transmits data to printers and wireless networks

Chest Lead Unit
- 6 retracting leads
- Transmits data to the limb leads

Recharging Base
- Outside the room on a cart or nurses’ station surface
- Network connection optional, for hospitals without wireless networking

Wireless Printer
- Outside the room on a cart or nurses’ station surface
- Already available for printing from personal digital assistants
Existing approaches have more physical component connections. This means more places that the equipment can break down, especially because these components are tied together with long cords.

Wireless solutions eliminate many of the physical connections, allowing more freedom of movement for the operator, and fewer electrical connections to break.
This diagram illustrates how the equipment fits into the hospital environment.
This is an overview of system components spread across three zones: outside the patient room, optional placement in or out of the room, and components that are needed in the patient room for ECG acquisition.
The data flow between components helps design teams separate design tasks and understand required connections.
System Definition

Interferences

There are always phenomena that can interfere with proper equipment performance. These interferences need attention in the final system design, and where possible should be designed out of the system.

For example, wireless data transfer to the archive system eliminates lost/damaged electronic media.
Translating functions into subcomponents helps define product requirements.
The system could include two versions of the recharging base. If a hospital has a wireless network, the base does not need a network connection, wireless tranceiver, nor antenna. This saves money.

On the other hand, hospitals with wired networks can still take advantage of wireless ECG measurements by using the version that has all of those components. This approach still has the advantages of fast data archiving with no physical media.

Either way, wireless printers can provide the printouts needed for immediate interpretation by ECG order requestors.
Phase Two Concepts

Options with Two Retracting Leads
Once the system components are clarified, new work can begin on form ideation and exploration. These designs only use retracting leads for the arm connections. This approach does not stow as cleanly as designs that retract all leads.

Cardiolantern 1
Portable component does not stand on its own. Intended to be carried directly to the patient, leaving the base behind.

Cardiolantern 2 (transport mode)
Easy to carry, easier to set down on any flat surface.

Cardiolantern 2 (use mode)
Arm lead retractors end up outside the legs at about the knee, allowing the leads to be connected to the wrists.

Cardiolantern 3 (transport mode)
Easier to carry when stowed. Handle is too small for easy carrying.

Cardiolantern 3 (use mode)
Easier to carry when stowed. User interface can be folded out for continued use, or in for protection.

Paddle
The chest lead component connects to the back for transport. Large user interface allows easier use.
Phase Two Concepts

Ten Retracting Leads
In order to achieve a tighter configuration for transport, a system like this provide stowage for all the leads.

Mini-Retractor
Extremely compact form factor allows two-finger holding and transport.

Separated Components
Leads retract into pockets in the device.

Positioned for Use
Components might actually be too small, susceptible to loss and theft.

ECG Belt
Wireless system for chest lead replacement. Five organic LED screens illuminate signal hotspots, and self-configure for Wilson’s chest lead emulation. A user interface on the sixth segment allows technicians to operate from the side.

Uncoiled
The belt has segments that are adjustable to accommodate different patients.

Coiled
Easier to carry when stowed. User interface can be folded out for continued use, or in for protection.
Phase Two Concepts

HeartSense System

This form exploration brings together many features to help the electrocardiogram technician take readings faster, with less equipment. As part of a wireless network, the device eliminates data loss due to damage to or loss of physical media.

Handle with grip contains batteries (rechargeable).

LEDs indicate whether or not a lead is attached correctly. Figure diagram helps with lead placement.

Retracting leads are docked within the device.

Chest leads dock within the detachable chest unit.

Protective cover with opening at the bottom also supports user interface during use on the bed.

Touchscreen interface shows data and allows interaction. Technicians always have a pen, so keyboard layout can have smaller keys. Remote order entry eliminates the need for data entry in many cases.
Phase Two Concepts

HeartSense System

LEDs on the chest unit are arranged in a pattern reflecting placement on the chest, to help with proper lead placement.

Detachable chest lead unit fits in a depression on the back of the instrument.

Retraction mechanisms on lead wires include callouts for proper lead placement.

Actual Size: 5.5 in x 7.6 in
HeartSense System

A model of the system is useful for evaluation by users, and informs further development.
**Design Criteria Review**

This is a summary of the design criteria addressed by the HeartSense concept. Some criteria are met by the physical design, and a few would be easily addressed by careful attention to the user interface.

### Interaction

**Initiating Contact**
- Standardize procedures to reduce variability.
- Appear non-threatening to the patient.

**Procedures**
- Minimize patient discomfort.
- Simplify the procedure.

### Mobility

**Maneuverability**
- Move easily through rooms, hallways, and elevators.
- Help avoid obstacles.
- Move up and down ramps.
- Move over changes and gaps in flooring.
- Do not tip over, harm people, or lose control when moving.

### Information

**Channels**
- Facilitate the organization of orders from multiple channels.
- Allow for multiple channels for orders.
- Allow capture and review of orders.

**Patient/Technician Data Entry**
- Minimize intrusion in patient space.
- Facilitate patient/technician data entry.
- Confirm that the right procedure is being done on the right person.
- Reduce keyboard data entry.

**Data Acquisition and Transfer**
- Use inexpensive data transfer media.
- Reduce data loss.
- Make data transfer fast/automatic.

### Equipment Management

**Maintenance**
- Allow access for cleaning and disinfection.
- Protect parts that cannot withstand cleaning agents.
- Enable access for repair and maintenance.
- Survive repeated use.
- Alert users when it is broken.
- Facilitate circulation of broken equipment to repair facilities.
- Facilitate regular maintenance and repair.

**Waste**
- Minimize the amount of all waste, especially toxic waste.