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INTRODUCTION:

The emerging nature of telemedicine is an environment in which health care providers seek to share a vast array of medical information which is captured, disseminated, and displayed in a variety of modalities ranging from email to high resolution imagery and real-time video teleconferencing. In theory clinicians should be able to select and use the information modalities and electronic medical record systems they prefer, with the technical systems integration issues of information discourse among disparate sources being transparent.

The primary objective is to develop a first responder device for collection of ECG and wound data, transmitting that data wirelessly to a central medical collection point where the data is interpreted and used to remotely direct the treatment of the patient prior to and during medial evacuation. Data once received at the central location must be merged with the patient's record stored in the Hospital Information System (HIS). This merging process will require the development of an interface engine that will allow the collected data to be transferred to the patient's record within the HIS. A commercial-off-the-shelf (COTS) telemedicine integration tool will be used for the rapid configuration and dynamic integration of medical data collection instruments and medical information systems. The integration will include medical information and image display modalities and legacy electronic medical records systems. ViTel Net's MedVizer™ Informatics Integration Platform (MIIP) and Dvision Toolkit will be used to integrate with wireless miniature computer technology, using Windows and Linux based operating systems, to enable access to existing enterprise medical informatics systems, patient medical records, clinical repositories, and knowledge bases at the point of care. The same wireless device will be used to gather patient information (vital signs), populate patient records, and support data entry, clinical orders, treatment regimes to patient records, and interface to other information management systems impacted during hospital rounds and bedside treatment procedures. This device will be used by the healthcare provider at the point of care to have full access to available medical informatics and provide a means for entry of new information across the requisite information management system using a wireless hand held computer device. This will provide the physician the same capability, using miniature computer technology, from any location within the enterprise, from home, or while traveling. The hand held wireless computing device should be capable of supporting healthcare providers across the entire operational healthcare continuum. A similar device must be available to the field medic at the point of casualty where critical medical information is introduced into the healthcare evacuation system. Recent technological advances in the fields of miniature computers and wireless communication has enabled the exploration of this healthcare application.

Essential vital data must be able to be transmitted from the site of the incident and continue during the evacuation cycle. Such a device must have a small form factor and at the same time be sufficiently rugged for use by the first responder at the site of incident

as well as during transport. This device must also be adaptable to various communications modalities. The cardiology component must include and analytical capability and transmit only abnormal cardiovascular results and not the complete ECG read thus reducing communication requirements. The device must support image capture and transmission to enable the wound care component. The device will be developed as a laboratory prototype capable of demonstrating interoperability with the selected medical devices. It is the intent to test, evaluate, and this concept in laboratory type environment.
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Once tested and validated in both military and civilian peace-time care environments, the same concept of information enriched wireless networked centered health care can be extended to include forward support military health care facilities in both combat service support and operations other than war including homeland Security operations. The centric specific data collection instrument fully integrated with fixed hospital telemedicine and medical information systems will enable point of care data entry and retrieval of essential patient information across the continuum of the military and civilian health care enterprise. The application of the wireless system will improve the accuracy and quality of patient medical records; provide access to knowledge information systems, and immediate access to distributed medical experts in both routine and emergency situations. Moreover, it will enable point of care health care providers to make more informed and accurate medical decisions. Likewise such a device can improve follow-on care and effect outcomes by providing the means to capture accurate and timely patient care information from the point of first encounter through the care and evacuation chain to completion of care

The research hypotheses are:

- Wired and wireless communication infrastructure can be integrated to provide seamless communications sufficient to support medical applications.
- Microcomputer technology can be used to develop a centric specific data collection instrument with embedded wireless (long and short) communication functionality.
- A wireless computer device can be integrated with the Army's Patient Information Carrier, and legacy DoD medical information systems to retrieve and enter essential patient and clinical information.
- A wireless device for the collection of cardiovascular data and an interpretative algorithm can be integrated with the centric specific data collection instrument.
- Digital images can be wireless transmitted to the centric specific data collection device and transmitted wirelessly.
- HL7 interface can be developed using XML and/or ODBC interface.
- Web-enabled technology can be integrated with the device to provide immediate access to distributed medical expertise and on line commercial off-the-shelf (COTS) medical knowledge bases.

Study Design:

The tasks during this research period will accomplish independently and subsequently integrated. The cardiology monitoring and wound care management functions were integrated with the centric specific data collection device. The HL7 task was accomplished to demonstrate that data exchange between commercial legacy health information systems and the military health information systems can be negotiated through this interface. The data then collected through the cardiology and wound care will be gathered and populated to a patient record, where with the HL7 interface data elements can be exchanged. .

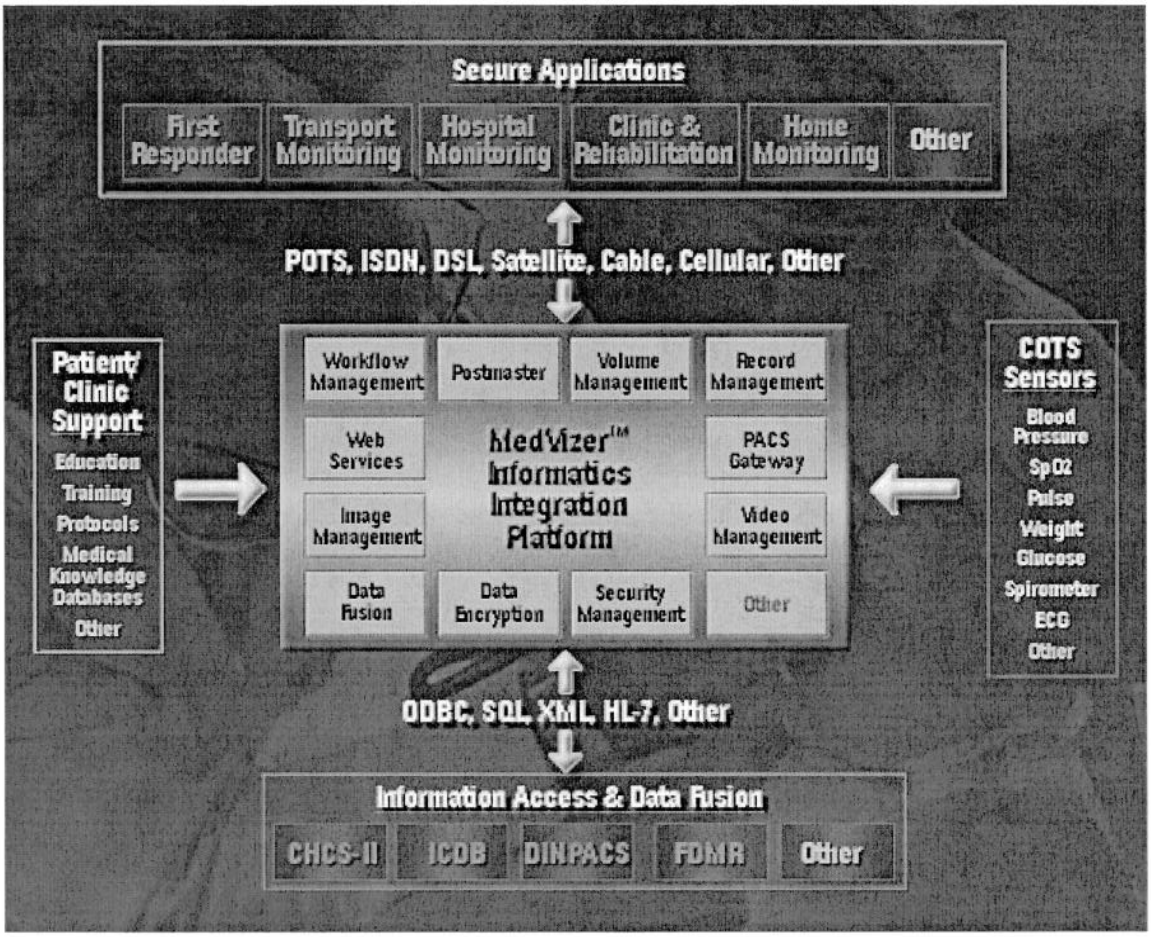
This revised approach continues to enable ViTel Net to apply the planned research methodology as described in our proposal—including computer modeling and simulation—followed by prototype development and bench testing. Following a successful bench test, the prototype is introduced into a "live" environment where it can be integrated with an existing medical informatics system for data retrieval and input process testing. The final step will be the introduction of the integrated device into field and clinical settings for testing and evaluation.

The research project from conception was projected as a four-year project. The research and development methodology that serves to guide the project is a four-step process, corresponding to the project year, as follows:

- **Step 1: Concept Formulation** – During this period effort was devoted to defining requirements, conducting preliminary analysis, developing the initial problem solution approach, and formulation of the design concept.
- **Step 2: Laboratory Development** – Work during this period is focused to the design and building prototype models, prototype testing within a "sterile" laboratory environment, and refining the prototype model based upon the results of the laboratory test.
- **Step 3: Field Application** – Prototype models will be subjected to field applications were limited test are conducted. Results of the test are applied and compared with the design objectives, and necessary engineering and design modifications are applied to the prototype design.
- **Step 4: Clinical Demonstrations** – Targeted clinical demonstrations will be conducted within a controlled environment to enable a more robust comparison with stated objectives and actual outcomes as well as user adaptation. These results will enable the final engineering changes in preparation for clinical trials.

The MedVizer™ Tools were redefined and expanded into a more comprehensive COTS based Informatics Integration Platform consisting of a core set of functionalities that enable the rapid integration of medical information systems, medical sensoring devices, medical imaging devices, and secure data devices that are used across the operationally defined continuum of care. The need for the seamless integration of systems that would enable the interaction of patient to physician and physician-to-physician to facilitate rapid response to healthcare needs was essential. The MedVizer™ Informatics Integration Platform (MIIP) provides the tools necessary for such integration.

The following graphic shows the MedVizer™ Informatics Integration Platform:



The MedVizer Informatics Integration Platform has been demonstrated to facilitate rapid integration and implementation of teleconsultation systems within military treatment facilities, including the following:

BODY:

Task 1: Cardiology Monitoring Device

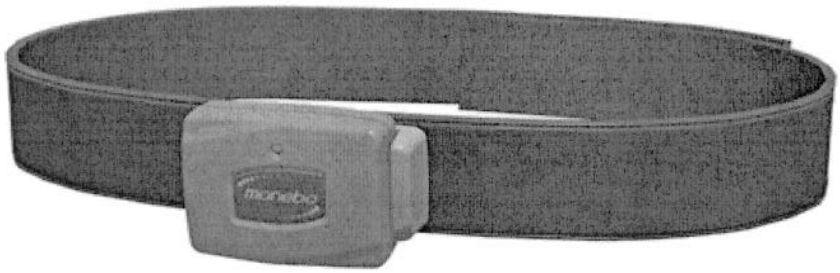
Cardiovascular disease is the leading cause of incapacitation among middle-aged workers. With careful management of this disease many of those afflicted should be able to return to the work place and live a normal productivity life. Part of the recovery process and continued well-being involves continuous monitoring of the cardiovascular system. Most monitoring systems are restrictive requiring the patient to collect cardiovascular data using a single lead ECG, blood pressure monitor and

oximeter at a single point in time while resting. A more beneficial cardiovascular monitoring system would be one that is capable of monitoring heart functions of patients while he/she performs their daily activities, not just a point in time. The "holter monitor" systems frequently used for continuous patient monitoring is limited in that such a device has no means of warning a patient or a healthcare provider of an impending problem. An ECG device that will enable the continuous monitoring of a patient during periods of activity and that by using the Centric Specific Data Collection Instrument (Task 3) will automatically send abnormal data to a central clinical monitoring station where it can be read and/or through use of interpretative software will be analyzed and indicate alarms if the data is out of norms.

Monebo Technologies has developed a device for monitoring patients during periods of activity in a controlled exercise type environment. The cardio monitoring system consist of three components:

- **Acquisition:**

The CardioBelt™ is the data acquisition subsystem in the Monebo ECG system.



The CardioBelt™ consists of a simple sensor unit with three embedded electrodes, which may be wirelessly connected via Blue Tooth to a nearby processor such as a PC or PDA/PocketPC. It uses one lead with three electrodes inserted in a flexible material and connected to an embedded processor unit. This configuration provides for the capture of a modified Standard Lead 1 ECG signal.

- **Embedded in the CardioBelt Electronics Package:**

Embedded electronic package captures, filters, amplifies, and digitizes body surface potentials and transmit the digitized signal using Bluetooth technology to the PC for further ECG display and analysis system.

- **Operating and User Software:**
    - The Automatic Arrhythmia Detection Software that analyzes ECG signals captured from the surface of the human body.
    - The ECG analysis, interpretation, risk stratification, and alarm software analyzes body surface ECG signals.

This device was integrated with using the Blue Tooth short-range communications embedded in the Centric Computer System. The automatic arrhythmia detection software filters out unnecessary information and data allowing for the continuous flow of data to the data collector. The collected data is then transmitted using secure internet mode to the ViTel Net PostMaster Server where it decrypted and placed in the respective individual's medical record. A separate computer, acting as the Clinical Call Center system was used to access the stored patient data and using the Monebo ECG analysis software the data was analyzed. There was no effort to evaluate the accuracy of the data transmitted and analyzed; the sole purpose of this effort was to demonstrate the capability to integrate the product using the MedVizer MIIP tools.

The integration from a technological perspective, within a controlled environment, posed no problems using the MedVizer MIIP integration tools. At the time that this work was completed the Monebo Software was in a preliminary state of development and did not include the many of the analytical software tools under development. When this additional analytical software it appears that the processing requirements may be excessive and no long enable the use of the small Centric Computer System used in this experimental work.

As Monebo continues it's product development process consideration should be given for further investigation for the integration of the product in a manner that would facilitate monitoring recovering patient's that have been released from the close monitoring provided in a hospital setting to further recovery at home but where cardiovascular monitoring is still required. This device once further developed integrated with the ViTel Net Centric Specific Data Collection System potentially could fill this existing void in the health care continuum,

Task 2: Wound Management.

The recovery period for wounded military personnel is lengthy and costly often with the final several months of recovery completed as an outpatient with periodic visits to a medical facility. Patients recovering from surgical procedures likewise often require frequent wound healing evaluations as outpatients. The cost to the government in providing quality care to personnel recovering from wounds and surgical procedures is unknown. However, within the civilian population, it has been estimated that the cost is more than $10 billion each year. This estimate includes both those recovering from wounds as result of surgery and as a result of injuries resulting from an accident. Of this expenditure by providers, the majority is made up of precious nursing hours and costs related to extended stays in facilities for wounds that are difficult to heal.

Recovery from such wounds often requires a multidisciplinary involvement to include nutritional, dermatology, infectious issues, and general healthcare. A means of monitoring the patient's health status, to include blood pressure, temperature, heart rate, and in some cases respiration on a daily basis as well as the healing process of the wound is needed.

The design considerations for the Wound Management Kit were that it must be simple enough to be used by a patient with minimal training, simple user interface, use standard off the shelf products, be fully integrated with other healthcare products developed by ViTel Net during the course of this research contract. ViTel Net developed the Wound Care Kit described below.

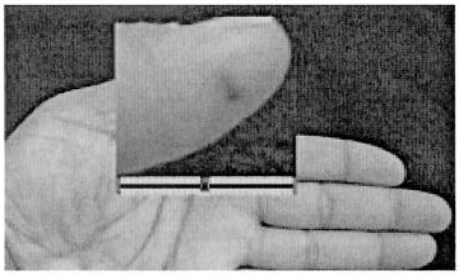
Wound Field Kit

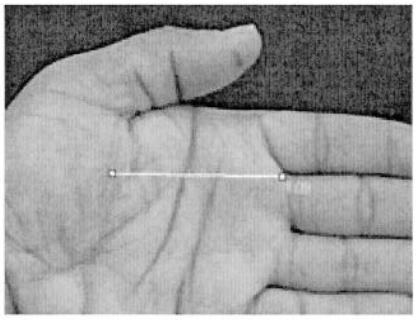
Required Key Features of the Wound Care Device

- Wound dimension measuring
- Image annotation
- Image enhancement tools
- User-friendly touch-screen/stylus interface
- Digital camera with auto focus and auto flash
- POTS, wireless, and cellular communications

The ViTelCare™ Wound Field Kit

A wound care management tool was developed for use by patient caregiver as a means of acquiring, documenting and annotating wound images in the field and sending these images with annotations back to a wound care nurse (WOCN), physician or other healthcare practitioner for immediate review and response for a corrective treatment plan. The wound care application can be configured to communicate via standard telephone line, broadband, or cellular without interfering with existing telephone service.





Operational Workflow:

Kit contains two hardware components and ViTel Care software:

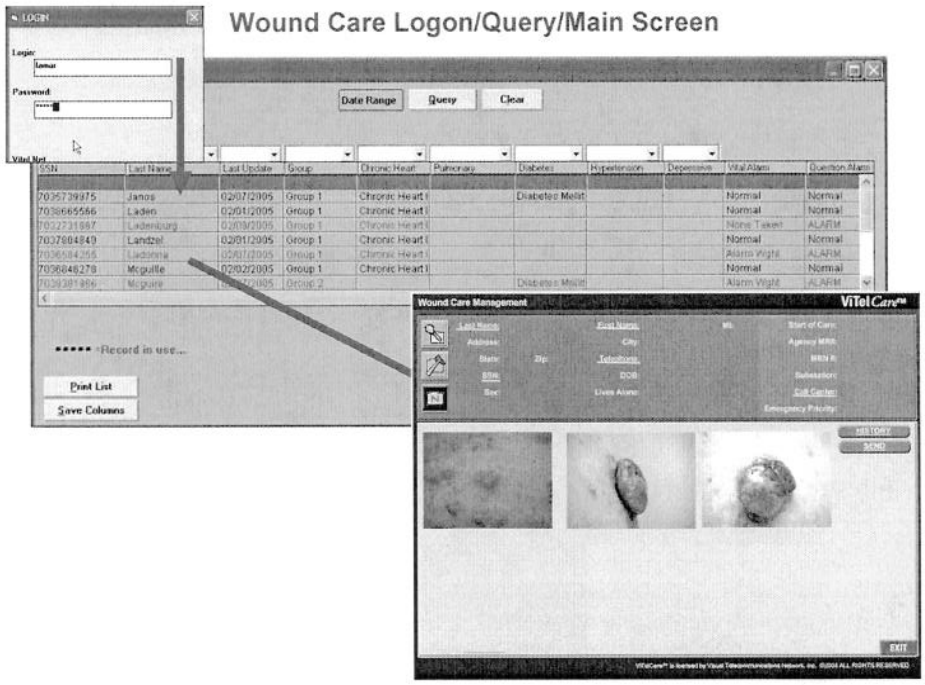
1. Wireless Ricoh digital camera with 80211 b/g card
2. Wireless handheld Fujitsu PC (Lifebook)

The kits are to be used for the purpose of transmitting wound images from the patient's home to the call center at the client's office where a wound specialist will review the wound and call the nurse in the patient's home if needed for treatment recommendations or for later follow up.

Periodically throughout the handheld laptop is synchronized with the call center. What is synched is a patient list with only the patient name and ID transmitted to the handheld PC. This will allow one to select a patient from the roster, take an image, wirelessly transmit the image to the handheld PC, and from the handheld, transmit the image to the call center, via wireless cellular or phone line. Should a patient be newly admitted and not previously synched, one can manually enter the patient's name an ID number and create a new record. The Wound Care ViTel Net software is a mini version of the VuLink wound care application displaying only patient names and patient ID's.

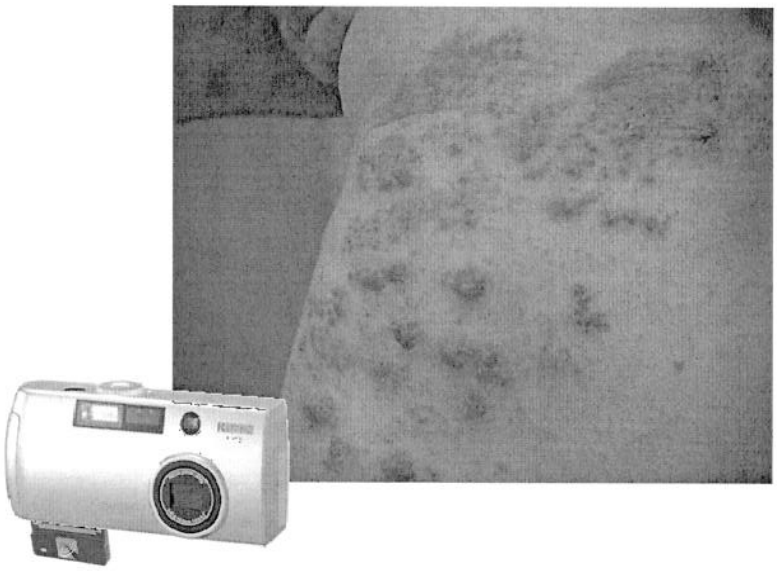
Selecting the patient

1. Once the handheld is turned on, the ViTel Net Wound Care icon will appear, clicking on the icon will launch the application program.
2. A list of patients will appear, listed alphabetically with a scroll bar on the side to scroll up or down to view patients not currently displayed on the screen. A query function allows one to enter a letter, indicating the first letter of the patient's last name, which will advance to that section of the patient list.
3. Doubling clicking on the patient will bring up that patient's medical record that is storing images. Previously captured and transmitted image are identified as sent.
4. A thumbnail of images will be displayed horizontally or vertically to allow a number of images to be shown on one screen. The images will be sorted as most current first. When a new image is received from the camera, that image will now be the first image shown for that patient...

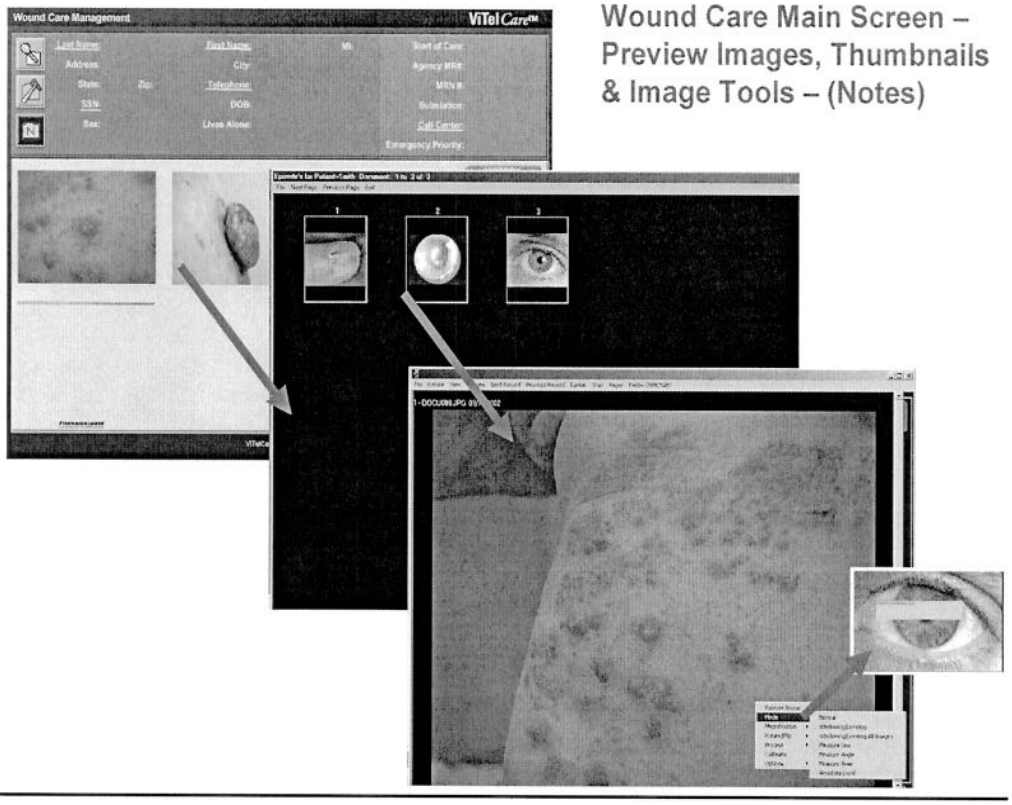


Taking an image

1. Each time prior to use the camera should be checked for stored images prior to use. The camera's memory should be empty of images.
2. Once the patient record is open, the camera can be activated and begin taking images of the patient's wound.
3. Using the camera option button, one can preview the image, select ok, and wirelessly transmits the image to the handheld device.
4. Once it is confirmed that the image was received at the handheld, the image on the camera MUST be deleted. Deleting the image minimizes the risk of an image being transmitted to an incorrect patient record.



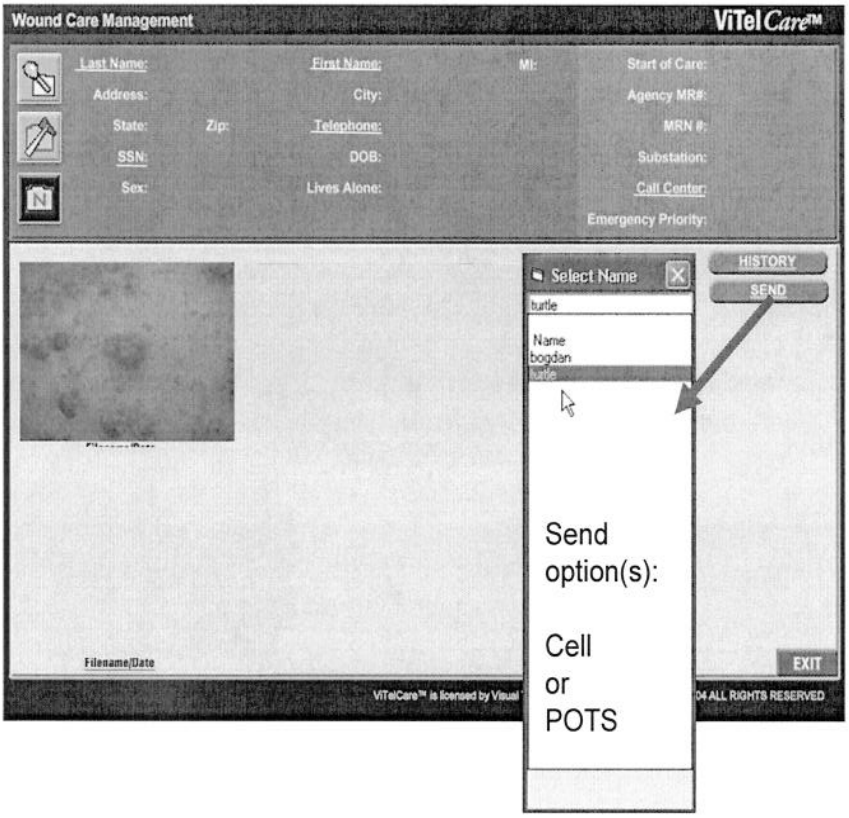
Wound Care - Take Photos and Upload Images to Tablet



Wound Care Main Screen – Preview Images, Thumbnails & Image Tools – (Notes)

Transmitting the image

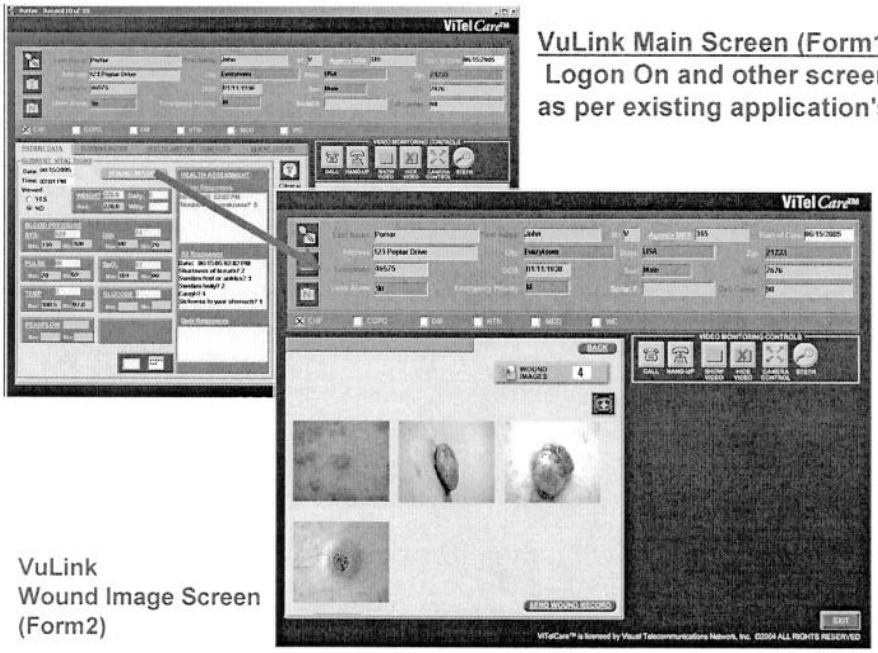
1. Once the image has been transmitted to the patient record on the hand held device one has the option to imbed a text box in the image before sending... This text entry may include any questions concerning immediate treatment, color or odor of discharge, size or depth of wound, etc.
2. The mode of transmission (cellular or phone line) is then selected and the call is launched
3. Only images from the current episode are transmitted. This will help limit the file size and transmission time.



Wound Care Tablet Send Options – Episode sent

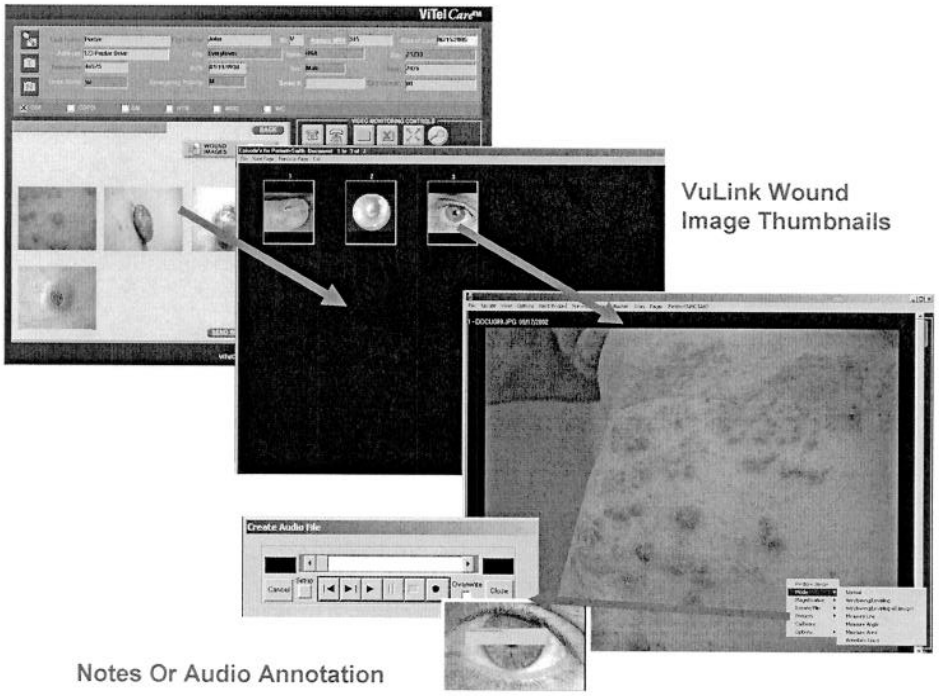
Receiving the image

1. The call center will receive the images were they are automatically added to the patient's record. If there is no previous record for this patient a record will automatically be created.
2. In the wound care section of the VuLink workstation screen, the care coordinator (wound specialist) can view a thumbnail summary of images received with the most recent image shown first.
3. Double clicking an image will enlarge the image and show any imbedded icons for text that was added by the field nurse
4. The wound specialist can view the imbedded text, add new text, or record an audio file that is imbedded into the image.

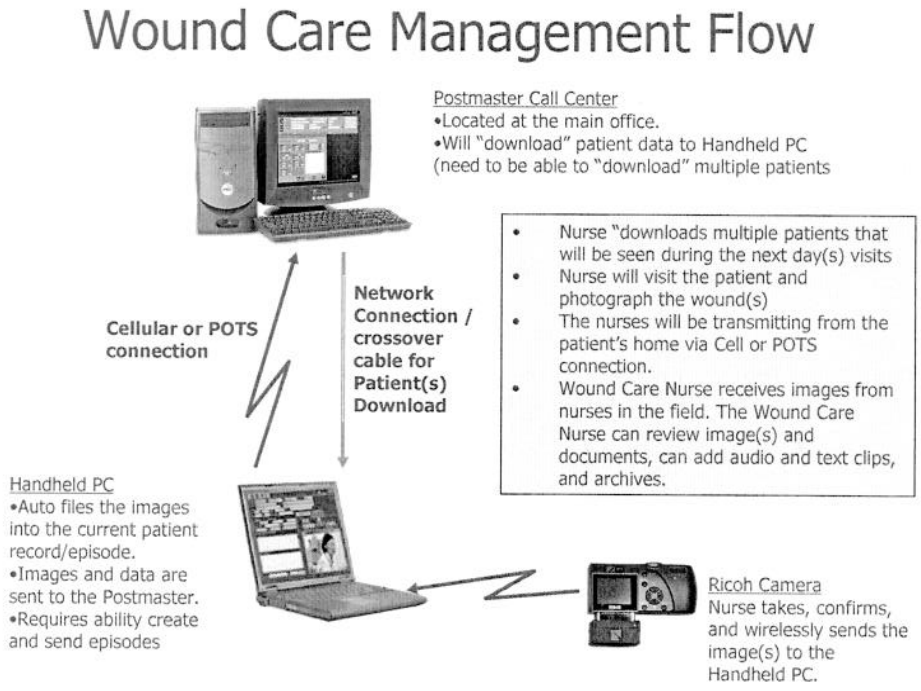


VuLink Main Screen (Form1)
Logon On and other screens as per existing application's

VuLink
Wound Image Screen
(Form2)



The Wound Care Management Work Flow is Diagramed Below:



Task 3: Centric Specific Data Collection Instrument

The objective of this task is to develop an integrated data collection device capable of connecting to medical devices using either direct connect or wireless and transmitting collected data wireless and wired communication circuits. Such a device must be fully integrated computer system weighing less than two pounds and be able to connect directly to multiple COTs medical devices using either short-range wireless communications technology or directly through a serial or USB connection. The data collected by the device must be automatically transmitted to a central site were the data is integrated with the patient's medical record, and presented to the caregiver for review.

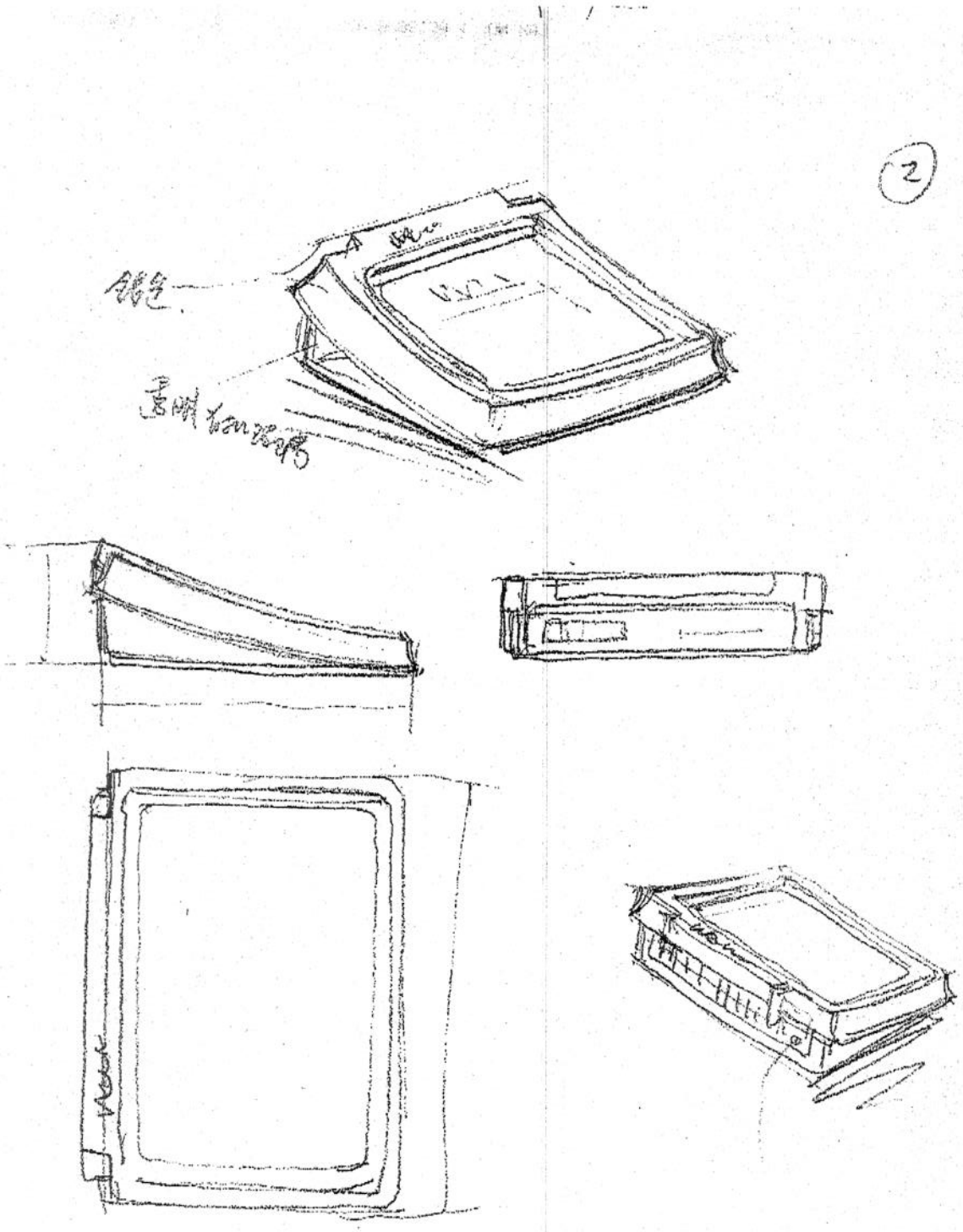
Currently available small computer systems, such as PDA's, have been evaluated and have not proven satisfactory as a data collection device. Commercially available PDA's and similar computer devices cannot connect directly to COTs medical devices and are limited in capacity to connect wirelessly to such devices. Wireless connections require the installation of a wireless PCMCIA card for short-range communications to connect to a single medical device, often multiple PCMCIA cards must be used to connect to very specific medical devices. Once data is collected an additional wireless communications PCMCIA card must be inserted in the device to establish the communications link. These current systems are far too cumbersome for use by first responder or point of care healthcare providers.

These Research Objectives were Accomplished:

- A prototype miniature computer device with embedded short-range wireless communications and long range wireless communications was developed. capability to demonstrate interoperability with COTs devices.
- The embedded short range (Blue Tooth) was used to connect to Blue Tooth capable COTS medical sensors; a wired serial/USB connection was used to connect to non-Blue Tooth enabled sensors.

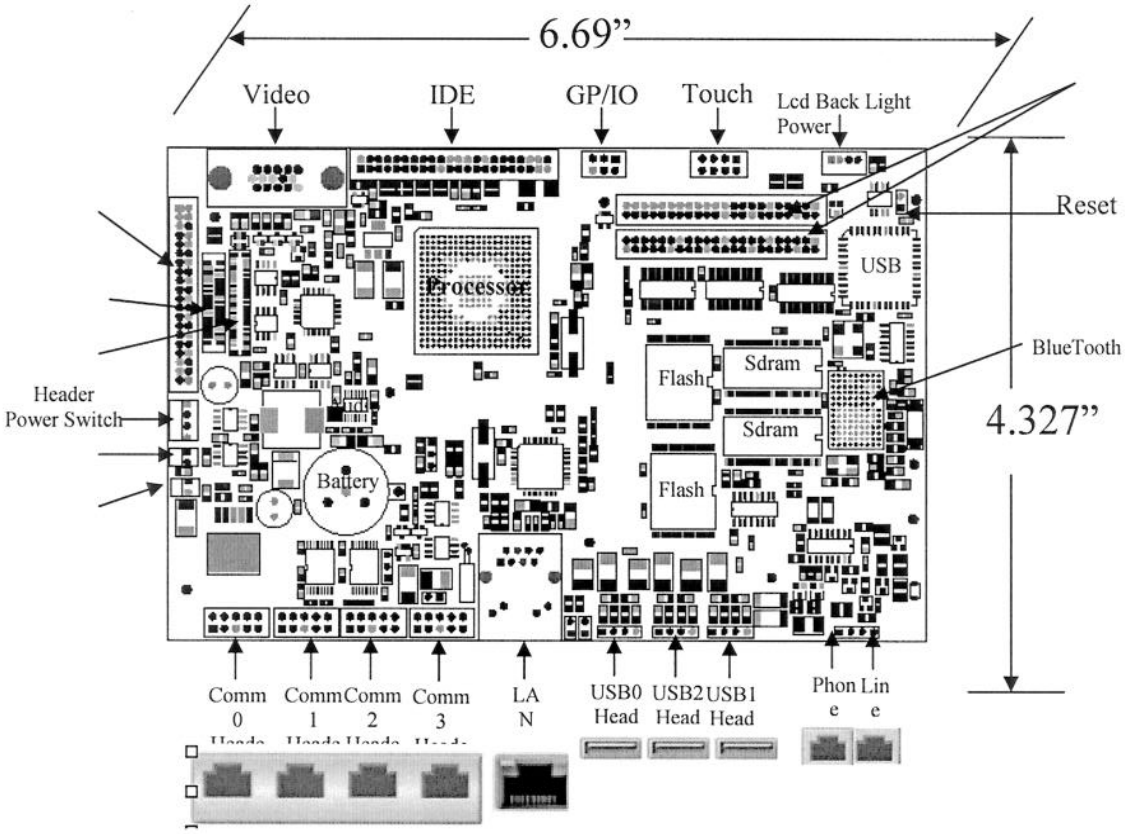
To accomplish these objectives it was necessary to design a complete system including the computer board, viewing screen, and housing for the computer. The concept was to have a self contained device that could only be used as a data collecting instrument and that was entirely controlled using touch screen icons, eliminating need for keyboard or mouse. The system is also designed to operate using either standard AC or DC electrical power. The system would have built in a speaker and microphone, blue tooth, cellular modem, and flash memory. The initial art design concept is shown below:

Initial Art Design Concept:



Key to developing the system was the design and development of the PC board. Our goal was to make the board as small as possible with all required functionality, with exception of the COTS medical sensors to be embedded on the board. Developing a

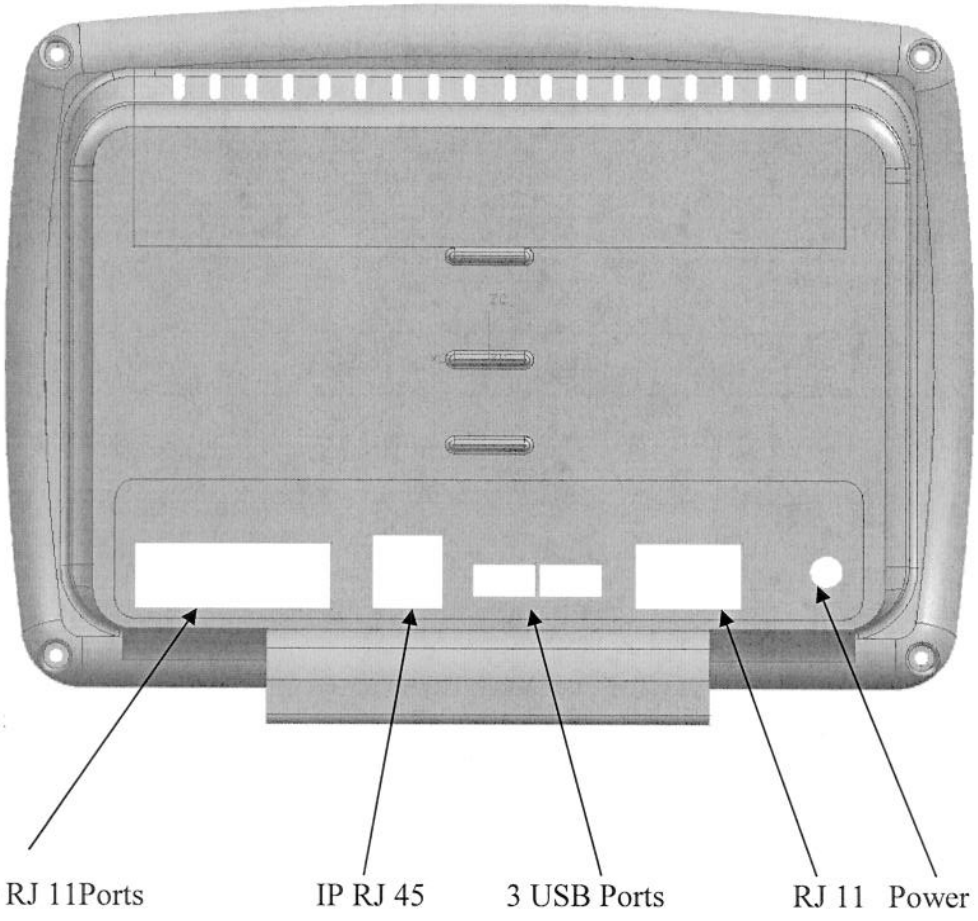
PC board that was sufficiently small and that would support all necessary functionality was a significant accomplishment. The final design of the Data Centric PC Board is shown below:



Once the PC Board was developed and tested in the laboratory it was possible to proceed with the design of the system housing. The initial design was changed to conform to the design of the board. The final design is shown below:

FRONT VIEW

REAR VIEW



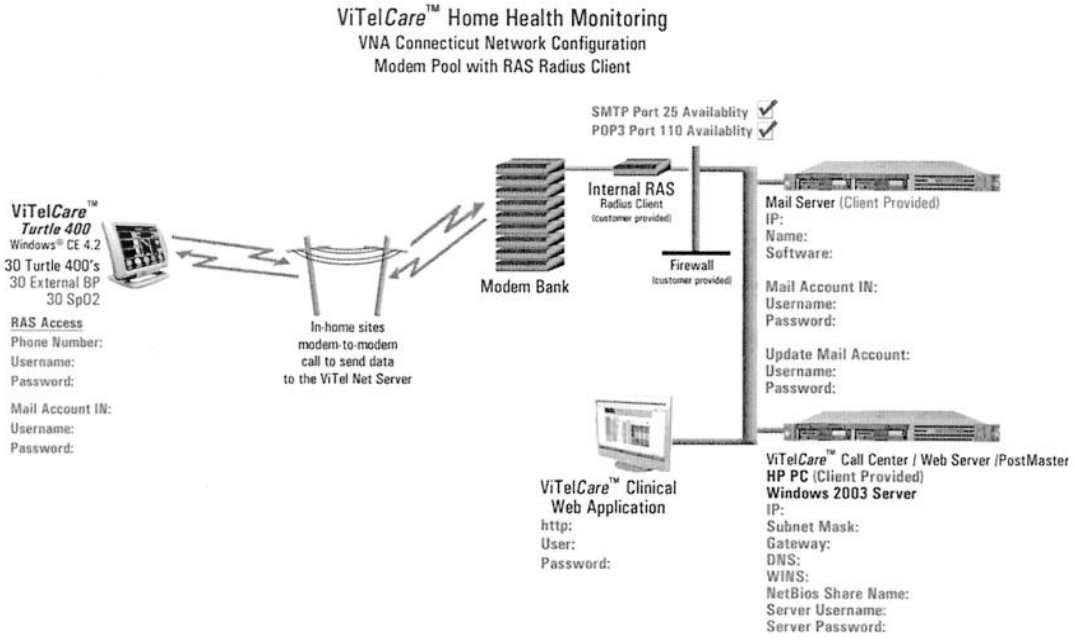
The Centric Specific Data Collection Instrument has successfully been interfaced with the following medical devices:

- A&D Life Source Blood Pressure and Pulse Device

- Welch Allyn Blood Pressure and Pulse Device
- LifeScan Glucometer
- Roush Glucometer
- AccuCheck Aviva Glucometer
- Nonin SpO2 Blood Oxygen and Pulse
- Welch Allyn Temperature
- Piko Electronic Peak Flow Meter
- R&K Electronic Stethoscope
- Zoe Fluid Status Monitor
- ProTime PT/NR
- Life Source Weight Scale

Collected data is automatically encrypted and sent using standard telephone or broad band connection to the ViTel Net Postmaster. The Postmaster receives the in-coming message, decrypts the data and files it to the respective individual's medical record.

A typical network using the Centric Specific Data Collection is shown below.



Task 4: HL 7 Interface

An objective throughout the course of this research project has been to develop the ability to achieve interoperability between hospital information systems. ViTel Net developed an XML interface which was successfully used to transmit collected

patient data to a legacy DOD Hospital Information System. A second interface was developed, using ODBC to develop an interface with another legacy DoD Hospital Information System. However, these two systems cannot share clinical information or data. Neither of these systems can directly exchange data with commercial hospital information systems. In theory, with the evolving Health Level Seven (HL7) messaging standards becoming the "accepted" standard for the exchange of key sets of information, interoperability with and between various Hospital Information Systems should be achievable. To achieve such interoperability an HL7 interface engine is needed to serve as a gateway for the translation of data to legacy hospital information systems both government and non-government.

ViTel Net has developed a data transmission communication interface that supports multiple modalities to include HL7, XML and ODBC. Using HL7 messaging format data and a simulated hospital information system data collected using the Centric Specific Data Collector was successfully transmitted using both XML and ODBC interface engine. Using the developed interface engine ViTel Net successfully transmitted medical data collected using the Centric Specific Data Collector to the following Hospital Information Systems, all of which are now operational:

- AHLTA "Armed Forces Health Longitudinal Technology Application" Test Data Base
- Veterans Administration Hospital Information System
- Nemours Epic Hospital Information System
- McKesson Hospital Information System
- Cerner Beyond Now Hospital Information System

KEY RESEARCH ACCOMPLISHMENTS:

The MedVizer Dvision Tools, a commercial-off-the-shelf (COTS) telemedicine integration tool has proven, within a laboratory environment, to be a rapid integration and configuration telemedicine tool. It has been demonstrated within this environment to be capable of dynamically integrating disparate medical teleconsultation systems, medical information and image display modalities, and electronic legacy hospital information systems within a wired and wireless environment.

REPORTABLE OUTCOMES:

Most notable was the development of the Centric Specific Data Collector instrument and the ability to communicate collected data securely to a central site from which the data using HL7 interface engine was transferred to the patient's medical record retained in the hospital information system. Most notable was the success achieved with the Veterans Administration.

CONCLUSIONS:

Continued development of the Centric Specific Data Collection Device is planned for the next research period. The accomplishments to date are being applied to specific worthy projects wherein proof of concept applications are tested and evaluated in government and commercial healthcare systems.

REFERENCES:

None: