

**System Requirements
for the
Patient-Initiated Emergency Response System**

a project of the
NATIONAL HEART ATTACK ALERT PROGRAM
Response to BAA/RFP NLM 99-108/VMS

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APPENDIX A - REFERENCES

1 SCOPE AND OBJECTIVES

This document describes the system requirements for the Patient Initiated Emergency Response System (PIERS) including the system concept, system architecture, and any standards or guidelines to be used in the development. The medical requirements, which are the basis for the functional requirements of the system, are described in a separate document [Ref 1].

The overall objective of the Patient Initiated Emergency Response System (PIERS) is the use of technology to lower the barrier between the acute coronary syndromes (ACS) patient and his entry into the medical system, by reducing delays in the three stages where delay can occur. These stages are as follows:

Stage I.	Patient and bystander recognition of the symptoms and signs of ACS
Stage II.	Pre-hospital action by emergency medical services providers
Stage III.	Actions by health care providers at the hospital to identify and treat patients with ACS

Specific objectives of the PIERS development effort, which are discussed in Sections 2 and 3, are to:

- Develop a simple, inexpensive system to support a clinical pathway for providing the earliest possible detection and treatment of ACS including acute myocardial infarction (AMI) in high-risk groups and in the general population
- Prototype a system focused on reducing Stage I delays in high-risk groups and in the general population
- Provide data to Emergency Medical Services (EMS) and hospital systems to improve timeliness and efficacy of Stage II and Stage III processes.

2 SYSTEM CONCEPT

2.1 Medical Requirements Summary

There is a need for a simple, adaptable and inexpensive system to support a clinical pathway for providing the earliest possible detection and treatment of ACS including AMI in high-risk groups and in the general population (medical statistics on current mortality, etc.). Detailed medical requirements for this system are described in a separate document (Reference 1). The medical requirements include acquisition of historical and electrocardiographic information, and the presentation of that data in a format suitable to triage the patient appropriately, as summarized here:

- A Stage I electrocardiogram (ECG) with capabilities for automatic and remote physician interpretation will be developed. The application will support pre-hospital diagnosis of ACS (both AMI and prodromal symptoms – e.g., unstable angina), in high-risk patients and should compare favorably to an in-hospital 12-lead ECG. The medical issues to be addressed include lead configuration, data collection, data storage, data interpretation, data transmittal, and clinical timeline.
- An automated, computer-based decision support system that translates current history derived from patient dialog (general population and high-risk patients), stored baseline ECG and newly recorded ECG and stored patient past medical history (high-risk patients) into recommended early intervention procedures.
- Identification of and procedures for handling the multiple differential diagnostic possibilities than can mimic ACS, particularly those that are life-threatening (e.g., pulmonary embolus and pulmonary edema).
- Transmission of the results of ECG monitoring and decision support to a remotely located physician.
- Integration of proposed system with current EMS, 911 systems, and selected hospital emergency departments.
- Identification of and procedures for handling situations that cannot be resolved by an automated system (e.g. indeterminate probability for ACS).
- Mechanism for collecting data related to outcomes of Stage I processes.
- ECG characterization (Marquette Algorithm) and display.
- User-friendly computer display for physicians to enter ECG interpretation and initiate EMS dispatch.
- Rapid transfer of ECG medical information and interpretation to receiving facility.
- Rapid transfer of medical history to EMS provider.

2.2 Rationale for System Concept

The requirements of the Patient Initiated Emergency Response System are being driven by three primary considerations: 1) the barriers that exist to using EMS; 2) the documented benefits of early medical care for patients with ACS, particularly AMI ; and, 3) the wide variability of EMS procedures in the United States.

2.2.1 Barriers to High-Risk Patient Participation

Many Americans delay seeking emergency medical services for a variety of reasons. Anecdotal evidence from Maryland Emergency Medical Services and Emergency Department physicians indicate the primary barriers are embarrassment, denial, fear, uncertainty about the what the problem is, attempts to consult with a personal physician or relative, and concern about the cost of care.

Models for Patient Behavior

The medical community has developed a number of models linked to health behavior change. The *Social Learning Theory* model, one of the health behavior change models, is a comprehensive analysis of human functioning in which human behavior is developed and maintained on the basis of three interacting systems: behavioral, cognitive and environmental. The willingness to change is related to self-efficacy, and self-efficacy is influenced by persuasion from an authority, observations of others' successful performance of a behavior, and physiological feedback. This model claims people learn to change their behaviors by active participation. In fact, according to Reference 2, elements of a successful behavior program include:

- Relapse prevention training
- Modeling a desired behavior
- Feedback about progress
- Problem-solving skills
- Prompts/cues
- Self-monitoring behavior.

Many of these elements are present in the PIERS.

PIERS Reduces Barrier to Participation

The functionality built in PIERS reduces barriers to high-risk patient involvement with emergency medical services by a behavior program that actually involves the patient in the system. The first operating mode of the PIERS provides for periodic system operability checks and practice in system operation for the patient. The results of the operability check are provided to the patient in a formal manner that allows the patient to assess the operability of the equipment as well as how well the patient can use the equipment. This mode directly addresses elements concerning relapse prevention, feedback and self-monitoring behavior. The second operating mode of PIERS provides for periodic collection of medical data as well as an interim evaluation of ECGs. The medical data is stored to provide a baseline for the patient in a future medical situation and the ECG data supports long-term monitoring of the patient's cardiac health. This mode directly addresses feedback about progress, modeling a desired behavior, and self-monitoring behavior. The third and last operating mode provides for easy and direct access to medical expertise and services at the onset of chest discomfort. This mode directly addresses feedback about progress and self-monitoring behavior.

2.2.2 EMS Service Factors

One of the primary goals of PIERS is, in effect, to bring critical elements of the emergency department to the patient. This is done in three ways:

- At-home (or wherever the patient may be) 12-lead ECG measurements at onset of chest discomfort;
- Cardiologist interpretation of ECG reading and patient history; and
- EMS services alerted to the patient's condition, medical history and location.

A typical timeline for patients with AMI is discussed in the Medical Requirements document (Ref. 1). The data show that as many as 250,000 patients with AMI die in the first hour and yet the typical patient does not arrive at the Emergency Department until 160 minutes after the onset of chest pain. Independent analysis for elapsed times between 911 call initiation and arrival of EMS services in Maryland reveals response times in the 10-minute range. The impact of elapsed time on outcomes is also well documented (Ref. 3,4) as is the benefit of additional medical services beyond the basic EMS capabilities. In summary, the discharge rate from the hospital increases with both shorter delivery times of EMS services and the application of additional capabilities/protocols by EMS personnel.

The PIERS addresses EMS service factors in three ways:

- Lowers barriers to engaging EMS services because of multi-mode operation
- Provides patient medical history information, including current medications, and comparative ECGs to the EMS providers to facilitate an EMS service call
- Directly links cardiac medical expertise with patient and EMS providers.

2.2.3 Variability of EMS Services

The Emergency Medical Services (EMS) in the United States are organized by states or local jurisdictions (e.g. county or municipality), and consequently, are subject to a wide range of regulations and controls. The net effect is that the protocol used by EMS providers can vary dramatically from location to location. Thus any system designed to bring the Emergency Department (ED) to the patient and decrease the barriers to using EMS in the case of an acute coronary syndrome (ACS) must be adaptable to accommodate local EMS protocols. The PIERS satisfies this requirement since the hardware/software installation can be configured for many arrangements or operating protocols and many arrangements of participants.

Finally, the load on a PIERS installation is expected to be small enough to be compatible with many possible installation configurations. According to Reference 5, in Maryland in 1999, there were a total of 40,618 cardiac-related EMS trips [5,636 cardiac arrest; 4,814 CHF (congestive heart failure); and 30,168 MI (myocardial infarction)]. Since each trip corresponds to a Mode 3 call in which the EMS services were activated, the total number of Mode 3 calls for the State of Maryland is estimated to be approximately 250,000 per year. Assuming one PIERS in the geographic area served is by a single emergency medical dispatcher, and approximately 20

dispatchers in the State, then each PIERS can expect to receive approximately 125,000 Mode 3 calls per year or approximately 35 calls per day. It is estimated that an equal number of Mode 1 and 2 calls will be received, but since these two modes are highly automated, the impact on PIERS operation will be small.

2.3 Concept Overview

The basic concept of the system is to bring critical parts of the Emergency Department to the patient in a simple, rapid, reliable, inexpensive, non-threatening way that would lower the barrier to entry into the medical treatment system. By minimizing embarrassment and fear, by not requiring transportation to a specialized facility at which time and “face” may be lost, by serving, in effect, as an objective reviewer, we believe this system will reduce the time between symptom onset and treatment application for patients with ACS. Ideally, such a system would lead to fewer false-positive trips to the emergency department, as well. PIERS must be integrated seamlessly with the current EMS and 911 system and not become an additional cause of delay between symptom onset and treatment.

In the absence of on-going acute ischemia or available provocative tests, coronary artery disease is detectable only by history. Both the past medical history, particularly cardiac risk factors, and the current history of a syndrome involving chest discomfort are key elements that provide clinical clues to an ACS. In the presence of on-going symptoms, the ECG is a simple, inexpensive, objective test that can often detect cardiac ischemia. The emergency department procedures for the initial evaluation of the ACS patient include past and current history, and a comparison of a past with a current ECG.

Two distinct, but related groups of patients at risk for developing ACS, including acute myocardial infarction, recognized are: 1) high risk patients -- those with known coronary, peripheral or cerebrovascular atherosclerosis, and 2) the general population.

As an initial step, this system will provide patients at high-risk for developing an ACS with the capability of transmitting current and past historical information, responses to questions that are indicators of ACS, baseline ECG, and current ECG from any telephone to a central facility which is available immediately at all times. This capability will be provided by a nearly credit-card sized device the patient carries with him at all times. He will receive this device through his physician, who identifies him as being in the high-risk category. The information transmitted by this device is processed by a decision support module that will immediately activate EMS providers if an AMI is in process. All information is transmitted to a Cardiac Teleconsultant who interprets the ECG in combination with the medical history. After interpreting the information, the Cardiac Teleconsultant can direct the patient to report immediately to a Chest Pain Evaluation Center, to obtain an appointment with his physician as soon as possible or the EMS provider could be dispatched if that did not happen automatically (see Figure 2-1).

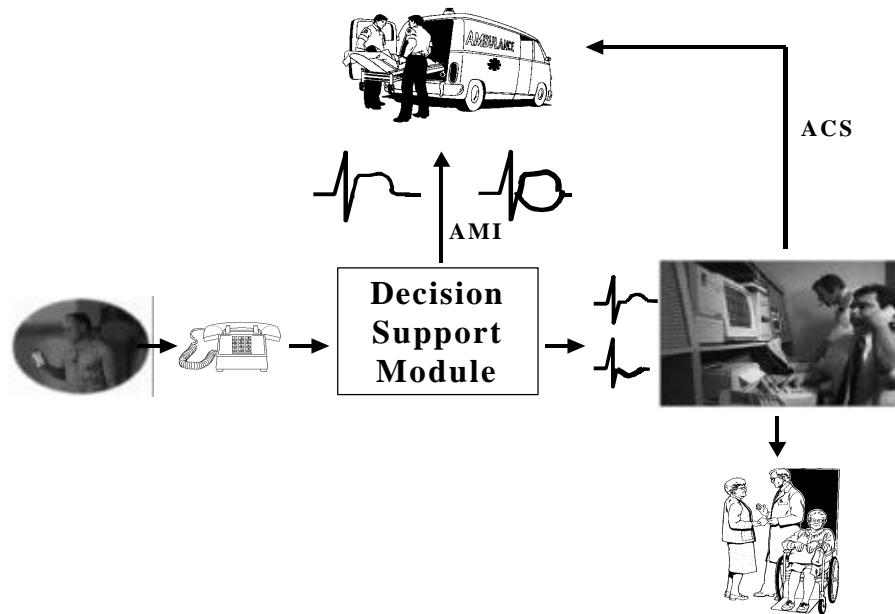


Figure 2-1 PIERS Schematic

For the general population, the Patient's Personal Module (PPM) will be made available at selected public places, such as pharmacies, sports arenas, etc., where, with the help of trained personnel, the ECG may be reported and evaluated by the PIERS Cardiac Teleconsultant. In addition, to eventually serve those who cannot access the ECG module of the PIERS, we believe that data collected by the PIERS can be used to evolve a computerized, telephone-accessible decision support system to field calls. This PIERS concept will be realized by the system with the following capabilities:

- Highly portable, patient monitoring and data handling device for high-risk patients
 - device will store past medical history, current medications and baseline ECG
 - device will obtain and store current ECG
 - device will store ACS indicator questions and patient responses
 - device will be capable of transmitting stored information and current history to a central computer, physician and/or treatment facility via phone line
 - device will allow for patient interaction via the same phone line used to collect current history

- Integration of monitoring, data handling and medical interpretation functions within a clinical pathway that provides continuity of patient care between emergency medical technicians and the hospital emergency department or Chest Pain Center
- Ongoing collection of outcome data will be used to continuously evolve an improved automated decision support system. In essence, historical and ECG data will be used to risk stratify patients and define the best treatment pathway with increasing levels of automation, as the data permit and as the system evolves. This future decision support system will be based on history derived from patient dialog and will be adapted for both high-risk patients and for the general population.

2.4 System Users

The PIERS can be configured for different sets of medical providers. All possible participants are listed below.

2.4.1 Patient

The patient is at high risk for ACS and has been provided with a PPM by his physician. The patient uses the device in accordance with prescription. The prescription will require the patient to use the PPM in periodic system checks (Mode 1), periodic data transmission (Mode 2), and immediate ECG reporting in the event the patient experiences chest discomfort, or other AMI symptoms (Mode 3). The patient and a person who might frequently be with the patient will receive training in PPM operation for all modes, and the circumstances and symptoms for which the patient should initiate Mode 3 operation. Other forms of training, including written materials, self-help materials, videos and internet-based training will supplement this initial training.

2.4.2 Personal Physician

A physician will likely prescribe the service for a patient and initialize the patient device. The personal physician will initialize the device with patient history and a baseline 12-lead ECG for the patient using the device. The training personnel at the personal physician's office will provide initial patient training in using the device and will be point-of-contact for patients who have questions and/or problems associated with device operation. The personal physician will receive all ECGs obtained during Mode 2 and 3 operation. The personal physician is responsible for managing the content of the data stored on the device and specifies how often the patient exercises Mode 2 operation.

2.4.3 Service Technician

The Service Technician is responsible for maintaining the system and assisting patients, when necessary, to assure trouble-free operation. During Modes 1 and 2 operation, the Service Technician responds to automatically or manually initiated alerts which indicate a system problem, verifies that the system provides necessary instructions to the patient (or personally

instructs the patient, if necessary), checks the quality and timeliness of transmitted data, and verifies that the system forwards the transmitted data to the Personal Physician.

2.4.4 Cardiac Teleconsultant

The Cardiac Teleconsultant receives ECG data, ECG processing results, patient history and responses to automated questions from the system, interprets the data, speaks with the patient, and determines the next steps in the patient's care. The Cardiac Teleconsultant will alert EMS for necessary patient transport and immediate interventions (with the option of patient information forwarding to the EMS), as well as forward the patient data to the ED. A record including the patient name, date of call, relevant historical data (answered by touchtone) and diagnosis and disposition (entered by Cardiac Teleconsultant) will automatically be routed to the Personal Physician.

2.4.5 Emergency Medical Services

EMS receives a dispatch from either the Cardiac Teleconsultant or the patient (via 911). If an ECG has been obtained from the system, the Cardiac Teleconsultant will also advise EMS of diagnosis and recommended interventions during transport. EMS will alert the ED physician of an incoming patient.

2.4.6 Emergency Department Physician

The Emergency Department physician will be notified by EMS of a cardiac patient in transport. Any current history or ECG data obtained by the system will be available as well as a diagnostic summary from the Cardiac Teleconsultant.

2.5 Concept of Operation for Patient Initiated Emergency Response System

The proposed Patient Initiated Emergency Response System (PIERS) has three distinct modes of operation for the patient to interact with the system. This section summarizes the overall concept of operation for the PIERS for each of the operating modes, the framework for the PIERS operation, and demonstrates how the PIERS will achieve the primary design goal - breaking down the barriers for using the system by a high-risk patient.

2.5.1 Event Sequence

Each use of the PIERS involves a sequence of events. Time is not a critical parameter for Modes 1 and 2 of the PIERS since these modes are not associated with the presence of chest discomfort. However, it is critical for Mode 3 operation. The general sequence of events, regardless of mode, has been broken into six steps:

- The sequence is initiated when the patient is prompted to use the system (Modes 1 and 2) or the patient senses chest discomfort (Mode 3);
- Patient puts on electrode patch and enables ECG sampling
- Patient places telephone call to PIERS;

- System processes patient data;
- The system generates a response to a call:
 - 1) Cardiac Teleconsultant reviews data and, if necessary, dispatch EMS personnel to patient (Mode 3); or,
 - 2) System analyzes PPM operability and reports to patient and personal physician (Mode 1); or
 - 3) System collects ECG and possibly other data for interpretation and storage on the patient's ECG device (Mode 2); and
- Patient meets periodically with personal physician to maintain ECG unit information.

This general sequence of events is used as a reference when discussing the operating modes.

2.5.2 Summary of Operating Modes

What follows is a brief discussion of 3 possible operating modes by which the patient could use the system. These 3 modes are meant to provide an inclusive relationship between the high-risk patient and the medical services and to break down the barriers (cost, unfamiliarity with use, public attention, consumption of services, lost time) between the time a patient senses discomfort (Event 1), and the patient places a telephone call to PIERS (Event 2). To avoid replication, those steps common to all modes are described first.

2.5.2.1 Common to All Modes

When the patient chooses to operate the system, he first selects the operating mode on the PPM (default is Mode 3). For all modes, the patient attaches the ECG electrodes as previously instructed, activates data collection, and responds to questions stored in the PPM. The PPM will then retrieve patient history from memory (all modes) and initiate an ECG sampling and recording of 60 heartbeats. The patient initiates a phone connection to the System Server at a designated regional location. The history and recorded ECG data are transmitted with continued ECG sampling up to the number of desired beats. The System Server announces status at the end of the interaction.

If the ECG recording was not successfully received by the System Server, the patient will be prompted with questions and instructions to assist in using the ECG. If the ECG is still not successfully transmitted, additional (mode dependent) questions can be provided to obtain needed information and, if necessary, a maintenance action will be planned and, if necessary, EMS will be notified.

The PPM is connected via analog modem to an auto-answer modem bank supported by a rotary telephone switch at the System Server. The modems are capable of simultaneous voice and data transmission, so the patient can receive voice messages from the phone while the phone line is transferring digital information.

2.5.2.2 Mode 1: Operability Check and Practice Use

The patient is encouraged to practice using the system and to verify its operation. The process is totally anonymous and totally automated (other than patient actions); consequently, minimal

consumption of resources (i.e., minimal cost) and minimum patient visibility or effort and consequently minimal barriers are incurred. The System Server verifies that parts of the ECG unit are operating and that the data can be successfully transmitted to the System Server. The patient is alerted to any performance issues or malfunctions via immediate feedback (display and/or recorded voice message, telephone call and/or mail). A scenario for Mode 1 operation is shown in Table 2-1. The two left-hand columns estimate the minimum and maximum time between successive events in the scenario. Note that time is not critical in the Mode 1 scenario. The third column lists the events in the scenario and has a rough correspondence to Section 2.5.1 above. The last column contains explanatory material.

Table 2-1: Mode 1 Scenario

T+ (HR:MIN)

Min	Max	Event	NOTES
00:00	00:00	Calendar prompt to exercise ECG unit	<ul style="list-style-type: none"> • Calendar maintained by ECG unit or server • Exercise the maximum amount of circuitry possible
00:05	48:05	Activate unit with leads for patient training	
00:32	48:15	Electrodes attached by patient & ECG recorded	<ul style="list-style-type: none"> • Electrode Reusable • First-level data validation by ECG device
00:31	48:30	Patient responds to automated questions	<ul style="list-style-type: none"> • Use buttons on PPM
00:30	48:25	Patient connects to communication service	<ul style="list-style-type: none"> • Direct connect to phone line with future wireless option
00:32	48:05	Data Transfer to System Server	<ul style="list-style-type: none"> • ECG & history data, question responses
00:35	48:15	Data validity checks	<ul style="list-style-type: none"> • Kinds of checks include device malfunction, bad comms, battery low, data corrupted, other • Service technician interrupts if malfunction indicated or follow-up call added to technician work list
00:36	48:16	Automated ECG interpretation	
00:37	48:17	Automated Response to Patient	<ul style="list-style-type: none"> • LCD message display and recorded voice • Contact Service Technician if unit needs repair
12:00	96:00	Report Results	<ul style="list-style-type: none"> • Automated Service log maintained for Service Technician

2.5.2.3 Mode 2: Periodic Health Status Check

For the general high-risk patient and for those with certain medical conditions, the patient is requested to periodically use the system to update the patient's ECG report and recent patient history. Examples of such historical features are chest pressure (character, frequency, level of exertion required to provoke, episodes per week, etc.), dyspnea, palpitations, syncope or near syncope, etc. Mode 2 operation is semi-automated; it receives patient history data and a current ECG from the ECG unit over the communication service. The System Server does data checking for validity. Any invalid indicators result in an alert to the Service Technician who will assist the patient as required (during normal working hours) or a follow-up call is added to the technician's worklist. Once accepted, the ECG waveform is interpreted by an algorithm such as the General Electric/Marquette algorithm. The assembled data is sent to the personal physician to interpret the information. When appropriate the patient visits the personal physician who has responsibility of updating patient's medical history and ECG data stored on the PPM during the office visit. The personal physician's office is also responsible for keeping medical records necessary for medical management, insurance and legal purposes. Table 2-2 provides a scenario for Mode 2; the column headings are identical to Table 2-1 and, as in Mode 1, time is not critical other than convenience to the patient.

Table 2-2: Mode 2 Scenario

T+ (HR:MIN)

Min	Max	Event	NOTES
00:00	00:00	Calendar patient prompt	<ul style="list-style-type: none"> • Calendar maintained by ECG Unit or server
00:30	48:00	Activate unit with leads for medical purposes and patient training	
00:32	48:15	Electrodes attached by patient & ECG recorded	<ul style="list-style-type: none"> • Electrode Reusable • First-level data validation by ECG device
00:34	48:45	Patient connects to comms	<ul style="list-style-type: none"> • Initially, direct connect to phone line • Use of voice over IP (simultaneous data and voice) • Patient interview via controlled voice recordings
00:36	48:50	Data transfer to system server	<ul style="list-style-type: none"> • Data validity checks • Data retransmissions, if needed • Service technician interrupts if malfunction indicated or follow-up call added to technician work list
00:36	48:16	Automated ECG interpretation	
00:37	49:00	Response to Patient	<ul style="list-style-type: none"> • LCD message and voice interaction
12:00	96:00	Report Results	<ul style="list-style-type: none"> • Forward to personal physician

2.5.2.4 Mode 3: Symptomatic

The patient is experiencing chest discomfort or other symptoms of concern but is reluctant to call 911. He uses the PPM to collect an ECG and then uses the communication service to call PIERS which receives patient history data including responses to programmed medical questions and current ECG waveforms. The System Server does the same data validity checking as in Modes 1 and 2 and initiates a request for the patient to retransmit the data set if appropriate. As in Mode 2, an ECG interpretation algorithm performs an ECG assessment. If the historical and ECG data clearly indicate AMI, then EMS is immediately dispatched without any additional human intervention. The patient's data are then forwarded to a Cardiac Teleconsultant who is connected with the patient for voice interaction; the patient is informed EMS is on the way. In the event the historical and ECG data do *not* clearly indicate ACS, then the patient's data are forwarded to a Cardiac Teleconsultant for review and the patient is placed in direct voice contact with him. The Cardiac Teleconsultant then executes appropriate action. Possible interpretations include:

1. Priority Event - EMS will be immediately dispatched. The patient will be informed that the EMS is being sent and he may be advised to keep the system active for continued real-time monitoring. When EMS is dispatched, the patient data, such as demographics, history, medications, and baseline and current ECG can be transferred to the EMS service. Once a hospital ED is selected, the history data as well as the ECG data are made available to the designated ED.

2. Non-priority Event – The Cardiac Teleconsultant concludes that the ECG and historical data do NOT indicate that a life-threatening event is in progress. The patient is advised to call 911 if he believes that emergency treatment is needed. He is further advised to seek medical attention according to a number of scenarios detailed in the medical requirements document. The point here is that there are a number of possible outcomes besides AMI: a) life-threatening but not AMI; b) unstable angina –needs EMS dispatch; c) crescendo angina – needs to see physician today or come to ED today (Cardiac Teleconsultant may need to make appointment on-line); d) change in angina but not particularly alarming (needs to see primary physician within 72 hours); non-cardiac and non-emergent (see physician and appointment can be made by patient).

Table 2-3 provides a scenario for Mode 3 operation.

Table 2-3: Mode 3 Scenario

T+ (HR:MIN)

Min	Max	Event	NOTES
00:00	00:00	Chest discomfort event	
00:01	00:15	Patient acknowledges symptoms	<ul style="list-style-type: none"> • Depends on severity of pain & patient Awareness
00:02	00:30	Patient activates device	<ul style="list-style-type: none"> • Use of voice over IP (simultaneous data And voice) • Programmable, tailored current history questions and patient response • Caller ID immediately available to client Workstations

00:05	00:45	Electrodes attached by patient and ECG collected	<ul style="list-style-type: none"> • Reusability
00:07	00:50	Patient responds to questions	<ul style="list-style-type: none"> • Questions and responses stored on PPM • Indicators of ACS
(2 min)	(2 min)	Data transmitted to System Server and processed	<ul style="list-style-type: none"> • Data validity checks • Data retransmissions, when needed
00:08	00:50	Automated ECG Interpretation	<ul style="list-style-type: none"> • Dispatch EMS, if required
00:10	01:00	Data available to Cardiac Teleconsultant	<ul style="list-style-type: none"> • Follow-up interpretation of ECG
00:11	01:11	Voice contact with patient	<ul style="list-style-type: none"> • Follow-up directives to patient
00:20	01:30	Data to ED	<ul style="list-style-type: none"> • Option for additional functionality ED Workstation
12:00	24:00	Data to Personal Physician	<ul style="list-style-type: none"> • Update of patient record • Updates to patient's personal module

2.6 Program Innovations

The Patient Initiated Emergency Response System described herein provides an easy, convenient and comfortable pathway for high-risk patients to enter medical care in the case of heart problems. This section discusses the innovations introduced by the PIERS in providing this pathway compared to existing technology and protocol. To answer this, one must summarize the state-of-the-art in this domain.

2.6.1 State-of-the-Art

The state-of-the-art in providing a pathway to medical services for high-risk patients is summarized in several statements.

- The two critical indicators of myocardial ischemia, or ACS, are (1) the history, both current and past (including cardiac risk factors), and (2) the ECG (baseline and during chest discomfort).
- The ECG interpretation algorithms that have proven effective in signaling potential ischemia or ACS require a 12-lead input; fewer leads are not as effective as the standard 12-lead ECG.
- While there are miniature devices for monitoring ECG and transmitting the waveform to a call center, none have been integrated with a 12-lead interpretation algorithm and decision support protocol to provide ambulatory patients (i.e., outside a medical facility) with a capability for diagnosis of ischemia and ACS.

- No products for alerting of possible heart problems is integrated with a communication system that links cardiologist expertise with an EMS service and local Emergency Departments.
- For current ECG device designs, placement of electrodes of a 12-lead system is sufficiently difficult that a patient cannot reliably place the leads without trained assistance. Few products are currently available to facilitate placement the electrodes.
- Most current 12-lead ECG systems rely on adhesive surrounding the electrode and a conductive gel to maintain electrical contact between the electrode and the skin. The adhesive is not effective for reuse - certainly not more than 1 or 2 reuses, if any.

2.6.2 PIERS Capabilities Summary

The proposed Patient Initiated Emergency Response System, through components and a set of procedures, provides capabilities that:

- Equip identified high-risk patients with a small, low-cost device for obtaining 12 lead ECG readings.
- Transmit ECG waveforms via any telephone to designated facilities that are equipped to record, interpret, and display the ECG waveform.
- Obtain current patient history by interactive responses to programmed questions. Combine with past history retained in the Patient's Personal Module.
- Store and forward past and current medical history to designated facilities.
- Incorporate an ECG interpretation process that performs automatic ECG interpretation and other support for Cardiac Teleconsultant, who, in cases other than clear-cut myocardial infarction or myocardial ischemia, decides what pathway the patient should take based on clinical and ECG formation.
- Transmits all relevant information to the EMS, assuring that the latest patient status and physician recommendations are available to the EMS team.
- Has the patient's personal physician receiving all operability and medical data and being responsible for maintaining the information content in the Patient's Personal Module.

2.6.3 PIERS Innovations

Having stated these assumptions and summarized the proposed system capabilities, the benefits of the proposed Patient Initiated Emergency Response System are:

- Diagnostic accuracy is improved over any existing (known) home monitoring device.
- The monitoring device is portable and can be unobtrusively carried by a patient outside the home.
- Builds confidence in and familiarity with the PIERS by providing for automated and human guidance via periodic use in non-critical situations.

- The critical “time-to-first-call” is reduced by building patient confidence. The EMS will not be dispatched unless the patient is clearly having an infarction or ischemia, or a cardiology specialist dispatches the EMS.
- When the EMS is dispatched, patient history and medication information relayed to the EMS team will reduce time for diagnosis and improve emergency treatment at the patient’s location and at the ED.
- For patients with certain conditions and who are equipped with the Patient’s Personal Module, periodic reporting of ECG and recent history will be useful for disease management (and potentially reduce the likelihood of a life threatening cardiac event).

3. System Functional Requirements

The Patient Initiated Early Response System consists of a Patient's Personal Module that resides with the patient, a telephone-based communications service between the PPM and a System Server, and one or more associated client workstations that link the medical care providers.

As discussed in Section 2, PIERS provides patient services in three operating modes (see Figure 3-1). The three modes can be implemented by many combinations of organizations, including EMS providers, hospital emergency departments (ED), chest pain centers, personal physicians, and commercial service providers. The system is intended for Stage I applications as defined in the initial NHAAP RFP and has the primary function of minimizing the delay between the onset of ACS symptoms and the application of therapy. By providing critically important information to EMS and emergency department healthcare providers, it may also reduce delay and improve care in Stage II and Stage III.

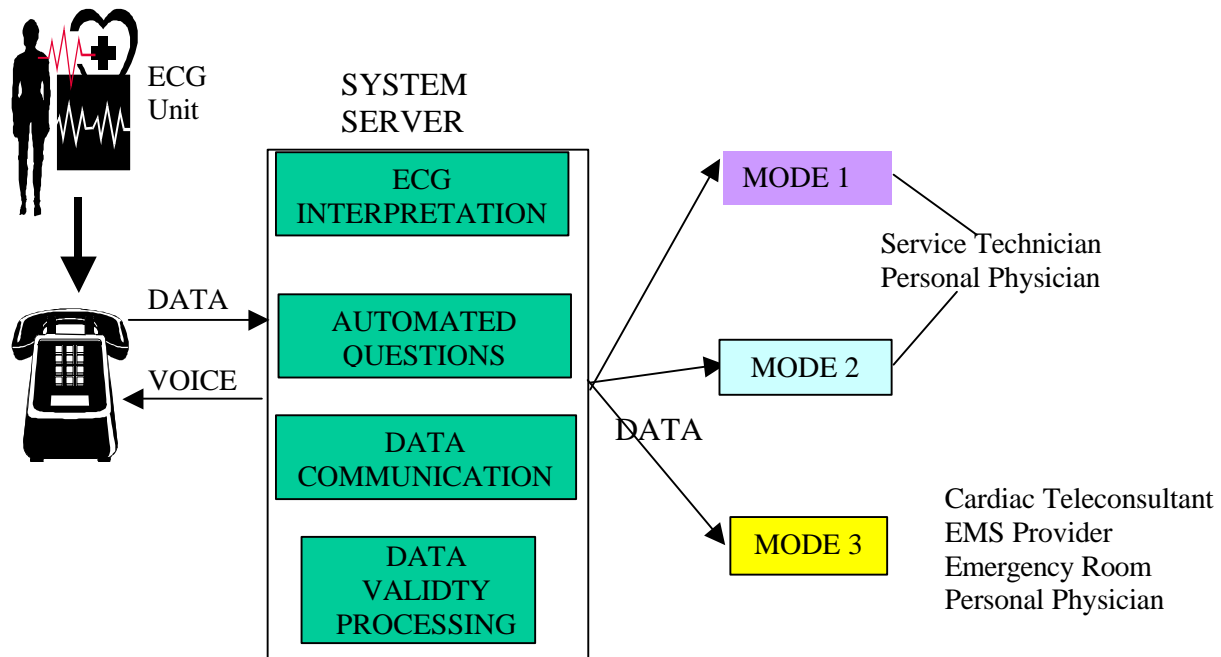


Figure 3-1 PIERS Operating Mode Schematic

The functional requirements for the hardware and software comprising the PIERS are based on the medical requirements presented in Reference 1. The requirements describe the function and performance of the elements of PIERS. In particular, requirements on design variables such as data content and accuracy, data collection and processing frequency, connectivity to processes outside the system, data storage and archiving, user interaction, possible decision outcomes and others are described below.

The major functional elements of the system, summarized in the following paragraphs, are:

- Patient's Personal Module

- Data Communications
- System Server
- Decision Support
- Client Modules

The devices and algorithm(s) employed will, to the extent possible, be an accepted industry standard and FDA approved.

3.1 Patient's Personal Module

The ECG element and the Data Management element are the two components of the Patient's Personal Module.

3.1.1 Performance Requirements

The top-level function of the ECG element allows a symptomatic patient, with minimal training and practice, to rapidly obtain an ECG within the confines of the patient's home or office workplace and transmit the ECG to a remotely located physician. A goal for timeliness in Mode 3 (as defined in Section 2) of this function is receipt of the ECG by the physician within **15 minutes** of the onset of symptoms. There is no specific timeliness goal in Modes 1 and 2. The ECG must contain sufficient data to allow the remote physician to diagnose ACS with a high degree of certainty.

3.1.2 Functional Requirements

The top-level function of the ECG element decomposes into the following sub-functions:

3.1.2.1 Electrode Configuration and Placement

ECG quality adequate to diagnosis ACS indicates a 12-lead system. For some Mode 2 uses, a single bipolar lead configuration may be employed. The rapidity and ease with which a patient can attach electrodes is critical to patient acceptance and the timeline reduction necessary to realize clinical benefit from the system. A goal for this function is to allow electrode placement within 5 minutes from onset of symptoms by a patient who is highly stressed. An electrode placement error of 1 inch is acceptable for limb leads. The system must include a method for preventing and/or detecting and correcting limb lead reversal. Electrode placement errors of 0.5 inches are required for precordial (chest) electrodes. Ideally, the electrodes would be reusable to allow for training and practice benefit from Modes 1 and 2. Inexpensive disposable electrodes could also provide this benefit.

3.1.2.2 Lead Interface

The lead interface consists of wires which route the ECG signal from the electrodes to signal conditioning within the ECG device. The wires should be harnessed and connected in such a way as to add less than 5 seconds of time to the ECG data collection process for a trained and practiced patient under moderate duress of chest discomfort and provide less than 1% attenuation of the ECG signal.

3.1.2.3 Signal Conditioning

The signal conditioning should have adequate input sensitivity for typical ECG voltages (typically less than ± 200 mV) at electrodes, analog to digital sampling at a rate of at least 200 samples per second at an amplitude resolution of 256 steps (8 bits).

3.1.2.4 Waveform Storage

The ECG device will provide for storage of 10 ECG recordings, 30 seconds in length each in non-volatile memory that can be cleared by a software command (typically issued by a remote data receiver).

3.1.2.5 Data Processing

ECG data will be processed so as to allow display of a diagnostic quality ECG waveform after transmission to a remote site. Data processing will provide for addition of time tags to recordings, checks for data integrity and checks for data validity.

3.1.2.6 User Interface

The ECG element will support user controls that originate in the Data Management element. The user interface will allow a patient to initiate a recording after lead placement is complete, initiate data transmission upon connection to the communications service, and provide indications that another ECG recording should be made.

3.1.2.7 Recorded Questions

A series of questions used in Modes 1 and 3 operation will be stored in memory. After the ECG data is collected these questions will be displayed and the patient's responses, which are entered using buttons on the module, will be recorded. Candidate questions for Mode 3 operation are presented in Appendix B.

3.1.3 ECG Element Design Requirements

Design goals for the ECG electrode system are as follows:

- Initially, a patch electrode that, while not reusable, obviates the need for the patient to place multiple electrodes – he needs to place only a single patch using two fiduciary points.
- As a future goal, reusable, quick connection to extremities via elastic bands and to the chest via elastic band (or harness) that will provide a full set of precordial leads.
- Clear physical indications for limb lead location and precordial array orientation.
- No use of conducting gel (to permit reusability and to avoid potential for inter-electrode conduction via gel smearing).

Additionally, the lead interface should provide for 10-wire cable gathering to a single bundle that connects to the recording device via a single plug.

3.2 System Server and Client Modules

The client-server architecture provides the link between the patient and the portions of the medical community being brought to the patient's aid. The System Server receives ECG and patient data as well as the responses to automated questions from the Patient's Personal Module. These data are processed and forwarded to various client modules based on the operating mode indicated in the data. Mode 3 data are also temporarily stored for retrieval by EMS, and/or ED personnel until the patient has been formally received by ED or has been definitively diagnosed as not having ACS.

3.2.1 Performance Requirements – System Server

The primary performance requirements placed on the system server include:

- the number of calls it can process simultaneously,
- the maximum time to process any call,
- the maximum dead time in any one call,
- the time to detect server status change, and
- the time to redirect call to redundant/backup system.

An order-of-magnitude analysis of the number of Mode 3 calls that the system server will receive on any day based on data from Maryland Emergency Medical Services is provided in Section 2.2.3. This number, which is in the range of 30 calls per day, is increased by two orders of magnitude as a worst case to account for Mode 1 and 2 calls as well as a single PIERS server serving the entire State of Maryland. Three thousand calls per day corresponds to approximately two calls per minute. The average duration of each call is mode dependent. Mode 1 calls are expected to last as long as it takes to verify and process the patient information and return a response to the patient (5 minutes estimated). Mode 2 calls are expected to take, on average, approximately as long as Mode 1 given that in some cases the Service Technician will interact with the patient. Mode 3 calls should take approximately twice as long as Mode 2 calls since the Cardiac Teleconsultant may keep the patient on the telephone while EMS providers are responding. Consequently, a conservatively high estimate of an average of 6 calls active at any time is used as a performance requirement.

The time to process any one call is not critical for Modes 1 and 2 operation; however, the patient will perceive excessive time delays as a non-responsive system. Consequently, for Modes 1 and 2, the preliminary performance requirements placed on the maximum time to process any call is 30 minutes and the maximum time the patient has to wait between interactions with the system during a call is 30 seconds.

Time is critical for Mode 3 operation, consequently the maximum time for the System Server to validate the data, process the ECG and then forward the information package to the Cardiac Teleconsultant is 5 minutes.

Reliability of the System Server and communication links is critical to PIERS operation. Consequently, the System Server will include the ability to detect when the system is not operating and roll over calls to a backup system. System status checks will be done every five seconds and calls will be redirected within one second of a non-operating system being detected.

3.2.2 Functional Requirements – System Server

The following capabilities will be resident on the System Server:

- Mode determination,
- Network link creation and status monitoring with participating organizations,
- IP address configuration, control and assignment,
- Interface between telephone and internet mediums,
- The ability to configure the PIERS to accommodate many combinations of participating organizations, and
- Automated ECG interpretation.

The System Server has two primary purposes: 1) automatic interpretation of ECG and dispatch of EMS provider if warranted, and 2) router for the information passed between the participants of PIERS. The System Server receives an ECG, interprets it to decide if there is an AMI in progress and if so, dispatches EMS immediately without human intervention. In addition, the System Server maintains a record of the system configuration, attaches the system configuration information to the data set it receives from the patient, and transmits the augmented data set to the next destination dictated by the system configuration.

The System Server contains dedicated hardware and software that receives calls from the patient, and parses the operating mode from the data in the call. If the data is Mode 3, then the System Server processes the data using the GE/Marquette algorithm and assigns an interpretation based on the algorithm output and a strategy for deducing an AMI based on the output. If an AMI is indicated then the System Server automatically notifies the appropriate EMS provider. In all cases, for Mode 3 operation, the System Server forwards the patient data to the Cardiac Teleconsultant. Once the data has been forwarded, the System Server maintains the connection with the patient to enable voice over communications between the Cardiac Teleconsultant and the patient.

If the operating Mode is 1 or 2, the System Server forwards the patient data to the site providing these services and maintains the connection with the patient to enable voice over communications between the Service Technician and the patient, if the patient is having difficulty operating the PPM.

Our preferred system option is for the patient to communicate via direct phone line to the System Server which, in the preferred configuration, is collocated with the Cardiac Teleconsultant and for all clients to communicate via the internet (or by normal voice phone as a backup).

The software at the System Server contains a configuration file that identifies the sequence of IP addresses that are used in operating modes 1 and 2. The configuration file is maintained by a PIERS administrator, who is responsible for the information regarding the participating

organizations. The information from an example configuration file for Mode 3 operation is shown in Table 3-1.

Table 3-1 Conceptual Configuration File: Mode 3

Destination	IP Address
1. EMS	723.725.725.725
2. ER	723.726.726.726
3. Service Technician	723.724.724.724

In addition to routing data, the System Server has the responsibility of verifying that the links to the participating organizations are active. The System Server will periodically query each IP address in the configuration file to verify the address is accessible. If the address is not accessible, the System Server will implement a backup configuration.

PIERS configuration requirements are discussed in Section 3.5.

3.2.3 Performance Requirements – Client Modules

The basis of the PIERS is the ability to bring the important parts of the emergency department to the patient in a cost-effective and efficient manner. This is accomplished by integrating cardiac physicians with the EMS providers and Emergency Department services. The client modules discussed below enable the integration.

The client modules are associated with medical care provides linked to PIERS as discussed in Section 2. The performance requirements for these modules focus on processing and response times as well as data integrity. Time is most critical for the Cardiac Teleconsultant, consequently the software components comprising that client module will be designed and implemented to minimize processing time and provide the physician an awareness of elapsed time since the Cardiac Teleconsultant module received a data set. In particular, the time to respond to connectivity checks will be less than 1 second.

Data integrity will be insured by keeping a copy of the original data set transmitted by the PPM and providing it to the personal physician who has the sole responsibility to maintain the data on the PPM.

3.2.4 Functional Requirements – Client Modules

The functionality of the client modules is contained in software components that receive, process, display and transmit patient information as each client organization contributes to a response in one of the three modes. The functionality of the client modules will be implemented according to the usability guidelines presented in Reference 6.

Patient Personal Module Diagnostics

This software component will analyze the data set from the PPM to identify abnormalities indicative of malfunctions on the PPM or distortion of the data packets during transmission. This component will also identify abnormalities associated with individual electrode data.

Network Status Display

For options that use the telephone system, this software component will monitor the status of the connections between the different client modules. The results are displayed in a window on the client module. An example window for the network status display is shown in Appendix B (Figure B-1).

Patient Historical Data Display

This software component will display the medical data that the personal physician has placed on the PPM. The medical requirements document has identified three distinct data groups: demographics, medications, medical history including cardiac risk factors, and baseline ECG. The data will be organized and displayed in a window. An example window is shown in Appendix B (Figure B-2).

Patient New Data Display

This software component will display the new ECG transferred from the PPM. The display will be similar to the historical data display but include controls to customize the presentation. An example window for the patient new data display is shown in Appendix B (Figure B-3).

ECG Interpretation

The GEMS team member will provide the GE/Marquette ECG interpretation algorithm to PIERS. This software component will use the interpretation algorithm to process the new ECG data. An ECG results display is also included in this component.

EMS Provider Screen Display

This software component strips the relevant information from the patient historical data and the Cardiac Teleconsultant's Log and then displays it on the EMS provider display. MEMS personnel identified candidate information as shown in Appendix B (Figure B-4).

Interpretation Log Display

This software component allows the Cardiac Teleconsultant to enter his interpretation and any other annotation of the patient's ECG. The information is forwarded to the cognizant client modules (configuration dependent but likely to be EMS, ED and personal physician) as well as entered into a

database for tracing and bookkeeping purposes. In addition, this module allows for creating an ECG hardcopy with annotation.

Voice Link to Patient

This software component displays a button that allows the Cardiac Teleconsultant to open a direct voice line with the patient.

Directives Display

This component displays a window that allows the physician to issue his directive for this patient. The following software buttons will be displayed: alert EMS, patient visit ED, patient visit personal physician, re-position electrodes, record another ECG.

PPM Data Manager

This software component is used by the personal physician to maintain the information stored in the PPM. The component consists of an editor that allows the personal physician to display and edit the three groups of data stored on the PPM (i.e., medications, medical history, baseline ECG). It also allows the personal physician to issue a request for a data set to the service technician, which is entered on the technician's work list.

Service Technician

This software component consists of a work list of patients that the service technician has to contact and a database of information about personal physicians that the service technician needs in order to provide ECG data.

Automated Questions

In Mode 2 operation this software component generates questions based on patient history and responses to previous questions. The responses are recorded and forwarded to the personal physician as part of the data set. These questions are discussed in more detail in Section 3.3

These software components are combined to produce the desired functionality for the three operating modes as summarized in Table 3-2.

Table 3-2 - Software Components Assigned to Client Modules

Client Functionality	Service Provider	Cardiac Tele-consultant	ED/Chest Pain Ctr.	EMS	Personal Physician
<i>OPERATING MODE</i>	1 and 2	3	3	3	1, 2 and 3
1. Network Status Display	X	X	X		
2. Patient Historical Data Display	X	X	X		X
3. Patient New Data Display	X	X	X		X
4. ECG Interpretation Display		X	X		X
5. EMS Provider Screen Display		X	X	X	
6. Interpretation log Display		X	X		
7. Service Technician	X				
8. PPM Diagnostics	X	X			
9. Automated Questions	X				
10. Voice Link to Patient		X	X		
11. Directives Display		X	X		
12. PPM Data Manager					X

3.3 Decision Support

3.3.1 Performance Requirements

The system implements decision support using the information transmitted by the user and the information generated during an automated question and answer session conducted by the decision support system and the user. The capacity requirement for the interactive query process is determined by the maximum number of questions in any one session and the maximum number of questions available for all question set trees. Phase II Clinical evaluation will provide firm specifications, but, based on the Home Link CHF, PIERS will average approximately 10 questions to the patient per Mode 1 session, but in disease-specific Mode 2 question sets, the average will be approximately 20. The total number of questions in the question set tree for each disease will average approximately 50; and, the number of disease-specific question set trees will be approximately 10.

3.3.2 Functional Requirements

3.3.2.1 Interactive Patient Query System

The automated questioning and answer capability will be developed based on the Home Link System. The Home Link System is a patient monitoring system defined by JHMI cardiologists and developed by The Applied Physics Laboratory (APL). PIERS will adapt Home Link software to provide a flexible control for patient interactions with recorded voice questions and prompts. While other products exist that support home monitoring of patients, the Home Link provides unique features defined to support the JHMI developed advances in disease management. For background on the Home Link capabilities and application in PIERS, see Appendix B.4.

The PIERS will adapt Home Link software to provide a web-based means of: 1) authoring recorded voice questions or statements, 2) providing the patient interaction for any recorded voice interactions, 3) selecting the questions for Mode 2 interactions including question branching, 4) interim storage of results in one or more of the client workstations, 5) presentation of patient responses to the appropriate client, 6) presentation of any past responses from the patient, and 7) alertment to the physician of any conditions enabled by the physician. The physical interfaces will be substantially different – phone Interactive Voice Response interface board for Home Link vs. web-based interface for the PIERS. Nevertheless, substantial reuse and consequent development savings can be achieved by adaptation of the Home Link software.

Appendix B.4.2 includes an example patient interaction script for Mode 2 calls that have been implemented as a demo of this capability. The Appendix also provides instructions for remotely exercising the demo.

3.3.3 Design Requirements

The decision support component of the system will be built using the general design techniques presented in Reference 7. These include: 1) a decision support modeling method, 2) existing protocols for medical knowledge used in the decision process, and 3) commercially available tools to implement the decision support software. The approach to modeling the decision process will use simple rules to express the relationships between the patients cardiac risk factors and the GE/Marquette algorithm results.

The domain knowledge required to implement this decision support system already exists and has been demonstrated in other decision support systems. Sources of this knowledge include existing protocols used in emergency departments and the development that went into the GE/Marquette algorithms for automated ECG interpretation.

The decision support system will be implemented using knowledge-based system shells such as CLIPS, Nexpert Object or the MatLab Fuzzy Logic toolbox. These shells provide high-level implementation of the decision support algorithm which reduces both development costs and development risk.

Software development will make maximum use of available software components and all custom components will be written in a high-level language for the Microsoft environment. Consequently, software testing will emphasize functional testing at the component and integration levels.

3.4 Communication Services

3.4.1 Performance Requirements

The system will provide for universal access by supporting commonly available communications. Current choices are limited to the public switched telephone network (PSTN) by direct dial-up from patient to System Server. Communication between the Cardiac teleconsultant and the other client modules will be done in a web-enabled fashion using an Internet Service Provider (ISP)

as an intermediary. Communications services should add no more than an average of 10 seconds to any one data transfer, patient query session.

3.4.2 Functional Requirements

The functions of communications services are the following:

- Automatic dialing, call negotiation, user authentication, and data connection between the Patient Personal Module (PPM) to the system server,
- Retrieval and transmission of data from the PPM to the System Server,
- Ability for a technician and/or physician to converse with a patient without interrupting data communications,
- Ability for the System Server to interrogate the patient with scripted questions and for the patient to be able to respond by simple button pushes at the PPM or telephone, and
- Automatic disconnection after session completion

Numerous industry examples exist of point-to-point communications used for transmission of cardiac rhythm data over the PSTN. Generally existing point-to-point communications do not allow voice and data to be maintained simultaneously. There are industry examples of self-contained videophones that do provide for simultaneous data and voice over a single telephone line and standards exist for doing this. The communications service using a point-to-point approach consists of communications functions distributed between the PPM, the System Server, and the PSTN. The PPM originates calls, provides authentication data, retrieves appropriate data from memory and formats and transmits it. The PPM receives query codes (or analog queries) and transmits patient responses. The System Server auto-answers calls from the PPM, queries for and processes receipt of PPM authentication data, and provides queries or codes for pre-stored queries and receives PPM responses. Both the PPM and System Server respond to degraded line conditions and negotiate to provide optimized data transfer rates. The PSTN provides standardized connectivity between the PPM and the System Server and supports the use of a telephone rotary answer capability at the System Server, so that multiple callers can be serviced simultaneously. This approach requires data be provided to remote users (e.g. Cardiac Teleconsultant, ED, EMS) in a separate step.

A web-enabled approach not only facilitates voice and data (using voice over IP also known as “internet telephone” approach), but also allows the most flexibility by allowing all facilities – PPM, System Server, EMS, ED and Cardiac Teleconsultant to be simultaneously connected. The web-enabled approach also facilitates future upgrades to connectionless broadband and municipal wireless services as these become increasingly available to the public. The communications service using a web-enabled approach consists of communications functions distributed between the PPM, the System Server, the ISP, and the PSTN. This approach requires not only the PPM functions of point-to-point, but also that the PPM auto-connect via a point-to-point protocol and PSTN to an ISP with a high availability point-of presence. To ensure that attempts to connect are not frustrated by busy signals, multiple access numbers (and/or alternate ISPs) should be programmed into the PPM. Future upgrades would allow the PPM to connect to the ISP using the best technology available to the patient. The ISP provides the interface to other web participants. The ISP should host a dedicated broadband connection between the system server and the Internet. Optimized data transfer negotiation is handled between the PPM and the ISP, and between the ISP and the system server.

Note that to insure a high standard of reliability for the critical patient-system server-Cardiac teleconsultant connection, web-based communications are only being considered from the Cardiac teleconsultant to the other client modules.

3.5 Organizational Models

3.5.1 System and Protocol Configurability

The Emergency Medical Services (EMS) in the United States are organized by states or local jurisdictions (e.g., county or municipality), and consequently, are subject to a wide range of regulations and controls. The net effect is that the protocol used by EMS providers can vary dramatically from location to location. Thus any system designed to bring the ED to the patient and decrease the barriers to using EMS in the case of an ACS must be configurable to accommodate local EMS protocols.

3.5.2 System Configurations and Interfaces

System configuration is facilitated by modular design of the software. The minimum configuration consists of the PPM unit linked to the System Server and the Cardiac Teleconsultant Module. The System Server receives the data from the PPM, does processing focused on ECG interpretation and data validation and forwards the data to the Cardiac Teleconsultant for review and patient disposition. The System Server may dispatch an EMS provider, if not, the teleconsultant may activate a call to EMS, which dispatches the EMS unit.

In order to provide training, advising and administration services to the patient, the minimum functionality can be extended to include a commercial organization (i.e. the service technician) as a client module. This client may be the preferred location of the System Server. The core functionality can also be extended to include an EMS and/or ED client module. Clinical data concerning the patient (historical and ECG) can be transmitted to the EMS provider to assist in their on-site evaluation. Finally, the core functionality can also be extended to include a link to patient's personal physician.

In addition to selection of system modules and communication paths, the functionality of modules would be adapted to local procedures and operational protocols as well. For example, one region may choose to dispatch the EMS based on automatically tested criteria, while others may require that a physician be consulted before alerting the EMS. A brief discussion of the inherent flexibility in the client modules follows.

3.5.2.1 EMS Provider

The EMS mobile unit is in communication with the EMS dispatcher using existing services. The EMS providers can receive patient medical history data (i.e., the EMS screen) via several methods. These include a summary provided by voice over a radio link to data transfer to the mobile EMS unit using radios.

3.5.2.2 Cardiac Teleconsultant Interface

Physicians are directly involved in Mode 3 operation for interpretation of medical data as it is collected. Note that for Mode 3 operation, this interface could be located at the Chest Pain Center, the ED, or a physician's office. It could also be located at the commercial service site where staff medical personnel review the data as it is collected. The Chest Pain Center and hospital ED interfaces are identical.

3.5.2.3 Service Technician

The process of collecting and analyzing the data (stored ECG and stored medical history) for system operability verification will be done automatically. Since the process is automated, the computer can be located anywhere as long as the communications links exist. Thus configurations that include a private company in Pennsylvania providing service technician support to Maryland Emergency Medical Services are technically possible.

3.5.2.4 Personal Physician's Office

The final step of Phase 2 and 3 operation is the patient visit to a personal physician. The personal physician reviews the ECG reading and updates the medical history and ECG data on the patient's PPM unit. This functionality gets exercised with the physician's judgment as part medical care. No special requirements are placed on the location of the personal physician other than the availability of an internet or telephone connection.

3.6 System Support for Clinical and Engineering Evaluation

The system will include on-line monitoring and data extraction features to support both clinical and engineering evaluation in Phase II, Phase III, and beyond.

In Phase II, study protocols will be developed which could be used for testing the efficacy of the proposed system in a clinical setting. In Phase III, the Phase II product and associated medical protocols will be evaluated in an effectiveness trial in high-risk patients.

In Phase II, engineering tests will be conducted on the functional prototype. In Phase III, the functional prototype will be field tested in a patient population. Engineering tests will be conducted with the EDM version developed in Phase III.

Specific tests will be designed for data collection, data storage, ECG data processing, ECG signal conditioning, data storage, data interfaces, and user features. Initial Phase II testing will use pre-stored digitized ECG data associated with baseline pathologies and patient histories. Implemented algorithms will be tested to ensure that the baseline pathologies are accurately characterized by ECG processing and clinical decision support. As the Phase II functional prototype matures, simulated ECG signals for the same pathologies will be used. The communications capabilities will be tested using communications simulators and the public telephone system via FCC approved interface devices. Additional engineering evaluation data

(primarily user features and communications infrastructure issues) will be collected in the Phase III clinical evaluations using the functional prototype.

APPENDIX A

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