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# Vital Signs Monitoring from Home with Open Systems

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**Abstract.** This study investigates the applicability of a novel codification scheme based on two healthcare informatics standards (namely the VITAL (ENV 13734) and DICOM Sup. 30 Waveform Interchange) in addressing the robust interchange of waveform and medical data in remote healthcare applications. To further address system validation and clinical acceptance issues, pilots were set-up between home-monitoring stations and a hospital-based telemedicine consultation center. The pilots focused in assessing applicability, technical feasibility and performance of the proposed codification scheme based on the two standards. This paper presents the system and services requirements as studied for a home-care application, the design goals for the preservation of security stature, the practical issues of validation and the results of integrating these codification schemes into a commercial patient connected device.

## 1. Introduction

### *1.1 Issues and needs addressed by the study*

Medical technology has developed in an unstructured manner with bio-signal monitoring devices being developed in a way that precludes communication between them and with hospital information systems. The need for technical standardization in healthcare environments and the development of protocols enabling communication in a structured and open way, with subsequent clinical, administrative and research benefits, is more than obvious.

Furthermore, in all the countries of the European Union there is an increasing emphasis being placed on the role of general practice and community medicine in improving the health of people. Concomitant with the changing nature of healthcare delivery is an expansion of demand on these services as a result of demographic changes, an increasing proportion of the elderly in the population and a shift in the nature of the disease burden.

Into the light of the above, healthcare providers need to consider how to harness information management and communication technologies into a "hospitals without walls" concept. Success may lead to cost reduction and containment and more effective healthcare delivery, particularly in regions of limited infrastructure or geographically challenged.

* The views developed in this paper are that of the author and do not reflect necessarily the position of the European Commission

### *1.2 Aims and objectives of the study*

This paper presents the work undertaken in the framework of the Vital Home project, funded by the European Commission-Directorate General Enterprise (former DGIII Industry), under the Information Society Initiative for Standardization (ISIS) Programme.

This project has addressed the issues of medical data interchange in a standardized manner and clinical management of home-monitored patients, via the integration of VITAL ENV 13734 and DICOM Supplement 30 Waveform Interchange 'standards'.

Amongst its objectives has been the development of a small-scale pilot with bi-directional communication between home-care monitoring and a telemedicine consultation set-up as well as the security management for the provision of accurate information and the preservation of the integrity, availability and confidentiality of patient related information.

The project exploited the considerations necessary to determine baseline performance for products, components and services to meet the appropriate criteria for attaining systems integration in a home care environment. Finally, aiming at validating the system and 'standards', the project was evaluated, through the conduct of real-life assessment, by expert clinicians able to test/trial the development outcome in clinical situations.

## 2. Methodology

In the first phase, the user requirements were determined followed by the system and services description, thus providing the system architecture and functional characteristics document. In this context of featuring the system, this paper also presents a Data Protection Scheme formulated by a risk analysis survey.

In the second phase of the project, a detailed validation plan has been determined to provide guidance throughout the demonstration and results' assessment. The integration of the standards has been modeled in compliance with the object-oriented software engineering concepts, in order to realize a class hierarchy for the medical data exchange and the technical and physiological alert and data management, in accordance with the standards under study.

In the final phase of the project, software and hardware specs as well as functional requirements have been addressed and implemented, in order for the system to ensure the quality and safety specifications prerequisite for patient connected devices. Finally, the overall system has been verified accordingly with a protocol of procedures, in order to ensure controlled conditions that can be directly referenced to a standard level of practice.

### *2.1 In consideration of system and services description*

As a result of concentrating, evaluating, prioritizing and itemizing user requirements, we have derived the functional specifications for the proposed remote care system. Common concerns regarding the system and specific features to be incorporated include issues like simplicity of the equipment use, high level alarms and rapid response facilities (clinical instruction protocols). The Vital Home *services description* reflects the application and security requirements, whereas the *system description* reflects the system requirements.

The application requirements include the integration of the 'standards' over a platform of home telemonitoring, the continuity of secondary and primary care, the seek for open systems, the codification of medical procedures and the development of a pilot system.

The security requirements address the issues of patient record confidentiality and security, healthcare professional integrity and finally the product design and safeguards for the patients' and healthcare professionals' safety in the product design processes.

The system requirements dictate a system of minimal hand operation, with friendly user interface, secure operation and access to privileged users. Directions from the remote Healthcare Center in free text form and annotation must be possible. The monitoring system will allow acquisition and transmission of bio-signals and related medical data (3-lead ECG, Blood Pressure, Heart Rate and Pulse Oximetry) [1]. There will be rigorous h/w testing for failure avoidance and fault tolerance testing of the s/w, whereas its architecture will be sufficiently modular to allow its migration to relevant telemetry services.

### *2.2 Risk analysis review for the home monitoring services*

Security and interoperability are probably the most important requirements for a Health Information System [2,3]. Risk Analysis is a theoretical approach for the establishment of secure Info Systems. It tackles security problems and assists the analysts to select countermeasures that ensure a level of security, analogous to the level of risks, in a cost-effective manner.

The risk analysis method chosen for the Vital Home pilot system was the *CCTA Risk Analysis and Management Methodology* (CRAMM) [4]. CRAMM consists of three stages; definition of the system model/identification and valuation of its assets, identification of threats and vulnerabilities/risk calculation and selection of security countermeasures.

In the first stage, the identified assets of the Vital Home system are *Data Assets* (Electronic Medical Records-EMR, Vital Signs and Logging Information), *S/W Assets* (EMR S/W, Vital Signs Encoding-Decoding S/W, Vital Signs Viewing S/W and Activity Log S/W) and *Physical Assets* (provider's server, communication equipment, patient's computer and communication equipment and the Portable Vital Signs Monitor (PVSM).

In the second stage, threats to the system and vulnerabilities have been evaluated through CRAMM. Most important identified threats: (a) *System and Network S/W Failure* or *power failure* (causing unavailability of the service provider's server, patient's PC or the PVSM), (b) *Application S/W Failure* (causing unavailability of the EMR S/W, the Vital Signs Viewing S/W or the Vital Signs Encoding-Decoding S/W), (c) *H/W Maintenance Error* (causing unavailability of the PVSM) and (d) *User Error* (causing unavailability of the Vital Signs data). The calculation of the risk level for each asset identified as high risk cases the: *Masquerading of user identity* (vital signs monitoring service), *power failure, System s/w failure* (PVSM) and *Application s/w failure* (EMR S/W, vital signs viewing S/W, vital signs encoding/decoding S/W), reflecting a user need for authenticated use of resources, availability of electric power, system reliability and s/w quality respectively.

In the third stage, the aim was to select appropriate countermeasures for managing the identified risks. CRAMM produced a list of countermeasures for the remote vital signs monitoring service, which have been further examined and prioritized in terms of the following criteria: a) effects on the operation of the healthcare organization, b) implementation cost, c) future plans of the organization in terms of growth, d) views of management and their long term goals, and e) indication that specific threats on the system are expected in the near future. Additionally to technical and organizational countermeasures addressing the security needs for s/w quality and system reliability, special care was taken for the authenticated use of system resources and user identification. A series of procedural and technical security measures, including Role-based Access Control Protection Profiles, have been proposed for role identification, responsibility assignment, and user/applications/equipment authentication [5].

### *2.3 Assessment and validation plan*

The Vital Home system was to be validated under two generic concepts: One is the definition of a strict process/procedure for the system and software development through various development phases and the other is s/w verification. We have considered system development as model building comprising of five different models: requirements model (aiming at capturing the functional requirements), analysis model (aiming at giving the system a robust and changeable object structure), design model (aiming at adopting and refining the object structure to the current implementation environment), implementation model (aiming at implementing the system) and test model (aiming at verifying the system).

### *2.4 Codification Scheme Design*

The Unified Modeling Language (UML) notation [6] has provided the class hierarchy for modeling ECG, Pulse Rate, Blood Pressure and $SpO_2$ data, as well as alert and overall data management at the remote care Center. In Figure 1, the Object Class Diagram, which shows the information model for the implementation of the Vital Home Codification Scheme is illustrated.

The VITAL standard has been used for modeling the device, the vital signs and relative monitoring information, whereas DICOM Supp.30 has been used for mapping part of the VITAL information model attributes transmitted during the monitoring application into a DICOM Information Model, providing storage and management of requisite information.

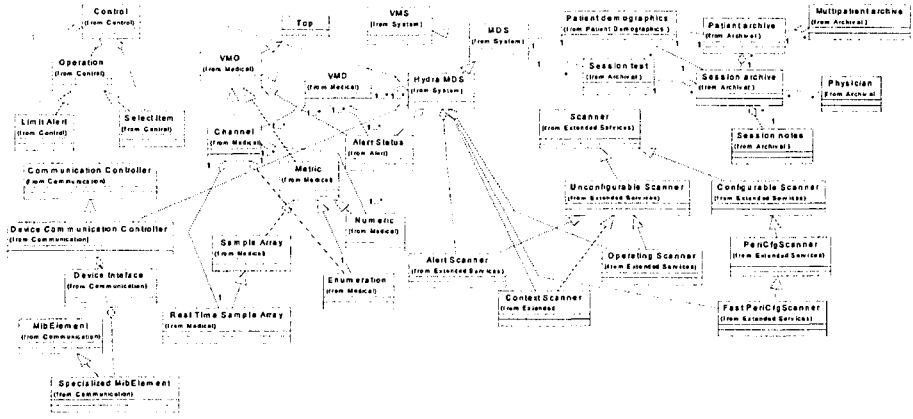


Figure 1 Object Class Diagram of the Vital Home codification scheme

### *2.5 System integration*

The system developed is architecturally divided into two operational sub-systems: The first serves the tasks of acquiring and encoding the vital signs and is located at the patient's home. The second one collects, through a communication link, the vital signs in order to decode, monitor and store them and is located at the remote Healthcare Center. The acquisition station is hosted in an industrial portable PC equipped with a digital modem that provides linkage to the physical communication layer [7]. Vital signs are acquired using a

Johnson&Johnson DINAMAP Plus III monitor via an RS-232 interface. All data collected, transmitted and received at the consultation end are archived (for security and legal purposes) on a dedicated DBMS [8].

*2.6 Pilot trials and system verification*

Four types of heart disease patients were considered in the pilot trials: Coronary Insufficiency, Hypertentional Heart Disease, Arrhythmia and Post-surgical patient after bypass operation. These cases established a representative sample and an adequate internal validity for the study.

During demonstration, participating medical personnel have evaluated the system in terms of functionality and usability. A brief, practical and easy to fill out Data Collection Sheet has been used in order to record for every patient the most crucial information needed for the evaluation. All doctors involved filled out a questionnaire for every case they attended. The Data Collection Sheet was designed according to the Common Industry Format (CIF) for Usability Test Reports [9,10].

## 3. Results and Conclusions

In terms of technical issues, demonstration activities concentrated on verifying the compliance to user functional and technical specifications and assess system performance. The results show the stability and robustness of the system in real-life medical situations, with rigorous error recovery, alarm handling and barely any transmission interruptions.

In terms of clinical results, pilots have demonstrated the potential advantages perceived from the system, pointing out an increase of the availability of potentially critical information, thereby improving the care provided to the patient and extending the value of tele-presence. Amongst potential benefits are increased patient survival rates, faster theater preparation and earlier requests for staff/equipment in emergency situations, fewer inappropriate pre-hospital procedures, reduced average length of hospital stay, improved confidence for the patient and improved potential education of patients and relatives.

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