The Bravehealth Software Architecture for the Monitoring of Patients Affected by CVD

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***Abstract* — The Bravehealth project is a large scale Integrated Project (IP) launched in the 7th Framework Programme. Bravehealth proposes a patient-centric vision to Cardio Vascular Disease (CVD) management and treatment, providing people already diagnosed as subjects at risk with a sound solution for continuous and remote monitoring and real time prevention of malignant events. Mainly, this paper describes the BVH Software Architecture. The role and the rationale behind the various system components is widely explained. The set of adopted technological solutions is presented and, finally, it is shown how the architecture succeeds in achieving a flexible, scalable and efficient system able to cope with many different medical scenarios.**

Keywords-Cardio Vascular Disease; Architecture; DSS; Data Mining.

I. INTRODUCTION

E-Health is largely recognized (see for instance [4], [5], [7] and [9]) as one of the most promising and powerful solutions to address Cardio Vascular Disease (CVD), being able to ensure an increase of the quality of care delivered and of the quality of life of patients, while decreasing overall healthcare costs. Nevertheless, in spite of these widely agreed and demonstrated benefits, the technical maturity of the majority of the solutions implemented is poor, the concrete use of e-Health services for supporting remote management of CVD is still very limited, there is a lack of a standardized approach, the market remains highly fragmented and focused on specific scenarios. Moreover, even though Decision Support Systems (DSS) can be a key added-value of the e-health (see for instance [1] and [2]). no convincing and standardized approaches for such an issue have been developed yet, especially regarding the use of Data Mining [3] techniques, applied to data related to patients affected by CVDs.

The Bravehealth (BVH) project [6] aims at coping with these problems introducing an efficient, flexible and scalable patient-centric system including a Software Architecture suitable for being applied to a plenty of different scenarios. The BVH focus is on CVD, but the designed Software Architecture (based on standard protocols and languages) and the Decision Support System, which is a key element of such an architecture, are so flexible that they can be reused for different diseases and for different typologies of patients.

The main objective of the proposed architecture is to enable the cooperation among the *Patients* and the *Medical Supervisors* (e.g., physicians, nurses, etc.) following the Patients, finalized at an early diagnosis and prevention of the occurrence of malignant events or complications. Another ancillary aspect is the capability of providing the Medical Supervisors with suggestions concerning the most appropriate provisions to be taken in case the system detects anomalies in the Patient health status. This will be obtained thanks to a synergistic approach of a compact wearable device with the capability of monitoring several clinic parameters in order to perform a timely diagnosis of patient's conditions, with advanced data fusion techniques implemented on it and with innovative algorithms and solutions for the Decision Support System. The correct way of working must be continuously monitored by appropriate technicians, referred to as *Technical Supervisors*.

This paper is organized as follows. Section II introduces the main components of the proposed architecture, along with a brief description of each of them. Section III details the main macro-tasks considered in the Bravehealth project and their relation with the architecture, with particular focus with the Decision Support System. Finally, conclusions are drawn in Section IV.

II. BVH MAIN COMPONENTS

The main actors and components of the BVH system are shown in Figure 1, using UML [8] formalism. The BVH main components are: (i) the *Wearable Unit (WU)*, (ii) the *Patient Gateway (PG)*, (iii) the *Remote Server (RS)*, (iv) the *IPTV*, (v) the *Patient Client (PaC)*, (vi) the *Medical Supervisor Client* and (vii) the *Technical Supervisor Client*.

The *Wearable Unit (WU)* is the component the Patient "wears" and includes the sensors responsible for sensing Patient's physiological data, as well as the functionalities for collecting the relevant measures and for transmitting them towards the Patient Gateway (PG). Such functionalities can be properly configured by the Remote Server (RS) (in cooperation with the PG). Then, the WU also includes the functionalities for actuating the received configuration information. Physiological data transmission towards the PG takes place either periodically, following the instructions deduced from the configuration information, or after properly selected triggering events again deduced from the configuration information, or on-demand following specific requests. Finally, the WU interfaces the Patient through an ad hoc interface which is intended to provide the patient with very simple status messages such as the WU battery charging status or possible malfunctioning/misplacing (more elaborated information is sent to the Patient by the HMI Component embedded in the PG, as detailed later).

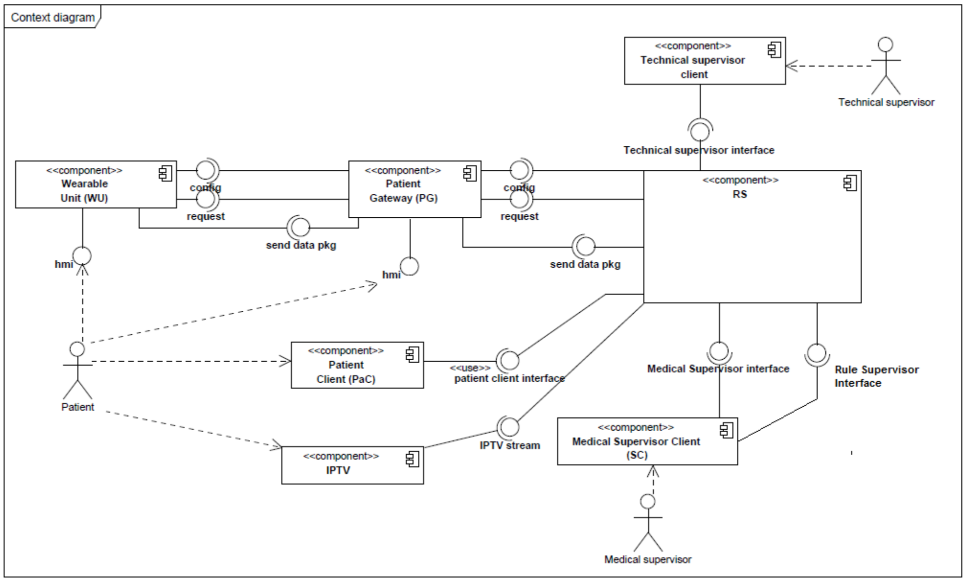

Figure 1. Main components of the BVH architecture

The *Patient Gateway (PG)* proposed Software Architecture is shown in Figure 2, using UML formalism. The PG is the Component which represents the mean by which the information data flow from the WUs to the RS and vice versa. Moreover, the PG is devoted to perform a preliminary analysis on raw data (physiological and context) collected from the WU, to store data into a local memory cache and to forward them (both raw and elaborated) to the RS. The above-mentioned preliminary analysis makes use of Data Processing and Decision Support capabilities running at the PG finalized at deducing elaborated information from raw data collected by the WU to be exploited by the RS Decision Support System and at detecting, in a fast way, anomalies with respect to the regular Patient behavior. The PG is configured (in terms of scheduled activities) by the RS. The PG also receives from the RS the configuration for the WU: this configuration could be modified by the PG on the basis of some internal elaboration and then forwarded to the WU. The PG can request specific data from the WU. Finally, the PG is able to provide the Patient with information about the status of his health, as well as specific instructions determined by the Medical and/or the Technical Supervisors.

The *Remote Server (RS)* proposed Software Architecture is shown in Figure 3, using UML formalism. The RS is the core architectural component of the BVH system and contains most of its intelligence. The RS performs the complex algorithms of the Decision Support System (DSS) component, stores data (physiological and context data, both raw and elaborated) collected from all the PGs (related to all patients) with which it is connected and provides the front end logic of the interfaces with the BVH actors (Patients, Medical supervisors and Technical supervisors). The RS is in charge of computing (automatically or by means of the intervention of Physicians/Technicians) the most appropriate configurations for the PGs and the WUs. Such configurations, among other information, include the scheduling of the activities to be performed by the WUs and by the PGs. The RS can request data stored into the PGs and/or the WUs (raw or elaborated context and physiological data). The RS provides the front end logic to the users' client components (*Medical Supervisor Client* (MSC), *Technical Supervisor Client* (TSC), *Patient Client* (PaC) and *IPTV*) through the set of exposed interfaces, illustrated in Figure 1.

The *IPTV* is a Component which is used by the Patient in order to interface with the BVH system: thanks to it, the Patient could visualize the status of his health, as well as a list of specific instructions and/or high resolution videos.

The *Patient Client (PaC)* is a Component which is used by the Patient in order to interface with the BVH system. Through this interface, the Patient is able to visualize the status of his health, as well as a list of specific instructions and/or low resolution videos.

The *Medical Supervisor Client* is the Component which is used by the Medical Supervisors in order to interface with the BVH system. The Medical Supervisors could use this component (i) to access (including insert, modify or delete) configuration or sensor data of a particular Patient, (ii) to manage notifications/suggestions produced by the BVH DSS, (iii) to access all patient history.

The *Technical Supervisor Client* is the Component which is used by the Technical Supervisors in order to interface the BVH system. A Technical Supervisor could use this component to monitor and to modify the status of the PGs and of the WUs or the patients' data and to apply diagnostic operations in order to correct possible malfunctions.

III. BVH MACRO-TASKS DESCRIPTION

In order to facilitate the understanding of the rationale behind the proposed Software Architecture, the description of the BVH Components appearing in Figures 1-3 will be performed with reference to five specific *BVH Macro-tasks*. A BVH Macro-task includes all the procedures which aim at the same high level objective.

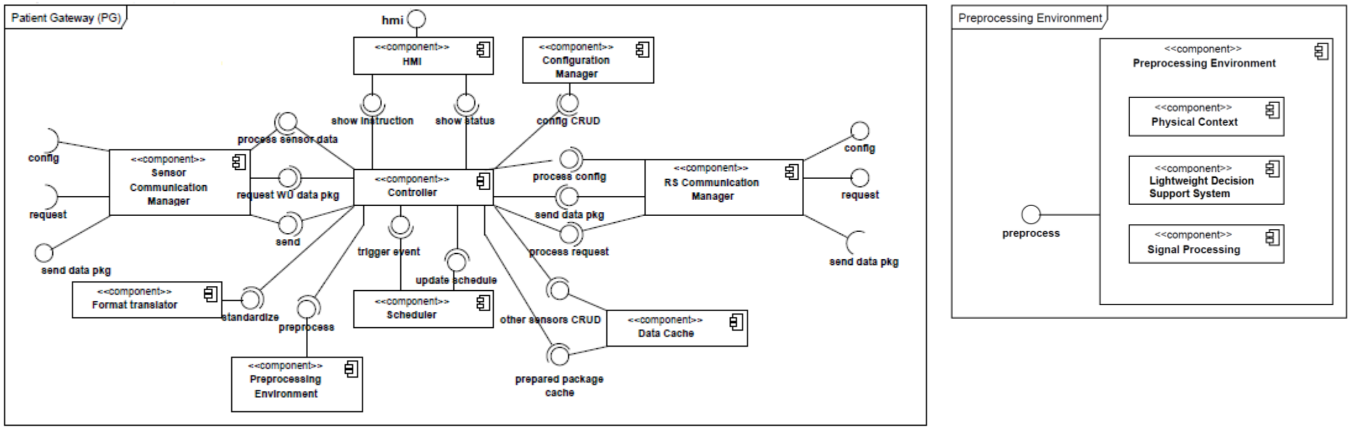

Figure 2. Patient Gateway (PG) Software Architecture

A. *PG and RS orchestration*

This macro-task deals with the orchestration of the PG and RS Components. The main components involved in this macro-task are, at the PG side, the PG Controller, whilst, at the RS side, in consideration of the complexity of the involved tasks, in order to get a real-time processing speed, the orchestration task is distributed among the RS Gateway Controller and the RS Patient Configuration Manager, involved in the management of the Sensor Data and of the Configuration Data, respectively. The above-mentioned components operate according to a flexible logic guaranteeing a high degree of reconfiguration and, in particular, assuring the possibility to replace, in a natural way, the current WUs/PGs with more advanced ones, as well as to add/remove/replace storage, pre-processing, decision support system, configuration and interfacing capabilities.

The *PG Controller* is devoted to orchestrate all the PG components in order to execute the whole logic of the PG. The PG Controller is triggered by events coming from the PG Scheduler: the latter is updated by the former and includes the scheduling of the events involving the PG.

The *RS Gateway Controller* is in charge of the whole logic related to the communication with the PG and the management of the Sensor Data, which include both the raw data produced by the WU sensors and transmitted by the WU to the RSs through the PGs, and the elaborated data which are the output of the pre-processing of the above-mentioned raw data performed at the PGs and/or at the RS.

The *RS Patient Configuration Manager* is in charge of the management of the Configuration Data, i.e. the data relevant to PG and WU configurations. In particular, the RS Patient Configuration Manager is in charge of managing the configurations of the PGs and of the WUs on the basis of Patient information (e.g., status, case history, medical protocols, the output of the DSS, etc.) and of physicians' or technicians' decisions. Moreover, the RS Patient Configuration Manager is the Component of the RS in charge of performing the whole application logic related to the management of the Patient Data, which include the patient personal information, as well as the data relevant to the patient status validated by medical diagnoses.

B. *Flow and Management of Sensor Data and of Configuration Data*

This macro-task deals with (i) the flow of the Sensor Data collected by the sensors (the ones embedded in the WUs, as well as other kind of sensors such as environment sensors) to the PGs (where they can be subject to formatting and preprocessing) and eventually to the RS, (ii) the flow of Configuration Data (for PG/WU configuration) from the RS to the PGs and, eventually to the WUs. Each WU is configured by the RS (with the possible cooperation of the PG) to send, either periodically, or whenever events occur, patient specific information (e.g., physiological data) to the PG. In addition, a PG could also request to a WU on-demand data or other types of information.

The *PG Sensor Communication Manager* is in charge of interacting with the WU and/or with other kinds of sensors in order (i) to receive Sensor Data and (ii) to send either Configuration Data or data requests to the WU. In particular, such component has to interwork with the communication channel (e.g., Bluetooth) which is used for the data exchange between WUs and PGs.

The *PG Format Translator* is a Component able to translate the Sensor Data collected by the sensors, which are raw data, into a standard format suitable for the PG Preprocessing Environment (see next section).

The *PG Data Cache* stores all Patient related data (measurements, scheduling information, status, configuration, etc.), i.e., the raw ones, the ones formatted by the Format Translator component and the ones elaborated by the PG Preprocessing Environment.

The *PG RS Communication Manager* (PG side) and the *RS Gateway Controller* (RS side) interwork with the communication channel (e.g., UMTS) which is used for the data exchange between PGs and RS. In particular, these components manage the sending of Sensor Data (which could include both raw data coming from the WU and/or data formatted by the PG Format Translator and/or data elaborated by the PG Preprocessing Environment) from the PG to the RS, as well as of Configuration Data in the opposite direction.

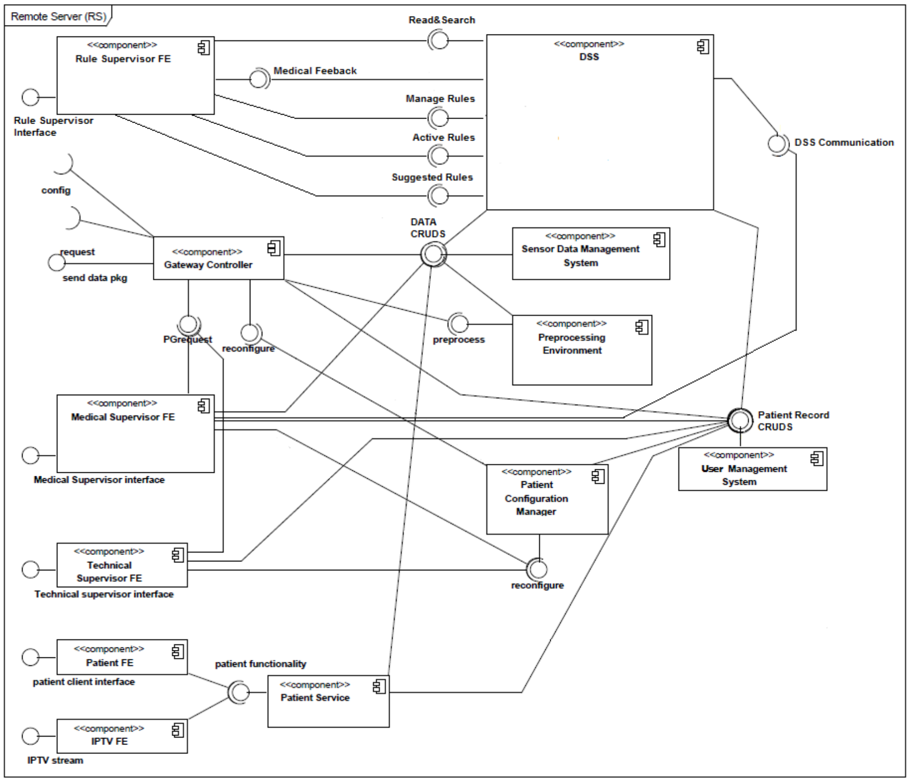

Figure 3. Remote Server (RS) Software Architecture

Aiming at enhancing RS performances, two main database components with associated database management (updating, adding, removal) logic have been foreseen at the RS, namely the RS Sensor Data Management System and the RS User Management System storing the Sensor Data and the Configuration/Patient data, respectively; these two databases are managed by the RS Gateway Controller and by the RS Patient Configuration Manager, respectively.

The *RS Sensor Data Management System* stores all Sensor Data, both the ones directly arriving at the RS from the PGs and the ones resulting from elaborations of these data performed by the RS DSS and/or the RS Preprocessing Environment. RS components such as DSS, Preprocessing Environment, Patient Service, Medical Supervisor FE and Gateway Controller could use these data through the *DATA CRUDS* interface.

The *RS User Management System* stores all Configuration Data and Patient Data (these two kinds of data, being strictly related since PG and WU configurations are tailored to the associated patient, are stored in the same database component). The RS Medical/Technical Supervisor FE, the RS Supervisor Management System and the RS Patient Configuration Manager could use/update these data through the *Patient Record CRUDS* interface. Moreover, the RS User Management System has the key role of interworking with the Hospital Information System (HIS), in order to extract information relevant to enrich the Patient Data.

C. Data Processing and Decision Support at the PG

A key feature of the BVH architecture is the fact that some light processing of Sensor Data already takes place at the PG, whilst an heavy processing of Sensor Data is demanded to the RS. This issue adds many degrees of flexibility to the whole system allowing to perform the most urgent elaborations close to the patient, with evident advantages in terms of privacy/security, decoupling from both possible PG-RS communication link and RS server problems, saving PG-RS communication channel capacity, etc. The PG processing in question is performed within the *PG Preprocessing Environment* component, in turn, including its subcomponents: (i) the *PG Signal Processing*, (ii) the *PG Physical Context* and (iii) the *PG Lightweight Decision Support System*.

The *PG Signal Processing* includes algorithms for filtering and processing the signals coming from the WU, e.g., in order to remove noise and compute a set of ECG descriptors (or features), e.g., QRS-T-Angle [10], QTdispersion and so on. These descriptors are used for measuring the distances among different electrocardiograms with the aim of detecting anomalies, detecting and segmenting heart beat and supporting physician’s diagnosis.

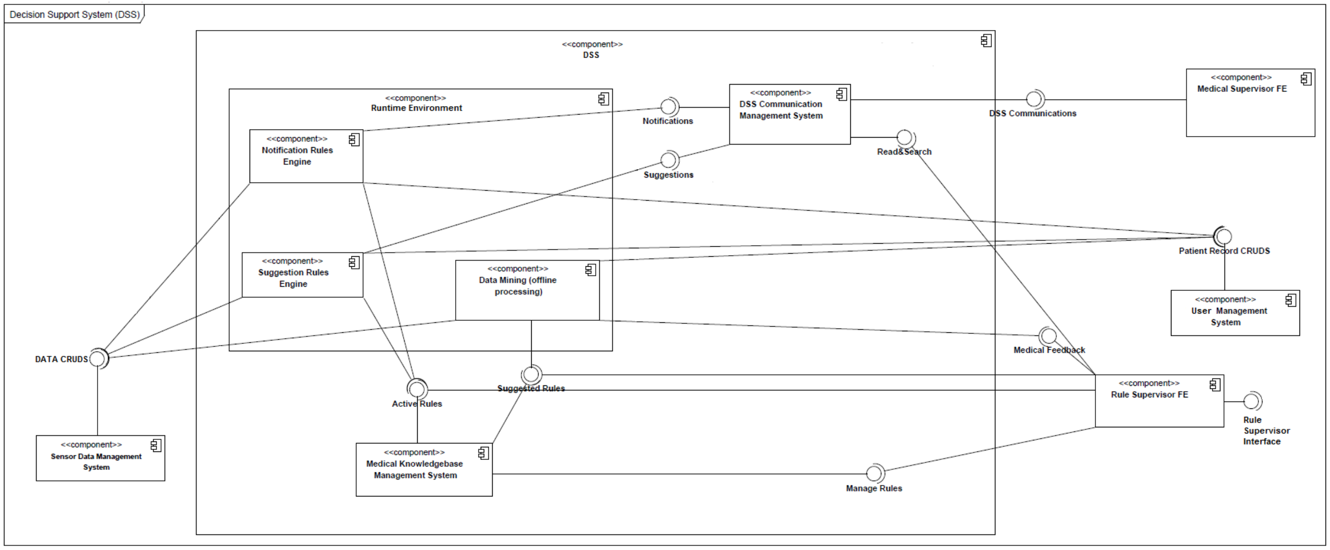

Figure 4. RS Decision Support System (DSS)

The *PG Physical Context* includes algorithms that, on the basis of the signals coming from the WU and/or from other possible sensors, extract context information (e.g., information about the activity, the location, the environment related to a certain patient): such information will be made available by computing a family of physical context factors (e.g., location of the patient, etc.). These factors will be made available to other data processing modules (e.g., the Lightweight Decision Support System described below) for further information extraction procedures.

The *PG Lightweight Decision Support System* analyses the Sensor Data available at the Patient Gateway (raw data coming from the WU, ECG descriptors and other physiological parameters/context factors coming from the PG Preprocessing Environment) with the aim of identifying specific patient profiles and abnormal behaviors. This analysis is performed by using unsupervised machine learning algorithms (e.g., data clustering) with the aim of identifying patterns that are typical of a given patient. In turn, these patterns are used to detect anomalies with respect to the regular behavior of the specific patient.

D. Data Processing and Decision Support at the RS

The *RS Preprocessing Environment* includes Signal Processing and Physical Context functionalities, whose rationale is similar as the corresponding ones at the PG.

The *RS Decision Support System (DSS)* (see Figure 4), following the on-line application of appropriate rules to the Sensor, Configuration and Patient Data, provides the Medical Supervisors with Notifications and Suggestions. The rules which are used for deriving notifications and suggestions are stored in the database component referred to as *Medical Knowledgebase Management System (MKMS)*, also providing the associated database management (updating, adding, removal) logic. Such rules are managed by the Medical Supervisors authorized to manage the DSS, through the *Rule Supervisor FE*. In particular, as shown in Figure 4, the DSS component consists of the following subcomponents: (i) the *Notification Rules Engine*, (ii) the *Data Mining*, and (iii) the *Suggestion Rules Engine*.

The *Notification Rules Engine* is the engine that interprets the logic rules defined on the basis of medical protocols and standard procedures adopted by physicians. These rules are directly uploaded by the Medical Supervisors in the MKMS, where they are labeled as “*Active Standard Rules*”. The Notification Rules Engine *on-line* applies the Active Standard Rules to both the Sensor Data coming from the RS Sensor Data Management System and to the Configuration/Patient Data coming from the RS User Management System. Following the application of each rule, the Notification Rules Engine takes a decision in the form of a “notification” which is sent to the Medical Supervisors, via the DSS Communication Management System.

The *Data Mining* is the core Component of the DSS. It analyses (through an *off-line* processing, but continuously in progress during the BVH system operation) the available historical data (i.e. the Sensors Data stored in the RS Sensor Data Management System and the Configuration/Patient Data stored in the User Management System) with the aim of identifying correlations, regularities and patterns that represent the information extracted from data. The analysis is performed through both unsupervised (e.g., data clustering) and supervised (e.g., data classification and regression, pattern recognition) machine learning algorithms in order to identify correlations, regularities and patterns in the data. This information is used to infer new rules which are stored in the MKMS being initially labeled as “*Suggested Inferred Rules*”. Then, following the approval from a Medical Supervisor authorized to manage the DSS (performed by means of the *Rule Supervisor Front End (FE)*), each rule can be labeled as “Active Inferred Rule” and can be interpreted and used by the Suggestion Rules Engine.

The *Suggestion Rules Engine* is the rule engine that interprets the Active Inferred Rules derived by the machine learning algorithms running in the Data Mining module. The Suggestion Rules Engine *on-line* applies the Active Inferred Rules to both the Sensor Data coming from the RS Sensor Data Management System and to the Patient/Configuration Data coming from the RS User Management System. Following the application of each rule, the Suggestion Rules Engine takes a decision in the form of a "suggestion" which is sent to the DSS Communication Management System and, eventually, to the Medical Supervisors.

E. User Interface

In the BVH system there are three kinds of users, namely the Patients, the Medical Supervisors and the Technical Supervisors. For each kind of user a specific interface is foreseen. The *Medical Supervisors* access the BVH system through the Medical Supervisor Client. They could use this Component to manage (insert, modify or delete), through the Medical Supervisor FE, specific Configuration, Patient or Sensor Data, as well as to manage, through the Rule Supervisor FE, the notifications/suggestions produced by the DSS. The *Patients* can access the BVH system both at the PG, via the PG HMI (Human Machine Interface) and at RS, via the Patient Client (PaC) and/or the IPTV. The PG HMI is a simple, usable and friendly interface which can display physicians-filtered instructions and/or proper information stored in the PG Data Cache Instead, the RS Patient Service is delegated to provide a "device-independent" RS HMI functionality to the Patients which can access the Sensor Data and the Configuration/Patient Data stored in the RS databases, via both their television set (via the IPTV and IPTV FE Components) and/or via their personal computers/smartphones (via the Patient Client (PaC) and Patient FE Components). The *Technical Supervisors* access the BVH system through the Technical Supervisor Client and the Technical Supervisor FE. They could use this Component to monitor and modify the status of the RS, the PGs and the WUs and to apply remote diagnostic operations.

IV. CONCLUSION AND FUTURE WORK

The proposed BVH architecture includes a set of consistent technological solutions which, considered altogether, contribute for achieving a flexible, scalable and efficient system able to cope with a plenty of different scenarios. The most meaningful of such solutions are: (i) the PG and RS orchestration, thanks to the adoption of general purpose, event-driven controllers, is not customized for a specific scenario, but is conceived for allowing, in a natural way, the adding/removing/upgrading of the various system components; (ii) the decoupling of the Sensor Data handling from the Patient and Configuration Data handling allows a faster and more flexible data management; (iii) the use of a two-scale Decision Support including a *light* processing of Sensor Data taking place at the PG, and a more *heavy* processing of Sensor Data demanded to the RS, allows to perform the most urgent elaborations close to the patient, with evident already depicted advantages in terms of privacy/security, decoupling from PG-RS communication link problems, decoupling from RS server problems, etc; (iv) the use within the RS Decision Support Systems (DSS) of two set of rules deriving from medical protocols and standard procedures and from machine learning algorithms running in a Data Mining module allows the DSS to produce notifications/suggestions for the Medical Supervisor integrating the medical experience with advanced data extraction techniques. In addition, in the proposed DSS all heavy computations are demanded to an *off-line* (non real-time) Data Mining component, whilst the *on-line* (real-time) Rules Engines have to perform light/standard computations, with the evident advantages in terms of reaction speed; (v) the use of several user interfaces tailored to the requirements of the three BVH system users.

As far as future work is concerned, the next research step will be the tailoring of appropriate algorithms for the PG and RS Decision Support components (algorithms already partially identified by the authors), to perform effective data extraction from a huge amount of CVD related data.

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