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CHRONIOUS: A wearable platform for monitoring and management of patients with chronic disease

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Abstract— **The CHRONIOUS system has been developed based on an open architecture design that consists of a set of subsystems which interact in order to provide all the needed services to the chronic disease patients. An advanced multi-parametric expert system is being implemented that fuses information effectively from various sources using intelligent techniques. Data are collected by sensors of a body network controlling vital signals while additional tools record dietary habits and plans, drug intake, environmental and biochemical parameters and activity data. The CHRONIOUS platform provides guidelines and standards for the future generations of "chronic disease management systems" and facilitates sophisticated monitoring tools. In addition, an ontological information retrieval system is being delivered satisfying the necessities for up-to-date clinical information of Chronic Obstructive pulmonary disease (COPD) and Chronic Kidney Disease (CKD). Moreover, support tools are being embedded in the system, such as the Mental Tools for the monitoring of patient mental health status. The integrated platform provides real-time patient monitoring and supervision, both indoors and outdoors and represents a generic platform for the management of various chronic diseases.**

I. Introduction

THE CHRONIOUS system has been designed in order to be a flexible platform which through the integration of sensors and services will cover both chronic disease patients' and their caregivers' needs. Data are collected by sensors controlling vital signals, dietary habits and plans, drug intake, environmental and biochemical parameters as well as activity data. Noticed abnormal health conditions are reported to the responsible healthcare professionals supporting decision making and analysis of data. As indicated in literature for such wearable platforms, the user needs are related to issues like usability, wearability, data storage and transmission, embedded decision support, power supply, interoperability and personalized services.

The CHRONIOUS system provides a patient-specific platform, which requires the minimum effort by the patient. In the user requirement gathering phase it became clear that patients who will use the CHRONIOUS system will be older, and will have few or no technology skills at all. The updated version of the system, according to those main principles, fulfills the user requirements.

An open architecture design has been used to exploit the benefits of the final platform upon other chronic diseases, besides COPD [1] and CKD [2] and fulfill the requirements defined from user requirement phase. The system consists of seven primary functional blocks [5], which are the Sensor Framework, the Data Handler, the Home Patient Monitor (HPM), Smart Assistant Device, the CHRONIOUS Central System, the Clinician Framework and the External Devices, such as the Body Weight Device, the Blood Pressure, the Blood Glucose Device and the Spyrometer device.

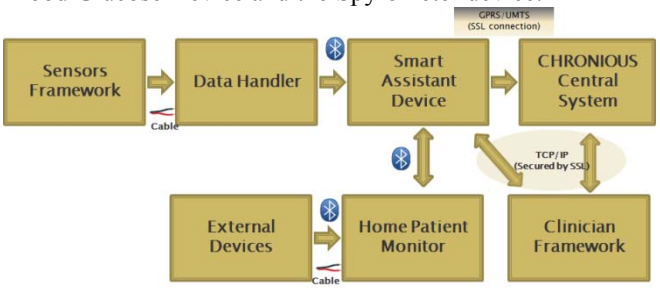

Fig. 1: The functional blocks of the CHRONIOUS platform and their interconnection

II. System Architecture

The Sensor Framework is one of the most critical parts of the system. It consists of a tight-fitting and washable shirt which provides the support for the stabilization of the body sensor network (Fig. 2). Several miniature sensor devices, utilizing non-invasive methods, are responsible for the recording of the vital signals and their further transmission for the analysis. The sensors which are utilized in this framework are: a 3-lead Electrocardiogram (ECG), a microphone as a context-audio sensor, a pulse oximeter, two respiration bands (thorax and abdominal), an accelerometer and sensors for measuring humidity as well as body and ambient temperature.

Sensing capabilities and sensor networks play a key role in the design, performance and acceptance of the wearable system. The choice of the localization of non-invasive devices has to satisfy several criteria and limitations like monitoring the most significant signals for the identified diseases, obtaining the best signal/noise ratio, fixing and ergonomic aspects as well as unobtrusiveness. Allowing the user maximal mobility requires wearable sensors.

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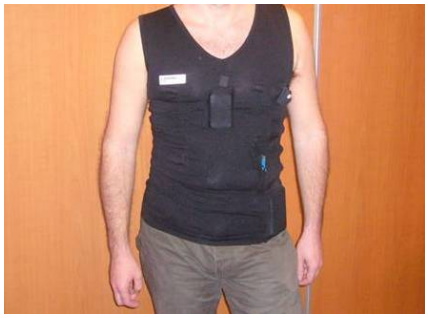

Fig. 2. The wearable platform with all sensors integrated to the CHRONIOUS jacket

The wearable platform [9] contains also the data handler device, which is placed at the lower part of the shirt. It has been designed and developed aiming at the collection of all the signals coming from the body sensor network. The data handler resides on the wearable system worn by the patient and connects wirelessly to the Smart Assistant Device, in order to avoid cables. This device is responsible for raw data collection from the sensors and sensor monitoring by periodically checking the status of the sensors along with their remaining battery levels. The size of the data handler, displayed in Fig. 2, has been reduced in order to be unobtrusive and easily integrated to the jacket [10].

Fig. 3. The data handler device

The Smart Assistant Device that is being used in the CHRONIOUS project is a Personal Digital Assistant (PDA) [11] in order to take advantage of the computational power of such a device. The Smart Assistant Device contains an intelligent core [3], [4], which analyzes incoming data, facilitating data mining techniques and decides upon the severity of a probably pathological episode.

Part of the intelligent core is the Mental Support Tool, which calculates a stress index and classifies the mental condition and stress levels of the patient. In Fig. 4 the generic block diagram of the intelligent core is being presented, where the main modules as well as their interconnections are being displayed. The functionalities of the Intelligent Core application are divided into three different and independent processes:

1. Alarms and Displays: This output is being triggered when the estimated severity is critical.
2. Data transmission to Central System for further analysis: In case an abnormal situation regarding the patient's health status has been identified from the Decision Support System or a simple threshold has been exceeded by the value of a signal then this process is being triggered and a forced synchronization between the Smart Assistant Device Database and the Central Database is being performed.
3. Storage to the Database: In case the Decision Support System doesn't identify any severe episode, the extracted features and the processed data as well as the output of the Decision Support System are being stored to the Database.

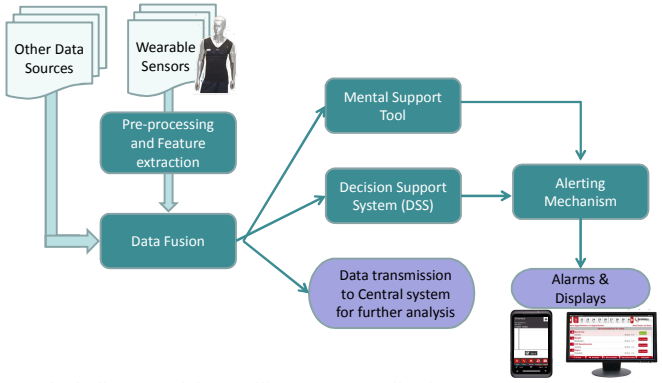

Fig. 4. Block diagram of the Intelligent Core application

A first layer of intelligence is located on the Smart Personal Digital Assistance device (PDA) and is devoted to data analysis and worsening conditions identification by means of computational reasoning methods (e.g., Artificial Neural Networks, Bayesian Networks, and so on). Various heterogeneous data, either patient inputted or sensors acquired are being collected in the PDA and feature extraction algorithms are initially applied in order to extract useful features for further analysis (i.e. Heart rate extraction from sensors' data or CHO consumption from patient inputted information regarding the food intake). These features are being further processed and fused in order to combine this heterogeneous information and annotate them in the time domain.

The Mental Support Tool is being embedded in the intelligent core component of the PDA application and integrates various processes. It detects a stressful situation by combining various parameters stored in PDA Database and evaluates the identified situation by estimating a Stress Index and providing a respective advice to the patient. Moreover, the Mental Support Tool, evaluates the patient's adherence to the system's scheduled activities and recommendations, keeps patient's moral high and motivating him/her to assist the disease management system and finally provides tips once a day with short messages of clinical knowledge. The attributes that affect the stress index and their weights have been specified based on the clinicians' feedback and a discretization of the continuous signals that have been selected as attributes.

The HPM is responsible for displaying the data of the Smart Assistant Device on a larger screen offering a more comfortable and user friendly way to the patient and caretakers interacting with the system.

The above described information is processed locally and then transmitted to the CHRONIOUS Central System for

further manipulation and long-term storage.

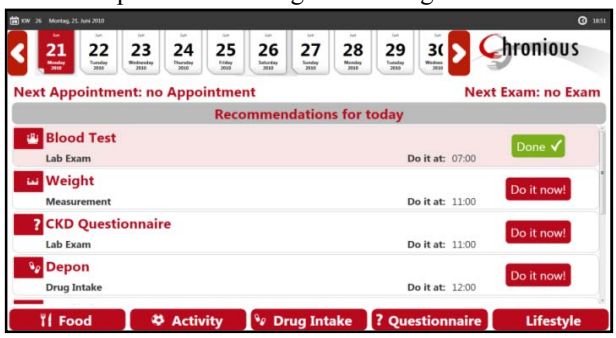

Fig. 5. Main screen of the Home Patient Monitor Interface

A second layer of intelligence, the Central Clinical Decision Support System (CDSS) located on CHRONIOUS Central system, is a knowledge based system developed by formalizing the know-how of clinicians that are expert in patients' monitoring, and also the clinical guidelines. This system is capable of supplying suitable suggestions by analyzing and correlating a wider amount of information, i.e., correlating information collected from sensors in combination with other clinical patient data. The encoding formalism was selected pursuing flexibility, simplicity, functionality and interoperability requirements. In particular, the formalization consists of an ontology and a set of rules [7], [8]. The use of an ontology [6], developed according to W3C standards, assures the definition of a clear structure of the encoded knowledge and its interoperability and easy integration with other possible implementations. Moreover, the adoption of ontologies and rules made easier the cooperation with clinicians and the elicitation of their know-how, since such a formalism is easier to understand than others for them and more similar to their way of thinking. Actually, the knowledge elicited from clinicians about patients' monitoring came exactly in the form of rules.

The corpus of knowledge used by the system is upgradable: clinicians have the possibility of building and modifying the encoded knowledge base, through a knowledge base editor equipped with the enhanced capability of verifying the rule consistency with respect to the knowledge already encoded. Rules have been defined on the basis of general clinical guidelines, by considering physiologically acceptable parameters and by introducing some more restrictive parameters specific for COPD. Since COPD is often characterized by the presence of co-morbidities, at the Patient Sensing Framework level only general threshold values can be suggested. More specific reasoning will be performed at the level of the CDSS, allowing different sensitivity to changes in some of the parameters depending on patient's phenotype. The values suggested for the CHRONIOUS COPD Clinical Guidelines for the Patient Sensing Framework are reported in Table I.

TABLE I
THRESHOLDS AND RULES FOR TRIGGERING THE FORCED UPDATE

Wearable Sensor	Alarm - immediate action	Sending data trigger
Body temperature	T > 38°C	T > 37.5°C during 4 consecutive hours
Weight	> 2kg in 24 ore	(every 24h)
Heart Rate (HR)	HR > 120 BPM	HR > 100 BPM,
ECG	Indicators of arrhythmia	(every 24h)
Arterial Pressure	Diastolic > 100, systolic > 150	Diastolic > 85, systolic > 130
SpO2	SpO2 < 91%	91% < SpO2 < 94%
Respiratory Frequency	f > 20 BPM	f > 15 BPM
Inspiratory Time	Ti < 1 sec	
Expiratory Time	Te > 5 sec	
Respiration Asynchrony (Resp. Freq.)/(tidal volume)	f/Vt > 100 BPM/L	(every 24h) 60 < f/Vt <100 BPM/L
Minute Ventilation	>10L	
Coughs Counter	> 60-70 per hour	
Symptoms self-evaluation questionnaires: Breathlessness, Cough and Sputum Scale (BCSS) [13]	Dyspnea at rest (check on respiratory frequency)	(every 24h)

Finally, the Clinician Framework is being interconnected to the central system in order to assist clinicians in patient health status monitoring and disease management. A major challenge occurs when decision-makers are fed with so much information that they cannot process and synthesize it intelligently and rapidly.

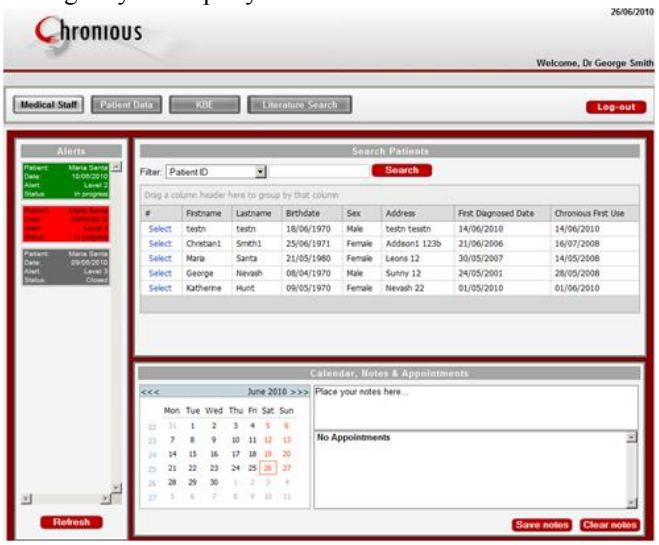

Fig. 6. Screenshot of the clinician interface, which is a web-accesses platform

The clinician framework enhances the personalization of the decisions. As chronic diseases are greatly affected by dietary and nutrition habit, a nutritional planner module manages patient's nutrition individually based on characteristics, preferences, health situation and disease stage. Another critical module, embedded in the web-based platform of the clinician framework is the drug intake management and monitoring. The clinician designs the prescription in his/her interface and the patient prompts a

reminder generated automatically. A sample of the interface is being presented in Fig. 6 where caregivers can access vital signs information, alert messages, review patient data and update patient charts.

III. Risk Analysis

The safety of any medical device system is dependent on the application of a disciplined, well-defined, risk management process throughout the product life cycle. Hardware, software, human, and environmental interactions must be assessed in terms of intended use, risk, and cost/benefit criteria.

All hardware/software developed must be proven to be safe and efficient Core to safe hardware/software is the hazard analysis and risk management process. The development of the assessment is based on the use of project documents and other sources of information, the results that the partners hope to generate, the form(s) that the exploitation of these results may take and the conditions needed to enable result exploitation (e.g. cost, ability to acquire investment capital, market prospects, legal, normative or ethical requirements).

All of the risk analysis techniques involve identifying and prioritizing the risks to the quality of the system under test. Typically, the risks are grouped or organized by major risk categories, such as functionality, performance, security, and so forth. A cross-functional team of project stakeholders usually identifies the risks. Rather than rely only on the stakeholders' opinions and recollections, the analysis was also drawn upon historical bug and field failure data from similar projects, requirements and design specifications, sales figures, market research, and anecdotal information from customers, competitors, or clients. In CHRONIOUS approach the ISO 14971 : "Medical devices - Application of risk management to medical devices" standard [12] was used.

IV. Conclusion

The CHRONIOUS system exploits innovative IT solutions providing effective description of the health status of the patient as well as advanced messages and alerts about the severity estimation of the condition or possible critical health episodes. The Decision Support System exploits both a supervised classifier and a rule-based system in order to limit the error of the decision, increase the accuracy of the system and justify the identified events by providing the rule or the critical parameter to clinicians. A personalization of the decision is even more feasible with the CHRONIOUS system due to the fact that several profiles have been created, describing with accuracy the health status of the patient, and used as an input to the intelligent part of the system. In addition, the Mental Support Tool is an added-value to the system, evaluating the stress level and contributing to disease monitoring by helping the patient to avoid or face stressful situations that may have implications to his health.

In order to increase the effectiveness and the accuracy of the CHRONIOUS system, healthy and pathological data are collected and evaluated as well as their clinical annotation resulting in the improvement of the accuracy of the system. The integrated platform raises quality of life and provides highly qualified and efficient healthcare services. Through the project, advanced medical research is performed through the provision of advanced disease prediction and diagnosis tools. The exploitation of the monitored parameters and the prevention, diagnosis and in some case prognosis of diseases are being increased, while formal care burdens are being reduced, improving formal care by reducing the patients visits for routine examinations. Moreover, the project improves the informal care effectiveness without increasing intrusion and reduces costs of informal care, which is particularly high for people suffering from chronic diseases.

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