

## Clinical validation of the CHRONIOUS wearable system in patients with chronic disease

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**Abstract**— The CHRONIOUS system defines a powerful and easy to use framework which has been designed to provide services to clinicians and their patients suffering from chronic diseases. The system is composed of a wearable shirt that integrate several body sensors, a portable smart device and a central sub-system that is responsible for the long term storage of the collected patient's data. A multi-parametric expert system is developed for the analysis of the collected data using intelligent algorithms and complex techniques. Apart from the vital signals, dietary habits, drug intake, activity data, environmental and biochemical parameters are recorded. The CHRONIOUS platform is validated through clinical trials in several medical centers and patient's home environments recruiting patients suffering from Chronic Obstructive pulmonary disease (COPD) and Chronic Kidney Disease (CKD) diseases. The clinical trials contribute in improving the system's accuracy, while Pulmonologists and Nephrologists experts utilized the CHRONIOUS platform to evaluate its efficiency and performance. The results of the utilization of the system were very encouraging. The CHRONIOUS system has been proven to be a well-validated real-time patient monitoring and supervision platform, providing a useful tool for the clinician and the patient that would contribute to the more effective management of chronic diseases.

### INTRODUCTION

CHRONIC diseases are health conditions that are persistent and long-term in nature. Chronic diseases are not often resolve spontaneously and are rarely cured completely. Although chronic diseases are more common among older adults, they affect people of all ages and are now recognized as a leading health concern of the European health system. The nature and the cause of the chronic diseases usually varied as well as the extent of their impact among the patients [1], [13]. In most chronic diseases, the situation is not reversible but after the initial diagnosis, the management of the disease includes mainly the improvement of the patient's symptoms. The management includes medication and/or lifestyle changes such as diet and exercise, and stress management. In general, the treatment aims to alleviate symptoms, prevent progression of disease and preserve optimum respiratory functioning to improve

performance of activities of daily living and enhance quality of life.

The CHRONIOUS system defines a framework which has been designed to provide services to clinicians and their patients suffering from chronic diseases. Its goals are achieved by providing a multidisciplinary, sophisticated, and adaptive chronic disease platform in which several state of the art sensors are integrated satisfying both patients and clinicians' requirements. The platform outcome provides a clear view of the health status of the monitored patient through a highly personalized level of processes. The aim is the improvement of healthcare service by offering an online health management solution that addresses the patient-professional interaction, personal data security, reduction of hospitalization and related costs. Nowadays, very few of chronic disease management tools commercially available are accompanied with patient-professional interfaces for communication and education purposes – they are mostly research devices and systems [2-4].

Due to the variety of the data that are collected from the system – are reported at the Methodology Section, an intelligent mechanism is included for their in-depth analysis (CHRONIOUS Intelligent Core). For this reason, an effective intelligent Decision Support System (DSS), operating on the wearable device, is integrated to detect pathological episodes. The necessity for the powerful and efficient algorithmic process is prerequisite since a feedback from the system to the patient as alarm or message or all, to the clinician is critical for the decision on a specific treatment.

During the CHRONIOUS project clinical pilot studies have been organized aiming at the collection of patient's data. For validation purposes, CHRONIOUS was focused on chronic obstructive pulmonary disease and chronic kidney disease, being these widespread and highly expensive in terms of social and economic costs. The validation protocol considered also the most frequent related comorbidities, such as diabetes, involving the patient's category which will take advantage of the highest foreseen benefits. This enables an open architecture for further applications, which meets different needs coming from several chronic diseases. Through its advanced flexibility and interoperability capabilities, the platform is easily adapted to any specific chronic disease constraints. The initial phase A of the clinical studies involves the participation of patients in controlled environment for the adaptation of the system to the specific needs of the disease. Additionally, several improvements have been realized for the enhancement of system's performance. The phase B includes several

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installations of the system in patient's homes and the recordings of every day signals and responses. All the collected data are stored, as was planned, in the central CHRONIOUS database.

### METHODOLOGY

A short description of the CHRONIOUS system follows. A more detailed presentation of the system regarding the applied methodologies and the techniques that has been utilized has been already reported in previous references [5,6].

#### Chronic Obstructive pulmonary disease (COPD) System Description

The patient at home is equipped with a jacket (Fig. 1) able to record cardiac/respiratory/audio and activity signs, external devices (weight scale, glucometer, blood pressure monitoring device, spirometer, air quality sensor) and a touch-screen computer to send reminders on drugs intake and to collect information on dietary habits and mental status.

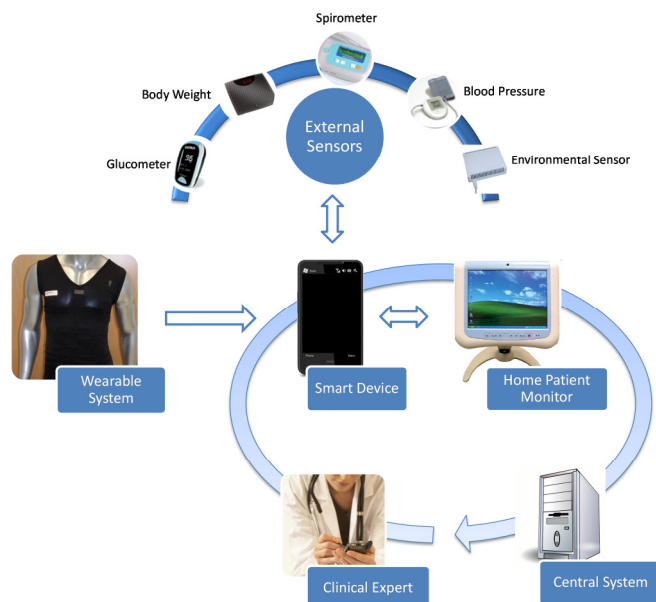


Fig. 1: The CHRONIOUS architecture for COPD patients

The CHRONIOUS wearable system (Fig. 2) consists of a tight-fitting and washable shirt, which provides the support for the stabilization of the body sensor network composed of several miniature sensor devices utilizing non-invasive methods which are responsible for the recording of the characteristic signals and their further transmission for the analysis. These 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 humidity and temperature sensors. The wearable system contains also the data handler device, which is responsible for the collection and wireless transition of signals to the Smart Device (SD). Additional external devices measure blood glucose, body weight and blood pressure and interact with the smart assistant device providing additional clinical

information.

The Home Patient Monitor (HPM) facilitates an interface that is dedicated to the interaction with the patient. The reminders of activities to be done are shown to the patient every day. Moreover the patient is required to insert manually, through the touch screen, information on: (i) Food Intake, (ii) Drug Intake, (iii) Activity Data and (iv) Questionnaire Information, which requires a daily completion of disease-specific and mental-related questions by the patient.

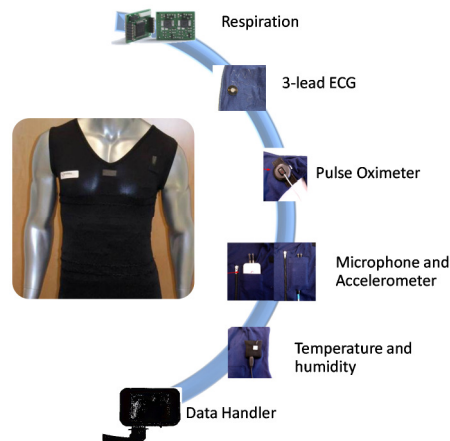


Fig. 2: The CHRONIOUS wearable system

The Smart Device (SD) that is being used in the CHRONIOUS project is a Personal Digital Assistant (PDA) in order to take advantage of the computational power of such a device. The SD contains an Intelligent Core, which consists of a DSS and several additional and supportive functionalities enhancing the accuracy and the efficiency of the final decision (i.e. Feature Extraction, Preprocessing and Signal de-noising, Heterogeneous Data Fusion, Missing Values Replacement and Feature Selection) [7]. The DSS is a hybrid system, which combines a Random Forest (RF) [10], a Support Vector Machine (SVM) [11] and a rule-based system which run in parallel. The SVM and the RF were selected for the hybrid classifier implementation due to their higher classification accuracy. Moreover, clinicians provided some simple rules, indicating a threshold value for some attributes and the output classification level of each rule [8].

A second layer of intelligence, the Central Clinical Decision Support System (CDSS) located on the CHRONIOUS Central system, is a knowledge based system developed by formalizing the know-how of clinicians who 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 central system embeds also Graphical User Interfaces (GUI), which, through web access, allows the clinicians to see the monitored parameters and suggestions by the system.

### Chronic Kidney Disease (CKD) System Description

The main differentiation of the CHRONIOUS CKD system is the absence of the wearable system. The jacket is not needed to record data and the patient's data/information flow initiated from the interface (HPM and PDA) and the external devices parts. Data collected from sensors are utilized for the description of motion/activity. The environmental sensor used to contribute in the quality of patients living environment and the social-context to monitor patient's lifestyle. Depending on the CKD specific needs, blood glucose, body weight and blood pressure were measured through the external devices. Due to the patient's weakness the employment of a larger touch screen (HPM) for the visualization of questioners and rest information, was a necessity for the system. Additionally, as reported in the System for COPD patients description, a PDA has been utilized as SD device hosting the intelligent part which is a hybrid classification system (combining a RF, a SVM and a rule-based system) aiming at the categorization of patient's health status.

#### Patients studies: COPD studies

The trial involved 30 patients among the clinical site of the University Clinical Hospital of Barcelona and the Careggi Hospital in Florence. Patients did not find any particular difficulties in using the CHRONIOUS system and they followed the measurement protocol with a good average adherence rate, showing high compliance to the use of CHRONIOUS. All data acquired by such patients were processed by the DSS and resulted in a time series of patients' status values which showed the substantial stability of patient conditions, providing the same evaluation reported by two weeks-visits performed by the physicians blind to CHRONIOUS data. The system did not report any false alarm and the clinicians judged as correct the classification of patient conditions provided by the DSS.

TABLE I  
QUESTIONS USED IN THE ANALYSIS

Code	Description
A	In general I'm satisfied with CHRONIOUS System
B	My health has improved after using this technology
C	The system helps me better manage my health status and needs
D	CHRONIOUS system helps me to check my health status
E	I feel safer since CHRONIOUS monitors my health status
F	Since I'm using this, I can better follow the prescriptions
G	Since I'm using this, I reduced the number of doctor visits
H	The use of CHRONIOUS system saves me time
I	I am sure that the CHRONIOUS system always works
J	CHRONIOUS system tools are easy to use
K	it was easy to learn how to use the CHRONIOUS system
L	CHRONIOUS system ensures the privacy of my data

#### Patients studies: CKD Studies

The trial involved 28 CKD patients enrolled in Feltre Hospital in Feltre and San Paolo Hospital in Milan (30 at the beginning but 2 dropped out). All patients were in stable and good condition at the time of enrolment. All of them were very scrupulous and were highly compliant to the

measurement protocol, i.e., average compliance estimated at 89,3%. As stated by clinicians in their periodic assessment of patients' conditions, the overall clinical status remained mostly stable for all the patients. Only in one case, the renal function of a patient worsened. The DSS gave the right response to clinicians as will be discussed next. Generally, the DSS outcomes confirmed the stability of patients' condition: the system raised no severe and emergency alert (i.e. "red alert"), but only a number of mild alerts ("yellow alert") due to some patients conditions that required more attention by clinicians. Clinicians were satisfied by the DSS outcomes since it offered them the possibility to identify several relevant situations.

#### Clinicians' Evaluation

In the CHRONIOUS evaluation, the opinion of experts was considered, being this more critical, especially towards possible innovative tools of work. Eight clinicians from all pilot sites were asked to complete a dedicated questionnaire (1 Nephrologists from Feltre Hospital, 2 Nephrologists from Milano hospital, 3 Pulmonologists from Careggi Hospital in Florence and 2 Pulmonologists from Barcelona Hospital).

## RESULTS

The questions that have been utilized at the evaluation of the system by the clinical experts are presented in Table I. Moreover, in Fig.3, the COPD patients' satisfaction rate is presented, while Fig.4 depicts the CKD patients' satisfaction rate. With the alphabetic letters the cause is described. The maximum satisfaction is in level five (5) and the minimum rate of satisfaction is described with level zero (0).

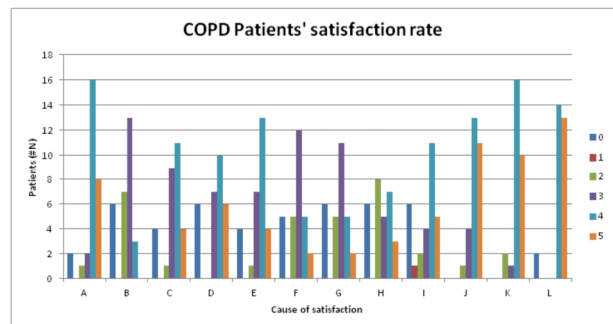


Figure 3: COPD Patients' satisfaction rate

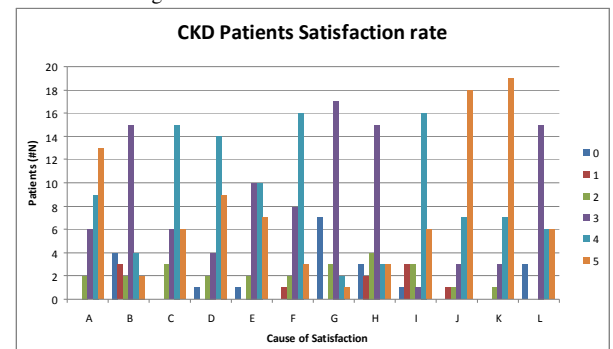


Figure 4: CKD Patients' satisfaction rate

In order to measure the degree of the acceptance of the system by the clinicians a widely accepted System Usability Scale (SUS) questionnaire has been employed (Table II). In Fig. 5, the satisfaction rate of the clinicians as well as the origin of their doubts are presented.

TABLE II  
SUS QUESTIONNAIRE

Code	Description
A	I think that I would like to use this system frequently
B	I found the system unnecessarily complex
C	I thought the system was easy to use
D	I would need the support of a technician to use this system
E	I found the various functions in this system well integrated
F	I thought there was too much inconsistency in this system
G	Most people would learn to use this system very quickly
H	I found the system very cumbersome to use
I	I felt very confident using the system
J	I needed to learn a lot of things before using this system



Figure 5: Clinicians' satisfaction rate

### CONCLUSION

As observed in Fig. 3 the majority of the COPD patients are satisfied by the CHRONIOUS system. COPD Patients felt safer and better monitored and they were able to better manage their health status since they used the CHRONIOUS system (C, D, E). The system has been judged to be easy to learn how to use and simple to use (J, K). Almost all COPD patients felt comfortable using the system concerning privacy security (L). Patients' health status is reported not to be improved (B) since this was only an observational study. In this validation study, the majority of the patients strongly believe (with score 5) that CHRONIOUS platform and system tools are easy to learn and use them in daily life (Causes J, K). Moreover, as observed in Fig. 4, more than 10 CKD patients strongly believe (with score 5) that the CHRONIOUS platform and system tools are easy to learn and use them in daily life (Causes J, K). Additionally more than 15 CKD patients (with score 4) are generally satisfied with the CHRONIOUS platform. They also believe that CHRONIOUS help them to continuously check and manage their health status and needs. Furthermore, it seems more feasible for patients to follow the clinicians' prescriptions and they feel safe concerning the system functionality and performance. The negative issue of CHRONIOUS platform usage is observed in cause G, where more than six 6 CKD patients did not reduce the number of doctor visits during the validation procedure.

Based on the above analysis, a large percentage of CKD and COPD patients are generally satisfied or have a positive thinking of CHRONIOUS platform. Due to the limited time period that the system supports chronic disease patients, the judgment about the reduction of the patient's medical visits as well as their health status improvements couldn't be clearly evidenced. It can be associated directly to the short duration of the trial (only 4 months). From the clinical point of view, although some of the user's feedbacks referred to small systems contribution on clinicians every-day schedule, the general consensus is that the utilization of the system in larger target groups will highlight systems' clinical value. Furthermore it seems feasible for CHRONIOUS to ensure data privacy for patients under consideration. In general, CHRONIOUS can be a really helpful and easy to use platform for patients suffering from COPD and CKD in combination with other health problems as high blood glucose level or arterial pressure.

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