E-REMEDY, HOME CARDIAC REHABILITATION: A BOLOGNA-EUROPEAN COMUNUNITY SPECIAL PROJECT

Ivan Corazza[1], Romano Zannoli[1], Sebastiano Zannoli[2], Angelo Branzi[1]

1: Institute of Cardiology, University of Bologna, Italy

2: Airmachine, Cesena, Italy

CORRESPONDING AUTHOR:

Romano Zannoli

Institute of Cardiology, University of Bologna

Via Massarenti, 9

40138 Bologna

Italy

Email: romano.zannoli@unibo.it

Phone: +39 051 6363433

ABSTRACT

Nowadays, cardiac rehabilitation is performed in some specialised centres, inside or near the hospitals, with an increasing costs for the National Health Service. The need to reduce costs and to increase the number of patients submitted to the therapy, makes “home rehabilitation” proposal a major opportunity for cardiology. E-Remedy project, a Bologna-European Community special Project, developed, tested and validated a new rehabilitation system base on a rehabilitation machine installed at the patient home, connected to a server-client system inside the hospital, where a specialist can supervise the procedure. To perform the measurements of critical physiological variables, (electrocardiogram (ECG), air-flow, oxygen consumption (VO2), blood pressure (BP) and oxygen concentration in blood) rehabilitation machine (bike) was equipped with dedicated sensors. Through an embedded computer, the physiological parameters were sent, via internet, to a server in the hospital and were monitored and stored by analysis software. The specialist, from the rehabilitation centre, settled the protocols, the alarms and scheduled the sessions for each patient. Exercise was monitored in real time through an user-friendly interface provided with a communication system between specialist and patient. Tests performed in the Institute of Cardiology of the University of Bologna demonstrated the possibility to perform complete rehabilitation sessions by remote-control, without any mayor problem. Cardiologic evaluations gave good responses in term of easiness of use, noise rejection and tolerability by the patient. Future improvements, in terms of quicker and safer internet connection, more powerful analysis software and more easier communication between specialists and patients, are possible.

INTRODUCTION

The number of hospital discharges of patients affected by cardiovascular diseases in Europe (EU), resulting from European Register of Cardiovascular Diseases (Eur. Soc. Cardiol. Sophia Antipolis, France 1999) is 19 cases /thousands per year (1995). The diagnostic angiographic procedures are estimated in about 1250/million per year, Myocardial infarctions patients, about one half of them (650/million). The number of open-heart cardiac surgery procedures is about 415/million per year. Due to the need of dedicated instruments and personnel, only a limited part of outcome cardiac patients is presently submitted to rehabilitative programs:

A cardiology rehabilitation therapy may be prescribed to myocardial infarctions patients, to patients during pre/post cardiac surgery interventions, to patients affected by cardiovascular diseases in general. A correct rehabilitation therapy, based on an accurate cardiac monitoring system, allows to (a) evaluate and reduce the risks for the patient submitted to the procedure; (b) to quiet patients, permitting them to restart physical activity after even long periods of complete inactivity[1].

Actually, patients submitted to rehabilitation procedures can be estimated around 30%. The remaining 70% have the disagreeable feeling to pass from the hospital environment, where they are protected and followed, to their home, without any protection and support at all. This is particularly true for patients living far from the city centres, where home assistance is more difficult to be obtained[2].

Home rehabilitation with monitoring seems therefore a good solution to these problems.

The goal of the **e-ReMedy project** was to increase the quality of the rehabilitation services provided by EU hospitals and rehabilitation centres to patients, while reducing the costs incurred. To achieve the above goals, the project developed, tested and validated a new home rehabilitation system with dedicated sensors, based on the installation of a rehabilitation

machine at the patient's home, controlled by a specialist through Internet. By using e-Remedy personnel has not to move out from the hospital and can set and control in real-time all the procedures, with the possibility to intervene and communicate with the patient[3].

The global project focused on the rehabilitation of patients having cardiology, respiratory and orthopaedics problems: this paper focuses on cardiologic rehabilitation[4,5,6].

MATERIALS AND METHODS

System Architecture

The project results enable to perform most of the rehabilitation process at home, by means of:

- **Rehabilitation machine:** Aerobic one, to exercise the entire body;
- **Innovative sensors.** To perform the measurement of critical physiological variables, like cardio-electric activity (ECG), air-flow, oxygen consumption (VO2), blood pressure (BP) and oxygen concentration in blood.
- **A data storage system** placed in the rehabilitation Centre to collect and store patients and exercises data;
- **Client Systems,** placed in the hospital or outside it. This system is the interface through which the specialist connects to the Server and sets rehabilitation sessions, performs filtering and computations, displays the variables via animated graphics, detects alarms and communicates with the patient in real-time;
- **A real time "secure" internet-connection** between the rehabilitation machine, the Server and the Clients.

FIGURE 1

Operativity

On the basis of patient's characteristics and needs, the specialist outlines a rehabilitation protocol divided in successive sessions.

Using home-side installed instrumentations, the patient activates a session at scheduled time, obtains an approval by the supervisor centre and executes at home the rehabilitation exercises foreseen in the protocol. All the rehabilitation procedures are programmed and guided by the specialist, who sets and schedules the sessions.

During the exercises, physiological variables are measured, stored in the on-board PC, displayed locally and transmitted via WEB to the rehabilitation centre. The patient is continuously informed about its status and performances via graphical presentations of the acquired variables, status messages and alarm messages. Physiological variables are also displayed at the centre, to allow the specialists to monitor the exercise and to immediately identify possible problems. To provide a more direct medical assistance, a direct communication via instant messages or mails is available. Variables are also automatically monitored by the system, to check if alarm thresholds are exceeded.

The software at the centre provides the specialists with support in the detection of anomalies during the execution of the exercises, the analysis of the patient data, the preparation of the updated training program based on past data. Data relevant to all the patients are stored in a repository at the centre. This allows the comparison of the present procedure with those performed in the past. In addition, this allows comparison of patients with similar diseases and the performance of statistical analyses[4,7.]

To realize the whole E-ReMedy Project six partners with different application fields were involved and gathered in a Consortium with the partnership and the financing of European Commission.

Air Machine (Cesena, Italy), a manufacturer of special instruments both for gymnasium and medical applications, designed and developed the rehabilitation machines implemented with sensors to measure arterial pressure, electrocardiogram, oxygen consumption and blood oxymetry. These special devices were developed by the Institute of Cardiology (University of Bologna, Bologna, Italy), starting from a previous experience in the field. A 2 channels ECG system was developed by using commercial technology both for electronic and electrodes. On the basis of ECG signal, other cardiac variables (e.g. cardiac frequency) were computed by devoted software.

Oxygen concentration in blood was measured by a commercial device (Pulsoxymeter EG302, Medlab, Karlsruhe, Germany) interfaced with the rehabilitation machine.

Oxygen consumption was monitored by a new system, developed in the Institute of Cardiology (patent number EP 1234 541 A1). This instrument is based on a different approach and allows a simple measurement without the usage of any masks[8], particularly suitable for a rehabilitation procedure.

For blood pressure measurement, a system based on the arterial occlusion oscillatory method, was used. This apparatus was composed of an air-inflated chamber mounted on one patient's arm, and a low-price pressure transducer (Moretti Spa, Arezzo, Italy)) connected to the chamber. Oscillatory signals and measured values were both sent to the server , to have the possibility to verify the correct measurement .A/D conversion of the analog signals was performed by a device integrated on the board of the rehabilitation cyclette. All the acquired signals were locally analysed in real-time to obtain further information (e.g. the cardiac frequency), checked for possible problems (e.g. the ECG abnormalities), stored, and sent via internet to the remote server.

The rehabilitation machine was connected to the home ~~client computer through a wireless communication infrastructure~~internet and then to the Server in Rehabilitation Centre via the

telephone line. Server was accessible by authorized specialists involved in the project, through a secure internet connection. Internet connections, distributed software system for data transmission, storage and analysis have been developed by TXT (Milan, Italy), BMT (Bath, UK) and EMPHASIS (Athens, Greece).

Three end-users, Institute of Cardiology (Bologna), CSC (Barcelona, Spain) and Medical Centre MEDICA (Athens, Greece) provided the user requirements of the system and hosted and test the e-ReMedy prototypes in their pilot installations.

Table 1 summarizes the technical specifications of the cardiologic system.

TABLE 1

Cyclettes for cardiac rehabilitation (RHC 400, Airmachine, Cesena, Italy) used ad hoc developed firmware with Nucleus Operative System (Figure 2). This software allows to manage: a) visual communication with the patient through an user-friendly interface; b)acquisition of biomedical signals; c)real-time internet communication with main Server to import patient information and rehabilitation protocols and to export medical signals and session information[7, 9.]

FIGURE 2

FIGURE 3

The client computer at the control side allowed the complete management of the rehabilitation procedure. Software on the PC (Fig. 3) used by the specialists communicated with the server and, through it, with the machine at the patient side. For each patient, specialist choosed and customized the rehabilitation protocol, scheduled the sessions and followed in real time the

patient through a specific interface (Fig. 4). When the patient decided to undergone a session, an alarm occurred on the control client computer and the specialist could start the rehabilitation process. An easy to use window was open and the specialist was put in direct communication with the patient side. Protocol was sent to the rehabilitation machine and the session started. Some alarms were set to prevent the patient from dangerous situation (maximal heart rate, maximal speed, etc)[7].

FIGURE 4

All the data concerning a specific patient and session were stored and were always available for the specialist to perform post-processing analysis and to compare parameters through all the rehabilitation period.

The security of the whole system was guaranteed by protected specialist's access and data cryptography.

In order to test the final prototype, 61 sessions were performed on 6 subjects (aged between 26 and 55 years) without cardiovascular diseases. The sessions were structured as detailed below. Protocol details were defined in such a way as to guarantee adequate exercises and effective testing of E-ReMedy functionality. Before undergoing the rehabilitation sessions, all the subjects were submitted to a standard ECG stress test with VO2 in our laboratory. Maximum and minimum time duration values and power and pedaling speed were settled on the basis of the stress test results.

Rehabilitation sessions were performed with the bike in a hospital's laboratory under the constant supervision of a specialist cardiologist with the bike connected to internal LAN. Eight kinds of sessions were settled in order to test the functionality of the whole system.

For example, session 1 was made of three steps: (a) Warm-up: 5 minutes module at 1 Watt of power; (b) Exercise: 30 minutes module at 70W; (c) Recovery: 5 minutes module at 1 Watt. The duration of the session was of 40 minutes and, for each module, alarms were settled[10.]

RESULTS

The whole system was user-friendly and allowed to the specialist to perform complete rehabilitation sessions by remote-control, without any mayor problem. Cardiologic evaluations gave good responses in term of easiness of use, noise rejection and tolerability by the patient[10].

FIGURE 5

Figure 5 shows an example of a rehabilitation session performed by the system Parameters of interest have been post-processed and then plotted against time. Subjects well-tolerated the system and supervision allowed to follow step by step the exercises. It was demonstrated that E-ReMedy System works properly with different kinds of sessions. Digital communication between server and clients (specialist and patients) was always adequate to the needs and all the protocols were executed in real-time without errors.

DISCUSSION

The population in Europe is expected to become increasingly elderly; this implies that a reduced proportion of younger people will be asked to finance the social security system. As a consequence, the reduction and containment of health-care and social security costs is a specific EU policy. The main objective of EU is not to limit the costs, but to maximise the efficiency gains and to improve the price/quality ratio, ensuring that high quality services are accessible to the widest possible community at socially acceptable costs The same approach identifies the “use of informatics in medicine” as a key mean to achieve the above goals. The ***E-ReMedy*** project was outlined for helping reducing rehabilitation costs, thus contributing to meet the challenges set by such a policy. According to the end-users partners estimation, with an appropriate setting, home rehabilitation can provide a marked reduction in total health care costs per patient requiring rehabilitation therapy, approximately by half. This may permit a doubling of actual procedure numbers without cost increase, which can help to satisfy the increasing request of rehabilitation therapy.

Results obtained in the cardiology context, which is a field of increasing demand, show that e-Remedy system could be a good solution, by moving the rehabilitation sessions out of the hospital, at patient’s home . The system demonstrated to work properly and to be well-tolerated by patients and specialists. Future improvements in software and hardware architecture are possible, to make the communication quicker and safer and the use easier.

As far as the e-ReMedy system is user friendly and well accepted, some problems, related with internet connection and database writing, could happen. Nowadays, connection technology can guarantee good levels of security and stability but exceptions have to be taken into account. Interruption of phone or DSL lines, lack of electric energy supply or any other kind of emergency must be evaluated by the technicians and the software developers in order to minimise the impact on the rehabilitation session and to guarantee the patient safety.

Software interface during procedure could be changed, with the insertion of new graphs (pressure, oxygen consumption and saturation) and with the possibility to personalise ECG visualization (time and amplitude scales). Moreover, statistical analysis and final reporting can be enhanced. Also the security protocols of the data transmission, cryptography safeguard of privacy and sensitive data and firewall protection of the databases could be upgraded.

The validation experience highlighted two main critical aspects of home rehabilitation solution: a) the distance between patients and specialists, and b) the “legal” responsibility of the procedure. For the point (a) the possibility to have dangerous situations for the patient cannot be underestimated and an adequate protocol of intervention must be scheduled. This is easier for patients who live nearby the hospital, because the territorial emergency apparatus is well known and may be easily activated. On the contrary this is very complex for patients living in isolated of distant places, where the emergency intervention system is not known (consider that with E-Remedy it is possible to manage rehabilitation sessions all over on the world! The point (b) is very critical because of the rules defining the responsibility (legal and economical) between the patient and the health institution. In most European countries when a patient is in the hospital he is under the responsibility of the medical staff of the particular clinical institute. When the patient is at home he is under the responsibility of le General Medicine Doctor on the territory. The execution of the rehabilitation session at home, under the control of a specialist doctor of the hospital is a “mixed” condition which has no simple solution at the moment and which may be solved in different way in different countries. The same problem is amplified if we consider the costs of the process, which have to be divided between hospital and territory.

Taking into account the limited experience in this field, patients to be treated with home rehabilitation should be chosen carefully, avoiding critical pathologies. Until now, medical risks have reduced drastically the number of projects on home rehabilitation, especially for cardiologic patients and the only few actually active are in the prototype phase. In the recent

last years, the number of rehabilitation centres born near existing hospitals increased increasing the costs more than the benefits. The home rehabilitation may reverse this tendency, at least to decrease the demand pressure on the existing hospital centres. For this a right equilibrium, between a too much precautionary behaviour and management of real dangerous situations, must be found.

A future improvement for the e-ReMedy System is the connection of a TV camera and a microphone with bike to video-monitor the patient during the procedure. In this way the specialist can follow not only the parameters of interest but directly how the patient performs the session. This improvement will prevent the rehabilitation from dangerous situations and will reduce the risk for the patients. To make possible such integration, an higher communication speed, between the rehabilitation machines and the server at the hospital, is necessary. One more positive effect of this improvement will be direct communication between the patient and the specialist, with the possibility for the patient to communicate the physical sensations and for the doctor to use these information to interpret correctly the physiological parameters.

With this upgrade E-ReMedy will further increase his potentiality in the direction to fulfil the requirements of the specialists and could be a real positive contribute for the health European policy.

REFERENCES

1. Fletcher GF, Frolicher VF, Hartley HL, Haskell WL, Pollock ML: *Exercise Standards: A Statement for Health Professionals From the American Heart Association*. Circulation 1990; 82(6): 2286-2322.

2. Pollock ML, Franklin BA, Balady GJ, et al.: *AHA Science Advisory. Resistance exercise in individuals with and without cardiovascular disease: benefits, rationale, safety, and prescription: An advisory from the Committee on Exercise, Rehabilitation, and Prevention, Council on Clinical Cardiology, American Heart Association; Position paper endorsed by the American College of Sports Medicine.* Circulation 2000; 101(7): 828-33.

3. Gordon NF, Haskell WL: *Comprehensive cardiovascular disease risk reduction in a cardiac rehabilitation setting.* Am J Cardiol. 1997; 80(8B): 69H-73H.

4. Orsi C: *Annex 1. Description of the work.* Tele-Medicine Platform to support Home Rehabilitation based on Internet Technologies. Project Number: IST-2000-25146; 27/09/2000.

5. Zannoli R, Specchia S, Alonso A, et al.: *D11 – User Requirements*. Tele-Medicine Platform to support Home Rehabilitation based on Internet Techniologies, Project Number: IST-2000-25146; 31/03/2001.

6. Orsi C, Zannoli S, Fantini F. *Abstract: E-Remedy, an European Community project: a telemedicine platform to support home rehabilitation based on Internet technologies*. 12th International Conference on Mechanics in Medicine and Biology (ICMMB-12), 2002. Edited by K. Karalis, 171:172.

7. Silveri I, Zannoli S, Walzer C, Dorling C, Gerakakis S, Corazza I: *D52 – First prototipe user manual*. Tele-Medicine Platform to support Home Rehabilitation based on Internet Techniologies, Project Number: IST-2000-25146; 20/11/2002.

8. Fabbiani L, Marangoni F, Graziano M, Corazza I, Zannoli R. *Abstract*: *La misura del consumo di ossigeno senza ausilio di maschera.* XII Congresso S.I.R.C., Imola, 22-24/09/2005, Ed. Clueb, 117.

9. Zannoli R, Corazza I, Specchia S, Bonantini S, Branzi A. *Abstract: The E-Remedy System: set-up for cardiology*. 12th International Conference on Mechanics in Medicine and Biology (ICMMB-12), 2002.Edited by K. Karalis, 121-123.

10. Silveri I, Zannoli S, Walzer C, Dorling C, Gerakakis S, Corazza I: *D62 – Final prototype, testing and evaluation report*. Tele-Medicine Platform to support Home Rehabilitation based on Internet Techniologies, Project Number: IST-2000-25146; 12/02/2003.

		CARDIOLOGY
PATIENT'S HOME	*Rehabilitation Machine*	Cyclette (RHC 400, Airmachine, Cesena, Italy) with on-board computer
	Medical Sensors	2 channels ECG sensor, 1 air flow sensor, 1 blood pressure sensor, 1 oxygen concentration in blood sensor, front-end electronics and A/D conversion unit.
HOSPITAL OR REHABILITATION CENTRE	*Central Consultancy and Decision Support System*	Advanced data processing; Statistical and data comparison; Reporting tool; Advanced data rendering; Rehabilitation planning tool.
	Central repository	Patients' Record Database; Session's Repository; Rehabilitation Models.
	Rehabilitation process management tool	Security and Authentication Manager; Information Exchange Manager; Schedule Organizer; Rehabilitation; Workflow Manager; Patients' Records Manager.

Table 1: technical details of the project.

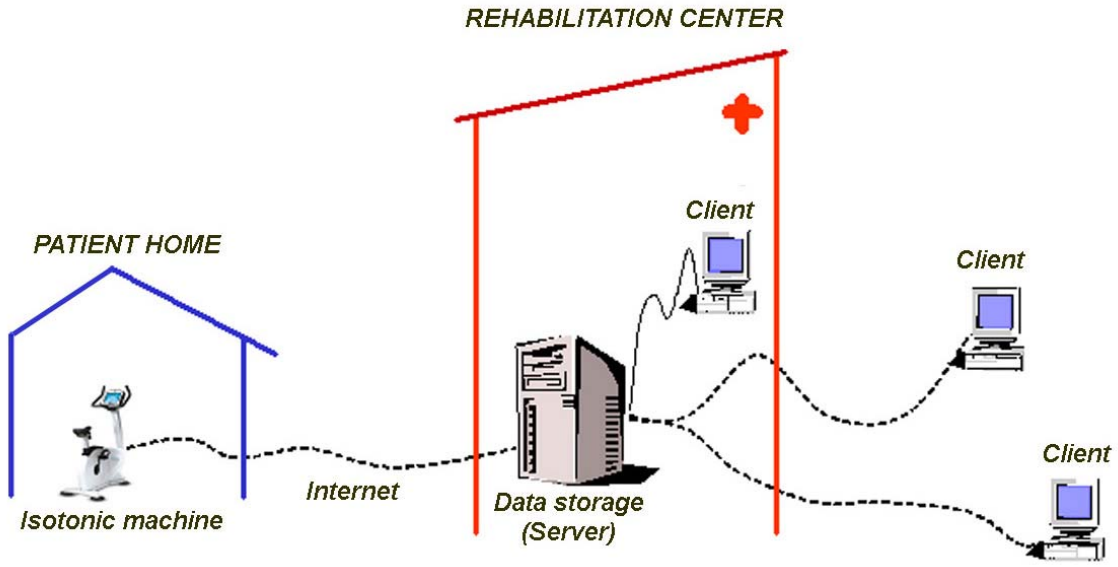
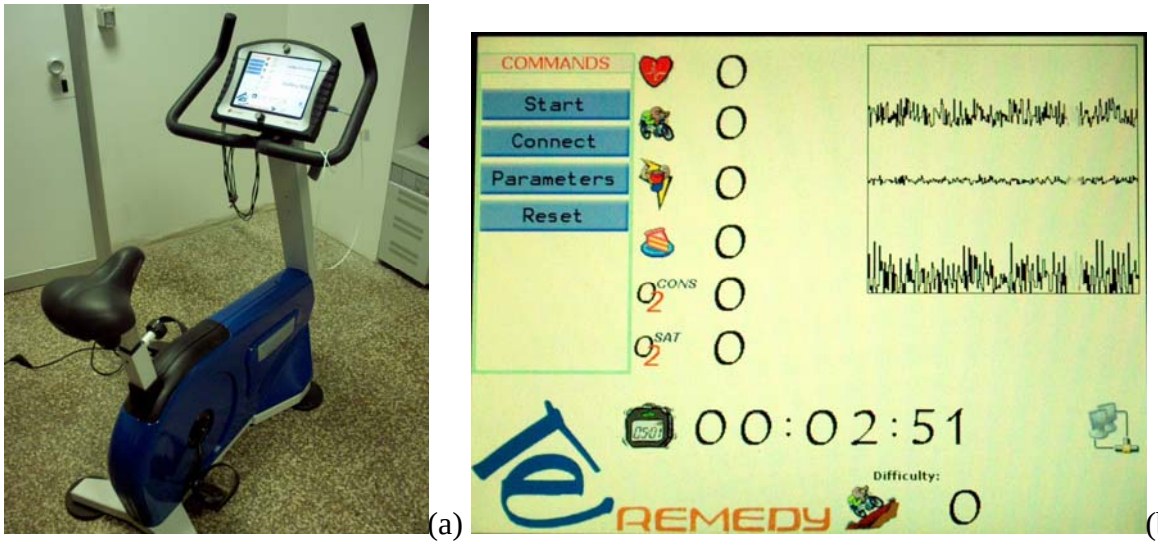


Figure 1. e-ReMedy architecture: the rehabilitation machine is placed at patient home and it is connected via internet network with the server at the hospital. Data collected from the Server are accessible in the local intranet area from authorized personnel. The access is possible from remote client, too.



(a) (b)

Figure 2: (a) Cyclette for cardiologic rehabilitation with ECG, pressure and oxymetry sensors. (b) Bike's software interface: signals are displayed in real time and parameters (heart rate, oxygen consumption and saturation, energy dissipation, exercise duration) are showed in the centre of the screen. A simple set of commands (Start, Connect, Parameters and Reset) allows to manage the rehabilitation session.

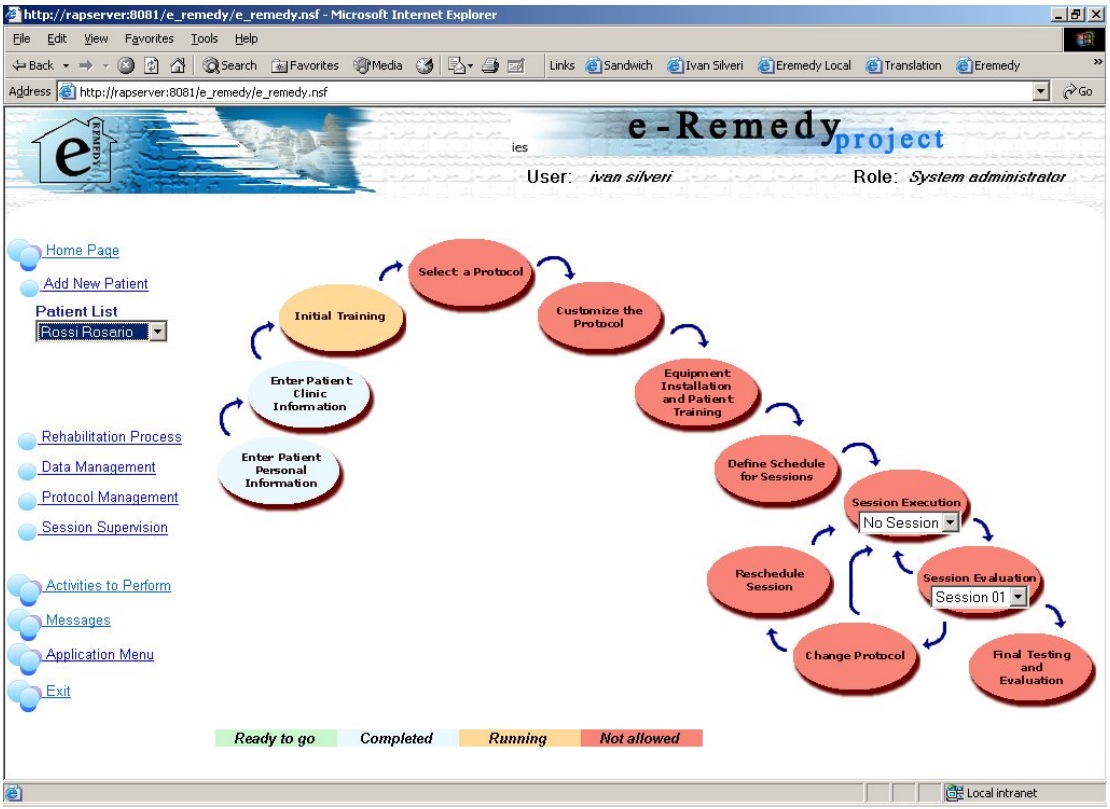


Figure 3: software interface in client side. Specialist must follow, step by step, a specific procedure. Each step is mandatory to perform the next one. At the beginning the specialist has to enter patient's data. Then, after an initial training, it is possible to chose a specific protocol and to customize it. The rehabilitation machine is then chosen and sessions scheduled.

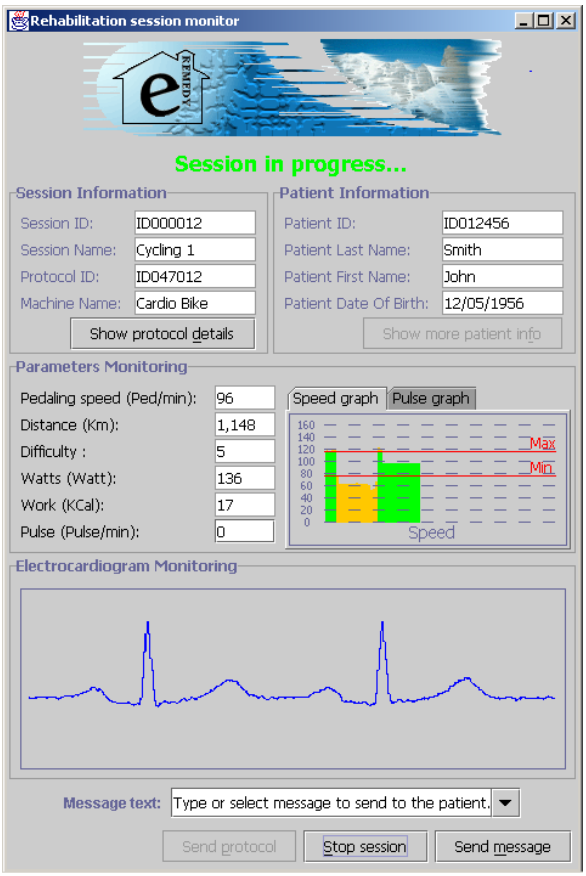


Figure 4: Specialist interface for cardiological rehabilitation . The physiologic parameters are shown in real time in numerical form and analog signals (ECG).Specialist can follow the session by monitoring the parameters of interest; He can stop the exercise if a dangerous situation arises and he can send messages to the patient. ECG is shown in real time at different selectable time scales..

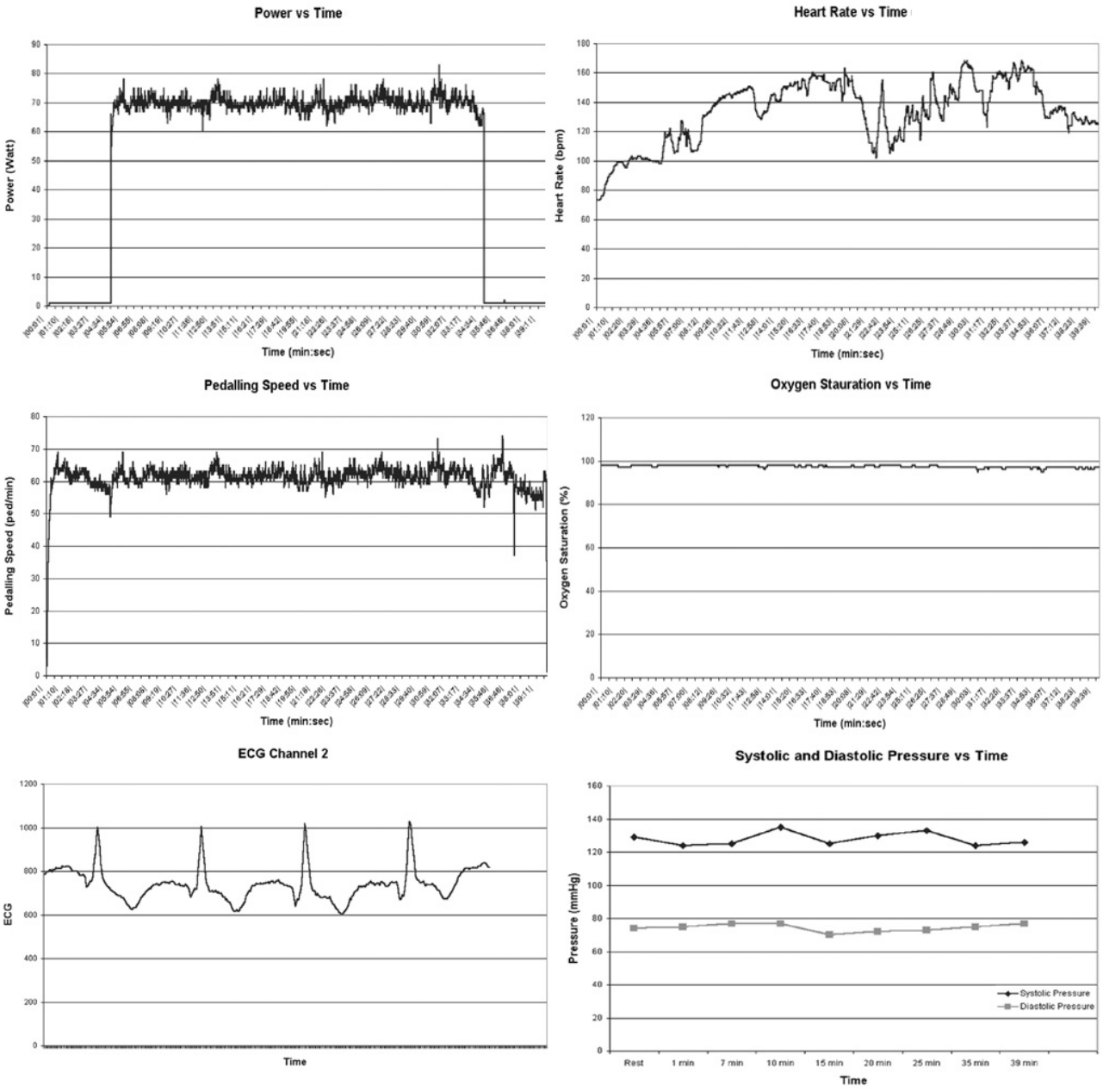


Figure 5: Example of signals recorded during a rehabilitation session and post-processed by the specialist. Power, heart rate, pedalling speed, oxygen saturation, electrocardiogram, systolic and diastolic pressures are shown.