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# Telemonitoring System for Valve Related Cardiac Emergencies

Final Report

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# CONTENT

# 1 EXECUTIVE SUMMARY

The second phase of a the originally three-phase R&D project on a novel tele-monitoring system for valve related cardiac emergencies has been completed.

The system consists of a hand-held device for the parallel recording of the sound of the heart valve and the electrocardiogram of the heart. An on-board pre-installed software helps the user to navigate through the different options and settings. Up to three sequential recordings can be stored on the device. The acquired data can be downloaded wireless via an integrated bluetooth link to a computer for remote control and post-processing later on. The large amount of data needed for research purposes during the initial phases, complex network infrastructure and access rules at the University Hospital in Zurich have led to the decision not to proceed with a complete remote tele-monitoring at this stage.

The main features of this project phase were the integration of head and main unit of the phase I prototype into a single handheld device including hardware and software optimization, and the preparation of a clinical study for the validation of this system for BSCC heart valve patients. A first preliminary test with heart valve patients from the University Hospital in Zurich has been successfully conducted under supervision of Professor Turina.

Hard- and software of the handheld device have been optimized with respect to available space, memory and battery power. These efforts led to a final integration into a single recording unit for improved handling. First tests have been conducted in Switzerland to investigate differences in operation with detached and fixed pick-ups.

A study methodology had to be identified and evaluated together with the University Hospital in Zurich. Finally, software has been developed to download, manage, visualize and playback recorded data.

The project has been realized by Miromico, Zurich (Switzerland) and IPT Telemedicine, Gelsenkirchen (Germany). In addition, Miromico has been supported for the device optimization and assembling by Strela Development AG (Switzerland).

The project duration was significantly longer than originally expected. This was mainly due to the need for several design and production phases for the hand-held housing, and the need to redesign the software platform for the clinical use. It took quite a long time to arrange and finally conduct short tests with a very small number of patients (all non BScc). The overall funding for phase II had been USD 199'400 in total.

A prototype sample of hand-held device with fixed pick-up plus viewer software will be shipped to Bowling-Pfizer by end of January 2007.

# 2 MONITORING SYSTEM FOR HEART VALVE PATIENTS

## 2.1 PURPOSE OF PROJECT

The main purposes of the overall project was the development of a tele-monitoring prototype system for valve related cardiac emergencies using telephonic transmission of heart sounds and ECG, a detailed plan for the validation of this system, and finally a full study of the benefits of the system through integration into the existing and operating service of IPT which will be installed at the University Hospital in Zurich.

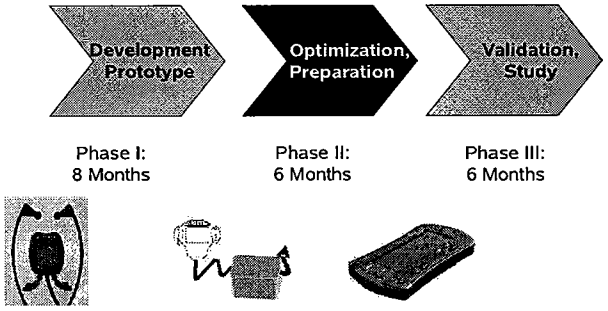


*Figure 1: Overview main project phases*

Phase I of this project has been started in September 2003, covering a period of eight months. It had been the project goal to set-up the initial monitoring system including the development of a first prototype of the portable device combining ECG and heart sound recording and transmission.

During the first phase, several important tasks have been performed successfully, which are

- the design of a complex medical monitoring system and the definition of consistent interfaces for the technology as well as the monitoring process.
- the development of the hand-held, battery-powered monitoring devices consisting of head and main unit, and based on an existing Swiss stethoscope technology (CADIscope I/II) and off-the-shelf available microphones and electrical components.
- the fabrication and testing of the prototype boards for a combined audio/ECG unit (head unit) and the central processing, storing, and communicating part (main unit).
- the performance of a few "live" tests of different pick-ups incl. microphones with artificial heart valve patients supervised by cardiologists and cardiosurgeons at the university hospital in Zurich.
- the set-up and and preliminary testing of call-center hardware and software, including

firewall, FTP server and remote station software, for the particular needs of the heart valve monitoring service.

- the electronic transmission of sound and ECG data to the file server of the call-center for the display and the play-back of the signals.

Phase II of this project had been started in autumn 2004. The purposes of phase II was the integration of head and main unit of the phase I prototype into a single handheld device including hardware and software optimization, and the basic preparation of a clinical study for the validation of this telemonitoring system.

Important tasks which had been performed successfully during phase II are

- the re-design of the overall system according to the research character of the project and the available technology at the patient site.
- design and molding of hand-held housing.
- detailed design and optimization of hardware and firmware of the hand-held device.
- manufacturing and assembling of the hand-held device.
- initial electrical and performance tests of hand-held.
- re-design of the viewer software for optimized downloading and for accessibility and data management at the hospital.
- initial development of methodology for patient tests.
- preliminary tests with four prosthetic heart valve patients at the University Hospital in Zurich under supervision by the head of cardio-surgery; comparison of device performance between fixed and detached pick-ups

## 2.2 SYSTEM OVERVIEW

The system consists of a handheld recorder for heart sound and electrocardiography (ECG) with built-in bluetooth link to a computer. The determination of methodology and protocol for the planned study later on revealed the need to transmit a larger amount of data from the recording unit to the hospital. Mobile phone technology (GSM/GPRS) was not appropriate for that purpose. And state-of-the-art modem technology was not appropriate either (although successfully tested in-house) due to the technical restrictions concerning data transfer from outside the hospital. In the end, a bluetooth transceiver has been integrated to provide a general interface to any external device. This decision turned out to be very helpful, since tests could be conducted and analyzed at the hospital site without tremendous IT overhead, while having a standard interface to proceed either with bluetooth based modems or mobile phones in future developments.

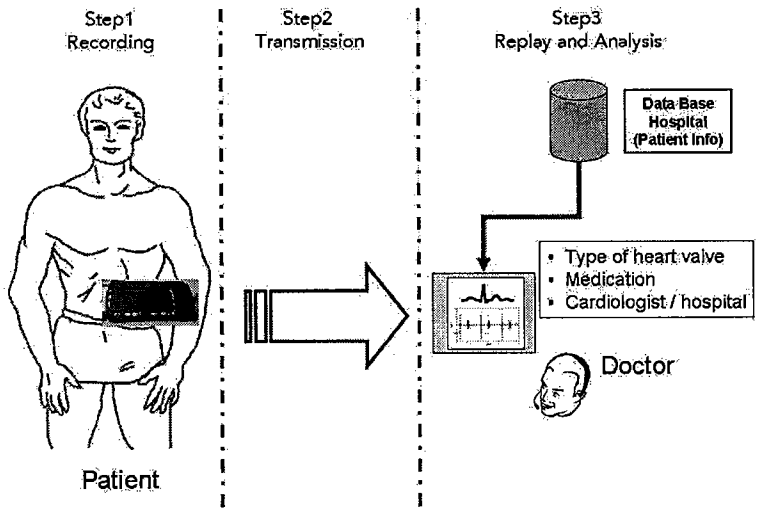


*Figure 2: Overview process of recording and transmission between BScc patient and doctor*

In the existing system, a doctor can record the sound of the heart valve at three different positions, namely Aerp, Aorta, and Mitral. The maximum time per recording position is about 12 seconds each. The recorded signals must be downloaded to a computer via a wirelees bluetooth link for replay of the data (sound, ECG) and check of available reference information for this patient such as type of implanted heart valve, applied medication, or previous recordings.

The new system relies on phono-cardiography. It is non-invasive, atraumatic, and potentially very sensitive to identify degeneration and changes in artificial heart valves. The improvement in terms of signal processing will be possible due to he use of temporal correlation between ECG signals and valve activity. To provide the patient with a maximum of comfort and convenience in application, the recording unit must be a small, lightweight handheld device.

## 2.3 VALVE VALIDATOR: THE HANDHELD MONITORING DEVICE

The design of the unit is based on the CADIScreen design study presented at the London workshop in 2004. The system consists of an active pick-up for ECG and sound recording, a DSP platform to handle signal recording, data management, user interfacing and power management, a rechargeable 3.6V $Li^+$ battery, and a bluetooth transceiver for wireless interfacing with external units such as computers or modems.

Figure 3 and 4 show a view of the final device. Since several attempts with the envisioned retractor did not work-out properly it has been decided to test configurations with fixed pick-ups and with detached pick-ups being connected to the main unit through a short cable.

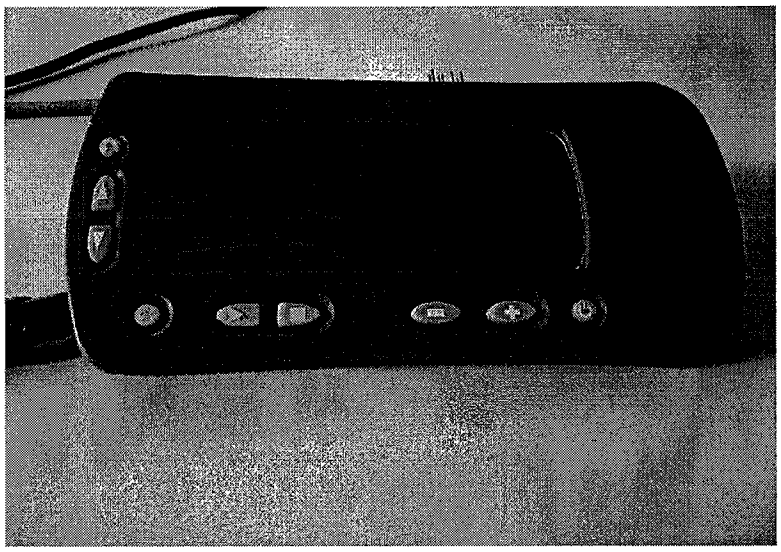

*Figure 3: View of the hand-held device*

The hand-held can be operated in 5 different modes called *Record*, *Replay*, *Transmit*, *Config(uration)*, and *Power off*. Submodes and settings can be reached through scrolling up/down or right with the buttons on the left side or below the display. The font size was considered to be large enough. The user interface has been designed to offer a reasonable guidance through the recording and transmitting process as well as to set-up the gain for ECG and sound.

After several test with membranes and available microphones it has been decided not to proceed with the PVDF technology due to the dependency of the signal quality to pressure as well as the problems associated with the use of PVDFs and the related electronics into the pick-up.

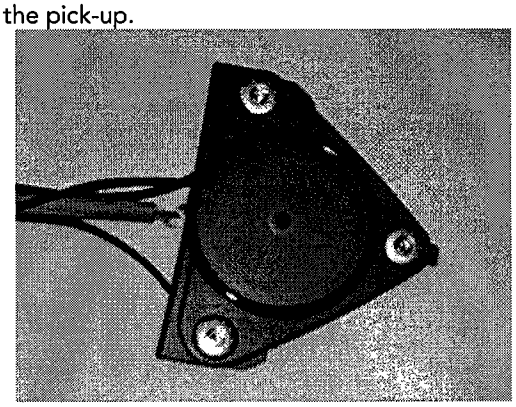

*Figure 3: Front view of pick-up with connectors for electrodes plus membrane for microphone.*

The technical specs for the hand-held are as follows:

- Power supply: 3.6$V_{DC}$ rechargeable Li-Ion battery

- Endurance: about 2 weeks between recharges for typical usage (one recording per day)
- Sampling rate: 32 kHz
- Bandwidth (audio): 16 kHz
- Bandwidth (ECG): 100 Hz
- Max. duration of recording: 3*12 = 36 seconds.
- Electret microphone with membrane.

The design of the housing had been modified several times to meet requirements of mechanical handling, electronic sub-units and prize. Poor material quality and fitting problems due to insufficient molding required frequent interaction with CAD designer and Chinese manufacturer. Still, the finally released housing leaves room for improvements, e.g. to increase size and easiness of operation of the buttons.

The display has been re-designed, too, to meet power, size and interfacing requirements.

The integrated head phone jack offers the possibility to connect a head phone to the Valve Validator. Through listening to the sound during a so-called pre-recording state it is possible to identify the best position for the pick-up on a patient's chest prior to the final recording. The head phone feature provides an adequate means to control the signal quality during the real recording, too.

## 2.4 VALVE VALIDATOR: THE VIEWER

The following figure shows a screen-shot of the viewer:

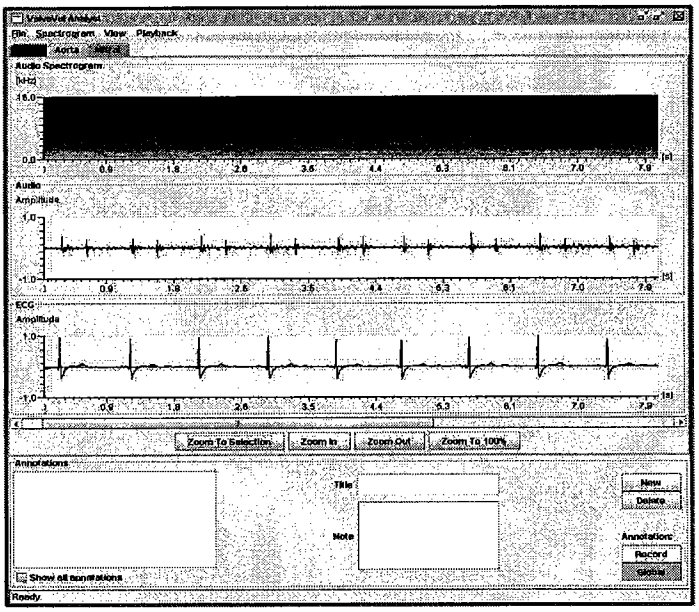


*Figure 5: Screen-shot of the Valve Validator Viewer*

The viewer contains the following features:

- Management of bluetooth data transfer from device to computer.
- Display of audio spectrogram, audio data, and ECG data.
- Display and storage of patient and device specific data (patient ID, device name, bluetooth key, profiles)
- Management of several record files per patient for comparison.
- Up to 10 annotations per event; max. no. of 1024 characters per annotation.
- Measurement of time interval between two events.
- Playback of audio and ECG data with wandering marker.
- Zoom in/out and autoscale.
- Selection of specific measurement area for playback.

The viewer runs on Windows XP PCs but requires Java Runtime Environment. Intermediate tests by Professor Noll have been the basis for some feature improvements such as setting markers, measuring events (length, distance) etc. In total, the feedback on usability and available features was very positive.

## 2.5 METHODOLOGY FOR PATIENT TESTS

The methodology and a possible screening protocol had been investigated in a joint effort with the University Hospital Zurich (USZ) and the Heart- and Diabetescenter in Bad Oeynhausen, Germany. An earlier project proposal on a joint *European test center to evaluate the present status of patients with Björk-Shiley convexo-concave heart valves* from March 2004 had been the basis to plan patient recruitment, and clinical examination. Screening program and medical tests to provide reference data included electrocardiogram and phonocardiogram recordings, exercise testing, and echocardiography.

Test recordings with the Valve Validator would have been conducted right after completion of the reference screening. The recording should have been done by one of the doctors and by the patient himself to test applicability and quality of the technique.

Prof. Noll and Prof. Turina from the USZ were supposed to conduct all tests and to evaluate the results.

## 2.6 PRELIMINARY TESTS AT UNIVERSITY HOSPITAL ZURICH

Tests have been conducted at the USZ with four male patients:

- Patient 1: 37 years, 85kg, 192cm, aorta, Carbomedics No. 31
- Patient 2: 72 years old, 85kg, 170cm, aorta, , Carbomedics No. 23
- Patient 3: 63 years, 88kg, 170cm, mitral, St. Jude Medical No. 29
- Patient 4: 71 years, 85kg, 180cm, aorta, Carbomedics No. 25

It had been impossible to acquire any BScc heart valve patient for that purpose and in the

envisioned time frame. Measurements have been conducted with and without detached pick-up, and with and without contact gel for the electrodes (ECG).

The following figure shows the result from one recording (patient no. 4) with detached pick-up and contact gel on electrodes.

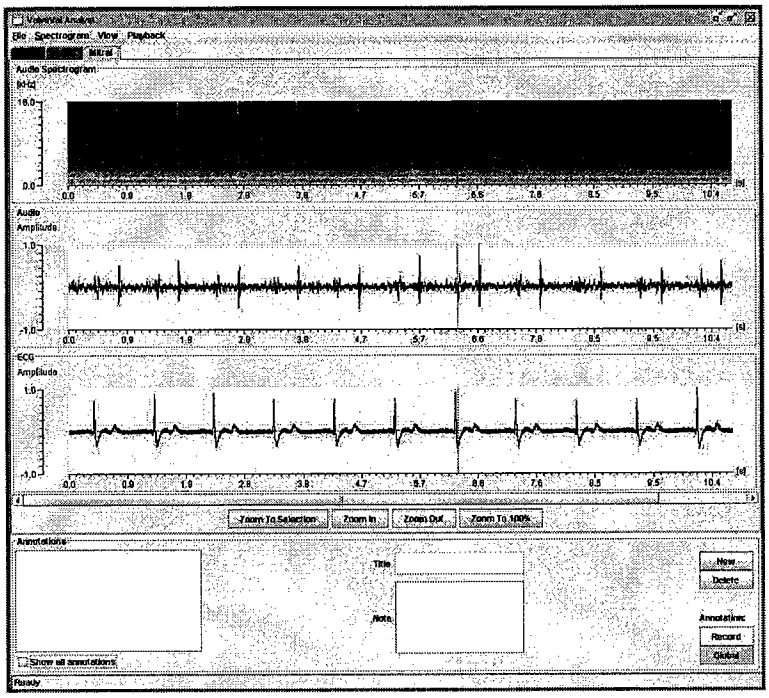


*Figure 6: Screen-shot from recordings with patient no. 4, having the pick-up detached and using contact gel for improved conductivity.*

Results form these first tests are:

- Best results have been achieved for detached pick-ups and the use of contact gel on the electrodes; proximity of mic and readout-electronic to head-phone might create interference problems.
- Operation by the patient himself requires some improvement in the device handling, e.g. Larger buttons.
- Signal quality is quite sufficient; however, improved amplifier setting and amplification would help.
- Use of viewer (playback of sound, ECG and sound visualization, annotations etc. have been considered as very helpful and good to use.

# 3 CONCLUSION AND OUTLOOK

A prototype system of the Valve Validator has been developed, manufactured and tested. Despite several technical and organizational challenges, major tasks and units of the originally proposed system have been accomplished. Preliminary tests at the USZ under supervision by Professor Turina have shown promising results regarding signal quality and data processing.