Mobile Health Care: Towards a commercialization of research results

Dimitri Konstantas[1,3], Richard Bults[1], Aart Van Halteren[1], Katarzyna Wac[3],
Val Jones[1], Ing Widya[1], Rainer Herzog[2], Barbara Streimelweger[2]

University of Twente[1], Ericsson GmbH[2] and University of Geneva[3]
{Dimitri.Konstantas, Katarzyna.Wac}@unige.ch
{R.Bults, A.T.vanHalteren, V.Jones, I.Widya}@ewi.utwente.nl
{rainer.herzog, barbara.streimelweger}@ericsson.com

Abstract: MobiHealth[1] and HealthService24[1] are two major EU projects targeting the development and validation, with extensive medical trials, of innovative systems and services for mobile health care. Biosignals are measured by sensor devices connected to a wireless Body Area Network. These signals are transmitted reliably and securely over public wireless networks (e.g. GPRS, UMTS) to a remote healthcare organisation where healthcare professionals can monitor, diagnose and provide advice to patients in real time. The developed system and its services is in the last phase of the pre-commercial validation, expecting a commercial release of the system late 2006.

1 Introduction

Today the health sector faces serious and increasing problems in the management of resources for disease prevention, follow-up and remote assistance of patients. The cost of intramural patient care is increasingly creating problems for both patients and social security organizations, while on the other hand citizens are becoming more health conscious, demanding advanced health services and ubiquitous health care. One solution that can contribute in relieving the pressure on health care organizations come from extramural (i.e. remote) monitoring of the patients' health state. This direction of mobile health (m-health) services was investigated and different systems are proposed by many manufacturing companies. However, a comprehensive service for remote health monitoring is today practically non-existent.

Towards this direction we have completed **MobiHealth** [MobiH] and are running **HealthService24** [HS24], a commercial validation project for the development and deployment of value-added mobile health (m-health) services, using public wireless GPRS or UMTS networks. The MobiHealth project was completed in February 2004, delivering a technically validated and fully functional prototype of a biosignal monitoring service which creates a possibility for monitoring extramural patients. Biosignals (e.g. 1 to 7 lead ECG, respiration frequency and oxygen saturation) are

measured by sensor devices integrated in a wireless Body Area Network (BAN) and subsequently transmitted over public wireless networks. With the completion of the MobiHealth project we proceeded towards the first phase of the commercialisation of the system and its services. The goal of the HealthService24 project is to validate the system's services at „friendly" healthcare organisations in order to have a fully marketable solution at the end of the project. A series of trials in both projects (nine different trials scenarios in MobiHealth and three in HealthService24) allowed us to evaluate the development process of m-health services and their deployment in the clinical process of healthcare organisations,. In addition, we were able to evaluate the usability of existing and forthcoming public wireless networks,as enabling technologies for successful deployment of mobile healthcare services.

2 The MobiHealth System and Services

MobiHealth developed a wearable healthcare BAN and a generic mobile services platform providing a health monitoring service for patients and health professionals. Remote patient monitoring is only one of the possible m-health services that can be provided. Other services are tele-treatment using information feedback and event notification in case of patient distress or abnormal biosignal levels.

2.1   The MobiHealth Body Area Network

The concept of the Body Area Network originally came from IBM [Zim99] and was further developed by other researchers at, for example Philips [DPB01], University of Twente [Jo01] and Fraunhofer [Sc01]. In the Wireless World Research Forum's Book of Visions, we defined a BAN as "*a collection of (inter) communicating devices which are worn on the body, providing an integrated set of personalised services to the user*"[WWRF].

In the context of the MobiHealth project, the healthcare BAN is a health monitoring system consisting of wirelessly inter communicating sensors, actuators, communication and processing devices which are worn on the patients' body. The MobiHealth BAN incorporates a range of networked sensor and actuator devices, together with a communication and processing node.

Sensor devices can be self-supporting and/or front-end supported. Self-supporting sensors have a power supply and facilities for amplification, conditioning, digitisation and communication. Self-supporting sensors are independent building blocks of a BAN and ensure a high degree of configurability. However, each sensor device runs at its own internal clock and may have its own sampling frequency. Consequently, mechanisms for clock synchronization between sensor devices (and BAN devices in general) may be needed.

Front-end supported sensor devices share a common power supply and data acquisition facilities. Consequently, front-end supported sensors typically operate on the same front-end clock and jointly provide multiplexed sensor data as a single data block. This avoids the need for synchronization between sensor devices. A front-end supported sensor

device is responsible for the data acquisition process. It ensures that a physiological phenomenon, such as patient heart activity, muscle activity or blood pressure, is first converted to an electrical signal, subsequently amplified, conditioned, digitised and communicated inside the BAN.

Intra-BAN communication is performed via Bluetooth [BT03], providing the technology for ad-hoc networking of BAN devices (i.e. sensors, actuators and the Mobile Base Unit). Extra-BAN communication is done via GPRS or UMTS (WiFi is optional). The Mobile Base Unit (MBU) is the central node in the BAN; and it can be any mobile device (e.g. PDA ot smart phone) with sufficient processing power able to manage the BAN and provide extra-BAN communication services. It aggregates the biosignals from the sensor devices, performs basic signal interpretation (e.g. determining pulse rate and SpO2), controls the actuators and acts as a communication gateway for intra- and extra-BAN communications [Do03]. Figure 1 shows the architecture of a BAN.
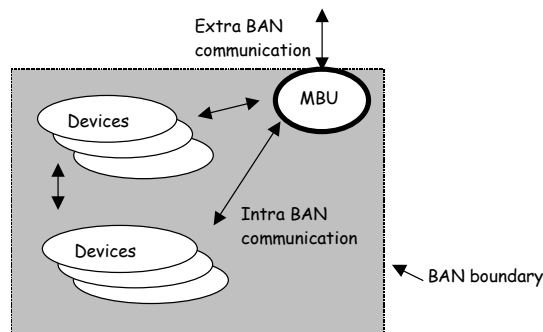
Figure 1 : BAN architecture

The MBU transmits the BAN biosignals to a back-end system (implementing the m-health services), which may be located within the health care organisation ICT infrastructure or at a health services provider's site. From there the measurements are dispatched to the health care professional who monitors the measurements on-line or off-line after measurements processing.

2.2 MobiHealth Service Architecture

Figure 2 presents the MobiHealth monitoring service architecture showing the correlation between the MobiHealth sub-systems and their services. The dashed-dotted boxes indicate the physical location where a service will be executed. The rounded boxes represent the service entities of the architecture, where the oval shapes depict the service access points (SAP).

Figure 2 shows an M-Health Service Platform (MSP) as a middle-ware layer between end-user services (i.e. patient data monitoring service and M-Health services) and communication service providers; the MobiHealth monitoring service does not incorporate the MSP. MSP acts as an 'intelligent' communication service provider between the MBU monitoring service and M-Health services while abstracting from the

underlying (data) communication service characteristics. MSP provides the following services:

o *BAN registration*: BAN register their ID at the MSP, which authorises the BAN to advertise its services and maintains a list of active BANs.
o *BAN service discovery*: BANs advertise their services which are „discovered" by the MSP. MSP adverstise these services to applications, which subscribe to these services.
o *BAN data encryption*: the platform encrypts data that is conveyed over unsecured networks
o *BAN configuration*: BAN measurement configuration and adaptability (e.g. prioritazation of biosignals) depending on local context information (e.g. GPRS „goodput").
o *BAN data transmission control*: BAN data transmissions are controlled (i.e. start, suspend, stop) by the MSP.
o *BAN data storage*: the service platform can act as an intermediate storage provider to applications. Applications determine the minimal duration of the storage.
o *BAN data monitoring*: the service platform can apply filtering algorithms on the BAN data to determine if an interesting event has taken place (e.g. a patient has dropped on the floor) and report this event to the application layer.
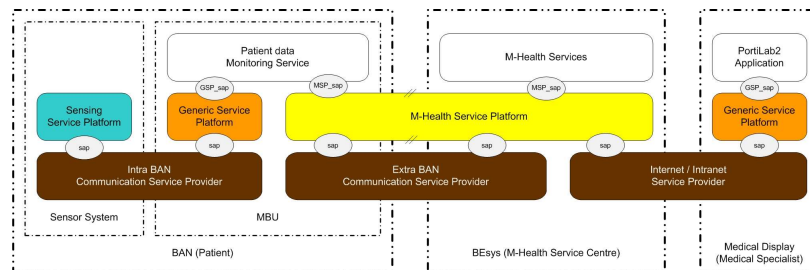

Figure 2 : MobiHealth functional architecture

In addition, Figure 2 shows a generic service platform located on the MBU that facilitates interaction between the MBU's monitoring service and the sensing service platform (i.e. sensor device). At the right side of the figure, the Medical Display consists of the PortiLab2, a signal processing software package that allows (patient) data from the M-Health services, to be viewed and processed in real-time. The generic service platform facilitates interaction between the PortiLab2 application and the MSP.

2.3   MSP Requirements

To leverage the healthcare BAN for use as a *remote* monitoring tool several issues and considerations were taken into account in the design and development of the MSP. These issues reflect both, commercial and social needs or restrictions, as well as technical limitations of underlying software and hardware. The most important ones being *scalability*, *security* and *extra-BAN communication restrictions*.

Scalability: MSP must be able to support services that cover niche healthcare cases that require the simultaneous monitoring of small numbers of patients (e.g., ranging from 10 to 100 BANs) to large-scale chronic disease management processes (e.g., 100.000+ BANs used to monitor COPD patients). In addition geographical scalability, that is global coverage, should be supported.

Security. MSP connects BANs with the Internet. Consequently, a BAN is potentially vulnerable to attacks from malicious Internet users who may either try to break into the system or executed a denial of service (DoS) attack. Therefore, MSP should protect a BAN from these attackers. In addition, mechanisms that ensure BAN data integrity must be included. Each BAN should authorise itself with the service platform, which should only allow authorized BANs to send BAN data (i.e. preventing masquerading) and access controls are needed to prevent unauthorised access to BAN control signals and/or data.

Resolve 'inverted-producer-consumer' problem. Traditionally, providers of data (such as web servers) are deployed on a computing infrastructure with sufficient network and processing capacity. Consumers of data (such as web browsers) assume that providers are available most of the time (except for maintenance) and have sufficient bandwidth to serve a reasonable number of consumers. This model was the one adopted by the public wireless network operators where the data consumer, i.e., the mobile device, initiates a network connection to the producer. Based on this assumption, most network operators of GPRS and UMTS networks hand out private (non-routable) IP addresses to mobile devices. Connection establishment initiated from a fixed host on the public Internet to a mobile device is therefore inhibited.

However, in the MobiHealth system each BAN is a data *producer*. For the service platform, the producer and consumer roles are thus inverted because the provider of data is deployed on a mobile device (i.e. the MBU) while the consumer of data is deployed on a fixed host with sufficient processing and communication capacity. The MBU may be temporary unavailable, due to the short life-time of batteries or because it has moved to an area without coverage of the public wireless infrastructure. The service platform therefore masks the inversion of the producer-consumer roles from the BAN and the end-users (a patient wearing the BAN or a medical specialist analyzing the BAN data).

2.4   The MobiHealth Trials

The MobiHealth system and services were validated with a number of trials [Ha04] that spanned four European countries and covered a range of conditions including pregnancy, trauma, cardiology, rheumatoid arthritis and respiratory insufficiency and made use of patient BANs and health professional BANs (nurse BAN, paramedic BAN). The trials were selected to represent a range of bandwidth requirements: low (less than 12 Kbps), medium (12 – 24 Kbps) and high (greater than 24 Kbps) and to include both non-real time (e.g. routine transmission of tri-weekly ECG) and real time requirements (e.g. alarms, transmission of vital signs in a critical trauma situation). For each application the generic MobiHealth BAN was specialized by addition of the appropriate sensor set and corresponding application software. The nine trials were :

Trial 1 - Germany : Telemonitoring of patients with cardiac arrhythmia
Trial 2 - The Netherlands: Integrated homecare for women with high-risk pregnancies
Trial 3 - The Netherlands : Tele trauma team
Trial 4 - Spain: Support of home-based healthcare services
Trial 5 - Spain : Outdoor patient rehabilitation
Trial 6 - Sweden : Lighthouse alarm and locator trial
Trial 7 - Sweden : Physical activity and impediments to activity for women with RA
Trial 8 - Sweden: Monitoring of patients with respiratory insufficiency
Trial 9 - Sweden : Home care and remote consultation for recently released patients in a rural area

3 Main Results of the MobiHealth project

The MobiHealth project was completed successfully in February 2004 and a series of important results were obtained. First of all the project developed an architecture for, and a prototype of, a generic service platform for the provision of ubiquitous healthcare services based on wireless Body Area Networks and 2.5/3G networks. The developed system was used to validate the ability of the commercially available 2.5/3G networks to support advanced mobile health services. The performed trials allowed us to identify the usefulness and the user acceptance of the services in different medical specialties, as well as the problems and issues that need to be resolved for its deployment. Finally the project trials allowed us to identify the market considerations and the different actors that need to be involved in a commercial deployment.

During the trials different types of data were collected by the evaluation team responsible for evaluation of the results. The trials were evaluated using a methodology developed in the project. Specifically we evaluated the trials from the technical point of view (technical evaluation), the medical point of view (end-user and social evaluation) and from the business point of view (market evaluation).

The technical evaluation focused on the evaluation of the performance of the communication infrastructure characterized in terms of: availability, bandwidth characteristics, percentage of data loss/corruption, transmission delay and its variation ("jitter"). In addition to the network performance the technical evaluation also assessed the overall system in terms of validity, accuracy and robustness of the Sensor Service and application, the BAN and the intra-BAN communications, time delays etc.

The system performance related parameters were logged at the BAN side, while the generated traffic was logged by the 2.5/3G network measurement system. Logs at the BAN side record any problems regarding access to the network and the process of transmitting the data to the BEsys. The network log reports were used to verify if any of the logged problems at the BAN side could have been caused by the current status of the network during that time.

The performance characteristics of the MobiHealth communication infrastructure were derived in two ways: objective and subjective evaluation. The *objective evaluation* of

the infrastructure included active and passive measurements. For the active measurements an external data stream was generated (that is, we had no real MobiHealth data) and the performance characteristics of the communication paths were measured. The passive measurements were performed in the up-and-running MobiHealth system so that real MobiHealth data were used. During the passive measurement phase, the participating operators also performed core-network data logging of the MobiHealth traffic characteristics 0.

The *subjective evaluation* of the infrastructure's performance was done by the end-users (healthcare professionals) who expressed their perceptions of functionality and performance characteristics as experienced during the usage of the MobiHealth system.

Part of the technical evaluation was the **2.5/3G Network Evaluation**. The analysis of the network performance evaluation data collected during the trials provides interesting results regarding the performance of the UMTS networks and technical issues related to MobiHealth BAN. Although the current UMTS networks are stable and functional, there are many barriers and technological details that need to be resolved before stable and viable m-health services can be introduced into the market. Some of the most important problems are the restricted available data bandwidth for uplinks, delay variation, delays in transmission and handovers.

The end user evaluation described the usability/acceptance of the MobiHealth Services seeking the subjective opinion of users regarding the new services, their usability, user interaction, satisfaction, suitability, usefulness, acceptance, independence and experiences. Also questions about *perceived* performance characteristics of the system, like: system accuracy, validity, robustness, its speed or availability of the service were addressed to the professional users. End users in this project were defined as the patients and the health care personnel who were involved in the trials and were using the MobiHealth system.

The end-user evaluation data were collected using diaries, questionnaires, interviews and some objective measurements, e.g. walking distance and step-length for mobility assessment. End-users' evaluation results were compared against the performance measurements of the platform to analyse existence of expected correlations. An example of correlation between user experience and measured technical performance would be the receipt of an unusable poor quality ECG, which cannot be interpreted by the professional, coinciding with large delays and packet drops in the system indicating communication throughput problems.

The goal of *the market evaluation* was to provide a set of criteria which would allow valid statements and decisions regarding the market value and potential of the MobiHealth system in the respective trial settings to be made. The factors which were important and decisive in this context included: health political issues, existing market structures and processes, market players, business scenarios, value chains, potential users, users' characterization (behaviour, acceptance requirements), health economic relevance, realization of market potentials (how much and when), barriers of entry, opportunities and threats.

4 Towards commercialization : The HealthService24 project

One of the results of the MobiHealth project was the validation of the fact that today there is no concise mobile monitoring service available in Europe. There are various systems, services and applications available [LR04], which allow users to monitor their health status and transmit some type of vital signal information to remotely located medical personnel, like for example pregnant women can be monitored from home, instead of being admitted to the hospital, Rheumatoid Arthritis patients can be monitored remotely during rehabilitation exercises at home, the glucose level can be registered and the patient can download the data once a day/week to a PC and send it to the hospital. However, the currently available services allow patients to monitor and transmit their state over a wired phone (home services), meaning that the mobility of users is very limited, as they need a telephone line and electricity connection. The commercially available medical tools today are only on the level of administrative information (the doctor has a PDA with which he can access the medical record of the patient and send information using GSM/GPRS). The mobile solutions that start appearing in the market either are simple technological solutions with no complete integrated service to support them or at best they simply provide the possibility for the patient to store the vital signal measurements and upload them at the evening to the hospital server. HealthService24's target is offer a viable mobile health care service permitting healthcare professionals to remotely assess, diagnose and treat patients, whilst the patients are free to continue with daily life activities.

A HealthService24 patient/user is equipped with variety of vital constant sensors, like blood pressure, pulse plethismogram and ECG interconnected in a wireless Body Area Network managed by a PDA or mobile telephone and worn on the body, and thus moving around with the person. These way patients can stay mobile but be continuously monitored and receive advice when needed.

The measurements are transmitted wirelessly using UMTS (or GPRS) to a data centre acting as an intermediary between patients/users and health care providers and providing three services: data repository (just collecting of the received data), streaming service (forwarding data to a doctor), and alarming service (interpretation of the received data and sending of an alarm signal to a predefined destination (using SMS)). The data centre may also provide technical support and, if needed, act as the first-level medical support for the HealthService24 users.

From the data-center, the data are wirelessly transferred to health care providers, where they can be viewed (e.g. on a laptop). Healthcare professionals, to whom the patients' data are transferred, can remotely assess, diagnose and treat patients.

4.1 Validation trials

In order to test and verify the system, the service and the network infrastructure for its suitability and the restrictions it imposes on mobile health care applications, nine validation trials will be conducted within the project in three different countries in Europe: Netherlands, Spain and Cyprus. Three different groups of patients will test the

service: (high-risk) pregnant women, cardiac patients and COPD-patients (Chronic Obstructive Pulmonary Disease) with respiratory problems. The (high-risk) pregnant women trials will be carried out in Netherlands, the COPD-patients trials in Spain, and the cardiac patients trials in Cyprus.

We are currently (May 2006) conducting three validation trials at each test side. Each trial lasts approx. 3 months. As the market validation is an interactive process, the results obtained during the first set of trials will be fed into the next phases. Each set of trials is carried out by a hospital/clinic specialised in the particular disease/health problem to guarantee the highest possible quality level and credibility of the results.

As the number of patients/ users needed per group for a validation trial varies depending on the expected hospital days, different numbers of patients need to be validated within each group. Taking the above into consideration and to assure reliable results from the validation trials, a minimum of 8 pregnant women per trial shall be monitored and 15 COPD- and cardiac patients, which means that in all three trials per patient group at least 25 (high-risk) pregnant women, 45 COPD-patients and 45 cardiac-patients will be monitored.

For the **(high-risk) pregnant women** trials, the trials use the HealthService24 to support integrated homecare for women with high-risk pregnancies. Women with high-risk pregnancies are often admitted to the hospital for longer periods of time because of possible pregnancy-related complications. Admission is necessary for the intensive monitoring of the patient and the unborn child. Homecare with continuous monitoring is desirable and can postpone hospitalisation and reduce costs, as well as offering more security for the mother and unborn child. In this trial, patients will be monitored using the patient-BAN. The maternal and foetal bio-signals are remotely transmitted to the hospital. An additional objective of the trial is to evaluate if such a solution postpones hospitalisation and reduces costs. This trial takes place in Enschede, the Netherlands in the *Medisch Spectrum Twente* Hospital.

For the **COPD-patients trials**, the trials use the HealthService24 to support remote assistance for elderly and chronically ill patients suffering from co-morbidities including the COPD. The MobiHealth nurse-BAN is used to perform patient measurements during nurse home visits and the MobiHealth patient-BAN is used for continuous monitoring during patient rehabilitation at home or outdoors. It is very important to facilitate patients' access to healthcare professionals without saturating the available resources, and this is one of the main expected outcomes of the HealthService24 remote monitoring approach. Parameters to be measured are oxygen saturation, ECG, spirometry, temperature, glucose and blood pressure. The trials take place in the Barcelona, Spain, at the *Hospital Clínic i Provincial de Barcelona.*

For the **cardiac patients trials**, the HealthService24 is tested by two groups of patients:

Group1: Patients who had an acute episode and have been admitted and stabilised but need continuing monitoring of condition and drug regime for a further few days. With the HealthService24 these patients will be allowed an earlier discharge, with an appropriate follow up (using the HealthService24) in the place of their choice.

Group 2: Patients in a suspected acute episode, brought in for examination; a decision needs to be taken whether to keep the patients at the hospital for observation, or to discharge them home. In case a patient is discharged, and there is a suspicion of an abnormal condition, the patient will be equipped with the MobiHealth patient-BAN enabling constant monitoring of the patient's state. The cardiac patients' trial take place in Agia Napa, Cyprus, at the *LITO Polyclinic*.

4.3   Evaluation procedure

Metrics for evaluating the test results include general indicators such as quality of life (and care) for both patient and doctor, economic benefits for a patient/government of not staying in hospital (and freeing a hospital bed), overall costs of the service and adaptation issues to adjust the service to national requirements as well as reliability, accuracy and sensitivity of the equipment and ease of use for patient and health professional.

During the trials different types of data arebeen collected in view of an evaluation of the results. The targets of the evaluation include both technical and socio-economic aspects. From the technical side, the state of the UMTS (and GPRS) infrastructure and its suitability for mobile health applications is verified, while from the socio-economic side the added value that the HealthService24 can bring to different healthcare domains will be explored and the related issues for its commercial deployment will be evaluated.

4.4   Status of the HeathService24 project

From the first days of the project we realized that the market is already mature and ready to accept the deployment of m-health services, as proposed by the HS24 project. For this reason an adaptation of the time frame of the short and long term objectives was made.

Figure 3 : HealthService24 user interface

In addition Ericsson, being the prime industrial partners in the project, adapted its internal structure and processes in order to fulfil in a shorter time the objectives of the project. As a result we were forced to delay the start of the trials for 4 months and adapt the existing system, bringing it closer to a commercial product. Finally in September 2005 the trials were started with an adapted system that was stable with additional functionality and with a simple and ergonomic user interface providing easy to read information to the users (Figure 3).

Flexible mechanisms allowing the prioritization of the signals to be sent, so in case of low bandwidth the least "important" signals are *not* sent to the hospital but stored locally, permit to send signals coverign the complete spectrum of life transmission to off-line storage, in case of connectivity breakdown or for energy conservation.

5 Conclusions

The up to the day of writting (May 2006) results of the project indicate that several issues need to be resolved by both network operators and hardware manufacturers for a better support to mobile health services [Bu04][Wa04]. Ambulatory monitoring is more successful for some biosignals than others, for example some measurements are severely disrupted by movement artefacts. Some monitoring equipment is still too cumbersome for ambulatory use, because of the nature of the equipment or because of power requirements (powering always-on devices and continuous transmission will continue to raise technical challenges for the next decade for mobile applications!). Furthermore even with 2.5 and 3G, we still suffer from limited bandwidth for applications that serve many simultaneous users.

Other challenges relate to security, integrity and privacy of data during transmission to both local transmission (e.g. intra-BAN) and long range (e.g. extra-BAN) communications. Legislation differences between European countries do create some problems in the adoption of mobile systems. Some harmonization is expected in the future but it will take time to become reality.

Business models for healthcare and accounting and billing models for network services need to evolve if technical innovations are to be exploited fully. Standardisation at all levels is essential for open solutions to prevail. At the same time specialization, customisation and personalisation are widely considered to be success criteria for innovative services.

The main problems identified for the introduction of new mobile health services based on Internet technologies into hospitals, relate to the changes required to support these new services, in both technological level and work practices level. From a technology point of view, the introduction of new mobile services requires a modern ICT infrastructure with secure connections to the Internet. However, many hospitals today do not have this kind of ICT infrastructure. Some hospital IT departments didn't even accept the use of standard HTTPS to retrieve vital sign information. On the other hand other hospitals demanded that the mobile system is fully integrates with their existing IT system, using the same data exchange standards and formats.

A second technology related problem concerns the precaution measures taken by the majority of the hospitals in the use of wireless communication devices inside the hospitals. Due to lack of serious studies regarding the interference of wireless communication devices, like telephones, with medical equipment, most hospitals prohibit the use of any such device within their premises. This has as an immediate consequence that any wireless medical system will have difficulties to be officially authorised to function inside the hospital. Nevertheless, from the reactions and interest of the hospitals and the patients we are very optimistic that the proposed MobiHealth/HS24 system and services will be a commercial success.

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