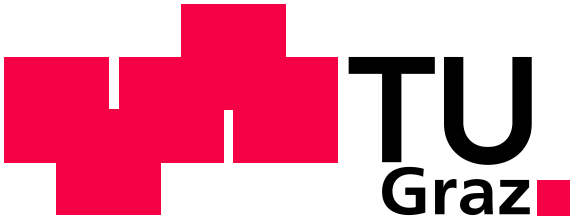
Keep In Touch (KIT) – An mHealth Concept for Patient-centered Telehealth Services



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Doctoral Thesis

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The underlying work of thesis was carried out in cooperation with

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Preamble

The present work was created by me personally and represents a scientific account of a patient-centered data collection via mobile phones using Near Field Communication (NFC) technology as the key enabling technology. It is based on scientific activities, which were carried out in the scope of research & development projects incorporated in respective project teams. The complete solutions and results derived from these projects are based on my own efforts, those of further AIT employees as well as external project partners. This statement's purpose, therefore, is to represent my original contribution to these projects and therewith separate it from the contributions of the other participating members.

The scientific functions, which I carried out in these projects, consist, in essence, of individual or teamwork execution of the following tasks in relation to the mobile phone-based patient terminal in telemonitoring applications:

- Requirements analysis
- Solution design
- Implementation
- Conducting feasibility and usability tests as well as clinical studies
- Data evaluation
- Paper writing

During my functions in the scope of patient training and technical support in previous mobile phone-based telemonitoring projects without use of NFC technology e.g. for supporting heart failure patients (Mobitel study) [94] or obesity patients [P5], I have determined the weak points of these solutions and identified the requirements for improved solutions. Together with colleagues at the AIT, I formulated the patent specification [PAT1], which describes a mobile phone-based telemonitoring solution with NFC technology. The obesity patient data were evaluated by me and published in teamwork with co-authors [P5].

Based on these functional requirements and a first demonstration work (originating from my previous diploma thesis), a generic NFC module for contactless linking of sensors to NFC-enabled mobile phones was developed in an AIT-internal technological development project. My functions in this project consisted of the technical examination of NFC technology, technology selection, NFC module circuit design, creation of documentation and communication with the external technology partner, who laid out and manufactured the final module. Furthermore, I participated in the quality management process and conformity evaluation proceedings. The concept of the NFC module firmware design and development was created and implemented purely by me. The firmware controlled the NFC module in relation to data collection from a sensor and its transfer using the contactless interface to an NFC-capable mobile phone. One charac-

teristic of the firmware served for integration of the NFC module into a blood pressure monitor of an industrial medical device manufacturer (A&D Medical, Tokyo, Japan). My further participation consisted of overseeing the EMV test of the complete system (blood pressure monitor with an integrated NFC module) and the risk management documentation regarding the integrity of the data chain from the interface in the blood pressure monitor to the NFC module up to the mobile phone. Based on these documents and my documentation for the NFC module, the manufacturer resubmitted the blood pressure monitor, extended with the NFC module, to another conformity evaluation process and brought it to the market as the world-wide first NFC-enabled medical device.

Further feasibility and usability evaluations were made using this NFC-enabled blood pressure monitor and the generic NFC module for connection to further sensors, where I was primarily responsible for their preparation, execution, evaluation and publishing [P3, C7, A6].

In order to link a new noninvasive cardiovascular measurement device to an electronic study system, I have outfitted this device with a NFC module and developed the firmware accordingly in order to transfer the sensor data to a mobile phone using the contactless interface, which then transmitted these data to the study system. Furthermore, the design of the mobile phone-based data collection process for the study physicians originated from me. In this design, the RFID tokens were used for the first time for authentication and identification of multiple persons in a multi-user scenario. The specifications of this data collection solution for the clinical environment were conceived and published by me [C5]. The data, which were gathered in the scope of the clinical study, were evaluated and published by me in cooperation with the clinical partner [C6].

In the scope of the Elicard and Diabmemory proof-of-concept telemonitoring projects, the patient terminal solution itself and, especially, its interaction with the back-end system in relation to deployment, management and maintenance was conceived with my participation, implemented by developers and tested with my help. For connecting to further sensors, I have housed the NFC module with a separate power supply in a case and developed the firmware according to the data protocols of each respective device with an external interface. The RFID-based dialog book, which was mainly designed and developed by me, was used in these projects. I was involved in the entire lifecycle of the complete solution through my functions as Helpdesk and Administrator, where I worked with the software components (mobile software and back-end service), created the modification requirements and executed tests. Parts of the data, which were collected in the scope of these projects, were evaluated by me or with my participation and published together with the technical specifications of the complete solution [P3, A1, A4].

In a further research and development project I have created a concept for an additional contactless data collection method based on the combination of NFC and Bluetooth technologies. This concept was designed and developed into a functional prototype

under my main responsibility. With the help of a student, this solution was combined with a 1-channel ECG recorder and integrated into an existing blood pressure monitor, in order to record an ECG signal while performing a blood pressure measurement. The technical concept was published by me [P1] or with my participation [C2, A5]. The data collected in the scope of a clinical study for evaluation of this solution were evaluated and published by me [P2].

Due to my know-how in the areas of NFC technology and mobile phone-based telemonitoring, built up in the course of these activities, I also made a significant contribution in a proof-of-concept project on the topic of medication compliance management, where NFC-capable medication blister packaging was given out to diabetes patients together with NFC phones. My contribution in this consisted of system and process design of the complete solution for patient-centered medication compliance data collection. The technical solution of the complete system including statistical data from the application was published and presented by me [C1].

Besides my functions in the scope of the aforementioned projects, I provided support in regard to content and implementation of a student project [C3] and acted as the AIT-internal supervisor for two diploma theses. The goal of these theses was a prototypical use of NFC technology for monitoring of activities of daily living [A3] as well as identification of multiple users and automatic configuration of various sensors in a wireless sensor network [A2].

Acknowledgements

This thesis would not have been possible without support and funding by the AIT Austrian Institute of Technology GmbH.

I wish to thank, first and foremost, my advisor Guenter Schreier who originated the idea of “Keep In Touch” and gave me the opportunity to contribute to the realization of this solution in the course of a PhD thesis at the Technical University of Graz in cooperation with the AIT.

Guenter Schreier also deserves my deepest gratitude for persistent personal guidance, fruitful discussions, constructive comments, and support throughout this thesis.

Furthermore, I am also deeply grateful to Peter Kastner and the remaining members of the Assistive Healthcare Information Technology business unit for constructive collaboration and their help in putting things together.

I consider it an honor to work with all clinical partners from the

- General Hospital Medical University of Graz, Department of Cardiology,
- Elisabethinen general hospital in Linz, Internal Department II- cardiology,
- Medical University of Vienna, Department of Internal Medicine III, Division of Endocrinology and Metabolism,

as well as the DIABMEMORY project members from the VAEB.

I dedicate this thesis to all patients and study participants who have been using the Keep In Touch patient terminal.

Last but not least, I want to express my gratitude to my family and grandmothers and especially to my wife Letizia for accompanying and supporting me throughout the entire work.

Abstract

Background: Close interaction between patients and their caregivers by means of home- or telemonitoring appears as promising approach to cope with challenges in health care caused by chronic diseases. A crucial point in this area is to provide patients with an adequate technical solution in order to communicate with their doctors for providing health related parameter and receiving guidance to optimize the treatment.

Objectives: Design and implementation of a patient terminal solution based on mobile phones and medical sensor devices enabled with Near Field Communication technology linked to a Web based telemonitoring system. Clinical evaluation and use in proof-of-concept telemonitoring projects focusing on patient-centered care of chronic diseases like chronic heart failure, pulmonary arterial hypertension, type 1 and type 2 diabetes mellitus.

Results: An easy-to-use patient terminal was developed that enables patients to document all kind of health related data simply by touching medical sensor devices and smart objects with a mobile phone. Acquired data were transmitted to a Web based telemonitoring system to be observed by doctors and nurses. Deployment of patient terminal equipment was carried out easy by means of shipping it via mail service to the patient's home and having the patient putting it in operation autonomously.

The developed system was evaluated in laboratory setting by students as well as in two clinical settings on and by 46 patients suffering from chronic heart failure. Results of these evaluations showed technical feasibility and the potential to be adopted in real telemonitoring scenarios. Modified versions of the patient terminal were deployed in routine-like proof-of-concept telemonitoring projects: 40 patients suffering from chronic heart failure and pulmonary arterial hypertension have been using the system for three years and acquired more than 90,000 data items. 235 patients suffering from diabetes mellitus type 1 or 2 have been equipped with the patient terminal and documented a total of almost 190,000 data items during an operation period of 21 months. Preliminary results from these projects indicate that NFC acts as enabling technology. By means of this intuitive user interface elderly end even technical unskilled people have proven that they are able and willing to take an active part in therapy management.

Conclusion: The availability of easy-to-use patient terminals is essential to provide telemonitoring to chronic ill people and allow them to actively take part in the management of their situation. This strong patient involvement is a big step towards the ultimate goal of personalized healthcare services providing high levels of efficiency, quality, and safety and at the same time moderate costs for the healthcare system.

STATUTORY DECLARATION

I declare that I have authored this thesis independently, that I have not used other than the declared sources / resources and that I have explicitly marked all material which has been quoted either literally or by content from the used sources.

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Graz, am …… ……..

(Unterschrift)

Publications

This thesis is based on the following publications, patents as well as on unpublished observations:

Papers

P1: **Morak J**, Kumpusch H, Hayn D, Modre-Osprian R, Schreier G. Design and evaluation of a telemonitoring concept based on NFC-enabled mobile phones and sensor devices. IEEE Trans Inf Technol Biomed. 2012;16(1):17-23.

P2: **Morak J**, Kumpusch H, Hayn D, Leitner M, Scherr D, Fruhwald FM, Schreier G. Near Field Communication-based telemonitoring with integrated ECG recordings. Appl Clin Inf. 2011;2(4):481-498.

P3: Kastner P, **Morak J**, Modre R, Kollmann A, Ebner C, Fruhwald FM, et al. Innovative telemonitoring system for cardiology: from science to routine operation. Appl Clin Inf. 2010;1(2):165-176.

P4: Lamedschwandner K, Bammer M, Oberleitner A, Schmid G, Cecil S, Preineder H, Nakovits T, **Morak J**, Schreier G. Wirkungen elektromagnetischer Felder bei Einsatz der NFC-Technologie im Gesundheitswesen. e & i - Elektrotechnik und Informationstechnik. 2010;3:25-28.

P5: **Morak J**, Schindler K, Goerzer E, Kastner P, Toplak H, Ludvik B, Schreier G. A pilot study of mobile phone-based therapy for obese patients. J Telemed Telecare. 2008;14(3):147-9.

Selected Conference Papers

C1: **Morak J**, Schwarz M, Hayn D, Schreier G. Feasibility of mHealth and Near Field Communication technology based medication adherence monitoring. Conf Proc IEEE Eng Med Biol Soc. 2012. p. 272-5.

C2: Kumpusch H, Hayn D, Kreiner K, Falgenhauer M, **Morak J**, Schreier G. A mobile phone based telemonitoring concept for the simultaneous acquisition of biosignals and physiological parameters. Stud Health Technol Inform. 2010;160(2):1344-8.

C3: Kreiner K, **Morak J**, Pinsker M, Edegger K, Schreier G. Feasibility of a mobile anticoagulation telemedicine system using automated decision support. Stud Health Technol Inform. 2010;161:86-94.

C4: Cecil S, Schmid G, Lamedschwandner K, **Morak J**, Schreier G, Oberleitner A, Bammer M. Numerical Assessment of Specific Absorption Rate in the Human Body Caused by NFC Devices. Second International Workshop on Near Field Communication (NFC). 2010. p. 65-70.

C5: **Morak J**, Hayn D, Kastner P, Drobics M, Schreier G. Near Field Communication Technology as the Key for Data Acquisition in Clinical Research. NFC '09. First International Workshop on Near Field Communication. 2009. p. 15-19.

C6: **Morak J**, Schwetz V, Hayn D, Fruhwald FM, Schreier G. Electronic data capture platform for clinical research based on mobile phones and near field communication technology. Conf Proc IEEE Eng Med Biol Soc. 2008. p. 5334-7.

C7: **Morak J**, Kollmann A, Schreier G. Feasibility and usability of a home monitoring concept based on mobile phones and near field communication (NFC) technology. Stud Health Technol Inform. 2007;129(1):112-6.

Selected conference proceedings and abstracts

A1: **Morak J**, Schreier G. mHealth based on NFC technology – Preliminary results from medium scale proof of concept projects. Proceedings of the eHealth2012. 2012 Mai 10-11; Vienna, Austria. OCG. 2012. p. 131-137.

A2: Akyildiz S, **Morak J**, Drobics M, Schreier G. Development and Evaluation of a Multimodal Wireless Data Hub for eHealth Applications. Proceedings of the eHealth2012. 2012 Mai 10-11; Vienna, Austria. 2012. p. 241-246.

A3: Graf H, **Morak J**, Schreier G. Wireless Sensor Platform for AAL and Telehealth Applications. Tagungsband der eHealth2011 – Wien, 26.-27. Mai 2011. p. 169-174.

A4: **Morak J**, Modre R, Schreier G. Keep in Touch – mobiles Telemonitoring überschreitet die Grenzen von Bluetooth. Tagungsband der Telemed 2010 in Berlin, Erfolgsmodell für moderne Patientenversorgung, 3-5 November 2010. p. 21-31

A5: Kumpusch H, **Morak J**, Hayn D, Schreier G. Intuitive Acquisition of Electrocardiograms for Telemonitoring via Mobile Phone. Tagungsband der eHealth2010: Health Informatics meets eHealth, 6.-7. Mai 2010. p. 87-92.

A6: Drobics M, **Morak J**, Kastner P, Schreier G. Intuitive Erfassung von Gesundheitsdaten mittels NFC. Tagungsband von Ambient Assisted Living 2009 2. Deutscher AAL-Kongress mit Ausstellung, 27.- 28. Januar 2009 in Berlin.

A7: Pinsker M, Schindler K, **Morak J**, Hayn D, Kastner P, Riedl M, Ludvik B, Schreier G. Experiences Using Mobile Phones as Patient-terminal for Telemedical Home Care and Therapy Monitoring of Patients Suffering from Chronic Diseases. In: icchp 2008: Proceedings of the 11th International Conference on Computers Helping People with Special Needs; 2008 Jul 9-11; Linz, Austria. 2008. p. 1305-1312.

Patent

PAT1: Schreier G, Kastner P, Kollmann A, **Morak J**. Messgerät und Verfahren zur Erfassung und Übertragung von Messdaten (AT 502495, PCT Patent WO/2007/041727).

Content

Figures

Tables

Abbreviations

AIT ..... Austrian Institute of Technology GmbH
AHD ..... Application Hosting Device
PCB ..... Printed Circuit Board
CHF ..... Chronic Heart Failure
DM1 ..... Diabetes Mellitus Type 1
DM2 ..... Diabetes Mellitus Type 2
ECG ..... Electrocardiogram
EDGE..... Enhanced Data Rates for GSM Evolution
eCRF..... electronic Case Report Forms
EDC ..... Electronic Data Capture
ePRO ..... electronic Patient Reported Outcome
GPRS..... General Packet Radio Service
HSPA ..... High Speed Packet Access
ICT ..... Information and Communication Technology
ID ..... Identification (or Identity)
ISM ..... Industrial, Scientific and Medical
J2ME..... Java 2 Mobile Edition
KIT ..... ”Keep In Touch”
LED..... Light-Emitting Diode
LTE ..... Long-Term Evolution
MAC..... Media Access Control
NDEF ..... NFC Data Exchange Format
NFC ..... Near Field Communication
OTA ..... Over The Air
PC..... Personal Computer
RFID ..... Radio Frequency Identification
SIM ..... Subscriber Identity Module
SMS ..... Short Message Service
SOA ..... Service-Oriented Architecture
UMTS..... Universal Mobile Telecommunications System
VAEB ..... Health Insurance Company for Railway Workers and Miners
WAP..... Wireless Application Protocol

1 Introduction

Today's healthcare systems are facing serious challenges keeping up healthcare delivery on a certain level with consideration of cost-effectiveness. One is the increasing of the world's aging population in both developed as well as developing countries. The "An Aging World: 2008" report [1] forecasts a total number of 1.3 billion elderly people (65 years and older) in the year 2040. This will be a double (7 to 14%) of this age group's proportion compared to 2008.

Coming along with this situation is a rise in chronic conditions and diseases like cardiovascular diseases (CVD), diabetes, respiratory diseases and cancer [2]. These are often resulting from poor lifestyle [3]. Consequently, as more and more people will reach a higher age, the prevalence of chronic diseases will tend to increase significantly. This will lead to rising costs that may far exceed the healthcare systems' financial resources.

In addition to the problem of rising costs, healthcare systems are facing a shortage of health professionals. As the availability of health professionals will not increase in the same dimension, a nearly steady health professional manpower will have to care for more and more elderly people suffering from chronic diseases [4]. This situation suggests that delivery of healthcare needs to be reviewed in order to manage the aging population's demand for good quality-of-care at affordable costs.

1.1 Telemonitoring

eHealth applications such as home or telemonitoring appear as promising approaches to attenuate some of these problems and challenges. Home or telemonitoring evolves from the field of telemedicine and is based on the inclusion of the last free resource to be brought into process of healthcare, the patient him/herself [5]. As information is the primary asset in the field of medicine and, particularly, treatment of chronic diseases, it utilizes information and communication technologies (ICT) to include patients into data and information flow. It establishes a virtual communication link between patients and their caregivers to allow for timelier intervention than known from conventional consulting a medical practitioner or the outpatient clinic.

One step further, a closed-loop telemonitoring setup with bidirectional communication allows for realizing a patient-centered care approach [6], enabling patients to receive exactly the care they want and need at exactly the location, time and manner they want and need it [7].

1.1.1 **Barriers to Overcome**

Figure 1 shows the closed-loop telemonitoring concept consisting of the two main participants, i.e. the patient and the doctor, as well as the technical part in between these human roles called the telemonitoring infrastructure.

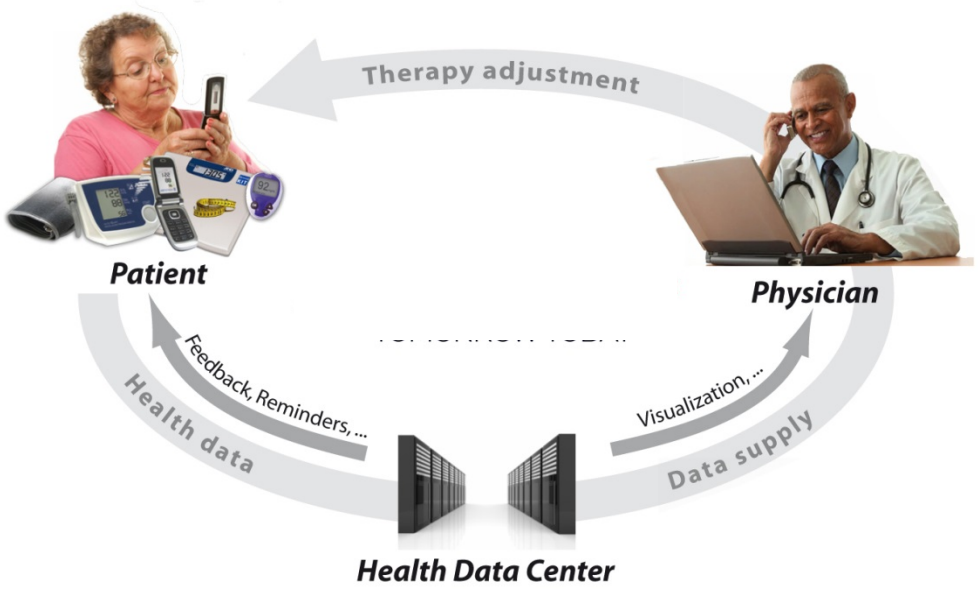

Figure 1: Overview of the telemonitoring system.

Digital representation of all data allows for a store-and-forward based information sharing as well as for analyzing and processing them. Based on these features, the telemonitoring infrastructure aims to overcome the following barriers currently affecting the patient-doctor interaction and the entire treatment process:

I. Space – Transferring information instead of having the patient always come to the doctor's office creates a space-independent patient-doctor interaction.

II. Time – In addition to space independence transferring data in a store-and-forward manner allows reviewing the physiological data uncoupled from the moment of acquisition. Secondly, this time independence also enables the doctor to review the data on a more frequent basis that allows him/her to react on worsening and critical situations as early as possible.

III. Knowledge – Having the history of a patient's physiological data instead of a single sample leads to a well-founded and hence more precise diagnosis. The treatment based on this diagnosis could be set up more individually and optimized. In addition to that, a telemonitoring system is able to provide process and decision support based on clinical knowledge (e.g. guidelines), helping the doctor in treating the patient in the most effective and efficient way.

IV. Systems – Since the interaction between the patient and the doctor is only one part in healthcare delivery, the telemonitoring infrastructure needs to be interoperable with other subsystems to allow for an integrated care concept involving all stakeholders of the national healthcare system (e.g. general practitioners, medical specialists, hospitals, care institutions, insurance companies, etc.).

1.1.2 **Basic Principle**

As mentioned before, this approach includes the patient into the information flow. Therefore, he/she has to actively take part in the treatment process by means of self-management [8] in combination with a close link to his/her doctor (providing him with all information necessary for optimizing the therapy).

The patient lives at home and is asked to autonomously collect a subset of the following information depending on the given disease or chronic condition:

- vital signs derived from medical sensor devices
- symptomatic data such like pain or well-being
- lifestyle data about physical activities or nutrition
- therapy-specific data such as medication intake.

These regularly acquired data have to be sent to the doctor in a timely fashion (at least on the same day). Depending on the course of these data, the doctor or even the telemonitoring system itself sends back messages in order to improve the current situation. A message could be sent for one of the following reasons:

- individual therapeutic feedback
- therapy adjustment (e.g. change of medication prescription)
- reminder (to send the data or take the pills as prescribed)
- alert (vital signs are exceeding thresholds)
- request for consultation or laboratory test
- motivational feedback (e.g. to improve compliance)
- health tips
- etc.

In order to provide all data to the doctor and send back the messages, both the patient and the doctor have to handle their endpoints of the telemonitoring infrastructure: the so-called patient- or doctor terminal.

The most common terminal device for the doctor may be a personal computer which is already used in a doctor’s daily work. Hence, no deeper look on this end user interface will be considered here. Instead, this work will focus on the characteristics, design, and functions of the patient terminal.

1.2 **Patient Terminal**

The term “patient terminal” refers to the entire equipment handled by the patient in order to digitally acquire and report information representing the current health status, de facto therapy settings, and lifestyle parameters as well as to receive guidance information on how to react to a given situation.

The patient terminal consists of two major parts, which are based on different sensing technologies as well as common ICT components.

The first part is a set of different sensor devices to acquire the patient’s vital signs. The characteristic of the sensor set depends on the patient’s individual needs based on his disease or chronic condition. One or more of the following devices may be used by the patient to record his/her vital signs:

- Blood pressure meter
- Body weight scale
- Blood glucose meter
- Oxygen saturation monitor
- ECG recorder
- Spirometer
- Blood coagulation monitor
- etc.

In addition to these sensors, a patient may also be using one or more of the following items, which can be categorized as acting devices or lifestyle sensors which can record information about the patient’s behavior:

- Smart medication blister
- Pill dispenser
- Insulin pen
- Nutrition scale
- Pedometer / activity monitor
- etc.

In most cases, these devices - also called “agents” - feature a memory for storing a batch of measured values and a data interface for providing these data for further processing or visualization.

The second part of the patient terminal is a dedicated device that handles all data and manages user interaction and communication. In eHealth jargon this component is called an application hosting device (AHD), since it is a hardware device running a software application to perform these tasks. The terms AHD and agent are defined by the Continua Health Alliance (CHA) [9], which is an industrial consortium to promote and establish industry standards and guidelines in order to create interoperable telehealth devices and services.

In the following sections the components and functions of an AHD are explained followed by a paragraph listing the different kinds of implementation.

1.2.1 **AHD – Components and Functions**

The AHD is represented by an electronic device that, amongst other parts, consists of the following four major components [10] (Figure):

- Central processing unit (CPU) with memory for operation and data storage
- PAN/BAN interface
- User interface
- WAN interface.

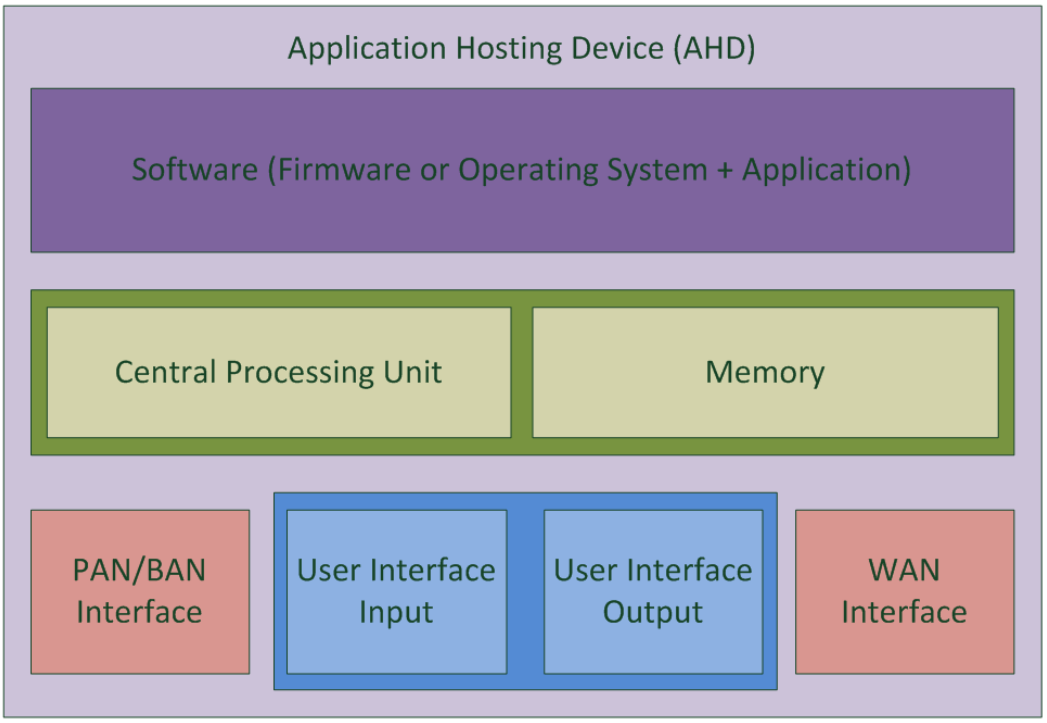

Figure 2: Components of an Application Hosting Device.

By means of either a wired or a wireless interface the AHD opens up a personal area network (PAN) or a body area network (BAN). This so-called wireless medical sensor network (WMSN) can be based on standardized technology such as Bluetooth [11, 12], Wi-Fi [13], ZigBee [14], or ANT+ [15] or on any proprietary RF interface [16] or even on optical linking technologies like IrDa [17]. In terms of wired interfaces, the universal serial bus (USB) or the standard RS323 serial interface [17] are commonly used.

Sensor devices linked to this network can be interrogated by the software running either directly on the CPU (firmware) or on top of an operating system or dedicated runtime environment. By means of a user interface consisting of output components like a display, speakers, or simply LED lights and input components like buttons, a keypad, or even a touchscreen, the user can physically interact with the AHD.

In order to communicate with the central part of the telemonitoring infrastructure the AHD is linked to the Internet by means of a Wide Area Network interface (WAN). This interface can be based on wired technology like a dial-up modem to be connected to the landline telephone network or an Ethernet link to an existing Local Area Network (LAN) infrastructure that is connected to the Internet. Additionally, the WAN interface can also be realized wirelessly either by a 2G, 3G, or 4G mobile network or by using a Wi-Fi link to an Internet-connected LAN.

The main functions of the AHD are interrogation of the sensor devices linked to the PAN or BAN interface and forwarding of the gathered data to the remote telemonitoring system. Depending on the use case, the AHD has to provide additional features such as annotation of received sensor data or even authentication in case of multiple users or when enhanced security is needed. In some cases manual data entry is required in order to answer a questionnaire or to enter additional parameters which cannot be acquired automatically using one of the mentioned sensors.

To provide patients and doctors with an overview related to the current situation the acquired data have to be aggregated, processed and visualized. Finally the aggregated data can be transmitted directly or stored locally to be synchronized afterwards. During synchronization the AHD may receive the messages from the backend system. All these information have to be visualized within a clear and well-arranged user interface.

1.2.2 **State of the Art AHD Solutions**

a) Personal Computer

Personal computers (PCs) such as desktop devices or notebooks provide a broad range of user interfaces (keyboard, mouse, touch pad, large display and speaker) and are well-known from office work and represent a major part in the field of consumer electronics. Using the PC as an AHD in terms of telemonitoring is done by installing a dedicated software application acting as a client to communicate with a remote Web service. It can be combined with other applications such as an email or video chat client (e.g. to communicate with the doctor). Sensor devices are mostly connected via USB or RS232 interface or wirelessly linked by means of a transceiver dongle to be interrogated by the software. Commercially available solutions like HealthVault (Microsoft Corporation, Redmond, WA) [18] and SenseWear (BodyMedia Inc., Pittsburgh, PA) [19] are two of many examples of how to collect sensor data and forward them via PC.

b) Set-top Box and Gaming Console

The television is one of the most used electronic entertainment devices. The user interface is represented by a large display and a remote control. Connecting a set-top box running a dedicated software application to an existing television allows for using this well-known user interface to enter and visualize health-related data. The set-top box itself manages the interrogation of the sensor devices, the communication with the

Web service, as well as the visualization of all data. Already used examples of set-top box-based patient terminals are the MOTIVA system (Philips Healthcare, Andover, MA) [20] and the ZydaDoc®Home solution (Zydacron telecare GmbH, Graz, AT) [21].

Gaming consoles are quite similar to set-top boxes. They are also connected to a television and provide wired or wireless interfaces for interacting with sensor devices and communicating on the Internet. In many cases, these gaming consoles also are able to run third-party software applications. Gaming consoles like the Nintendo Wii (Nintendo, Kyōto, JP) or Xbox with Kinect interface also show potential to act as patient terminals, especially if physiotherapy exercises are part of treatment and have to be monitored [22].

c) Health Terminal

In order to provide patients with a dedicated device that allows for a more flexible and broader application in the field of telemonitoring, a specific type of AHD was designed that acts exclusively as a patient terminal and nothing else. This circumstance simplifies the process of certification according to the Medical Device Directive (MDD). This device type, called a health terminal, is a small box to be placed in the household (living room or kitchen) and keeps all necessary components for collecting, transporting, and visualizing all data independently. Information output is realized by display and speaker, while a set of buttons placed around the display act as the input interface. Buttons are pushed by the patient in a dialogue-like interaction to answer a visualized question. Depending on the integration level, a preselected set of sensor devices is supported to be interrogated by the firmware or software application running on this health terminal. While the RTX3371 (Tunstall Healthcare, Yorkshire, UK) [23], as well as the Health Buddy System, and the T400 Telehealth System (Bosch Healthcare, Waiblingen, DE) [24], provide standardized wired and wireless interfaces to support third-party sensor devices, the TeleStation (Philips Healthcare, Andover, MA) [25] comes with a proprietary interface supporting only devices from the same manufacturer.

d) Personal Digital Assistant (PDA)

The personal digital assistant became available around the year 1990. It was a mobile device to be held in one hand and operated with the other one. It can be seen as the intention to create an ultra-mobile computer to be carried in the pocket with a user interface similar to those known from a desktop or notebook computer (touch-sensitive display with a virtual keyboard). Linking technologies such as Bluetooth or USB were used for synchronization of personal information with a computer. It was able to run third-party software applications to enter and visualize any kind of data, including those associated with health. Thus, this type of device was used in a lot of research projects and trials aiming to equip patients with a mobile patient terminal [26, 27, 28, 29].

While the PDA arose from the idea of creating a pocket computer for having personal information available on the move, the mobile phone, on the other side, evolved from

voice communication as known from traditional landline telephone networks. More details about the mobile phone's evolution and reasons to be used as AHD are presented in the following.

1.2.3 **Mobile Phone**

Over the past decades since the rollout of mobile telephone services, the mobile communications industry has presented drastic technology advances [30]. In the beginning of mobile network technology, communication was based on analogue and circuit-switched connections. Subsequently, this kind of communication was overtaken by using digital electronics that enabled additional kinds of services like text messaging and communication of data based on packet-switched connections.

Digital mobile networking technologies advanced from Global System for Mobile communications (GSM), over 2G networks like the General Packet Radio Service (GPRS) and 3G networks such as the Universal Mobile Telecommunications System (UMTS), Wideband Code Division Multiple Access (WCDMA), and High Speed Packet Access (HSPA) to 4G networks like the Long Term Evolution (LTE) and the Worldwide Interoperability for Microwave Access (WiMAX) [31]. These developments and the rapid implementations by the mobile network operators (MNOs) allows for high bandwidth and ubiquitous availability of voice and data services. Hence, the user has access to the internet at any time and any place.

In parallel to that, the user's end devices have evolved from simple voice telephony devices to feature-rich electronic devices. While in the first years the user end device only allowed for a limited set of functions, such as voice and text communication plus simple features (clock, alarm-clock), during the beginning of the 21st century the mobile phone converged with many other developments in the field of office and consumer electronics.

Now, it resembles a mobile computing platform providing personal information management functions (email, contacts, calendar), Web browsing, entertainment (music players, digital cameras, video players), and other forms of personal computing [32]. Devices contain highly integrated powerful processing and graphic acceleration units capable of hundreds of millions of instructions (even floating-point operations) per second paired with random-access memory (RAM) of up to hundreds of megabytes and gigabytes of mass storage memory [33]. With respect to user interface, sensors and wireless interfaces mobile phone technology has demonstrated a high level of progress. Thus, devices already may feature high-resolution displays with multi-finger touch recognition and / or a full QWERTY layout keyboard, high-resolution cameras with video recording capabilities, sensors for measuring acceleration, rotation, ambient light, and even barometric pressure. In order to provide geolocation services and communicate with their surrounding environment devices, they provide a GPS receiver paired with a digital compass sensor and wireless networking transceivers for Wi-Fi, Bluetooth, and ANT+ connectivity [34, 35, 36, 37].

According to the International Telecommunication Unit (ITU), the mobile phone shows the highest market penetration rate compared to ICT devices like personal computers or even televisions [38]. In addition to that, the mobile phone has become a ubiquitous accessory for everyday use that hosts highly personalized applications and delivers personal services. Because of this situation and all technical advantages given by this type of device it shows high potential to act as a universal toolbox for collecting, processing, exchanging, and visualizing data even of personal nature associated with one's health and wellness.

1.3 Roles and Processes in Telemonitoring Applications

Using a PDA or a mobile phone as an AHD is one of the application fields belonging to the term mHealth. During the last years the term "mHealth" has been most succinctly defined as services related to health and wellness delivered via mobile communications devices [39]. Beside a mobile phone based closed-loop telemonitoring application to support therapy management, this definition includes many other services ranging from simple helpline calls [40, 41] over mobile communication technology to providing education and awareness [42, 43, 44] or the adoption of tablet computers for clinical ward rounds [45], including concepts for mobile disease and epidemic outbreak tracking [46, 47]. On the one hand, most of these applications including patients who handle the device for providing or receiving information are based on the mobile phone's basic communication features such as voice communication, text messaging and using a Web browser. On the other hand, especially designed devices running one or more dedicated applications interacting with additional equipment are mostly deployed to personnel in closed environments (hospitals, care institutions, etc.) that are trained in using them.

In closed-loop telemonitoring applications operated by a telemonitoring service provider, the mobile phone acting as the AHD has to be treated with special care. Thus, in the current situation it is a rarity that patients use their already existing private mobile phones. In most cases, patients receive a specific device selected from the broad range of market offer. Since the mobile phone has to interact with several sensor devices and has to be handled by the patient for a long period of time, selection needs to be done in consideration of many requirements including user interface design, technical features, supported standards, availability and support services as well as costs.

Depending on the status of a telemonitoring project, either a pilot, proof of concept, or even in routine-operation, different roles may be involved to some process steps in order to equip the patient with an already prepared patient terminal and support him/her in using it on a regular up to daily basis. These processes are related to the following different phases to be run through when a patient and his/her doctor enter treatment via closed-loop telemonitoring:

a. Registration Phase:

When a patient is supposed to start using telemonitoring, he/she becomes registered on the telemonitoring system. During this registration process, the patient's anamneses data are collected and entered into the system under the patient's account. If the telemonitoring system is not operating independently but is part of a larger healthcare IT system, these data can be simply imported. Afterwards, the appropriate therapy is chosen and configured in relation to the patient's needs. During this configuration, the set of monitoring parameters to be recorded by the patient are defined together with the initial threshold for each individual vital sign to be analyzed by the system. The registration is typically performed by a **doctor**, thus, he/she is the main actor of this phase.

b. Preparation Phase:

After registration the patient has to be provided with the entire equipment consisting of the mobile phone and the set of sensor devices enabling him/her to acquire the selected vital signs. Depending on the used linking technology between AHD and sensors, the connection has to be preconfigured. After linking the AHT to the patient's account, the equipment can be handed out to the patient. This can be done either in-house (e.g. clinic), at the patient's home (visit by mobile trainer) or even remotely by shipment of the components (using mail service). In addition to that, the patient has to be trained in using the patient terminal. Training can take place during equipment handout or prior to shipment while the patient is in-house. Alternatively, the patient could learn how to use the equipment autonomously based on a user manual or could be taught remotely by means of instructions given via a phone call. Once all components are installed in the patient's home environment and ready for use, the preparation phase is finished. During this phase the **patient** as well as the **technical support and / or a mobile instructor** are the main actors.

c. Monitoring / Intervention phase:

As soon as the patient succeeds in acquiring data, the monitoring phase starts to operate, as shown in figure 1. Data are collected regularly and provided to the caregiver by means of the telemonitoring infrastructure. Depending on the patient's current state, messages generated by an algorithm or a caregiver in person are sent back to him/her. If the system or the doctor recognizes a worsening condition, an intervention has to take place. This could be a modification of the current therapy parameters (e.g. medication prescription), a completely new treatment procedure, or even an admission to the clinic for detailed medical observation. In this phase, the **patient** and medical staff like the **doctor or even a telemonitoring nurse** represent the main acting roles.

d. Maintenance Phase

From time to time, the monitoring phase could be interrupted for a short or even longer period of time for different technical reasons. In most cases, the **patient** contacts the **helpdesk** and reports a problem with one or more devices. The helpdesk tries to solve the problem remotely either by giving instructions during a phone call or – if implemented – by means of IT-supported remote device management functions. If none of

these interventions succeed due to malfunction or even physical damage, one or more components of the patient terminal have to be exchanged. This can be done just like at initial handout. Either the patient brings in the components, a technician comes to his/her home for replacement, or the new device is sent via mail service and the patient returns the damaged one in the same way. Depending on the technical solution of linking a sensor device to the AHD, a sort of pairing and / or configuration process has to be performed. This situation also affects the process of replacement. Another process being part of the maintenance phase is updating the software or even the firmware / Operating System (OS) of the AHD. Depending on the implementation, this may also require technician staff to get hold on parts of the equipment or a phone call to instruct the patient in performing a specific procedure.

e. Timeout Phase

The monitoring phase could also be interrupted by phases where the patient is not sending his/her data due to personal or even medical reasons. If the patient is away for vacation, takes a stay at a health resort or was admitted to a hospital for inpatient medical care, the telemonitoring concept has to manage this situation. Data analysis, reminders and alerts have to be disabled for this specific period of time. This can be done by the **doctor** who coordinates the treatment or by the **helpdesk** after being informed by the **patient** about a timeout period.

f. Termination Phase

If the patient completely stops telemonitoring due to any reason, the patient terminal or at least parts of it may have to be returned to the provider for further reuse or phase them out. For privacy and security reasons, it usually is of great importance that the AHD has to be decoupled from the backend system and all personal data have to be deleted from the device's memory. These tasks are performed by **technical staff** after receiving the devices face-to-face or by mail service.

1.4 Influence of Technical Aspects

In terms of asset costs, the mobile phone seems more beneficial than a set-top box, a dedicated health terminal or even a PC. But there are yet other costs to be considered. Besides operating the IT system, there is some workload for setup, deployment, instruction and maintenance also leading to significant expenses and hence, heavy contribution to the overall costs of operating a telemonitoring system. Thus, during design of the entire system and selection of technologies and components it is essential to consider special requirements helping to reduce these operation costs.

1.4.1 State of the Art Wireless Technology

In the early years of using a mobile phone for interrogating a sensor device, infrared technology according to the Infrared Data Association (IrDA) was used [48, 49]. It was

the first short-range wireless linking technology available in mobile phones and handheld devices. But integrating IrDA was discontinued after emerging of Bluetooth technology, which is now integrated in almost any mobile phone, in addition to other devices known from office or consumer electronics. In an mHealth context, Bluetooth is currently the most popular wireless technology for linking a mobile phone operating as an AHD to one or more sensor devices.

Bluetooth operates in the industrial, scientific and medical (ISM) frequency band of 2,4GHz and allows for setting up a master-slave oriented wireless network with an operation range of up to 100m. Different versions of the Bluetooth specifications have been published by the Bluetooth Special Interest Group (SIP) [50] over the last years and implemented by the industry. These different versions vary in terms of operating range, modulation methods, data rates, energy consumption, encryption, specific features as well as the range of supported profiles.

Bluetooth profiles contain definitions of possible applications and specify how two or more Bluetooth devices have to behave at the beginning and during communication. RFCOM, also known as the Serial Port Profile (SPP), is supported by almost any Bluetooth-enabled mobile phone. Thus, from the beginning, it was the most-used Bluetooth profile implemented by sensor device manufacturers.

1.4.2 **Usability vs. Security Using Bluetooth**

Although, the feasibility of using Bluetooth technology in mHealth applications could be demonstrated in a lot of research and telemonitoring pilot projects, this technology still shows some drawbacks when it comes to the need of a balanced interplay of usability as well as security on an adequately high level.

One thing is the need of setting up a paired connection between the AHD and each sensor device in order to make them communicate. But, so far, performing this setup procedure is not that intuitive. On a mobile phone, this procedure includes several manual steps such as opening the Bluetooth menu, enabling Bluetooth and starting the device and service discovery. Once a device and a service have been selected, the user is asked to enter a PIN code to finalize the pairing process [51] that guarantees encrypted data transmission. This configuration procedure (device / service discovery and pairing) requires some basic technical understanding and can be performed by technically skilled persons, but may overstrain especially elderly patients [52]. Therefore, the most common way is to provide patients with a pre-paired patient terminal. This approach, however, also means a more complex replacement procedure if one or more devices need to be exchanged (a technician who replaces them and does the pairing again).

Having a sensor device paired with the AHD means that only this mobile phone is able to receive the data from this sensor device. Receiving of data can be handled by the means of interrogating the device’s memory or automatically if the sensor device

transmits the measurement values immediately after sensing without storing them. Both variants have been implemented by different manufacturers and have to be considered during design of the software application. This may also affect the application's usability as it sometimes needs to handle both variants at once. Interrogation of the device's memory needs an action to be taken by the patient that initiates this process (at least launch of the application). If the device memory keeps a batch of values with some of those not belonging to this patient, he/she has to take care of filtering and selecting the correct values. In case the recent measured value is transmitted to the AHD immediately, the application may forward the data to the backend system automatically or only after being confirmed by the patient. This implies further action to be taken by the patient. If the application is implemented in a way that does not ask for this confirmation, wrong values could be forwarded to the backend system automatically (e.g. the guest problem: a guest uses the weight scale in the bathroom).

Unrelated values occur if any other person than the actual patient use a sensor device. Using Bluetooth assignment of measured values to the patient is only defined by the virtual link between the paired AHD and sensor device. But what if it is intended to share one or more sensor devices like a blood pressure meter or a weight scale among several persons living in the same household? This kind of multi-user scenario cannot be covered by using Bluetooth technology since a sensor device is paired and therefore linked to one specific AHD usually belonging to one person. This can only be handled by means of different patient accounts on a single AHD which is atypical when using a mobile phone.

Next to the mentioned drawbacks given by Bluetooth, the application running on the mobile phone itself lacks in usability when it comes to security and vice versa. In general, the AHD handles the data of only one patient and is linked to the account of this patient at the backend system. These data need to be treated with a high level of confidentiality since they are personal and related to one's health situation. Therefore, some security measures are needed to:

- prevent spy-out attacks of locally stored data
- avoid eavesdropping of transmission to backend system
- ensure secured upload access to backend system.

These measures can be handled by means of user credentials (username and password) for authentication as well as encryption (of data and transmission). On the one hand, frequent entering of username and password heavily affects the usability, especially for elderly people. But on the other hand, leaving out authentication before each use implies critical risk potential, being unacceptable in healthcare applications. Solving this problem of providing high security without the need of remembering and typing the username and password would require a token-based identification approach as known from radio frequency identification technology (RFID).

1.4.3 **Potential of NFC and RFID Technology**

A wireless technology that became available in mobile phones over time is Near Field Communication (NFC) technology. NFC evolved from RFID technology that additionally uses features of common wireless technology like Bluetooth. Definition of standards to ensure interoperability as well as certification of conformity is managed by the NFC Forum [53]. NFC operates in the ISM band of 13.56 MHz and supports communication within a range of a few centimeters (<10) at a data rate of up to 424 Kbit/s [54]. The short operating range is the major advantage of this technology as a communication between two items starts automatically when they are brought in proximity.

The intention in development of NFC technology was its integration into mobile phones to enable this kind of ubiquitous accessory, acting as a virtual smart card for ticketing, loyalty and payment applications by waving it in front of a reader terminal [55, 56]. The major advantages of such a virtual card are remote deployment and maintenance by means of a mobile Internet connection. Having the mobile phone act as a contactless smart card is the so-called card-emulation mode of NFC.

In addition, NFC supports the card-reader mode that enables the mobile phone to act as reader device for reading passive RFID tags and cards of certain RFID standards. The third operation mode is called peer-to-peer (p2p) mode and supports the communication between two active devices (e.g. two mobile phones exchanging electronic business cards, picture or music files) [57].

NFC is supposed to change the way we interact with the physical world in a subtle but pervasive way and provides an intuitive method to link any object of the physical world to the virtual world of the Internet, hence, it may act as “the” enabler for the “Internet of things” [58, 59].

In the field of mHealth, this technology might be a game changer as well. As mentioned before, the short operation range leads to an automatic data exchange when objects are brought together. Using a gesture of pointing the NFC-enabled mobile phone towards a specific object, communication with this object starts immediately. An application running in the mobile phone or the firmware itself could behave discriminatively, depending on the data received from this object and hence, perform a specific action. This causality enables the user to express the willingness to perform a specific action simply by touching the corresponding object with the mobile phone.

Many process steps to be taken during data acquisition could be simplified or even left out by means of such an interaction concept. It may enable patients with full authority to acquire their data without being bypassed through automatic data transmission and provides potential for usability as well as security both on a high level.

1.5 Related Work

After NFC technology has appeared scientists and researchers focusing on human computer interface and health IT developed and presented many mHealth applications based on mobile phones and NFC technology.

In [60] Bravo et al. RFID tags were used to be touched with mobile phones operated by nurses in order to manage and document nursing tasks in a hospital environment. In 2011, more than 50,000 Dutch nurses that provide home healthcare were equipped with NFC enabled mobile phones to document all administrative data during visiting a patient at home by touching RFID tags and smartcards [61]. Prinz et al. [62] demonstrated an NFC based solution that enabled patients for self-reporting their health status information by touching a tagged board with an NFC enabled mobile phone. In Vergara et al. a mHealth solution for medication intake management was presented [63]. It used RFID tags on medication blisters and a software application running on an NFC enabled mobile phone to verify whether a medication had to be taken at this time or not depending on the current prescription.

Wagner et al. proposed a zero-configuration solution where an NFC enabled mobile phones was used by caretakers to configure a patient's telemonitoring equipment by pairing wireless sensor devices with a base station [64]. A similar approach was presented by Won-Jae Yi et al. who used RFID tags to establish a Bluetooth connection between an NFC enabled mobile phone and a wireless medical sensor [65].

While Huijuan Zhang et al. presented a theoretical work how to use NFC as an interface for wireless sensors to be interrogated by NFC enabled mobile phones [66], Jara et al. showed a detailed system picture focusing on ambient assisted living [67]. He presented "an architecture based on the internet of things to support mobility and security in medical environments" where NFC and RFID technology were used to ensure failsafe identification management as well as to capture information from medical systems. In [68] Jara et al. a prototype application was demonstrated that uses NFC to transmit ECG data in real-time to be visualized on a mobile phone's display. Although in this prototype the data source was based on a PC in-between an ECG sensor device and a desktop NFC transceiver, it shows the potential of an NFC enabled phone to simply collect physiological data.

Strommer et al. studied the "Application of Near Field Communication for Health Monitoring in Daily Life" and presented the use of a mobile phone to easy collect data from medical sensor devices to be sent to a Web based telehealth service. They proposed a hardware module to interface medical sensors by wired interface. Additionally, this module supported NFC to transmit these sensor data to a mobile phone [69].

Although many concepts and prototypical implementations have been demonstrated, compared to the work presented here there was no scientific approach found in the literature which dealt with the prototyping of a complete telemonitoring system and subsequent evaluation in laboratory, clinical and routine-like environments.

1.6 Background and Motivation

This thesis was inspired by working as a training person, helpdesk, and administrative authority in several clinical trials and proof of concept telemonitoring projects using a patient terminal based on mobile phones. Being in close contact with patients as well as physicians was helpful for understanding the central role of patients and, thus, identifying the requirements of an adequate patient terminal for everyday usage.

As mentioned before, current concepts using mobile phones and sensor devices linked via Bluetooth technology show drawbacks in many areas like usability, security, user authority, or maintainability and, therefore, are not able to cover these requirements entirely.

Thus, the goal of this thesis was to design, develop, and evaluate an easy-to-use and easy-to-maintain patient terminal concept based on mobile phones and NFC technology called “Keep In Touch” that enables patients to keep in touch with their caregivers simply by touching their medical sensor devices and other items. The system should provide a generic design to be integrated into a telemonitoring platform to run clinical trials as well as proof-of-concept studies and telemonitoring services for chronic diseases in routine operation. The specific focus of this work was placed on patients suffering from cardiovascular diseases and diabetes mellitus.

The basic requirements of the intended mobile phone based patient terminal concept can be summarized as follows:

- A secure and easy-to-handle logon procedure should guarantee for authenticated access to the backend system to securely transmit acquired health parameters and receive reminder or feedback messages.
- The implementation of the patient terminal should be based on an adequate technical solution for interrogating measured data without difficult manual interaction.
- The patient terminal should provide one consistent solution to acquire all kinds of health-related data (measured data and subjective information) triggered by a simple action.
- The patient should have full authority in terms of data acquisition to be able to decide which data should be sent to the doctor and at what time this action should occur.
- Unique identification of patients has to be realized to guarantee unequivocal mapping of data and patient records and thus, to enable multi-user operation with a single set of sensor devices.
- The system architecture of the patient terminal has to be designed with respect to usability for both patient and maintaining staff. Plug and Play connectivity and OTA configuration should ensure for easy installation and maintenance.

2 Methods

In the following section the development process of a patient-centered telemonitoring system and its evaluation are presented.

The starting point was an analysis of several medical sensor devices to point out the requirements for integration into an NFC and mobile phone based telemonitoring system. In the following, a basic hardware platform was developed and combined with further hardware and software components to create a patient terminal. This patient terminal concept was then connected to a telemedicine platform to be used and evaluated in several telemonitoring projects.

2.1 Technical Evaluations and Developments

2.1.1 Survey of Device Communication and Integration

Before designing and developing a communication infrastructure to integrate medical sensor devices into a telemonitoring system the following devices were used to identify the individual requirements regarding communication and allover integration:

- Wrist blood pressure meter (boso medicus PC3, BOSCH + SOHN GmbH, Jungingen, Germany)
- Digital blood pressure monitor (UA-767Plus BT, A&D Medical, Tokyo, Japan)
- Personal body weight scales (UC-321PL, A&D Medical, Tokyo, Japan)
- Blood glucose meter (OneTouch Ultra II, Lifescan, Milpitas, CA, USA)
- Blood glucose meter (Precision Exceed, Abbott Laboratories, Abbott Park, IL, USA)
- Spirometer (Spirotel, Medical International Research, Roma, Italy).

Each device was analyzed in terms of communication interface, data format, protocol, and user interface.

The following tools were used to record, analyze, and reproduce the communication protocol of the given devices:

- USB to UART cable (TTL-232R, Future Technology Devices International Limited, Glasgow, UK) [70]
- device interrogation software (DiabAss, mediaspects GmbH, Konstanz, Germany) [71]
- terminal software (HTerm, developed by Tobias Hammer) [72]

- Serial interface analysis software (Free Serial Port Monitor, HHD Software Ltd, London, UK) [73]
- An online hexadecimal-binary converter tool [74].

2.1.2 **Device Interface Development**

To realize touch-based data acquisition from medical devices, two different types of hardware platforms have been designed and developed. Both platforms were based on wireless technologies such as RFID, NFC and Bluetooth and have been manufactured by handcraft to be integrated into or be externally connected to a medial sensor device.

2.1.2.1 KIT 1.0 Hardware Platform

An NFC communication module was designed and developed to act as a wireless data interface between the medical sensor device and an NFC-enabled AHD. A generic design was chosen to provide an all-purpose interface for integration into various sensor devices. The developed hardware was based on the NFC transceiver chip PN531 (NXP Semiconductors, Gratkorn, Austria) and a common microcontroller (µC) (MSP430F123, Texas Instruments, Dallas, TX). The NFC Chip is a digitally-controlled NFC modem for contactless communication at 13.56 MHz. The implemented communication stack operated by an integrated 80C51 core is able to handle ISO14443A and MIFARE RFID products as well as the NFC IP-1 peer-to-peer protocol compliant to ISO/IEC 18092 and ECMA-340 standards [75]. The µC is a low-power 16-bit reduced instruction set computer (RISC) type microcontroller designed for battery powered applications. It provides a broad range of interfaces, various general purpose in- and output lines, eight Kbytes of program memory, as well as 256 bytes of random-access memory (RAM) and runs at a maximum clock rate of eight MHz [76].

Both core components were assembled onto a 25 x 35 mm sized printed circuit board (PCB) pictured in Figure a. This PCB offered 24 connector pins to be connected to a power supply (2 pins), a JTAG programming interface (8 pins), a separate antenna (5 pins), and a serial data interface (2 pins) of a sensor device. Furthermore, three digital input, two digital output, and two analog pins have been considered.

The NFC transceiver chip was equipped with an external matching circuit to drive the external antenna in an optimized way. The antenna was designed as a five-layer PCB with two opened shielding layers at the top and bottom, two isolating layers, one layer for the flat coil. The coil has a symmetric design and consists of six crossed turns with a grounded tapping between turn three and four. The antenna (Figure b) was connected to the NFC module through five connections pins (shield, antenna, tapping, antenna, and shield).

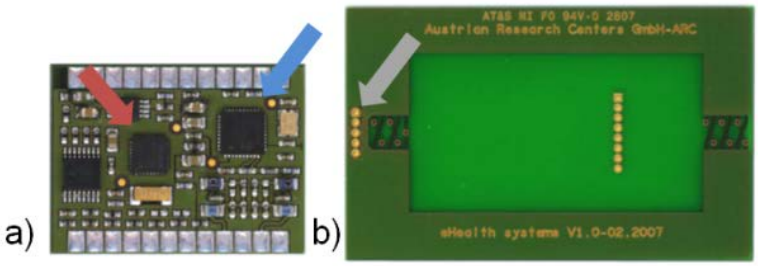

Figure 3: a) A printed circuit board with NFC transceiver chip (PN 531, blue arrow) and microcontroller (MSP430F123, red arrow); b) Separate antenna with five connection pins (gray arrow).

Depending on the given sensor device, the NFC module has been assembled with the antenna in various combinations and embedded directly into the device's housing or fitted in a separate box to be connected externally. To be able to interrogate the data from the variable sensor devices, the module's hardware interface as well as the software have been adapted individually (see results section).

Depending on the installed firmware, the developed NFC module allowed providing data to the mobile phone in two different ways:

- usage of RFID tag as intermediate storage
- peer2peer communication with mobile phone.

Both solutions required the user to hold the mobile phone in front of the sensor device or external box as long as all data were read. In order to enable the mobile phone to launch the installed software application automatically, the RFID tag-based solution was used in the majority of cases. Using a peer2peer communication required the application to be launched previously. Additionally, this method was not compatible with every NFC-enabled mobile phone available during development phase.

2.1.2.2 KIT 2.0 Hardware Platform

Subsequently to the KIT 1.0 communication concept, a new version called KIT 2.0 was designed to acquire a huge amount of data over a larger distance not limited by the operation range of NFC technology. The intention was to initiate the transmission process in the same simple way as known from pure NFC by bringing both devices, the mobile phone and the KIT 2.0-enabled sensor device, close together.

In this concept, NFC and Bluetooth technologies were combined in a way that NFC was used to activate Bluetooth and to setup the connection link by exchanging the required pairing information. After this process both devices can be separated again and communicate to each other via the Bluetooth link that was established automatically. This concept requires the use of a mobile phone with both NFC and Bluetooth capabilities.

The KIT 2.0 communication module was based on the following core components and realized by linking them as shown in Figure . The program execution of the firmware running on µC and the resulting communication flow are provided in the result section.

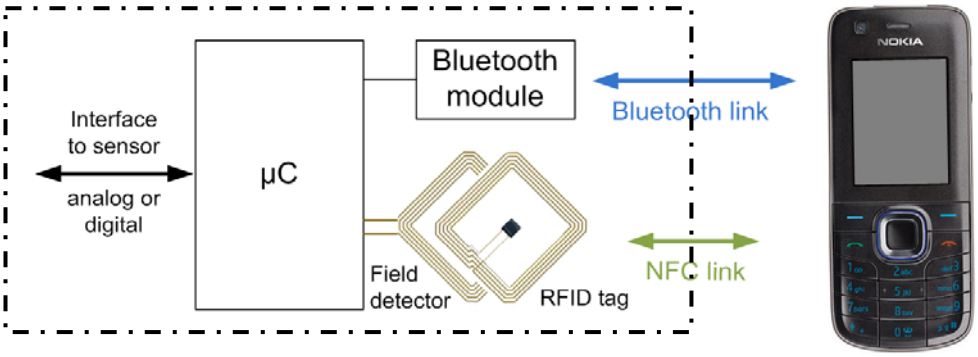

Figure 4: Components to automatically establish a Bluetooth connection via NFC by bringing a mobile phone close to a sensor device. The KIT 2.0 communication platform (framed area) consists of a microcontroller (µC), a Bluetooth module, an RFID tag, and a field detector.

a) Bluetooth Module

The BNC4 (Amber Wireless, Cologne, Germany) [77] is an embedded Bluetooth module according to Bluetooth 2.0 specification with an integrated antenna and a UART interface for communication (Figure). It supported the Serial Port Profile (SPP) allowing data transmission in transparent mode. It was either configured to operate in this mode as a slave item or it was switched off totally. This module optionally supported authentication and encryption by setting a PIN code. This option was disabled in order to avoid entering a PIN code on the opposite device.

Figure 5: Bluetooth module.

b) RFID Tag

The essential data required to establish a Bluetooth connection to the specific module were stored on an RFID tag (MIFARE Classic 1K, NXP Semiconductors, Eindhoven, Netherlands) [78]. These data were the module's MAC address and the name of the desired service (Table 1), which were encoded in an NDEF message type that could be read by the mobile phone.

Table 1: Data stored on an RFID tag needed to establish a Bluetooth link.

Parameter	Value
MAC	5E050DB7DAF2
Service name	COM1

c) Field Detector

The purpose of the field detector was triggering the system to activate the Bluetooth module after recognizing the NFC field of a nearby mobile phone. The designed field detector consisted of a coil with a few turns of copper and provided the induced voltage to an interrupt-capable input pin of the microcontroller. This coil was located close to or congruent with the RFID tag to recognize when the RFID tag was read by the mobile phone.

d) Microcontroller

A µC (MSP430F2410, Texas Instruments, Dallas, TX, USA) [79] was utilized as a core component. This type of µC is similar to the chip used in the KIT 1.0 NFC module, but provides more analog input pins and two independent operating universal serial asynchronous receive transmit (USART) modules. Furthermore, it includes 56 Kbytes of program memory plus four Kbytes of RAM and runs at a maximum clock rate of 16 MHz. This µC was connected to the Bluetooth module and the field detector. The hosted firmware consisted of a communication stack and the main application on top of it. The stack managed the Bluetooth communication and handled the trigger events generated by the field detector. The main application was able to use analog and digital inputs to get data from a connected sensor device.

2.2 **Telemonitoring System – Components and Infrastructure**

2.2.1 **Patient Terminal**

A patient terminal concept based on mobile phones and NFC technology was designed and developed in order to meet the requirements of high usability and security. This patient terminal allowed for intuitive interaction and acquisition of health parameters simply by touching objects and sensor devices. The following components were used to create the touch-based patient terminal setup:

2.2.1.1 Application Hosting Device

A mobile phone with NFC capabilities was used as an AHD. A Java 2 Micro Edition (J2ME, Oracle, Redwood City, CA) [80] software application was developed and adapted to run on one or more of the following NFC-enabled handsets as shown in Figure :

- Nokia 3220 with separate NFC shell (Nokia, Espoo, Finland)

- Nokia 6131 NFC
- Nokia 6212 classic
- Nokia 701
- GT-S5230N (Samsung Electronics, Suwon, Gyeonggi-do, South Korea).

Figure 6: Overview of NFC-enabled mobile phones: a) Nokia 3220, b) Nokia 6131 NFC, c) Nokia 6212 classic, d) Nokia 701, e) Samsung GT-S5230N.

The developed software application called MobileMonitor used the Java Specification Request (JSR) 257 (Contactless Communication API) for accessing the mobile phone's NFC interface. For communication via Bluetooth the JSR 82 (Java APIs for Bluetooth) was utilized. The application was developed in a generic design to be used in different telemonitoring scenarios. Therefore, it was based on a configurable workflow engine to provide an individual data acquisition procedure depending on the range and combination of data to be collected.

A graphical user interface guided the patient through the data acquisition process. This process was initiated by touching a contactless smart card (see 2.2.1.2) acting as patient-specific token for identification and authentication. This touch gesture led to automatic application launch. Following this, the patient had to enter a set of health parameters. Entry of health parameters was carried out by touching KIT-enabled sensor devices and smart icons (enabled with RFID tags, see 2.2.1.3). In addition to touch-based data acquisition, the patient was able to enter partly the same data (blood pressure, body weight, and blood glucose) manually. Other data could only be entered manually (insulin dosage, bread units, and comments).

Acquired data were aggregated and stored on the mobile phone. They were synchronized with the remote telemedicine platform via mobile Internet connection. Depending on the configured workflow, the application synchronized the data automatically after the patient had performed the last step or waited until he/she had touched the ID card again which triggered this process at any step.

Figure shows the application running on a Nokia 701. The display shows the main data entry menu for patients suffering from diabetes. In this case, the data acquisition process is configured in an open and non-predetermined workflow.

Figure 7: Nokia 701 with running MobileMonitor: green checkmarks indicate that data have been acquired and are ready for synchronization.

2.2.1.2 Patient ID Card

A contactless smart card type Mifare Classic 1K (NXP Semiconductors, Gratkorn, Austria) was used as a security token to identify the patient and authenticate access to the telemedicine platform. The card was programmed with a special record according to the NFC Data Exchange Format (NDEF) specified by the NFC Forum. Touching this card with the mobile phone resulted in an automatic launch of the installed J2ME application. This record included the following data for accessing the user interface for data acquisition and reading messages:

- User ID (seven characters)
- Encryption key (five ciphers).

Data could be read by accessing the smart card's memory using the NDEF standard key (Key A = D3 F7 D3 F7 D3 F7, hex). Write access was inhibited by using a private key (Key B).

The ISO7816 format-compliant plastic card (Figure) with an inlayed RFID transponder was printed with a project-specific logo, the user ID phrase, and two fields to which the patient's first and last name could be written manually.

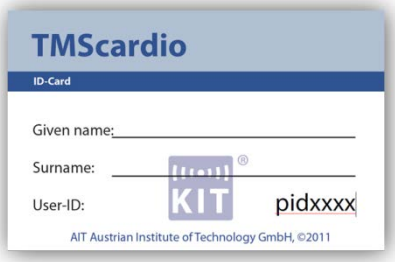

Figure 8: Patient ID card.

2.2.1.3 RFID Dialogue Book

A symbol-based patient questionnaire concept was designed for answering questions displayed on the mobile phone. Instead of using the mobile phone's curser, the user was asked to touch the appropriate symbols on the icon table with the mobile phone. A foldable icon table has been printed with several 50 x 50 mm sized icons. An RFID tag was stuck underneath each icon, which electronically stored the meaning of the respective icon.

Depending on the indication and the resulting questionnaire, the following icons have been used:

- Three icons with the meaning "good", "medium", and "bad" have been placed to indicate the current well-being state.
- One of up to eight icons showing different sports could be touched to document performed physical activities.
- Up to five icons representing a gradient from very low to very high were used to indicate the intensity of a performed activity.
- Four icons with the meaning "yes", "no", "more", and "less" were used to answer questions related to the intake of prescribed medication. These icons were also used generically to answer typical yes / no questions displayed on the mobile phone.

In Figure , an example of the dialogue book is shown. It was made of coated cardboard with four foldable leaves (one for holding the user ID card and three for keeping the RFID tags and icons). This specific version was used for patients suffering from chronic heart failure and pulmonary arterial hypertension.

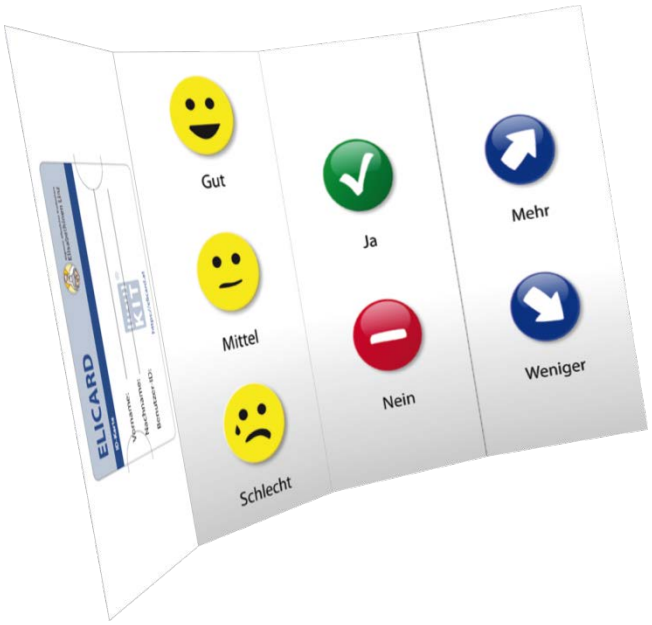

Figure 9: A dialogue book with icons and RFID tags to be touched for answering questions displayed on the mobile phone. The yellow icons were used to indicate the well-being state or subjective pulmonary functions (good, medium, and bad), the meaning of the green, red, and two blue icons was yes, no, more, and less, respectively;

2.2.1.4 KIT Devices

Based on the results obtained from the survey (see section 3.1.1), the following medical sensor devices were selected to be equipped with the KIT 1.0 or KIT 2.0 technology:

a) Blood Pressure Meter

Based on the existing digital blood pressure monitor UA-767 (A&D Medical, Tokyo, Japan) that provided an internal connector with UART interface, a new version featuring the KIT 1.0 interfaces was developed together with original manufacturer. The new device was called UA-767Plus NFC (Figure a) and has been certified as a medical product. For this purpose the KIT 1.0 NFC module (including antenna) shown in Figure b was prepared to be easily integrated into this meter device.

Figure 10: KIT-enabled blood pressure meter UA-767Plus NFC (a) and NFC module with antenna and connector (b) for easy integration.

The module was linked to the meter's internal connector and placed right next to its display (Figure 2 a). An RFID tag (MIFARE Classic 1K, NXP Semiconductors, Eindhoven, Netherlands) was stuck underneath the enclosure's front plate to be congruent with the module's antenna (Figure 2 b).

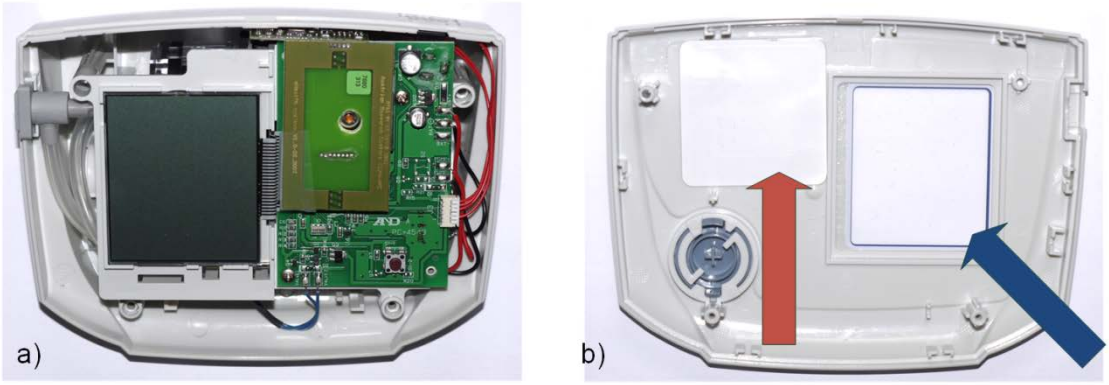

Figure 2: (a) An opened blood pressure meter with an integrated NFC module and (b) the inner side of the cover plate with the RFID tag (red arrow) and display window (blue arrow).

After a successfully performed measurement, a data packet containing the recently measured systolic and diastolic blood pressure and the heart rate was automatically sent via UART to the NFC module. The data were converted and extended by an up counting session identifier (see 3.1.2.1) and written to the memory of the attached RFID tag. Each time a new measurement was performed, the recently written data were overwritten by the current data set.

b) Body Weight Scales with a KIT Box

The 3.5 mm jack bush of the digital body weight scales UC-321PL (Figure 3 a) was used to connect an external KIT box (Figure 3 b).

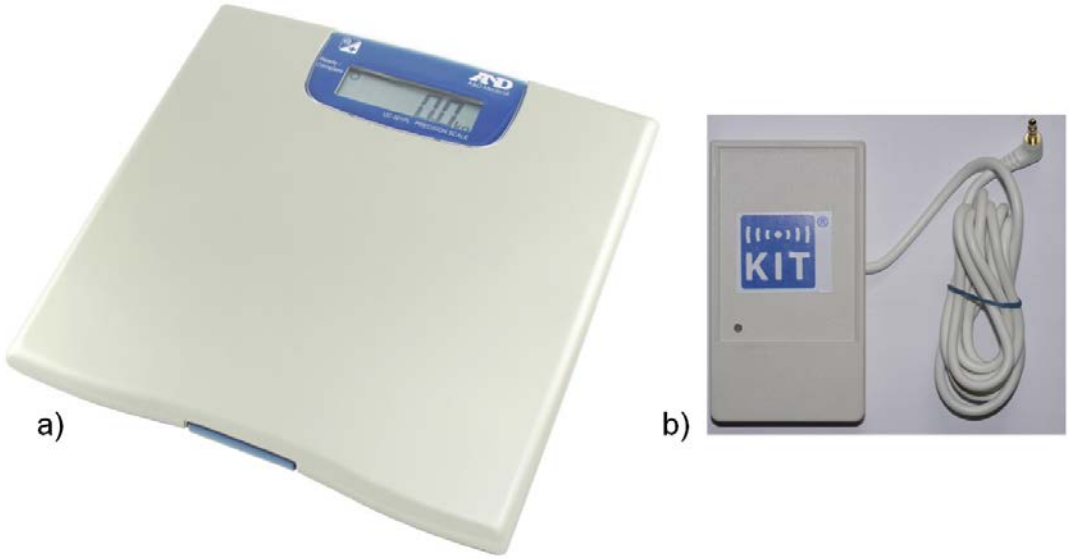

Figure 3: Body weight scales UC-321PL (a) and KIT box (b) to be connected via cable.

This KIT box was based on the following components shown in Figure 4:

- hand case (104 x 57 x 18 mm) with included battery compartment (2x AAA)
- KIT 1.0 NFC module with antenna
- RS 232 to UART level converter circuit
- bicolor LED (red, green)
- RFID tag

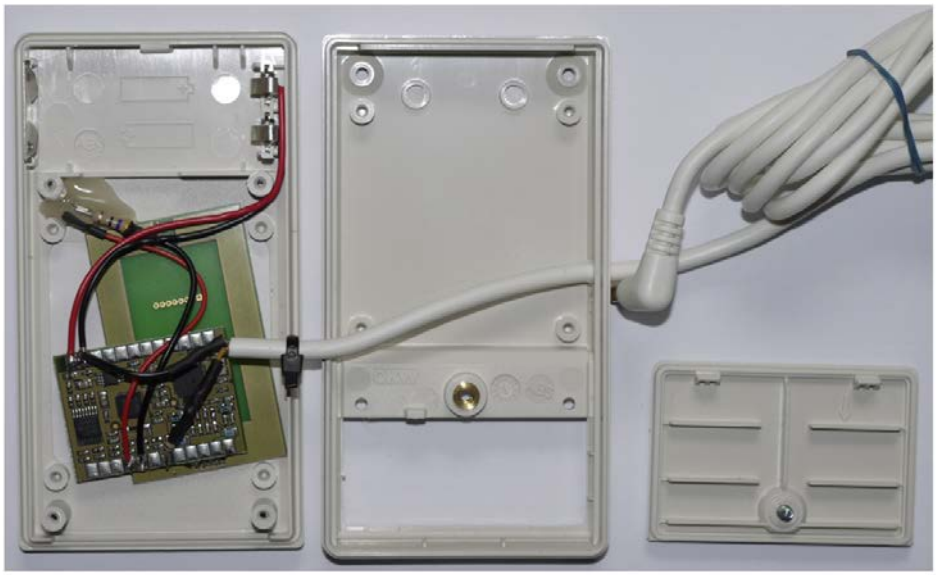

Figure 4: An opened KIT box with an integrated NFC module and RFID tag.

A cable (120cm long) with three leads was fixed to the KIT box. It was connected to the body weight scales via a 3.5mm jack. After measuring the body weight (initiated by triggering the device's button) the displayed value was sent to the KIT box automatical-

ly in a proprietary format. The NFC module converted those data, extended them by a session identifier and wrote them onto the RFID tag by overwriting the most recent record. During the measurement and “write to RFID tag” state, the LED was lit up green. Afterwards, the light turned off automatically. In case of a red blinking LED, the device indicated weak battery condition.

c) Blood Glucose Meter With KIT Box

The 3.5 mm jack bush of the OneTouch Ultra II blood glucose meter offers a bidirectional UART interface for interrogating the meter’s memory by the means of a request-response-communication protocol. This interface was used to connect an external KIT box (shown in Figure 5 a) to wirelessly link the meter to an NFC-enabled mobile phone. This KIT box was designed especially for this version of the body weight scales and has been manufactured prototypically (Figure 5 b) based on the following components:

- hand case (60 x 35 x 15 mm)
- battery compartment for three AAA batteries (54 x 37 x 15 mm)
- DC/DC converter (1.5 - 5.5 V to 3.3 V)
- KIT 1.0 NFC module, separated antenna (mounted outside of the enclosure)
- Bicolor LED (red and green)
- Push button
- RFID tag.

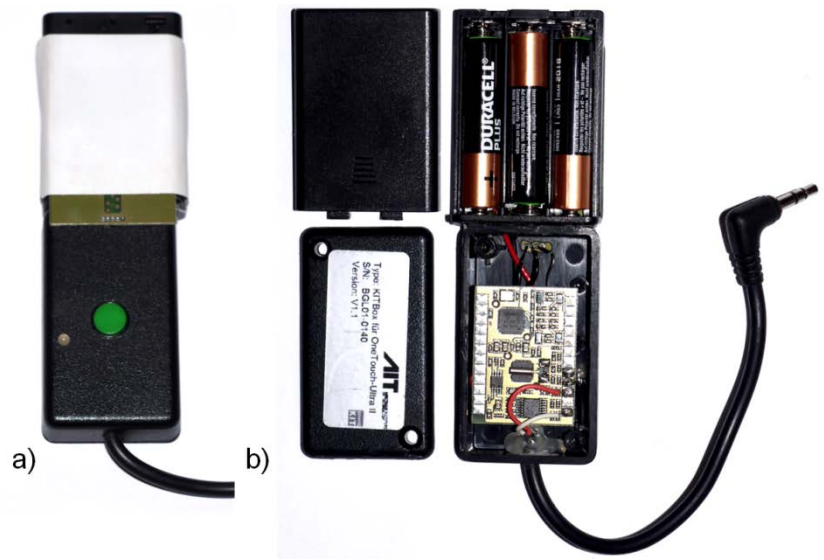

Figure 5: Front (a) and rear view of opened of KIT box for blood glucose meter.

The KIT box was inserted into the meter’s bag and connected to the meter by means of a three lead cable (12cm) with a 3.5 mm jack (Figure 6).

Figure 6: Bag with inserted blood glucose meter OneTouch Ultra II and connected KIT box.

After performing one or several measurements, the user had to push the push-button which led to a wakeup of the NFC module. It started to interrogate the meter's memory and the LED lit up red. It was able to receive up to 35 data sets consisting of blood glucose level and corresponding time stamp. These data were encoded and written in ring buffer format onto the RFID tag (see 3.1.2.1 b). After writing the new data onto the RFID tag, the NFC module sent a command to delete the meter's memory. Afterwards, the LED lit up green for 10 seconds to indicate that data could be read by the mobile phone. As soon as the LED turned off, the NFC module turned to standby mode and remained so until the button was pushed again. If the LED didn't light up green, but blinked red the device indicated a weak battery condition.

d) CardioMonitor

The CardioMon™ (Medifina Medizinprodukte-Vertriebs GmbH, Vienna, Austria) is a mobile medical device (Figure 7) for measuring a range of parameters of the cardiovascular system. This non-invasive haemodynamic monitor uses a conventional upper-arm blood pressure cuff to measure the patient's systolic and diastolic blood pressure and heart rate using the oscilometric method [81]. In the course of a second measurement cycle, the device records several peripheral pulse-waves and uses a neural network-based mathematical algorithm to calculate the aorta pulse wave, stroke volume, total peripheral resistance and augmentation index.

Figure 7: Picture of CardioMon™.

In case of this device, integration of the KIT 1.0 communication module was carried out in collaboration with the corresponding developer team. The NFC module was connected via UART interface and embedded into the meter's enclosure. The communication protocol and the data format were defined to transmit the complete data set of a single measurement to the NFC module automatically right after the measurement was finished. These data comprised of six 3-digit American Standard Code for Information Interchange (ASCII) strings for systolic and diastolic blood pressure, heart rate, stroke volume, total peripheral resistance, and augmentation index as well as two 100 byte-arrays accumulating the measured peripheral and the reconstructed central blood pressure curve. Data were written onto the RFID tag without further conversion. As soon as the NFC module finished writing the data onto the RFID tag, the CardioMon's buzzer sounded to indicate that data can be interrogated by the mobile phone.

e) Blood Pressure / ECG Monitor

A sensor device was created that allowed for concurrent measurement of blood pressure and recording of ECG signal. It was equipped with the KIT 2.0 communication platform to allow for real-time streaming of ECG data.

Therefore, an ECG signal amplifier was developed prototypically. It was based on the AD620 (Analog Devices, Norwood, Massachusetts, USA) and a second order band pass (0.2-125 Hz) to filter the signal. A driven right leg circuit was used to reduce common mode interference. The analog signal was amplified by 1400 and connected to one of the analog input pins of the µC of the KIT 2.0 communication module. Thus, the µC recorded a single channel ECG signal (e.g. Einthoven I) with a resolution of 8-bit at a sampling frequency of 250 Hz. All components have been assembled onto a 45 x 60 mm PCB which was fitted inside the enclosure of a third-party blood pressure meter. The UA-767 (Figure 8) known from first development (2.2.1.4 a) was used because of the existing UART interface. Three metallic dry electrodes were connected to the PCB and fixed on the meter's rear side. They have to be touched with the fingertips of the left and right forefinger as well as the right middle finger (reference electrode).

A link between the µC and the blood pressure meter's main board was used to automatically start a measurement by emulating the meter's start button. One of the µC's UART interfaces was connected to the blood pressure meter's serial interface. After a successfully performed measurement, the µC automatically received a few bytes of data containing the recently measured systolic and diastolic blood pressure and the heart rate.

The RFID tag (programmed with the pairing information of the respective Bluetooth module) and the antenna for the field detector were attached to the inner side of the meter's cover plate. A bicolor LED was integrated to indicate the system's state. If the LED illuminated green, the system was switched on and waited for a connection. Red indicated that a connection has been established.

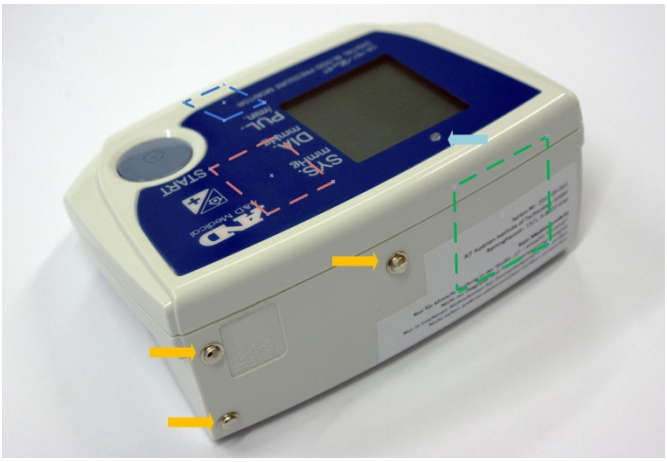

Figure 8: Modified blood pressure meter with three electrodes (orange arrows), integrated microcontroller with ECG amplifier (green square), Bluetooth module (blue square), RFID tag with field detector (red square), and light emitting diode (light blue arrow).

2.2.2 **Telehealth Platform**

The developed patient terminal setup was linked to a Web-based telehealth platform by means of mobile Internet technology and SMS services. This system was designed to serve for electronic Patient Reported Outcomes (ePRO) studies with a simple data capture process (acquire, forward, and store) as well as for closed loop telemonitoring applications with involvement of professionals and use of feedback channels.

The system was based on a basic core framework, independent modules for providing further services, and a number of interfaces for connecting remote clients to the core framework and vice versa. Figure 9 shows the architecture of the telehealth platform, the components of which are described in the following sections.

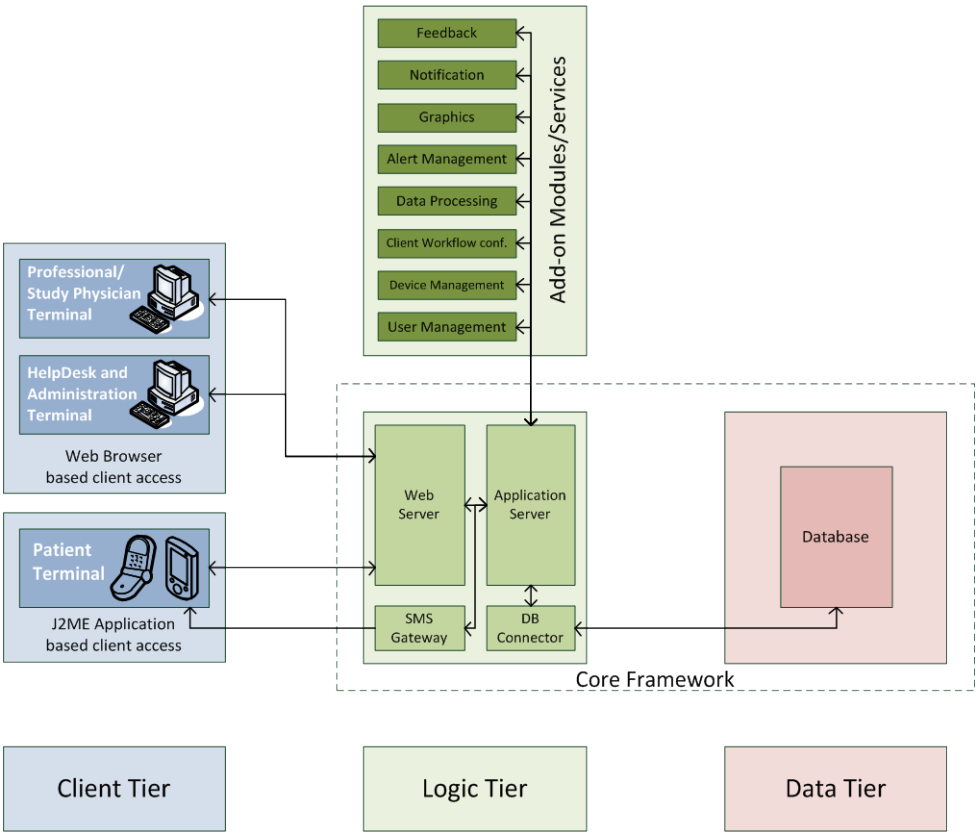

Figure 9: Overview of the three-tier system architecture consisting of client, logic, and data tiers.

2.2.2.1 Core Framework

The core framework was developed as part of a three-tier client-server architecture using state of the art Internet technology. The Zope web / application server (Zope 2.11.3, Zope Corporation, USA) [82] was responsible for basic business logic and data representation while the relational database system (PostgreSQL 9.0, PostgreSQL Global Development Group) [83] was used for persistent data storage.

2.2.2.2 Modules

Additional modules and services were developed to provide further particular functionalities. By means of a service-oriented architecture (SOA), services were able to communicate with each other. Depending on the final use case (ePRO studies or closed loop telemonitoring application) the following modules and services were connected to the core framework. The goal of this concept has been to provide a flexible and easy-to-setup telehealth platform for different applications, which after deployment are easy to use for patients and physicians and easy to maintain by the helpdesk and administration staff.

User Management

This module provides functionalities for managing user hierarchies with groups, roles, and rights, for registering new users or deleting them, and for setting or resetting new or forgotten passwords.

Device Management

All tasks related to patient devices were managed by an independent module. It allowed managing the pool of available devices consisting of mobile phones, SIM cards, user ID cards, and monitoring devices. Items could be assigned to users and mobile access was enabled or disabled with this service. This module additionally provided functions such as remote application wipes or log file requests.

Client Workflow Management

This module allowed selection of parameters to be acquired by the patient and configuration of the data acquisition workflow. This configuration also included the setup of the questionnaire asked by the MobileMonitor.

Data Processing

An automated event detection algorithm analysed received monitoring data immediately and compared them with the given thresholds. Algorithm parameters (thresholds, trends, time intervals) could be adjusted individually. If an off-limit condition was identified, an event was generated and forwarded to the alert management module.

Alert Management

This module provided the physicians with an event list showing all open events generated by the event detection algorithm. Events are deleted from the list after acknowledging, followed by inspection of the corresponding monitoring data. The events were categorized into off-limit condition, missing values, and weekly check.

Notification

If an event occurred that needed a reaction by the physician or the helpdesk, a message was sent to the corresponding person via email or text message (SMS). This module was also triggered if a patient was due to send his/her data. In this case, a reminder text message was generated and sent to the patient’s mobile phone.

Feedback

A rule-based feedback engine (Drools, JBoss, Atlanta, GA) [84] running on a separate application server (Tomcat 5.5, Apache Software Foundation, Delaware) [85] analyzed the monitoring data and generated text-based feedback messages to be sent to the patient after being approved by the physician.

Graphics

Static graphical data representation was generated by ChartFX (Software FX, Boca Raton, FL, USA) [86]. Images were generated in real time when requested by the client.

Interactive graphical representation of data was established by a Java applet, which was developed in the course of a diploma thesis [87].The full data set was downloaded to a separate browser pop-up window, and then the user was able to navigate through the chart by means of scrolling and zooming.

2.2.2.3 Client Interfaces

The telehealth platform provided a series of Web interfaces for accessing the system from outside and for interacting with remote clients initiated by the system itself.

Browser-based Web Interface

This interface provided authenticated access to the system via a standard PC and a Web browser. It was the primary interface for professionals and the helpdesk for viewing or editing patient data or managing devices. In a few cases it was also used by the patient him/herself for entering health parameters or reading feedback.

Mobile Upload Channel

This data interface was used for managing synchronization of acquired data between the MobileMonitor and the telehealth platform. It was based on a TCP/IP connection over GPRS, EDGE, UMTS, or HSDPA. Transmission was initiated by the patient after the data acquisition process. Data transmission was encrypted using SSL and had to be authenticated using the user ID card. If data could not be sent, they were stored locally to be synchronized next time.

Notification / Feedback Channel

This channel was based on two mobile technologies: text messages and mobile Internet services. Notification messages to be sent to physicians or the helpdesk, or reminder messages for patients without sensitive information were sent via SMS. If a feedback message containing sensitive information had to be delivered to the patient, the second part of this channel was included. The message was transmitted securely by downloading it via the MobileMonitor after it was triggered remotely through an SMS. This channel was also used to indicate that the medication prescription had been changed.

MobileMonitor Setup / Maintenance Channel

This channel was also based on SMS and mobile Internet. An SMS sent by the device administration module triggered one of the following tasks:

- Reset itself
- Get a new password
- Send a log file
- Download a new configuration.

Apart from the “reset” command SMS, the MobileMonitor automatically opened a data connection to transmit or receive the respective data. This channel was used in conjunction with the device administration and client workflow management module during handout of the devices, in case of a configuration update (medication change), or when the patient informed the helpdesk about problems with the MobileMonitor.

2.2.3 **Professional and Study Physician Terminal**

After authentication, professionals or study physicians were able to connect to the telemedicine platform using a standard PC with a Web browser. Depending on their role and corresponding rights, they were able to register new patients, edit monitoring parameters, enter anamnesis data, prescribe medications, and view event lists, monitoring data and charts. An input mask allowed entering notes regarding the current state or treatment changes or sending messages to the patients as well as the helpdesk.

2.2.4 **Helpdesk and Administration Terminal**

Also the helpdesk was able to access the telehealth platform via PC and Web browser. This role enabled viewing the same data as presented to the professional. In addition to this, the helpdesk was able to manage the devices in terms of assignment, setup, and maintenance.

2.3 **Evaluation and Use**

The developed system was verified and validated in several laboratory surveys, clinical trials, and telemonitoring applications. Table 2 gives an overview of different scenarios of evaluation and use which are described in the following.

Table 2: Overview of scenarios, used technical concept, devices and user groups. (used abbreviations: MP: mobile phone; BPM: blood pressure meter; ID: ID card; BWS: body weight scales; DB: dialogue book; BGM: blood glucose meter)

Category	Technology	Aim	Used components	User group	Related publications
Laboratory evaluation	KIT Prototype	Feasibility	MP, BPM	Students	**C7**
	KIT 1.0	Usability	MP, BPM	Adults and the elderly	**P3**
	KIT 2.0	Performance	MP, BPM with ECG	Technicians	
Clinical trial	KIT 1.0	In-clinic EDC	MP, ID, CardioMon®	Heart failure patients (inpatient treatment)	**C5, C6**
	KIT 2.0	Feasibility and usability	MP, ID, BPM with ECG, BWS, DB	Heart failure patients (at home)	**P1, P2**
Proof of concept	KIT 1.0	Routine monitoring of CHF patients	MP, ID, BPM, BWS, DB	Heart failure patients (at home)	**A1**
	KIT 1.0	Routine monitoring of diabetes patients	MP, ID, BGM, BPM, BWS, DB	Diabetes patients (at home)	**A1**

2.3.1 **Laboratory Evaluation**

2.3.1.1 Feasibility Test of the KIT 1.0 System

The first feasibility evaluation was conducted based on a blood pressure monitor (BOSO medicus PC2, BOSCH + SOHN GMBH, Jungingen, Germany) with prototypically implemented NFC interface. This prototype was able to provide the data to an NFC-enabled mobile phone (Nokia 3220, Nokia, Espoo, Finland) as part of an URL. The mobile phone was able to read this URL without a specific software application and automatically launched the browser that uploaded the recent measured data to a remote database by sending an HTTP get request. Students of a health-care-management course were asked to perform measurements and to transmit the values to the telehealth platform. The purpose of the survey was to quantify and compare the following three types of mobile phone based data acquisition and transmission:

- WAP browser
- Manually operated J2ME application
- Automated data acquisition using NFC technology.

The survey was conducted in a controlled environment according to the following protocol:

1. Prepare the mobile phone for use as a patient terminal. In case of WAP technology, the Web address has to be entered and stored as a shortcut. When using a J2ME-based software application, the program file(s) had to be downloaded and installed first. In case NFC was used, no further preparation was necessary.
2. Put on the cuff and perform a blood pressure measurement. Afterwards, the displayed values have to be transferred to the mobile phone by entering the numbers via the keypad (WAP and J2ME) or by touching the device (NFC).
3. Start data upload to the remote database by the means of pressing the “OK” button and wait until the system has acknowledged a successful transmission, indicating that the values were successfully stored on the web-based database.

Each student had to test each method (WAP, J2ME, and NFC) to transmit at least one dataset to the monitoring center. Before testing each method, the students had to weigh the following general user requirements according to their individual appraisal from 0 (not relevant) to 100 (very important):

- easy to learn and use
- feasibility for feedback
- single, integrated solution
- privacy
- availability of service
- reliability of service
- low cost.

Subsequently, the students had to rate each requirement from 1 (don’t agree) to 5 (strongly agree) for all three methods. The rating was set to 0 in case of a certain method didn’t support a given requirement.

“The overall quantifier for each requirement and method was estimated by multiplying the averaged weight value by the averaged rate value. Results were presented as mean +/- SD. To assess the significance of differences between the methods statistically, the Friedman – Test was used. P < 0,05 was considered to be statistically significant.”

Further details have been published in [**C7**]

2.3.1.2 Usability Test of the KIT 1.0 System

After initial feasibility tests based on the prototype blood pressure meter and the Nokia 3220 NFC phone, the system was redesigned. The new concept was based on the dedicated software application (MobileMonitor) running on the mobile phone (Nokia 6131 NFC) and a new data exchange format between blood pressure meter and mo-

bile phone. To evaluate the usability of this system in a representative patient group, a small batch series of blood pressure meters (UA-767Plus NFC) was manufactured. The devices were given to persons older than 40 years. Participants had to use the two components to acquire their blood pressure data and to send them to the telemedicine platform. Users had to perform this task according to the printed instructions as displayed in a user manual. The workflow of the data acquisition procedure is shown in Table 3.

Table 3: Data acquisition workflow in usability test.

Step	Interaction by the user	Behavior of the mobile application
1	Measure blood pressure	
2	Touch blood pressure meter with mobile phone	Launch application Next: show read data (5s) Next: upload data (10-30s) Next: show “transmission successful” (5s) Next: close application

It was documented each time whether the user was able to perform the task

- independently with the user manual,
- independently after demonstration,
- with additional help, or
- not at all.

Each participant was asked to complete a questionnaire with general questions regarding usage of mobile phones and self-monitoring of blood pressure.

Further details have been published in [**P3**]

2.3.1.3 Performance Evaluation of the KIT 2.0 System

Prior to the clinical evaluation of the developed blood pressure / ECG monitor based on the KIT 2.0 communication platform, the used components had to be tested to find the best hardware setting for providing high performance with respect to usability.

This evaluation was performed using a prototype device of the developed blood pressure / ECG monitor. The performance test was separated in two parts and dealt with the evaluation of the prototype’s setup and pairing behavior.

1) Detection Test

The two Nokia devices 6131 NFC and 6212 classic with the preinstalled J2ME software application were used to establish a Bluetooth connection to the developed prototype device. The following alignments of the mobile phone for initiating the pairing process were tested:

- vertical, display up (D1)

- horizontal, display up (D2)
- vertical, display down (D3)
- horizontal, display down (D4).

Ten attempts for each device and different alignment were performed. In this test the J2ME application was already running. A successful attempt to establish a Bluetooth connection required both events:

- reading the RFID tag
- triggering of the field detector

The incidence of both events were linked by an AND relation and averaged over ten attempts to calculate the success rate.

2) Cross-over Test

To demonstrate the concept's Plug and Play interoperability, a cross-over test was performed using five different mobile phones and five units of the developed blood pressure / ECG monitor. This test was performed in two separated steps:

- one mobile phone (Nokia 6212 Classic) was used to establish a connection to the five devices one after the other to perform a concurrent acquisition of blood pressure and ECG recording
- five mobile phones (three Nokia 6212 Classic and two Nokia 6131 NFC) were used consecutively to connect to a single blood pressure / ECG monitor device to perform a measurement.

In both cases the pairing list in the Bluetooth section of the mobile phone's menu was checked to verify that the devices were not paired permanently.

2.3.2 **Clinical Evaluation**

2.3.2.1 MOCADI

The first clinical employment of a KIT-based telemonitoring system was in the course of a clinical pilot trial. In this case, it was linked to the telehealth platform acting as an electronic data capture (EDC) system to evaluate CardioMon's feasibility for monitoring various patient groups with specific cardiac disorders. CHF patients who were hospitalized at the Department of Internal Medicine - Division of Cardiology of the Medical University of Graz were asked to participate in this trial. Their cardiovascular parameters were measured using the CardioMon. A study physician performed the measurements twice a day during the in-hospital stay. Data were acquired and transmitted to the telehealth platform using the Nokia 6131 NFC with a preinstalled MobileMonitor. Additionally, data were also documented manually in a patient-specific case report form (CRF) for later comparison. To identify each person, the study physician as well as every patient were equipped with an ID card to be read by the mobile phone during the data acquisition process as summarized in Table 4.

Table 4: Data acquisition workflow as used at the MOCADI trial.

Step	Action by the study physician	Behavior of the mobile application
1	Touch physician's ID card	MobileMonitor launch, authentication of physician Next: ask for sensor data (symbol-based)
2	Put on cuff and start measurement	
3	Touch CardioMon to interrogate the data	Read data and check the CardioMon symbol Next: ask for patient ID
4	Touch patient's ID card	Read ID information and start sending data Next: ask for sensor data
5	Manually document the measured data in a patient-specific CRF	
6	A) repeat the procedure (step 2-5) B) quit by pressing the hang up button	A) same as above B) close MobileMonitor

New patients were registered automatically after touching a new patient ID card. Full registration had to be completed afterwards using the study physician interface (PC with a Web browser).

In case of failure during data transmission, the data were stored locally to be transmitted with the next acquired record. However, all errors related to the data acquisition and transmission process as well as related to the measurement device were documented to determine the system's reliability.

Further details have been published in [**C5, C6**].

2.3.2.2 eT Trial

The KIT 2.0 communication platform and the developed blood pressure / ECG monitor were evaluated in the course of a clinical pilot called eT trial to evaluate a new kind of an "eHealth Terminal" (eT). The study was conducted at the Medical University of Graz and was approved by the corresponding ethics committee (21-283 ex 09/10). Patients have been recruited by study physicians at the Division of Cardiology and signed informed consent, which was obtained from all participating patients. The following criteria led to an inclusion to this trial:

- male or female,
- aged 18-75 years,
- ability to handle the entire telemonitoring equipment, and
- sinus rhythm at inclusion examination.

During the registration process, the study physician entered the past medical history data and performed an ECG recording. Afterwards, the patient received the telemonitoring equipment consisting of:

- patient ID card
- NFC-enabled mobile phone (Nokia 6212 classic)

- KIT 2.0-enabled ECG / blood pressure sensor device
- body weight scale (UC-321PL) with KIT box
- icon table for documenting well-being (good, medium, bad) and medication intake
- step-by-step user manual.

Patients were instructed in using the system by initially observing the trainer in operating the system followed by one assisted data acquisition by the patients themselves. After handout of the telemonitoring equipment and successful training, patients were asked to use the system for a period of one week two times per day according to the workflow illustrated in Table 5 with the following two slightly different usage scenarios:

- morning: sensor device had to be applied to the chest so that the three electrodes contacted the naked skin
- evening: electrodes had to be touched with the fingertips.

Table 5: Data acquisition workflow in eT trial using the KIT 2.0-enabled ECG / blood pressure sensor device.

Step	**Interaction by the patient**	**Behavior of the MobileMonitor**
1	Touch ID card	MobileMonitor launch, user authentication Next: ask for touching sensor device
2	Put on cuff Touch sensor device	Establishes a connection to sensor device Next: ask to contact the electrodes
3	Contact electrodes (fingertips or chest)	Triggers sensor device to perform measurement -> displays ECG signal and quality level while measurement runs Next: ask for body weight
4	Step on body weight scales and touch NFC interface	Read body weight Next: ask for CHF medication
5	Touch one of four icons to confirm intake of CHF drugs (up to 4 times)	Read the tag data of the touched icon (up to 4 times) Next: ask for well-being
6	Touch one of three smiley icons to indicate current well-being	Read the tag data of the touched icon, upload all data and close application

Medical intervention was not intended during the observation period. In case of questions or technical problems, patients could contact the study physician or a technical helpdesk.

“At the end of the seven day observation period, the patients returned the system and attended the final examination where an ECG (12 lead) was acquired using a clinical ECG recorder. To assess individual patient satisfaction, the patients were asked to fill-in a standardized usability questionnaire.

The total number of autonomously performed data acquisitions and the cumulative monitoring period were used to assess overall patient adherence. General user acceptance and usability were assessed by analyzing all individual questionnaires."

Further details have been published in [**P2**].

2.3.3 **Proof of Concept**

After development, evaluation, and modifications, the entire telemonitoring system including the KIT-based patient terminal was considered to be ready for therapy management proof-of-concept projects as a final step of the evaluation before adopting this approach for routine operation.

2.3.3.1 ELICARD

A KIT-based telemonitoring system was setup to run a proof of concept at the Elisabethinen general hospital in Linz, Upper Austria. The system was used to support professionals from the outpatient clinic for cardiovascular disease in treating their patients suffering from Chronic Heart Failure (CHF) and Pulmonary Arterial Hypertension (PAH). The application was registered at the Austrian data protection committee. AIT acted as technical service provider and also provided the helpdesk.

Patients visiting the outpatient clinic as well as those with inpatient treatment who were eligible for participation were registered after signing informed consent. In the course of the registration, the attending physician entered anamnesis data, selected and configured monitoring parameters, and defined the medication to be monitored by the system. A doctor's letter was generated and printed to inform the general practitioner about the treatment supported by the telemonitoring system. Before discharge, the data acquisition procedure using the KIT-based telemonitoring equipment was presented to the patient by the physician. The equipment was comprised of the following components:

- Patient ID card
- NFC-enabled mobile phone (Nokia 6131)
- Blood pressure monitor (UA-767Plus NFC)
- body weight scale (UC-321PL) with KIT box
- pulse oximeter (only for PAH patients)
- dialogue book to document well-being (good, medium, bad) and medication intake and further yes / no questions (see figure 9).

The helpdesk was notified by the system automatically, that a new patient, who needs to be outfitted with the telemonitoring equipment, has been registered. The components were configured and prepared (including a graphical user manual) to be sent to the patient's home via mail service. After an additional explanation by the helpdesk via phone (if necessary) the patient acquired and transmitted his/her health data on a daily basis according to the following workflow (Table 6) with two separate paths.

Table 6: Data acquisition workflow in ELICARD for patients suffering from CHF.

Path	Step	Interaction by the patient	Behavior of the MobileMonitor
1	1	Measure body weight	
	2	Touch ID card	MobileMonitor launch, user authentication Next: ask for touching a device
	3	Touch KIT interface of body weight scales	Read and transmit body weight data Next: close application
2	1	Measure blood pressure	
	2	Touch ID card	MobileMonitor launch, user authentication Next: ask for touching a device
	3	Touch blood pressure monitor	Read blood pressure data Next: ask for CHF medication
	4	Touch one of four icons to confirm intake of CHF drugs (up to 4 times)	Read the tag data of the touched icon Next: ask for next drug (repeat step 4, up to 3 times) or ask for well-being (continue with step 5)
	5	Touch one of three smiley icons to indicate current well-being	Read the tag data of the touched icon, upload all data and close application

Table 6 shows the workflow as defined for patients with CHF. Patient suffering from PAH had to answer additional questions regarding:

- difficulties with breathing
- whether oxygen saturation was below a certain threshold
- whether a laboratory test had already been done
- whether a new prescription was necessary.

These questions were answered by touching the same icons as used in step four and five. If the MobileMonitor was not able to transmit the data due to a lack of mobile connectivity, the data were stored locally to be synchronized next time.

Patients suffering from CHF transmitted their data on a daily basis while PAH patients were asked to perform the procedure only three times a week. Transmitted data were processed once a day by the event detection algorithm to identify off-limit or missing data conditions. The physician acknowledged the individual events after inspection of the corresponding monitoring data. If necessary, the physician could trigger an intervention, which also had to be documented in the system. In case of missing values, the system automatically sent an SMS to the patient's mobile phone to notify that data were due.

In case of malfunction of any system component, the helpdesk at AIT Austrian Institute of Technology was called either by the physicians or the patients themself. If the problem could not be solved remotely by means of sending a "reset"-command via SMS, the faulty device was replaced via mail service.

Further details have been published in [**A1**].

2.3.3.2 DIABMEMORY

The second proof of concept utilizing the KIT-based telemonitoring system was in the course of a medium-scale telehealth project in cooperation with the Austrian Health Insurance Company for Railway Workers and Miners (VAEB) that operated its own health resort. At their stay at this health resort, insured persons were asked to participate in a health program called “Gesundheitsdialog Diabetes”. Patients who had a high risk for diabetes or who already suffered from diabetes received the opportunity to get in close contact with their caregiver and general practitioner to permanently receive reliable and individual medical attention. The remote telemonitoring system called DIABMEMORY was used as a therapy management component for this project. It was provided and operated by AIT and included helpdesk service.

Persons who were willing to participate signed the informed consent and were able to choose between a manually operated Web browser-based user interface using a PC or the KIT-based patient terminal consisting of the following components:

- patient ID card
- NFC-enabled mobile phone (Nokia 6212, Samsung GT-S5230N, or Nokia 701)
- blood glucose meter (One Touch Ultra II) with a KIT box
- blood pressure monitor (UA-767Plus NFC), (optional)
- body weight scale (UC-321PL) with KIT box, (optional)
- dialogue book for documenting well-being (good, medium, bad), activity, and activity intensity.

Components were preconfigured by a technically skilled person and handed out to the patients after the first week of their three weeks stay at the health resort. How to handle the devices was explained in the course of an initial training session immediately after handout. Subsequently, patients were asked to start acquiring their data and had to continue after discharge from the health resort.

Depending on the patient’s underlying disease, an individual data acquisition and transmission scheme was defined. Blood glucose meters were given to anyone, while blood pressure meters and body weight scales were only given to selected patients. Patients suffering from Type I Diabetes were asked to perform three blood sugar measurements per day. Type II Diabetes patients had to perform at least three blood sugar measurements per week. In both groups, blood pressure and body weight had to be measured only once per week (if the respective devices were handed out).

The workflow of the MobileMonitor version for this project was designed in a more flexible way. The procedure of data acquisition (Table 7) was both started and finished by touching the patient ID card. When the application was running, it asked for a few data measurements (blood sugar, blood pressure, body weight, well-being, activity and its intensity). The user interface provided an input field to enter free text comments. Patients were able to decide whether they wanted to acquire only a single parameter per

session or more, by touching up to all items one after each other. The patient decided when to close the data acquisition session by touching the ID card again. This action triggered the MobileMonitor to aggregate, locally store, and upload the data. In case of mobile network blackout, the data were transmitted within the next session.

Table 7: Mobile data acquisition workflow used in the DIABMEMORY system.

Step	Interaction by the patient	Behavior of the MobileMonitor
1	Measure body weight and / or blood pressure and / or blood glucose level	
2	Touch ID card	MobileMonitor launch, user authentication Next: display main menu (symbol-based user interface asks for touching a device or an icon or to enter a comment)
3	Touch KIT interface of device or icon	Read data from device or icon data Next: display main menu
4	[Repeat step 3 as often as necessary]	Read data from device or icon data Next: display main menu
5	[Enter a free-text comment]	Store free-text comment Next: display main menu
6	Touch ID card	Aggregate and transmit all data Next: display “transmission was successful” Next: close application

Patients were able to enter all data manually using the phone’s keypad (Nokia 6212 classic) or the virtual keypad on the touchscreen (Samsung GT-S5230N and Nokia 701). Patients using mobile phones with a touchscreen could use their fingertip to select the icons for well-being, activity, and activity intensity on the touchscreen and did not have to use the dialogue book.

In case of any problem related to software or device malfunction, patients could call the helpdesk at the health resort or a technically skilled contact person at AIT.

Further details have been published in [**A1**].

3 Results

3.1 Device Interrogation and KIT Prototyping

3.1.1 Device Interface Analysis

Different devices were analyzed in respect to their communication characteristics. The detailed analysis, which can be found in the appendix section, revealed a broad variety in terms of interfaces, communication protocols and data formats. Table gives an overview of the investigated devices and compares a set of communication parameters.

Table 8: Comparison of medical sensor devices.
(used abbreviations: VCC = Voltage of power supply, TTL = transistor-transistor-logic)

Device / Type / Feature	boso medicus PC3	UA-767Plus BT	UC-321PL	OneTouch Ultra II	Precision Exceed	Spirotel
Type	blood pressure meter	blood pressure meter	body weight scale	blood glucose meter	blood glucose meter	Spirometer / peak flow meter
Connector	2.5mm jack	internal connector	3.5mm jack	3.5mm jack	slot for test strip	proprietary connector
Leads	3	4	2	3	3	3
VCC support	no	yes (6.0V)	no	no	no	yes (3.0V)
Level type	RS-232c	TTL	RS-232c	TTL	TTL	RS-232c
Baud rate	4800	9600	9600	9600	9600	9600
Framing	8/n/1	8/n/1	8/n/1	8/n/1	8/n/1	8/n/1
Bidirectional	no	no	no	yes	yes	yes
Real time clock	yes	no	no	yes	yes	yes
Memory	yes	no	no	yes	yes	yes
Communication trigger	button pushed	measurement finished	measurement finished	external command	cable connection	external command
Human-readable data format	no	no	yes	yes	yes	no

3.1.2 Use Case and KIT Integration Design

The broad differences in interfaces, communication parameters, and protocols revealed from the survey led to the design and development of two different interface and communication concepts. In the following, both concepts based on the aforementioned hardware platforms (chapter 2.1.2) are presented. The results presented in this section

demonstrate the individual and device-specific characteristics of the firmware and, hence, the user interface and the behavior of the device.

These results can be separated into the following three different scenarios which depend on the device's communication protocol:

- Automatically transmitted single measurement value
- multiple measurement values interrogated from the meter's memory
- Biosignals streamed in real-time during measurement including device control.

The first two scenarios can be handled using the KIT 1.0 hardware platform, while the third use case can only be covered by the KIT 2.0 interfacing and communication concept.

3.1.2.1 KIT 1.0

Based on the KIT 1.0 hardware platform, the following two different application flows were developed to meet the requirements of the use cases when interfacing the devices mentioned above.

a) Automatic Data Transmission

For devices which provided a wake-up signal during activation and sent a single value set automatically after the measurement was performed, the following workflow (Figure 10) was designed and implemented.

In case of unavailable timestamps (i.e. the device only provided the raw measurement value), the firmware application generated a unique session ID to distinguish two sequential measurements with identical value sets. This session ID was then stored on the RFID tag together with the encoded measurement data.

After the initial power-up and initialization process, the firmware application imported the actual session ID stored on the RFID tag and stepped into idle mode. After recognizing the wake-up signal, the system observed the incoming line of the UART module and received the data sent by the device immediately after the measurement has finished. If the received data were recognized as valid, they were encoded and the session ID was incremented. In the following, both data were written onto the RFID tag. As soon as the write process was finished, the system returned to idle mode and waited for the next wake-up signal generated by the measurement device. After this process, which took less than 400 ms in total, the data stored on the RFID tag could be accessed via the mobile phone.

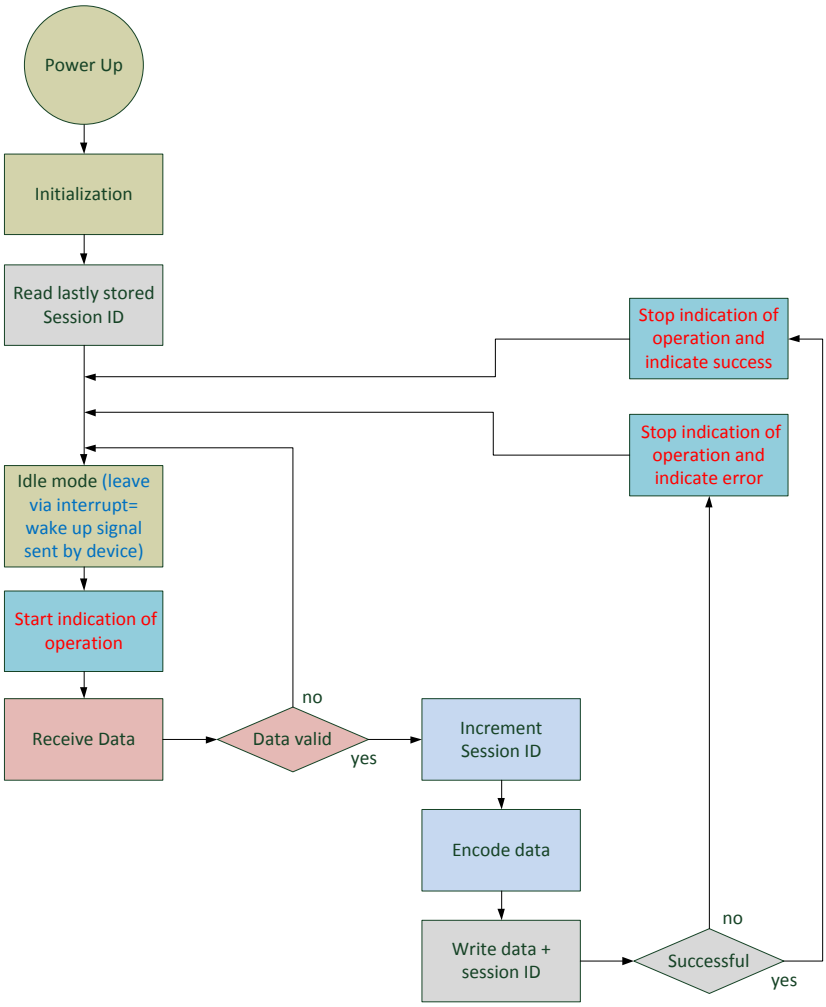

Figure 10: Program flow of KIT 1.0 firmware for treating automatically transmitted single values.

This concept was realized on the KIT 1.0 hardware integrated into the blood pressure monitor UA-767Plus NFC, the KIT box for the body weight scale UC-321PL, and the CardioMon. These devices provided a single measurement value without timestamp immediately after the measurement process was finished.

b) Interrogating Device Memory

For devices which provide an internal memory and a data interface to interrogate the memory via software application running on a personal computer, the following application workflow (Figure) was designed and implemented.

Devices which feature a memory, in most cases also provide a kind of user interface and, thus, the ability for setting an existing clock module. Since the timestamp of the measurement event was stored together with the measurement value in the meter's memory, an additional unique session ID was not necessary to distinguish measurement values. To store more than a single measurement value, a special file system was created within the memory area of the RFID tag. This file system was realized as a

ring buffer that kept a predefined quantity of measured values including time stamp. Depending on the quantity of data sets read from the measurement device the file system always stored this predefined quantity of last measured values. Thus, the system always overwrote the oldest storage entries in the memory of the RFID tag.

Since the measurement device stored the data within its memory and didn't transmit them automatically after the measurement was finished, the external connected KIT hardware hat to interrogate the memory to get the date. Since the device didn't provide any information about its current state (i.e. measurement has just finished) this process had to be triggered by the user him/herself after performing the measurement by pushing the button on the KIT box. After pressing the button, the LED illuminated red to indicate the system's operation. During this period that lasted up to three seconds (depending on the data stored in the device's memory), data were received, encoded, and written onto the RFID tag. As soon as data were written successfully, the meter's memory was deleted completely. Afterwards, the LED illuminated green for ten seconds to indicate that the operation has succeeded and the data stored on the RFID tag could be accessed via the mobile phone. In case of an error, this state was indicated by a five second red blinking period of the LED.

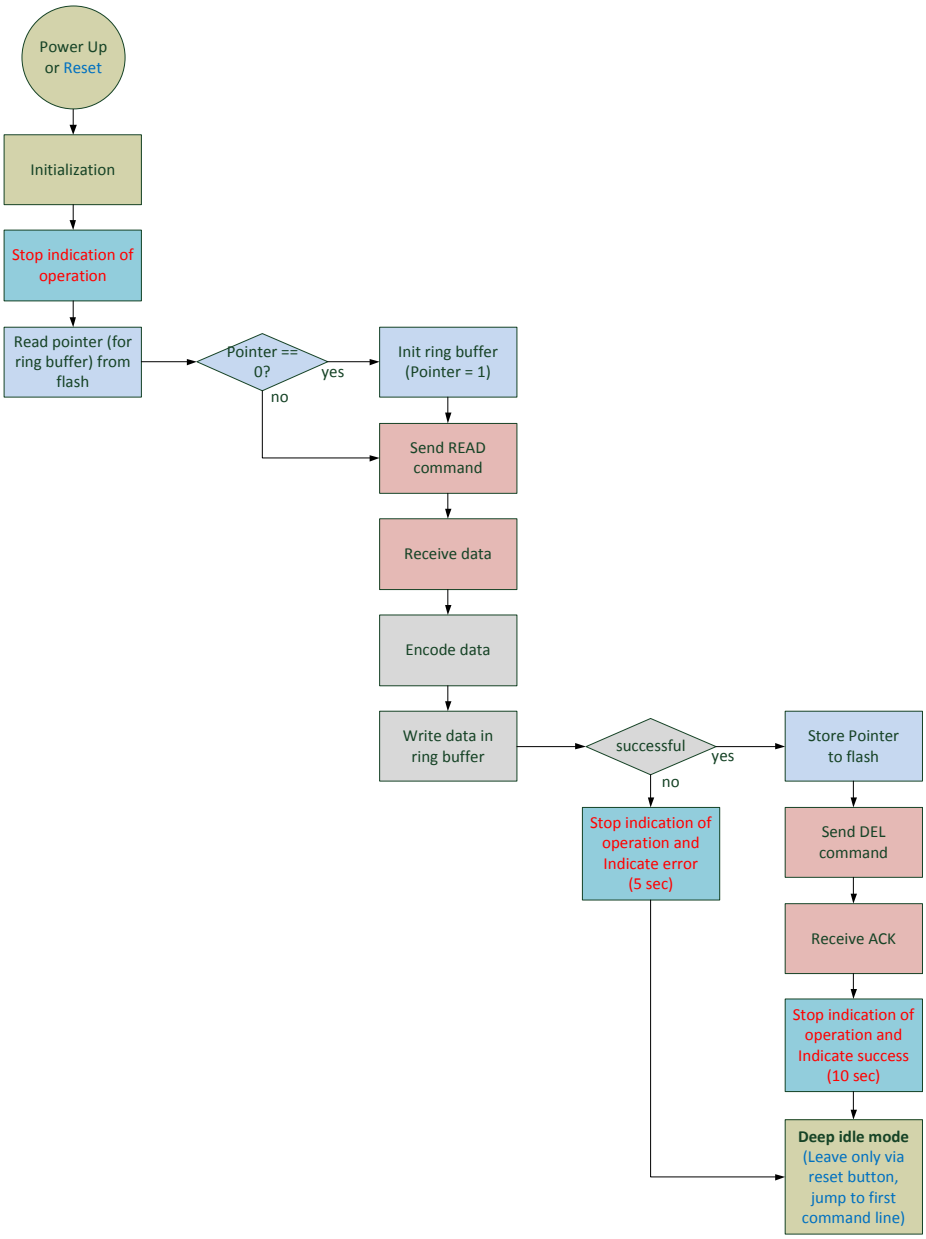

Figure 20: Program flow of KIT 1.0 firmware for treating an array of measurement values interrogated from a device's memory.

This concept was used in case of the KIT box for the blood sugar meter OneTouch Ultra II. The KIT box was able to store 35 recent measured values including timestamp. In case of the Spirotel spirometer and the MIROxy pulseoximeter, this concept was realized prototypically without a ring buffer for keeping more than one value set. Thus, after hitting the button, only a single value set could be read by the mobile phone.

3.1.2.2 KIT 2.0

Compared to both KIT 1.0-based workflows, where the KIT interface operated independently from the mobile phone by using an RFID tag as an intermediate storage medium, the KIT 2.0 system was strongly based on a direct interaction between both

components. Thus, this concept was able to provide bidirectional communication and the feature of remote control by the software application running on the mobile phone.

In this concept, a Bluetooth connection between a mobile phone and the device with the connected or integrated KIT 2.0 module was established automatically by bringing both components close together. The entire process is shown in Figure 11. Prior to this action both components were in idle mode without a pre-paired Bluetooth connection. The mobile phone had NFC switched on permanently and scanned its environment for RFID tags. The KIT 2.0 module was in sleep mode with the Bluetooth chip deactivated.

When these devices were brought together for a short, but sufficient, period of time, the mobile phone could recognize the RFID tag and the installed J2ME application launched automatically (if not already running). The application interrogated the data from the RFID tag (MAC address and service of Bluetooth device) and requested the mobile phone's Bluetooth module to establish a connection to that specific service (X) on the device (Y) defined by the read MAC address.

Simultaneously to these processes on the mobile phone side, the field detector of the KIT 2.0 module recognized the field generated by the mobile phone when brought to close distance for the short period of time and triggered the µC to leave idle mode. In the following, the Bluetooth chip was enabled and configured by the firmware application running on the µC. Thus, it could be addressed as a Bluetooth slave device running the dedicated service based on the serial port profile.

After the Bluetooth module was configured and the mobile phone was able to find the service, an inquiry was sent by the mobile phone to establish a connection.

The module's Bluetooth chip received this connection inquiry and automatically responded with permission to establish the connection and additionally indicated the connection status to the µC. Then the µC answered a data string back to the Bluetooth module that was sent to the mobile phone transparently over the established Bluetooth link. The mobile phone received the data string from the device consisting of an identifier and the status of being ready to receive and execute commands.

After the last command was sent and responded to with the corresponding data, both components terminated the Bluetooth connection automatically. This was initiated by the mobile phone, which sent a final command to the µC. This command prompted the KIT 2.0 module to close the connection by disabling the Bluetooth chip and to jump back to the idle mode. The µC acknowledged and subsequently performed this command. The KIT 2.0 module remained in idle mode until it was woken up again by the field detector recognizing the external field of the NFC-enabled mobile phone. On the mobile phone side, the application recognized the closed Bluetooth connection and could proceed in program sequence, for example, processing and forwarding the received data.

In case of an unintended detection of an external field, the KIT 2.0 module was activated but switched back to idle mode automatically after 20 seconds after not receiving the connection inquiry.

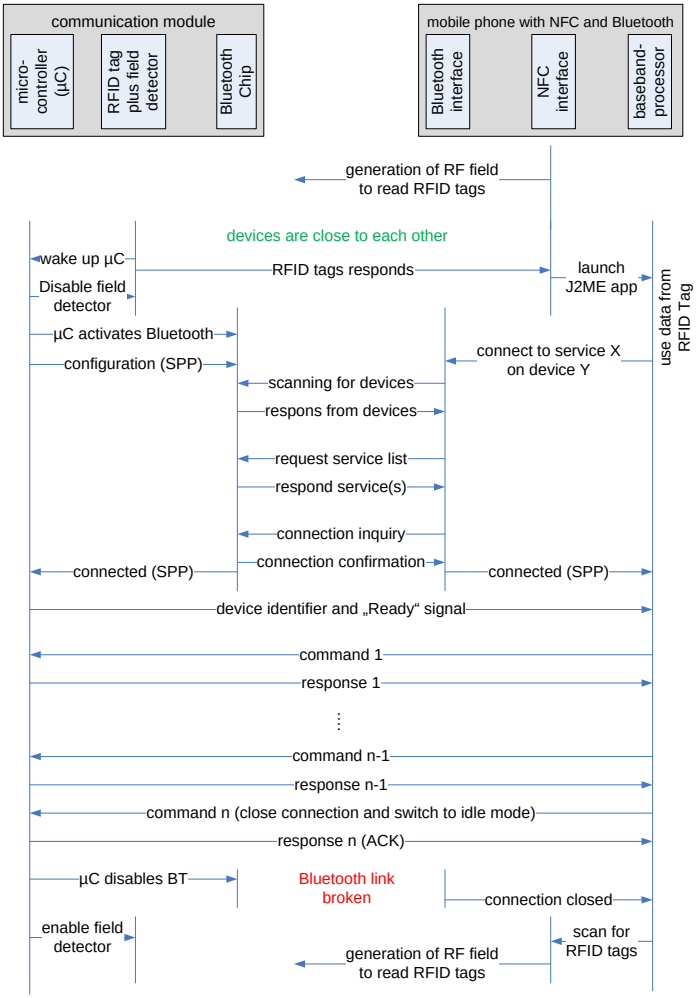

Figure 11: The sequence of establishing a Bluetooth connection between the KIT 2.0 module and a mobile phone with NFC and Bluetooth capabilities.

3.2 **Evaluation**

3.2.1 **Laboratory Evaluation**

In the following, the results from the laboratory evaluations are shown, i.e. from those projects where no real patients were involved and no approval from an Ethics Committee was required. Descriptive statistical results are presented in mean ± SD.

3.2.1.1 Feasibility Test of the KIT 1.0 System

In total, 14 students (6 f, 23.2 ± 4.9 years) were asked to evaluate the NFC-based concept of a mobile phone based patient terminal by comparing with existing solutions based on WAP and J2ME technology. The evaluation was performed by completing questionnaires, which were used for further analyses. Overall, NFC was rated as the

most suitable technology when compared to WAP and J2ME. The detailed results displayed in Table 9 indicate that general usability aspects (easy to use and learn) were weighted as most important (33%). Availability (21%) and Reliability of service (15%) were rated as second and third, respectively.

Table 9: Weighted comparison of WAP, J2ME and NFC; cursive values indicate the most suitable technology for a given requirement.

Requirement	**Weight [%]**	**Quantifier**			**p-value**
		WAP	**J2ME**	**NFC**	
Easy to use and learn	33	99.6 ± 23.6	128.6 ± 21.0	*138.6 ± 37.9*	< 0.01
Availability of service	21	59.5 ± 13.1	*80.8 ± 14.3*	78.1 ± 23.4	< 0.01
Reliability in service	15	32.7 ± 11.6	48.2 ± 11.6	*58.5 ± 15.5*	< 0.01
Integrated	12	35.0 ± 12.0	31.6 ± 7.4	*38.9 ± 10.0*	n.s.
Low cost	11	*41.0 ± 13.1*	36.9 ± 9.9	33.3 ± 12.9	n.s.
Feedback	5	*16.1 ± 4.8*	11.5 ± 5.3	12.3 ± 8.1	n.s.
Privacy	3	5.8 ± 2.6	9.2 ± 2.9	*10.2 ± 2.4*	< 0.01
Total	100	289.7 ± 40.4	346.7 ± 38.1	*369.9 ± 82.8*	< 0.01

"Comparing the quantifier for each method indicated that NFC was the most suitable technology in terms of general usability aspects (easy to use and learn). NFC was also found being the most suitable solution when a single, integrated system is needed, regarding privacy, as well as reliability of service."

Further details have been published in [**C7**].

3.2.1.2 Usability Test of the KIT 1.0 System

The system's usability was evaluated on 30 untrained adults (14 females) with a median age of 51.0 ± 12.8 years. All persons received the NFC-enabled blood pressure meter, the mobile phone, and a graphical step-by-step user manual and had to acquire and transmit their blood pressure values using the mobile phone. The statistical overview of this evaluation and the results from the questionnaire are presented in Table .

Table 10: Statistical data of participants, questionnaire outcome, and usability test results.

Parameter	**Total**	**Male**	**Female**
Patients [n]	30	16	14
Age [y] (min-max)	51.0 ±12.8 (40 - 80)	51.6 ± 12.5 (41 – 80)	50.4 ± 13.5 (40 – 76)
Using a mobile phone regularly [n]	23	13	10
Aware of own situation of high blood pressure [n]	10	7	3
Taking blood pressure specific medication [n]	7	7	4
Usability / learnability			
Acquired independently after reading the user manual [n]	21	13	8
Acquired independently after receiving a presentation [n]	8	2	6
Needed help by third person [n]	1	1	0

“97% (29 out of 30) were able to operate the system appropriately, 21 (8 f) immediately after reading the step-by-step manual only, eight (6 f) needed one time demonstration about how to read out data values from the devices by touching the device with the mobile phone appropriately. One male (80y) failed to operate the blood pressure meter and did also not manage to operate the mobile phone.”

Further details have been published in [**P3**].

3.2.1.3 Performance Test of the KIT 2.0 System

The results of both parts of the performance test are shown in the following:

a. Detection Test

The results of the detection test revealed the success rates of both mobile phone types with different alignments in front of the RFID tag / field detector. Successful establishment of a Bluetooth connection depends on the readability of the RFID tag by the mobile phone and the quality of the field detector.

The two used mobile phones showed differences in terms of buildup and NFC antenna fitting. The Nokia 6131 NFC is a clamshell phone with the NFC antenna mounted in the forefront of the display part. The Nokia 6212 Classic is a bar type phone with the NFC antenna fitted underneath the battery cover coiled around the entire body of the mobile phone.

Both devices were aligned in four different directions (vertical or horizontal with display up or down) to touch the meter's enclosure at the position where the RFID tag / field detector was located. Each direction was tested ten times with both mobile phones. The results indicate a difference in the performance of the two handsets with advantages of the Nokia 6131 NFC that provided a better reading performance. Independently of its direction, all attempts to read the RFID tag (RT) as well as all attempts to trigger the field detector (FD) had been successful. This resulted in 100% of established Bluetooth connections (BC). Table 8 shows the results of this test.

Table 8: Results of the detection test: a Bluetooth connection was established successfully only if both events (reading of RFID tag and field detection) were successful.

Device	**Nokia 6131 NFC**				**Nokia 6212 classic**			
Direction / Attempt #	D1	D2	D3	D4	D1	D2	D3	D4
1	1|1	1|1	1|1	1|1	0|0	1|0	1|1	1|1
2	1|1	1|1	1|1	1|1	0|0	0|0	1|1	1|1
3	1|1	1|1	1|1	1|1	1|0	1|1	1|1	1|1
4	1|1	1|1	1|1	1|1	1|1	0|0	1|1	1|1
5	1|1	1|1	1|1	1|1	1|1	1|1	1|1	1|1
6	1|1	1|1	1|1	1|1	1|0	1|0	1|1	1|1
7	1|1	1|1	1|1	1|1	1|1	0|0	1|1	1|1
8	1|1	1|1	1|1	1|1	0|0	1|1	1|1	1|1
9	1|1	1|1	1|1	1|1	1|0	0|0	1|1	1|1
10	1|1	1|1	1|1	1|1	1|1	1|0	1|1	1|1
RT [%]	100	100	100	100	40	30	100	100
FD [%]	100	100	100	100	70	60	100	100
BC [%]	100	100	100	100	40	30	100	100

The test also revealed that the reading behavior of the Nokia 6212 Classic was dependent on its position. With a vertical placement and the display directed to the user only four attempts resulted in successful Bluetooth connections. Similar results were obtained using a horizontal placement with display to front. This resulted in three successful connections out of ten attempts. Better results could be obtained when flipping the mobile phone. Moving it onto the device with its display down also resulted in 100% of successful connection independently of whether it was aligned horizontally or vertically.

Thus, the success rate of the realized KIT 2.0 communication platform using an RFID tag and a field detector depended on the mobile phone used for this trial. The results can be explained by the differences in NFC antenna constructions of those two mobile phones.

b. Cross-over Test

In this test, each attempt to establish a connection was successful without a manual user interaction to perform the pairing process. In both instances of this test, either using five measurement devices and one mobile phone or vice versa the list of paired devices stayed unchanged.

In addition to the demonstration of the concept's Plug and Play interoperability, the test revealed the system's behavior when an undesired field detector event occurs in case of any NFC-enabled mobile phone which didn't attempt to establish a connection. In this case the device left standby mode and enabled the Bluetooth module, but automatically switched it off again after 20 seconds and returned to idle mode.

3.2.2 **Clinical Evaluation**

In this section the results from two projects that used and evaluated the KIT system (KIT 1.0 and KIT 2.0) in a clinical setting are shown. Descriptive statistical results are presented in mean ± SD.

3.2.2.1 MOCADI

The developed EDC system has been evaluated at the Department of Internal Medicine - Division of Cardiology of the Medical University of Graz. During a total a period of 77 days, 25 patients (14 f, mean age 77.5 ± 10.0 years) suffering from CHF were observed with the CardioMon during in-hospital clinical treatment. Observation was performed by a study physician and the mean period per patient was 6.0 ± 5.0 days.

From each CHF patient participating in this clinical trial, a mean of 13.2 ± 10.6 data sets were acquired during the hospital stay after an acute cardiac decompensation. Each patient was measured twice a day. Figure 12 and Figure 13 show two plots of the received data acquired from a 69.2 year old female CHF patient during a hospital stay with a length of about two weeks. The data are averaged over two consecutively performed measurements.

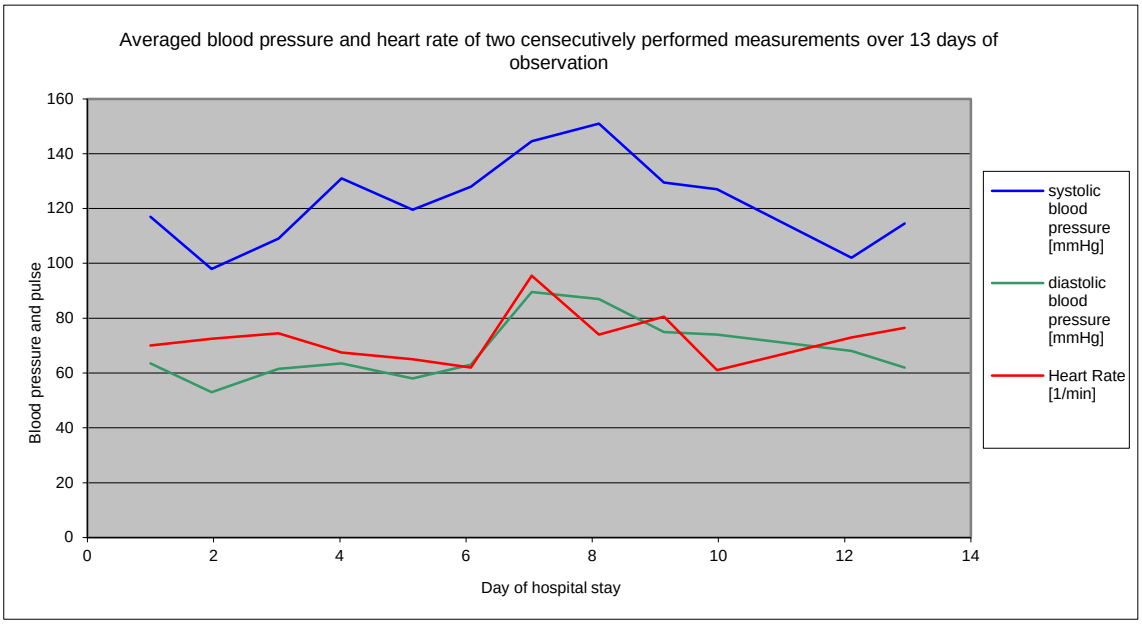

Figure 12: The course of blood pressure and heart rate data acquired from a 69.2 year old female heart failure patient during the 13 days hospital stay.

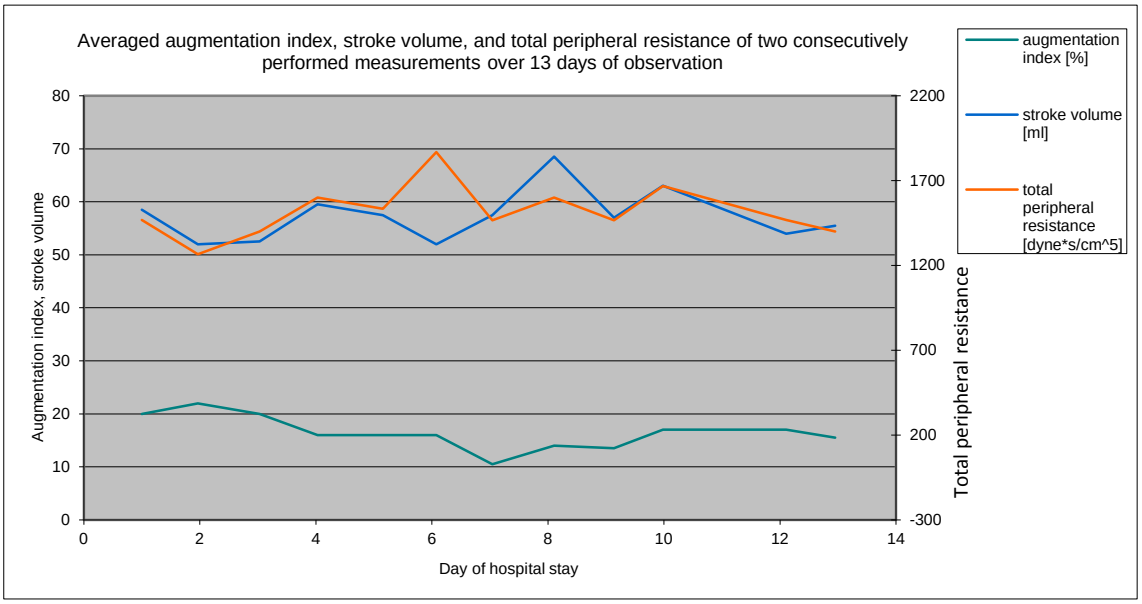

Figure 13: The course of augmentation index, stroke volume, and total peripheral resistance data of a 69.2 year old female heart failure patient during hospital stay.

The study physician manually documented 331 (164x2 + 3x1) successfully performed measurements. At the backend system, a total of 323 data transmission sessions were recognized. These transmission sessions carried a total of 331 acquired data sets which were stored in the database. A correlation of the manually documented and electronically acquired data sets revealed a 100 % concordance and proved the system's accuracy in terms of linking medical data to corresponding patients.

“Comparing the time table with the timestamps of interrogating the CardioMon via NFC and the timestamps of the records being stored in the central database revealed that in eight of the 331 instances the MobileMonitor had to store the data locally due to temporary GPRS/EDGE network blackouts. In all those cases the locally buffered record was eventually transmitted successfully, either with the subsequent record (7 cases) or on the next day (1 case).”

Further details have been published in [**C5, C6**].

3.2.2.2 eT Trial

The results of the clinical pilot trial for evaluation of the technical feasibility of the developed sensor device, patient adherence, general user acceptance, and usability are listed in the following. Patient characteristics and monitoring results are summarized in Table 9. A total of 21 patients (54.1 ± 14.7 years, 4 f) were enrolled into the clinical trial and have been observed over a period of ten weeks. All patients suffered from CHF with a median CHF severity of NYHA II. In addition to CHF, three patients had already suffered from stroke and two patients suffered from diabetes mellitus or COPD, respectively.

Table 9: Patient and transmission characteristics of eHealth terminal trial.

Parameter	**Total**	**Mean (SD)**
Patients (female) [n]	21 (4)	
Age [years]		54.1 (14.7)
Patients in NYHA class (I / II / III / IV) [n]	9 / 7 / 5 / 0	
Patients with stroke / diabetes mellitus / COPD	3 / 2 / 2	
Dropouts (female) [n]	1 (1)	
Patients with at least one transmission per day [n]	18	
Monitoring period [days]	140	
Transmissions [n]	211	10.6 (3.8)
Adherence rate [%]	82.2	
Transmissions of subgroup with 18 patients [n]	209	11.6 (2.1)
• Adherence rate [%]	89.3	
Received data items [n]	1501	
• ECG signals [n]	211	10.6 (3.8)
• Blood pressure [n]	198	9.9 (3.8)
• Body weight [n]	211	10.6 (3.8)
• Well-being		
o Good [n]	161	8.1 (4.1)
o Medium [n]	46	2.3 (3.2)
o Bad [n]	4	0.2 (0.5)
• Medication [n]	673	33.7 (15.3)

A total of 262 data sets were finally stored in the system's database. 41 data sets were acquired during the training session at the hospital and 211 data sets were acquired in real-life settings at the patients' homes by the patients. One female participant didn't start to acquire and transmit her data and was thus rated as a dropout. In case of two patients, only a single data set could be transmitted due to technical problems (weak battery condition and defective body weight scales). The cumulative monitoring period of all active patients (N=20) was 140 days. By expecting 13 autonomously acquired data sets per patient, the overall adherence of all 20 participants was calculated at 82.2%. In consideration of two participants with technical problems, the remaining 18 patients showed a patient adherence rate of 89.3%.

"All transmitted monitoring data sets included 211 ECG signals with a mean duration of 40.2 ± 17.9 seconds, 211 body weight values, 211 indicators for the patients' well-being (161 x good, 46 x medium and 4 x bad), and 198 valid blood pressure values (in 13 cases blood pressure measurement was not successful due to an incorrect appliance of the cuff). Depending on the patients' therapy, between one and four drugs were to be documented by the patients, leading to a final number of 673 data sets about heart failure medication intake for all active patients."

Further details have been published in [**P2**].

3.2.3 **Proof-of-concept Phase**

In the following, the results from two proof-of-concept projects in real world healthcare settings are shown. Descriptive statistical results are presented in median and IRQ.

3.2.3.1 ELICARD

The telemonitoring system started operation at the Elisabethinen general hospital, Linz, on March, 1st 2009. At the end of January 2012 after a period of 35 months, 40 patients from Upper Austria were registered and equipped with the patient terminal equipment to be monitored by their attending physicians.

23 CHF patients (6 females, median age 74.8 years, IQR [64.6-78.2]) were consecutively admitted to the service. All of them had been hospitalized because of cardiac decompensation and were registered before discharge.

After the system had been updated to meet the requirements for monitoring patients suffering from PAH, physicians started to admit this patient group also. From August 2010 17 PAH patients (11 females, median age 68.3 years, IQR [62.3-72.3]) were consecutively included to be monitored by their attending physicians. Thirteen patients were admitted after visiting the outpatient clinic while four patients had in-hospital treatment prior to that.

Preliminary results of the 35 month operation period are summarized in detail in Table 10. During this period, a total of 91,575 data items were received in the course of 26,625 data transmission sessions in both patient groups. In 13,154 of those sessions

only body weight values (path 1) were transmitted while the remaining 13,471 transmission sessions transported blood pressure values and questionnaire data (path 2).

The cumulative monitoring period of the CHF patient group was 13,602 days (median 716, IQR [250-1,016] per patient). In this period, a total of 22,057 data transmissions (median 1,078, IQR [328-1,689] per patient) were performed (path 1 + path 2). In 11,143 days at least the blood pressure values and questionnaire data (path 2) were transmitted, which resulted in a patient adherence rate of 81.9%.

The PAH patient group was monitored over a cumulative period of 6,482 (median 495, IQR [259-534] per patient) days. A total of in 4,568 (median 313, IQR [125-387] per patient) data transmission sessions were observed. 2,240 (median 148, IQR [65-190] per patient) sessions were used to transmit body weight values (path 1) and 2,328 (median 165, IQR [67-195] per patient) to transmit the remaining data (path 2). Considering six requested transmissions per week, this patient group showed an overall adherence rate of 82.2%.

In the CHF patient group, 163 cases of weight gain and 169 cases of weight loss (more than 2 kg within 2 days), as well as 2,519 off-limit conditions of systolic and diastolic blood pressure, heart rate, and body weight were detected. These events lead to 501 changes of individual thresholds and 215 interventions in terms of changing the medication scheme.

In the PAH patient group 57 positive and 70 negative rapid weight changes and 78 total off-limit conditions were recognized. This resulted in 109 threshold modifications and 87 changes in medication prescription.

During the 35 month operation period, three CHF patients (2 f) were classified as never-beginner while two HI patients (1 f) stopped using the system after a run-in period of 35 and 50 days respectively. They stated that they were not willing to handle the devices every day. In the PAH patient group, no person dropped out from monitoring. In total nine patients were monitored by the system until death or until admission before death. Four CHF (1 f) and five PAH (4 f) patients died after a median monitoring period of 343 (IRQ [309-392]) days and 133 (IRQ [130-210]) days, respectively.

Table 10: Patient and transmission characteristics after 35 month operation of the ELICARD system.

	CHF		PAH	
Parameter	**Total**	**Median [IRQ]**	**Total**	**Median [IRQ]**
Patients (female) [n]	23 (6)		17 (11)	
Age [years]		74.8 [64.6-78.2]		68.3 [62.3-72.3]
Patients in NYHA class (I / II / III / IV / nn) at inclusion [n]	0 / 2 / 18 / 0 / 3		0 / 5 / 10 / 1 / 1	
Never beginner (female) [n]	3 (2)		0	
Dropouts (female) [n]	2 (1)		0	
Monitoring period [days]	13,602	716 [250-1,016]	6,482	495 [259-534]
Transmissions [n]	22,057	1,078 [329-1,590]	4,568	313 [125-387]
• Path 1	10,914	531 [170-805]	2,240	148 [65-190]
• Path 2	11,143	580 [179-827]	2,328	165 [67-195]
Adherence rate [%]	81.9		82.2	
Transmitted data items [n]	72,201		19,374	
• Body weight [%]	15.12		11.56	
• Blood pressure [%]	15.43		12.02	
• Well-being [%]	15.43		12.02	
• Medication [%]	54.02		38.45	
• O2 saturation [%]			12.02	
• Breathing [%]			12.02	
• Labor test [%]			0.98	
• New prescription [%]			0.95	

In 136 cases the helpdesk was called due to problems with devices. In more than 65% of those cases, the problem could be resolved remotely by sending out a “Reset“-SMS or by giving a further explanation of how to handle the device in the current state. At the early beginning, seven mobile phones were replaced in the outpatient clinic due to a MobileMonitor software update. One month after starting to monitor PAH patients, nine mobile phones were replaced all at once via mail service due to a changeover from the Nokia 6212 to the Nokia 6131. 19 mobile phones were replaced individually due to problems with the MobileMonitor that could not be resolved remotely. One ID card was replaced together with a mobile phone.

Home visits by the helpdesk were made in eight cases to flash a firmware update into the KIT box connected to the body weight scales. Before the new firmware was brought to the field, the KIT box was replaced 9 times. Five blood pressure meters and two of the body weight scales were replaced. Replacement was always made using mail service. In six further home visits by the helpdesk, patients received an additional individual training session on how to handle the devices.

Further details have been published in [**C1**].

3.2.3.2 DIABMEMORY

In May 2010 the DIABMEMORY system started operation. After a period of 21 months a total of 359 persons (57 f) with a median age of 57.0 (IQR [51.5-64.5]) years were registered onto the telemonitoring system. These patients were enrolled as part of their participation in the “Gesundheitsdialog” healthcare program in the course of their visit to a specific health resort focused on diabetes treatment.

Most of these patients were suffering from type II diabetes (326 in total). The remaining persons were suffering from type I diabetes (26) or had been classified with increased diabetes risk (7). More than two thirds of all patients, 252 in total (52 f, median age 59.4 years, IQR [52.9-65.1]) chose the KIT-based patient terminal to collect their health data and communicate with their caregivers. Ten of these 252 patients (4 f, median age 52.9 years, IQR [48.7-61.4]) only received a mobile phone and an ID card, since they wanted to keep their existing blood pressure and blood glucose meters. Thus, they typed in their measurements manually. The remaining 107 patients (5f, median age 54.5 years, IQR [48.1-61.4]) used their personal computer to access the Web system for entering all data manually. Up to January 2012, a total of 242 NFC-enabled blood glucose meters, 212 NFC-enabled blood pressure meters, and 48 NFC-enabled body weight scales were handed out to those patients who chose the KIT solution.

Five percent of all mobile users, 13 in total (4 f), were classified as never-beginners, since they were registered, equipped and trained, but did not start to acquire their data autonomously. Four (2 f) patients started with telemonitoring, but stopped participation within the first week after leaving the health resort. These 17 patients were excluded from the following analysis.

During 21 months of operation, a total of 105,634 data transmission sessions were performed (median 271, IQR [131-503]) by the remaining 235 patients with mobile access. All data carried by these sessions consisted of a total of 189,883 data items (median 581, IQR [239-1,092]) and 2,614 manually written comments (median 1, IQR [0-9]). The major part of transmitted data items was represented by blood glucose values (58.8%). The remaining items comprised data related to blood pressure, body weight, activity, and well-being with a proportion of 17.2%, 4.6%, 10.7%, and 8.7%, respectively. An analysis of time-related participation (duration between first and last transmission) of these 235 patients revealed a cumulative monitoring period of 72,303 days (median 289, IQR [140-488]).

A detailed comparison of the KIT-enabled patients with DM1 (18, 5 f, median age 49.5 years, IQR [40.5-56.7]) and DM2 (211, 41 f, median age 59.7 years, IQR [53.2-64.9]) is presented in Table 11. Calculating a mean transmission rate in both patient groups (DM1 and DM2) by means of averaging all transmitted data items over cumulative monitoring period revealed 28.76 and 17.81 data items per patient per week, respectively. A breakdown of different parameters showed an average rate of 23.33 blood

sugar values, 1.93 blood pressure values, 0.41 weight values, 1.14 well-being indications, 1.57 activity (incl. intensity) events, and 0.38 comments per week recorded by DM1 patients. Comparing this situation with the target of three blood sugar measurements per day and one blood pressure measurement per week revealed that this patient group fully complied with the guidelines. DM2 patients also showed a high adherence. Blood sugar, blood pressure, and body weight values as well as well-being indications, activity events and comments were recorded with an averaged quantity of 9.88, 3.25, 0.86, 1.6, 1.98, and 0.24, respectively per patient per week, which fits into the guidelines of three blood sugar and one blood pressure measurements per week.

Table 11: Comparison of DM1 and DM2 patients after 21 months operation of DIAB-MEMORY.

	DM1		**DM2**	
Parameter	**Total**	**Median [IRQ]**	**Total**	**Median [IRQ]**
Patients (female) [n]	18 (5)		211 (41)	
Age [years]		49.5 [40.5-56.7]		59.7 [53.2-64.9]
Monitoring period [days]	5,605	274 [101-514]	64,415	298 [140-467]
Transmissions [n]	19,056	732 [234-1,776]	84,997	268 [121-458]
Transmitted data items [n]	22,726	906 [267-2,192]	161,696	572 [239-1,073]
• Blood glucose [%]	82.2		56.2	
• Blood pressure [%]	6.8		18.5	
• Body weight [%]	1.4		4.9	
• Well-being [%]	4.0		9.1	
• Activity (+intensity) [%]	5.5		11.3	
Comments [n]	308	2.5 [1.3-12.5]	2,239	1 [0-8.5]

During the 21 months of operation, a total of 42 mobile phones had to be replaced due to problems that couldn't be solved remotely. In 34% of those cases, the application running on the mobile phone could not be fixed by sending a reset SMS.

After 4 months of operation, the firmware of the KIT box for the body weight scales has changed due to problems with energy consumption. Thus, all already handed out items had to be flashed with the updated firmware. 20 units located at the inventory of the health resort had been updated locally and 35 devices had been replaced via mail service. Only two blood pressure monitors had to be replaced due to problems with the internal NFC interface. In both cases, the problems could be traced to a loose plug connection inside the device's enclosure. After re-fixing the plug, the devices were sent back to the health resort to be handed out again.

In case of the KIT box for the blood glucose meter, the broad application in a population of more than 200 patients revealed a mechanical design problem of the given implementation. Due to manufacturing by manual work, the KIT box was fragile and broke

apart in both enclosure components when the user tried to replace batteries. This lead to a short-circuit fault that inhibited the device's function. Thus, until January 2012 more than 70 KIT boxes had to be recalled. After fixing the site of fracture the items were sent back to the patients directly or to the health resort to be handed out again.

Further details have been published in [**C1**].

4 Discussion

The contribution of the present work has been to design, prototype and evaluate the patient terminal concept based on mobile phones and NFC technology in a three step process:

- Technical feasibility,
- Clinical feasibility,
- Applicability in real world medical settings.

After initial prototyping followed by a first laboratory test comparing this solution with manual data entry methods on mobile phones, the system was refined to meet the basic requirements. The NFC module and first KIT 1.0-enabled devices were developed together with the application running on the mobile phone. In the following, the resulting setup was evaluated in a usability test on a group of adults and elderly. The results of this usability evaluation indicated that NFC may be the enabling technology to provide elderly and technically unskilled persons with an intuitive solution for data acquisition and that it may help to empower them in performing regular data acquisition in order to benefit from telemonitoring solutions.

Subsequently, the concept was brought to a clinical environment. Therefore, a particular identity management system using RFID-based tokens was implemented to support different users and different roles on a single terminal device. This terminal was not used by patients, but by study physicians for collecting clinical data from a KIT 1.0-enabled sensor device recording various cardiovascular system data. The results obtained from this clinical trial revealed that the proposed solution indeed allows for intuitive and time-saving data acquisition within a clinical environment. It supports consistent and fail-safe identification of all persons and objects such as study participants, investigators as well as sensor devices and allows for collecting clinical research data in a process-oriented and, hence, comfortable way [**C5, C6**].

After first clinical use, the software application was reviewed again to be used in two proof-of-concept telemonitoring applications operated in a routine-like setting. One was especially designed to support the treatment of patients suffering from chronic heart failure and pulmonary arterial hypertension. It was deployed at the cardiology department of the Elisabethinen general hospital, in Linz, Upper Austria. The second telemonitoring system using the same, but slightly modified, patient terminal setup was deployed for patients suffering from diabetes who were insured at the VAEB. The results of both projects confirmed the previously made assumption that this kind of patient terminal is suitable also for elderly and technically unskilled persons. From a usability point of view, all patients were able to handle the mobile phone for regular up to daily acquisition of blood pressure, body weight, blood glucose level, well-being state, documentation of medication intake and even physical activity. Consequently, they

showed a high level of adherence to telemonitoring and stayed willing to use the system for months or even years [**C1**].

Based on experiences from these two projects with the need to continuously equip new patients and maintaining the patient terminals of existing ones, the KIT 2.0 setup was developed. Since the KIT 1.0 infrastructure was capable of handling data with a volume of a few hundred bytes only, the KIT 2.0 concept based on the combination of NFC and Bluetooth technology was developed in order to support the acquisition of biosignal data. This concept was realized in combination with a blood pressure meter with an integrated ECG recorder and evaluated in the course of a clinical trial with patients suffering from chronic heart failure. The results of this evaluation revealed that KIT 2.0 offers an intuitive solution for acquiring any kind of data in large volumes. It can be easily integrated into an existing KIT 1.0-based application in order to extend the sensor setup with any biosignal sensor that is interrogated in the same way of simply touching it with the mobile phone [**P1, P2**].

Advantages and limitations of the developed patient terminal concept and its components are discussed in the following three chapters followed by a chapter providing an outlook of NFC technology in the field of mHealth.

4.1 General Characteristics of Keep in Touch

The first prototype made after focusing on NFC technology to design and develop a touch-based patient terminal was based on the transmission of an URI from the blood pressure meter to the mobile phone. No specific application was required, since reading an URI from an RFID tag and retrieving the corresponding service using the integrated Web or WAP browser was a common feature of an NFC-enabled handset [88]. This approach allowed for using any NFC-enabled mobile phone independently which person it belonged to. All necessary data like measurement value, target system and account were encoded in the URI.

Since this approach did not provide any security measures, the concept had to be revised and resulted in a typical AHD approach with a dedicated software application running on the mobile phone. This application managed the connection to the backend service (by hardcoded server address) as well as the patient identification management (user account). Thus, the sensor device just had to provide its own identifier (e.g. serial number), the measured value and an identifier for the value to make it unique.

From a technical point of view, the architecture of this setup is quite similar to those of mHealth solutions based on Bluetooth technology. But in terms of interactions between the user and the devices, both approaches are totally different. On the one hand, the KIT system requires patients to interact with the sensor devices any time data are to be collected, which gives them full control and authority. But on the other hand, each interaction is simplified to the physical gesture of touching an item. This intuitive kind of interaction is embedded into a workflow-oriented step-by-step procedure, which is trig-

gered by touching a token represented by the ID card. This action launches the application installed on the mobile phone that prompts the patient to enter the vital signs, enter some documentation and answer questions.

Entering vital signs is carried out automatically by directing the mobile phone to an item. By means of this action, the patient selects the sensor device to establish a connection, interrogates the data and expresses the willingness to add these data to his/her health record. In comparison to Bluetooth, this KIT 1.0 approach based on NFC technology allows to combine all of these steps into a single one without the need for manual interaction using the keypad in order to setup device pairing or configure communication parameters. Touch-based data acquisition provides patients with an intuitive user interface and full authority over their data. This concept allows for, but in some cases requires, a differentiation between single-user and multi-user devices. A single-user device is commonly used only by a single person (e.g. blood glucose meter), while multi-user devices may occasionally be used by other persons (e.g. weight scale, blood pressure meter). This differentiation has to be considered at implementation of the software application as well as the NFC interface for these individual devices. The KIT patient terminal solution addresses this issue by reading only the recently measured value from the blood pressure meter and the body weight scales. In case of the blood glucose meter, a list of measurement values is stored and read out. Reading a single value does not only solve the aforementioned “guest problem”, but also allows for a dedicated multi-user scenario with two or more persons living in the same household and sharing these devices. Using Bluetooth or any other wireless technology (e.g. WI-FI, ANT+) realizing this scenario would require further technical measures such as a user selection switch on the sensor device as used at the smartLAB®profi+ (HMM Holding AG, Dossenheim, DE) blood pressure monitor [89].

In order to document any other information, which cannot be measured by sensor devices, in general, data have to be entered manually. With KIT technology, these data can be entered also by simply touching an item. An item can either be a real physical object with an RFID tag attached (e.g. medication box [90]) or just a simple graphical icon printed on a sheet of cardboard (see dialogue book in figure 9) with an RFID tag stuck underneath each icon [91, **P3**]. A patient can touch an object from one’s own intention in order to document some information (e.g. touch-tagged “Nordic walking stick” -> documentation of physical activity “Nordic walking”). A similar approach was used by Graf [**A3**] in order to document daily living activities. Another way to achieve this would be to get asked a question and answer it by means of touching the appropriate icon out of two or more.

Using KIT 2.0 components, the action performed by the patient is the same as known from KIT 1.0. The patient simply touches the sensor device to initiate an interaction. In the background, however, a Bluetooth connection is established automatically without the need to manually perform several steps of the pairing procedure as known from common scenarios. Since this Bluetooth connection provides a larger operating dis-

tance and a higher data rate, KIT 2.0 allows for different use cases in the field of mHealth:

- Transmission of large volumes of data from a memory (e.g. stored recordings from a Holter ECG device)
- Streaming of real-time sensor data (e.g. ECG signal from a chest belt)
- Sensor device without own user interface (e.g. spirometer is fully controlled by software on the mobile phone).

4.1.1 **Usability**

The intuitive solution of touch-based data acquisition provides a high level of usability, which, among others, is essential for gaining user acceptance. User acceptance is one of the most important prerequisites when it comes to elderly and technically unskilled persons. The process of data acquisition is easy to use, as it can be conducted without a single key press neither for digging into a menu to start the application nor for configuring the communication link to sensor devices.

High usability is also given by the fact that KIT provides only a single and, hence, consistent solution for acquiring all kinds of data. Table 14 shows an overview how different data can be acquired using KIT technology.

Table 12: List of linking technologies and data types to be transmitted.

Link	Technology	Data volume	Data type
KIT 1.0	RFID	few bits or bytes (static)	User and object identification, symptomatic data, compliance data, etc.
KIT 1.0	NFC	bytes to kbytes (dynamic)	Vital signs: blood pressure, body weight, blood sugar, O2 saturation, step counts, etc.
KIT 2.0	NFC+Bluetooth	kbytes to Mbytes (dynamic)	Streamed or stored (large volume) biosignal data: ECG records, 3D accelerometer data, plethysmography, etc.

The incidental coupling of devices allows for a Plug and Play-like expansion of existing patient terminals and the use in multi-user environments. These features also contribute to this high level of usability, which has an enormous influence on the effort for training the patients as well as on the patients' adherence.

4.1.2 **Security**

In terms of security the KIT solution provides an easy-to-use mechanism to secure all data. The ID card is not only used to launch the application but also to store user credentials. These data are used to login to the application and to authenticate the patient against the backend system. Although the MobileMonitor can be started manually in the application menu, the ID card is absolutely necessary to log in. In addition to that, all data stored locally are encrypted based on these credentials. Thus, an attacker

needs to get both, the mobile phone as well as the ID card in order to hack the stored data. If the card gets lost, the patient needs to contact the helpdesk to receive a new one. But this ID card does not work until the helpdesk has sent a new configuration SMS to the phone number that is assigned to this patient.

Data reliability also belongs to the field of security. As demonstrated in MOCADI, the KIT approach allows for an error-proof assignment of measurement values to patient records. Not only for clinical research, but also for routine telemonitoring applications, the automated data acquisition procedure prevents for intended or unintended entry of wrong or faked data.

4.1.3 **Maintenance**

Due to the fact that devices do not have to be paired, they can be simply replaced without any configuration in case of damage or malfunction. Thus, neither the patient or a relative nor a technician is required to add a new device to an existing patient terminal setup. This is valid even for mobile phones and KIT 2.0 devices with Bluetooth technology. This circumstance allows adding or replacing devices via mail service, which is less time consuming and more cost-effective.

The push functionality of the entire telemonitoring system does not only deliver feedback messages and updates of the MobileMonitor configuration. This channel is also used as a link to maintain the MobileMonitor remotely in case of problems. If the patient contacts the helpdesk due to any issue, the helpdesk can send out an SMS that causes the application either to send a log file to the administrator, reset itself and delete all data, or to exchange a new encryption key with the backend. Thus, the mobile phone can be partly maintained remotely, which reduces the need for sending it in.

4.2 **Keep in Touch in Routine Operation**

4.2.1 **ELICARD**

A lot of mobile telemonitoring solutions for heart failure patients have been evaluated in clinical trials [92, 93]. One of these is the Austrian MOBITEL (MOBIle phone-based TELemonitoring for heart failure patients) trial [94]. Results of this randomized, controlled and multi-center trial indicated significant improvements of patient outcomes, while reducing the frequency and duration of hospitalizations. The telemonitoring system was developed and operated by AIT. The patient terminal used in the MOBITEL trial was comprised of a mobile phone to be handled manually in order to document the data (case report forms in WAP browser). Although this system was used by elderly patients with a median age of 65 years, it was proven as feasible. In terms of usability, however, the manually operated solution required an enormous training effort and suffered from a high dropout rate of 20 percent.

Lessons learned from this clinical trial led to the creation of the KIT-based patient terminal setup as it was used in ELICARD in a routine-like operation. The major progress of the KIT system over the MOBITEL patient terminal was found in usability, which was notably improved. The effort for training the patient in using the mobile phone and the devices could be reduced significantly. Since the actions of launching the application and touching one item after another to acquire all data were easy to use, the process of educating patients could be limited to one or two demonstrations at the hospital before discharge. At home and after receiving the personal devices via mail service, the patient studied the one-page pictured user manual and autonomously started to acquire his/her data. In few cases the helpdesk was contacted to receive further guidance.

The high level of usability also led to a high adherence rate. CHF and PAH patients with a median age of 74.8 and 68.3 years, respectively, were able to integrate the data acquisition process into their daily routine as – according to their statements – it was not complicated and time-consuming. In ELICARD, adherence was also at a high level due to frequent contact between doctors and patients. Although the system provided feedback functionality by means of push messages, the doctors preferred to call their patients via telephone to discuss the current situation.

4.2.2 **DIABMEMORY**

Usage of mobile phones for telemonitoring of patients suffering from diabetes was also researched by AIT [95, 96, 97]. Kollmann et al. presented a mobile diary for type I diabetes patients based on a J2ME application, which was handled manually by the means of the phone's keypad. Basic design concepts taken from this application were blended with the KIT developments used at the ELICARD system. It was refined to be used in a pilot project called DIABMEMORY with 50 diabetes patients (type I & II) of the VAEB. From the beginning, the use of DIABMEMORY enjoyed a high level of user acceptance. As a consequence it was continued and extended as a proof of concept for routine telecare of patients suffering from diabetes.

This success was due to two main reasons. One was the extensive supervision provided by the technical as well as the medical personnel of the VAEB in combination with the patients' general practitioners. Patients were included during a three-week stay at a health resort of this insurance company and received special care in order to generate awareness about their health situation and receive guidance on how to manage it. The second factor of success was the high level of usability provided by the KIT-based patient terminal. User stated that it was easy to grasp the procedure and to integrate it into daily life for documenting all relevant data at any time even on the move.

From a psychological point of view, the ID card was not only recognized as a token for starting and finishing the data acquisition procedure, but also as a key for securely saving personal data. Since the MobileMonitor version of DIABMEMORY stored all data locally for serving as a diary to be regularly observed by the user, patients felt relieved that access to these data was secured. The ID card also granted access to read the

feedback messages, which consisted of highly personalized information. This function was used frequently. On average, each patient received two feedback messages per month.

Although all project partners, including patients, were burdened by the frequently occurring damage of the handcrafted KIT boxes for the blood glucose meter, these events did not lead to the loss of any data. Since the blood glucose meter stored all data, they were transmitted afterwards with another KIT box which was sent via mail service to replace the broken one. In the beginning, broken devices have been repaired and were sent back to the VAEB to be handed out again. Later (from January 2012), these broken devices have been totally replaced by an entirely new version based on an industrially manufactured enclosure.

Besides these technical problems at the beginning, patients often remarked that it would be more comfortable to carry only one mobile phone instead of two – the private one and the provided one. But due to the rarity of NFC enabled mobile phones at that time the patients' private devices were not qualified for running the MobileMonitor. This situation was accepted by the VAEB during the proof-of-concept phase but will have to be changed in the transition to full routine operation of DIABMEMORY with inclusion of industrial partners. Cooperation with a mobile network operator would allow for setting up a specific plan for telemonitoring purposes. Hence, patients could get their new personal mobile phones also applicable for telemonitoring from this mobile network provider together with a contract for this specific plan which may be subsidized by the VAEB.

4.2.3 **Distinguishing Different Indications**

A comparison of CHF and PAH patients with diabetes patients - all of them equipped with the KIT patient terminal - shows a different distribution in acquired data. In CHF and PAH patients, the transmitted blood pressure, body weight and well-being data are uniformly distributed, while in diabetes patients, blood glucose data were acquired more often. Compared to blood glucose data the remaining parameters were less often documented at different frequency.

This is due to the fact that vital signs are of different importance depending on the disease. The patient terminal needs to be designed considering this situation in addition to other circumstances like the patient's age or life situation. With KIT technology, these conditions were considered by means of a process-oriented approach with workflow support.

Patients suffering from CHF or PAH mostly stay at home and need to collect the relevant data every day or every other day. Since these patients are generally of higher age [98], the workflow of data acquisition needs to be designed in an appropriate way in order to avoid intentionally or unintentionally leaving out of crucial data. Additionally, there should be no chance for getting lost in a submenu. Thus, in this case the Mo-

bileMonitor requests all necessary data in a kind of dialogue workflow. One device or item has to be touched after another in order to follow the displayed instruction or answer a question. In order to consider the situation where sensor devices may be distributed in the home (having the weight scale placed in the bathroom, while operating the blood pressure meter mainly in the kitchen or living room where the medications are taken), data acquisition is separated in two paths. One is the acquisition of the body weight while the other path combines the remaining data (blood pressure and all questions). Once the last data item of each path was acquired the application transmitted the data immediately and visualized feedback indicating that the transmission was successful. This feedback was found to be essential for those patients, as they need to be assured that their data can now be seen by the doctor. Otherwise, as observed during the MOBITEL trial, they were unsure and sometimes contacted the doctor in order to check whether the data had been received [94].

In telemonitoring of diabetes patients, use cases are totally different to those as given for CHF and PAH patients. Diabetes patients are also of younger age, are in working life and are usually mobile. The most crucial parameter to be monitored is the blood glucose level. It has to be documented regularly, sometimes even several times per day, partially in combination with intake of bread units and insulin. Other vital signs, such as blood pressure or body weight, are of less importance as reflected by a sample rate of only once per week. Documentation of well-being and physical activities is done occasionally. Thus, it is not feasible to combine different data and create a predefined path that has to be run through. This resulted in a fully open data acquisition without a predefined workflow. The patient has full authority in terms of timing and data to be acquired. He/she is able to document only a single parameter at a time at exactly the time when it occurs or he/she gets the possibility to acquire more parameters at a time and it is up to the patient to leave out any parameter. Since this approach allows for always adding another parameter, the application doesn’t recognize automatically whether the last parameter was entered. Thus, the patient has to provide this information in order to start the transmission process. In this case, he/she touches the ID card to indicate that the data acquisition process has finished.

These two different workflows were deployed by means of individual compilation of the MobileMonitor application. But in order to configure the scope of parameters to be acquired and the sequence of a predefined path, the MobileMonitor could be configured remotely. This allowed for an individual setup for each patient definable by the doctor.

4.3 **Technical Limitations**

During long-term operation of these two proof-of-concept telemonitoring projects and conducting several clinical trials using patient terminals based on mobile phones and NFC technology also some problems became evident. Most of these problems can be traced back to the fact that these developments and prototypes were created in the

early years of NFC technology. Thus, they were caused by limits in the few available products and standards and exhibited the following issues.

4.3.1 **KIT Interface Design**

4.3.1.1 KIT 1.0

Next to manufacturing issues of the KIT box for the blood glucose meter, which have been solved by designing an entirely new enclosure, the following problems of the KIT 1.0 system were recognized.

a. Energy Consumption

The major issue given by the NFC module is the high energy consumption often leading to a short operation period of just four to six months before batteries have to be replaced. One reason is the standby current of 100µA at 3V power supply. The other reason is the high operation current of 120mA during the short period of 100-300ms that flows during the process of writing the data onto the RFID tag which is attached to the antenna of the NFC module. While the standby current could be decreased to zero by means of design measures (using an electronic relais), the operation current may be reduced significantly through better fine-tuning and matching of antenna and RFID tag.

A more advanced way to reduce the operation current would have been to communicate data in card emulation mode or in passive p2p mode. This was the initial intention during development of KIT 1.0, as the NFC transceiver chip used in the NFC module supports the p2p mode according to the NFC Interface and Protocol-1 (NFCIP-1) definition in ISO/IEC 18092 / ECMA-340 [99]. But the problem in using this protocol was the fact that on the mobile phone side, p2p communication was either a proprietary implementation or not at all available (at least in the beginning). Additionally, the application had to run already in order to allow for p2p communication. Thus, we decided to use an RFID tag attached to the antenna acting as an intermediate storage medium to exchange data with the mobile phone. RFID tags of the selected standard could be read by almost any NFC handset at this time.

b. Timestamp

Another issue was the lack of time information when data are exchanged by means of an intermediate storage medium instead of end-to-end communication. The NFC module itself or the used blood pressure monitor and body weight scale did not provide any information indicating the time of measurement. Thus, the data sent to the mobile phone came without a timestamp. To add a timestamp to each data set provided by those devices, the real time clock function of the mobile phone was used when reading the data. Therefore, the user had to touch the device immediately after measurement.

In case of the blood glucose meter a slightly different approach was chosen, since the used device was able to store a batch of measured values together with a timestamp. The memory of the blood glucose meter was interrogated by the NFC module, convert-

ed into an optimized data format, and written onto the RFID tag. Since the memory structure of the RFID tag consisted of blocks with a size of 16 bytes, several single values including timestamp should be filling the block size in a most optimized way. During data conversation prior to writing them onto the RFID tag, the year information of the timestamp was left out. This situation led to problems after turn of the year, resulting in values tagged with a future timestamp stored on the mobile phone and consequently in the data base of the backend system. In the following, this issue was cleared by implementing a dedicated filter function in the MobileMonitor.

c. Reset Function

Another issue in respect to usability and maintainability was the fact that the memory of the KIT box for the blood glucose meter could not be deleted by the user him/herself. Erasing the memory required an additional device to be plugged to the KIT box instead of the glucose meter. Thus, if the KIT box had to be restored to initial condition, it was necessary to send it back to the helpdesk. A self-resetting function based on an additional (hidden) pushbutton at the KIT box or a dedicated erasing-function by the MobileMonitor would have simplified some maintenance tasks.

d. Data Structure

The data of the blood pressure meter and the body weight scale to be transmitted to the mobile phone were represented in a human-readable ASCII format. This format kept the device's serial number, the session ID (identifier for each measured value) and the value set consisting of a label and the corresponding value (e.g. systolic blood pressure: sbp=132). In case of the weight scale, the measurement unit (kg or lb) was also used. It separated the integer and the decimal part (e.g. body weight: bwt=081kg4). In case of the KIT box that stored up to 35 blood glucose level values, the data format was not based on human-readable ASCII characters, except for the device's serial number. A session ID was not necessary, since each stored value has its own timestamp. This data tuple was encoded in binary (4 bytes) without any label or unit. Thus, there is a batch of proprietary data formats without consistency among all those devices. In addition to that, the data are stored in a custom NDEF message, which can only be read by a custom application supporting this NDEF type and knowing the individual data formats.

4.3.1.2 KIT 2.0

The realized prototype of the KIT 2.0 concept based on the developed hardware and the NFC-enabled mobile phones by Nokia was similar to an already demonstrated system [100]. It also lacked sufficient security measures to provide protection against MITM attacks and eavesdropping. This is due to the fact that the used mobile phones (Nokia 6131 and 6212) were only able to execute J2ME applications. Since these devices were the only commercially available devices with integrated NFC capabilities at that time, using them was the only way to access a handset's Bluetooth and NFC functions by means of software and, hence, to control their interplay. Unfortunately, the

Bluetooth API of the J2ME framework was not capable of activating a phone's Bluetooth modem or automatically setting a PIN code during the pairing process to establish an authenticated and encrypted Bluetooth connection [101].

This circumstance led to the implementation of a prototype based on an unauthenticated and unencrypted Bluetooth connection so that the user was not required to enter a PIN code manually. Due to the fact that Bluetooth cannot be activated by the application, it had to be switched on all the time. As a consequence, permanently activated Bluetooth led to faster discharging of the phone's battery.

In the future, this approach may be realized by means of an improved NFC-Bluetooth interplay providing full security and high usability. The most promising option would be a better combination of those two connecting technologies at operating system level or even on the device's hardware level using an integrated Bluetooth-NFC modem.

4.3.2 **Application and Mobile Phone**

As the following limitations are associated with the mobile phone in general, there are no remarkable differences between a purely Bluetooth or an NFC-based mHealth solution.

a. J2ME Platform

As mentioned before, the J2ME application framework available in common mobile phones provides only a limited set of features in comparison to smartphones capable of running applications more natively. Depending on the J2ME version, the maximum size of the software application was limited to a few hundred Kbytes. Applications need to be signed using code-signing certificates in order to run feasibly. This procedure had to be repeated after a certificate had expired.

b. Setup

Setting up a mobile phone acting as AHD for telemonitoring required two steps to be performed. One was the preparation of the device itself (e.g. insert subscriber identity module (SIM) card, set date and time, configure key lock, etc.). The other step was the installation of the software. If an operating SIM card was already inserted, installation could be done very easily as described before (download after touching an RFID tag). If this was not the case, the device had to be connected to a computer or a memory card, on which the application was stored had to be inserted. These two procedures required a batch of steps to be performed manually.

Independently form the type of installation, the security and access conditions (e.g. access to local file system, access to Internet) had to be set and the application had to be launched manually in order to start several listeners (e.g. for NFC or SMS event).

c. Update

During updates, almost the same steps as required for installation had to be performed. Thus, a guided update by the patient him/herself was only done in very few cases. Mostly, mobile phones were sent back to the helpdesk to be updated and configured.

d. Internet Connectivity

While the Nokia 6212 and the Nokia 701 supported UMTS-based 3G connectivity, the Nokia 6131 and the Samsung GT S5230 supported only EDGE technology. Patients living in areas with higher population often faced connectivity problems in the morning when they had to transmit their data. This was not due to a lack in network coverage, but due to the fact that EDGE connectivity lacks Quality of Service (QoS). Since changing the mobile phone was no option, several patients had to be provided with SIM cards for another mobile network operator that served fewer users in that area. This was not the case with 3G-capable devices and is not expected to be an issue in future mobile Internet technology such as 4G based on LTE.

4.3.3 **NFC-enabled Phones - Availability and Differences**

One of the most hindering facts during design and development of this mHealth approach using NFC technology was the limited availability of NFC-enabled handsets. Nokia was the first, and for a long time, the only device manufacturer offering this type of devices on the consumer market. Other manufacturers did provide NFC devices as well, but only for pilot trials and in limited areas of the world and not for the entire consumer market.

In addition to the lack of devices, those devices which were available on the market showed a high level of variety in terms of antenna design, operating range, support of different standards, and security measures. For example the Nokia 6131 provided the best NFC antenna design to read RFID tags and cards (see table 11), while all other devices required a more specific alignment or even movement in order to read cards. But on the other hand, the Nokia 701 did not require setting security and access conditions manually and, therefore, allowed for a quicker configuration.

4.4 **Outlook**

In the course of this thesis the first NFC-based patient terminal for telemonitoring of patients suffering from cardiovascular diseases and diabetes has been developed and evaluated in clinical environments and proof-of-concept telemonitoring projects. Although this work was just the initial step, it presents a starting point to provide patients suffering from chronic diseases with an easy-to-use patient terminal. However, there are still a lot of open questions to be discussed in order to design an overall system architecture that considers not only stakeholders in the healthcare system but also in the world of ICT and device manufacturers.

4.4.1 **New Ecosystem**

a. Mobile Phones

In 2013 the diversity and regional availability of NFC-enabled mobile phones has changed dramatically compared to the early years. The term mobile phone has now to be split into feature phone with an ordinary firmware and smart phone with a sophisticated operating system. Starting in December 2010, NFC-enabled smartphones based on operating systems like Android OS (Google Inc, Mountain View, CA), Blackberry OS (RIM, Waterloo, ON) or Windows Phone (Microsoft, Redmond, WA) appeared on the marked. In March 2013 more than a hundred individual devices – manufactured by different companies like Samsung, Sony, Nokia, HTC, LG and so on – were available. When these operating systems appeared, development of mobile applications also became much simpler and, hence, more popular due to easy-to-handle development tools and powerful APIs. Additionally, development of so-called “apps” became popular due to a new sort of distribution by means of dedicated application stores like the PlayStore (Google Inc, Mountain View, CA) or the App Store (Apple Inc, Cupertino, CA). This concept allows for simple installation of any software application by searching a Web-based catalogue with any keyword and selecting the desired app from the result list. By the end of 2012, tens of thousands of apps related to health, fitness and wellness were available in different application stores.

In order to take advantage of this broad variety and availability of NFC-enabled smartphones, the KIT-based patient terminal will also be ported to the Android OS. Besides simplifying the deployment process (by using the PlayStore), this transaction will also be beneficial in respect of NFC functionalities, push features, security and maintainability.

Next to mobile phones and tablet computers, Android is also a popular operating system of smart television (TV) devices. These are connected to the internet as well and able to run the same apps as known from mobile devices. In January 2013, Sony demonstrated a remote control featuring an NFC interface [102] that could be used in combination with an Android-based smart TV in order to serve the same functionality as demonstrated by the KIT system.

b. Sensor Devices

In addition to mobile phones and other consumer electronics products enabled with NFC technology, a few medical sensor devices started to appear, which also featured touch-based interrogation by means of NFC. Most of these devices originated from Japanese companies, as they are based on the Japanese FeliCa technology, which was developed by Sony. FeliCa also belongs to the NFC standard and is compatible with almost any NFC-enabled smart phone. The line-up of these FeliCa-enabled sensor devices ranges from pedometer or activity monitor, over body weight scales and blood pressure monitor, up to blood glucose sensor and body compensation monitor. Since these devices are based on the “FeliCa Plug” interface that offers a memory for

storing measurement values to be interrogated by a reader device, each company using this interface may implement its own proprietary data format. Therefore, Sony has implemented a so-called NFC healthcare library [103] that takes care of these different proprietary implementations in order to ease the development of applications.

This new and continuously growing ecosystem of smartphones as well as sensor devices featuring an NFC interface will contribute to the ramp-up of development and deployment of easy-to-use mHealth applications.

4.4.2 **NFC as a Standardized Interface for Healthcare Applications**

Next to KIT devices and devices based on the Sony FeliCa plug, there are already other NFC-enabled products on, or at least in the pipeline towards, the market. Although these products may be compliant to the specifications by the NFC Forum, transmitted data are still of a proprietary format due to the lack of an existing standard.

Beginning in Q3 of the year 2011, the Continua Health Alliance also considered NFC to act as a potential linking technology between AHD and agents. Therefore the CHA started collaboration with the NFC Forum in order to facilitate the development of related Continua specifications for NFC-enabled personal healthcare devices [104]. Next to Bluetooth, the CHA's predominant wireless PAN interface, and ZigBee, the most popular wireless LAN technology, NFC was selected as the linking technology to create a Touch Area Network (TAN). It was added to the range of existing technologies in order to cover the "tap and go" use cases defined by a subteam of CHA's technical work group.

In Q4 2012, a version of the Personal Health Device Communication (PHDC) specification has been published by the NFC Forum as a candidate technical specification [105]. After final approval of this specification it can be expected that several products will appear on the market in a little while. In parallel to appearance of new devices the release of this specification will simplify the development of mobile applications. Based on this, mobile applications will exclusively communicate with these devices by means of standards. These standards will be implemented on operating system level, thus, developers will not have to take care of them anymore. In Android OS, the Bluetooth Health Device Profile (HDP) is already implemented. Thus, it can be expected that the NFC PHDC specification will be considered in Android OS as well, as soon as it is ready for integration.

These conditions will allow for Plug and Play interoperability of sensor devices and mobile AHDs beyond the borders of telemonitoring systems operated by different providers. In combination with the high level of usability provided by NFC technology and moderate pricing policy, this new health device ecosystem could lead to a more consumer-driven approach. This may end up in a situation where telemonitoring could become a service requested by the patient on his/her own instead of a measure offered by the doctor.

4.4.3 **NFC in Future eCards**

In the year of 2004, a national secure network for interconnecting medical practitioner offices with health insurance companies was prototypically deployed to the Austrian healthcare system. The nationwide roll-out of this so-called “Gesundheitsinformatioknsnetz” (GIN) was completed by the end of 2005. One of the most important parts of this system is the eCard. This is a secure smart card to be carried by each insured person in order to get identified. Also, each general practitioner is outfitted with a unique card called oCard. The eCard is a contact-based smart card to be inserted into a specific reader device at the medical practitioner office at consultation [106]. It can also be enhanced to act as a citizen card for digital signatures in application areas like eGovernment and Internet banking [107].

The next version of this eCard is expected to be a contactless smart card supporting NFC standards. The reasons are mainly related to durability due to the absence of a contact-based interface that causes physical exposure. The new contactless eCard will enable new applications and use cases in the field of mHealth as it can be read by NFC-enabled mobile phones. For the existing telemonitoring solution, the eCard could completely replace the ID card, i.e. for signing acquired health parameters and authentication of the mobile client against the backend system. With a full integration of telemonitoring into the national health information system, telemonitoring data could become an integral part of or at least linked to an electronic patient record, which is planned to be a major component of the GIN.

Further integration of mobile clients running on NFC-enabled mobile phones or tablets to be used by doctors may also enrich the doctor-patient interaction. Reading a patient’s eCard together with the doctor’s oCard could be used to grant access to the data of the particular patient to the particular doctor, momentarily or even temporarily. This may lead to new scenarios of doctor-patient interaction even on the move instead of being limited to the space of an office. A similar approach considering the care of the elderly based on nursing services was demonstrated by Falgenhauer et al. [108]. A context-aware terminal device was implemented in order to visualize data and configure access rights depending on cards placed on a reader device linked to a tablet computer.

4.4.4 **Advanced Patient Terminal concepts**

The present system uses the mobile phone to act as the one and only device to acquire, transmit, receive, and visualize all kinds of data. But there might be scenarios with coexistence of mobile phones together with other devices acting as an AHD.

Utilizing specific advantages given by NFC technology, like identification or automatic Bluetooth pairing as shown with KIT 2.0, allows for using other devices with the same level of flexibility, usability, and security. One way could be a setup as shown in figure 14. A device called gateway, which comes without any conventional user interface like

display and buttons, operates as a data hub. It receives the data from all digital sensor devices by means of any PAN technology like Bluetooth, Wi-Fi, or ANT+. In order to assign the measured values to the right patient, an ID card has to be put onto the gateway which features an NFC interface. Thus, the patient needs to place his ID card onto the gateway before performing a measurement. When data are sent to the gateway immediately or delayed, timestamps of measurements are correlated with the time point of placing the ID card and hence used to relate a measurement value to a specific person. If no ID card is put on the gateway at the moment of performing a measurement, data are discarded automatically. Successfully assigned data are transmitted to the backend system immediately. Thus, this function could also be integrated to the already existing and widely-used device category of Wi-Fi or Internet router simply by extending it with an NFC interface. This interface will not only care for failsafe assignment of measured data, but also for a simple configuration of the device infrastructure and system setup. If a new sensor device has to be added to an existing setup it has to be held close to the gateway. By means of NFC, the Bluetooth or Wi-Fi link between the device and the gateway becomes established automatically. Additionally, a simultaneous placing of an ID card together with a dedicated single-user device configures the gateway to take the data from this device without the need to place the ID card during measurement anymore. This concept would also allow for multiple backend systems. The destination of a data set might be defined by the ID card or even by a combination of ID card and sensor device. A first prototype of this concept was presented by Alyildiz et al. [**A2**].

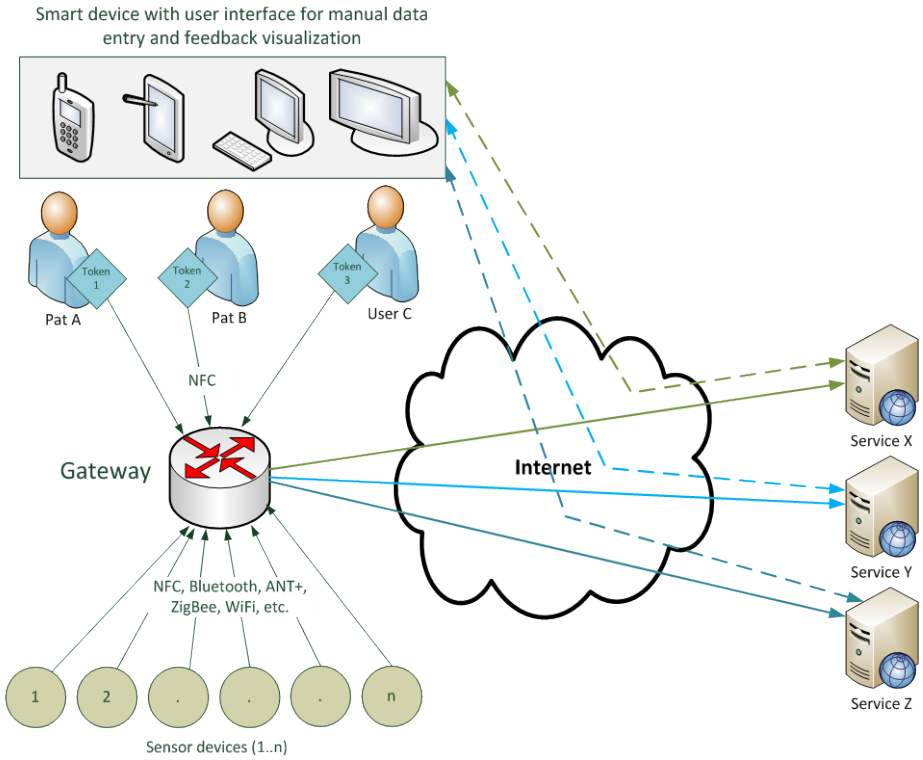

Figure 14: The concept of splitting a patient terminal into gateway and feedback device(s).

Since this approach automatically cares for all sensor data, at least one additional device is needed that cares about the remaining data. This device has to provide a conventional user interface enabling the patient to enter symptomatic data or document medication intake as well as to visualize the alerts and received feedback information. Thus, this devise can be represented by any device featuring an Internet connection, like an ordinary mobile phone, tablet computer, laptop or desktop computer or even a smart TV or gaming console. There is no need for a specific wireless interface to interact with the sensor devices. The user interface can be realized by means of a Web application instead of a native client application. This approach provides full platform-independence and enables the end users to select their devices of choice from a broad range of different vendors and even to switch to another device and back again at any time.

The importance of these devices for the entire society is growing continuously, since they determine the way we communicate and receive information. Even the healthcare system is influenced by them as they provide Web 2.0 applications, social networks, and serious games with the potential to gain the patients' awareness and promote health-related behavior change [109, 110, 111].

5 Conclusions

Motivating patients suffering from chronic diseases to actively take part in managing their situation by means of telemonitoring requires providing them with an appropriate way of communicating with the system and staying in contact with their caregivers. Since the mobile phone is already a ubiquitous accessory that meets the technical prerequisites, it has the potential to act as the patient's terminal device, at least for persons who are familiar with this technology. But deploying this concept to the elderly and technically unskilled persons still remains a challenge. The major task is to provide them with a user interface that allows managing all kinds of health related information and everything else that belongs to them (e.g. sensor devices) in an easy-to-use and, at the same time, secure way.

The presented KIT approach based on mobile phones and NFC technology shows potential to solve this problem by bridging the gap between the physical world of objects and the virtual world of information. It transforms any item that may be important for telemonitoring into a smart object that can be accessed by the simple gesture of touching it. Thus, KIT represents a mobile patient terminal solution that is not only able to overcome barriers of time ("anytime"), and space ("anywhere"), but also to include "everything". The intuitive and intentional way of interacting with "everything" provides a high level of usability. Hence, it can be used by "anyone", even elderly and technically unskilled persons. In combination with a closed loop telemonitoring service, it has the potential to provide pervasive healthcare service to assist patients and their caregivers in therapy management for chronic diseases.

Although further research and developments need to be done to ensure broad deployment of such pervasive healthcare services with full integration into national health IT infrastructures, the results obtained so far in clinical trials and medium scale proof-of-concept telemonitoring projects are promising. By means of KIT technology, patients suffering from different diseases like chronic heart failure, pulmonary arterial hypertension, type I and type II diabetes have proven that they are able and willing to take an active part in therapy management. This strong patient involvement is a big step towards the ultimate goal of personalized healthcare services providing high levels of efficiency, quality, and safety and at the same time moderate costs for the healthcare system.

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Appendix

Device interface analysis

The results of the survey regarding the communication interface and protocol revealed broad diversity among the analyzed devices. In the following the individual properties and communication parameters of the different devices are listed.

a) Wrist blood pressure meter (boso medicus PC3)

This device with a user interface based on a display, a START button, and a hidden SET button provided an internal memory to store the data (systolic and diastolic blood pressure, heart rate, timestamp) of up to 250 measurements. These data could be interrogated over a three lead 2.5 mm jack bush which was used to connect the device to a PC via a serial cable using RS232c voltage level (low = 3…9V, high = -3…-9V). After connection a dedicated software application was used to activate interrogation mode (nine static lines appeared on the display). By means of pressing the START button an entire memory dump was sent in the following data format:

UB0401 201A5F3B0000FF00C0F0D0605UB0401 20…….. UB0401 21

Information is encoded in ASCII format and has to be separated and partly interpreted as HEX data as shown in Table :

Table A1: Interpretation of encoded data sent by the blood pressure meter boso medicus PC3

ASCII String (hex coded)	Decimal value	meaning
UB0401	-	start string for each new data set
20/21		next data set/finished
1A	26	systolic minus diastolic blood pressure
5F	95	diastolic blood pressure
3B	59	heart rate
0000FF0		separator between value set & timestamp
0C	12	month
0F	15	day
0D	13	hour
06	6	minute
05		checksum

b) Digital blood pressure monitor (UA-767Plus BT)

This device provided an internal interface to connect an integrated Bluetooth communication module. The 4 leads of this connector were used to power the Bluetooth module (6.0Vcc and GND), to indicate the operation state (IRQ), and to send the data (TX) using TTL voltage level (low = 0...0.5V, high = 2.5…5V). Immediate after a measurement was finished data were transmitted automatically in the following ASCII format to be interpreted as HEX data:

80 20 55 3C 51 82

This dataset only includes the measurement data since the device doesn't provide a real time clock. After a start string (80) the following four HEX values (20 55 3C 51) represent the difference between systolic and diastolic blood pressure, the diastolic blood pressure, the heart rate, and the mean arterial blood pressure respectively. Decimal representation of these HEX values equals the data shown on the meters display (same as *Boso medicus PC)*. The data string ends with a checksum over the prior five HEX values (82).

c) Personal body weight scales (UC-321PL)

This body weight scales comes with a button to activate the weighting process, a display, a slide switch, and a 3.5 mm jack bush. Using a two lead serial cable (GND and TX) this device can be connected to a PC's RS232 interface. TX line was grounded in OFF-mode and changed to RS232c level after pushing the device's button. Through the slide switch on the bottom side the user can choose between two different data modes (A or B) and two different units (kg and lb).

In mode A the signal from sensor was digitized and streamed permanently. The streaming rate was 50 byte per second. The receiving part had to analyze this stream and calculate the final value of the body weight based on the transmitted time series.

In mode B a data string was sent automatically after the body weight was measured. This required the user to stand steady for at least 8 seconds. After the final value was calculated by the device itself the result was displayed and the following data strings were sent depending on the chosen unit.

ST,+077.60kg or ST,+0171.1lb

Data were provided in human readable ASCII characters comprising of algebraic sign, value with decimal place, and unit. Further information such as a unique device ID or a time stamp was not provided due to lack of a real time clock. After transmission the device continued displaying the result for 15 seconds and turned off automatically.

d) Blood glucose meter (OneTouch Ultra II)

The user interface of this meter comprised a display, an “OK” plus two navigation buttons, a port for inserting test strips, and a 3.5 mm jack bush for data connection with a PC. Buttons were used to set up the language as well as the real time clock, to enable or disable annotation function, and to choose the unit (mg/dL or mmol/L). An internal “first in – first out” (FIFO) memory was able to keep up to 500 measurements. The meter was activated by inserting the test strip and switched off automatically when pulling the strip after a measurement was performed successfully. After a measurement the user was able to annotate each individual value with additional information.

To import the stored data into a PC software one had to connect the device to an USB port using an USB2serial cable providing the TX and RX line with TTL voltage level. By means of sending individual commands the software took control of the meter. Thus it was able to read or even manipulate a set of data like

- time (read and set)
- unit (read and set)
- device serial number (read)
- memory (read and delete)

To read the memory the following command based on seven HEX characters had to be sent to the meter:

11 0D 44 4D 50 0D 0A (HEX)

This command caused the meter to answer with the following ASCII coded data string:

P 007,"XBF4077BY","MG/DL " 05A7
P "MON","12/15/08","12:15:41 "," 131 ","A","01", 00 09A2
P "MON","12/15/08","12:08:52 "," 087 ","B","06", 00 09B6
P "MON","12/15/08","12:06:40 "," 123 ","N","00", 00 09AE
P "MON","12/15/08","10:04:00 "," 094 ","N","00", 00 09AD
P "MON","12/15/08","10:03:27 "," 089 ","N","00", 00 09B9
P "MON","12/15/08","10:01:33 "," 090 ","N","00", 00 09AC
P "MON","12/15/08","10:00:54 "," 090 ","N","00", 00 09AE (ASCII)

The human readable data string contained the following relevant information:

P 007,"XBF4077BY","MG/DL " 05A7

Total number of measurements, device serial number, unit, checksum

P "MON","12/15/08","12:15:41 "," 131 ","A","01", 00 09A2

Day of measurement, date (m/d/y), time (h/m/s), glucose value, reference to meal (A…after, B…before, N…no comment), code for further annotation, checksum

e) Blood glucose meter (Precision Exceed)

The design of this device showed similarity to the blood glucose meter mentioned before but in addition to measuring the blood glucose level it allows to measure the blood β-ketone value. The device provided a user interface comprising a large display and three buttons to navigate through a menu to setup the date, time and unit. The internal memory was capable to store up to 450 events (blood glucose and/or β-ketone values). An electrode port on the meter's bottom side was used to insert test and calibration strips for blood glucose and/or β-ketone measurement as well as a data cable. The meter was activated by inserting the test strip. A symbol shown on the display prompted the user to apply a drop of blood to the strip's capillary. An acoustic signal indicated the detection of blood and a countdown of five seconds was visualized to indicate the analysis process. Thereafter the value was shown in case of a successful performed measurement. After pulling the strip out of the electrode port the device switched off automatically. Thereafter the user was able to connect the meter to a PC using a dedicated data cable. This serial data cable for bidirectional communication with RX and TX lines was linked to the PC's RS232 port (cable requires TTL level converter chip) or to the USB port. A dedicated software application running on the PC was then able to interrogate the device to read out the stored data.

Once the data cable is plugged into the meter it automatically entered transmission mode and announced its presence by sending the following data sequence (***blue***… data sent by meter, ***red***… data received by meter)

<ENQ> --->

<--- <ACK>

<STX>1XCEED<ETX>C1C2<CR><LF> --->

<--- <ACK>

<EOT> --->

After this session to announce the presence the line was considered neutral and the software running on the PC was able to begin communication with the meter.

The communication protocol of this device was conform to the "Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems" known under ASTM-e-1381-95 and supported the following command set to interrogate the meter's data:

- device serial number (read)
- device date and time (read)
- events (read and delete)

An event can be one of the following items:

- glucose level (in mg/dL)
- glucose control event (in mg/dL)
- β-ketone level (in mmol/L)
- β-ketone control event (in mmol/L)
- time change event
- power-on-reset event

To read the list of all stored events the following command had to be sent to the meter:

<STX>1GET_EVENTS<ETX>C1C2<CR><LF>

Thereafter the meter responds with the following data string:

<STX>101<TAB>0<TAB>20110616<TAB>17:30<TAB>00148<TAB>0<CR><ETB>C1C2<CR><LF>
<STX>201<TAB>0<TAB>20110616<TAB>12:10<TAB>00165<TAB>0<CR><ETB>C1C2<CR><LF>
<STX>301<TAB>0<TAB>20110615<TAB>19:33<TAB>00083<TAB>0<CR><ETB>C1C2<CR><LF>
<STX>401<TAB>0<TAB>20110615<TAB>09:01<TAB>00121<TAB>0<CR><ETB>C1C2<CR><LF>
<STX>501<TAB>0<TAB>20110614<TAB>17:30<TAB>00188<TAB>0<CR><ETB>C1C2<CR><LF>
<STX>601<TAB>0<TAB>20110613<TAB>20:27<TAB>00094<TAB>0<CR><ETB>C1C2<CR><LF>
<STX>701<TAB>0<TAB>20110613<TAB>11:58<TAB>00101<TAB>0<CR><ETB>C1C2<CR><LF>
<STX>0END_OF_DATA<ETX>C1C2<CR><LF>

The meaning of the individual episodes is outlined in the following colored example:

<STX>101<TAB>0<TAB>20110616<TAB>17:30<TAB>00148<TAB>0<CR><ETB>C1C2<CR><LF>

consecutive number of event, type of event, valid time flag, date, time, value, out-of-range flag, checksum

f) Spirometer (Spirotel, Medical International Research, Roma, Italy)

This device is a handheld spirometer for patient use to acquire the following spirometry parameters:

- Forced Vital Capacity (FVC)
- Forced Expiratory Volume in 1 second (FEV1)
- FEV1/FVC ratio (FEV1%)
- Forced Expiratory Flow 25–75% (FEF 25-75)
- Peak Expiratory Flow (PEF)
- Forced Expiratory Time (FET)

In addition to that a pulse oximeter finger clip can be connected to the spirometer to allow for spot or continuous recording of:

- Oxygen saturation level (%SpO2)
- pulse rate

Thus, the device is suitable for asthma and COPD patient monitoring as well as sleep apnea desaturation recording. Additional respiratory symptoms can be acquired by visualizing programmable questions.

For this purpose and to view the recorded data locally, the device featured a user interface consisting of a liquid crystal display with two lines of 16 alphanumeric characters and five keys to operate the device.

After performing a measurement the data were stored in the internal memory. Stored data could be transmitted directly via a telephone line by means of acoustic coupling between the spirometer and a common land line telephone device.

In addition to that the device provided a proprietary data port to be linked to a PC using a serial data connection based on a RS232 cable. In the following a dedicated software application was able to interrogate the stored data for further processing. The connection provided bidirectional communication using the RX, TX, and RTS line. By means of a dedicated protocol the software application was able to command the device. The meters firmware supported a command set of up to 26 commands each represented by a single hex value.

In order to read the full dump of all spirometry and oximetry data the following command sequence had to be sent to the meter (***blue***… data sent by PC, ***red***… data sent by meter)

<00h> (get status) --->

<--- <32h 35h 34h 30h 30h 39h 32h 34h 33h>

<66h > (get all spirometry data) --->

<--- <response 1st record of spirometry data, FFh>

<06h > (ACK) --->

<--- <response next record of spirometry data, FFh>

<06h > (ACK) --->

I

<--- <response last record of spirometry data, FFh>

<06h > (ACK) --->

<--- <04h>

<77h > (get all oximetry data) --->

<--- <response 1st record of oximetry data, FFh>

<06h > (ACK) --->

<--- <response next record of oximetry data, FFh>

<06h > (ACK) --->

I

<--- <response last record of oximetry data, FFh>

<06h > (ACK) --->

<--- <04h>

Spirometry and oximetry data were sent in hex coded values to be interpreted as outlined in the following:

Single spirometry data record:

Data stream: 0Bh 07h 0Fh 0Dh 23h 0Ch 01h DFh 04h 32h 01h DEh 01h 01h F7h 00h

Meaning: Timestamp, FEV1, PEF, FEF2575, ID_PAR_TL, PAR_TL, Traffic light (TL)

Interpretation: Year…2011, Month…07, Day…15, hour…13, minute…35, second…12, FEV1…479cl, PEF…1074L/min, FEF2575…478cl/s, parameter reference used…FVC, Reference value…503cl, Traffic light parameter reference…GREEN

Singele oximetry data record:

Data stream: 0Bh 07h 0Fh 0Dh 29h 31h 5Ah 62h 60h 3Bh 49h 44h

Meaning: Timestamp, SPO2_min, SPO2_max, SPO2_avg, BPM_min, BPM_max, BPM_avg

Interpretation: Year…2011, Month…July, Day…15, hour…13, minute…41, second…49, SPO2_min…90%, SPO2_max…98%, SPO2_avg…96%, BPM_min…59 1/min, BPM_max…73 1/min, BPM_avg…68 1/min