IST Programme

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Pre-Trial User Evaluation Report:

Pre-Trial #1 (August-September 2003)

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Contents

Executive Summary

This document reports on the results of the first pre-trial of the MobiHealth project from the perspective of the trial owners. A trial owner is the doctor, nurse, physiotherapist, administrator and technical provider involved in putting together and running the trial. A trial is a field test of the MobiHealth Body Area Network prototypes and the necessary communications infrastructure.

The trials follow the guidelines outlined in Deliverable 1.4 of the project. That deliverable determines the methodology used for evaluating the field trials.

Running over the summer and mainly in the month of September 2003, Pre-Trial #1 of the MobiHealth prototype tested Version 3.0 of the BAN in trials running in Barcelona (ES), Moenchengladbach (D), Enschede (NL), Luleå and Boden (SE). It was the purpose of this pre-trial to familiarise trial owners and in a limited way their clients (patients, care recipients) with using the BAN and communications; to evaluate the performance and user-friendliness of the equipment; and to provide data to the system providers for upgrading their prototype to Version 3.1. In turn Pre-Trial #2, scheduled for November, will evaluate the enhanced performance of Version 3.1 of the BAN in similar field tests in the same regions. The project will end with the running of a third set of trials of the system at each location, to take place in December 2003 and January 2004.

The user evaluation is based on a questionnaire filled in by each trial owner having completed their pre-trial. The sections below quote directly from the answers given.

A brief description of each trial follows:

Germany

Trial 1 Secondary prevention in coronary heart disease

In the future trial the patient is able to transmit ECG and blood pressure via GPRS from home or elsewhere to the health call centre, where the vital signs are monitored by a cardiologist. The intention is that irregular patterns in these vital signs will be quickly detected and appropriate intervention can be effectuated. The trials are designed to determine whether 2.5-3G wireless communications can support such services. *In this pre-trial the unit was tested by several medical and technical personnel and one cardiac patient, as well as persons at the call centre.*

Sweden

Trial 1: The Lighthouse alarm and locator

The purpose of the Lighthouse trial is to test the effectiveness of a new GPRS/UMTS-based personal alarm and locating device for clients of the care centre, especially the elderly, and the personnel, according to several determining factors: safety, convenience,

empowerment of user, mobility of user and improvement in efficiency of care given. *In this pre-trial, the connectivity and positioning were tested by one trial owner in the Lighthouse and one test person in the city.*

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

The aim of the trial is to follow the patients' activity level during the course of a week, by means of continuous monitoring of heart rate and self-reporting of the activity level, monitoring walking distance to determine the factors that impede the patient from performing those activities that she wishes to perform. The primary research question is to examine the correspondence of heart data and monitored activity to the self-reports of activity level. It is also intended to evaluate how the women experience using the mobile technological devices. *In this pre-trial the trial owner tested the system with a colleague.*

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

The end trial is to examine whether mobile health facilities with monitoring of some relevant vital signs can contribute to an earlier detection and treatment of COPD and also reduce the need for check-ups and hospitalisation. *In this pre-trial, two professionals and one test-person wore and tested the unit off and on over several days, performing different activities. One trial owner wore the BAN system continuously for 17 hours.*

Trial 4: Home care and remote consultation for recently-released patients in a rural area

The end goal of this trial is to find a way to communicate vital signs from a person at home to an Registered Nurse and/or a physician for consultation and diagnosis in order to reduce visits to the hospital and give trustful and safe care at home. A subsequent aim is to use this methodology and evaluate the consequences in terms of experiences of healthcare and living at home with severe illness (quality of life, ethical considerations etc.) and also evaluate the consequences for the Nurse Aids, Licensed Practitional Nurses and Registered Nurses in their work. *In this pre-trial, two professionals tested the system in several different environments, at home, in a healthcare department, and in a car driving over a wide rural area.*

Spain

Trial 1 Support of home-based healthcare services

The end resulting trial involves use of GPRS for supporting home-based care for elderly chronically ill patients, usually suffering from more than two concurrent conditions. The MobiHealth Nurse-BAN will be used to perform patient measurements during nurse home visiting. *This pre-trial involved technical and medical personnel only, and was run exclusively in the hospital and between the hospital and the telecommunications services.*

Trial 2 Outdoor patients' rehabilitation

In the scenario description for the trials as originally designed, the patients involved in this trial are chronic respiratory patients who could benefit from rehabilitation programmes to improve their functional status. The study aims to check feasibility of remotely supervised outdoors training programs based on control of walking speed enabled by use of the BAN. The physiotherapist will receive on-line information on

patient's exercise performance and will provide feedback and advice. *In this pre-trial exclusively technical and medical personnel tested the system, and the test was run in the hospital and between the hospital and the telecommunications service partner.*

The Netherlands

Trial 1: Tele Trauma Team

This trial is for a sensor, visual and transmission system for trauma/medical care delivered by an ambulance, at the scene or on the way to the hospital. The main objectives are to examine the feasibility and safety of monitoring various vital signs, recording the site of the accident and communicating with and guiding the paramedics, all by sensors put by a paramedic upon the patient or worn by himself, and relaying these data to the trauma hospital. *There was no pre-trial on this occasion.*

Trial 2: Integrated home care for women with high-risk pregnancies

The purpose of this study is to evaluate whether monitoring at a distance of vital signs (e.g. CTG, maternal blood pressure) is feasible, safe, and can postpone hospitalization for women with a high-risk pregnancy. *This pre-trial monitored ten healthy pregnant women at a hospital and two at home.*

Part One: Field Pre-Trial Details per Site

Testing period:

Germany

Trial 1 Secondary prevention in coronary heart disease

9th-September – 22nd September 2003; preparation (trying out the BAN equipment with staff only, limited communication tests, getting the BAN up and running, familiarising staff with Portilab, accessing measurements) 50 hours. Following this, tests were done with two patients, lasting a total of circa six hours.

Sweden

Trial 1: The Lighthouse alarm and locator

2nd October (1 hour), 3rd October (1 hour), and 8th October (3 hours) 2003.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

8th September-12th September. On the 8th September the test ran from 8.30 to 16.00 , on the 9th to the 12th from 9.00 to 16.00 each day. On 8th September a volunteer tested the BAN, and from 9th to 12th only the activity sensor was trialed, not the ECG.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

3rd September (1 hour), 7th-8th September (17 hours, continuously overnight), 20th-21st September (in total 6 hours), 22nd September (2 hours) 2003.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

10th–11th August, 26th September, 29th and 30th September 2003, approximately four hours a day.

Spain

Trial 1 Support of home-based healthcare services

End of August until end of September 2003. The testing was done each day periodically (during the morning) and lasted around four hours every day.

Trial 2 Outdoor patients' rehabilitation

End of August until end of September 2003. The testing was done each day periodically (during the morning) and lasted around four hours every day.

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial at this stage.

Trial 2: Integrated home care for women with high-risk pregnancies

August, September 2003. In this period we mainly monitored patients in the hospital. The reason is that the BAN and Bluetooth sent data to the computer correctly up to a distance of a metre. As soon as the iPAQ was placed in between, communication failed. 10 pregnant patients were monitored for several hours each.

Location of test (all locations where BAN was tested/data read)

Germany

Trial 1 Secondary prevention in coronary heart disease

Cardiologic Office; Merinus Metten PhD, Moenchengladbach.
Medical Call Center; GesundheitScout24, Duisburg.

Sweden

Trial 1: The Lighthouse alarm and locator

BAN was tested at the Lighthouse care centre and in the city centre of Luleå.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

The location of the test of the BAN was at the Department of Health Science, Boden. The test was inside the department, with the test-person walking around in the department during the day.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

The BAN was tested in the homes of the Trial Owners (Susanne Andersson and Staffan Andersson) in the countryside and in the city centre of Luleå.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

There were five pre-trials: Test 1 and 2 in Boden, Test 3 in a private home in Storsand north of Boden, Test 4 in Luleå and Test 5 in a car driving from Storsand to Boden for 45 minutes.

Spain

Trial 1 Support of home-based healthcare services

The BANs were tested in the Clínic hospital in Barcelona. The data was sent to the server placed in Telefónica (Madrid) and then the access to the information was done from portable PCs also at the hospital (Barcelona).

Trial 2 Outdoor patients' rehabilitation

The BANs were tested in the Clínic hospital in Barcelona. The data was sent to the server placed in Telefónica (Madrid) and then the access to the information was done from portable PCs also at the hospital (Barcelona).

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial at this stage.

Trial 2: Integrated home care for women with high-risk pregnancies

- at the hospital
- at home with pregnant women.

This pre-trial tested 10 women at the hospital and two when they were at home. The 10 hospital patients were monitored at the birth centre of Medisch Spectrum Twente in Enschede, under the supervision of a gynaecologist.

Person(s) testing BAN

Germany

Trial 1 Secondary prevention in coronary heart disease

Professionals:
Baerbel Krell
Merinus Metten
Christian Hund
Stefan Roedig

Patient:
Michael Dahlmanns

Sweden

Trial 1: The Lighthouse alarm and locator

Professionals:
Anna-Lena Andersson
Stefan Kullberg
Maria Porsberger
Eeva-Kajsa Nilsson

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

One professional person tested the BAN, with a test-person at the Department of Health Science.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

A healthcare professional himself (Staffan Andersson), and an independent tester, instructed by another professional (Susanne Andersson).

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Two professionals, Monica Hansson, Agneta Granström.

Spain

Trial 1 Support of home-based healthcare services

There were two technicians testing the BANs and the global system plus two professionals evaluating the results and the measurements done by the sensors.

Trial 2 Outdoor patients' rehabilitation

There were two technicians testing the BANs and the global system plus two professionals evaluating the results and the measurements done by the sensors.

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial at this stage.

Trial 2: Integrated home care for women with high-risk pregnancies

R. Quartero (gynaecologist) and C. Sluimer (resident gynaecology) from the medical point of view and selecting patients. Technical professionals: J. Peuscher of TMSi is working on the Portilab software, and A. van Halteren of University of Twente is working on the iPAQ.

BAN (Mobi serial number, iPAQ model, and extras):

Germany

Trial 1 Secondary prevention in coronary heart disease

Mobi SN 0924030051
IPAQ SN 4G2ADW34N07V

Sweden

Trial 1: The Lighthouse alarm and locator

iPAQ SN 4G2ADW34N072
Mobi SN 0924030048
GPRS SN 9V36KD41AMTG
GPS receiver and 2 Sony Ericsson p800s
SIMs for GPRS connection (provided by TeliaSonera)

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

IPAQ SN 4G2ADW34N086
Mobi SN 0924030012
GPRS SN 9Y36KD41AMWC
SIMs for GPRS connection (provided by TeliaSonera)

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

iPAQ SN 4G2RDW34N07D
Mobi SN 0924030021
GPRS SN 9434KD41KLJK
SIMs for GPRS connection (provided by TeliaSonera)

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Mobi S/N 0924030029
iPAQ S/N 4G2ADW34N06W
GPRS S/N 9Y36KD41AMAC
SIMs for GPRS connection (provided by TeliaSonera)

Spain

Trial 1 Support of home-based healthcare services

iPAQ S/N 4G2BDW34R04S
iPAQ S/N 4G2BDW34R05W
iPAQ S/N 4G2BDW34R05T

Mobi S/N 0924030041
Mobi S/N 0924030044
Mobi S/N 0924030018
GPRS/WLAN NOKIA D211 (PCMCIA provided by the hospital CSC)
SIMs for GPRS connection (provided by Telefónica Móviles)

Trial 2 Outdoor patients' rehabilitation

iPAQ S/N 4G2BDW34R04S
iPAQ S/N 4G2BDW34R05W
iPAQ S/N 4G2BDW34R05T
Mobi S/N 0924030041
Mobi S/N 0924030044
Mobi S/N 0924030018
GPRS/WLAN NOKIA D211 (PCMCIA provided by the hospital CSC)
SIMs for GPRS connection (provided by Telefónica Móviles)

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial at this stage.

Trial 2: Integrated home care for women with high-risk pregnancies

At time of publication the equipment was at the house of a patient. The written documentation was unavailable temporarily as it was in the case of the resident who was on leave**.**

Sensors tested (parameters measured):

Germany

Trial 1 Secondary prevention in coronary heart disease

ECG (3-lead)
Marker / Alarm button
Movement sensor
Manual input of blood pressure levels

Sweden

Trial 1: The Lighthouse alarm and locator

Activity/ drop sensor
3-lead ECG (heart rate)
Alarm button
GPS (position)
Camera (still image)

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

3-lead ECG
Activity sensor

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Activity sensor
3-lead ECG (heart rate)
Pulse oximeter (SpO2, pulse rate)

Trial 4: Home care and remote consultation for recently-released patients in a rural area

3-lead ECG
Pulse oximeter (plethysmogram, SpO2, pulse rate)
Note: respiration was scheduled to be tested but was not, due to the lack of the appropriate sensor, which had been delivered in the pre-BAN but this sensor was accidentally not delivered from Enschede in this version of the BAN.

Spain

Trial 1 Support of home-based healthcare services

SatO2
ECG
spirometry

Trial 2 Outdoor patients' rehabilitation

Pulse oximetry
ECG
mobility

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial at this stage.

Trial 2: Integrated home care for women with high-risk pregnancies

Heart rate of the mother
Heart rate of the unborn child
EMG mother
Blood pressure

(Note: Blood pressure is a variable. CTG measurement is part of another home care project for pregnant women. Measurements of the BAN are a substitute for CTG monitoring.

Part Two: Outcome (Assessment)

Activating iPAQ

Germany

Trial 1 Secondary prevention in coronary heart disease

We encountered problems with GPRS connection (success rate 0%), with some tricks (inserting GPRS sleeve in the right moment etc.). GPRS connection is available in most cases but this takes some time and patience. Not yet user-friendly enough to run trial.

Sweden

Trial 1: The Lighthouse alarm and locator

The iPAQ had to be reset several times during the test.
The information in the user manual on how to start the iPAQ up was quite clear *(Note: this trial used the translated version of the latest manual – version 1.6 Swedish, based on version 1.3 English - unlike the other Swedish trials who used a slightly earlier version – this demonstrates an already considerable improvement in the user manual).*
The battery on the MBU (iPAQ and GPRS jacket) did not have a long life.
At times the iPAQ could not be turned off.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

The iPAQ and the GPRS sleeve had to be reset many (2-3) times before the correct status on the iPAQ was activated.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

During 20/9 and 21/9 they tried to activate (start) iPAQ for one hour (each day), but did not succeed to reach “MBU sending” status. Had to reset iPAC 5-6 times (each day), and was not able to find in the user manual what was wrong. On 21/9 the professional concluded that the Back-End system might not be up and running. At times the iPAQ could not be turned off.

Success rate: 10% number of resets on iPAQ and GPRS sleeve. Only approximately one out of ten resets of the system resulted in making the iPAQ active so you could fill in the manual data.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

There was start-up failure. The iPAQ had to be rebooted 7 out of 10 times. There were also no problems encountered in activating the iPAQ. The problem was to turn it off; the iPAQ is always on, even in the cradle.

Spain

Trial 1 Support of home-based healthcare services

The application and the system do not seem to be very stable, the communications often fail. Being more specific, the main problem relates to the establishment of the GPRS connection and the transmission of the data from the iPAQ to the Back-End system. In order to make sure that the GPRS connection has successfully been established, you have first to restart the iPAQ. Then, when it starts running, you have to take the iPAQ out and in from the GPRS jacket. Once this has been done, it is still necessary to test that the communication is properly established. In order to do so, it is necessary to open the command screen in the iPAQ and enter the following line: 'ifconfig ppp0', obtaining a long technical message which tells if the connection is working or not. The actual meaning of the message should not be considered by the user. Rather he only checks that it is a long one. If the previous steps have been successful, , and in order to send the sensor's data from the iPAQ to the Back-End system, you have to press the 'send data' button on the iPAQ's screen. However, this doesn't mean that data are being successfully transmitted. In our measurements we found that only 20% of the time this works properly. In the remaining 80% of the cases, the data never get stored at the Back-End system.

Trial 2 Outdoor patients' rehabilitation

Same as section for Spain Trial 1 immediately above.

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial at this stage.

Trial 2: Integrated home care for women with high-risk pregnancies

The capacity of the battery is a problem, but activating the iPAQ is not a problem. The BAN sends five minutes of data to the iPAQ. Then it notices that the iPAQ is not turned on (while it is on) and the process of data sending stops. Monitoring at home never lasted longer than this 5 minutes, over and over.

Sending

Germany

Trial 1 Secondary prevention in coronary heart disease

The sending mode does not work sufficiently, in most cases there is no connection when pushing the Start button on the IPAQ ("Check Mobi Device"). Sends data without problems in approx. 10% of attempts.

Sweden

Trial 1: The Lighthouse alarm and locator

Portilab did not work in the Lighthouse care centre, so it is not known if data was sending; this was due to not being able to connect to the Back-End server, and was only a temporary fault.

Note: A later check shows that two files were stored in the Back-End system but there were only 2 and 7 minutes of data stored. The first test should have been at least one hour. There was no indication of communication failure to the user.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

On 8th September, data was sent for about 50 minutes to the BE system.
On 10th–12th September, it was not possible to send data. There was no connection to the BE – and no indication on the MBU for that, the text was only "MBU activated", not "MBU sending" so the interpretation of the trial owner was that it was not possible to send data.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

Succeeded in reaching sending status on 22/9. According to technical personnel, data was sent for approximately 40 minutes.

In the overnight continuous test, the success rate was 0%. No data was transferable to the Back-End system.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

In Tests 1-4, connection start-up failed seven out of ten times. The signal "no connection, check Mobi" appeared. After rebooting the iPAQ it started up and was transmitting at once, but after ten minutes of sending the iPAQ disconnected. After restarting the iPAQ the Mobi was still sending. According to the display, the Mobi worked during the whole test.

In Test 5: while the trial owner was driving, the Bluetooth light stopped and the green light indicating GPRS was blinking. After reboot it did not start again. It took four reboots to start. The Bluetooth and green light for GPRS functioned but the Mobi did not connect. The trial owner tried to start the iPAQ 6 times without result.

Spain

Trial 1 Support of home-based healthcare services

The IPAQ's software appears as the weakest link of the system. Several problems were detected:

The connectivity between the IPAQ and its GPRS jacket is not reliable. The IPAQ needs to be rebooted almost after each data transmission. Rebooting the device implies connecting the GPRS jacket at the right moment, inserting the password and restarting the application. Doing it once or twice it is not such a big deal but being a professional or a patient and repeating the procedure many times a day…. The "Start Mobihealth" application is very poor. On the left-hand side, 2 icons appear and disappear; do they give any kind of information? This is not known.

The following aspect is more critical. The application has different states such as: de/activated, un/registered, sending. The states are communicated to the user through a text message and are linked with the state of the button (Start/Stop). After many essays we conclude that the application is not stable, the sequence of states is unpredictable for the same inputs.

In other words, the application only ends working properly (i.e. sending the measured data) in around 20% of the cases. As you can imagine working in such conditions becomes frustrating. It is complicated for a healthcare professional to deal with such poor material, but impossible for a patient (elderly) who generally has fewer contacts with technology.

The battery of the device must be full, or almost, if we do not want the communication to fail more than it has been said. The IPAQ has to be almost connected most of the time. The mobility is then reduced.

Trial 2 Outdoor patients' rehabilitation

Same as section for Spain Trial 1 immediately above.

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial at this stage.

Trial 2: Integrated home care for women with high-risk pregnancies

There was a lot of trouble in sending the data. Until now the problem(s) is (are) still not solved. We are working on it, together with Aart van Halteren. of University of Twente. This problem has lasted until now. The iPAQ is brought to the University, they fix it, there is another try and the problem comes back every time. The heart of the problem is the communication between the BAN and the iPAQ. At this moment the situation is as far as a few weeks ago.

Mobi-iPAQ-Back-End system communication

Germany

Trial 1 Secondary prevention in coronary heart disease

There were difficulties in getting connection between the Mobi and iPAQ. Communication between the Mobi and iPAQ shut down after approximately four minutes in the best case. In the connection between the iPAQ and the Back-End system, about 50% of data were never seen again.

Sweden

Trial 1: The Lighthouse alarm and locator

Mobi turned off spontaneously several times during the test. The test person had to check if the Mobi was on all the time. During the start-up procedure the iPAQ had to be reset several times. Bluetooth and GPRS (at least as far one could see in the status announcement on the MBU) were working and sending. There is no information whether communication was successful or useful data was received.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

From the Mobi to the iPAQ: about 75% of the time when the iPAQ and Mobi were started up, the blue icon, which should indicate that the Mobi is sending to the iPAQ, came up on the screen.

From the iPAQ to the Back-End system: 95% of the time there was no apparent connection between the iPAQ and the Back-End system; that is, there was no text on the iPAQ reading “Status: MBU is sending”.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

During 20-21/9 there was no success in contact with the Back-End system since it was shut down. The Mobi turned off spontaneously several times during 20-22/9. The test person had to check if the Mobi was on all the time. During start-up procedure the iPAQ had to be reset several times. Bluetooth and GPRS were working. It was considered to be a problem not to be able to know that the Back-End system was up and running. This was considered to be a great advantage to know.

In the overnight continuous trial start-up failed more than ten times (indicator of no connection and command to check the Mobi). There was a spontaneous disconnection five times, and the Mobi spontaneously turned off twice. The battery duration on the Mobi was approximately 20 hours.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Back-End system not tested. Because a good Portilab manual had not yet been written for the medical people it was very difficult to check if they had got any test data on the Back-End system by using the PortiLab application.

We tried but we were not able to get any connections with the Back-End system during Pre-Trial 1.We think the reason was that the Back-End system was not running. After the Pre-Trial 1 period we were able to have connections with the Back-End system and then it worked.

Spain

Trial 1 Support of home-based healthcare services

The IPAQ's software appears as the weakest link of the system. Several problems were detected:

The connectivity between the IPAQ and its GPRS jacket is not reliable. The IPAQ needs to be rebooted almost after each data transmission. Rebooting the device implies connecting the GPRS jacket at the right moment, inserting the password and restarting the application. Doing it once or twice it is not such a big deal but being a professional or a patient and repeating the procedure many times a day….
The "Start Mobihealth" application is very poor. On the left hand-side, 2 icons appear and disappear; do they give any kind of information?.

The following aspect is more critical. The application has different states such as: de/activated, un/registered, sending. The states are communicated to the user through a text message and are linked with the state of the button (Start/Stop). After many essays we conclude that the application is not stable, the sequence of states is unpredictable for the same inputs.

In other words, the application only ends working properly (i.e. sending the measured data) in around 20% of the cases. As you can imagine working in such conditions becomes frustrating. It is complicated for a health care professional to deal with such poor material, but impossible for a patient (elderly) who generally has fewer contact with technology.

The battery of the device must be full, or almost, if we don't want the communication to fail more than it has been said. The IPAQ has to be almost connected most of the time. The mobility is then reduced.

Trial 2 Outdoor patients' rehabilitation

Same as for Spain Trial 1 immediately above.

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial at this stage.

Trial 2: Integrated home care for women with high-risk pregnancies

In earlier experiments data were sent from the iPAQ to the Back-End system. This data stream is ok. No trouble was experienced in getting the data, by internet, out of the server (UT) on the portable computer.

Sensor view on iPAQ

Germany

Trial 1 Secondary prevention in coronary heart disease

If sensors are fit well, ECG #1-#3 is presented accurately. It is necessary to zoom in the viewer in order to see meaningful data. Data can be interpreted broadly (not in detail with a scale); as the medical responsible person said.

Sweden

Trial 1: The Lighthouse alarm and locator

The “Sensor view” window displayed no ECG- or activity curves, but the marker (for alarm) and “saw” signal were visible.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

No sensor signal could be seen on the sensor viewer.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

ECG, pulse oximetry, and activity could not be viewed in the sensor viewer. Restart was attempted, but unsuccessfully, not even on 22/9 when data was sent for 40 minutes. Again, there was no advice from the user manual for iPAQ only for using PC and direct connection with Bluetooth to Mobi, which should not be used in the Swedish trials.

In the overnight continuous trial, the activity sensor seemed to work sufficiently. This was valid for both step registration and body level registration. The pulse oximeter worked fine. There was no valid signal from the ECG; the data seemed to consist of spikes (over-amplified signal). Only the EXG1 and EXG2 sensors were represented, and never the third EXG.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

The ECG showed a signal with spikes; this was not working as it should. There was no valid signal from the ECG. EXG1 and EXG2 were represented, but never EXG3. The signals could not be used by a healthcare professional. Pulse oximeter works fine; with the parameters showing on the screen.

Spain

Trial 1 Support of home-based healthcare services

The results presented in the IPAQ do not permit a correct interpretation. The display of numerical results is satisfactory but the graphics are useless since no scale is available. The professional cannot base his/her whole evaluation on this information. As a conclusion we must say that the interaction with the IPAQ should be much more simple, stable and user-friendly.

Trial 2 Outdoor patients' rehabilitation

Same as section for Spain Trial 1 immediately above.

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial at this stage.

Trial 2: Integrated home care for women with high-risk pregnancies

Because of the communication problem between BAN and iPAQ this group focus on data transmission, and did not concentrate in this stage on the other performance criteria.

Manual input

Germany

Trial 1 Secondary prevention in coronary heart disease

Sending of data by manual input does not work; there was no help desk function available at the time. The software in the iPAQ seems to work all right, but there is no way of knowing if the data arrives and no way of knowing if it is displayed.

Sweden

Trial 1: The Lighthouse alarm and locator

Not tested because the input data was not seen in the Portilab at the time of the trial, although it was apparently sent. A later investigation by Paul Buysmans in Twente determined that two packets of data had arrived.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

There are many steps involved in using the activity list, i.e., choosing the activity and then sending. Except for that, it works well (although one can sometimes forget to send the data, so a reminder to send – light or sound - after data has been entered would be useful).

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

When filling in the manual input/activity list it was easy to forget that one had to press the action button to send the activity to the BES. There were many steps to remember.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

This worked fine, and was easy to use during the test.

Spain

Trial 1 Support of home-based healthcare services

No experiences were recorded here.

Trial 2 Outdoor patients' rehabilitation

No experiences were recorded here.

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial in this area.

Trial 2: Integrated home care for women with high-risk pregnancies

We made no use of it. Because of the main communication problems between BAN and iPAQ we did not focus on manual input. It is not excluded.

Portilab

Germany

Trial 1 Secondary prevention in coronary heart disease

The display is okay, ECG signals seem to be valid, ExG 1, ExG 2 and ExG 3 are presented. Marker button is working, mobility is presented in a proper way. A medical evaluation can be done.

Sweden

Trial 1: The Lighthouse alarm and locator

It has not been possible to get through to Portilab and view the (possibly) sent files; this is probably due to a breakdown in communication with the Back-End system.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

Files were recorded from the BAN, but on clicking on files no signals could be seen when accessing Portilab. *Note: it would be an interesting way of starting PortiLab and get the data presented for the user, if we could just click on a file from the browser. However, this functionality had never been planned to do it this way; today several complicated steps through PortLab are necessary.*

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

One trial owner was not able to get in to Portilab and view her file. Files had been recorded for view in a demonstration at Telia's headquarters on 9th September, but on that occasion also no actual signals could be demonstrated.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Was not tested due to theft of the machine which contained the software from the doctor who was testing. At the time of Pre-Trial #1, this was the only computer with Portilab installed.

Spain

Trial 1 Support of home-based healthcare services

Since the data and the "∗.plc" configurations were not compatible between Portilab1 and Portilab2 not many examples and situations were tested before the BANs delivery. Still, important comments about the Portilab2 application are discussed.

It is not mentioned that Portilab2 does not work under any version of Windows OS. For instance, Portilab2 will not run under Windows NT. Such consideration must be taken into account and spread by the programmers since time can be saved.

Patients section

It is a cause of concern that the application does not provide any tool to link a patient ID with a BAN ID. It is known that the association patient-BAN is not unique; a patient can be monitored with different BANs in different measurements and the same BAN can be used for different patients. It depends on the trial. But, when a professional needs to load a data file from a specific patient he/she has to know the BAN ID (plus day and hour of the measurement). From a clinical point of view this is not efficient because that means that the nurse/doctor has to write down a 12-character ID and enter it in the application (Portilab2).

Moreover, the nurse or doctor might need to monitor more than one patient at once or visualize different measurements at the same time. When working in real time the need is obvious. If the nurse or doctor works with recorded data he/she may also need to compare data between patients or even data from the same patient with pre-recorded measurements. This option is not available in the current version of Portilab2.

A basic solution would have been to open the application as many times as patients or measurements were to be monitored, but this would not work; the application does not seem to be very stable working this way.

Configuration section

A remark has to be mentioned concerning the import of new configurations (∗.plc) in the configuration section. It is not a major problem but it can provoke a waste of time. The fact is that the manoeuvre of importing a new configuration is far from intuitive.

The button conceived to achieve the import of the "∗.plc" is apparently the "add" button in the right-hand corner of the screen. But it isn't. If a new configuration has to be imported the mouse pointer has to be in the grey zone and by pressing the right button a menu gives the possibility to import a new configuration. It is clear that the import can be done, but the way of doing it is not intuitive.

There is another way of entering a new configuration applying when a new configuration has been created (not imported). The "∗.plc" has to be saved in a concrete path which is not given.

The problem of linking the BAN' and the patient's id has been enhanced since the BAN identification number is not easily visible. In order to see it, the GPRS jacket must be removed. If this embarrassing step wants to be skipped, there are some solutions like a post-it or a table, which crosses the BAN id with the BAN number (i.e. "outdoors9") already in a post-it. It is obvious that none of these solutions named above are suitable for a proper and easy use of the system. This is the reason why it should be mandatory to take some of the decisions explained underneath.

When the professional enters Portilab and wants to see the data of a patient, she/he has to know with which BAN and the exact time (beginning and ending) the measurements have been produced. Moreover the measurements are not displayed chronologically (by hour, not by day!!). As you can appreciate the day and some other information is not visible in the menu. To know exactly which measurement we want, we have to go to a TME site were they are displayed.

There is another cause of concern, after a few measurements, the list will be endless and thus confusing. The possibility to structure or delete measurement should be available.

The professionals have the feeling of a lack in terms of usability from the clinical point of view. Most of their suggestions have not been followed and this makes it really difficult to make a good evaluation of the product or even impossible in some trials to make use of the system. As an example of this, it would have been absolutely necessary (and it was said from the very beginning of the design phase) that the name of the patient and other eventual information was directly inserted on the iPAQ during the measurement.

The presentation of the results and measurements is also poor. The measurements cannot be evaluated without a scale. The data interpretation is not possible. The "data storage" option allows the storage of part of the measurements. The data is stored from the beginning until the "stop" button is pressed. It would be interesting to decide when we want the data to begin to be stored.

Trial 2 Outdoor patients' rehabilitation

Same as section for Spain Trial 1 immediately above.

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial in this area.

Trial 2: Integrated home care for women with high-risk pregnancies

Jan Peuscher of TMSi is working on it. He perfected the Portilab software. We use this software and are satisfied about the results. We see what we want to see.

Part Three: Usability and empowerment

Functionality

Germany

Trial 1 Secondary prevention in coronary heart disease

Using the BAN takes a lot of practice and patience. The largest problems are GPRS connection and the usability of the iPAQ software ("sending data mode")

Sweden

Trial 1: The Lighthouse alarm and locator

It was not at this point possible to test the whole system as it was meant to function (no access to Back-End system with Portilab, no confirmation therefore of data arrival). The whole system seems too unstable to test on "real" patients at this point.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

The test person stated that it was convenient to carry the Mobi and iPAQ. The equipment did not hinder the person in his job as a teacher.

For the professional, it is difficult to say something about the functionality before being able to see how the data is presented in Portilab.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

One trial owner states that up until today it is not possible, in her opinion, to receive signals from the sensor/data that are of use for her in her daily work as a physiotherapist. She could not determine whether the signals/data that she received were correct and did not know how to interpret them. She believed the whole system seems too unstable to use on "real" patients.

Another tester stated that the Mobi carried in the belt was most convenient, and also provided the best facilities for good registration from the activity sensor when mounted on top of the Mobi.

The pulse oximeter with the IR sensor on the left ring finger was very convenient, with no problems to wear it overnight. The cables were long enough to allow the Mobi to be disconnected from the belt and placed to one side during the night. The ECG cables were disconnected during the night (but then, no trials in Sweden will use overnight registration with ECG electrodes).

Trial 4: Home care and remote consultation for recently-released patients in a rural area

The BAN was carried around without any problems; also no problems were experienced with driving the car. The sensors were easy to use and the test person had no difficulties with them at all. It was possible to perform activity in daily life.

Spain

Trial 1 Support of home-based healthcare services

Not very user friendly, as stated above, the percentage of success in terms of GPRS connection and data storage is pretty low.

Trial 2 Outdoor patients' rehabilitation

Same as section for Spain Trial 1 immediately above.

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial in this area.

Trial 2: Integrated home care for women with high-risk pregnancies

The women (colleagues) that carry the BAN are enthusiastic. The BAN is light to carry and the stickers cause no trouble. The wires (from stickers to BAN) are too long. The women can imagine that staying at home with this equipment and being monitored at a distance is a great service. Because they are healthy pregnant women it is always difficult to answer the question of safety in case they were high risk pregnant women.

Ease of use

Germany

Trial 1 Secondary prevention in coronary heart disease

The BAN (front end and sensors) seems to be wearable and convenient by carrying it in the little bag. Putting on the sensors is no big problem for patients after a little training.

Sweden

Trial 1: The Lighthouse alarm and locator

Applying the sensors on the test person is time-consuming, but is quite easy. It takes too many steps to start up and to use the iPAQ. If a button on the iPAQ is pressed by mistake (with the stylus) there is no immediate information on how to get back. The Mobi's "on" status must be periodically checked, and this is advisable because it turns off very often. The manual is easy to understand (this is the latest version 1.6 Swedish). The sensors do not feel uncomfortable.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

If things go well a connection between all the equipment is made the first time on start-up, and then the equipment is relatively easy to use. In this pre-trial the manual input on the activity list is the most tricky thing to do because there are many steps to take. Another issue is that the text is small, which can be a problem for patients.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

It takes some time to apply the sensors on the test person, but is quite easy. There are too many steps to start up and to use the iPAQ. If one by mistake pushes a button on the iPAQ (with the pen) it is not indicated how to get back to where one was the moment before. In order to know if the Mobi is still on, it has to be checked now and then, and it turns off all the time. Switching between the different windows did not work.

In the overnight continuous trial, several activities were easily possible to perform while using the unit, even with all the equipment on the body including the iPAQ/GPRS sleeve in one's pocket: making a sandwich, eating and drinking, toilet visits, walking and running, and gardening. One small complaint was that at night, the screen light was disturbing *(Note: there is possibly a solution to this. It could be changed in configuration of the iPAQ: "Light stay off when iPAQ in cradle").*

Trial 4: Home care and remote consultation for recently-released patients in a rural area

The BAN is easy to use. The screen and icons on the iPAQ are easy to understand. The instructions were good except for Portilab.

Spain

Trial 1 Support of home-based healthcare services

It is definitely not easy to use for a professional in the first pre-trial but it is impossible for a patient to deal with the iPAQ the way it works now in a "real" trial.

Trial 2 Outdoor patients' rehabilitation

Same as section for Spain Trial 1 immediately above.

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial in this area.

Trial 2: Integrated home care for women with high-risk pregnancies

The patients can use the devices. Until now patients were colleagues and only two of them used it at home. With a lot of sending trouble.

Safety

Germany

Trial 1 Secondary prevention in coronary heart disease

The system is not yet reliable enough to be considered safe. It is not possible to make clinical decisions with the system at this stage of development.

Sweden

Trial 1: The Lighthouse alarm and locator

Not a safe system today, given the breakdowns in communication and the habit of the Mobi to switch itself off.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

The system is not safe as it works today, as it is so unstable. The text and the icon on the MBU cannot be trusted; there is noting which indicates when the communication system has gone down.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

A test person in the pre-trial said she did not have trust in the BAN as it was today. As the system works today, she would not prefer to wear it herself.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

The BAN is at this moment in the trial process not safe to use. The ECG curve cannot be interpreted and the data cannot be sent safely when it is unknown whether the parameters are showing correctly on the sensor view or Portilab.

A security code for the system has not yet been implemented; additionally, a login on the user level has not been implemented yet.

Spain

Trial 1 Support of home-based healthcare services

Due to the problems in terms of connections failing, the system is not considered safe enough for real clinical cases.

Trial 2 Outdoor patients' rehabilitation

Same as section for Spain Trial 1 immediately above.

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial in this area.

Trial 2: Integrated home care for women with high-risk pregnancies

No problem in this stage. Because of the experimental character we only “use” healthy pregnant women. They cannot answer the safety question. I think that until the end of the MobiHealth period we only use healthy pregnant women. Because of the communications breakdown the system as a whole is not safe. Only when the system is safe can we answer the question of the feeling of safety of the pregnant women.

Mobility

Germany

Trial 1 Secondary prevention in coronary heart disease

It seems that data is not transmitted when IPAQ is more than 5 metres away. No outdoor measurements were performed. The BAN for itself does not restrict mobility.

Sweden

Trial 1: The Lighthouse alarm and locator

The trial owner could move around while wearing the BAN. However, there might be distance issues with moving far from a power source such as the MBU as the battery did not last for long (on the MBU).

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

To get full mobility in this pre-trial, the critical factor is the battery consumption in the iPAQ. Participants may wish to be outdoors for many hours.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

The pulse oximetry sensor prevented the test person from performing activities that he wanted to do: for example, when cooking he almost cut the sensor cable off. He felt that there were a large number of cables everywhere. He also felt that it was hard to get the iPAQ to work. He felt that he was aware all the time that he carried the BAN (and particulary the pulse oximetry sensor). He wore the BAN for a total of 8 hours during 20-22/9 (divided into 2+4+2 hours).

In the overnight continuous trial, the test user found it easy to move around and perform tasks with the full BAN on his body.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

The BAN can be used as a mobility test in the home and in a car, because of its size and easiness of use.

Spain

Trial 1 Support of home-based healthcare services

The battery of the device must be full, or almost, if we do not want the communication to fail more than it has been said. The iPAQ has to be almost connected most of the time. The mobility is then reduced.

Trial 2 Outdoor patients' rehabilitation

The battery of the device must be full, or almost, if we don't want the communication to fail more than it has been said. The iPAQ has to be almost connected most of the time. The mobility is then reduced. This causes some strong difficulties to arise for the "outdoors training" trial.

The Netherlands

Trial 1: Tele Trauma Team

There was no pre-trial in this area.

Trial 2: Integrated home care for women with high-risk pregnancies

The BAN does not restrict the mobility of the patients. The wires are too long. Because of the communication problems we were not able to test until now the sending of data when the patient is moving around. They mostly tested the sending of data when they were at home.

Part Four: Other Comments

Germany

Trial 1 Secondary prevention in coronary heart disease

The application and the system is yet not stable and user-friendly enough to perform trials with patients who do not have much experience with new technology and a lot of patience (in our trial site only two patients have the ability to use the BAN).

Right now we are dealing with a prototype version. To run the trial these problems have to be solved in an upgraded version:

- the connectivity to GPRS must be more stable ("IPAQ/GPRS-sleeve-problem")
- the communication between the IPAQ and the BE-system must be more reliable ("application-problem") and the configuration must be more user-friendly.

Sweden

Trial 1: The Lighthouse alarm and locator

Map with a dot indicating test persons was clearly seen on the computer and mobile phone. However, the test person at the city was not found due to the fact that the application shut down when the test user (playing the part of a patient in the city) made a phone call. The Sony/Ericsson P800 can apparently not send data at the same time as you make a phone call. GPRS can therefore not send data at the same time as a phone call. In addition, on the current system the maps are old, not detailed enough; to be able to find a person more modern maps where all new buildings are shown are needed. Also, the GPRS communication broke down during the test. Also, the connection with the Mobi always broke down during testing.

The still image is fine. Presentation picture of the patient and personnel at the Lighthouse care centre was displayed when calling either from the Lighthouse or vice versa.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

There must be more than one test to say more about the usability, as both the professional and the test person were new to this system.
The same test person will test the equipment again after the upgrade.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

One trial owner thought it would be good if the user manual contained a section about how to "scan" what was wrong – the most common things: for example, how to know if the Back-End system is shut down, or if by mistake the wrong button was pushed, how to get back. Other details to be asked were how long it took to charge the battery on the iPAQ, and how to switch between windows on the iPAQ.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

There should be some kind of icon or hourglass on the screen on the iPAQ to show when the iPAQ is working. Also an indication is needed to show if the iPAQ can reach the Internet and the Mobi is really sending anything to the Back-End system.

Spain

Trial 1 Support of home-based healthcare services

Apart from the design aspects, the system reveals a high instability. In its current state, and even for field trials, the system is non-reliable and non-user-friendly enough to be acceptable both for safety and ethical reasons.

Trial 2 Outdoor patients' rehabilitation

It is mandatory for this trial to have on line measurement of the vital signs. At the moment we don't have this option available and this makes very complicated to go on with the trial.

The Netherlands

Trial 1: Tele Trauma Team

No information.

Trial 2: Integrated home care for women with high-risk pregnancies

The group underestimated the technical problems. We are ready for months and have enough pregnant women to work with us in the experiment. But it takes too long before we have a good technical system.

Part Five: Preconditions for Further Trials

Germany

Trial 1 Secondary prevention in coronary heart disease

The next pre-trial will occur as soon as the upgrade is installed. If an upgrade is not delivered, a real trial will be done with two patients using the 3.0 system with GPRS.

Sweden

Trial 1: The Lighthouse alarm and locator

If Version 3.1 is delivered in mid-November and works very well we will do Pre-Trial 2. It is going to be done as soon as possible after the upgrade is ok. A real trial will then be in Week 48. Test persons have been informed and agreement is signed. They are ready and waiting. So it looks good from The Lighthouse side.

Preconditions for being able to do a proper trial would be that the start-up is easier and more "automatic". Functionality should be able to keep the GPRS connection "up". We expect better applications for technical tests on the iPAQ itself, better logging functions, and overall improved stability. PortiLab needs improvement. For this particular trial there is the requirement for GPS in the BAN. There is also the enquiry whether there can be an SMS-messsage from the Back-End system to the mobile phones when the alarm goes off. There is a need for a better battery capacity regarding the GPRS part of the system.

Trial 2: Physical activity and impediments to activity in women with Rheumatoid Arthritis

We will do a Pre-Trial 2 as soon as the system is upgraded,(the next day after it has been delivered and someone has installed it). Two patients have been called and they have agreed to participate. The maximum number of patients will be five.

Trial 3: Monitoring of vital parameters in patients with respiratory insufficiency

As soon as Version 3.1 is delivered Pre–Trial 2 will start. Two persons (healthy) who are willing to participate as test-persons and the physiotherapist also has two or three test persons (healthy). After Pre-Trial 2 there will be an evaluation and a new report as in Pre-Trial 1. Concerning a "real" trial: if the system is found to be stable enough and working very well a real trial can be performed within a week of evaluating 3.1, but not if Version 3.1 is evaluated and tested as mentioned above. If it is so we will test on more "healthy" pre-selected COPD patients.

Trial 4: Home care and remote consultation for recently-released patients in a rural area

Our plan is to do Pre-Trial 2 as soon as Version 3.1 is delivered and working. Directly after Pre-Trial 2 we start the real trial . Everybody involved is informed and we start with “real” patients as soon as everything works OK.

Spain

Trial 1 Support of home-based healthcare services

As soon as we receive the new version 3.1 we will proceed to do Pre-Trial 2. Once we make sure that the system is reliable enough the next step will be the real trial. The conditions for doing the real trial are just having a secure enough system for dealing with patients.

Trial 2 Outdoor patients’ rehabilitation

As soon as we receive the new version 3.1 we will proceed to do Pre-Trial 2. Once we make sure that the system is reliable enough the next step will be the real trial. The conditions for doing the real trial are just having a secure enough system for dealing with patients.

The Netherlands

Trial 1: Tele Trauma Team

No information.

Trial 2: Integrated home care for women with high-risk pregnancies

If the communication problems are solved and we have 5 BANs we can test the stability of the system. If we start half November we have 3.5 months to test it. We can then monitor as many women as we want because we can vary the length of the period a women carries a BAN. Only when the communication system is stable can we evaluate all the other aspects of the trial (user friendliness of the equipment, data sending when the patient is mobile, lifetime of the battery etc.).

Part Six: Conclusions

This pre-trial generated useful feedback for the system providers to use in the current upgrading and fine-tuning phase of the Body Area network and GPRS/UMTS connectivity. While some characteristics were specific to an individual pre-trial, there was quite a lot of overlap in the experiences of the trial owners in different regions of Europe, and the partners could see a great deal of commonality to the issues which are now being addressed in the development of Version 3.1. A few are noted below.

Start-up: it is a general requirement for the start-up to be easier, and to proceed more automatically than in the current version.

GPRS connection stability: This was considered to be a very important issue. At this stage of the prototype, the connection tends to be difficult to achieve and breaks off unexpectedly. *System providers indicate that this has been dealt with at time of publication and will feature in Version 3.1.*

With regard to length of time connected, there is an interesting fact to note: in Swedish Trial #2, Physical activity and impediments to activity in women with Rheumatoid Arthritis, in the 8th September test, the data was sent for a full 50 minutes to the Back-End system. As connection time in the other pre-trials tended to be between two and seven minutes, it would be very interesting for the system providers to investigate what particular factors caused this apparently ideal condition.

Batteries: battery capacity is a 'bottleneck' for many of the trials. In Barcelona, particularly, the dependence on battery life was deemed to be crucial to the Outdoor training trial.

Mobility: this is related to the battery, with test users being dependent on being close to a power source as the batteries tend to drain quickly.

Wearability: users generally state that carrying the iPAQ and Mobi is easy and not too intrusive, and it is light and unrestrictive (an exception was Barcelona).

Visibility of errors on iPAQ: partners requested that there be some kind of signal or sign if the iPAQ was disconnected or not functioning properly.

Security: in this version of the BAN and Mobi, security has not yet been addressed; this was planned and the security upgrade is scheduled for Version 3.1.

Logging functionality: this was not built into this version, but once again, this feature is planned for Version 3.1.

General stability issues: tendencies to break off communication, to shut down or even stay switched on were noted. *These are projected to be removed in the bug-fixes which are coming with Version 3.1.*

Portilab: in general this needs serious upgrading and tailoring to the specific use in MobiHealth and an illustrative, clear step-by-step manual would be needed. Records tend to not have a chronological order, for example. *One anomalous comment was from MST on the pregnancy trial: they mention that they are satisfied with the Portilab system. It would be helpful to analyse why Portilab is successful there. This work is understood to be in progress and will be more usable in Version 3.1.*

Manual input: there were calls for increased user-friendliness (too many steps to follow, and sometimes one forgets to send because of the complexity). *These have already been addressed in the work for Version 3.1.*

User manual: there was difference of opinion on this, with some partners finding the manual useful and others becoming confused by it. *The main reason for this difference is that those trials held earlier used an early version of the manual, while later trials used an improved version with far more transparency and user-friendliness.*

In summary, this pre-trial succeeded in showing the areas and features of the system which have room for improvement, and in most cases at time of publication the systems providers have indicated that these improvements have already been or are already being implemented in Version 3.1.

A further report evaluating the performance of the prototype Version 3.1. in Pre-Trial 2 will be written, with an extra chapter devoted to comparison of the two versions with a view to assessing the above-mentioned improvements in functionality, data transfer and ease of use.