Adherence Verification and Aid in Ambulatory Blood Pressure Monitoring

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***Abstract*—Ambulatory blood pressure monitoring (ABPM) is used i.a. as a diagnostic tool, to measure nocturnal blood pressure and to reduce white coat syndrome. In order to obtain valid and reliable measurements the patient needs to follow guidelines concerning the behaviour and the context. In order to verify the measurements and to provide adherence aid to the patients an adherence strategy was performed and with this in mind developing and testing a proof of concept prototype. We found that adherence verifying is feasible to make in order to provide healthcare professionals information about the validity and reliability of the blood pressure measurements. We also found that adherence aid was feasible for informing patients to relax in a quiet environment before and during measurements.**

I. Introduction

Hypo- and hypertension can be found among a large range of people e.g. diabetics, elderly, pregnant women with complications etc. and can lead to serious health conditions [1]. Ambulatory blood pressure monitoring (ABPM) is a technique used to measure blood pressure at regular intervals during a 24 hour period. The ABPM should be performed under everyday circumstances at work and in the patient's home with the use of portable electronic blood pressure monitor that automatically measures and saves the blood pressure. Among others it can be used as a diagnostic tool, to measure blood pressure during the night, reduce the white coat syndrome and to see the effect of medication [1][2]. During these measurements there are risks of data getting corrupted if recommendations such as not to speak [2][3][4][5] or move during measurement [2][3][6][7] or be exposed to background noises [4][7] are not followed correctly.

According to Bang et al. [5] it is documented that both self-measurements at home and ABPM have a significant better reproducibility and predicts cardiovascular events more precisely than blood pressure measurements taken at hospitals, clinics or at the general practitioner. In order to prevent overmedication all patients with hypertension (without organ damages) should, if practicable prior to treatment, have performed an ABPM or self-measurements at home. This could indicate whether the patient suffers from "white coat syndrome" - a phenomenon in which patients exhibits elevated blood pressure in a clinical setting [5].

Background noise affect the sympathetic and endocrine system, resulting in acute physiological responses e.g. changes in heart rate, stress hormones and blood pressure. These effects are not caused by a specific sound pressure but depend on the individual situation which means that 80 dB at work might cause less effect than 65 dB when carrying out a mental tasks or 50 dB when being a sleep. Persons who have lived for several years in a noisy environment still respond to acute noise stimuli [8]. Therefore decibel-peaks in background noise are considered to cause the unwanted physiological responses.

In order to tell whether the blood pressure measurement is corrupted and to prevent these data from being corrupted, adherence verifying and adherence aid is considered useful. Furthermore it could improve patient's adherence level and quantify the quality of healthcare data obtained in home settings.

The aim of this strategy is to determine whether it is feasible to apply context aware technology to better detect and avoid errors as well as bias when evaluating measurement data. Specifically, the Android platform will be used to detect movement and background noises and evaluations of the technology will take place through laboratory tests.

II. Method and materials

The Adherence Strategy Engineering Framework (ASEF) is used to investigate the following elements: Domain, stakeholders, context and technology [9]. The Full Adherence Model (FAM) [9] provides knowledge concerning all elements of the healthcare intervention in relation to an ABPM. The findings form the content of a Reduced Adherence Model (RAM) [9] in which the basis for developing an adherence increasing technology.

During the design and developing process a low-fidelity prototype sets the scenarios while a high-fidelity prototype is used to test the proof of concept.

A. Adherence verification

The context aware sensors in a device with Android is used for adherence verification to determine the blood pressure measurements are corrupted or not.

Through the microphone, the environmental sound is measured. This takes place five minutes before measurement for a period of two minutes and gives an indication of the daily sound environment that the patient is experiencing.
Another background noise measurement is started one minute before the blood pressure measurement until one minute after the measurement is started – two minutes in total. Furthermore an algorithm detecting high peaks will give an indication of the blood pressure measurements validity.

A movement sensor in form of an embedded accelerometer, will be detecting if the patient's arm is at rest before and during the blood pressure measurement. The sensor will detect changes in acceleration for a period of two minutes starting five minutes before the blood pressure measurement begins. The acceleration will be used to categorize the movement as fast or slow. This acceleration sensing will also take place one minute before and during the blood pressure measurement.

B. Adherence aid

To guide patients in following the recommended guidelines during the period of the ABPM, three different notification types will be presented for the patient. The system will notify the patient five and one minute before the blood pressure measurement and again when the measurement is done. The first notification consists of one beep and one burst of vibration. This will drag the patient's attention to the device informing the patient to be seated in a relaxed position. The next notification consists of two beeps and two bursts of vibration, informing the patient to be quiet and to be seated in a relaxed position. After the measurement the patient will be notified for the third time by three beeps and three bursts of vibration. The device will give the patient textual information on the device screen to remind the patient of guideline recommendations before and during the blood pressure measurement. The first text appears five minutes before the measurement and stays on the screen for 30 seconds. This text will inform the patient, that he should sit down and rest in a quiet environment for the following six minutes. The second text appears one minute before and that the he should not be moving until the measurement is completed.

C. Data analysis, storage and transferring

In order to measure the environmental sound the microphone within the Android device is used. The maximum decibel level of the signal during a 10 second period is compared with the moving average. One of the main aims is to detect noise peaks in the patient's sound environment. Through empirical tests a peak was determined as a sudden sound with a decibel level of 30 dB higher than the average.

An averages of the two two-minute measurements are calculated and stored locally together with the decibel levels and the analysis as a string in a XML-file on the device.

To detect movement the accelerometer is used. If the device changes position the acceleration is evaluated against two thresholds to detect if there is fast or slow movements. If fast or slow movements are detected a string will be saved in the XML-file. Furthermore if both fast and slow movements has been detected the acceleration-detection is stopped in order to extend battery life.

After the ABPM has been done the adherence system should be stopped and an email including the XML file should be sent to the specified email address via WI-FI. If the device is not connected to a WI-FI network, the email will be saved on the phone from where it can be accessed by cable.

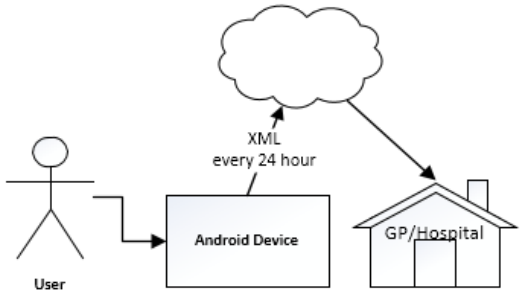

Fig. 1 System diagram

D. Test protocol

In order to determine whether the before mentioned verifications are feasible to detect and evaluate, there will be performed two test runs. During the tests the prototype is exposed to four different scenarios:

- Exposure to loud environment
- Exposure to movement
- Exposure to completely silent environment
- Exposure to silent environment with sudden loud claps - peaks.

The results will be evaluated to determine whether the prototype detected the tested exposures properly.

To evaluate the effect of the adherence aid, three test persons are used. Each test person will perform four tests during a typical day; two without aid and two with aid. Each test last two hours – a total of eight hours per test-person. For the tests without adherence aid, the device will be attached to the person, but the aid will be disabled. For the tests with the adherence aid, the device will be fully operational.
The tests will show if the devices adherence aid has an impact of how the person reacts before and during the blood pressure measurement.

E. Materials

The Android device used in this study is a HTC Nexus 1 with Android 4.0.3 as operating system. The software prototype is developed using Eclipse Juno with Android SDK. Emails were sent to a given email address through a Wi-Fi network.

III. RESULTS

The prototype is tested as described in the test protocol. The results from the evaluation on the adherence verifying are showed in table I. The table shows what kind of exposure the evaluation prototype was exposed to and whether the prototype detected it or not.

TABLE I EVALUATION OF THE PROTOTYPE

Exposure	Exposure detected
Loud environment	Yes
Movement	Yes
Silent environment	Yes
Sudden loud claps	Yes

Figure 2 shows the average sound pressure during the measurements in the six test runs with and without adherence aid.

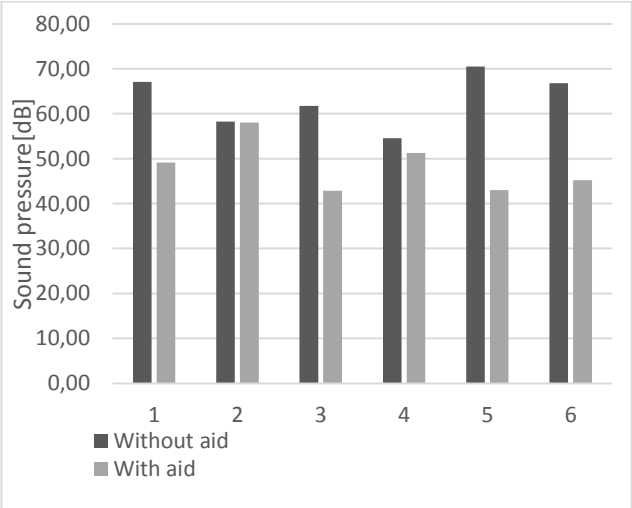

Fig. 2 Average sound pressure

Furthermore table II presents in how often movements were detected relative to total number of measurements to compare the test-persons behaviour when measurements are performed without adherence aid and with adherence aid. The last column shows the improvement in percent.

TABLE II DETECTION OF MOVEMENTS DURING TESTS

	Without aid	With aid	Improvement
Before	Detected / Total	Detected / Total	
Slow movement	18/48	7/51	23,77 %
Fast movement	20/48	7/51	27,94 %
During			
Slow movement	18/48	3/51	31,61 %
Fast movement	18/48	4/51	29,65 %

IV. DISCUSSION

The following section discusses the feasibility, results and challenges which were identified during the construction and evaluation of the adherence system prototype.

A. Using context aware technology for adherence verification

The detection of movement and environmental noises used as adherence verifiers works as a proof of concept. It was found that the system could detect the exposures in four different test scenarios. The verifiers are very important information for the healthcare professionals who evaluates the blood pressure measurements, as they serve as additional input. They could help to give an estimate on why a measurement was too high or too low and if it should be considered corrupt.

B. Using context aware technology for adherence aid

Even though health care professionals inform and instruct patients to follow guidelines about resting five minutes before blood pressure measurement and not to talk during measurements, patients are not always aware of these recommendations and the importance of following them [4]. This indicates the need of adherence aid and as shown in table I the test-persons benefits from the provided aid as the movement decreases both before and during blood pressure measurement. However the movements five minutes before measurement only improve by ~ 65.21 %. This could indicate that the aid should be provided before the context aware sensor starts measuring movements. This will give the patient time to sit down and relax before detection of movement starts.

The ABPM should be performed on a typically day [2][3][5][7] and therefore it is not possible or advisable to stay in quite environments. The patient is exposed to noise from other people talking, telephones ringing, traffic noise, appliances in the home or at work etc. However the aid could help patients lower the sound from appliances that the patient can control; mute the TV or phone when the blood pressure measurement is being performed.

C. Relevance and further discussion

One of the main topics which can be brought for discussion is the device's ability to provide adherence verification and aid for the whole period of 24 hours. With the current sensitivity of the accelerometer the used device does not have enough battery to last 24 hours. This indicates that the there should be another more battery saving way to detect movement. Furthermore the used device is not able to detect decibel levels above 92 dB which makes the peak-detection less consistent.

D. Future work

Development of this novel adherence strategy as well as the new technology is not complete. This is the first edition of the adherence strategy, which includes a proof of concept prototype. Both should be improved in the future by further development and tests which in the end improves the adherence strategy.

Furthermore the adherence system should be tested on and evaluated by patients to determine which notifications the system should use in order to aid but not disturb the patient's daily life. Before the system is being tested on patients the environmental noise verification should be developed further and tested again. The thresholds used to determine environmental noises in this study are empirical, and biological or review study should be made to determine these thresholds used to verify environmental noise.

In the future it will also be feasible to investigate, which factors have the most significant impact on the blood pressure during an ABPM and thereby investigate which factors is most relevant to detect and eliminate. It might be that speech during measurement affects the blood pressure more than the general environmental noises in the room the patient is living in.

There are still a lot of ideas and concepts which need to be implemented to this particular adherence system. One of the main concepts is the speech detection function, which determines whether the patient is speaking while the ABPM is being performed. This will provide the most optimal ABPM specified by the guidelines [2][4][5][7][10]. Because of absence of knowledge at the time of developing the detection algorithm, this particular technology has not been implemented yet. In addition the sound pressure measurements should be A-weighted in effort to account for the relative loudness perceived by the human ear, as the ear is less sensitive to low audio frequencies [11].

In order to ensure that the verification and aid is being provided at the correct time, this system could benefit from automatically synchronization with the ABPM before measurements are started. This would ensure that the two systems are synchronized at all times. It should also be possible for the system to stop at the same time as the ABPM device, as the patient would probably move or speak is soon as he feels that the cuff is deflated.

V. Conclusion

A well-functioning adherence strategy prototype to prevent data from being corrupted during APBM is developed. The strategy which consists of adherence verification and adherence aid has been proved to function under test-environments. The adherence verification helps to determine whether the test-person is exposed to a loud environment or is moving before and during the blood pressure measurement. The adherence aid reminds follow guideline recommendations and thereby securing more reliable measurements. However some major improvements need to be made before the strategy can be fully implemented as additional to the ABPM system. The verification of environmental noises could be more refined, by adding for instance a speech detection algorithm. Furthermore, the test protocol should be more comprehensive and include real patients.

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