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Validation of a Real-time Wireless Telemedicine System, Using Bluetooth Protocol and a Mobile Phone, for Remote Monitoring Patient in Medical Practice

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Abstract: This paper validates the integration of a generic real-time wireless telemedicine system utilising Global System for Mobile Communications (GSM), BLUETOOTH protocol and General Packet Radio Service (GPRS) for cellular network in clinical practice. In the first experiment, the system was tested on 24 pacemaker patients at Aalborg Hospital (Demark), in order to see if the pacemaker implant would be affected by the system. I the second experiment, the system was tested on 15 non risky arrhythmia heart patients, in order to evaluate and validate the system application in clinical practice, for patient monitoring.

Electrocardiograms were selected as the continuously monitored parameter in the present study. The results showed that the system had no negative effects on the pacemaker implants. The experiment results showed, that in a realistic environment for the patients, the system had 96.1 % up-time, 3.2 (kbps) throughput, 10^{-3} (packet/s) Packet Error Rate and 10^{-3} (packet/s) Packet Lost Rate. During 24 hours test the network did not respond for 57 minutes, from which 83.1 % was in the range of 0-3 minutes, 15.4 % was in the range of 3-5 minutes, and only 0.7 % of the downtime was ≥ 5 and ≤ 6 minutes. By a subjective evaluation, it was demonstrated that the system is applicable and the patients as well as the healthcare personals were highly confident with the system. Moreover, the patients had high degree of mobility and freedom, employing the system. In conclusion, this generic telemedicine system showed a high reliability, quality and performance, and the design can provide a basic principle for real-time wireless remote monitoring systems used in clinical practice.

Key words: Telemedicine, GSM, GPRS, BLUETOOTH, Safety, Healthcare

Abbreviations: BLUETOOTH: Short-range wireless radio technology within 2.4 GHz spectrums; GPRS: General Packet Radio Service in GSM network; GSM: System for Mobile Communications.

1. Introduction

Telemedicine systems can be used for monitoring of vital clinical parameters from patients at home, and can be utilised for aftercare not only in remote rural but also in urban areas as well. Many studies have demonstrated the applications and advantages of such systems [2, 9, 10, 12-15].

We have recently, for the first time, developed a generic real-time wireless telemedicine system, for short and long term remote monitoring patients, utilising Bluetooth protocol and GSM/GPRS cellular network [7], and our hypothesis was as follow: This Wireless Telemedicine System, can make continuously and real-time remote monitoring possible during the patients daily activities [8]. The present study was designed to validate the integration of the system in clinical practice. To do so, we chose cardiology as a potential application area.

Heart arrhythmias are usually needed to be monitored and controlled in hospital environment for one to several days, to plane proper treatment. These patients are treated to normalise their heart arrhythmia by various interventions and the results are monitored by continuous ECG recordings.

The aims of the present study was, 1) to test the mentioned telemedicine system on a group of pacemaker patients, in order to see if the pacemaker implant would be affected by the system, and 2) to test the system on another group of not risky heart patients with heart arrhythmia, monitoring their electrocardiogram (ECG) while they doing their daily activities both indoor and outdoor, in order to validate and generalise the integration of our wireless telemedicine system for long term real-time monitoring in clinical practice. This paper presents the tests and the evaluation results of the system integration in relation to the following aspects: the system reliability and performance from a technical point of view, the patient safety utilising the system in clinical practice, the interaction between the patients / healthcare personals and the system, and the patient's compliance to the system.

2. Material, Methods and Statistics

Telemedicine System composed of a patient unit (a Danica Biomedical T3300 telemetry device, a Bluetooth module and a Sony Ericsson T610 Mobile phone, Denmark), GSM Network (SONOFON, Denmark), a Modem Server, and a Central Monitoring Station (Fig. 1).

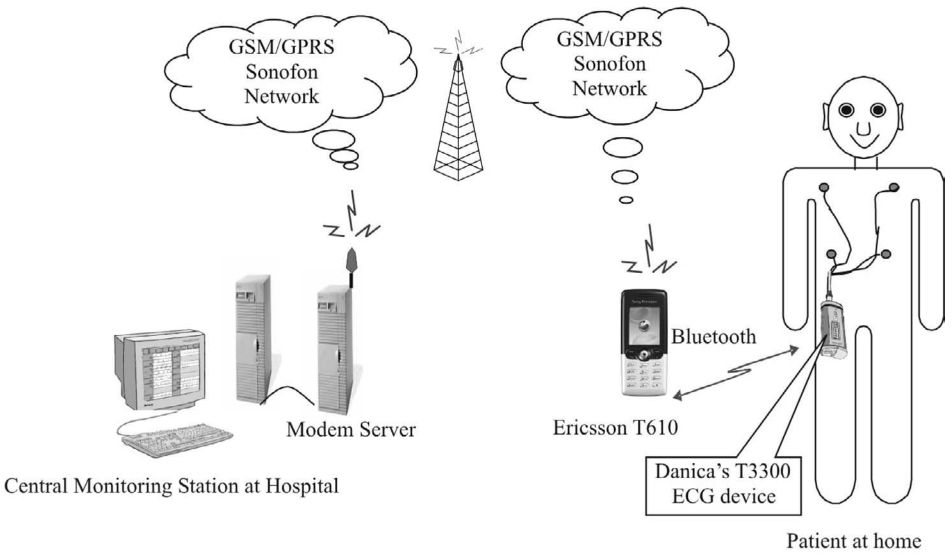

Fig. 1. A principal sketch of the wireless remote monitoring system containing a telemetry device, a Bluetooth wireless connection, mobile phone, a GSM/GPRS network connection, a mobile modem server and a graphical ECG monitoring station.

2.1 Experiment 1, Patient's Safety (Pacemaker Patients)

The safety of the wireless remote monitoring system was investigated according to the safety requirements recommended by International Commission on Non-Ionizing Radiation Protection (ICNIRP), International Radiation Protection Association (IRPA), World Health Organization (WHO), the Institute of Electrical and Electronics Engineers (IEEE), and Ericsson Stockholm, Sweden [4-6, 11, 16], and according to these recommendations, the system was fully safe to use [7, 8].

To test the system's safety on pacemaker patients, in order to be sure that the system does not have any electromagnetic interference affect on the implanted pacemaker, twenty four pacemaker patients aged (71 ± 10) years (17 males and 7 females) were included.

Each of the twenty four pacemaker patients was called in for a routine control of their pacemaker, at the Hospital (Aalborg Hospital, Denmark), before participating in the test. The control was made by pacemaker programmer device (Medtronic model 2090 or St. Jude Medical model 3510, depending on the implanted pacemaker's type). The pacemaker was controlled due to the pre-programmed permanent parameters (Mode, Base Rate, Hysteresis Rate, Search Interval, Recovery Time, Rest Rate, AV Delay, PV delay, V. and A. Pulse Sensitivity, Amplitude and Width etc.). Transcript of the surface ECG, arterial and ventricular intracardic electrograms (EGM) and other pre programmed parameter report were used as reference for control purpose in the experiments. EGM is a record of real-time arterial and / or ventricular intracardic electrograms curvatures, which shows if the pacemaker was triggered by any specific event that could have made any change to the pacemaker program and should be saved in its memory.

Afterwards, the programmer magnetic head was placed above the pacemaker at the location of the implant on the patient's chest, four surface ECG electrodes were mounted on the patient's chest and were connected to the programmer, and 4 more disposable ECG electrodes from the patient unit (a T3300 telemetry device and a T610 Mobile phone) were also mounted on the patient's chest. The patient unit was located at different distance from the patient's pacemaker implant (100 cm, 50 cm, 25 cm, 10 cm, and 0 cm). Zero centimeter means directly above the implant on the chest. For each of mentioned distance, the programmer was adjusted to record 10 minutes surface ECG, EGM, and other mentioned parameters. For each distance a transcript of the recorded measurement was written out and compared to the control transcript, in order to check if the patient unit has any electromagnetic interference on the pacemaker.

For subjective evaluation of the patient's compliance, concerning the affect of the patient unit on the heart, during the test, a questionnaire for expression of opinion was used. The pacemaker patients were asked to express their impression in a scale of 0-10 in case the patient unit causes any unpleasant felling in the heart during the test.

2.2 Experiment 2, Remote Monitoring Heart Patients at Distance

Fifteen non risky heart patients, aged (49 ± 14) years (6 males and 9 females), with irregularity in heart rhythms, were included on the base of the following inclusion criteria:

1. Age > 18 years
2. Intellectual capacity to understand the experiment's information and the consequences of the participation in the experiments.
3. The type of the Arrhythmia: Supra ventricular tachycardia.
4. Nothing or insignificant uncompensated sign by stethoscopy of lungs and / or x-ray of thorax.
5. The judged O_2 – saturation by Pulse Oxymerty ≥0.92.
6. The patients do not need hospitalisation for any other reasons.
7. Blood Pressure ≥ 100/70.

Each patient used a waistcoat, in each waistcoat a patient unit (a T3300 telemetry device and a T610 Mobile phone, and a battery package supplying 30 hours operation time to the mobile phone), were mounted. The T3300 operates with 2 AA batteries in 48 hours, and it is configured to interact with the Modem Server, via Bluetooth connection to the T610 mobile phone and GSM/GPRS Network.

For the sake of communication between the patients and the in charge healthcare personals, the patients had a fixed telephone line when they were at home and an extra mobile phone on them outdoor.

The patients were instructed how to mount the deposable ECG electrodes, how the patient-unit operates, and how they should change or recharge the batteries in advance. The patients were asked not taking shower with the patient-unit, and to report any difficulties they encounter during the monitoring period right away. The patients were asked to keep a diary of all activities performed during the monitoring period. All the reported activities were time locked.

For each of the patients, 24 hours continuously ECG monitoring was recorded while they were doing their daily activities indoor and outdoor.

To have a reference for control, the target of the reliability and the performance key-indicators were determined as follows:

1. Up-time > 99.95 % (SONOFON, the Danish network provider).
2. Throughput >3.4 (kbps) (System design requirement).
3. Packet Error Rate (PER) < 10^{-4} (packet/s) [1, 3] and Packet Lost Rate (PLR) < 10^{-4} (packet/s) [1, 3].

For evaluation of the system behaviors, the system log-file and the patients' diary were utilised. The log-file was employed for monitoring the reliability and performance. In order to evaluate the system reliability, key-indicators such as system up-time, system down-time distributions and system connection status were used.

The evaluation of the system performance was done by the key-indicators such as system throughput, system Packet Error Rate (PER) and Packet Lost Rate (PLR), which are the most well known key-indicators [3].

The quality of the received ECG data was evaluated both by monitoring the leads/electrodes status utilising the system log-file, and by a clinical examination of the transferred ECG quality in the ECG transcript, in cooperation with a cardiac specialist.

2.2.1 Usability of the system

To evaluate the system usability from the patients' point of view, three questionnaires for expression of opinion were prepared. The first one, for the evaluation of the system's degree of user-friendly, the second one, for the evaluation of the patients' degree of confidence in respect of using the wireless remote monitoring system during their everyday activities, and the third one for the evaluation of the patients' degree of the freedom and mobility during the monitoring period.

To evaluate the system usability from the healthcare-personals' point of view, the involved personals were asked to fill in two pre prepared questionnaires during the monitoring period, one for evaluation of the system's degree of user-friendly, and one for evaluation of the healthcare personals' degree of confidence in respect of using the wireless remote monitoring system as a new approach for monitoring heart patients.

The patients and the involved healthcare personals were asked to fill in each of the pre prepared questionnaire during the monitoring period. The questionnaire regarding the usability test (for the patients) contained the following questions (0 = minimum, 10 = maximum):

1. How long did it take for you (in minutes) to learn to use the patient-unit?
2. Express the degree of complexity using the mobile phone. (0 – 10 scale)
3. Express the degree of complexity, using the telemetry device. (0 – 10 scale)
4. Could you mange employing the system at home? ("yes" / "no")
5. Did you need help from the healthcare personal for using the system at home? ("yes" / "no")
6. Did you change the electrodes by yourself at home? (1, 2, 3, more than 3 and not at all)
7. Did you have difficulty changing the electrodes? ("yes" / "no")
8. Did you have difficulty changing the mobile phone's batteries? ("yes" / "no")
9. Did you have difficulty changing the telemetry device batteries? ("yes" / "no")

The questionnaire regarding the mobility and the degree of freedom test (for the patients) contained the following questions:

1. Express, in a scale 0 – 10, the degree of your mobility while your heart was monitored using the wireless remote monitoring system (0 = no mobility, 10 = full mobility).
2. Express, in a scale 0 – 10, the degree of your freedom while your heart was monitored using the wireless remote monitoring system (0 = no freedom, 10 = full freedom).

The questionnaire regarding the confidence test, from the patients' point of view, contained the following questions:

1. Are you used to employ a mobile phone? ("very much", "reasonable", "no preference", "not so much", "not at all")
2. How much did you understand the application of the system? ("very much", "reasonable", "no preference", "not so much", "not at all")
3. How confidant you are with respect to the use of the system? ("very much", "reasonable", "no preference", "not so much", "not at all")
4. What is you opinion about monitoring your heart from your home instead of being hospitalised for that reason? ("Very good", "good",

"no preference", "not so good" and "not good at all")

The questionnaire regarding the confidence test, from the healthcare personals' point of view, contained the following questions:

1. Are you used to employ a mobile phone? ("very much", "reasonable", "no preference", "not so much", "not at all")
2. How much did you understand the function of the system? ("very much", "reasonable", "no preference", "not so much", "not at all")
3. How confidante you are with respect to the use of the system? ("very much", "reasonable", "no preference", "not so much", "not at all")
4. How good the reliability of the wireless remote monitoring system is? ("Very good", "good", "no preference", "not so good" and "not good at all")
5. What is you opinion about monitoring heart patients from their home instead of hospitalising them for that reason? ("Very good", "good", "no preference", "not so good" and "not good at all")

The questionnaire for the usability test, from the healthcare personal point of view, contained the following questions (0 = minimum, 10 = maximum):

1. How long (in minutes) did it take for you to learn the employment of the patient unit?
2. Describe the degree of complexity, using the mobile phone. (0 – 10 scale)
3. Describe the degree of complexity, using the telemetry device. (0 – 10 scale)
4. Could you mange how the patient unit should be used? ("yes" / "no")
5. Did you have any problem instructing the patients how to use the system? ("yes" / "no")
6. How many times it succeeds you in instructing the patients changing the electrodes? (1, 2, 3, more than 3 and not at all)
7. Did you have any problem mounting the patient unit? ("yes" / "no")

2.3 Statistical Analysis

Data are presented in percentage (%) and Mean ± Standard Deviation (SD).

3. System's Functionality

The ECGs are collected, via 4 disposable electrodes, by the T3300 telemetry device. The T3300 is Bluetooth connected to a T610 Sony Ericsson mobile phone (Fig. 1). The T3300 invokes the T610 to establish a GSM or a GPRS connection to the public mobile network automatically. The transmission of the data, from the mobile phone to the Modem Server at the hospital, is carried out via GSM/GPRS network. The Modem Server receives the data and converts it to pre-defined format. The data then are sent to the Central Monitoring Station via serial cable. Central Monitoring Station interoperates and converts the received data to graphical ECG [7, 8]. The T610 is connected in the course of the real-time monitoring period. In case of network fall down or no GSM/GPRS network coverage, the Bluetooth module, via T610, repeatedly attempts for connection reestablishment until a complete connection is established. The GSM phone is functioning as a mobile modem to the T3300 telemetry device after the connection is established.

4 Results

4.1 Experiment 1, Patient's Safety (Pacemaker Patients)

The transcript of the pacemaker parameter for every distance (100 cm, 50 cm, 25 cm, 10 cm, 0 cm) for each of 24 pacemaker patient, were carefully examined and compared to the control transcript, which was recorded and printed out for each patient before the test, and no change in the pacemaker preprogrammed parameter, the surface ECG, and the intracardiac electrogram (EGM) was observed at all.

The pacemaker patients (n = 24) expressed their impression in the questionnaire, concerning the affect of the patient unit on the heart, in case the patient felt any unpleasantness in the heart during the test. The impression was expressed in a scale of 0-10 (0 = no influence, 10 = very unpleasant). The results showed that at 100 and 50 cm distance, all patients (100 %) scored "0". At 25 cm distance 92 % scored "0", 4 % scored "1" and 4 % scored "2". At 10 cm distance 75 % scored "0", 21 % scored "1" and 4 % scored "2". At 0 cm distance (directly above the implant on the chest), 88 % scored "0" (no influence), 8 % scored "1", and 4 % scored "2".

4.2 Experiment 2, Remote Monitoring Heart Patients at Distance

4.2.1 Reliability

The system up-time, when the heart patients (n = 15) were under normal daily activities, was (96.1 ± 0.026) % (Fig. 2). Comparison of the average up-time with the target (99.95 %) showed that the reached up-time was 3.45 % less than the target, which is not critical and it is acceptable for clinical application. During 24

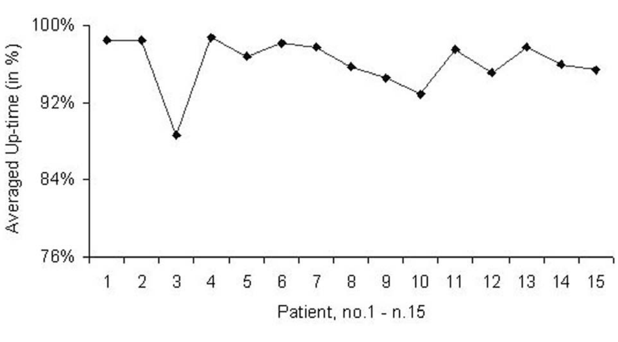

Fig. 2. The averaged system up-time in percentage during the test (24 hours continuously run-time). The x- axis shows the included heart patients.

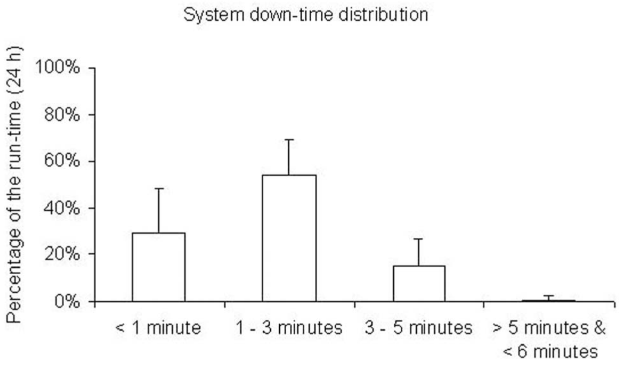

Fig. 3. The distribution of the down-time duration, in minutes, during the test (24 hours continuously run-time).

hours test the total downtime, was approximately 57 minutes in average (approximately 4.1 % of the 24 hours run-time), which is a reasonable outcome, according to the clinical experts.

The downtime distribution (Fig. 3) during normal activities showed that (29.3 ± 0.190) % of the 57 minutes downtime was less than 1 minute, (53.8 ± 0.151) % in the range of 1-3 minutes, while (15.4 ± 0.112) % of the 57 minutes downtime was in the range of 3-5 minutes, and only (0.7 ± 0.018) % of the downtime was more than 5 and less than 6 minutes (the network's peak hours and battery change). Comparing the reached results with the target (< 3 minutes downtime duration), showed that the system has fulfilled the requirement in 83.1 % of the down-time, which is not ideal but not critical either and it is acceptable for long-term remote monitoring patient for not critical clinical purpose.

The connection status test showed that the system was connected in (94.0 ± 0.038) % of the runtime. This is less than the target (99.95 %) but it is a satisfactory outcome in this stage of system development. The system was disconnected only in 4 % of the runtime, and it has spent 2 % of the runtime attempting reconnection because of uncompleted connection.

4.2.2 Performance

The throughput was (3.2 ± 0.147) kbps. Comparing that with the target (≥ 3.4 kbps), the reached throughput is a bit less, but it is not critical for remote monitoring non risky heart patient, according to the clinical experts.

Both the PER and the PLR were (0.001 ± 0.00) packet/s, which are less than the target (≤ 0.0001 packet/s) but are not critical for remote monitoring non risky heart patient, according to the clinical experts.

4.2.3 Quality

The quality test showed that (0.9 ± 0.010) % of the reported lead-status by the system log-file was bad lead-status and (0.8 ± 0.012) % of the reported electrode-status was bad electrode-status. These failures are originated from; electrode/lead malfunction, motion artifacts, and respiration artifacts, and these are representing the transferred ECG quality evaluated from the transcript. A subjective evaluation of the transferred ECG transcripts (in cooperation with the cardiologists) showed that approximately 5 % of the transcripts, in average, could not be interpreted and had unacceptable quality, that is, 95 % of the transferred ECG had good quality. This is less than the target (100 %), but it is not critical at all and is acceptable in clinical application on basis of clinical experiences.

4.3 Usability of the system

4.3.1 The degree of system usability

4.3.1.1 From patients point of view

The test showed that the patients spent (9.1 ± 3.66) minutes to learn how to use the patient unit. Regarding the degree of complexity using the mobile phone, 87 % scored "0" (minimum complexity). Regarding the degree of complexity using the telemetry device, 80 % scored "0" (minimum complexity). The results showed that all 15 patients could easily mange employing the system. Only one patient (62 years) changed the electrodes with difficulty, as he reported, but the rests had no problem with that.

None of the patients sought help from the healthcare personals in relation to operate the wireless remote monitoring system from their home, none of them either had problem with changing batteries for the mobile phone and the telemetry device as well. The results are summarised in Table 1.

4.3.1.2 From healthcare personal point of view

From the healthcare personnel's point of view (n = 4, scoring scale 0 – 10, 0 = minimum, 10 = maximum), the results showed that they spent (12.5 ± 2.88) minutes to learn how to use the wireless remote monitoring system. Regarding the degree of complexity using the mobile phone, 50 % scored 0 and the rest scored "2" and "3". Regarding the degree of complexity using the telemetry device, 50 % scored "1", and the rest scored "2" and "3". All four involved healthcare personals could easily mange employing the system. None of them had problem mounting the patient units on the patients first time at the hospital. The results are summarised in Table 2.

4.3.2 The degree of patient's freedom and mobility

For fifteen heart patients (n = 15) in a scoring scale 0 – 10 (0 = no mobility and 10 = full mobility) only 6.7 % scored "3", and 53.3 % scored "8" (reasonable mobility), the rest 26.7 % scored "10" (full mobility). Regarding the degree of freedom, in a scoring scale of 0 –10 (0 = no freedom, 10 = full freedom) only 6.7 % scored "3" (less freedom), and 46.7 % scored "10" (full mobility). The results are summarised in Table 3.

Table 1. system usability, from the patients' point of view, measured for n = 15 in a scoring scale 0 – 10 (0 = minimum, 10 = maximum).

Scoring scale 0 – 10, 0 = minimum, 10 = maximum, n = 15	The answers	
How long (in minutes) did it take for you to learn to use the patient-unit?	(9.1 ± 3.66) min.	
Express the degree of complexity using the mobile phone	87 %	"0"
	6.5 %	"1"
	6,5 %	"3"
Express the degree of complexity using the telemetry device	80 %	"0"
	13 %	"1"
	7 %	"3"
Could you mange employing the system at home?	100 %	"yes"
Did you change the electrodes by yourself at home?	60 %	"no"
	20 %	once
	20 %	twice
Did you have difficulty changing the electrodes?	94 %	"no"
	6 %	"yes"
Did you need help from the healthcare personal for using the system at home?	100 %	"no"
Did you have difficulty changing the mobile phone's batteries?	100 %	"no"
Did you have difficulty changing the telemetry device batteries?	100 %	"no"

Table 2. system usability, from the healthcare personals' point of view, measured for n = 4 in a scoring scale 0 – 10 (0 = minimum, 10 = maximum).

Scoring scale 0 – 10, 0 = minimum, 10 = maximum, n = 4	The answers	
How long (in minutes) did it take for you to learn the employment of the system?	(12.5 ± 2.88) min.	
Express the degree of complexity using the mobile phone	50 %	"0"
	25 %	"2"
	25 %	"3"
Express the degree of complexity using the telemetry device	50 %	"1"
	25 %	"2"
	25 %	"3"
Could you mange how the patient unit should be used?	100 %	"yes"

Table 3. The patients degree of the freedom and mobility in relation to the employment of the wireless remote monitoring system, measured for n = 15 in a scoring scale 0 – 10 (0 = no mobility, 10 = full mobility, and 0 = no freedom, 10 = full freedom).

Scoring scale 0 – 10, and n = 15	The answers	
Express the degree of your mobility while using the wireless remote monitoring system? (0 = no mobility, 10 = full mobility)	6.7 %	"3"
	13.3 %	"7"
	53.3 %	"8"
	26.7 %	"10"
Express the degree of your freedom while using the wireless remote monitoring system? (0 = no freedom, 10 = full freedom)	6.7 %	"3"
	20.0 %	"5"
	6.7 %	"7"
	13.3 %	"8"
	6.7 %	"9"
	46.7 %	"10"

Table 4. The confidence test in relation to the use of the wireless remote monitoring system, from the patient point of view, measured for n = 15 in a scoring scale 0 – 4 (0 = no at all, 4 = very much, and 0 = no good at all, 4 = very good).

Scoring scale 0 – 4, n = 15	The answers	
Are you used to employ a mobile phone? (0 = not at all, 4 = very much)	26.7 % 6.7 % 40 % 26.7 %	“1” “2” “3” “4”
How much did you understand the application of the system? (0 = not at all, 4 = very much)	6.7 % 20.0 % 53.3 % 20.0 %	“1” “2” “3” “4”
How confidant you are with respect to the use of the system? (0 = not at all, 4 = very much)	6.7 % 40.0 % 53.3 %	“1” “3” “4”
What is you opinion about monitoring your heart from your home instead of being hospitalised for that reason? (0 = not god at all, 4 = very good)	6.7 % 6.7 % 86.7 %	“2” “3” “4”

Table 5. The confidence test in relation to the employment of the wireless remote monitoring system, from the healthcare personals’ point of view, measured for n = 4 in a scoring scale 0 – 4 (0 = no at all, 4 = very much, and 0 = no good at all, 4 = very good).

Scoring scale 0 – 4, n = 15	The answers	
Are you used to employ a mobile phone? (0 = not at all, 4 = very much)	25.0 % 25.0 % 50 %	“1” “2” “3”
How much did you understand the function of the system? (0 = not at all, 4 = very much)	50 % 25.0 % 25.0 %	“1” “3” “4”
How confidant you are with respect to the use of the system? (0 = not at all, 4 = very much)	50.0 % 50.0 %	“1” “3”
How good the reliability of the wireless remote monitoring system is? (0 = not good at all , 4 = very good)	100 %	“3”

4.3.3 The degree of confidence with respect to the system application

4.3.3.1 From patients point of view

In scoring scale 0 – 4 (0 = not at all, 4 = very much) for fifteen heart patients (n = 15), only 26.7 % scored “1”, and the rest had either reasonable or very much familiarity to mobile phone employment. Only 6.7 % had less understanding to the system function, and the rest had either reasonable or very high understanding to the system function. Regarding confidentiality to the system, only 6.7 % expressed less confidentiality to the system, and the rest expressed either reasonable or very high confidentiality to the system. Thirteen out of fifteen patients (86.7 %) preferred monitoring from their home (in more natural environments). The results are summarised in Table 4.

4.3.3.2 From healthcare personal point of view

In scoring scale 0 – 4 (0 = not at all, 4 = very much, four health care personals, n = 4), 75 % expressed reasonable or good familiarity to mobile phone employment. The results showed that 50 % had less understanding to the system function, and 50 % expressed high confidentiality to the system. All four healthcare personals (100 %) expressed high system reliability and all four mean that monitoring at home (in more natural environments) is preferable. The results are summarised in Table 5.

5. Discussion

The mobile communication system for telecommunication-based home healthcare presented in the present paper provided high reliability and user/staff compliance. Mobile communication system has been considered in telemedicine for remote monitoring patient for a long time [2, 7-9, 15]. No study to date has described the integration of such functioning system in clinical practice. In the present study we tested and validated a generic wireless telemedicine system, we recently developed [7], on heart patients in their daily environments. The patient unit (a telemetry device Bluetooth connected to a mobile phone) was tested on pacemaker patients to see if it had electromagnetic effect on the implanted pacemaker. The results showed that there were no clinically significant adverse effects or program changes of the pacemaker settings. However, in a subjective evaluation regarding the patients' felling during the test, only in 10 cm and 0 cm some tickling felling was reported, although no effect in pacemaker function was registered. It is concluded that the patients can be advised to avoid bearing the patient-unit less than 10 cm from the implanted pacemaker.

It is obvious that in a more realistic condition, when the patients are doing deferent indoor and outdoor activities, including driving a vehicle with different speeds, being in different landscape or building environments or probably being close to different interference sources (e.g. microwave oven at home, or other heavy electrical machines outdoor) can, significantly, influence the reliability and the performance of the system [7, 8]. Advising the patients about the system limitations can improve the performance and reliability of the system.

The results regarding the degree of system usability in clinical practice from patients as well as healthcare personals' point of view, showed that the system including the patient-unit is easy to mount and easy to employ, and there was no significant problem changing the electrodes by patients themselves at home, in spite of the patients' age were in the range of 28 – 63 years.

The patients expressed their high degree of freedom and mobility using the system, and they expressed reasonably high confidence in respect of being monitored by the real-time wireless remote monitoring system. In the same way the in charged healthcare personals expressed reasonably high confidence regarding the application of the real-time wireless remote monitoring system in clinical practice.

6. Conclusion

The presented system is reliable, functions with a clinically acceptable performance, and transfers medical data with high quality, even though the system was tested under totally uncontrolled circumstances during the patients' daily activities. It is concluded, that the system is applicable in clinical practice and the patients as well as the healthcare personals expressed their confidence in using it. In other words, it can be conclude that the designed and implemented real-time wireless monitoring system is generally applicable in clinical practice e.g. cardiology.

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