EVALUATION OF WIRELESS COMMUNICATION FOR PERIOPERATIVE REALTIME MONITORING

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Abstract: Wireless communication tends to be one of the major trends in medical applications to increase usability and comfort in long time patient monitoring. Nevertheless, systems currently available at the market mostly concentrate on home-care or generally on scenarios that do not existentially depend on permanent transmission of continuous data streams. Anyhow, there exists a couple of short-range wireless transmission standards that allow appropriate data rates suitable to continuously transmit a sufficient set of patient vital status information. These technologies allow wireless communication even in perioperative use which is one of the most critical scenarios for online patient monitoring with the highest demands on reliability. To deal with the specific needs of this application area, the project described in this paper has been started with the discussion of different wireless communication standards. Based on the results a first demonstration prototype has been developed for a detailed analysis on the behavior and usability of the Bluetooth technology in operating room environments.

Introduction

The preliminary work on the analysis of available wireless communication standards focuses on the most common technologies with publicly available specifications which are namely Bluetooth [1], WLAN (IEEE 802.11) [2], WPAN (IEEE 802.15.4 / ZigBee) [3, 4], DECT [5] and IrDA [6]. Except the IrDA technology which uses infrared light for transmitting data, these technologies are radio based using different frequency bands. The different standards have been reviewed by their appropriateness regarding throughput, reliability, security and energy consumption. Regarding the issues taken from the preliminary examinations, a first demonstration prototype for a wireless vital data monitor covering electrocardiogram (ECG), blood oxygen saturation, plethysmogram, blood pressure (invasive/non-invasive) and temperature has been built using Bluetooth radio communication. As expected, the prototype proved the Bluetooth technology suitable regarding its throughput and latency in non-disturbed areas. To examine the applicability in the operation room scenario the device has been tested on various experimental animal surgeries as well as with synthetic measurement setups.

In the following sections the analysis that led to the choice of Bluetooth will be presented as well as the results of the first measurements with the prototype.

Comparison of Wireless Technologies

To review the different technologies concerning their appropriateness in a perioperative environment, the relevant criteria for an evaluation have to be defined first. The main criteria used in our project were chosen as follows:

- **Bandwidth**: Does the available bandwidth satisfy the demands for transferring all different parameter streams in an perioperative environment?
- **Range**: Is the transmission range between the mobile device and the fixed base station sufficient to allow an easy movement of the patient?
- **Energy consumption**: Is the average energy consumption low enough to allow a runtime of 12 hours or more for a battery powered device?
- **Robustness**: Does the technology provide any procedures to deal with errors caused by interferences with other devices, medical equipment or the clinical staff?
- **Availability**: Is this technology established in the market. Are there enough experiences with this technology to allow a substantial analysis of the advantages and disadvantages? Are there enough vendors offering devices? Is the technology standardized and is it an open standard?
- **Usability**: Are there any counter-arguments against using this technology in perioperative environments? Do any restrictions (e.g. restrictions on used frequency bands etc.) exist in single countries or regions?
- **Security**: Are there any mechanisms to ensure that no unauthorized person can receive and/or decrypt the transmitted data?

Depending on the particular demands there may exist other criteria and/or a special weighting of the single criteria. After defining these criteria, different technologies discussed for usage in medical environments have been identified and compared against each other.

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Table 1: Comparison of Wireless Technologies

	Bandwidth (max. gross)	Range (indoor)	Energy consumption (mA)	Robustness	Availability	Usability	Security
WLAN	54 MBit/s	100 m	150 - 400	o	++	−	−/+
DECT	552 kBit/s	50 m	150	++	−	−−	++
WPAN	250 kBit/s	100 m	0.5 - 20	+/++[1]	−	++	+/++[1]
IrDA	16 MBit/s	1 m	30 - 1000	−−	+	−−	−−
Bluetooth	1 MBit/s	100 m	0.3 - 5	+	++	++	+

Table 1 gives a short overview of the results of the comparison regarding only the key features. Note that the values in the table mostly denote maximum values (e.g. bandwidth) or average values from different vendors or implementations (e.g. energy consumption). Especially the values given regarding the energy consumption are ascertained from different vendor specifications and measurements performed in academic projects and should not be considered as absolute values valid for every single device on the market. The maximum values for the available transmission range are given for indoor scenarios. These ranges may vary in outdoor environments. The values given for the WPAN standard (ZigBee) are mostly based on estimations or first experiences because of the novelty of this technology. Criteria that could not be measured directly are given as a rating (going from −− to ++). The reasons that led to these ratings are given below.

The robustness of radio based technologies strongly depends on the modulation and the frequency band used. Technologies using the license-free ISM (Industrial, Scientific and Medical) frequency band (Bluetooth, WPAN and some WLAN types) are generally more error-prone to interferences because these frequency bands are free to use (in certain extend) for different types of devices possibly causing interferences on each other. IrDA, depicting the only optical technology, depends on a continuous intervisibility for transmitting data. This intervisibility is hard to guarantee in perioperative environments where a lot of people are working and the devices are moved from one location to the other. Therefore, the robustness of the IrDA technology is regarded as average for these scenarios.

WLAN and Bluetooth devices, being on the market for a long time, are available for a large range of application ranges. DECT telephones and modules for voice transmission are also very prevalent at least in Europe, but modules for data transmission are not so common making them hard to find. The ZigBee standard (or IEEE 802.15.4 - covering only the lower layers of the protocol stack) is relatively new, compared to the other technologies. Hence, only a few devices are available to the market implementing the entire standard.

[1] Estimations due to lack of material

In comparison to Bluetooth, WPAN or DECT, the output power of WLAN devices is very high, casting the suitability for using this technology in direct contact to the patient into doubt. Furthermore, the WLAN technology is designed for IP-based networks using a complete TCP/IP protocol stack. This can be a drawback when trying to use it in embedded devices and environments. The primary DECT technology, using the frequency band between 1880 and 1900 MHz can only be used in Europe, not in the US. A special version using the ISM band at 2.4 GHz exist but is not very common. Additionally, building up a design for two different device implementations can cause further problems. Because of the drawbacks of the IrDA technology mentioned before, the IrDA technology seems not to be very suitable for usage in a perioperative environment. The Bluetooth technology as well as the WPAN technology are working in the ISM frequency band, operate at low output power levels and provide simple protocol stacks suitable for embedded devices, making these technologies suitable for the given scenarios.

Security issues are from high imprtance in scenarios where sensitive data (like patient data) has to be transmitted. WLAN provides different security mechanisms from which at least one (WEP) has been proven to be vulnerable against attacks [7]. Therefore, the security from WLAN depends both on the available security features provided by the particular devices and the accurate usage from the clinical staff. DECT and WPAN also provide security features like encryption. Algorithms for attacking these features are not known to the authors. The IrDA standard does not specify any security measures for data transfer. Bluetooth offers some security features. The effectiveness of these mechanisms also depend on a diligent design.

All the advantages and disadvantages noted so far do not cover every single aspect of these technologies but they provide some basic fundamentals for chosing a suitable technology. In this project the Bluetooth technology was chosen because of its positive key features and the good availability in the market.

Implementation

Based on the positive aspects of the Bluetooth radio technology, a first demonstration prototype has been built to validate the usability in medical environments.

The main focus for the demonstration prototype has been set on the communication link and its analysis in a medical environment. Therefore, only approved sets of OEM-modules for vital parameter monitoring have been taken into account. Optimization of sensor systems for wireless use would be another interesting topic but will not be a main focus until general applicability of wireless monitoring is proven for life-critical scenarios.

Two sets of sensor systems have been compared for their suitability for the first evaluation prototype. The first one was a set of five single modules providing raw data stream without any high level functionality. These modules provide:

- **IBP** : invasive blood pressure
- **NIBP** : non-invasive blood pressure
- **SpO_2** : blood-oxygen saturation, pletysmogram and pulse frequency
- **ECG** : electrocardiogram
- **TEMP** : body temperature

As a second alternative a complete OEM monitor suite based on physically separated data acquisition unit and a PC-based visualization unit has been examined. This monitor suite provides complete monitor capabilities including a credited visualization software as well as link quality analysis.

To avoid side-effects caused by the mandatory link quality observation that has not been designed for use with wireless links, the test with the second device combination have been postponed until the general functionality has been proven with the raw data modules.

The chosen modules use a UART-encoded serial line as data output. The ECG-module and the IBP-module transmit data at a bandwidth of 9600 baud, the other modules use a bandwidth of 4800 baud at a serial setup with 1 stop bit, 8 data bits and no parity. This directly gives a first approximation of 30 kbit/s input bandwidth from the data acquisition modules.

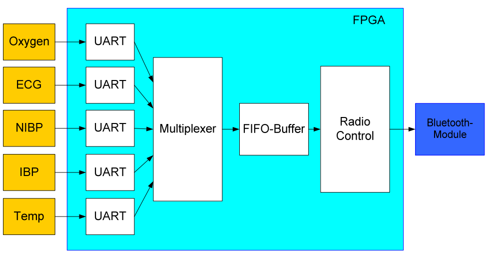

Figure 1: Communication Unit Structure

The five sensor modules are connected to a transmission unit. This unit is based on a Xilinx Spartan II FPGA providing the UARTS to decode the serial output from the sensor modules, a protocol encoder and stream multiplexer, a small amount of memory (FIFO) to store single packages until their transmission as well as a communication and link control state machine to handle the radio transmission. Additionally the communication unit inherits a Bluetooth module for the physical data transfer. A schematic of the sender unit is given in Figure 1.

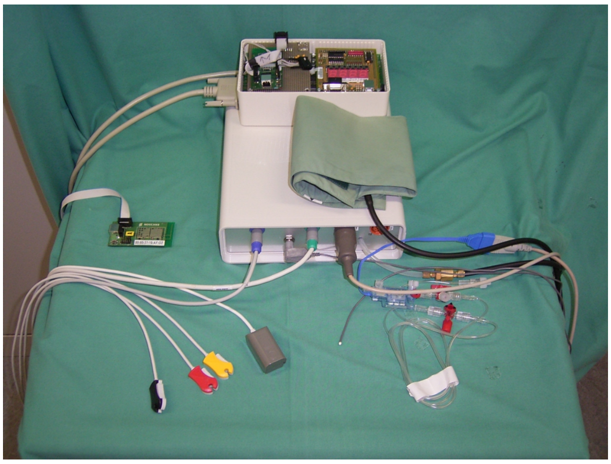

Figure 2: Demonstration Prototype

Figure 2 shows the sensor side implementation of the monitor environment. The upper box inherits the Bluetooth radio module as well as the sensor side control architecture and the power supply. The box below contains the medical sensor unit. Both parts are connected by a 25 pin connection cable to allow an optimal placement of the sensors at the patient while allowing the communication part to be arranged for best radio connectivity.

The receiver part is currently build up from a standard laptop computer running a custom visualization software.

Figure 3: Visualization

Figure 3 shows the graphical user interface used to visualize the health status parameters on the receiver side.

For a first impression of medical devices that display threats to the wireless monitor, the demonstration prototype was installed at an experimental cardiological operation on a goat. For estimation of communication errors the prototype was extended by a test mode that replaces patient data by synthetic values that can be verified by the receiver. To achieve a characteristic communication

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profile, the creation of synthetic data has been triggered by the arrival of measurement data and generated in the same amount like the measurement data. The operation included classical surgery as well as massive use of electro coagulation which is known to be a certain threat to different electrical and electronical devices. Neglecting possible inaccuracies deriving from the biomedical measurement, there was no noticeable impact of the operating room environment to the prototype or the transmission for an operation duration of approximately 4 hours.

Even if the Bluetooth-standard [1] provides a command to determine the connection quality, the implementation details on this method and the significance of its return values are not explicitly specified but left to the vendor of each Bluetooth module. Therefore, this method can not be treated as trustworthy for a detailed analysis. As an alternate way to get more information on error behavior, the Bluetooth-modules offer a device-under-test operation mode. This mode allows the estimation of communication errors besides the built in error correction which is commonly given as the bit error rate (BER).

The bit error rate gives a common measure of the quality of data transfer stating the percentage of the total amount of transferred data that are erroneous. In a non-disturbed environment with moderate background noise the average bit error rate for Bluetooth devices is specified by approximately 0.001% [8]. Unfortunately, Bluetooth devices are not capable of transferring user data while they are in device-under-test mode. Therefore, an alternative setup has been built using the same radio technology as the biomedical prototype to record the environmental characteristics.

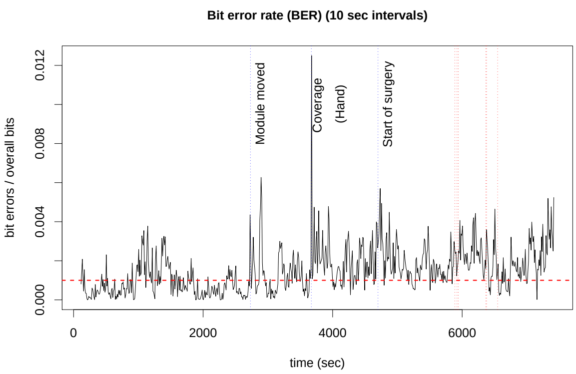

Figure 4: BER Measurement during Operation Setup and Surgery

At a second animal operation, this dedicated measurement setup has been arranged with a distance of 5 meters with the operation table in the middle between the sender and the receiver. Figure 4 shows the bit error rate with the amount of occurred bit errors summed up over intervals of 10 seconds. The horizontal mark shows the reference value of 0.001% for normal background noise. The first vertical mark shows a rearrangement of the radio module to fit the operation setup. The beginning of the measurement up to the third vertical mark shows the room characteristics during the preparation of the room and the anesthetization of the animal. The first vertical mark shows a repositioning of one radio module to fit into the room setup. Thereby the module has been covered by a concrete pylon with a diameter of 60 cm for about 3 seconds. The second mark gives a synthetic error injection by complete covering one of the modules by a human hand to test the setups functionality. From the third mark describing the operations start, a slightly increasing bit error rate can be recognized. At this point no additional devices have been taken in use that did not participate in the setup phase. All of the following marks show the use of a high frequency electronic scalpel and high-frequency coagulation which do no remarkable harm to the concurrent setup. Admittedly the used coagulation device was a high frequency coagulation device instead of a conventionally built electro-coagulator which is known to do much more interference to its environment. As a first result it showed up that the increased bit error rate did not occur in any comprehensible association with the use of any special electronical devices in this operation. Instead, the staff attending the operation increased from 6 persons during the setup phase up to 12 persons during the main operation what correlates with the increased average bit error rate. Due to the fact that Bluetooth use radio frequencies slightly above 2.4 Ghz which are likely to be absorbed by organic matter this leads to the conclusion that the positioning of surgeons and medical staff has to be kept in mind when arranging the location of the receiver modules.

Conclusions

The most common wireless technologies have been compared for their usability in medical realtime monitoring. Regarding bandwidth, communication range, energy consumption, robustness of communication and general usability, Bluetooth stated out as the currently most suitable technology for medical realtime communication. Based on this analysis a first demonstration prototype has been built.

The demonstration implementation made it possible to prove the concept of wireless monitoring in perioperative environments to be realizable in areas of undisturbed radio transmission without concerns on available bandwidth and latency. The measurements based on the demonstration prototype and the bit error measurement setup gave further knowledge on impact characteristics of typical operating room environment on the Bluetooth technology. As a very positive result the demonstrator has shown that bit errors at the physical layer can be corrected by the Bluetooth modules sufficiently not to get any errors on application layer. The used setup proved that Bluetooth practically behaved as expected on a theoretical basis and leads to the conclusion that the stability and robustness of Bluetooth seems to be well suited for operating room devices even under non-optimal boundary conditions. Based on the measurements the next phase of the project will be instantiated which will take the communication infrastructure and especially a roaming model for Bluetooth into account.

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