J. Biomed. Eng. Res : 274-281, 2006

CDMA-Based Ubiquitous SaO_2 Monitoring System for Oxygen Therapy Patients

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(Received August 8, 2006. September 13, 2006)

Abstract

In this paper, we propose a ubiquitous SaO_2 monitoring system for patients using oxygen therapy. For these patients, the ability to monitor oxygen saturation ubiquitously is very important for accurate adjustment of ventilator's flow rate to match the patient's time-varying requirements with the shortest lag time possible. We have developed a portable device to measure SaO_2 and transmit it to hospital in real-time or in store-and-forward mode through the integration of Bluetooth™ technology and the code division multiple access (CDMA) cellular network. We also developed software for doctors to receive and manage the patients' SaO_2 information. Performance of the developed system was evaluated as acceptable by assessing the accuracy of the measured oxygen saturation value and the stability of communication network. Test results in real clinical setting demonstrate that our system is feasible for immediate use in home oxygen therapy.

Key words : ubiquitous healthcare, oxygen therapy, CDMA cellular network, bluetooth™, personal digital assistance

I. INTRODUCTION

Oxygen therapy has been known as the only therapeutic modality not only to improve the quality of life but also to increase life expectancy in chronic obstructive pulmonary disease (COPD) patients [1]. The number of oxygen therapy users has been gradually increasing due to increase of the patient, a high awareness of proven benefit and widespread availability [2]. In this therapeutic regime, the optimality of care totally depends on the accuracy and adequacy of supplying oxygen to meet the instantaneous patient's demand. Technical difficulty in achieving this goal is based on the fact that a patient's oxygen requirements always vary with the degree of disease and daily activities. The Fifth Oxygen Consensus Conference, therefore, recommended users to be reevaluated for renewal a description within 90 days after being discharged from hospital [3]. However, one study reported that only 35% were reevaluated within 3 months and 58% among reevaluated patients could be discontinued oxygen therapy [4]. So, the continuous evaluation through a ubiquitous monitoring of the patient's oxygen saturation level will improve the efficacy of the oxygen therapy and eventually help in reducing costly hospitalization period. Various wireless communication technologies have been used for the implementation of remote patient monitoring systems [5-11]. Wireless telemedicine system can be classified into two groups in terms of network coverage, "short-range" networks like a Radio frequency (RF) [5,6], wireless local area network (WLAN) [7,12] and Bluetooth™ [13], and "wide-range" mobile cellular network such as Code Division Multiple Access(CDMA), Global System for Mobile (GSM) [9-11] and General Packet Radio Service(GPRS)[12,13]. With the advance of mobile telecommunication technology, cellular network has been actively being used for telemedicine with or without connection to a "short-range" network. One group has developed a ubiquitous patient monitoring system using WLAN and GPRS networks for in-hospital setting and off-site remote areas, respectively [12]. Recently, the other group has developed a telemedicine processor by the integration of Bluetooth™ and GPRS [13].

However, CDMA-based system to transmit biomedical signals to a remote site where healthcare service is provided has not been yet reported partly because its availability is limited in certain parts of the world. The main advantages of

This work was supported in part by the Korea Science and Engineering Foundation (KOSEF) through the Bioelectronics Program of the Specified R&D Grants from the Ministry of Science and Technology (MOST) and the Advanced Biometric Research Center (ABRC).
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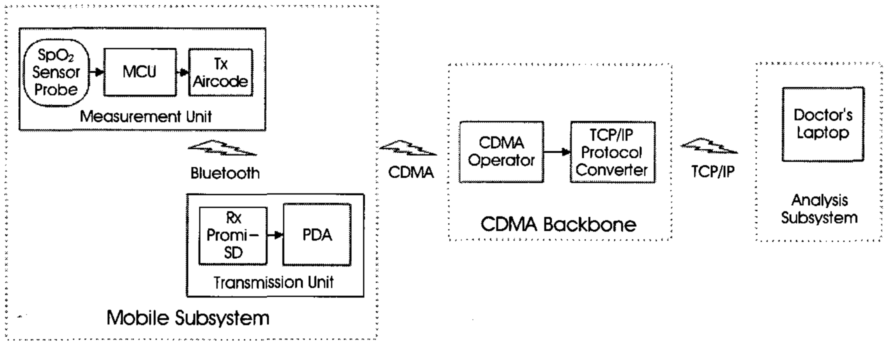

Fig. 1. Architecture of the ubiquitous SaO_2 monitoring system

this technology are bandwidth efficiency, capability to offer multiple accesses, economic feasibility and low transmit power. Based on these merits, CDMA has been becoming an effective and efficient communication tool for telemonitoring system [14]. Also, in the CDMA system, interference with other equipment is reported to be lower than the mobile phone which relies on the GSM [15]. Considering the importance of safety in the healthcare product, immunity to interference is an essential characteristic to wireless communication technology which will be utilized for a healthcare service.

In this paper, we present a ubiquitous monitoring system which aims at measuring and transmitting the patient's SaO_2 data at anytime and anywhere by using wireless communication technologies in the form of combination of Bluetooth^{TM} and CDMA cellular network. Even though the telemedicine system for patients with a chronic respiratory disease has already been devised [16], it can be used as a general purpose home-based monitoring system for healthcare delivery to patients staying in a house.

II. MATERIALS AND METHODS

A. Design Criteria

There are several criteria which should be considered in designing a portable device for ubiquitous SaO_2 monitoring [17][18]. These requirements will also be used when we evaluate performance of the developed system.

Ubiquitous Accessibility

The device should have the ability to ubiquitously access the server at a remote base station throughout the network with a high fidelity and stability.

Low Power Consumption

The device should run for at least one full daywithout battery recharge. Electronic circuitry design and component selection aims at minimizing the power consumption. Algorithm used in program and the measurement frequency should also be optimized to expand battery life.

Wearability

The device should be light and compact enough for patients to carry with the minimal disturbance during daily life.

Event Recording.

The device should have a function of time recording at predetermined specific events in order to investigate relationship between patient's specific activity and SaO_2 level.

B. System Architecture

The ubiquitous SaO_2 monitoring system consists of two subsystems of mobile system and analysis system as shown in Fig. 1. The mobile subsystem worn by patient acquires SaO_2 data at preprogrammed intervals or when the patient manually activates the recording button. The collected data is then wirelessly transmitted to the analysis subsystem which is installed at a remote healthcare provider's site and enables the physicians and doctors to monitor and analyze patients' SaO_2 level in real time. The connection between two units uses CDMA cellular networks and internet in sequence, which requires the signal protocol converted from CDMA to TCP/IP in the base station at the cellular network service company.

C. Description of Mobile Subsystem

The mobile subsystem is further divided into two units of a measurement unit and a transmission unit, which are connected each other by Bluetooth^{TM} short-range wireless communication technology. The former is an in-house built microcontroller-based circuitry and the latter is a PDA with the functionality of a CDMA cellular phone.

Measurement Unit

The measurement unit consists of SaO_2 signal processing module, Bluetooth^{TM} communication module and microcontroller circuitry as shown in Fig. 2.

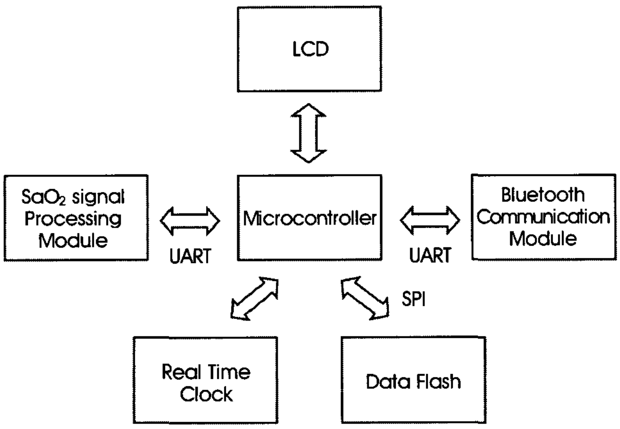

Fig. 2. Block diagram of the measurement unit

The SaO_2 signal processing module was built using a commercial finger-type pulse oximetry sensor and module (8000AA and OEM III, NONIN Medical. Inc., USA). As the Bluetooth communication module, we used the board-type wireless Bluetooth™ serial adapter with on-board antenna (ACODE-300, Initium Co. Ltd., Korea) for a short-range network. It features small size (18 × 20 ×11.7 mm), most important one for this application, power class 2 and 30m maximum RF range.

An 8 bit microcontroller (Atmega128, Atmel, USA) controls entire process of the measurement unit. Its peripheral devices such as UART and SPI together with 53 programmable I/O pins allow communication with two modules and peripheral components such as an LCD, an RTC(NJU6355, New Japan Radio Co.Ltd., Japan) and a 32 Mbits data flash(AT45DB321B, Atmel, USA). Numeric values of SaO_2, HR, activity and time are displayed on LCD. Four switch buttons were added to identify different events and to wake up the microcontroller from sleep mode. Each button has its own event (such as walking, stool, eating and etc) which needs to be predetermined by doctors. The power management circuit based on a step-up DC-DC converter provides 3.3V from two parallel AA batteries.

Measurement unit has two operating modes; real-time mode and save-and-forward mode, which corresponds to default and auxiliary mode, respectively. By automatic switching between these two modes depending on communication network status, data loss during transmission is prevented. Fig. 3 shows a flow chart for whole process in the measurement unit. Basically, the process is activated at every 5 minute. After waking up from sleep mode, the microcontroller turns on the measurement module and then the Bluetooth™ module through MOSFET switches connected to the power line of both modules. Once

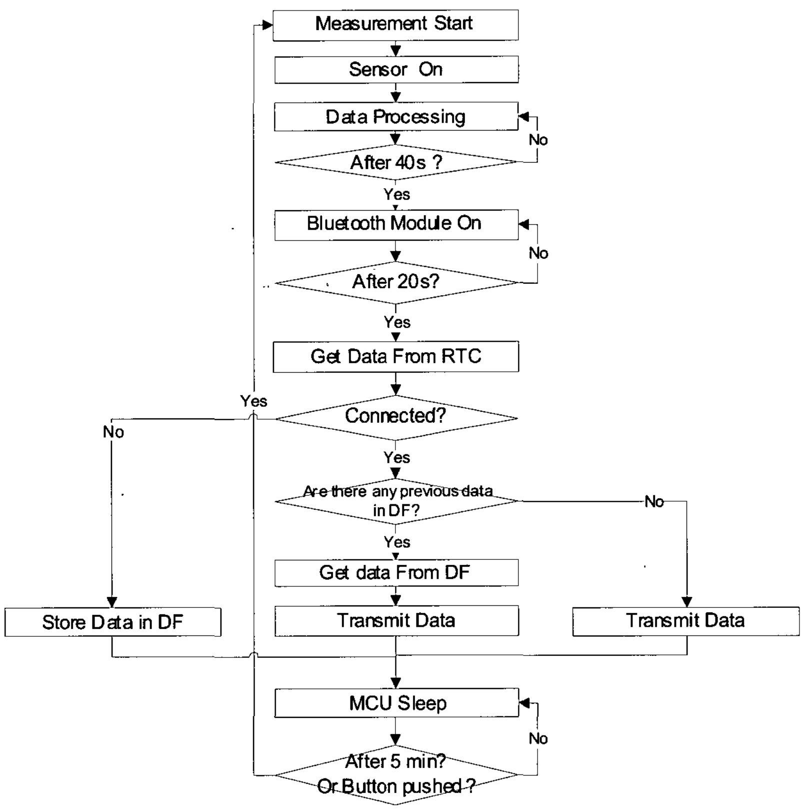

Fig. 3. Software flow chart of the measurement unit

the Bluetooth™ module succeeds in making a connection with a receiver module, presence of untransmitted previous data in the memory storage is programmatically checked by the microcontroller. If data flash is empty, only present data is transferred, otherwise stored data as well as present data is transmitted.

Data transmission is performed with a protocol comprising of 12 bytes as shown in Fig. 4. When the device fails to make a connection, the present data is stored in the data flash. After the current measurement process is finished, the microcontroller turns off two modules and then enters into a sleep mode for power save. Button press for specific activity event generates an interrupt to wake up MCU from sleep mode and then measurement is restarted. Since each data transmission consists of 12 bytes and the measurement is performed every five minutes, the maximum memory space for one day storage is given by, sampling frequency/day × # of bytes/sample = (24 × 60 / 5) × 12 = 3456 bytes.

In terms of data flash's memory capacity for the one day data storage, it is possible to decrease the sampling interval down to even a second order. With the current Bluetooth™ transmission rate of 9600bps, time required to transmit this data is about 24.9s.

Start 1Byte	Event 1Byte	Time 6 Bytes (Year, Month, Day, Hour, Minute, Second)	SaO_2 1Byte	HR 2 Bytes Upper 2 bits Lower 7 bits	Finish Byte

Fig.4. Data transmission protocol

Transmission Unit

The transmission unit is composed of a Bluetooth™ serial adapter (Promi-SD202, Initium Inc., USA) to receive data from the measurement unit, a PDA supporting a CDMA cellular phone and a bridge board as shown in Fig. 5. The Bluetooth™ serial adaptor features power class 1, about 100m RF range, RS-232 serial interface at 384 kbps.

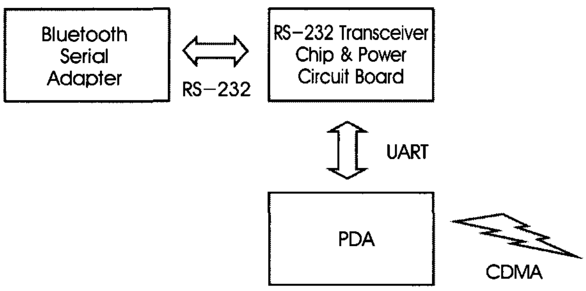

Fig. 5. Block diagram of the transmission unit

A user interface program developed with Microsoft embedded visual C++ 4.0, was installed on the PDA to display SaO_2 and heart rate as well as to transmit data through the CDMA cellular network. The transmission of data between the transmission unit and the analysis subsystem was implemented by the client-server model. The transmission unit serves as a client end and the analysis subsystem serves as a server control. Communication is performed using TCP/IP protocol over the CDMA network. Data can be transmitted over the network after the client is successfully connected to the registered server with a proper IP and port number.

D. Description of Analysis Subsystem

Analysis subsystem is basically an application program on a PC. The program was implemented by Labwindows CVI 7.0 (National Instrument, USA) on the Windows XP platform. Received data is presented in the form of a table and a chart recorder as shown in Fig. 6 where the displayed parameters include patient' ID, data number, SaO_2 value, heart rate value and event ID with time mark. In a chart recorder style display, each point indicating SaO_2 level has a different color. This helps doctors easily recognize the variation of SaO_2 level according to specific activities. All data shown in the display can be stored in a text file format and retrieved again for display in the original form. As valuable parameters for doctors, the maximum and minimum SaO_2 level could be a good indicator of patient recovery and of emergency situation, respectively. The adequacy of oxygen supply for a specific activity is also verified by examining the average SaO_2 level during that activity. This program can be made to sound alarms automatically when the measured SaO_2 is lower than a preset level and when the sensor is thought to be detached or mispositioned.

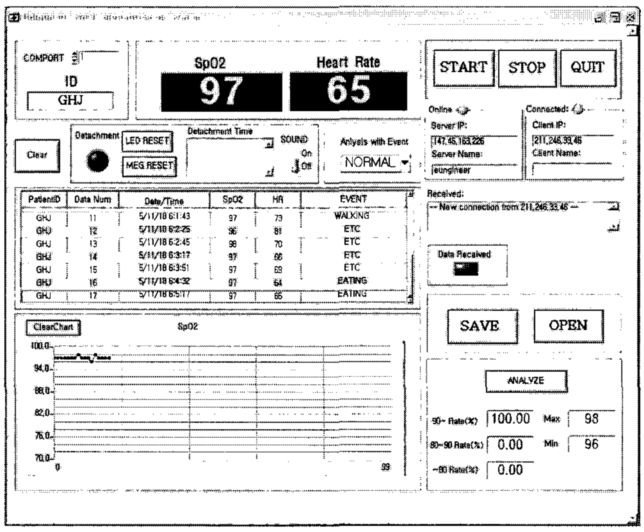

Fig. 6. Screen display of the analysis subsytem

E. Performance Evaluation

Evaluation of the system performance has focused primarily on the functionality and the usability which denote an accuracy of the transmitted SaO_2 data and the usefulness of the developed system to both doctors and patients, respectively.

In the functionality evaluation, three different tests were performed, where the function of the measurement system as well as the transmission of data through the entire network were tested. First, a commercial pulse oximeter simulator (Oxitest plus7, Datrend Systems Inc., Canada) was used to verify the basic performance of the measurement unit. We chose five simulated values in the range between 70% to 97% which corresponds to the possible worst and the best case, respectively. Each value was tested 50 times while SaO_2 value was decreased by 1 from 97% to 70%. In the second test, the developed measurement system was compared to a commercial one with five healthy volunteers (four male and one female). Two different systems, the developed system and a commercial pulse oximeter (YM5500, MEDIANA Co. Ltd., Korea) were connected to different fingers of the same volunteer and then operated simultaneously for the accuracy comparison of the measured SaO_2 values. Finally, we performed a simple experiment to verify the robustness of the communication over CDMA network. Experiment has been carried out in the subway running at an average of 60 km/h because this environment can offer both geographical (underground) and physical (fast moving) restriction.

In assessment of the usability, firstly, we applied the developed system to a healthy volunteer in normal life in order to investigate the feasibility of ubiquitous monitoring. The subject was required to do daily activities as usual as shown in Figure 7.

Secondly, we tested the complete system in real clinical setting at Seoul National University Bundang Hospital. Following the test scenario, the patient was wearing the developed system for five hours from 10 am to 3 pm. While staying in a room, the patient can move around the room wearing the measurement unit only with the transmission unit placed beside the bed. During this test, the PDA and Bluetooth™ serial adapter in the transmission unit were plugged in an external power supply. For four different activities of walking, having a meal, having excretions, and undetermined spare one, the patient was asked to push the button to let the measurement unit recognize the particular activity. The patient was also asked to go outside and walk around while wearing the entire system contained in a sling bag.

Fig. 7. Full-day test with a healthy volunteer. A: Having breakfast at home (a.m. 7:10), B: Reading a newspaper (a.m. 7:30), C: Leaving for office(a.m. 8:00), D: In the subway (a.m. 8:30), E: Working (a.m. 9:30), F: Transmission unit on the table, G: Lunch (p.m. 1:00), H: Tea time (p.m. 3:00), I: Working (p.m. 4:00), J: Dinner (p.m. 6:00), K: Exercise (p.m. 7:00), L: Sleeping (p.m. 11:00)

III. RESULT

A. Specification of the Developed System

The developed measurement unit using Bluetooth™ which includes AA-sized battery is comfortably wearable ($10.5\times 6.8 \times 2.2cm^3$ and 200g) as shown in Fig. 8. Power supply current level was approximately 80mA in scanning mode and 55mA in transmission mode, but, in sleep mode, below 1mA. If the Bluetooth™ serial adapter is turned off, the measurement unit continued operating with data saving for about 7 days without changing batteries.

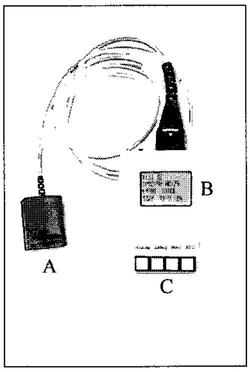

Fig. 8. Developed measurement unit. A: Finger clip sensor, B: LCD display for SaO_2, heart rate, event and time, C: Buttons for the event recording

In the transmission unit, the PDA, a major part of it, is 16 × 9.3 × 2 cm^3 and Bluetooth™ serial adapter is 8 × 1.5 ×1.5 cm^3 as shown in Fig. 9.

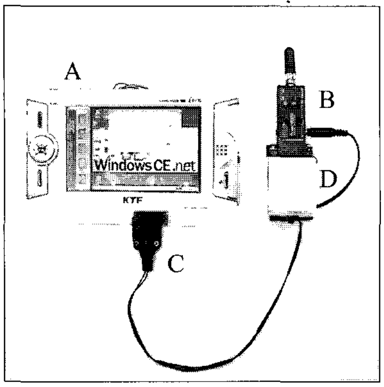

Fig. 9. Developed transmission unit. A: PDA, B: Bluetooth™ serial adapter, C: Cable for UART interface, D: Bridge board

For carrying easiness, we put the transmission unit in a sling bag together with a power adapter and extra batteries. Total weight of the transmission unit including the carrying bag is about 600g. The PDA using a 2000mAh lithium-ion polymer battery can run for around 4hr with one full charge. Bluetooth™ serial adapter powered by 2 AA-sized batteries can operate for about 6 hour 30 minutes because it should always maintain a scanning status waiting for calls from other Bluetooth™ module in the measurement unit. At this moment, PDA's battery capacity is a critical parameter to increase operating time without external power supply or battery exchange. Fig. 10 shows an appearance of a volunteer wearing and carrying the developed system.

Fig. 10. Total ubiquitous SaO_2 monitoring system. A: Small bag containing transmission unit, B: Measurement unit, C: Finger clip sensor

In the accuracy test using a simulator, the results are acceptable with the error within ±2%, which denotes that the developed wireless pulse oximetry can be used equivalently to a conventional one. The variance of the measured values in low range is bigger than high values, which implies that the measurement of low SaO_2 value is relatively less accurate and stable.

Also, in the comparison study with a commercial product and five healthy volunteers, the average difference between two devices was less than ±3%. There was no transmission error found in the test for data transmission through Bluetooth™ and CDMA cellular network. In the test of robustness and stability of CMDA cellular network, no connection failure occurred during the total 10 trials. This perfect performance was achieved mainly due to the errorless protocol supported by both Bluetooth™ and internet (TCP/IP) communication.

B. Tests for One Full-day and in Clinical Setting

In a full-day test with a healthy volunteer, about 200 SaO_2 values were collected and almost every value was in the range of 96 to 98 indicating normal state. There was no CDMA connection failure except only one case at the underground fitness club where the connection status was unstable. Additional battery was not required because the PDA and Bluetooth™ serial adapter was connected to an external power supply during indoor stay and the total outdoor activity time was less than four hours, the PDA's battery life.

In Fig. 11, the graph presents SaO_2 data acquired from a patient in clinical setting of hospital during 5 hours. The patient stayed in normal state in the morning and had lunch at 12:30 pm. After that, he took a rest silently, which resulted in high SaO_2 values. The patient went out and moved around the hallway riding on a wheelchair from 2:00 pm to 2:20 pm. Since he didn't use his muscles to move, there were no big changes in SaO_2 values. The patient's gesture using his right hand during a conversation caused motion artifact so that SaO_2 values sometimes fell down below 95.

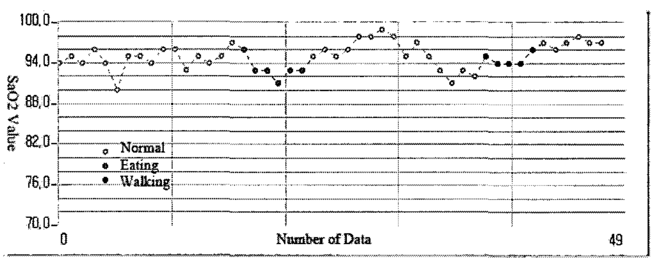

Fig. 11. Patient's SaO_2 data during 5 hours testing in clinical setting.

IV. DISCUSSION

A. Ubiquitous Access

Combination of Bluetooth™ technology and CDMA cellular network enables the ubiquitous monitoring of SaO_2 with high accuracy, stability and robustness. Since CDMA technology is based on ad-hoc networking technology and has no technical limitations of coverage unlike a GSM, anybody with a proper terminal device can access the network at anytime and anywhere, which makes the CDMA-based ubiquitous monitoring very possible. There is a concern about electromagnetic interference (EMI) from a cellular phone possibly disrupting the function of active medical devices. However, during the clinical test, none of the electronic equipments malfunctioned due to operation of the CDMA phone.

B. Power Consumption

In the measurement unit, we could achieve at least 5 days of battery life by properly using a sleep mode and minimizing the time when Bluetooth™ module is in inquiry mode. Since the PDA with the functionality of a CDMA cellular phone consumes relatively high level of power, at this moment, the PDA's battery life limits the entire system's operating time to four hours. Therefore, the regular charging of the battery is required to make this application suitable for a long-term application.

C. Mobility

The success of a telemonitoring device highly depends on the user mobility provided by the device. Even though the total system looks somewhat complicated, separating the whole system in to two units this study enhances the wearability of the measurement unit and thereby improves patient's mobility. Patients only have to carry the measurement unit within the coverage of Bluetooth™ module from the transmission unit. Considering that the COPD patients usually do not have much activity, the functionality of a cellular phone may not be necessary and then the transmission unit can be replaced by a notebook or desktop computer with just a Bluetooth™ adapter.

D. Event Recording

Occurrence time of the predetermined specific events was made to be recorded by patient's or caregiver's manual input of the corresponding button. After several times of practice, the patient could use this function without any difficulties. Simpler or automatic recognition using an accelerometer chip was considered. However, this was excluded from the system design because it was thought to be beyond the scope of this work.

E. Future Work

In order to improve the wearability further, we will work on the size reduction of the total system. Our basic approaches are to remove or replace the Bluetooth™-based devices. As a cellular phone-based system without short-range wireless communication using Bluetooth™ technology, the signal processing board can be connected directly to a cellular phone through its expansion port. Since the cellular phone becomes the necessities of daily life so that almost every adult is carrying one, this type of system will maximize the portability and usability.

The other approach is using a new short-range communication method of ZigBee™ as an alternative to Bluetooth™. Since the ZigBee™ technology was developed for low-power application, small size rechargeable lithium-ion battery can be used to power all circuitries and modules. As a result of it, the measurement unit including signal processing board and a ZigBee™ module can be designed as a form of wrist-worn watch, which makes it more comfortable for patients to wear all day long. In the transmission unit, a ZigBee™ module is directly connected to a cellular phone. Another promising point is that the ZigBee™ is a technology for sensor networks, which implies that this type of device can be applied to a multi-parameter monitoring system (such as ECG, Blood pressure, temperature and so on) based on body area network.

V. CONCLUSION

In this paper, a ubiquitous SaO_2 monitoring system was designed, developed and tested. Combination of Bluetooth™ technology and CDMA cellular network enabled ubiquitous transmission of patients' SaO_2 values to a remote healthcare provider site. Physicians in a remote hospital can efficiently monitor, collect and analyze the data by using developed program that provides various analysis tools. The performance test in real clinical setting has demonstrated that this ubiquitous system is feasible for immediate use in real-life patients under oxygen therapy.

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