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Wireless Application in Intravenous Infiltration Detection System

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Abstract

The IrDA wireless protocol has been applied to a fiber optics based point-of-care system for the detection of intravenous infiltration. The system is used for monitoring patients under infusion therapy. It is optimized for portability by incorporating a battery source and wireless communication. The IrDA protocol provides secure data communication between the electronic module of the system and the PDAs carried by the nurses. The PDA is used for initiating the actions of the electronic module and for data transfer. Security is provided by specially designed software and hardware.

I. Introduction

About 80% of hospital patients in the U.S. require intravenous (IV) therapy, and between 20% and 80% of IV lines fail due to infiltration, a clot in the cannula, an inflammatory response of the vein, or separation of the cannula from the vein [1]. Infiltration of medications during infusion therapy results in complications ranging from erythema and pain to tissue necrosis requiring amputation. At present, visual inspection by the clinical staff is the primary means for detecting IV infiltration. An optical-based IV Infiltration Detection (IID) system has been developed for monitoring changes in tissue properties due to infiltration. The IID consists of a fiber sensor and an IID electronic module (IEM). Fig. 1 shows an image of the fiber sensor in use. The IEM operates as a portable, standalone unit that monitors, analyzes, and stores the acquired signals. The objective is to develop an IID system capable of alerting healthcare providers in real-time when an infiltration occurs.

An animal study and a healthy subject study were conducted at Eastern Virginia Medical School (Norfolk, Virginia, USA) and University of Virginia (Charlottesville, Virginia, USA), respectively. Both studies demonstrate that the sensitivity and specificity of the IID are 0.97 and 0.98, respectively [2]. A clinical trial on 800 patients is currently underway at Virginia Commonwealth University (VCU, Richmond, Virginia, USA) Hospitals. The purposes of the trial are to validate the IID technology, to compare the results obtained from the IID with those observed by blinded floor nurses, to investigate human factor engineering issues, and to obtain user feedback. During the trial, the IEM collects and stores data from the fiber sensor. Study nurses (nurses who work exclusively for this trial) collect the data using an IrDA protocol (Infrared Data Association, irda.org) on a PDA [3]. The communication protocol consists of a proprietary layer of commands above the IrDA stack. The files collected by the IEM consist of subject parameters and the acquired optical data. They are then transported to the PDA, downloaded from the PDA to a designated computer at VCU, and automatically transmitted to an offsite server for analysis. The system is in compliant with the Health Insurance Portability and Accountability Act of 1996.

II. System Design

The IEM is a specially designed embedded device, controlled by an Atmel ATmega128(L) processor (atmel.com). It has a 4 MB external flash memory, a backlit LCD display, an interactive pushbutton, and two communication modes, wired (RS-232) and wireless (IrDA). The firmware is loaded onto the processor via the serial port. The code was written and compiled in IAR C Embedded Workbench (iar.com). The IEM is powered by four (4) AA batteries.

The HP iPAQ hx2495 PDAs are chosen for this project due to their IrDA capability and Windows Mobile 5.0 operating system. The program for the PDA was written with Microsoft Visual C++ 2005.

III. System Operation

The main components of the IID include the fiber sensor, IEM, PDA, a designated computer, and a designated server. Fig. 2 is a schematic diagram of the IID. Images of the IEM circuit board and a PDA are depicted in Fig. 3.

In the clinical trial, the floor nurses are responsible for attaching the fiber sensor to the patient and administering the IV, whereas the study nurses are responsible for entering patient data into the PDA, initializing the subject run, collecting run data upon run completion, and reporting any comments taken during and after the subject run. Only the study nurses have access to the PDAs.

The study nurse initiates a subject run on an enrolled patient by entering the following patient parameters into the PDA:

- age, gender, race, ethnicity,
- skin condition,
- subject location (cardiac ward, cancer ward, etc.),
- other host factors (such as family health history),
- type and dosage of infusate,
- infusion rate,
- catheter material, gauge size, insertion site,
- any catheter related infection, and
- any other infection(s).

Other subject identifiers such as name, social security number, insurance status, etc. are not collected. The PDA program is designed to be user friendly by incorporating drop down menus, large buttons, HELP captions, and pop-up messages. Fig. 4 displays one of the windows of the interactive questionnaire.

After collecting the subject parameters, the study nurse initiates data acquisition by sending a START command and forwarding the subject parameters from the PDA to the IEM via IrDA. The subject parameters become part of the data file for that particular patient. Time stamps representing the beginning of a run and detection time are logged by the IEM. The IEM acquires and records the data from the fiber sensor every three seconds until the floor nurse stops the infusion.

After a particular subject run, the study nurse can choose between either wired or wireless communication between the IEM and the PDA to retrieve the collected data from the IEM. The collected data set is given an automatically generated filename with a propriety extension. Both RS-232 and IrDA provide serial communication speeds of up to 115.2 kbps. Data sets from multiple subject runs (different subjects) are stored onto one PDA. The PDA is then placed in a cradle attached to the designated PC. The PC program uses Microsoft ActiveSync to collect the data files from the PDA. It also appends the filename to a MasterLog file that is saved on both the PDA and the PC. The PC then automatically sends the data to a designated offsite server over a secure connection. To facilitate a large clinical trial (n=800), the MasterLog file is synchronized between each PDA and the PC. This prevents the PDA from collecting the same data set.

A. Data Communications

The application of wireless technologies in medical devices is rapidly gaining popularity [4]. Various radio frequency (RF) protocols, including IEEE 802.11 (WiFi), IEEE 802.15.1 (Bluetooth), and IEEE 802.15.4 (ZigBee), have been applied for health monitoring. The advantages of RF protocols over IrDA are higher speeds, longer distances, and they do not require line-of-sight operation. However, introducing a new medical device with RF capabilities into a hospital environment requires a careful consideration of interference and security issues. Since the main goal of this clinical trial is to verify and validate the IID methodology, the IrDA technology was chosen as the wireless protocol.

The IEM contains an RS-232 serial port that can be used to load firmware to the processor and to send/receive data. Its serial port connector is a non-standard pin configuration for added security. The serial and IrDA ports can be used interchangeably.

The IrDA protocol is written with IAR C to the IrDA Data specifications [3]. Table I depicts the IrDA protocol stack. The IrPHY layer is present on the Microchip MCP2120 component of the IEM. The IrLAP, IrLMP, and IAS layers are implemented in the firmware on the IEM.

The HP hx2495 PDA comes with the IrDA protocol already implemented. The Windows Sockets API was used to access the IrDA communication functions. The four IrDA layers in Table 1 are present in the Windows API. Custom commands are implemented above the IrDA stack. These commands add additional data security. The IEM accepts only a pre-specified sequence of commands. Without a recognizable handshake, the IEM refuses to send out any data.

B. Data Protection

The collected subject parameters do not include any patient-identifying information. Data stored on the IEM are protected from unauthorized access by employing:

- encryption,
- a secure handshake,
- a custom file format,
- a custom cable connector with a special pin configuration.

The proprietary command layer implemented in the IrDA connection allows only authorized PDAs to retrieve data from the IEM. Specialized software is required to read the data from the custom format. Only authorized personnel have access to the stored data sets.

C. Data Processing, Analysis, and Reporting

The data from the first subgroup of 250 subjects will be used to examine the IID performance and to study the occurrence rate of infiltration. Analysis of the collected data is performed in real-time. Since this is a blind trial, the IEM will not alert healthcare providers of any possible infiltration. The time difference between infiltration detection by clinicians and by the IID is an important outcome of this trial. After the trial, the sensitivity and specificity of the IID will be computed and the commercially marketable IID will be developed.

D. Power Management

When utilizing IrDA, the issue of power consumption must be addressed, especially since the IEM uses batteries as the power source. The ATmega128(L) microprocessor offers several different sleep modes for managing power. The modes used in the IEM are power-save, standby, and extended standby. The power-save mode is used between samplings. The IEM wakes up, performs the necessary operations, and then sleeps. The necessary operations are: (1) to increment system clock, (2) to record signal when LED is off, and (3) to record signal when LED is on. Fig. 5 shows the current consumption with and without using the sleep modes.

Utilizing the power-save sleep mode allows the operation to last four times longer than without the sleep-mode. The standby and extended standby modes are used when the IEM is not in use. When the IEM is used frequently (i.e. weekly), it goes into the standby sleep mode between uses. The extended standby mode is employed when the IEM is expected to remain unused for a long period of time and the batteries are not removed. Currently, power-save and standby modes are controlled automatically by the IEM, and the extended standby mode is set manually. Pending on the results of the clinical trial, it is expected that the extended standby mode will be automatically set in the future.

During the laboratory tests of battery life with various sleep modes, the IEM was run continuously using the monitoring program until the batteries were depleted. Four (4) Walgreen's brand AA alkaline batteries were used for testing. Table II lists the time fraction, current (mA), and weighted current (mA) for sampling, backlit, IrDA active, and dormant functions. The weighted current is the product of the time fraction and current. The mean weighted current is calculated to be 3.96 mA, corresponding to a lifetime of more than 21 days with the sleep mode. Without the sleep mood the battery lifetime is only 5½ days.

During the trial, the power usage is monitored by the IEM firmware. When the batteries are near depletion, a warning message showing the estimated remaining battery life appears on the LCD display. When the IEM senses that there is not enough battery power to complete a 72-hour run, it refuses a START command from the PDA and sends a message to the PDA urging the study nurse to replace its batteries. The IEM is capable of monitoring a total of six different patients for 72 hours each with four AA alkaline batteries.

IV. Discussions

The research and development of wireless body area networks (WBANs) with sensors that monitor biomedical signals such as ECG, EMG, EEG, blood pressure, oxygen saturation, and movement are expanding rapidly [4], [5]. Network administrators must pay due diligence to the issue of interference when implementing multiple wireless networks in a close proximity. The optimal configuration of a WBAN is to acquire the signals from the sensors of one patient to a central personal server, which then relays the information to other servers in the network as needed.

ISO and IEEE have approved a standard (ISO/IEEE 11073-30300) for IrDA-based medical devices [6]. However, the 11073 family of standards (x73) has not fully matured. When fully

developed, implementation of x73 will allow plug-and-play capabilities for medical WBANs [7], [8]. The 1073–30300 standard will be implemented on the IEM in the future for increased interoperability and plug-and-play capabilities. Only minor modifications in the programming code, such as the removal of the proprietary layer of commands, are needed for full compliance to this standard.

PDA's are becoming more popular in the healthcare environment due to their mobility and versatility. The incorporation of the IrDA protocol on the IEM allows the nurse to only carry the PDA for system operation. The PDA may also be used for other tasks, such as accessing digital health records [9] or collecting data from other wireless sensors.

V. Conclusions

The IID has been demonstrated, in animal and healthy subject studies, to detect infiltrations with high sensitivity and specificity. It is currently being tested in an 800-patient clinical trial for validation. It is designed to consume minimal power while operating for portability. The application of the IrDA protocol allows a nurse to initiate tasks and collect data from the IEM with a PDA. In the future, the ISO/IEEE x73 standards for medical device interoperability can be applied to the IID system. The IID can be seamlessly integrated into existing sensor networks by using a RF protocol such as Bluetooth or ZigBee.

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Fig. 1.
IV catheter and fiber sensor.

Fig. 2.
IID system components and operation.

Fig. 3.
IEM (left) and PDA (right).

The screenshot shows a software window titled "IEM Controller" with a standard Windows XP-style title bar. The window contains a form with the following fields and values:

Field	Value
Infusate Comp.	[Empty dropdown]
IV Flow Rate	aminophylline amphotericin B
Cath. Material	Material
Gauge Site	3
Insertion Site	Left Arm
Other Infection	None
IV Related Inf.	None

At the bottom of the form are three buttons: "Previous", "Cancel", and "Next". Below the buttons is a "File Tools" section with a keyboard icon and an upward arrow.

Fig. 4.
Interactive Questionnaire.

Fig. 5.
IEM Current.

Table I
IrDA layers used in IID system

IAS (Information Access Service)
IrLMP (Link Management Protocol)
IrLAP (Link Access Protocol)
IrPHY (Physical Layer)

Table II**Power Consumption**

Function	Time Fraction	Current (mA)	Weighted Current (mA)
Sampling	6.67%	36.0	2.40
Backlit	0.21%	50.1	0.105
IrDA Active	0.07%	62.9	0.0440
Dormant	93.06%	1.51	1.41