A Portable Autonomous Multisensory Intervention Device (PAMID) for Early Detection of Anxiety and Agitation in Patients with Cognitive Impairment

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Abstract - The negative behavioral and psychological symptoms (NBPS) seen in patients with cognitive impairment (CI), such as anxiety, agitation and aggression have been reported to be the most problematic for healthcare providers. The consequences of delayed detection of NBPS can be devastating for both patients and caregivers; therefore early detection of symptoms that may lead into NBPS is essential. A proprietary device called portable autonomous multisensory intervention device (PAMID) has been developed to not only wirelessly monitor physiological conditions as a means for early detection of NBPS, but also automatically provide a real-time multisensory intervention to reduce NBPS if thresholds of physiological parameters reflecting the symptoms of anxiety are detected. This paper outlines the design, development, and test results of PAMID and its implementation to aid caregivers in their efforts. The purpose of this paper is to report the research results from an interdisciplinary project in the application of electronics in nursing science. The developed PAMID device is capable of not only detection of NBPS at its early stage, but also providing real-time intervention and encouraging evidence of the on-site intervention.

Keywords - Assistive bio-healthcare technology; multisensory intervention; patients with dementia; Bluetooth

1. INTRODUCTION

The health care system is becoming overburdened with the increase in patient populations that have some form of cognitive impairment (CI) and who require intensive supervision and/or long term care [1]. The negative behavioral and psychological symptoms (NBPS) found in some patients with CI such as anxiety, agitation and aggression have been reported to be the most problematic for their caregivers. Previous research has shown that NBPS that goes undetected can have devastating effects on the quality of life of patients and cause burnout in healthcare personnel. Recent evidence suggests that the care for patients with CI who also have NBPS costs approximately 80 to 100 billion dollars annually [2]. In order to control cost, provide optimal patient care, and prevent the burnout of professional and family caregivers caring for patients with neurological or cognitive impairment, efficient methods of detecting and managing NBPS must be implemented to aid caregivers in their efforts.

It is particularly true when it comes to the caregiving and treatment of special group with unique behaviors, such as patients with dementia (PWD) who have expression difficulties. Based on clinical nursing studies, agitation and anxiety among PWD are normally reflected by abrupt or dramatic variations in specific physiological parameters [3-5]. Among these parameters, heart rate, body temperature, and dermal impedance that is related to sweat level, can be measured accurately using the available microelectronic technology.

Past research efforts in physiological parameter monitoring have been focused on wireless sensing systems enabled by a variety of sensor networks and communication protocols [68]. However, upon detection of abnormal behaviors of special patient groups such as PWD, timely and on-site intervention is critical as well for immediate caregiving even with temporary absence of the caregiver, and follow-up treatment.

The purpose of this paper is to report the research results from an interdisciplinary project in the application of electronics in nursing science. The developed PAMID device is capable of not only detection of NBPS at its early stage, but also providing real-time intervention and encouraging evidence of the on-site intervention [4].

2. SYSTEM OVERVIEW

The Needs Driven Dementia-Compromised Behavior (NDB) model [4] has driven the design functions of PAMID. According to the NDB model, NBPS are expressions of certain physiological or psychological needs that the patients with dementia have but cannot express verbally. Anxiety and agitation are the consequences of these unmet needs. Early detection of anxiety is important so in order to prevent further agitation and aggression from occurring. Previous research indicates multi-sensory intervention produces a calming effect on patients with anxiety [6]. Thus, a technology that functions in monitoring real-time physiological parameters as well as alert the caregiver about the patient’s distress, and deliver active physical stimulus intervention until the caregiver reaches the distressed patient will have benefits for improving patient care and reducing unwanted NBPS. Figure 1 illustrates the framework of such a desired system for monitoring and intervention.

2.1. DESIGN CONSIDERATIONS

The function of the sensor unit in the PAMID is to monitor and detect agitation in the patient without the aid of
continuous staff intervention. Since the majority of criteria designed for the measurement of agitation are largely subjective and derived from caregiver observation of specific behaviors, the sensing unit was designed to find objective physiological parameters for establishing the criteria for measuring agitation in dementia. Culter & Sramek [5] describe agitation as being comprised of both symptoms of physical distress and more complicated observable behaviors. Physiological responses include increased heart rate and body temperature, diaphoresis (resulting in increased skin conductivity), increased respiratory rate, and increased blood pressure [6-9]. Thus, for the purpose of this research, the physiological parameters for measuring agitation in dementia were chosen to be the physiological changes seen in heart rate, body temperature, and electrodermal response (EDR). We used the Bluetooth RS-232 adapter when the communication range is less than 200 feet between any two units. If more patients are to be monitored using the single monitor unit, it is preferable to use the IEEE 802.11 RF-131G communication protocols.

For this research, the ultimate targeted subjects are PWD, in the system design, some other important non-functional considerations were also included. The device needs to be: a) safe for the patient and caregiver; b) transparent and non-intimidating to the patient; c) portable and wearable; d) low cost; e) easy to use by the caregiver; and f) customizable according to the patient’s preference. To satisfy these functional and non-functional requirements, physiological parameters for detecting and measuring agitation should firstly be established and appropriate settings for effective stimuli and intervention should be administered. Once these were chosen, the interface between the prototype and patient, and consequently the system packaging had to be designed.

2.2. SYSTEM ARCHITECTURE

Figure 2 shows the block diagram of the developed PAMID device that features functionality of NBPS associated physiological parameters monitoring and real-time multisensory intervention to the patients. Both functional and non-functional requirements have been considered in the system design. Subsystems of the PAMID are further detailed as follows.

**Sensor Unit**

Most commercially available sensor products, such as SensWear armband by BodyMedia [10] and the popular Polar band, can only measure single physiological parameter. The unique requirements of our research have allowed us to only design our own sensors for overall small size and wearability of the sensors. The customized heart rate sensor is consisted of a fabric electrode, a low-power instrumentation amplifier AD624 and filter circuits. The sensitivity of the heart rate sensor can be tuned both with hardware and embedded software for the sensing unit. A miniature 10 kΩ platinum resistive temperature detector (RTD) is used as the body temperature sensor. The EDR sensor employs an electrode that forms a voltage divider with a fixed resistor, to measure the impedance of the skin, which can represent the patient’s sweating level that is also associated with agitation and anxiety.

The RTD and ESR sensors are knit into an elastic chest belt with appropriate separation for accurate and reliable measurements. The heart rate sensor, with electrodes knit in the elastic belt, is integrated with a Freescale MC9S12
microcontroller and peripheral circuits, and the Bluetooth module on a single board; and well packaged with a 5 V rechargeable lithium ion battery and Bluetooth module in a small plastic housing that is attached to the chest belt. The heart rate monitor measures changes in the patient’s heart rate, the RTD sensor detects a patient’s variations in skin temperature associated with agitation. The RTD sensor is used to interpret the detected signal using the Calendar–Van Dusen equation [11]. The dimensions of the housing are 4”x2”x1”.

**Monitoring Unit**

A personal computer with serial Bluetooth module connection can be used as the monitoring unit as shown in figure 2. Every 15 seconds the sensor unit transmits the physiological parameters. The data is then sent to the monitoring unit wirelessly through the Bluetooth virtual serial port. We have used LabVIEW in the creation of graphical user interface (GUI) for easy access by the operator. The monitor displays the patient’s current physiological parameters that are received from sensing unit. Via the GUI, the operator or a nurse can customize the threshold values of the three physiological parameters for triggering the intervention unit by simply typing in the values that are based on the patient’s most recent records. Once one of the three measured parameters reaches the threshold value, the monitoring unit will trigger the intervention unit wirelessly. Meanwhile, the GUI monitor features an alarm system with blinking lights and beeping sound to alert the care giver. If not needed, the alarming function can be deactivated. The monitoring unit can also store the long-term data as part of the patient records that can be referred by the doctors. If interfaced with the protocol, the monitoring unit can also be connected with professional and first-aid networks.

**Multi-Sensory Stimulation and Intervention Unit**

The goal of the multisensory intervention unit is to reduce anxiety in patients by producing a calming environment as well as providing a distraction for the patients. The stimulation unit is packaged in a plush white whale doll. A study conducted by Nakajima et al. has shown that animal shaped toys could be used as a therapeutic tool for dementia patients [12]. A plush whale was chosen for this prototype in the hope that its ambiguous shape and light color would be less likely to produce hallucinations than other shapes. The Intervention unit in Figure 2 illustrates the placement of stimuli in the small whale device. According to the other literatures, music, aromatherapy, essential oils like lavender oil and lemon balm that has been integrated into the individual’s life have effectiveness in reducing agitation in dementia patients [13].

The intervention unit integrates multiple actuators that can emit multisensory stimuli. The actuators and the driving circuits are embedded in the plush whale doll. The aromatherapy is applied by an Aura Cacia fan diffuser. The light therapy enabled by colorful optical fibers has also been integrated into the unit as a soothing visual for the patient. It has been shown that light therapy has an extensive range, encompassing bright light therapy, dawn-dusk simulations, and ambient light alteration [14]. It has been shown that colorful LED lighting is a prominent component of Snoezelen multi-sensory room systems designed to calm patients [15].

Once the intervention unit receives the triggering message from the monitoring unit, it powers up the LED’s, MP3 music player, fiber optic, vibration motor and aromatherapy diffuser to emit multisensory stimuli to the patient. This offers an effective means for temporary patient intervention prior to more effective caring. The entire unit is powered by a 7.4 V rechargeable battery and controlled by a Freescale MC9S12 family of microcontrollers.

3. PILOT TEST AND RESULTS

The PAMID device was pilot tested on 6 healthy, volunteer community dwelling elders to examine the system reliability in measurements of the three physiological parameters, i.e., heart rate, body temperature, and electrodermal response; as well to determine if the device was appealing to the subjects. A computer simulation of the STROOP Color-Word Interference Test was used to induce physiological changes that reflect anxiety [16].

3.1. TEST PROCEDURE

Figure 3 shows a test subject and the sensor belt in test. Prior to the test, an informed consent was obtained according to human subject guidelines. Once the sensing unit was connected, nurses collected the physiological parameters to be measured using conventional instruments as a reference data. Then each subject was instructed on how to take the test. While subjects were taking the STROOP test, four sets of data were recorded by the computer with two minute intervals. The STROOP test was administered for 8 minutes. At the same time, research assistants observed and recorded the subjects’ physical reaction and the exact time that the PAMID sensory unit was activated. The exact time of PAMID’s activation was also recorded on the computer display. Once subjects completed the STROOP test, they were asked to complete the satisfaction questionnaire that asked them to rate how comfortable the sensing unit was to wear and how satisfied they were with the multisensory intervention unit.

![Figure 3. Sensor belt on a volunteer subject.](image-url)
3.2. TEST RESULTS

Figure 4 shows a data set collected by the monitoring unit from a four-minute non-congruent STROOP test on one senior male subject in the pilot study. The results indicate that PAMID has effectively detected the changes of the three target physiological parameters.

![Heart Rate Graph](image)

![Normalized EDR Value Graph](image)

![Body Temperature Graph](image)

Figure 4. A data set collected in the pilot test.

In the test on the particular volunteer, with reference to the heart rate manually measured by a nurse student using conventional method, the triggering threshold for heart rate was set to 102 counts/minute. Although there are system errors due to the programmed averaging values in 15 seconds, the registered data show the initial increase and eventual fluctuation of the heart rate. The EDR sensor measured a rising of the sweating level. This is in concurrence with the on-site nursing record, reflecting the frustration of the patient in the test. During the STROOP test, the volunteer eventually got stressed when he could not follow the color patterns. At time of approximately 90 seconds, the patient’s heart rate increased to 102 counts/minute and the intervention unit was immediately triggered. After time of approximately 160 seconds, the heart rate somewhat decreased and the intervention unit was deactivated accordingly.

Although more data is needed to show the effectiveness of the intervention to the patient, tests on this and other volunteers have demonstrated the sensitivity of the sensing and intervention unit and the validity of the system, respectively. Table 1 summarizes the performance of the PAMID device, which can be considered as the baseline to determine the triggering value for further subject.

Table 1. Summarized performance of the PAMID

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average change in heart rate</td>
<td>7 beats/minute</td>
</tr>
<tr>
<td>Percent change in heart rate</td>
<td>10%</td>
</tr>
<tr>
<td>Average change in skin temperature</td>
<td>1°C</td>
</tr>
<tr>
<td>Percent change in skin temperature</td>
<td>1.5%</td>
</tr>
<tr>
<td>Average change in electro-dermal response</td>
<td>1 μS/minute</td>
</tr>
<tr>
<td>Percent change in electro-dermal response</td>
<td>36%</td>
</tr>
<tr>
<td>Average score of the device appearance</td>
<td>2.7 out of 3.0</td>
</tr>
<tr>
<td>Average score of the device comfortability</td>
<td>2.8 out of 3.0</td>
</tr>
</tbody>
</table>

Note: the last two values were obtained as statistic results from all the volunteers.

4. CONCLUSION AND FUTURE STUDY

The results from this pilot study suggest that the developed PAMID is functional and capable of accurately measuring of physiological parameters that are associated with increased anxiety and stress. This study has also verified the sensitivity of PAMID in detection the changing rate of the physiological parameters, which is critical for effective triggering of the intervention unit. These results provide preliminary data set for future clinical trials on PWD and other population groups. Future work includes further verification and validation of the device as an assistive technology for health care providers and families in the care for patients who exhibit NBDS. With institutional review board (IRB) regulation obtained, the next phase of the research will be focused on clinical tests of the PAMID, in which invaluable information regarding the efficiency and correctness of the intervention scheme will be attained. It is our belief that with customizable measurement and intervention patterns for particular patients, the PAMID system can offer an effective Telehealthcare means.

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REFERENCES