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

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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 in patients with CI if thresholds of physiological parameters reflecting the symptoms are detected. This paper outlines the enhancement of PAMID and test results from a pilot study. This device to be developed will have significant applications in the emerging Tele-healthcare systems.**

I. Introduction

The health care system is becoming overburdened with the increase in patient populations who have some form of cognitive impairment (CI) and who require intense supervision and/or long term care. 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 [1]. 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 [6-8]. 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 of 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 provisional intervention via multisensory stimuli to PWD. The device has been tested on 100 healthy young adults and 6 senior volunteers. Preliminary results have shown the effectiveness of the physiological parameter detection and encouraging evidence of the on-site intervention [4].

II. 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. 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.

A. 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

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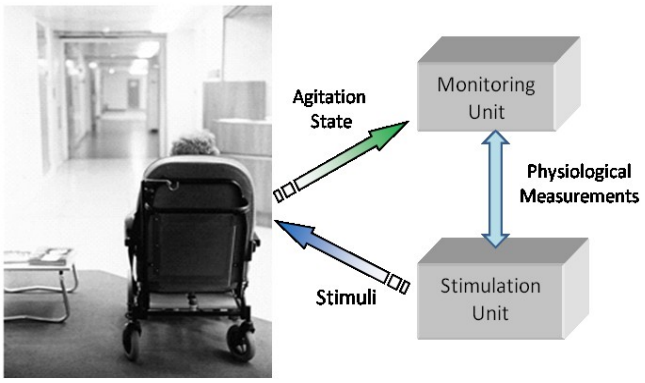

Fig. 1. Illustrative framework of the implemented system.

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 [6-8]. 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 electric skin response (ESR). We used the Bluetooth RS-232 adapter when the communication range is less than 200 feet between any two units. If there are more patients monitored using single monitor unit it is preferable to use RF-131G IEEE 802.11communication protocols.

As the ultimate targeted subjects are PWD in our research, in the system design, some other important non-functional considerations should also be included. They are mainly: 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.

B. 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.

1) Sensor Unit

Most commercially available sensor products, such as SensWear armband by BodyMedia [9] 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 (or other equivalent ICs) 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. Applying constant voltage to the skin through an electrode and by detecting the current that flows through the skin, conductance can be determined, which is nothing but ESR.

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 5V 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 [10]. The dimensions of the housing are 4"x2"x1".

2) 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.

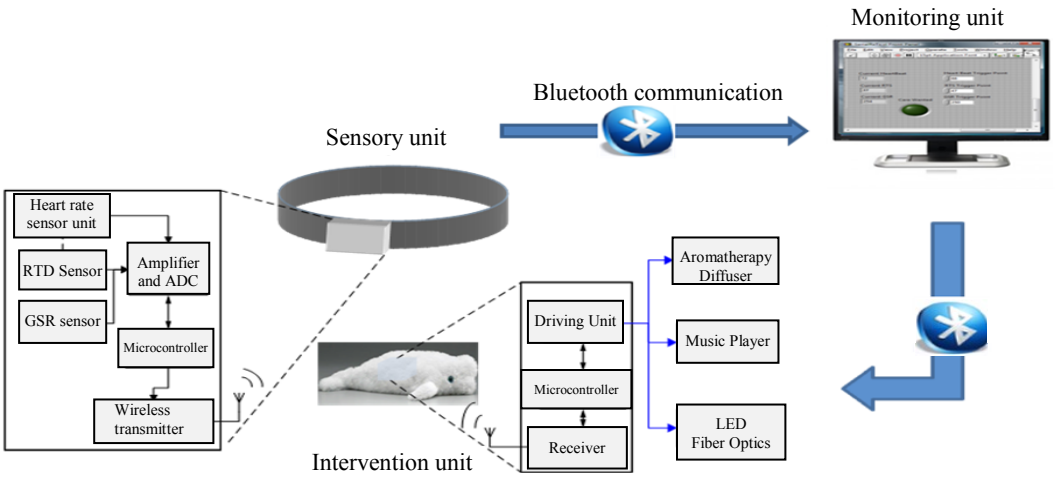

Fig. 2. Block diagram of the implemented system.

3) Multi-Sensory Stimulation and Intervention Unit

The goal of the physical stimulus 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 [11]. 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 [12].

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 [13]. It has been shown that colorful LED lighting is a prominent component of Snoezelen multi-sensory room systems designed to calm patients [14].

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.

III. PILOT TEST AND RESULTS

The PAMID device was pilot tested on 6 healthy, volunteer community dwelling elders to exam the system reliability in measurements of the three physiological parameters, i.e., heart rate, body temperature, and electro-dermal 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 [15].

A. 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 from the computer display at two minute intervals. The STROOP test was administered for 8 minutes. At the same time, research

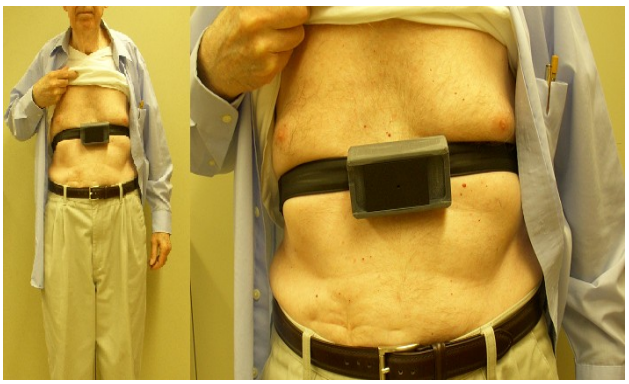

Fig. 3. Sensor belt on a volunteer subject.

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 STAI-6 and rate how comfortable the sensing unit was to wear and how satisfied they were with the intervention unit.

B. TEST RESULTS

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

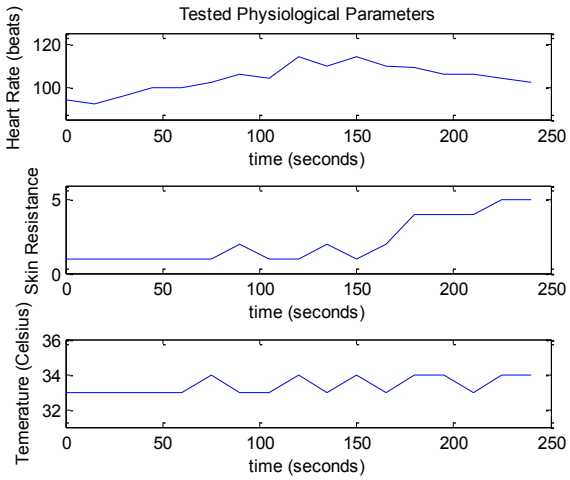

Fig. 4. A data set collected in the pilot test.

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 count/minute. Although there is system error due to the programmed averaging values in 15 seconds, the registered data show the initial increase and eventual fluctuation of the heart rate. 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 count/minute and the intervention unit was immediately triggered. After time of approximately160 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 validness of the system, respectively. Table 1 summarizes the performance of the PAMID device.

TABLE 1. SUMMARIZED PERFORMANCE OF THE PAMID

Parameters	Values
Average change in heart rate	7 beats/minute
Percent change in heart rate	10 %
Average change in skin temperature	1ºc
Percent change in skin temperature	1.5 %
Average change in electro-dermal response	1microsiemens/minute
Percent change in electro-dermal response	36%
Average score of the device appearance	2.7 out of 3.0
Average score of the device comfortability	2.8 out of 3.0

Note: the last two values were obtained as statistic results from all the volunteers. The values from table 1 are considered as the base to determine the triggering value for further subject.

IV. RESEARCH IMPLICATION 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.

V. ACKNOWLEDGMENT

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