

**NEA
Final Report**

Title: Assessment of Autonomous Multi-sensory Intervention Device to Detect and Manage Nighttime Pruritus among Children with Atopic Dermatitis
August 12, 2014

1. Purpose of Study

The purpose of this pilot study is to test the effectiveness of a biomedical device called the Portable Autonomous Multi-Sensory Intervention Device (PAMID) to automatically detect the onset of anxiety and scratching in a child with Atopic Dermatitis (AD). This device was also intended to deliver multi-sensory stimuli intended to distract and mitigate the agitation that results in nighttime pruritus, and alert the family caregiver of the child's distress.

2. Project Details

In April 2013, this project was granted a 1 year no-cost extension by the NEA in order that a redesign of the device could be completed as well as obtain IRB approval in order to proceed to the recruitment and testing phases of the project. The redesign consisted of a modification of the heart rate sensor and instillation of a sensor that detected scratching movement that was situated in a hand glove (see below technical description and expenditures).

As per the human subject guidelines, a new IRB application was submitted to the Oakland University IRB August, 2013 that outlined the modifications that were made to the heart rate sensor as well as the motion sensor in the hand glove. September 5, 2013, the Oakland University IRB informed the investigators that they did not approve our application as it was felt that the investigators did not address all the possible risks to subjects in the study due to the use of the hand glove. The investigators made the required modifications suggested by the IRB to consent forms and other documents and resubmitted the revised application September 17 2013. Unfortunately, this application was also rejected by the IRB October 2, 2013, requiring minor modifications to the application form, parental consent form and parent observation form. These were made by the investigators October 5, 2013 and resubmitted again for approval. In December 2013 investigators received yet another rejection of the application by the IRB. Many modifications that the IRB were asking for were ones that were corrected in the the September resubmission, and at this time a meeting with the chair of the IRB was requested by the PI to discuss the failure of obtaining IRB approval. It was revealed that because the device was intended for use in pediatric subjects, FDA approval would also be needed. This was estimated to take an additional 6 months, which meant that investigators were unable to recruit subjects for testing and data collection until final approval by both IRB and FDA was granted.

The research team met to discuss the feasibility of finishing this project in February 2013 with the knowledge that the extension was only given to April 2013. Due to the prolonged delay in obtaining IRB approval as well as final FDA approval, the team decided that this project could not be completed in the time extended to them by the NEA.

3. Technical Description of Redesign

Background

Prior to this project, the PIs had been collaborating in development and application of the PAMID device for senior patient monitoring and interference. The device had been tested in a pilot study on dementia patients in a nursing house in Michigan. In this project, PAMID device were modified for monitoring activities and providing possible intervention to children with eczema, particularly in nighttime when itch was more severe and skin damages by involuntary scratching could occur. However, after consulting with pediatric dermatologists, it became apparent that the original PAMID, which was

designed to sense heart rate, skin impedance and body temperature, might not be directly used for children's night time monitoring. The original physiological parameters to be detected certainly can reflect the anxiety of the eczema children prior to possible scratching activities. However, the time between the presences, detection of physiological changes and children's damaging scratching actions could be too short for parent's caregiving and scratching stopping. It's necessary to further reduce the time between the detection of children's anxiety, movement and parent's awareness and corresponding preventing actions.

Device Design

To shorten the awareness and actions lagging behind children's anxiety and scratching, and effectively prevent possible skin damages, the PAMID was greatly modified to accommodate instant scratching detection as an additional function. Other considerations include the method of attachment of the device to a glove worn by the child subject; the reduction of system size due to the wearability of the device. Considering the distance between rooms in a regular house, Bluetooth communication protocol was used in the system. A laptop equipped with Bluetooth receiver and interface software was employed as data hub to manage the data, inform parent for caregiving, and command the intervention unit to soothe the patient.

The system diagram of the demonstrated PAMID is shown in Fig. 1.

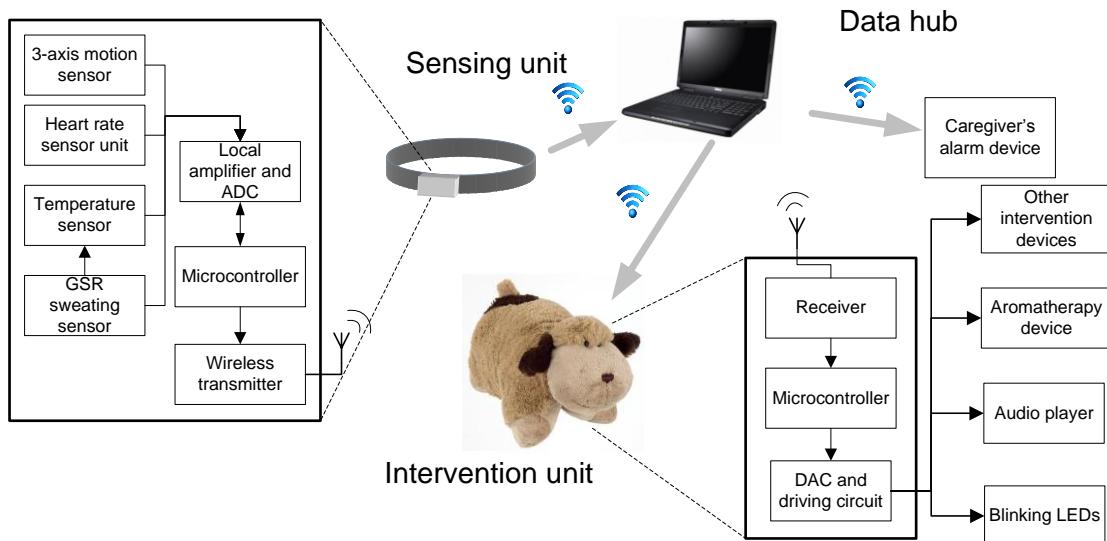


Figure 1. Illustrative system block diagram of the demonstrated PAMID.

In the sensing unit, in addition to the heart rate, skin impedance and temperature sensors, an Analog Device three-axis accelerometer ADXL345BC was added for instant scratching motion detection. In addition to its low working voltage, the accelerometer has a bandwidth of 0.1 - 2.1 kHz, which is suitable for human motion. A micro controller with memory for signal logging, storage and processing was the core of on-board data management. In application, the system was attached to the hand back of a glove worn by the kid with eczema. To avoid any faulty motion detection, the motion sensor was mounted to either index, middle or ring glove fingers at the middle phalanx location. The selection of the glove was under recommendation by pediatric dermatologists. Data of each axis motion collected in 8-hour duration in the night was analyzed and correlations among the three axes were extracted as characteristic motion of scratching. Real scratching motion signal is extracted through a reliable algorithm with signals of 3-axis motion of the patient's fingers as inputs. With the scratching signal detected, the

sensor unit communicates with the command unit and triggers the alarm to parents. Meanwhile, the command unit remotely turns on the intervention unit in which parent's voices or other soothing voices are recorded. The recorded audio will be played to distract, comfort the child with eczema prior to the arrival and caregiving of the parent. Electronics in the intervention unit was packed in a plush doll toy that was selected for the curiosity of the child. Arduino, an open-source electronics platform based on easy-to-use hardware and software, was used for microcontroller programming in data management.

PAMID Implementation

The modified PAMID was prototyped and preliminary tests were carried out on the developers, as planned in the proposal. No clinical tests were conducted due to the IRB issues we had experienced in the project period. The major functions of the system had been demonstrated on an experimental board before printed circuit board (PCB) design was designed and fabricated by commercial manufacturer.

Figure 2 shows the tested PAMID device and fabricated PCB board that processes and transmits the measured motion signals. In the test, the motion sensor is attached to the back of the index finger of a cotton glove; and the PCB board, measured 2" x 4", is wrapped and hidden on palm back of the glove. The PCB was designed at the co-P.I.'s research laboratory and was fabricated through a commercial PCB manufacturing service.

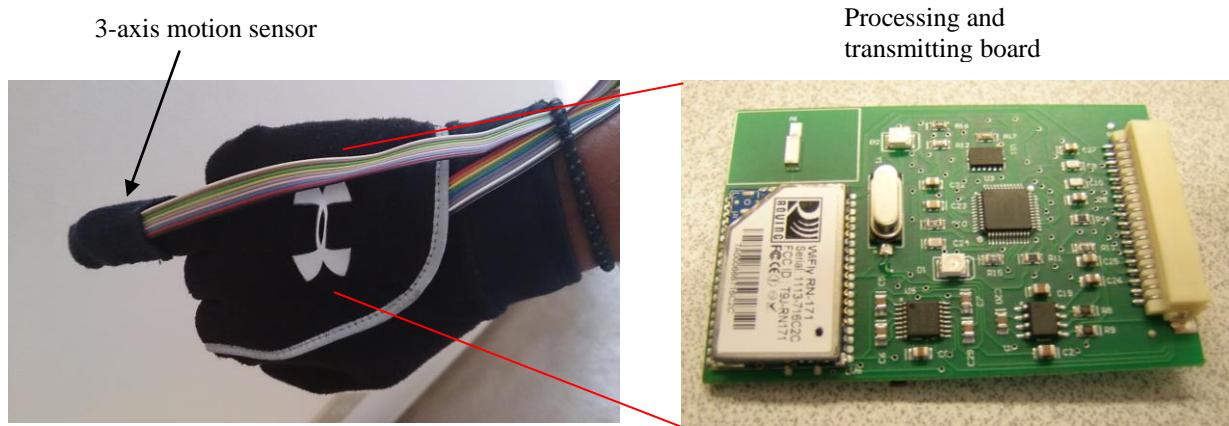


Figure 2. A testing PAMID device attached to a small adult glove.

Data Collected

The functions for heart rate, skin impedance and temperature measurements were verified by quick system checkup. Functions of data communication and alarm emitting of the command unit was tested using heart rate threshold as input signal. Figure 3 shows typical adult responses including heart rate, skin impedance (μS) and body temperature changes during an agitation period. A Labview graphic user interface (GUI) managing and on-screen visualizing system alarm to parents is also shown.

System initialization and scratching motion detection has been demonstrated. Fig. 4 shows a measured time domain data set of response in 3 axes when only 1g of acceleration in z-axis was applied to the motion sensor in a period of 30 minutes. This was performed for system initialization purpose. Data in the first three minutes were dropped because of the noise in system initialization. The amplitude in z-axis was much stronger than in the other directions. Responses in other two directions were also tested. The measurements demonstrated good rejections of signals from other two orthogonal directions when

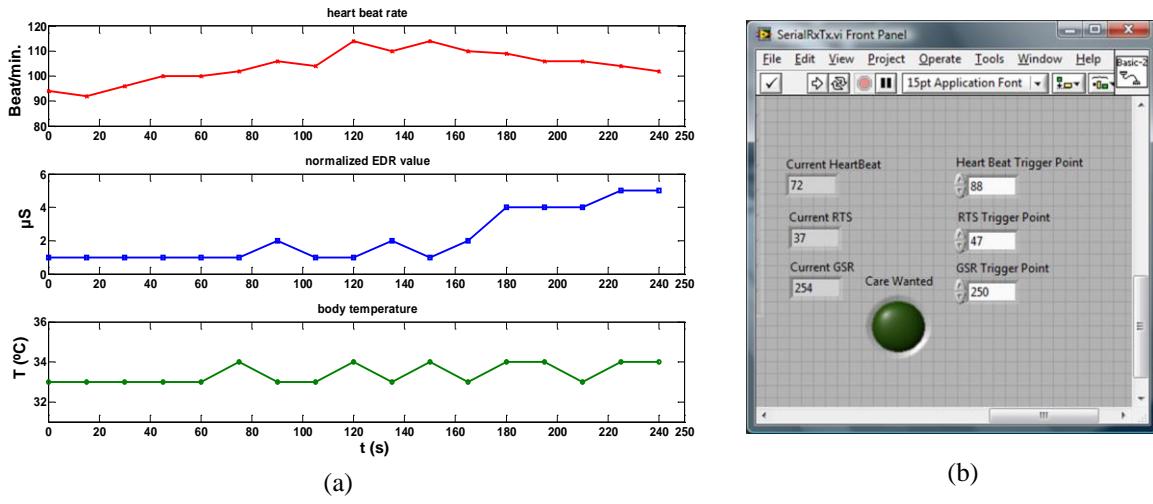


Figure 3. Heart rate, skin impedance and body temperature response and Labview GUI for data management and alarm.

motion in one direction was measured. Fig. 5 shows a frequency domain response in y-direction. A 3 Hz scratching signal is clearly detection in y-direction, while response in x-axis is flat, indicating the effectiveness of the detection. The detection pattern was also valid in other two directions. Once the scratching pattern was recognized by the algorithm pre-programmed in the microcontroller in the sensor unit, the unit will trigger the alarm signal to the parents and energize the intervention unit which is placed close to the subject.

At the time the project was terminated, algorithm on scratching pattern recognition was under development.

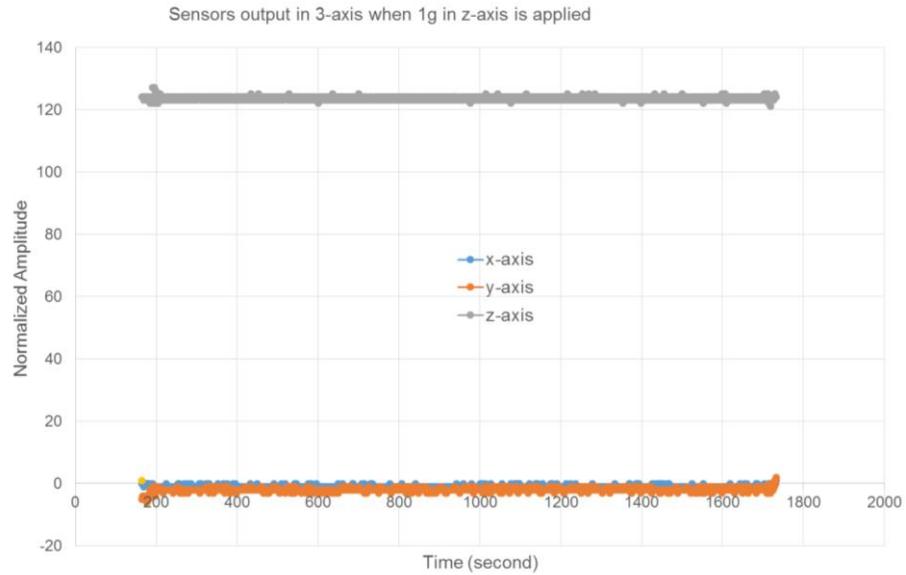


Figure 4. Initial characterization of the accelerometer with 1g of acceleration being applied to z-axis. Sensor responses in other two axes were minimal.

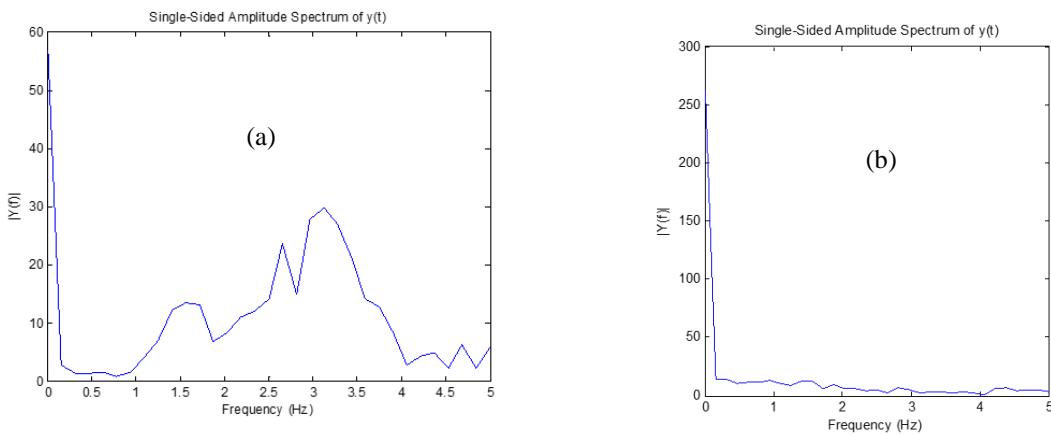


Figure 5. A 3 Hz scratching motion was detected in y-axis, while no x-axis motion was present in the measurement.

4. List of Project Expenditures

Parts, electrical components and shipping: $\$3372.25 + \$105.58 + \$25.93 + \$49.00 + \$234.67 + \$3381.01 = \$7168.44$

The list includes parts for two round to circuit finalization, which is very typical in electronics prototyping. Manufacturing of PCB boards and component assembling for the finalized design is another chunk of expenditure.

Student support: $\$2130 + \$5120 = \$7250$

The project supported tuition and stipend for a graduate student in Fall 2011 semester, which totaled \$5120. An undergraduate student was hired in Summer 2012 semester for circuit assembling and test, which totaled \$2130 of hourly pay.

Conclusion

Although we were unable to implement clinical testing of this device on children with eczema, the research in the development of the device and information discovered about research testing procedures with a pediatric population was valuable information gained through this research. The team plans to disseminate some of the preliminary findings from this research through professional publication and presentation noting the sponsorship of the NEA. As per our contract, NEA will be reimbursed for any unused funds. Thank you for the support you have given us for this project.

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