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24 Hour Ambulatory Research System Supporting Multiple Physiologic Sensors

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***Abstract*—The design and development of a 24-hour ambulatory physiological data collection system is reported. The system was designed specifically to support the needs of investigators studying mind-body interventions but could be used for a variety of research needs. The system is novel in that it supports a wide variety of physiologic sensors with a relatively high sample rate, full data storage, and standalone run-time of greater than 24 hours. Experience with data acquisition and methods for post-acquisition data analysis are also discussed.**

I. INTRODUCTION

In the field of complementary and alternative medicine there is a need to better characterize the physiological changes underlying health-related improvements after mind-body interventions [1,2]. Because stress and stress reduction may be an important factor in mind-body interventions, signals related to the stress response and the autonomic nervous system (ANS), among others, are of particular interest. Although there are studies examining these in the laboratory setting, little is known about the character of these physiologic signals from human subjects in their normal home environments over more extended periods of time. The degree to which changes observed in the laboratory, for example during meditation, persist outside the lab setting is not known. To make such studies possible, there is a need for lightweight, portable instruments of research caliber capable of simultaneously recording multiple physiologic signals for 24 hours or more. Whereas systems exist for long term ambulatory monitoring of certain signals covering one domain, such as Holter electrocardiogram (EKG) recordings, there may be added benefit from recording from multiple domains at the same time in one device, such as electroencephalogram (EEG), electromyogram (EMG), electro-oculogram (EOG), blood pressure (BP), temperature (TEMP), respiration (RESP) and electrodermal (EDA) activity. There are commercial instruments capable of monitoring various physiologic signals over a 24 hour period. Some are general in nature, supporting arrays of amplifier inputs typically used in EEG or EMG clinical applications. Others such as the NeXus-10 system [3], or the g.MOBIlab PocketPC-based device [4] support these plus additional sensors including respiration, temperature, and various auxiliary inputs. Although some are fairly broad in the support of various sensors, they are all proprietary products in nature and not designed for the frequently unique needs of research investigations in terms of raw data access, custom sensors, instrument interfaces, or multiple sampling rates. Some will not acquire data unattended for 24 hours without invention such as changing battery packs. Others have limited data file length restrictions with proprietary data formats. In general, for the advanced researcher, there is never the perfect piece of commercially available instrumentation to meet one's exact and changing needs over the course of an experiment. This often leads to the design and development of custom instrumentation to be able to support one's work.

This paper discusses the design and development of custom instrumentation capable of supporting a wide variety of sensors selected specifically to meet the ambulatory data acquisition needs of mind-body investigators. Of course the same customizable features that make the instrument attractive to mind-body researchers could be of interest in other areas of physiological research. Post-acquisition software analysis applications and techniques are also discussed.

II. OBJECTIVE

A. Instrumentation

The entire data acquisition system including sensors must be wearable by the human subject for the entire 24 hour data collection period. No system intervention should be required of the subject under normal operation. Some means of subject input must be provided to provide marker support synchronized to data collection.

Since the stress response and the autonomic nervous system are thought to underlie part of the effect of mind-body interventions, the sensors and signals recorded chosen are those thought to best reflect and quantify physiologic stress and ANS change. A minimum of six high gain

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biological amplifiers are needed for acquiring EEG, EMG, EOG, EKG at sample rates at least 205Hz and higher if possible. Simultaneous sampling is preferred for EEG channels. Greater than 12 bit sample resolution is necessary. Skin temperature along with some type of electrodermal activity measurement is required. Blood pressure monitoring of standard oscillatory function must be provided with sample intervals of 15 minutes during wakefulness; manually switchable to one hour intervals during sleep. Respiration is another desirable signal to be acquired which is often helpful during post acquisition signal analysis work.

Some type of monitor software application must be provided to ensure proper function of system and sensor placements before start of ambulatory acquisition session.

B. Analysis Tools

Software applications must be available to view and analyze the collected data after the ambulatory recording session. At the minimum, the tools need to support potentially very large data files and should support automatic and manual segmentation of the overall data file into manageable portions for further analysis. Editing software needs to support manual placement of calibrated visual cursors for all sensor values. Frequency analysis tools supporting customized statistical feature generation should be available with results exportable into database storage for subsequent high-level analysis. Binary data should be transferable into formats compatible with standard commercial physiological software tools and environments including MATLAB.

III. Data Acquisition Methods

A. Hardware Design

We have designed, built, and are using prototype instrumentation to meet the objectives of mind-body investigation data acquisition needs as depicted in Fig 1.

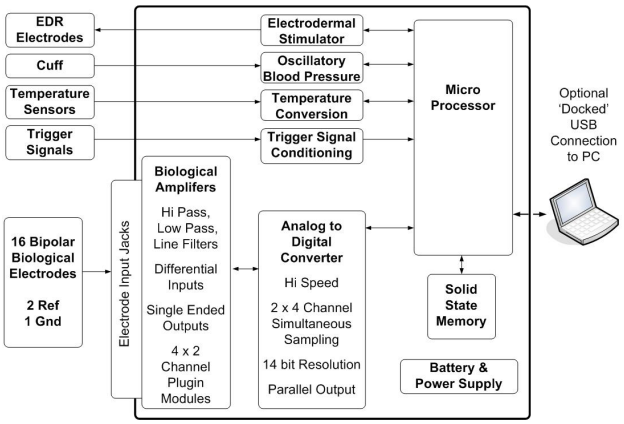

Fig. 1. Overall System Block Diagram. The microprocessor controls the high speed sampling of the biological amplifier inputs and low speed sampling of all other sensors, writing data to memory. Setup, control and data monitoring is available through optional USB connection.

The overall size of our unit is 254mm x 191mm x 83mm (10in x 7.5in x 3.25in) and the weight including batteries is 1.7kg (3.75lbs). Power for the system is provided by three separate custom Li-ion battery packs with voltages and capacities as shown Table I built up from 3.7V, 1400mAhr cells. Multiple linear regulators are used to isolate circuitry interactions. Battery charging is performed pre acquisition for each battery pack separately using external commercially-available precision Li-ion chargers. For safety reasons, the system is not usable for data acquisition while charging is enabled. Batteries are monitored for temperature limits and safety timeouts while charging and each battery cell is over-voltage and over-current protected. Our current ambulatory data collection instrument is pictured in Fig. 2.

TABLE I
BATTERY SUBSYSTEM CONFIGURATION

Volts	Where used	Capacity	Weight
+7.4	+5 digital and +5 analog	2800mah	200g(7oz)
–7.4	–5 analog	1400mah	100g(3.5oz)
+7.4	Blood Pressure Unit with pump	1400mah	100g(3.5oz)

All batteries are Li-ion chemistry with metal prismatic case style.

Fig. 2. Ambulatory data collection unit. Front panel sensor and electrode inputs, flash memory access, USB connector, and blood pressure connector are visible. The "handle" is a strain relief tie-off point for the leads, cables and hose.

B. Firmware Design

The entire data acquisition instrument is controlled by a standard Microchip PIC18LF8720 general purpose 8 bit, 80 pin microcontroller running at a rate of 6 MIPS (6 million instructions per second). The high level device control software was developed using the Microchip ICD2 debugger/programmer [5] and C18 software platform [6].

A custom-designed FAT16-compatible file system was built to efficiently store the collected data on the removable compact flash solid state storage device, which were available at 1.5 Gbyte capacities during the design period.

The main program loop handles the USB interface message transactions, manages sector sized data buffer writes to flash memory, initiates synchronous temperature measurements and electrodermal stimulation, triggers, and

asynchronous blood pressure measurements.

Currently the controller firmware consumes 7317 bytes of the program memory available space of 65536 bytes and 2659 bytes of available data memory space of 3840 bytes.

C. Sensor Configuration

Our system presently configured for sensors as shown in Table II, but of course, the configuration will change according to experimental need.

TABLE II
CURRENT SENSOR CONFIGURATION

Type	Description	Range	Filter, Hz		Samples per Second
			High Pass	Low Pass	
EEG	3 x Channel Bipolar EEG	500uVPP	0.5	75	512
EDR	Bipolar EDR	4uS-500uS	0.09	75	512
EKG	Bipolar EKG	1mVPP	0.5	200	512
EOG	Bipolar EOG	1mVPP	0.5	200	512
RESP	2 x Channel Bipolar Respiration	2VPP	0.09	75	512
BP	Oscillatory Blood Pressure	20-260 mmHg			1/900, 1/3600
TEMP	Surface Skin Temperature	15-42 C			1/60
MARK	2 x Channel Trigger	TTL logic level			Random

For EEG acquisition, electrodes are applied in standard International System "10-20" locations. Currently, we acquire three channels of EEG. The electrooculogram signal (EOG) is recorded Fp1 to right mastoid for subject comfort rather than closer to the eye. Electrocardiograms (EKG) are recorded from electrodes placed on the chest in standard locations.

Blood pressure is assessed with a Suntech Medical Instruments Model Advantage OEM module internal to the unit. The BP measurement is oscillometric with step deflation. Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method. The BP values that we currently use are systolic and diastolic pressure.

Skin conductance is continuously sampled between the surfaces of the non-dominant hand in response to a synchronized 16Hz constant current stimulus. Skin surface temperature is recorded using a probe sensor from ACR Systems, model ET-016-STP. The accuracy of the probe data converter is approximately 0.2degC over the selected linearization range of 15 to 42degC.

Respiration monitoring uses a light elastic strap around the chest wall as is routinely done for sleep studies. Respiration monitoring will allow assessment of heart rate variability (HRV) changes independent of sinus arrhythmia [7]. The second respiration monitor as shown in the current configuration has not been found useful and will be dropped from our configuration in the future.

D. Device Operation

It takes approximately one hour to apply electrodes and other sensors to a subject with the result as shown in Fig 3. A procedure has been established similar to what is used for clinical ambulatory EEG for the scalp electrode attachments.

Currently we are placing all sensors on the non-dominant arm and hand. We are monitoring EDA between the palm and surface of the hand. Skin temperature is sensed on the left forearm. The BP cuff is placed on the upper arm with its rather stiff inflation hose routed under the shirt coming out the neck where it joins with the arm wires and chest-clipped subject input switch, and subsequently joined in with the wires from the scalp electrodes. The bundle of leads then travels under the arm to the fanny pack containing the acquisition instrument where it is strain relieved to the handle on the front of the instrument before cables are separated and connected to appropriate instrument jacks.

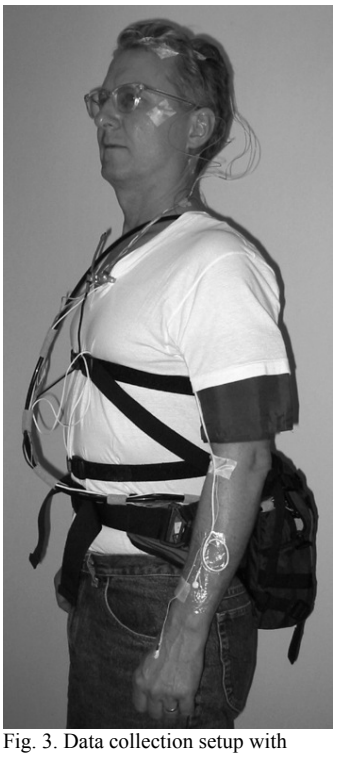

Fig. 3. Data collection setup with EEG, EOG, EKG, twin respiration, skin temperature, electrodermal sensors, and blood pressure cuff.

As a control condition, in the future we plan to assess EEG while seated following electrode application before releasing the subject for monitored activity during the next 24 hours.

IV. POST ACQUISITION DATA ANALYSIS METHODS

The post acquisition data processing work is typically very data intensive with large file sizes, heavy point by point and cross point calculation, and multiple operations. Very fast computers with high speed storage devices are recommended.

A. Data Conversion

The data is stored on device memory in a standard FAT16 file format but must be unpacked to channel by channel format at the high speed sampling rate supporting in the file. A custom software application has been developed to open the data file stored on the flash memory device and process the packetized data into a more standard interleaved channel data format typically used by physiologic software tools. Calibrated scaling factors are applied at this step to yield

accurate results with meaningful units from the raw digital data points.

B. Data Editing and Analysis

A custom visual EEG software application is used to view and segment the entire 24 hour datafile into segments of interest for further analysis. The current tool we use has been described in previous studies [8-12].

Currently our data analysis is focusing on identifying physiologic change related to meditative state. Fast Fourier Transform (FFT) is applied to the EEG channels with the bins then grouped into features of interest. Total and relative power is determined for delta (0-4Hz), theta (4-8Hz), alpha (8-12Hz), beta (12-20 Hz) and gamma (20-40Hz). Median peak frequencies are also calculated.

EKG peak detection of the QRS-complex is automatically performed using a custom implementation of a standard peak detection algorithm [13]. EKG recordings are screened off-line for electrographic artifacts or ectopic discharges by either automatic elimination of excessively long or short intervals or by semi-automated visual inspection tools. RR (RWave to RWave) intervals containing either artifact or ectopic beats are excluded from analysis.

The off-line software also generates a file containing a series of RR intervals from which average heart rate will be calculated. The Lomb periodogram is used to analyze the unevenly sampled data [14]. The results are grouped into LF (0.04-0.15Hz) and HF (0.15-0.40Hz) bands.

Respiration rate is obtained by simple counting and by Fast Fourier Transform (FFT) tools. Phasic changes in skin conductance greater than 10 microsiemens are counted. Mean tonic level over the time period of interest is also measured.

Blood pressure as well as skin temperature measurement values are represented as a level in the multi-channel data analysis display software, and are manually cursored and read-out.

C. Analysis Results Storage

The statistical results from the frequency analysis tools are linkable into an electronic database for further high level multivariable statistical analysis and combination with other experimental data.

V. Conclusion

We have successfully used our instrument to successfully collect 24 hour ambulatory data from more than 10 subjects. Comparisons with clinical grade medical instrumentation show our system is capable of yielding accurate, reliable results. Experience also shows improvements should be made which will be addressed in future work, including additional sensors, new types of sensors and changes in sensor locations to provide more subject mobility and comfort. Reduction in physical size and weight would be more convenient to the subject and improvements in the blood pressure cuff would be more comfortable. More efficient power supplies would simplify charging and could reduce overall instrument weight.

To support this work we extended existing editing tools to support the post-acquisition support for 24 hour data files. We have not yet met our objective of supporting generic binary file formats compatible with other commercial tools. We have learned we need to have more flexibility in the software tools used for editing and analysis and future plans call for adding native binary data support for other applications and environments.

In this work we added support for new data analysis techniques such as the Lomb-based HRV analysis. In the future we plan on investigating the extension of HRV analysis support with new techniques such as the Cosinor HF HRV analysis method [15]. In general, now that we have a customizable platform for physiologic signal acquisition and have the capability to add and change sensor configurations as necessary, we will be focusing further work on improving and supplementing post acquisition editing and analysis tools.

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