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October 16, 2000

Dr. Andrew Rawicz
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Re: ENSC 340 Functional Specifications for the POSSESS

Dear Dr. Rawicz:

The attached document, *Functional Specifications for the POSSESS*, describes in detail the requirements of the product we are developing. We are designing and implementing a system that will awaken a sleeping person based on his or her brain waves and eye movements. Our device will allow a person to awaken feeling refreshed, even if having slept for only a relatively short amount of time.

This document outlines and highlights the overall functionality and purpose of our unit. The requirements of our signal acquisition, conditioning, and processing units are explained. Information on our user interface and device test plan is also included. Finally, we explain to which physical, environmental, and safety standards our final product will comply.

QND Medical Devices is comprised of five talented and dedicated fourth-year engineering students: David Lee, Stephen Liu, Hiten Mistry, Roch Ripley, and Matt Ward. Should you have any comments, questions, or suggestions, please feel free to contact me at (604) 421-6126 or via the e-mail address listed above. Thank you for your time.

Regards,

A handwritten signature in black ink that reads 'Roch Ripley'. The signature is written in a cursive style and is enclosed within a simple, hand-drawn rectangular box.

Roch Ripley
President and CEO
QND Medical Devices

Enclosure: Functional Specifications for the POSSESS



**Functional Specifications for the
POSSESS**
Portable Sleep and Safety Enhancement System

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EXECUTIVE SUMMARY

In 1999, a third of all Americans slept less than 6 ½ hours per night and 45% of all Americans admitted that they slept less in order to be more productive. The statistics for young adults are even more startling: over half reported sleeping less in order to do more, while a third reported significant daytime drowsiness. Treating sleep as a luxury instead of a necessity has resulted in a nationwide “sleep debt” with devastating consequences. To cite only one example, drowsy American drivers in 1999 were responsible for over 100,000 automobile accidents and 1,500 fatalities. [1]

And the above represents only a fraction of what are easily documented statistics. Countless others wake up every day groggy and cranky, but no one sits at bedside to document the everyday complaints of these people. Since people are unwilling to sacrifice productivity for sleep, countless millions are waiting for a product that will let them be both productive and refreshed.

QND Medical Devices is developing that product. The **POSSESS**, or **P**ortable **S**afety and **S**leep **E**nhancement **S**ystem, monitors a sleeping person’s brain waves and eye movements. It then awakens a person only after he or she has completed a Rapid Eye Movement, or REM, stage of sleep. Immediately after an REM cycle of sleep, a person’s body temperature and metabolic rate are higher than at any other time during the night. Thus, upon awakening, a person will experience very little “sleep inertia,” or grogginess. [2]

The POSSESS is a microcontroller-based system that utilizes data collected from electrodes that are attached to a sleeping person’s head. Electrodes will be placed on the top of the head to monitor brain waves and near the eyes to monitor eye movements. Through an easy to use user-interface, the user will be able to specify how many cycles of REM he or she wishes to experience, with the number of cycles being directly proportional to sleep time. Upon the completion of the REM cycles, the unit will generate an alarm tone to wake the user. A user will also be able to specify a time window in which he or she wishes to awaken. The POSSESS will then awaken the user as he or she leaves an REM cycle within that time frame.

As its name indicates, POSSESS is a portable, battery operated system that can be used by virtually anyone, anywhere. If POSSESS is used by an automobile driver, Greek ferry captain, airline pilot, or long-haul trucker, then POSSESS does more than simply decrease fatigue; it acts as a safety device, reducing the risk of accidents. Thus, POSSESS has the potential to be more than a simple luxury item. It could potentially be used to by airline companies to ensure that their pilots are alert after napping during long flights, while also adding to customers’ peace of mind. Truck drivers, hospital interns, or even businessmen could also use it to help them stay alert and rested - the potential market is endless.

This document highlights the different functional components of the POSSESS and outlines their function and operation. Potential future system improvements, system limitations, and system operating conditions are also discussed.

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INTRODUCTION

No effective product exists that addresses the issue of using available time to sleep as efficiently as possible. As our lives become more hectic and the need for productivity rises, companies continue to develop ways to help people feel alert that are administered only while awake. Stimulants such as caffeine and ephedrine are offered, and not all of them are safe or effective. A Starbucks Coffee store is on virtually every corner. The myriad of statistics available concerning fatigue induced accidents supports the hypothesis that the current “solutions” to fatigue aren’t really solutions at all, but merely somewhat futile attempts to solve an increasingly important problem:

How can we pack more productivity into a day without walking around like sleep-deprived zombies?

While such “solutions” to grogginess have their place in society, the **PO**rtable **S**afety and **S**leep **E**nhancement **Sy**stem (**POSSESS**), tackles the above-stated problem from a different angle. The POSSESS, via a series of electrodes, monitors the brain waves and eye movements of a person during sleep. With this information, POSSESS is able to determine when a person is in REM sleep and, more importantly, when that person has just left an REM sleep cycle and should be awakened. By awakening a person after an REM sleep cycle, we minimize the amount of sleep inertia, or grogginess, a person feels upon awakening.

By designing this product, we at QND Medical Devices are hoping to reduce the number of fatalities and injuries seen daily in all types of vehicular accidents, as well as increase the quality of life for countless others. The days of forcing someone’s body to awaken when it’s not ready will be gone; instead, a person will be awakened only when his or her body is ready to be awakened.

This document is designed to outline the specifications for the functionality of the POSSESS as well as clarify QND Medical Devices’ December, 2000 deliverables. The intended audience of this document is Dr. Andrew Rawicz, Steve Whitmore, James Balfour, Jason Rothe, external design consultants, and the engineers of QND Medical Devices.

BACKGROUND

Brainwaves, emitted by all human beings, are easily recognizable through the use of an electroencephalograph, or EEG. Four major classes of brainwaves exist: delta, theta, alpha, and beta. A summary of these classes follows in Table 1.

Table 1: Classes of Brain Waves

Brain Wave Class	Frequency (Hz)	Amplitude (μV)
Delta	< 4	100 – 200
Theta	4 – 8	20
Alpha	8 – 13	20 – 50
Beta	> 13	< 20

Obtained from Carskadon and Rechtschaffen, “Monitoring and Staging Human Sleep”, The Sleep Reference Book, p. 1200.

Until now, the primary use of EEG recordings has been for academic and clinical research. Unfortunately, no consumer device exists that allows people to utilize their brainwaves to help them attain better sleep.

Clinical studies show that people experience different sleep stages during a night of sleep. An EEG can be used to detect the specific brainwave frequencies, and thus sleep stages, experienced during sleep. [3] A summary of sleep stages and their symptoms is provided in Table 2.

Table 2: Sleep Stage Identification

Sleep Stage	Brainwaves	Eye Activity
Stage 1	Mixed, Mostly Theta	None
Stage 2	Alpha “Bursts”	Rare (Slow, Rolling)
Stage 3	20 – 50% Delta	Rare (Slow, Rolling)
Stage 4	> 50% Delta	Rare (Slow, Rolling)
REM	Mixed Waves	Rapid (Random, Intermittent)

Obtained from Webb, W.B., Biological Rhythms, Sleep, and Performance, p. 4.

To identify a sleep stage with an EEG, a person’s brainwaves are sampled in segments of time called “sleep epochs”. A sleep epoch typically lasts 30 seconds. If the brainwaves sampled from three consecutive sleep epochs each contain brainwaves related to the same stage of sleep, that stage of sleep has been positively identified. [4]

As mentioned in Table 2, the REM sleep stage is characterized by mixed brainwaves and strong eye activity. Electro-oculogram (EOG) measurements are used to identify eye movements experienced during sleep. In order to determine when a person is in REM sleep, an EOG must be used in conjunction with an EEG. Brainwave measurements cannot be easily used to identify the REM sleep stage because of the diverse activity present in REM sleep. [3] Additionally, EOG measurements cannot be used alone because of the intermittent nature of eye movements during the REM stage.

Sleep inertia is defined as the grogginess and disorientation that a person feels after sleeping. Prominent sources indicate that sleep inertia for an individual will be minimized if that individual awakens at, or shortly after, the end of the REM sleep stage. [2,5,6] Theoretically, sleep inertia would be minimized at this point and an individual would awaken alert and refreshed.

The principles of sleep inertia and sleep cycles form the underlying science on which the technology of the POSSESS is based.

SYSTEM OVERVIEW

The system shall obtain input in the form of a user's brain waves and eye movements in addition to a user setting for minimum and maximum sleep time. The inputs are used to generate an output and wake the user when necessary. Figure 1 shows the system overview diagram. The diagram indicates that the inputs for the system are the pre-set alarm times, brainwaves, and eye movements from a sleeping person. The output indicates when the best time is for the user to awake. Note that all sensing of brainwaves will be accomplished with the use of electrodes.

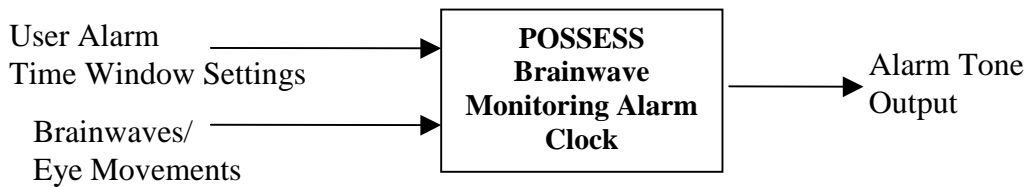


Figure 1: System Overview Diagram

Figure 2 shows a system block diagram of the POSSESS. The following sections will discuss each block in further detail.

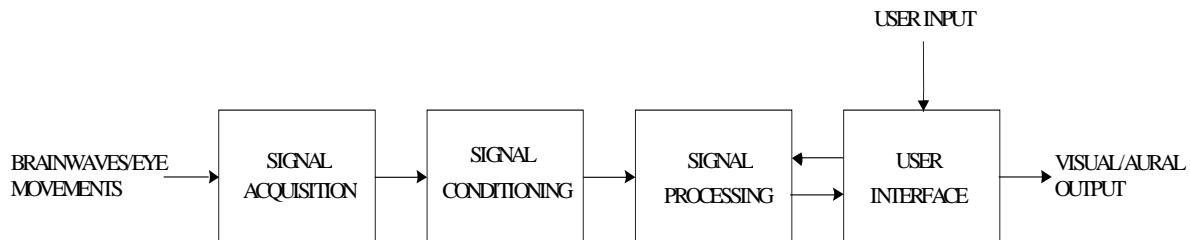


Figure 2: System Block Diagram

The system shall

- ⇒ use brain waves and eye movements as the standard signal input
- ⇒ use surface electrodes as the standard sensors
- ⇒ generate an alarm tone when required to wake the user
- ⇒ have a response time of no more than 90 seconds, defined as the time required for the system to process the signal and generate an output when necessary
- ⇒ feature an LCD text display to report system status and provide user feedback
- ⇒ use batteries as a power supply
- ⇒ have a power switch
- ⇒ accept as input a number of REM cycles for which a user wishes to sleep
- ⇒ accept as input a time window in which a user wishes to awake

Signal Acquisition

The signal acquisition stage, shown in Figure 3, shall be the first stage of the system.

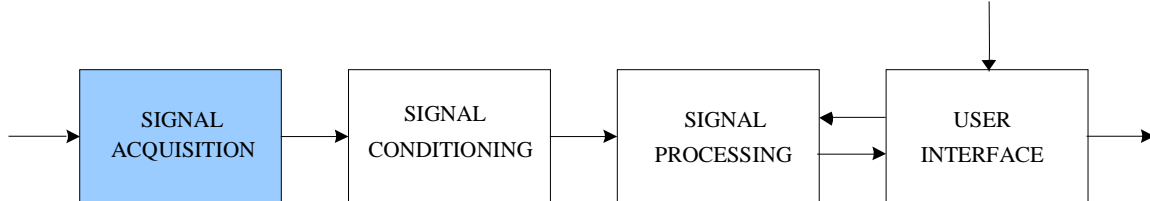


Figure 3: Signal Acquisition Relative to Other System Stages

The first stage of the system shall acquire the brainwave and eye muscle movement signals from the user. In effect, it will be the front end of a scaled-down EEG (electro-encephalogram) and EOG (electro-oculogram) setup. Figure 4 shows the context diagram of this stage.

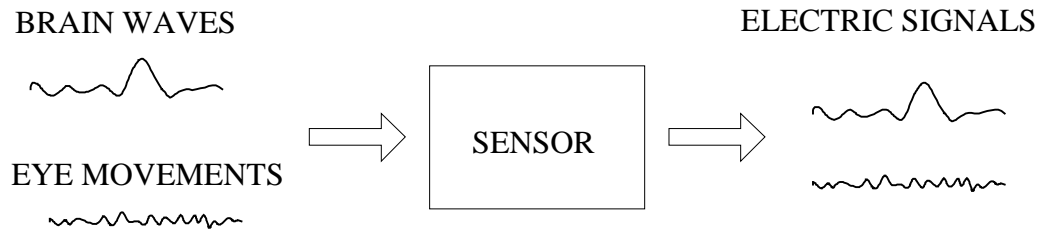


Figure 4: Signal Acquisition Stage

The signal acquisition stage is primarily composed of sensor electrodes attached to different parts of the user's head. Eye movement detection electrodes, for example, will adhere to the skin just above and to the side of an eye.

The electrodes must

- ⇒ detect signals of low frequency (5 – 40 Hz), and low amplitude (5 – 200 μ V)
- ⇒ possess a high SNR (signal-to-noise ratio)
- ⇒ have a low DC offset
- ⇒ attach easily and non-permanently to the user's skin
- ⇒ remain attached to the user for at least 8 hours
- ⇒ be comfortable for the user
- ⇒ have a low cost
- ⇒ convey brainwaves and eye movement signals to the signal conditioning stage

Signal Conditioning

The signal conditioning stage shall take inputs from the signal acquisition stage, and give outputs to the signal processing stage. Figure 5 shows the signal conditioning stage in relation to the other stages of the system.

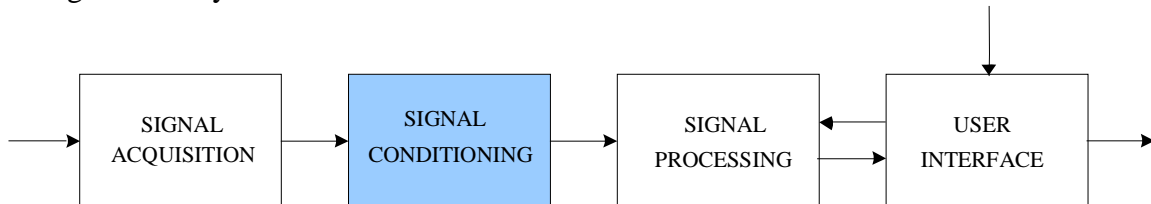


Figure 5: Signal Conditioning Relative to Other System Stages

Figure 6 shows that the signal conditioning stage is made up of two sub-stages, amplification and filtration. The unfiltered signals from the sensor electrodes of the signal acquisition stage shall be first amplified to manageable levels and then filtered to remove both high frequency and low frequency noise.

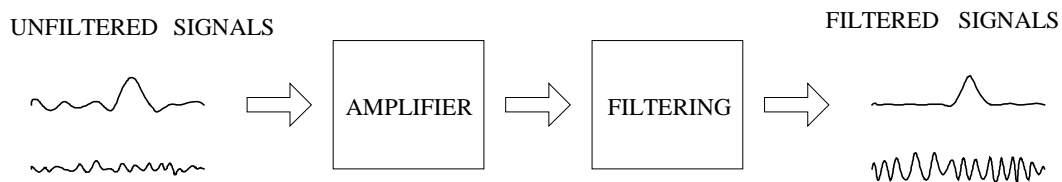


Figure 6: Signal Conditioning Stage

The signal conditioning components must

- ⇒ take inputs from the sensor electrodes of the signal acquisition stage
- ⇒ amplify the desired signal to a level compatible with devices in the signal processing stage
- ⇒ filter out signals of frequency higher than the biological range
- ⇒ greatly reduce 60 Hz power line “hum”
- ⇒ have a high CMRR (common mode rejection ratio)
- ⇒ reduce overall noise
- ⇒ make outputs available to the signal processing block

Signal Processing

The signal processing block shall take inputs from the signal conditioning block, and output to the user interface. Figure 7 shows its position relative to other system components.

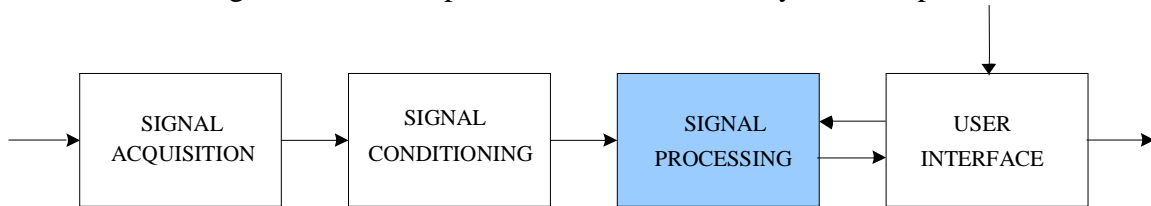


Figure 7: Signal Processing Relative to Other System Stages

Figure 8 shows that the signal processing block is made up of two sub-blocks, the signal analysis block and the processing block. Analysis involves converting from analog to digital, and processing takes the digital information and performs calculations to determine whether it is the right time for a person to wake up. These calculations must take into account the any input that the user makes through the user interface block that is relayed back to the signal processing block.

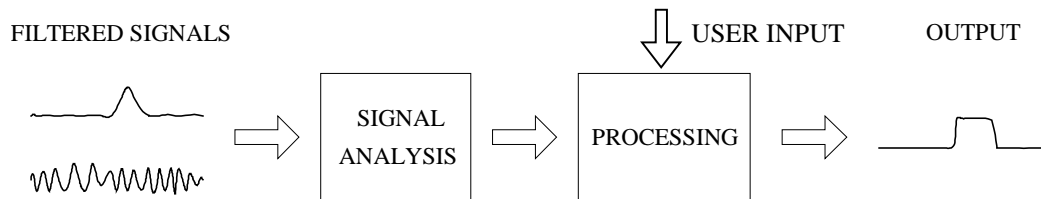


Figure 8: Signal Processing Block

Figure 9 shows a flowchart detailing the operation of the signal processing stage.

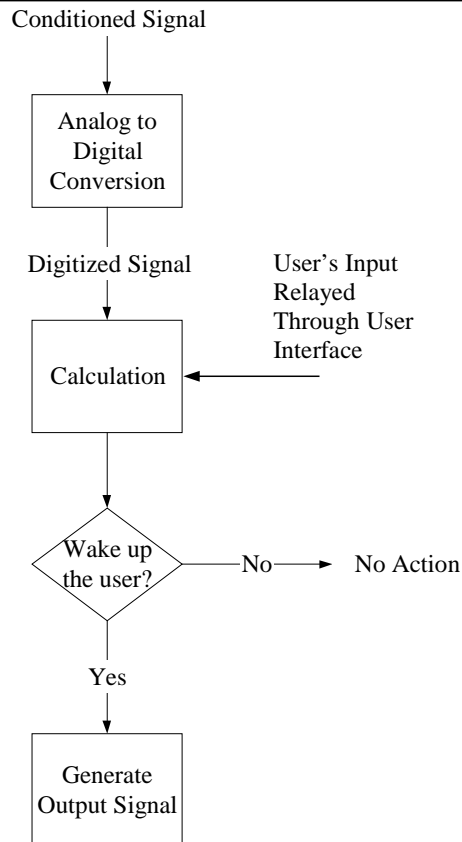


Figure 9: Flowchart of Signal Processing Stage Operation

First, the analog signal output from the signal conditioning block shall be digitized for mathematical manipulation. This digitized signal will be analyzed and compared to user input by a calculation block. If the conditions exist such that the user should be awakened, the system shall generate an output signal to the user interface. The signal processing block will be implemented via a system of integrated circuit devices.

The integrated circuit system must

- ⇒ receive inputs from the signal conditioning block and the user interface
- ⇒ have multiple data ports
- ⇒ be able to perform accurate and precise analog-to-digital conversion
- ⇒ have the ability to perform precision mathematics
- ⇒ have sufficient memory to store digital data until it can be processed
- ⇒ generate outputs to the user interface

User Interface

The user interface block takes inputs from the signal processing block and the user, and outputs information to the user. Figure 10 shows the user interface connected to the other system components.

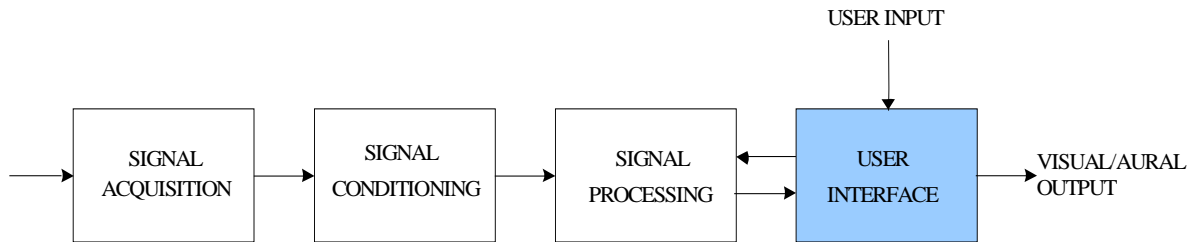


Figure 10: User Interface Relative to Other System Stages

The user interface block must

- ⇒ receive input from the user and the signal processing block
- ⇒ provide a display showing time and system status information
- ⇒ display system faults and electrode status
- ⇒ be able to display the windowed alarm time, number of requested REM cycles, and/or the current time
- ⇒ provide a power switch
- ⇒ feature buttons to silence the alarm and to select mode of operation
- ⇒ be able to control the alarm volume
- ⇒ output user settings back to the signal processing block

The user interface will take the form of a small text display and will feature numerous push buttons or switches for user input.

SYSTEM RELIABILITY

Accuracy

Accuracy of the POSSESS is largely dependent on factors such as user health, electrode contact, skin condition, and user demographic. Because of the large variance in these factors, it may be difficult for the POSSESS to attain an absolute accuracy rate for all users.

For prototyping purposes, a POSSESS unit will be designed to conform to a single, specific user of good health. The desired accuracy of this prototype unit is listed below.

Table 3: POSSESS Prototype Accuracy

Probability of Correctly Detecting Sleep Stage	80%
System Response Time	< 90 seconds

Durability

The POSSESS will follow the durability requirements below.

Table 4: POSSESS Durability

Minimum Usage Period Without Failure	2 years
Shock	75 G's
Drop Test	Withstand a drop from 2 m onto concrete
Water Resistance	Withstand minimal condensation, withstand small amounts of water in temporary contact with main unit

ELECTRICAL REQUIREMENTS

The POSSESS will have the electrical characteristics outlined in Table 5.

Table 5: Electrical Requirements

Battery Power	DC 12V
Max Power Dissipation	10 W

ENVIRONMENTAL REQUIREMENTS

The POSSESS will adhere to the following environmental requirements.

Table 6: Environmental Requirements

Operating Temperature	10 - 45 °C
Storage Temperature	-30 - 70 °C
Heat Dissipation	Minimal
Humidity	Will function over standard humidity ranges
Elevation	Will function over standard elevation ranges

PHYSICAL REQUIREMENTS

Enclosure

The POSSESS enclosure shall be strong and rigid to ensure reliability, and compact and light enough to ensure portability. The unit shall consist of a chassis capable of shielding the unit from external noise, and it will adhere to the physical dimensions as shown in Table 7.

Table 7: Enclosure Specifications

Height	10 cm Maximum
Depth	8 cm Maximum
Width	20 cm Maximum
Weight	2 kg Maximum

Accessories

Accessories for the POSSESS will conform to the physical specifications listed in Table 8. The electrode cap is designed to assist in maintaining good contact between electrodes and user skin. The electrode cable connects the electrodes to the main processing unit.

Table 8: Accessory Specifications

Electrode Cap	Fit 90% of Adult Heads
Electrode Cable Length	250 cm Maximum
Electrode Cable Radius	0.5 cm Maximum
Electrode Pad Diameter	4 cm Maximum

SAFETY REQUIREMENTS

As the POSSESS will be connected to a human user and will be located bedside, the product will have to meet the safety requirements as listed below. These requirements are in accordance with the Canadian Safety Association (CSA), the Consumer Product Safety Commission, the United States Food and Drug Administration (FDA), American National Standards Institute, and Health Canada. Safety standards from multiple countries will be met to maximize the safety of the user and allow for a larger product market.

Enclosure

The enclosure shall have no sharp corners or edges that would pose a danger to the user.

Electrical Isolation

The electrodes and cables must be isolated from the regular household power supply to avoid any harm to the user. All components will be shielded and protected from external static voltage sources.

Electrodes

Disposable pre-sterilized electrodes will be used and therefore no further sterilization will be required. Skin conditioners and conductive gel will be used to prevent any damage to the user's skin.

Cables

The cables will be positioned such that they lead from above the user's head to the base unit to ensure that the cables stay away from the neck. Such a setup will prevent the user from becoming entangled with cabling. The cables will also be shielded to avoid picking up of any electrical noise that could cause current flow to the electrodes. The cable will be encased in a soft plastic covering to prevent any cuts and scrapes that could occur. The cable will also consist of stranded wire that minimizes breaking or fraying.

Consumer Standards

The system will meet the following standards:

- ⇒ the Class I Medical Device Requirements as stated by Health Canada [7]
- ⇒ the standards for patient monitoring equipment as set by the International Electrotechnical Commission Sub-Committee 62D (IEC/SC62D): Electromedical Equipment [8]
- ⇒ the ANSI/IEEE Std 602-1986 Standard for Electric Systems in Health Care Facilities
- ⇒ Part 15 of the Federal Communications Commission (FCC) Rules: It shall not cause harmful interference by its emissions, and it shall accept any interference generated by outside devices
- ⇒ CSA, UL, and CE requirements

SYSTEM EVALUATION

Testing is critical in determining both the accuracy and reliability of the system. Our testing can be broken down into two stages, functional system tests and user evaluations.

The functional system tests are to be performed in the lab and include

- ⇒ basic signal recognition and processing
- ⇒ input signal tolerance measurements
- ⇒ system response time
- ⇒ system accuracy

Data for lab tests will be derived from two sources. Digitized sleeping EEG/EOG data will be one source of data. Digitized sleeping data can be found on the Internet and is available from electro-neurophysiology labs. Should the need arise, we will also be able to digitize our own brainwaves by paying for the services of a technician and EEG machine. Digitized data will be invaluable for debugging the POSSESS as we will not have to obtain a sleeping subject for each testing session.

A second source of data will be a live, sleeping person who will act as a user of our prototype device. While digitized data is extremely useful, a series of tests run with one or more different sleeping persons will be necessary to ensure that the POSSESS can function properly in a real-world situation.

Once the system has been tested with digitized data and a small number of human users, we will expand our tests to include those on random individuals. User evaluations will be performed on this group and they will provide feedback on the

- ⇒ effectiveness of the system
- ⇒ effectiveness of user training for system use and installation
- ⇒ system tolerance on user factors
- ⇒ system accuracy in a user environment

Once POSSESS has passed tests that involve random users, we will classify it as being ready for general use.

USER TRAINING

The user will require only a small amount of training to use the device. Most of the training will be aimed at electrode placement, as electrode placement will be the least intuitive aspect of device usage. Remaining user training will be directed at helping the user learn how to manipulate the user interface.

A short user's manual shall be written to aid in user training. Training will take the form of practice sessions with the device. Feedback from the user interface will help a user determine if the electrodes are in the correct position or not. Additionally, background information regarding sleep inertia and sleep cycles will be provided to the user so that he or she has a conceptual understanding of the scientific principles behind the device.

POSSIBLE SYSTEM LIMITATIONS

The system functionality may be limited by the following factors:

- ⇒ some physically disabled persons may require aid in system setup
- ⇒ correct placement of electrodes is assumed for expected system operation
- ⇒ users with above average movement during sleep may cause electrodes to disconnect or move out of correct position slightly and therefore degrade system performance
- ⇒ brainwaves of elderly users could be harder to detect and might prevent correct system operation
- ⇒ the brainwaves of the following users will likely change during sleep and will therefore be harder to distinguish: [9]
 - users with certain illnesses, neurological and otherwise
 - users taking certain drugs or medications
 - users with high levels of alcohol consumption before sleep
- ⇒ hair on the scalp may affect performance of the electrodes. The user will be advised to brush aside excess hair and prepare the testing area to improve system performance
- ⇒ the device's aim is to provide the highest attainable awakening alertness level for each unique individual. Due to individual differences, results obtained by different users are not comparable

CONCLUSION

In this document, we have discussed the functional parameters of the operational prototype for a brainwave monitoring alarm clock. The POSSESS will be designed and developed based on the functional specifications described in this document.

While our specifications are aggressive, we believe that with hard work and dedication we can reach our goal and implement all the requirements outlined in this document. Our eventual functional prototype will be able to serve as a platform for future development: a more advanced user interface, the ability to run from AC power, as well as increased reliability and more complex sleep analyzing algorithms are all eventually possible.

The implementation of POSSESS has the potential to result in an increased quality of life for millions of people. We look forward to building a device that could have such positive, far-reaching social implications.

POSSESSion: it's a good thing.

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