NAPNEA

December 13, 2011 Dr. Andrew Rawicz School Of Engineering Science Simon Fraser University Burnaby, British Columbia V5A 1S6

Re: ENSC 440 Post-Mortem Report for a *Sleepwear Diagnostic System*

Dear Dr. Rawicz:

Please find the attached Post Mortem Report for a *Sleepwear Diagnostic System* (SDS) by NAPNEA. NAPNEA has developed a sensor-equipped shirt that quantifies physiological phenomena that occur during sleep and that can be used to diagnose sleep apnea. While future work remains, we believe that the SDS can one day provide an innovative and reliable solution to existing sleep apnea diagnosis limitations.

Our Post-Mortem Report provides a description of the current state of the device. It explains how the design has deviated from the original functional requirements and discusses the future work that is required to bring the SDS to its final production. The project's budgetary and time constraints are also presented and compared to the projected constraints that were proposed at the beginning of the semester. As a conclusion to ENSC 440, the engineers of NAPNEA have provided a recollection of their interpersonal and technical experiences throughout the course.

NAPNEA is comprised of five aspiring biomedical engineers: Alex Manousiadis, Allison Chew, Ekin Nalbantoglu, Eleanor Li, and Jason Cheung. If you have any inquiries or comments regarding this project, please feel free to contact NAPNEA by phone at 604.808.9675 or by email at jkc10@sfu.ca.

Sincerely,

Allison Chew Chief Executive Officer NAPNEA

Enclosed: *Post-Mortem Report for a Sleep Apnea Diagnostic Shirt*

Post-Mortem Report for a Sleepwear Diagnostic System

ContactPerson Jason Cheung jkc10@sfu.ca **Submitted**To Dr. Andrew Rawicz (ENSC 440) Mike Sjoerdsma (ENSC 305) School of Engineering Science Simon Fraser University **Issued**Date December 13, 2011

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1. Introduction

Over the past four months, NAPNEA has been developing a sleep apnea diagnostic tool known as the *Sleepwear Diagnostic System* (SDS). The SDS is a wearable device that detects the breathing mechanics of an individual while they sleep. The device operates under the principle that for healthy patients, chest and stomach motion during inhalation and exhalation is in phase. For sufferers of obstructive sleep apnea (OSA), the chest and stomach motion is significantly out of phase. The acquired chest and stomach expansion and compression data, combined with accelerometer data showing the individual's motion, are analyzed by a clinician after a full night's sleep to reveal abnormalities that could help in the diagnosis of sleep apnea.

With the help of Dr. Najib Ayas from the Vancouver General Hospital and the BC Genome Technology Development Platform, NAPNEA developed the concept for the SDS in August. Starting September, NAPNEA worked hard to produce a First and Second Generation Prototype that well-demonstrates the proof-of-concept of the device.

2.1 System Overview 2. Current**State**ofthe**Device**

The SDS consists of several analog physiological sensors, a multiplexer, a microcontroller with on-board analog to digital converters, and an SD-card writer. The First Generation Prototype included a wireless communication module for debugging purposes, and the Second Generation Prototype only implements fixed data storage. A high-level overview of the separate sub-systems is shown below in **Error! Reference source not found.**. The current state of each sub-system will be explained below.

2.2 Inputs

2.2.1 Stretch Sensors

The stretch sensors are made from a resistive fabric (EeonTex™) that, once stretched, provides a varying resistance from 4.5kΩ to 5.5kΩ. These sensors were combined with a voltage divider circuit to measure the resistance change. Their placement was chosen to provide optimal breathing data for typical sleeping positions: on either side, on the back, and on the front.

2.2.2 Accelerometer

The accelerometer is used to inform clinicians of the patient's sleep position. The sensor was calibrated to provide a zero-angle reading when the subject is lying flat on their back. Only two axes were

incorporated into the design to minimize data size and to provide only contextually relevant data. As can be seen in [Figure 2,](#page-9-6) only x- and z-axis information is necessary to capture a subject's rotation.

Figure 2: Bed Coordinate Plane Definition

2.2.3 Real-Time Clock (RTC)

A DS1307 RTC module is used to keep track of time and will allow clinicians to determine the exact time and duration of individual apneic events. The RTC module has been pre-programmed with Pacific Mountain Time (GMT +8:00), and communicates with the Microcontroller Unit (MCU) using interintegrated circuit (I^2C) protocol.

2.3 Signal Control and Processing

2.3.1 Multiplexer

A 16-channel MUX will be used to relay data from the three analog stretch sensors to the MCU. Although this component has more channels than needed, it was chosen because it is inexpensive, compact (40mm x 18mm x 1.5mm), readily available, and conveniently came with a breakout board. It also allows for additional components to be integrated with the SDS, should alterations be made to future-generation prototypes.

2.3.2 Microcontroller Unit

The Arduino Pro Mini has a 10-bit resolution and is able to capture accurate and continuous breathing data from the stretch sensors and accelerometer. However, it does not have enough analog and digital pins to accommodate all the hardware components and sensors. Since eight analog pins are required, an analog MUX (mentioned in the previous section) is used to rapidly and sequentially provide data to the MCU while only requiring one analog pin. Since sixteen digital pins are required, a second Arduino Pro Mini will be used; one Arduino will provide power sources and grounds for the sensors, and the second Arduino will contain all the data processing and embedded software of the SDS.

2.4 Signal Transmission and Output

2.4.1 Wireless Communication

This subsystem was included in the First Generation Prototype to send data wirelessly in order for the data to be graphically displayed in real-time on a computer processing unit (CPU). It was used solely for testing and debugging purposes and has been removed from the system for later prototypes.

2.4.2 SD-card Writer

For the second generation prototype, sensor data and time data was logged onto an SD card. SD cards are typically serial peripheral (SPI) devices. SPI devices communicate in master/slave mode, where the master initiates the data frame and the slave receives the data. For the SDS, the MCU acts as the master and the SD card acts as the slave. Data is stored in comma-separated value (CSV) files, with each line corresponding to 50 milliseconds of data from the four sensors followed by the time and date.

2.5 Software

After a full night's data has been logged the SD card, the data can be transferred and subsequently accessed by the data analysis software. The software application's graphical user interface (GUI) is presented in [Figure 3.](#page-11-1) Its layout and functions are described below:

- 1. Bottom Window
	- This window graphically displays all the data from the loaded file. The data can be zoomed in or out using a mouse scroll wheel. The portion that is highlighted in blue is expanded in the main, central window. This blue portion can be dragged left and right with a mouse.
- 2. Main Window
	- The arrows on this window represent the direction that the patient is facing (in this example, the patient is lying on their back, facing up) and the x axis shows the specific time at which this event occurred. When apneic events are detected, the data is highlighted in red (as seen in the figure). Otherwise, the background of this window is white.
- 3. Respirations Per Minute (RPM) Window
	- The right shows an analysis of the patient's "respirations per minute," which are attained using an algorithm involving Fourier transforms. The respirations per minute are only indicative of the data displayed in the main window, and not for the entire data set.
- 4. "Chest Phase Lag" and "Chest Sensor Controls"
	- Also provided in the GUI are the "chest phase lag" data, which shows the different in phase between the stomach and chest, and "chest sensor controls" that allow the clinician to select the sensors they would like to analyze. The chest sensor control is useful because, for example, when the patient is sleeping on their right side, the right sensor will not be stretching during this time and will be unnecessary in the data analysis.
- 5. "Optimize Analysis" Checkbox
	- Using this option will optimize the range of data to be used by the Fourier transform algorithm. For example, if the main window displays four and a half breaths, the application will instead analyze five breaths since the algorithm responds more accurately to integer values.

Figure 3: Software Application GUI

2.6 Prototype Images

All aforementioned hardware components have been integrated into the compact hardware module displayed i[n Figure 4.](#page-11-2)

Figure 4: Hardware Module with all Integrated Components

The stretch sensors are attached to the inside of the shirt, as represented in [Figure 5.](#page-12-0) The sensors are removable via snap buttons. The hardware module is placed inside the shirt's pocket and connected at the white molex connectors.

Figure 5: Inside of the Second Generation Prototype

As shown in [Figure 6,](#page-12-1) when worn, it is clear that the device looks like a normal shirt. Additionally, the electronic infrastructure does not negatively affect the user's comfort. These are two very important features that NAPNEA was happy to provide.

Figure 6: Appearance of SDS

3. Deviations

3.1 Sleepwear Shirt Functions

NAPNEA's main goal was to develop a comfortable, wearable shirt that could quantify and log mechanical breathing data of the chest and abdomen. Through research and feedback from academic papers and sleep clinicians, it was determined that such a device would be a sufficient take-home diagnostic tool for sleep apnea. As an appendage, NAPNEA also planned to provide the sleepwear shirt with the following additional functions:

- 1. Ability to monitor sleep position
- 2. Ability to monitor snoring

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- 3. Ability to monitor pulse rate
- 4. Ability to timestamp events

NAPNEA was able to integrate sleep position monitoring and event timestamps into the sleepwear shirt via an accelerometer, RTC, and modified embedded software. The developers were not, however, able to incorporate snoring and pulse rate monitoring or tidal volume calibration.

The addition of a microphone to gather snoring sound data was fully investigated. The microphone's amplification, filtering, and envelope detection circuits were developed, optimized, and successfully tested. Due to a strict set of functional requirements, necessitating that the sleepwear shirt be as comfortable and user-friendly for the patient as possible, including the microphone along with all its circuitry was not feasible.

Incorporating a pulse rate sensor proved to be more difficult than anticipated. NAPNEA first attempted to find an off-the-shelf sensor, but unfortunately the available products were either too expensive or too large to integrate into a shirt. Building a custom sensor required very complex circuitry and many components. Similar to the problems that arose with the microphone, even if NAPNEA was able to develop a working pulse rate sensor, the practicability of a pulse-rate sensor in the sleepwear shirt was lacking.

3.2 Sleepwear Shirt Performance

Because the sleepwear shirt is intended to be worn during a full-night's sleep, data must be logged for approximately 6-8 hours without interruption. However, for a reason not yet discovered by the NAPNEA engineers, the SDS can only log data for approximately 5 minutes. This is of great concern to NAPNEA and this problem will be fixed in the near future.

3.3 Software Integration

The software application provided to the clinician has not deviated from its original plans. However, the mobile application has deviated from being a platform specific phone application to a web application that allows the patient to upload their data to the web server. The clinician can then access the same web server and retrieve this data for analysis. On the same website, the general public can find out information about the company NAPNEA and the Sleepwear Diagnostic System.

4. Future**Plans**

While NAPNEA has created two prototypes that serve as excellent proof-of-concept models, modifications will have to be made to the SDS before it can be released onto the market.

4.1 Sleepwear Shirt

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4.1.1 Incorporation of Additional Features

NAPNEA could not include the aforementioned additional features to the sleepwear shirt because of circuit complexity and size. However, the size can be easily scaled down if custom printed circuit boards (PCBs) and surface mount technology are implemented. By scaling down these components, additional sensors can be easily incorporated in the shirt without compromising patient comfort.

NAPNEA must also reprogram the SDS such that data collection can occur continuously for 8 hours. Though the root of the problem has not been determined, it will be solved in the near future.

4.1.2 Enhance Usability

For the First and Second Generation Prototypes, NAPNEA carefully considered device usability as a high priority. The intention was for the SDS to require minimal and intuitive setup. Although the developers feel that sufficient usability was achieved, two simple modifications can be made.

Currently, the hardware module comes in a plastic pouch that can be easily connected to the inside of the shirt. However, this requires the patient to turn the shirt inside-out in order to connect the hardware, then right-side-in in order to wear the shirt. It is possible to make this connection accessible from the outside of the shirt while maintaining aesthetic appeal. With this solution, the patient can easily and quickly attach the hardware and wear the shirt with little fuss.

An external or remote switch to power the sleepwear shirt would also be greatly beneficial. With the current setup, because of the placement of the hardware module's switch, the switch must be activated prior to wearing. Though this step may seem trivial, it is not very intuitive. An external or remote switch would allow the patient to simply connect the hardware, wear the shirt, and turn it on.

4.2 Software

4.2.1 Web application for mobile devices

Currently, the web application is accessible to all mobile devices with an internet connection. However, the usability is restricted to uploading and downloading of patient sleep data files. Future work includes:

- 1. Plot and analyze the data that has been uploaded to the web server
- 2. Wirelessly stream the data from the microcontroller to the server
- 3. Plot in real-time all the data that is captured from the sensors
- 4. Expand server capability to handle larger data files

4.2.2 Clinician Login

To respect patient confidentiality, clinicians will only be able to access their own patient's data using their registered doctor login id and password.

4.2.3 Patient Login

Patients will only be able to access and view their own sleep data using their personal login id and password.

4.3 Pre-Launch Agenda

4.3.1 Accommodation of Body Types

Once all modifications have been made to the SDS, it will be in its final production stages. Because patients come in different genders and sizes, several designs for different shirts will have to be created. These designs will not change the function of the SDS, but will rather have various layouts based on waste and bust size.

4.3.2 Environment and Safety Concerns

Within the past four months, NAPNEA was not able to carefully consider environmental and safety issues. While NAPNEA believes that the SDS does not pose a serious threat to patients' safety, it may require minor alterations in order to meet certain safety standards. NAPNEA must also determine the specific environmental operating conditions of the SDS.

4.3.3 Clinical Trials

As with all medical equipment, clinical trials must be conducted. The procedure that pertains to the SDS is known as a diagnostic trial, in which patients who have signs or symptoms of sleep apnea are equipped with various diagnostic devices/systems. The results of each test are compared to verify whether the device-in-question can accurately produce results.

5. Budgetand**Time**Constraints

5.1 Budget

[Table 1](#page-17-0) contains the projected cost and the actual cost of the SDS's development up to April 13th, 2011

Table 1: Projected and Actual Costs of the SDS

The projected budget that NAPNEA had originally proposed proved to be very realistic. Without wasting materials or overspending, NAPNEA carefully anticipated that replacement items would have to be purchased in case of component damage or malfunction.

NAPNEA received \$400 from the Engineering Student Society Endowment Fund (ESSEF), \$150 from the Wighton Fund, and approximately \$100 in materials from the Genome BC Technology Development Platform (BCTDP). The BCTDP also provided NAPNEA with tools such as soldering irons, crimps, wires, proto-boards, hack saws, and other equipment required to fabricate the SDS prototypes.

5.2 Time

Table 2: Development Timeline

Approximately half of the scheduled tasks were started and completed on time. Many tasks were either delayed or prolonged due to unforeseen circumstances such as product shipment delay, component malfunction, improvements and modifications to product design, and design complexity.

Although NAPNEA deviated from the deadlines outlined in [Table 2,](#page-18-0) having a thorough timeline enabled the engineers to carefully track their progress and resulted in a logical, well-managed development process. It also allowed the engineers to be ambitious and to deliver a fully-functional prototype while understanding the limitations of completing a project in four months.

All things considered, NAPNEA executed superb time-management and organization skills. NAPNEA formed before the semester started; the project idea was determined and market research was performed well ahead of time, and research and development commenced on the first week of class. Though this project demanded a lot of hard work, the large workload was distributed evenly throughout the semester such that the engineers could create a high-quality, robust product without being too overwhelmed.

6. Interpersonal&**Technical**Experiences

Allison Chew

ENSC 440 was an interesting and revealing experience. Unlike so many other courses and projects, it was an endeavor that extended far beyond technical knowledge and practice. It involved an incredible amount of interpersonal and communications skills and has made me a more well-rounded person as well as a more well-rounded engineer.

As CEO, I led the product development process by setting goals and deadlines and delegating tasks throughout the semester. I was involved in nearly all aspects of the project, including research and development, hardware and embedded software design, component sourcing, prototype fabrication, and system debugging and testing.

From a technical standpoint, I feel that my previous co-op and undergraduate thesis experience equipped me with the all the work ethic and technical knowledge I needed for this project. I was already familiar with the product development process and understood the procedures that should be implemented in order to conduct research, development, design, re-design, and extensive documentation in a timely, organized, and professional manner. I was able to transfer many of my skills such as system testing and data analysis, C++ programming and GUI design, Arduino microcontroller and electronics interfacing, and embedded software design. While this project posed several challenges for me, especially during the individual component programming and system integration, most aspects of the project were within my field of knowledge. If I were to do this project over again, I would venture into unfamiliar territory and really challenge myself in the same way that my thesis and co-op projects challenged me. That way, I would be able to acquire a larger set of technical skills rather than putting my existing skills to the test.

The most interesting and challenging experiences I had during ENSC 440 stemmed from being the team leader and trying to find balance between enforcing high expectations and maintaining positive group dynamic and communication. This was my first time experiencing such an intense leadership role and while I believe that I did a good job, I know that I have a lot to learn.

I greatly enjoyed the freedom that ENSC 440 provided. This course allowed us to showcase our knowledge, creativity, and talents as engineers and challenged our time management and organization skills. I believe that NAPNEA completely rose to the occasion without losing any sanity, sleep, or interteam friendships. I am extremely proud of the work we have accomplished.

Alex Manousiadis

ENSC 440 was a positive, yet introspective experience. I learned a lot about self-motivation and group dynamics, as well as technical skills and physiological conditions surrounding a common illness. The experience has improved me as both a person and an engineer. Though I have witnessed many teams in prior semesters working at all hours of the day and night on their projects in the final weeks of their projects, the necessity to work frantically to get our project working never ended up happening to our group. As a whole, we were well-organized, set a good pacing and managed to set and meet deadlines throughout the semester. We used weekly meetings to keep abreast of new developments throughout the project and sent a great number of e-mails around to maintain a stream of communication between these meetings. All-in-all, the project never had any big surges or lulls, it just progressed steadily until we were satisfied with our final product.

I filled the role of the Chief Technical Officer (CTO) by providing a broad knowledge of technical concepts, ranging from signal acquisition to software and system debugging. I also provided several tools from my garage at home. While I did not focus on one particular facet of the project, I was involved in nearly all of them. From the beginning, I was interested in the physiological data that we would be analyzing, and wanted to throw every conceivable sensor available into our system. As time progressed, reality set in and we settled on a single, simple, yet effective means of identifying apneic episodes: paradoxical breathing.

The most challenging experience I had during the project involved time-management. I was enrolled in a full course-load to complete a minor in computer science while working on this project, and I feel that my time spent working on assignments for these other courses would have been better spent with the NAPNEA group improving the design of the project. I will use this lesson wisely, and ensure that future projects are under-taken when enough time can be dedicated to them to satisfy my inner perfectionist.

This project would not have been successful without the heroic efforts made by the dynamic group of individuals of team NAPNEA. The fact that we managed to complete the term without a single notable argument shows how cohesive and focused we all were on achieving our goals: the development of a quality product. I could not have asked to work with a better group of engineers.

Ekin Nalbantoglu

Ever since I first began engineering at SFU I have heard people talking about ENSC 440. There was a mixture of positive and negative opinions about the course so I was not really sure what expect. As I saw upper year students working in Lab 1 with bags under their eyes, clearly under a lot of stress, I started to think, "Oh ENSC 440 looks terrible! How can anyone get anything positive from a course that makes you look like that?" I naturally became more anxious about having to take the course as I did not want to go through all that stress. This must have left an impression on me (and my group members) because all of us started to think and be active about ENSC 440 before the semester even began. Even though we began with a different project, having done work together and gotten to know each other better was one of the reasons I believe we had a much smoother ride compared to other groups in the past.

This was the first example of the benefits or initiating things early. A large portion of ENSC 440 and almost all of ENSC 305 is documentation. Documentation can be long, boring and very time consuming. Adding last minute panic and stress to this list would have made my experience this semester a much less enjoyable one. We were always well ahead of schedule for this aspect of the course because of very thorough planning and setting deadlines well before actual due dates. This allowed for getting things done exactly the way we wanted or if something were to go wrong there was time to fix it. All of this translated into better moods, less panic and solid marks. I already knew this from before, but this was the first time I consistently did it for a course and I am grateful that I was in a group that emphasized its importance.

As the Chief Analytics Officer of NAPNEA a lot of my focus was on testing of the shirt and data processing and analyzing. An important part of this was the preliminary testing that had to be done before actually building the shirt to determine the optimal positioning for the stretch sensors. This part took a long time as we did many tests over and over again to make sure that we had the best sensor positioning possible, and also meant a lot of data processing which allowed me to utilize the Matlab skills that I had learned from my previous courses. My soldering skills also improved immensely from building and putting together the main module, and I was also, thanks to this course, for the first time able to use Arduino microcontrollers and XBee transceivers which now I realize are two of the most used components in the industry. I also explored the feasibility of a snore sensor with the components available to us and knowledge of amplifier and filter design again from courses previously taken.

Overall ENSC 440 and ENSC 305 were great courses (though very time consuming and sometimes stressful) because it allowed me to do things I never had the opportunity to do before and learn valuable skills that will definitely help my career as an engineer.

Jason Cheung

From the warnings passed along by peers to those passed along by instructors of the course, we knew that time management and group dynamics were critical to the success of our project. Although document submission deadlines as well as progress reports imposed by the course structure really helped to guide our efforts, and gave us a clearer picture of what our goals and achievements were.

Whilst working in this team setting, I have learned that sometimes it is useful to take leadership, but it is also necessary to sometimes follow instructions. What I really enjoyed were the weekly meetings where we would come together to work on our individually assigned tasks but also share ideas and updates. This method of group meetings seemed to really work, because although these meetings were not structured to have specific agenda items, we were constantly updating each other on our progress. While our group dynamics were mainly democratic, with everyone able to share their opinions during discussion, the group leader had an overview of the entire project and was able to define priorities for our group – and this worked very well. When I had achieved a certain task or have new ideas, I was able to inform the team freely so that they could be a part of what I had learned for example why I am designing things a certain way, or how it works. On the other hand, I could always use the other team member as a resource to get an overall understanding of how all the portions of the project work together to build the final product.

Team bonding outside of the work setting is equally important. The few times that we got together with the sole purpose to relax and get away from the project were lots of fun and we managed not to talk about the project once!

As chief risk officer, I was always alert to and ask questions and think critically. Questions like what could go wrong or what we could do better are often necessary to push the product in the correct direction. Although each team member focused on their specific duties, it was often important to step back and look at the big picture and decide whether certain goals were feasible.

While the hardware was still in the development stage, I had a chance to gain some hands on soldering experience to put the components together in a compact design. In the production stage, I witnessed the hardware and software working together.

On the software side of the project, I had to learn how to code in html, php, host a website on the SFU provided webspace, as well as to allow upload and download of data files. This website not only added functionality to our system, but is a professional way to promote our company and product.

Eleanor Li

I expected ENSC 440 to provide an opportunity for upper year Engineering students to apply all learnt theoretical concepts and hands-on lab skills into creating a device that we wished existed in our current society. In this regard, I was not disappointed. As a mainly self-directed course, ENSC 440 was the perfect channel in which we could make that "wouldn't-it-be-neat" idea into a reality.

As the Chief Creative Officer, I managed product fabrication of the Sleepwear Shirt, providing expertise on concepts like fabric choice, optimal stitching and sewing layout (taking into account both clothing dimensions and wiring arrangement). Sensor fabrication was also important; I provided NAPNEA several different sensor variations in order to find the best design. Additionally, I was involved with NAPNEA's branding and communication design, ensuring a crisp, simple design that would catch the attention of the audience and remain memorable. Lastly, I was the main editor for all documents involved in the course, guaranteeing that all papers were consistent throughout in content and tone.

ENSC 440 taught me to understand team dynamics, especially how to work well with others and their work ethics. I learned that teamwork is not only working together on a facet of the project but also being responsible in bringing teammates up to speed in the areas that you alone are working on. In this way, the whole team can remain on par with the entire project and with each other. ENSC 440 also furthered my skills of effective researching as I found different ways to shape the Sleepwear Shirt. Lastly, the research paths I took enabled me to learn new fabrication techniques, such as fusing plastic.

Our project was divided into several sections, with different members in charge of them. The greatest challenge I learned during this semester was that, although time was tight, it was a good idea to take the initiative in getting involved in as many sections as possible. In this way, I received the greatest benefit of more practice from the course. I found that if I wanted to get experience in circuitry or in microcontroller programming (and not just in product fabrication), it was up to me to step up and ask my team members to teach me. They were more than willing and this increased team connection and camaraderie.

Overall, ENSC 440 was a chance to see, direct and experience the entire design and development process for a project of our choice which contained deeper motivation for us than perhaps some of our other courses. Moreover, NAPNEA contained keen team members that showed acute responsiveness, alertness and responsibility in making the most of meeting times and in showing this project their inexhaustible enthusiasm and dedication. With that spirit, the semester flew by with no conflict although I do believe that it is within our positive dynamic to healthily resolve any that could have arisen. To me, having the teammates that I did in NAPNEA was an essential part of this success.

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