☐ Risk Review ☐ Design Review ☐ Milestone Review ☒ Technical Review ☐ _____

Overview			
Project Topic:	Review of all power module and sample prep module changes that occurred buy both GHL and CCG between SG3 and SG4. Final review of the CCG Modules.		
Meeting Date:	09 April 2025	Notes taken by:	Jamie Purcell
Attachments:	NAATOS Modules SG4 Technical Review.pptx Power Module: 🗁 Feb2025 Power Module Design Files • Mechanical BOM: Beta Power Module BOM (GHL-1-12000).xlsx • PCBA BOM: GHL NAATOS_Power Module Main Board_RevB_BOM (ODIC EXPORT).xlsx Sample Prep Module: 🗁 Feb2025 Sample Prep Module Design Files • Mechanical BOM: Gamma Sample Prep Module BOM (GHL-1-22000).xlsx • Main PCBA BOM: GHL NAATOS_Sample Prep Main Board_RevC_BOM (ODIC EXPORT).xlsx • Heater PCBA BOM: GHL NAATOS_Sample Prep Heater Board_RevB_BOM (ODIC EXPORT).xlsx Both Modules: • Firmware annotated changelog and tabulated information: NAATOS Modules_Firmware_Changelog.xlsx		

Attendance

Attendee	Representing	Attendee	Representing
Cheryl Taylor	Quality	Stephen Burkot	Technical Lead – Clinical Research, E&S
Jamie Purcell	Project Lead, Product Development	Simon Ghionea	Technical Team Member, E&S (EE)
Chin Hei Ng	Technical Lead - Modules, E&S	Andrew Miller	Technical Team Member, E&S (ME)
Josh Bishop	Technical Lead - Systems Engineering, Product Development		

Meeting Minutes

Agenda

- Review of design transfer and final deliverables received from CCG.
- Review of all changes to the power module that were introduced or implemented between the α-power module (SG3) and the β-power module (SG4), including all updates, modifications and fixes that GHL introduced after receipt of fleet from CCG.
- Review of all changes to the sample prep module that were introduced or implemented between the α-sample prep module (SG3) and the γ-sample prep module (SG4), including all updates, modifications and fixes that GHL introduced after receipt of fleet from CCG.

Objectives

1) final review of β-power module and γ-sample prep module designs

2) design lock of the NAATOS v1 Modules for SG4 and NAATOS TB preclinical pilot studies

3) final documentation of the design

Notes

Key Topics:

1) Power Module Review and Component Details (α → β)

Alpha vs Beta Module Design Differences Overview: Chin provided an overview of the alpha and beta module designs, highlighting key differences in architecture, usability improvements, and changes in heater operation and battery design (Slide 6).

- **Heater Design and Interface Changes:** Chin discussed changes in heater design, including operating voltage changes, power distribution, and improvements in heat delivery and consistency.
    - Alpha Module has 4-heater design that was changed to 2-heater design for Beta.
    - Alpha Module uses heat spreader made of the copper foil that is hand placed, switched to nickel plated copper block for Beta. Improvements in the copper interface design provide more consistent heating and prevent oxidation over time.
- **Holding Mechanism:** Chin described issues with the holding mechanism in the alpha module, including consistency problems and firmware expansion issues, and proposed a new design for better consistency.
    - Alpha Module has 4-leafspring design that applies vertical force only on the edges of the laminate and applied unequal/inconsistent pressure across the laminate, which translated to inconsistent heating across the wax valve and variable and slow actuation times. Moved to a stainless steel, uniform, weighted (20g) mass in the Beta design. The Beta design allows for more consistent heating in general which translated to a consistent and reproducible valve release and flow.
- **Battery Design Changes:** Chin discussed changes in battery design, including direct battery contact with the board, improved power management, and the use of larger batteries.

- Alpha Module has 2x 18650 Li-ion batteries in parallel housed under the PCBA and connected to the board via an off-the-shelf battery. Battery was changed to 6x 21700 Li-ion batteries in 2s3p configuration with a spring loaded, direct connection to the PCBA for Beta.
- Alpha module battery holder utilized a relatively thin wire (22-gauge) to connect the batteries to the board and we observed a lot of voltage drop across it, so a lot of the power losses were caused by the wire alone. Moved to a thicker 10-gauge wire in the Beta design to mitigate.

- **Power Management, Power Architecture, Board Redesigns and Firmware Updates:** Chin and Simon discussed various firmware updates and fixes, including temperature monitoring, valve power supply issues, and improvements in timing accuracy. Simon discussed differences in power management between alpha and beta designs.
  - Alpha module had frequent brownouts due to power architecture of the RevA board. The alpha architecture used a 5V Boost converter to regulate 4 heater zones. The converter never worked, so it was turned off (i.e. bypassed) and when turned off you can still get power to flow across, resulting in losses and not getting the desired voltage output, leading to inconsistent heating.
  - Beta design power architecture (RevB board) moved each heater to its own boost converter (2 total) powering a single heater, increased the voltage of each converter (from 5V to 9V (amp heater) and 6Vbuck (valve heater), and added a kill switch between the battery and the convertor to the. The RevB design resolved the brownout issue and the amp zone 9V boost converter redesign worked well.
  - The RevB board 6V buck converter (TPS55288 SMPS) did not work well (i.e., very high ripple voltages on the valve heater power supply output when turned on but not connected to load) and required both a hardware rework and a software workaround to function efficiently. Boards were reworked by ODIC to to reduce the ripple, however you cannot read the temperature sensor underneath the valve while the converter is running, because the noise is too high, therefore a firmware fix was also implemented that turns the converter off for every temperature sensor read (5 times a second). Board reworks were completed by ODIC.

2) Power Module Configuration for SG4: Chin discussed the major differences in functionality and programming in the power module between SG3 and SG4

- SG3 Power Module process steps: Step 1) Amplification: 32 min, Step 2) Actuation: 5 min. Total time: 37 min
- SG4 Power Module process steps: Step 1) Insertion: 0.5 min, Step 2) Amplification: 17.5 min, Step 3) Actuation: 5 min, Step 4) Cooling/readout: 7 min. Total time: 30 min
- Firmware v3.5
  - 1.1.1 Updated Module Notification Scheme. Left LED indicates and signals for device run status/errors. Right LED indicated and signal battery life/charging.
- Calibration method and setpoints varied between alpha and beta modules due to placement of the heaters. Details of both methods were reviewed and discussed. Primary method for all modules is to first set a default heater setpoint value, then measure with a calibration laminate containing a thermocouple. If outside of the acceptable temperature range the devices are tuned until their heater setpoints can achieve an acceptable steady state temperature as read on the calibration device. Of 33 power modules received from CCG, only 3 required custom setpoint tuning during calibration.

3) Sample Prep Module Review and Component Details ($\alpha \rightarrow \gamma$)

Alpha vs Gamma Module Design Differences Overview: Chin highlighted improvements in the sample prep module, including upgraded hardware, better power management, and changes in the heating mechanism.

- Alpha unit is a Scotch-yoke carriage system with brushless motor, daughter heater board with aluminum heat block that is very challenging to disassemble for service and had no kill switch (note: we experienced run away motor situation during testing that required complete disassembly of the device to access the board and kill power to the motor) and utilized a strike plate on the lid to keep tubes from floating out of the heater during shaking. The alpha unit had very poor heating characteristics, which required GHL team to modify the sample preparation protocol during SG3 to test the units.
- The gamma design contains upgraded Scotch-yoke carriage with better wear characteristics and improved insulation, upgraded motor and bearing, Clip-in tube retainer, taller heat block, upgraded flex cable, upgraded power management on main PCBA, more and larger Li-ion batteries (6x 21700 Li-ion batteries in 2s3p), pphysical battery disconnect (kill) switch, battery door for easier access.

- **Stall Detection and Guide Rail Improvements:** Chin explained the implementation of stall detection and the use of new guide rails with higher hardness rating to prevent excessive wear and binding issues.
  - Alpha module contained Nickel-plated stainless-steel rails. CCG delivered the gamma units to GHL with Delrin rails. GHL modified hardware after receipt from CCG and reverted to stainless steel (17-4 Ph) rails.
- **Heater Improvements:** Chin explained the heater improvements that were implemented in gamma design.
  - In the gamma design the tube carriage housing was enlarged and an inner/outer wall was introduced to provide and air gap for better insulation. The aluminum heater block was increased in height 50% for better sample coverage. A tube retention clip and debris shield were added to keep the tube in good contact with the heater during shaking. The heater trace on the heater PCB was increased. A more robust (40 pin) flex cable (FFC) was used to connect the heater board to the control board. The heat block is enclosed by the heater PCBA to reduce heat loss. Finally, a higher load, higher power motor was used to manage the additional weight introduced with the heater improvements.
- **Motor Over Voltage Problem:** Simon discussed the over voltage problem in sample prep boards that was discovered. During testing the motor would just instantly go to maximum speed. Required a board rework by GHL (RevC board) to prevent this issue from happening. The rework involves connecting the GND to MOTOR_CATHOSE with a large wire.
  - Team discussed that NONE of the devices shared with CoDiagnostics (aka CoDx) has had this board rework or ANY of the firmware fixes implemented to address all the board power issues and other various bugs, so they have unstable versions of the sample prep module. We all agreed to share all this information with them as soon as possible and volunteer to support them in the board reworks if they decide to implement these changes.
- **Qualification Process:** Stephen outlined the qualification process for the units received from CCG, including physical inspection, temperature profiling, and validation of various parameters. All devices received from CCG underwent extensive acceptance testing by the GHL staff, which identified several of the issued that required the reworks and firmware fixes discussed earlier.
- **Temperature Profile Concerns:** Stephen and Chin discussed concerns about over temperature readings and the need to potentially retune the temperature setpoints.

- Since we don't have a good idea for how accurate the measurements are with the thermocouple moving through the fluid while being calibrated we decided to leave the setpoints as is for SG4 and evaluate all the data that is collected to determine if the 'out of spec' samples prep modules (note: particularly unit 38 which appears to be the highest thermal outlier).

4) **Closeout and Follow-ups:** Jamie thanked the team for their hard work and thorough preparation for the review and emphasized the importance of technical reviews for documenting and summarizing information, which is crucial for transferring knowledge to partners and preparing for future work. Jamie also requested that the team add temperature profile data for both the alpha power module and gamma module to ensure it is documented in this review.

Inputs / Outputs
N/A

Next Steps

Decisions Made
This review will serve as the final review and documentation of the NAATOS v1 modules. No further development, rework or modifications to the current designs are expected.

Action Items

Description	Owner(s)	Target Date
Finalize and document the firmware updates and hardware fixes for the beta and gamma modules	Chin/Simon	May 5, 2025
Communication with CoDx to share the technical review summaries and offer to discuss /support upgrading their devices if desired.	Josh	ASAP
Document the thermal profile changes and the impact on the protocol, including the transition from the voice coil to the beta and gamma modules.	Chin/Andy	Completed
Prepare notes, meeting record, circulate for review and file.	Jamie	May 5, 2025
Prepare and File Drawing for both Modules in the Technical File	Chin/Jamie	July 1, 2025

Approval Signatures

Print Name	*Title*	*Signature*	*Date*
Cheryl Taylor - Quality	Quality Manger		15-Apr-2025
Jamie Purcell – Project Lead	Director, Diagnostics	Jamie Purcell Jamie Purcell (Apr 15, 2025 14:06 PDT)	15-Apr-2025
Chin Hei Ng – Technical Lead, Modules	Sr Research Engineer	Chin Hei NG Chin Hei NG (Apr 15, 2025 15:19 PDT)	15-Apr-2025
Josh Bishop – Technical Lead, Systems Engineering	Principal Research Scientist, Product Development		22-Apr-2025

NAATOS Module Technical Review_SG4_09APR2025

Final Audit Report 2025-04-22

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