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BME 401 Progress Report

February 28th, 2020

Verification and Validation Report

1. Introduction

Team 12 is creating a carbon fiber microelectrode array (CFMEA) design and manufacturing process for client Dr. Keith Hengen. The Hengen lab's state-of-the-art infrastructure for chronic, single-neuron recording is currently limited by the implanted lifetime of their nichrome microelectrodes, and they seek the development of a carbon fiber neural recording array of superior biostability that will enable long term (>1 year) *in-vivo* neural recordings. The outcome of the project will be a functioning carbon fiber microelectrode recording array suitable for chronic neural recording of mice.

2. Amendments to Project Element

2.1 Amendments to Project Scope

At Dr. Hengen's request, the project scope now includes creating an additional e-cube head stage-compatible microelectrode array printed circuit board (PCB) for use with nichrome microwires. It will be identical to its carbon fiber counterpart except for through-hole vias connections in lieu of solder pads.

2.2 Amendments to Team Responsibilities

Due to scheduling conflicts, Luis gave the progress presentation, and David is in charge of the V&V presentation. Additionally, the responsibility of manufacturer communications has been divided into 3D printing and PCB manufacturer responsibilities with Luis and David at the helms, respectively. The updated team responsibilities can be found in Appendix A.

2.4 Amendments to Budget Proposal

The budget has been adjusted to account for changes in alignment grid production expenses. Ion etching services were to be used, 3D printing will now be used. Consequently, costs allocated to 3D printing were increased. An amended budget is found in Appendix B.

2.3 Amendments to Design Specifications & Design Schedule

No changes were made to the design specifications or the design schedule.

3. Detailed Verification Plan

3.1 Verification of Carbon-Fiber Aligning Grid

The design specifications stipulated a 64 channel microelectrode array (MEA) that could be both, manufactured by hand, and fit in a 10.4mm x 10.9mm x 0.68mm volume. To meet these requirements Team 12 designed an aligning grid that facilitates the attachment of carbon fiber electrodes to a PCB constituting the array. The design of the aligning grid must balance a manufacturable wall thickness dimension and grid hole dimensions that maximize functionality.

The aforementioned designed challenge motivated a concurrent redesign of the PCB board (see section 3.2*).* The grid design was finalized to 254μm minimal grid wall thickness, and 381μm minimal grid hole width (see Figure 1). Grid height was finalized to 600μm. This aligning grid's receptacle size is 380% larger than the receptacle size of the original PCB's vias; this vast improvement in size is essential to meeting the 1-hour manufacturing design specification.

Trial testing determined that the previously chosen manufacturing process for the grid, deep reactive ion etching (DRIE), was unsatisfactory (see *section 6)*. However, the new design for the alignment grid made commercial 3D printing prototyping viable. The prototypes are being ordered from the rapid prototyping company *ProtoLabs*, via their stereolithographic printing service. *ProtoLabs' Microfine®* proprietary resin was chosen to print the alignment grids. The *Microfine®* resin is specifically designed to print parts with features as small as 50μm with tight tolerances. *Microfine®□* resin has previously been used in neural recording research applications (*Voigts et al.*). Luis also has positive experience with *Microfine®□* in a research setting. Cost of prototyping the grid is approximately $300.00 for 15 pieces. This is well within the overall project budget specification (allocating for 3 printing orders). After validating the design, a slower manufacturing process such as micro injection molding could significantly lower the cost per piece.

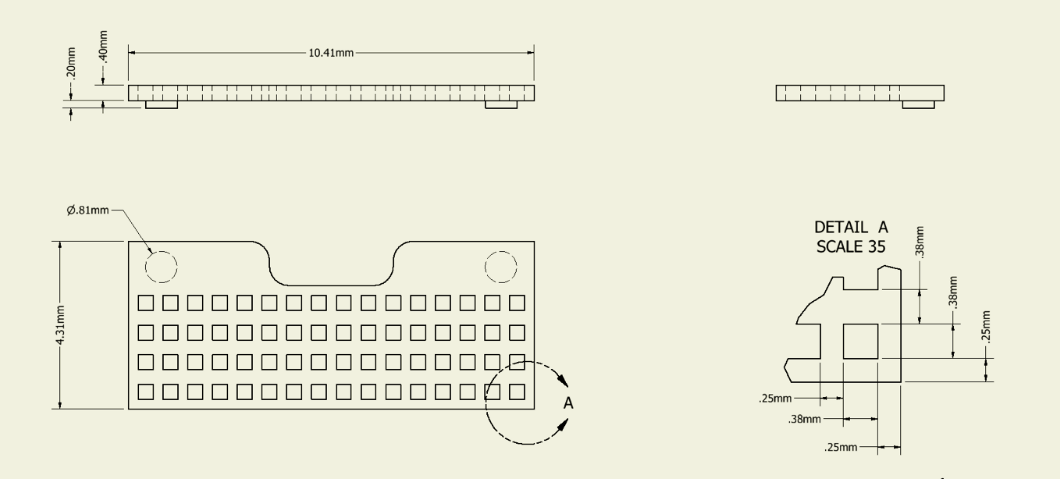

Figure 1. Schematic of final aligning grid. Detail A lists wall thickness and hole size dimension. Additional images found in Appendix C.

3.2 Verification of New Microelectrode Array Printed Circuit Board

Redesigning the CFMEA's 64 channel stackable PCB has proven to be an essential component to the successful completion of this project. The outcome of this redesign will be 2 improved boards -- 1 board to work with Dr. Hengen's tetrode technology, and a 2nd board to be used with the CFMEA technology. Bryan Broussard at Dynamic FPC design is helping make the necessary adjustments to do this redesign.

While making these modifications, it was important that the new boards meet all design specifications. In designing the circuitry of the new boards, team 12 maintained compatibility with the current stackable HS-640 E-cube head stage system. Team 12 also maintained the ability to stack 8 of these boards on top of each other (accounting for the aligning grid height) for

512 recording channels total. Physical dimensions were an imperative consideration during PCB redesign since the boards would be tether to a mouse's head when in use. The redesigned boards are the same dimensions (10.4mm x 10.9 mm), the same weight (5 grams), and the same thickness (0.2mm) as the old boards. Solder pad layout has been designed to maximize size and match the aligning grid's layout. The new PCB design is shown in Figure 2.

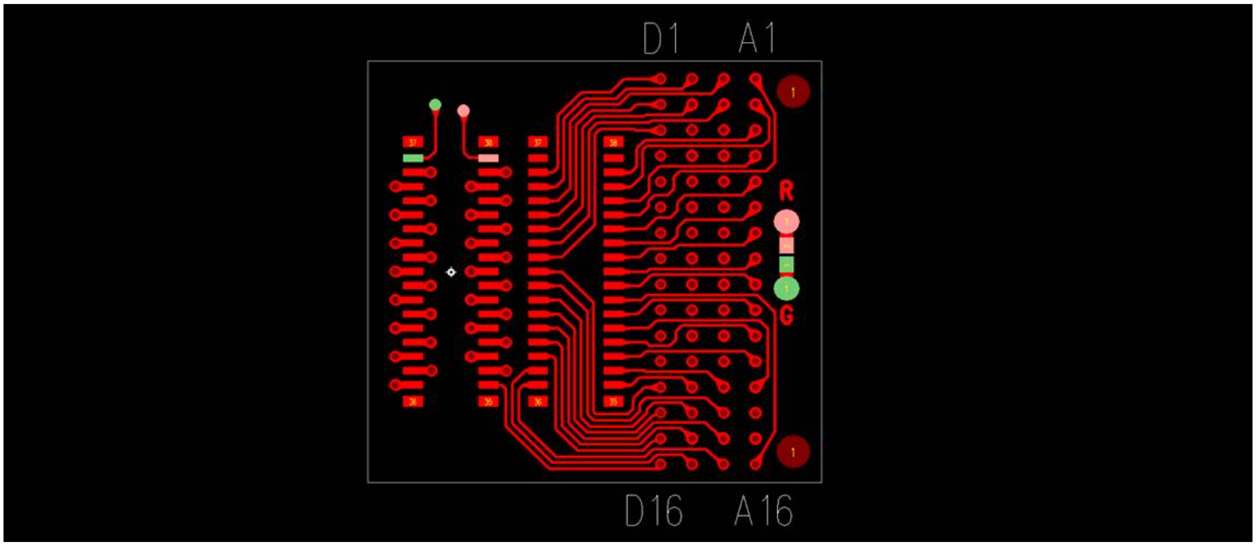

Figure 2. Layout of CFMEA PCB redesign. Center-to-center spacing of vias/solder pads was maximized to be 635μm in the vertical direction, and 762μm in the horizontal direction. Additional schematic found in Appendix D.

3.2 Verification Plan for Carbon Fiber PVA Coating?

The polyvinyl alcohol (PVA) coating has been proposed as a method of stiffening and strengthening the fibers. Changes to their gross mechanical behavior could improve loading efficiency by making the fibers much easier to handle. PVA will be verified as a potential source of stiffness for the fibers by measuring the thickness of the coating and the mechanical properties of the coating. The thickness surrounding the fiber correlates to the attachment efficiency while the mechanical properties are crucial to understanding how the fibers can be handled differently. The change in thickness change will be measured using a profilometer at the Washington University in St. Louis cleanroom while the mechanical properties of the PVA gel will be measured using the rheometer in the WUSTL Mechanical Engineering Department.

While the PVA coating might not be necessary to satisfy the project need, the proof of concept verifies it as a potential source of loading efficiency.

4. Final Validation Plan

4.1 Validation Plan for Carbon Fiber Aligning Grid

The final validation of the carbon fiber aligning grid will consist of validating the designs integrity during CFMEA manufacturing and validating its functionality in a finished CFMEA.

The former is meant to ensure that grid prototypes have sufficient structural integrity to sustain handling stresses during CFMEA manufacturing. This is a concern due to the thinness of the walls (250μm), and validation failure would require adjustments to the grid’s dimensions or selection of a different printing material/printing service. Additionally, team 12 will evaluate the production method for the grids by quantifying the print-fail-rate from the order and through visual inspection of grid prototypes under a microscope. At such a small scale, it would not be surprising to encounter variability among prints; however, it must remain at a level that would not interfere with the functionality of the aligning grid and a frequency that does not incur significant expense. Negative results in these validation tests would necessitate a transition to a more precise but higher capital cost and longer lead time manufacturing process such as micro injection molding. Conversely, if the prototypes surpass expectations, this may incur a design change towards thinner walls and larger grid holes.

Team 12 will also validate the functionality of the grid in facilitating CFMEA manufacturing, and sustaining electrical connectivity between a carbon fiber electrode and its respective solder pad. For CFMEA manufacturing facilitation, the most important metric is the carbon fiber loading time when done by an experienced Hengen lab technician. Design specifications will be met if the loading time for 64 fiber is within 60 minutes, however, sub-90 minute times are tolerable. Average single fiber loading times with and without the grid will also be collected. The connectivity between the PCB and the carbon fiber will be verified for each fiber mated to a PCB, and success rates will be reported. This metric must be close to 100% success.

4.2 Validation of the New Microelectrode Array Printed Circuit Board

The primary modification in both these boards is a redesign of the grid to create a 16x4 (64 total) layout for the vias as opposed to the 15x4 + 4 extra layout on the old board. The redesign of the grid will also include redoing the trace map for the board. Bryan has extensive experience with PCB design, and since only the location of the vias is changing, it is not expect for the performance of the boards to change in any way. However, the new tetrode boards will still be used to verify that the new trace map doesn't affect the performance of the PCBs. There is a group of researchers in Dr. Hengen's lab that works with the tetrode technology, and they will run their typical verification procedures on the new boards to make sure the new boards function properly.

A second modification to the tetrode boards is increased via diameter from 4 mil to 8 mil. The diameter of the vias was increased to make manufacturing the electrode arrays easier on the technicians in Dr. Hengen's lab. While the increased diameter is not expected to affect the electrical connection between the PCB and the tetrodes, the connections will still be verified as strong by comparing the impedance of a tetrode on the new board to the impedance of a tetrode on the old board. Similar impedances will indicate a strong connection between the tetrode and the via on the new board.

The only difference between the tetrode board described above and the new carbon board is that the carbon board doesn't have any vias, but instead has 64 solder pads that will work with the grid to connect carbon fibers to the PCB. Since the tracemap on this board is the same as on the tetrode board, the carbon PCB's performance should be the same as the tetrode board and doesn't need to be tested. Thus, the only major part of the PCB that needs to be tested is the connection between the carbon fibers and the copper pads on the PCB. Multiple different reflow solders (differing temperatures) or solder pastes will be tested to see which provides the strongest connection. The quality of the connection will be quantified by measuring the impedance of the carbon fiber on the PCB, in the same way as with the tetrodes.

4.3 Validation of PVA coating

The PVA coating will be validated by its ability to improve the loading efficiency and handling of the carbon fiber electrodes. Validation will come in the form of an assay measuring the improved handling of the fibers during insertion into the alignment grid and/or PCB. This assay will be a qualitative assessment based on testimony from experienced lab members. If technicians cannot differentiate between the handling of coated and uncoated fibers, then the PVA coating has not satisfied its function within the project and its use will be abandoned.

5. Discussion of FDA Process

Notable regulations are regulations associated with the use of the PVA polymer. The polymer is biocompatible and soluble in water and thus highly unregulated. Title 21 Article 3 of FDA codes state the polyvinyl alcohol can be used as a coating up to 6% (CFR - Code of Federal Regulations Title 21). Because our coating is only 5% and will be removed in excess water, the PVA can be used without concern for regulations.

Similarly, the materials used for the PCBs and grids, largely silicon, copper, platinum and 3D printed plastic, are not regulated. Silicon, copper and platinum are naturally derived and biologically inert. Platinum does have special regulations, but in the small amounts used in the PCBs, it does not qualify for special regulations (CFR - Code of Federal Regulations Title 21). 3D printed plastic can be disposed of without special treatment (CFR - Code of Federal Regulations Title 21).

6. Status of Project & Concluding Remarks

The alignment grid was a concept originally adapted from *Chestek et al.* to better organize the carbon fiber electrodes during the fabrication of the circuit. *Chestek et al.* used deep reactive ion etching (DRIE) to fabricate the alignment grid. This concept was trialed at the WashU cleanroom and shown to be similarly feasible. A trial pattern was etched into a silicon wafer and shown to produce a tapering into the silicon wafer. The tapering creates a V shape inside the design, which could ultimately be beneficial for loading the fibers. Unfortunately, this V shape results from erosion of the features and artificially widens the desired features producing inaccurate and inconsistent through-holes. Thus, DRIE has been deemed a last resort for the alignment grid and 3D printing will be trialed as a primary fabrication source for the grid.

Orders for the new PCB and aligning jigs will be placed shortly. Turnaround time for the grid prototypes is expected to be 7 days. PCB turnaround times have not yet been established. Consequently, validation of the aligning grid and PVA fiber coating will take place first. Team 12 expects to manufacture a full CFMEA prototype, and is striving to commence in-vivo validation of single-neuron recording with the CFMEA (which will last an additional year) prior to the conclusion of this project.

7. References

FDA, U., & Food and Drug Administration. (2018). CFR-Code of Federal Regulations Title 21. *Chapter I, Sec*, *312*, 21.

Patel, P. R., Na, K., Zhang, H., Kozai, T. D. Y., Kotov, N. A., Yoon, E., & Chestek, C. A. (2015). Insertion of linear 8.4μm diameter 16 channel carbon fiber electrode arrays for single unit recordings. *Journal of Neural Engineering*, *12*(4), 046009. doi: 10.1088/1741-2560/12/4/046009

Voigts, J., Newman, J. P., Wilson, M. A., & Harnett, M. T. (2019). An easy-to-assemble, robust, and lightweight drive implant for chronic tetrode recordings in freely moving animals. doi: 10.1101/746651

Appendices

Appendix A: Amended Team Responsibilities

Category	Task	Team Member
Administrative, Note-keeping, Presentations	Scheduling	Brennan
	Communicating with Dr. Hengen	David
	Notebook Updating	Luis
	Weekly Reports	Brennan
	Prelim Report and Presentation	Brennan
	Progress Report	David
	Progress Presentation	Luis
	V&V Report	Luis
	V&V Presentation	David
R&D	General Research	David
	Materials Research and Testing	Brennan
	PCB Modifications	David
	3D Modeling	Luis
Manufacturing	Communication with PCB Suppliers	David
	Communication with 3D Printing Suppliers	Luis

Table A. Amended team responsibilities. Salient point concern the division of labor between Luis and David on the progress and V&V report reports and on supplier communication duties.

Appendix B: Amended Budget Proposal

Item	Description	Price Estimate
PVA	PVA used for coating. A few hundred grams needed.	$20.00
Atomizer	Spray bottle for application of PVA Solution (20 mL).	$20.00
Aligning Grid Prototypes	3D printed prototypes via ProtoLabs SLA printing service (three 15-piece batches).	$900.00
Solder Paste	Material used to make electrical connections	$50.00
PCB Redesign	Professional rendering of PCB redesign	$1400.00
Misc. Costs	Fiber manipulation tools needed or other costs	$50.00
Total	**Best guess estimate for total project budget**	$2440.00

Table B. Amended Budget proposal accounting for 3D prototyping and PCB redesign expenses.

Appendix C: Carbon Fiber Aligning Grid Design

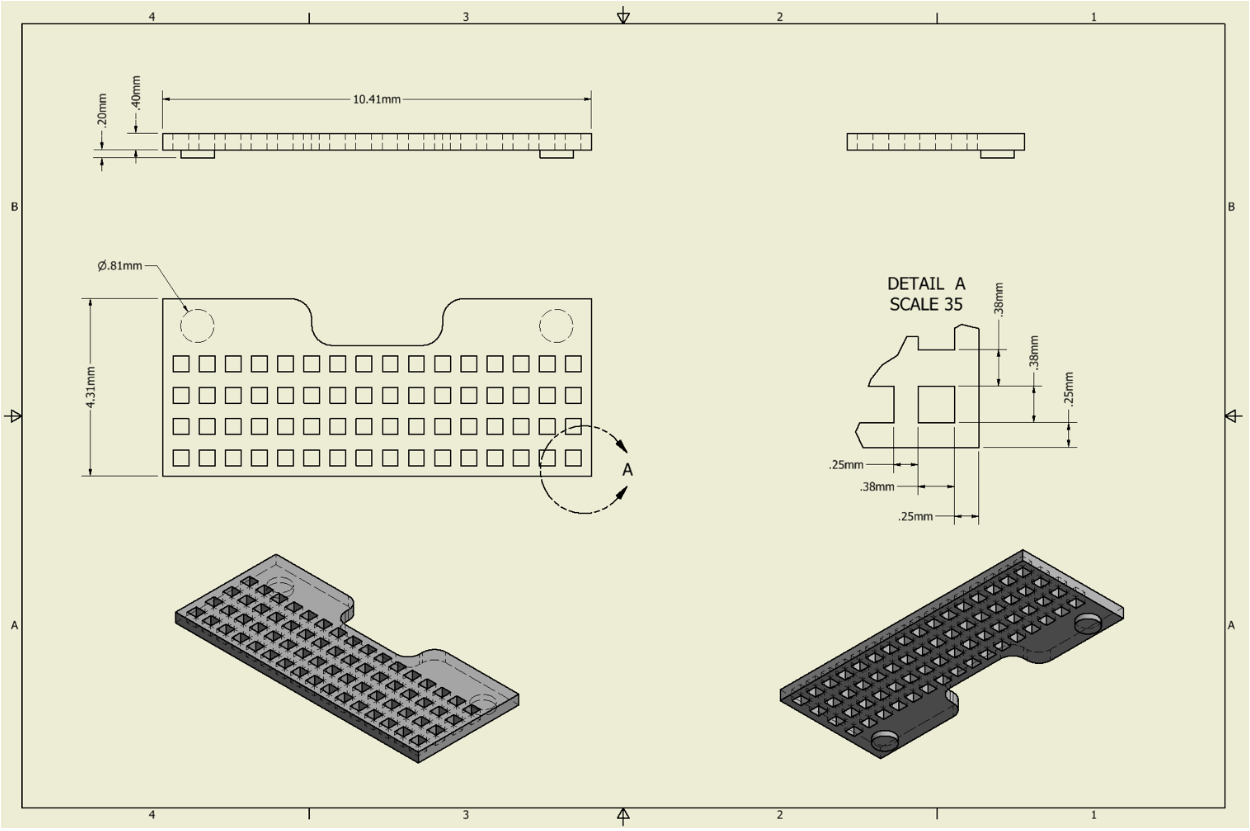

Figure C.1. Expanded version of carbon fiber aligning grid schematic depicted in Figure 1.

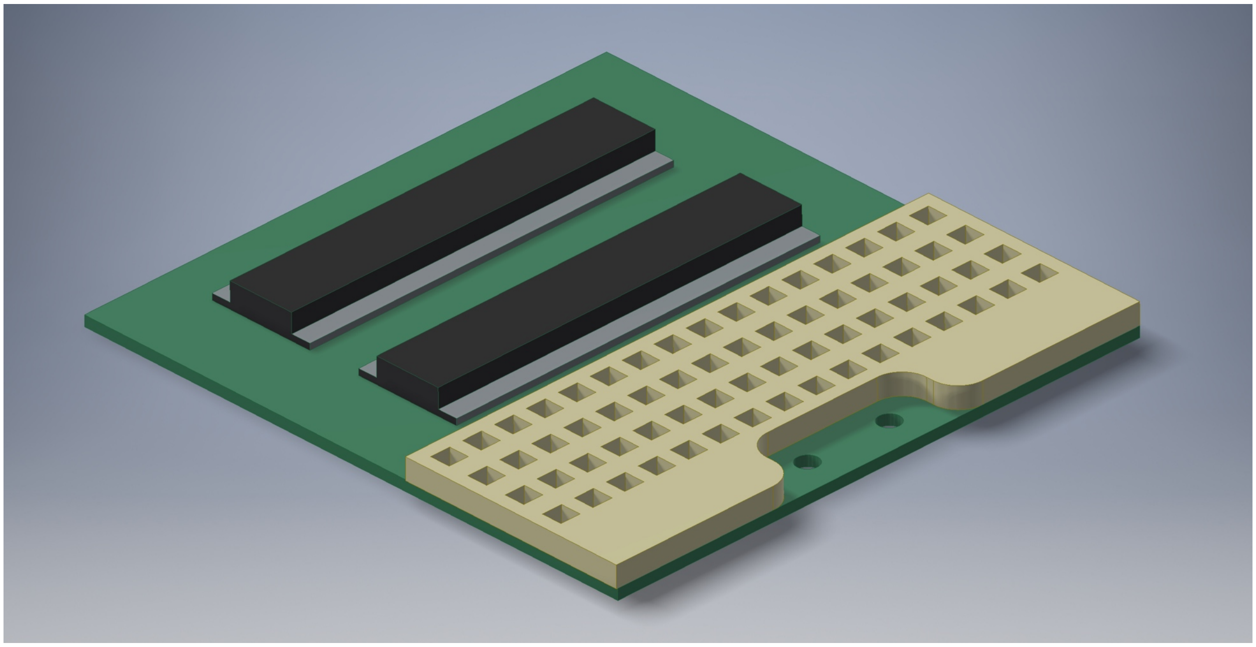

Figure C.2. CAD assembly of carbon fiber aligning grid mated to CFMEA PCB.

Appendix D: New CFMEA PCB Design

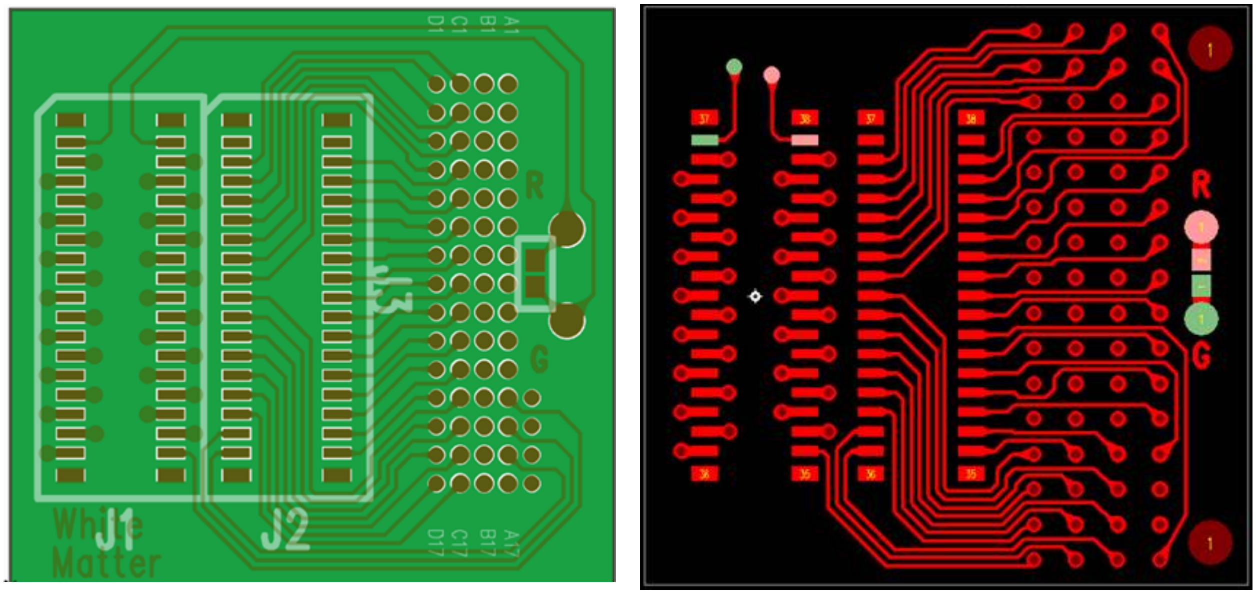

Figure D.1. Side-by-side comparison of original PCB design (*left*) and PCB redesign (*right*). Red circles on the right upper and lower corners of the PCB redesign are unplated through holes to facilitate placement of aligning grid.

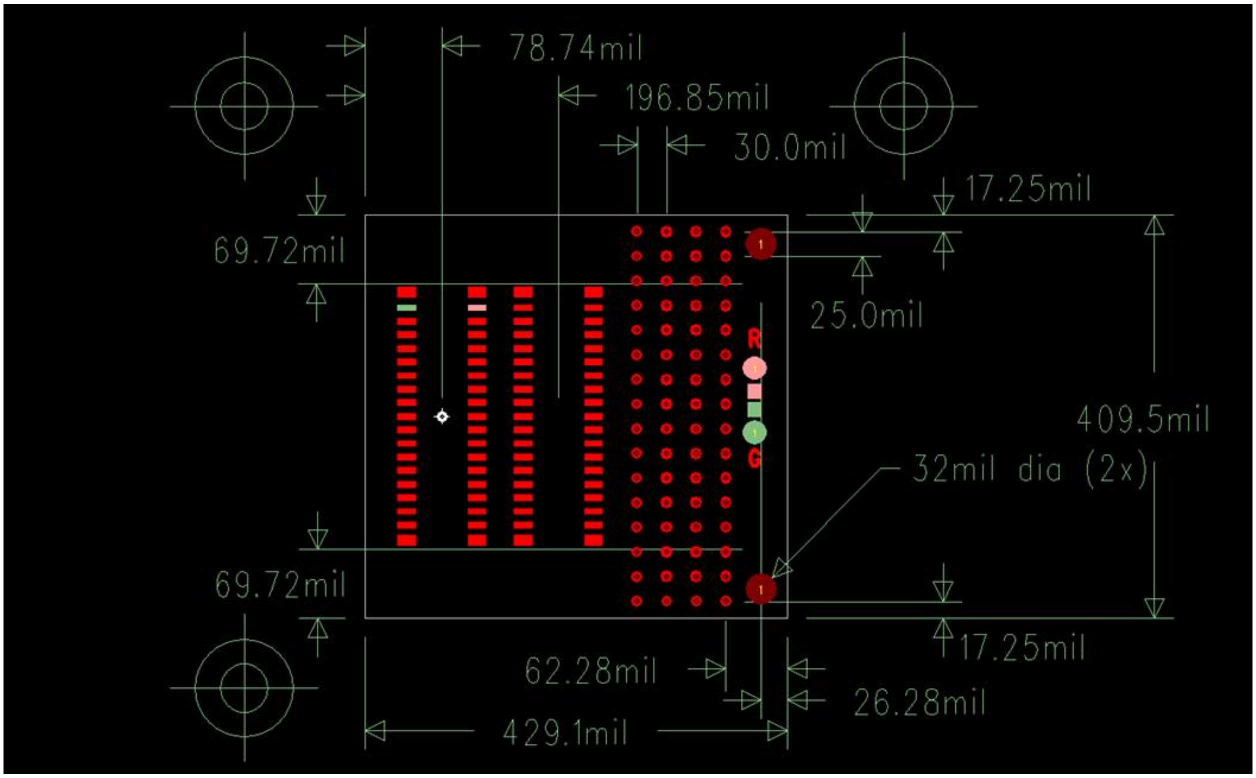

Figure D.2. Manufacturer schematic of PCB redesign with all relevant measurements. Due to industry conventions, dimensions are listed in units of thousands of an inch.