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Parallel Prototyping and the Engineer's Dilemma

Develop innovative products quickly, with superior quality, while controlling cost

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1. Introduction

In the high-stakes game of medical device development, time-to-market, safety, compliance and cost are all critical factors in attaining success. Couple this with the Engineer's Dilemma, develop innovative products quickly, with superior quality, while driving out costs, engineers find themselves faced with rapidly shrinking development cycles and rising competitive pressures. Parallel prototyping is a tactical tool that can reduce time-to-market and uncertainty.

This white paper demonstrates how the parallel prototyping of two materials, Aluminum Nitride (AlN) and Alumina (Al_2O_3), in a heating component design for low- to medium-volume production contributed to this success. It also addresses the verification, validation, form and fit testing relative to the FDA (Food and Drug Administration) approval process.

2. The Challenge

A leading manufacturer of respiratory therapy equipment approached Heatron to develop a heating element with very specific function, form, fit and cost requirements for their next generation breathing aid system.

The product configuration consist of a water jacket design that uses the insulating heat of warm water to maintain gas temperature and humidity all the way to the patient, thereby managing secretions, maximizing patient comfort and, above all, compliance with the prescribed treatment. The warm water is created as it passes through a heater. Heater power is continuously regulated to maintain the optimum temperature needed by the system.

3. Design Requirements

The heating element needed to be capable of fast thermal cycling and optimal heat transfer rate to maintain proper humidity and temperature for optimum patient comfort.

The heater control system had to regulate variations in flow rates and optimum temperatures to accommodate neonatal and adult patients while maintaining set body temperature and high humidity rates.

Specific design requirements include:

- Capacity to maintain a humid air temperature range between 25 °C to 43 °C adjusted for patient comfort (Resolution: 1 °C / Accuracy: ± 2 °C)
- Warm up time: ± 2 °C of 33 °C set point < 5 minutes at ambient 23 °C
- Control sensors: integral K-type thermocouple or other recommended options
- Electrical resistance: 64 Ohms (± 15%) 90 Volts
- RoHS compliant
- Constructed for low current leakage
- Designed to meet UL 60101-1 (safety requirements for medical electrical equipment and FDA clearance)

Finally, the heating element was a retrofit to the customer's existing medical device.

4. Impact of Parallel Prototyping to the Product's Design

Heatron reviewed multiple potential solutions to meet the design requirements, including Kapton® and all polyimide flexible heaters and four thick film heater materials. Both of the Ceramic Core technologies, Aluminum Nitride (AlN) and Alumina (Al_2O_3), proved leading candidates to achieve the design requirements.

To arrive at the optimum solution for this project, Heatron parallel tested Aluminum Nitride (AlN) and Alumina (Al_2O_3) Ceramic Core heaters. The criteria for determining which heater was best suited for the customer's system included thermal conductivity, heat transfer rate, and ramp rate for best humid air temperature output control.

Testing was also conducted to determine which technical solution provided the best cost/price advantage for lower total cost of ownership — enabling the customer to make the best decision for their particular market needs.

By parallel prototyping this project, Heatron was able to achieve a higher quality design, reduced R&D costs, faster path to market, and valuable insights that ultimately helped design a product superior to the competition.

5. Meeting the Challenge

5.1: Side-by-Side Comparison

Both Aluminum Nitride (AlN) and Alumina (Al_2O_3) are a clean, non-contaminating heat source. Durable, non-porous, moisture and chemical resistant, both have uniform surface temperature, low leakage current and low-outgassing.

Key Specifications	AlN	Al_2O_3
Max Watt Density	155 W/cm^2	11.6 W/cm^2
Thermal Conductivity	220 W/mK	35 W/mK
Ramp Rate	300 °C/sec	50 °C/sec
Coefficient of Thermal Expansion	4.6 x 10^{-6}/°C	6.7 x 10^{-6}/°C
Heat Capacity	0.72 J/g-K	0.88 J/g-K

The Alumina Ceramic Core heater has the highest insulation standoff per unit thickness and lower cost. Though it has lower maximum watt density, thermal conductivity and slower ramp rate, it meets the customer's specifications.

Parallel prototyping was used because side-by-side prototyping provides feedback comparisons that present alternative ways to achieve project requirements.

5.2: Component Design Verification and Validation

The objective at this stage in the engineering prototype is to verify that the design, materials, controls, and processes accurately represent the final production unit, and that the product will perform to specifications. This stage also includes evaluating pre-production prototype costs.

Heatron tested each heating element using:

- Real-time thermography to prove ramp up and cool down rates, and ensure desirable heat profile.
- Control system testing: thermocouple output when the thermocouple is installed at various locations of the heater assembly in a dynamic power up over set time period
- Safety testing to determine the heater circuit's voltage in isolation with respect to the thermocouple and load
- Repeatability and reliability of systems and processes
- Critical design review

A limited number of prototypes were developed to provide the basis for analyzing technical feasibility, form, fit, costs and market acceptance within the customer's product.

Preceding Heater's Profile

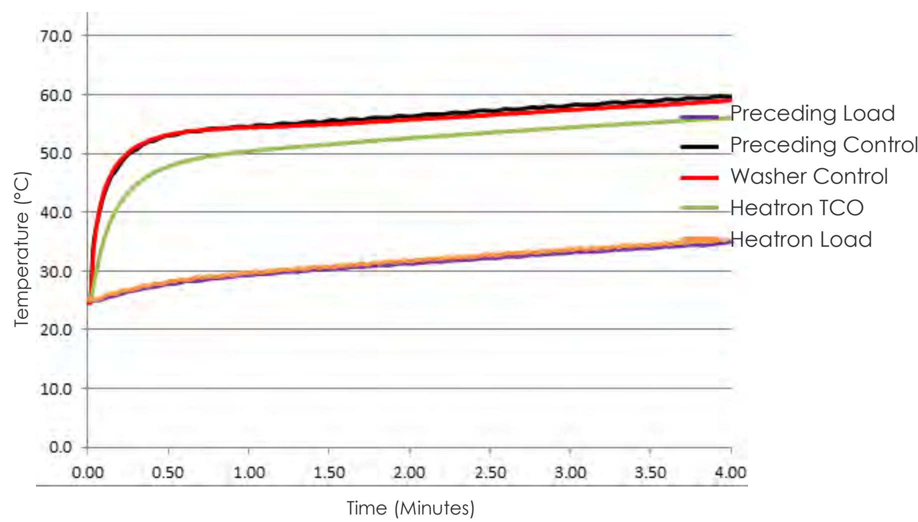
Heatron's Profile is optimized for greater efficiency

5.3: Product Design Verification and Validation

At this stage, the customer installed the heater assemblies in their equipment for complete system verification and to validate which best meet hospital staff and patient needs for design refinement.

- Functional testing
- Performance testing
- Usability testing
- Reliability testing
- Environmental testing
- Regulatory compliance
- Change control
- Pilot production readiness review

While parallel prototyping effectively helped determine which heating technology to build, the final solution was largely influenced by the customer's specific market needs.



5.4: Pilot Production Verification and Validation

This stage verifies the design has been correctly executed for the manufacture of the heating element and assembly into the customer's product. Rigorous design reviews at this gate confirm all customer specifications are met and the manufacturing process is feasible and repeatable.

- Heating assembly provides intended results
- Procurement analysis and plan in place
- Process instructions ensure ease of fabrication and assembly
- ISO 9001 quality system, documentation, material and component traceability
- Compliance testing to meet FDA requirements, RoHS, outgassing and other specifications
- Packaging and labeling
- Manufacturing readiness review

6. Product Discoveries

Design reviews at critical junctures led to new insights and opportunities to reduce development time, ensure efficiency and quality, and provide the lowest cost solution.

The evidence collected established the importance of the thermal-interface-material (TIM) to enhance heat transfer and justified its use. We improved thermal conductivity with a thermally insulating cover, making the heater transfer energy load better. Combined, this made for a much better retrofit that ran more efficiently. The heater's voltage isolation went from 2500 VAC to 4000 VAC with Heatron's design.

Thermocouple placement options were examined and we designed a mounting system that perfectly mimicked the target thermocouple response. We discovered a very simple system that allowed us to adjust the response so the existing control system's algorithms and firmware did not require modification.

Design reviews when parallel prototyping enhances the discovery process and uncover potential problems early, before the cost of correction are higher.

7. Benefits of Parallel Prototyping

The divergent/convergent nature of parallel prototyping stimulates greater discovery of unseen opportunities and constraints, which can lead to more diverse solutions and feedback from users.

The greater the degree of product development uncertainty, the stronger the case for parallel prototyping. Engineers learn from concurrent experiments. They see more data, sooner, and understand from a position of certainty. They are more likely to head off potential trouble spots and develop more robust designs. Moreover, parallel prototyping can double the user/patient involvement, which increases quantifiable user feedback. This facilitates higher patient satisfaction and greater compliance with the recommended treatment.

The trade-off to this speed and performance is in the initial development costs. In this case, one material property was contested against another. The total cost was actually less than serial prototyping, lowering the cost of total ownership.

Economies of scale are inherent in parallel prototyping since much of the development costs are fixed. Further, engineers gain an understanding of critical opportunities to improve device quality and insights for future enhancements.

Parallel prototyping provides greater assurance in the Design for Manufacture and Assembly (DFMA) process.

8. Conclusion

In solving the Engineer's Dilemma *(how do you develop a product quickly, with superior quality while controlling cost?)*, parallel prototyping offers great upside potential. There are many paths to a solution, but few are optimal.

Whether product development is in the highly regulated medical device industry or one with few constraints, parallel prototyping contributes to innovative ideas that accelerate time-to-market, reduce cost and yield a greater return on investment. All critical factors in attaining success.

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About the Author

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Craig has been designing thick film heaters and circuits for over 35 years, making him one of the most experienced engineers involved in Thick Film Electronics in the world. Craig is a listed inventor on numerous patents relating to thick film and his work has directly resulted in the production of millions of thick film circuits and heaters.

About Heatron

Heatron is a global leader in the design, engineering and manufacturing for heating solutions. Heatron's experienced engineers offer complete solutions, from initial concept and design to complex integration and manufacturing for low- to high-volume production requirements.

Heatron takes a complete systems approach to identify intelligent solutions for a wide range of thermal management and integration issues. Heatron models, simulates, designs, integrates and validates your component before productions to identify optimal design while driving out waste.

Our expertise in design, manufacturing and market standards provides our customers with the documentation and knowledge of agency approvals that is essential in today's tightly regulated environment.

To learn more,
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