

Crafting Precision and Aesthetics: The Development of R2's F1 Dermal Cooling System

Transforming a Vision into Reality

In the competitive landscape of dermatology, success depends not only on technological innovation but also on delivering a product that resonates with users and meets the demands of a global market.

When R2 Technologies sought to elevate their successful C2 Dermal Cooling System into a next-generation product, they partnered with Gener8 to navigate this challenge. The result was the F1 Dermal Cooling System—a testament to how collaboration between engineers, industrial designers, and stakeholders can produce a product that is both technologically advanced and commercially viable.

Founded in 2015, R2 Technologies originated from dermatology experts at Massachusetts General Hospital. Initially focused on internal clinical studies, R2 developed the C2 system as a clinical-use-only device for proof-of-concept work. By 2018, after multiple generations of clinical prototypes, they had defined the functional architecture of their product but needed an experienced partner to transition from clinical prototyping to full commercialization.

Unhappy with their original contractor, R2 turned to Gener8, known for its expertise in New Product Introduction (NPI) and development, to take their prototype to a market-ready device.

"NPI design was Gener8's niche. The biggest challenges were moving from NPI to manufacturing, and we felt well supported throughout that process. Gener8 truly stepped in and helped us navigate this critical phase."

-Kristine Tatsutani, Chief Science Officer at R2 Technologies

Challenge

R2 Technologies faced the critical challenge of transforming their clinically proven C2 Dermal Cooling System into a next-generation, globally scalable product without altering its core mechanical structure. With strict constraints on budget, timeline, and regulatory compliance, they needed a more aesthetically refined and user-friendly device while preserving the system's internal architecture. Partnering with Gener8, they overcame significant industrial design and engineering hurdles—ensuring the final F1 system met both technical and market demands.

glacial[®] skin

At A Glance

Customer
R2 Technologies

Product
F1 Dermal Cooling System

Services/ Market
Dermatology



The F1 system builds upon the proven foundation of the C2 Dermal Cooling System, enhancing its capabilities for large-scale, global distribution. Designed to treat pigmented lesions and areas of variable pigmentation, the F1 system applies precisely controlled cold temperatures through its advanced applicator tip.

With improvements such as treatment cycle use metering and enhanced usability, the F1 system maintains the core cooling mechanism while introducing critical refinements to elevate user experience and performance.

This case study highlights the journey of developing the F1 system, showcasing how R2's vision was transformed into a product that blends engineering precision with elegant design while ensuring compliance with stringent regulatory requirements.

A Vision with Constraints: Delivering Innovation within Boundaries

R2's primary goal was to upgrade its existing C2 system without altering the core internal components, thereby avoiding unnecessary costs and delays. The challenge was clear: create a more aesthetically appealing, user-friendly device that could be distributed globally while adhering to strict budget and timeline constraints.

Key Objectives:

- **Minimal Mechanical Changes:**
 - Retain the original system architecture to save costs and time.
- **Global Scalability:**
 - Ensure the design could be seamlessly adapted for different markets.
- **Enhanced User Experience:**
 - Incorporate ergonomic improvements and intuitive design features to improve clinical workflows.
- **Regulatory Compliance:**
 - Ensure the system met FDA 510(k) clearance requirements and adhered to 21 CFR 820.30 (Design Controls) and ISO 13485 Clause 7 (Product Realization).
- **Precise Cooling Control:**
 - The system must apply controlled cooling directly to the skin for specified periods.
- **Intuitive User Interface:**
 - The console must feature a simple, intuitive GUI that provides clear treatment parameters and error notifications.
- **Durable and Ergonomic Handpiece:**
 - The applicator must be lightweight, suitable for left and right-handed users, and provide treatment status indicators.
- **Secure System Design:**
 - The system must securely store available treatment cycles and prevent unauthorized access or cyberattacks.



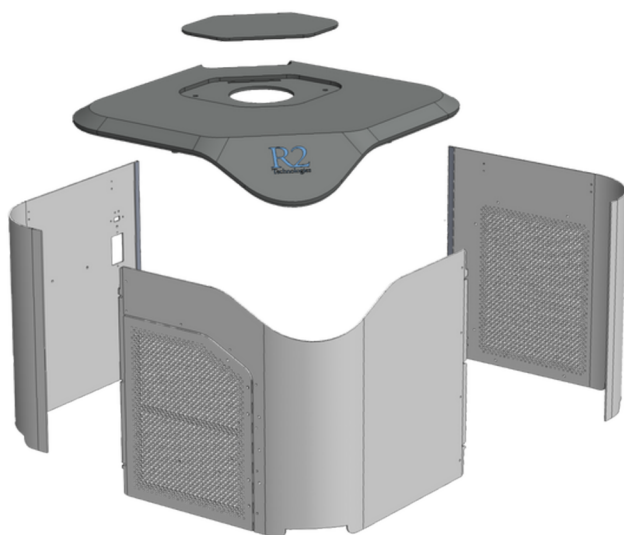
Original C2 Dermal Cooling System

Industrial Design Challenges: Fitting New Aesthetics onto Existing Infrastructure

One of the unique challenges involved reconciling the existing system's unappealing substructure with a new, polished exterior. Gener8's industrial design team was tasked with a challenge that required both creativity and strategic problem-solving.

Design Challenges Addressed:

- **Work Within Existing Constraints:** Develop an attractive, brand-consistent design without altering the internal mechanical structure.
- **Understand User Needs:** Conduct market and user research to create a design that is visually appealing and functional for operators.
- **Client and Stakeholder Alignment:** Maintain constant feedback loops with R2 Technologies, their sales representatives, and end-users to align the design with their vision and operational needs.



The Approach: Design-Engineering Synergy

The design process involved long collaboration periods between Gener8's industrial designers, mechanical engineers, and R2's stakeholders. By fully understanding the system's architecture and engaging with real users, the team could propose a design that met aesthetic goals without compromising mechanical integrity.

Key Design Strategies:

1. User and Market Research:

- Understanding User Experience: Gener8's design team conducted extensive research into the day-to-day use of competing products. Insights from operators highlighted pain points and informed ergonomic decisions.
- Stakeholder Interviews: Engaged with R2's sales representatives to align the design with market expectations and brand identity.

2. Design Execution:

- Simple, Recognizable Design Language: The new exterior design was sleek, minimal, and brand-forward, integrating easily onto the existing substructure.
- Ergonomic Improvements: Addressed common pain points like handpiece usability and overall device mobility, ensuring a more comfortable user experience.
- Strategic Aesthetics: The new design seamlessly hides the unappealing mechanical components while projecting a polished, professional look.

3. Collaborative Process:

- Continuous Feedback Loops: Regular discussions with mechanical engineers ensured that design proposals didn't conflict with system architecture.
- Client Involvement: R2 was kept involved at every stage, providing input and receiving updates to ensure alignment with their goals.



Engineering Precision: Making Complexity Simple

While the industrial design brought a new exterior to life, the engineering team focused on optimizing the internal components and cooling mechanisms. Their challenge was to enhance system performance while ensuring the design was robust enough for global deployment.

Core Engineering Achievements:

- **Enhanced Cooling Mechanism:** The F1's thermoelectric cooling (Peltier) system was refined to offer precise and consistent temperature control, essential for safe and effective treatments.
- **Modular Design for Serviceability:** Integrated modular components allowed quick replacements and reduced downtime.
- **Embedded Software and Updated GUI:** Improved user interaction and streamlined treatment workflows.
- **Scalability for Global Markets:** The device was engineered to comply with varied international standards, from power requirements to regulatory certifications.
- **EMI/EMC Design for US and China:** Ensured compliance with regional electromagnetic interference and compatibility regulations.
- **Manufacturing Transition:** Gener8 supported R2 in moving from NPI to manufacturing, navigating supply chain challenges and identifying options such as Costa Rica for production expansion.



Bridging Design and Functionality: A Collaborative Success

The collaboration between Gener8's industrial designers and engineers delivered a product that excelled both in form and function. By balancing innovative design with technical constraints, the F1 system was successfully launched on schedule and within budget.

Key Outcomes:

- **Market-Ready Design:** The final product featured a visually appealing and ergonomic design that required no changes to the core mechanical system.
- **User-Friendly Features:** The user interface and handpiece design received positive feedback from clinicians, reducing the learning curve and improving daily workflows.
- **Global Scalability:** The F1 system is now used across several continents, thanks to a design that adapts easily to different regional requirements.

Conclusion: From Concept to Consumer - Commercial Success

The F1 Dermal Cooling System is more than just an upgrade—it represents a refined approach to product development where industrial design, engineering, and client collaboration converge. For R2 Technologies, the result is a device that not only meets the technical demands of dermatology practices but also delivers an elegant, professional aesthetic that aligns with their brand.

As R2 and Gener8 continue to innovate, their partnership remains vital in driving advancements in dermatology technology, ensuring that future product lines meet evolving industry demands and maintain strong market traction.

Ready to bring your next product to market with precision and purpose?

Contact **Gener8** today and discover how our integrated design and engineering expertise can turn your vision into a commercially successful reality.

