



Medical Device Pendant Redesign

• January - May 2015

Objectives

- Improve ergonomics of proton radiation therapy system control pendant
- Reduce the maximum surface temperature of the pendant
- Re-architect software for automated test and integration

Approach

- Define system requirements and verification protocols
- Use computational fluid dynamics to simulate surface temperatures
- Accelerate design schedule and reduce risk by using a Computer-on-Module based design
- Create automated unit tests and software simulators
- Create rapid prototypes to confirm simulation results and iterate design

Results

- Reduced pendant weight by 49%
- Eliminated internal fan and created IPX1 enclosure
- Greatly improved ergonomics across a wide range of possible users
- Reduced maximum operational surface temperature from 125 °F to 90 °F
- Future-proofed system with modular embedded design

A Complete Product Development Partner



Brainstorming and Concept Generation



Feasibility Studies and System Architecture



Detailed Product Design



Prototyping



Design for Manufacturing (DFM)



Verification Testing



Manufacturing Assembly and Test Equipment



Sustaining Engineering

Complex Problem



Figure 1: Existing pendant design was too large for a handheld device

ProNova approached Synchroness with the need to redesign an existing pendant for a medical device. This pendant acted as a primary source of user interaction with the medical device, housing a touch screen, physical buttons, and electronics to drive the pendant and communicate back to the medical device.



Figure 2: Thermal images of existing pendant design show that the pendant's surface temperature reached 125°F while operating at room temperature

Given that the use case of this pendant was as a handheld device, the existing design was too large, too heavy, and with operating surface temperatures

nearing 125 °F, too hot to comfortably use. Vent ports for fan exhaust and the physical button design allowed dripping water ingress, not meeting the use environment requirements.

With the cost associated with re-architecting the software, the customer was hesitant to move to a new, lower-powered CPU unless it allowed elimination of the fan and associated vent ports. Cost constraints around the pendant's industrial design (ID) required that the decision to or not to include a fan be determined earlier in the development cycle as multiple iterations of the ID were not possible.

CFD Thermal Analysis of Electronics Enclosure

Using computational fluid dynamics (CFD), Synchroness engineers simulated increasing levels of heat dissipation and the resultant temperatures of the CPU die, main PCB, and pendant surfaces to evaluate feasibility of obtaining appropriate temperatures with redesigned electronics.

Simulations of the pendant included individual heat sources, natural convection, and thermal radiation, as well as various geometries, electronic components, materials, and surface finishes. These virtual prototypes showed that keeping internal power dissipation to less than 4.6W total would keep the maximum surface temperature below 90°F, which guided the CPU selection. In addition, the simulations demonstrated that the fan could be eliminated, making the enclosure smaller as well as watertight to IPX1.

Mechanical Design

With respect to the physical pendant redesign, the virtual prototypes allowed us to see hotspots for varying

All Simulations - Surface Temperature - 80°F to 90°F Scale

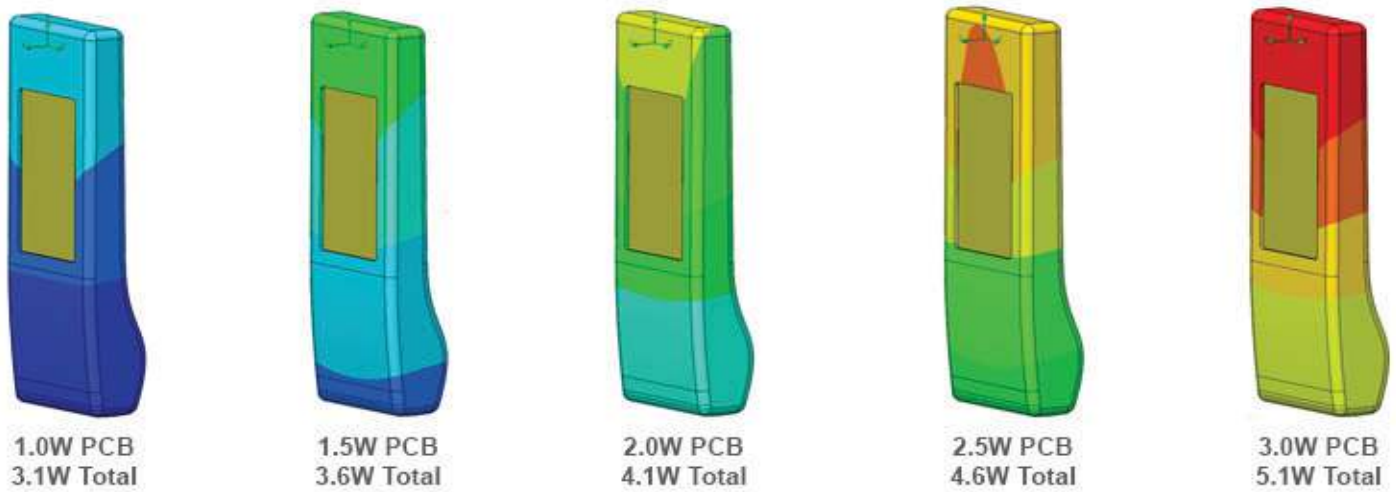


Figure 3: Pendant surface temperatures for given heat dissipation

configurations of enclosure geometry, enclosure material (aluminum versus ABS), and polyester-based powder coat properties. These simulations guided the design decision to use aluminum without the need for any costly physical prototypes.

Synchroness used low-cost rapid prototyping technologies to get full-scale color mockups into the hands of the customer and to evaluate ergonomics including button placement and weight distribution. The prototypes were also tested to verify the CFD analysis and to test preliminary IPX1 rating.

Embedded Systems Design

Although there are many varieties, all embedded systems have the same underlying architecture: processor, memory, and peripherals to interact with the outside world.

This core architecture is often designed from the ground up, providing a new set of problems to solve each time. This regularity provides an excellent opportunity for design standardization, a solution

offered by Computer-on-Modules (COMs). A COM is an embedded computer built on a single, modular circuit board.



Figure 4: COM used to reduce size and power consumption of pendant

While many manufacturers offer fully-contained System-on-Chips (SoCs), COMs extend the idea by combining all necessary hardware and software functionality into a ready-to-use solution for embedded computing. Synchroness performed a detailed trade study comparing COM features and performance, specifically looking for a module with low power consumption in a small form factor. Once a COM

had been selected, Synchroness embedded systems engineers integrated it into the pendant, providing the flexibility needed for a custom design.



Figure 5: COM integrated into Synchroness-designed board

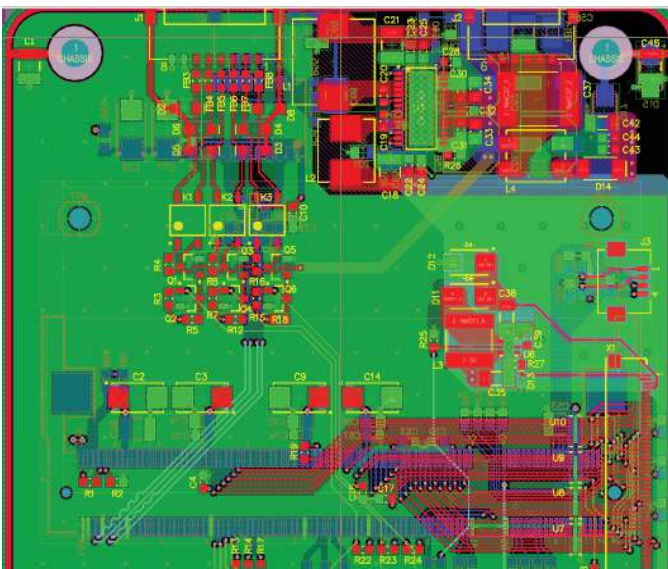


Figure 6: Pendant PCB layout detail view

Software

The pendant software had to be redesigned and re-implemented to integrate with new COM-based hardware solution. A key feature of the new software design was emphasis on making the software more testable. Synchroness software engineers

architected the software to allow unit-testing, and created automated unit tests for business logic in the application.

When it came to integration testing, the external software infrastructure that the pendant software interacts with was not available. So Synchroness software engineers built software simulators to stand in for the rest of the system, allowing testing to proceed without waiting for access to external resources.

Synchroness' Solution

From initial discussions in January through delivery of a functional prototype in May 2015, Synchroness provided our customer a new design that, with its reduced size, weight, and surface temperatures, is more comfortable for users. Synchroness' design reduced the steady-state surface temperature of the pendant to below 90 °F, with the results showing a maximum surface temperature of 87 °F when the pendant is operated in a 79 °F ambient environment. The actual intended ambient condition is 70 °F.

The redesigned pendant integrated mechanical and electrical packaging, including extensive EMI protection. With the prototype testing conducted and design provisions made, a swift pass of IPX1 testing is expected.

Synchroness reduced the time to solution by using embedded computer modules, which reduced engineering cost and risk. Computational simulations and early-development prototypes also reduced overall cost and risk, while ensuring the final delivered solution met customer expectations with decreased design iteration cycles.

Synchroness delivered test-driven software architecture via unit tests and stand-in software simulators. The COM is scalable, providing a future-proof design.

About Synchroness

For more than 18 years, Synchroness has provided inspired solutions to highly complex business and technical problems. The company has a strong portfolio of clients in the medical device, aerospace, and industrial equipment industries. By providing a full complement of engineering services aligned to the entire product lifecycle, Synchroness enables companies to accelerate product development and drive more predictability and productivity into their businesses. Working with Synchroness, companies gain the critical insights necessary to develop products that make a difference and create a better world.

About ProNova

ProNova Solutions, LLC was founded to meet the needs of cancer patients by making Proton Therapy accessible to a greater number of patients and physicians throughout the world.

ProNova is aggressively developing the next generation of this advanced cancer treatment by delivering a lower-cost, smaller, lighter, more energy efficient solution without sacrificing performance and improving upon existing capabilities. The fusion of state-of-the-art imaging, multi-axis precision positioning, superconducting magnet technology, and unprecedented closed loop treatment verification using Positron Emission Tomography brings ProNova customers clinical, operational, and financial benefits that will make major improvements in patient care, outcomes, and value.



Figure 7: Before (left) and after (right) images showing the size and corresponding weight reduction

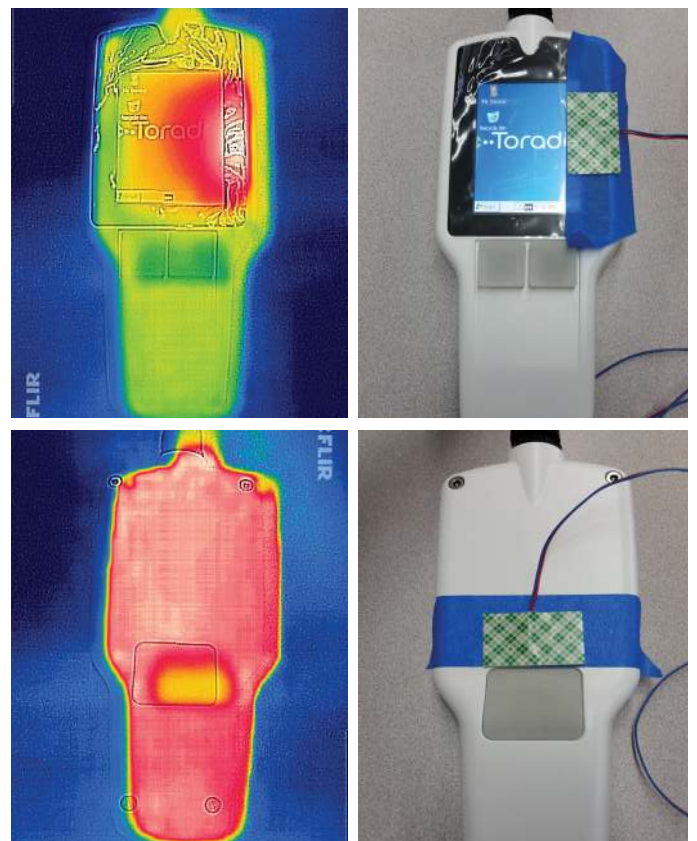


Figure 8: Surface temperatures were evaluated using a FLIR® thermal imaging camera and thermocouples