NUVATION
ENGINEERING

ELECTRONIC DESIGN CASE STUDY
HOME HEALTH CARE MONITORING DEVICE

PERSONAL HEALTH MONITORING • REGULATORY COMPLIANCE • CONNECTIVITY STANDARDS • COMPONENT OBSOLESCENCE
NEW PRODUCT INTRODUCTION • DESIGN FOR MANUFACTURE • PROJECT RISK MITIGATION

PROJECT OVERVIEW

A Nuvation Engineering client in the tele-health industry was seeking assistance upgrading a health monitoring device used by patients who are managing their care at home. The device collects data from various personal health monitoring devices (PHM) and uploads it to a central monitoring station manned by live agents.

The client was primarily a health monitoring services provider and developing electronic devices was not their core business. They needed the assistance of an engineering firm that could:

- Work with an RFP that was based on functional requirements and not complex technical specifications
- Provide up-front visibility of the entire project effort and costs from initial design to market-ready product
- Possess the diverse skill sets needed to execute both software and hardware development
- Manage all the complexities of medical and electronic device product testing and regulatory certification
- Manage the project until ready-to-ship products were rolling off the production line

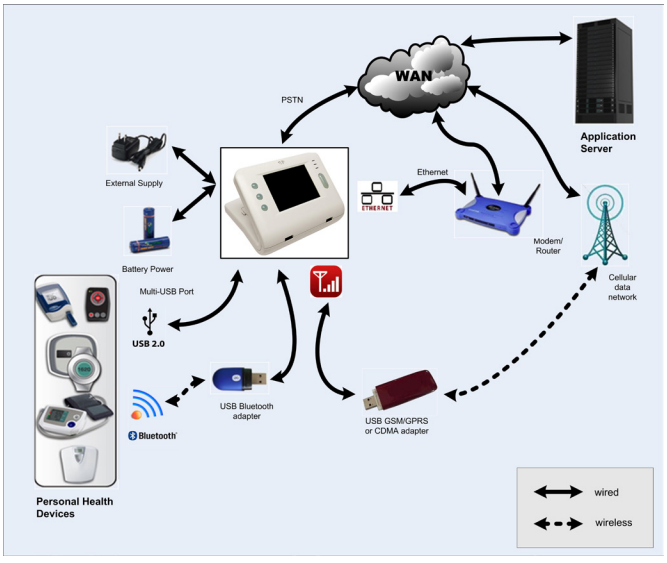


Figure 1- Personal health monitoring (PHM) devices being used in the home are connected to a device that collects and transmits the customer's health status to a central monitoring station.

REQUIREMENTS

The current device was several years old and some components had reached parts obsolescence. The device could also only support a single PHM device and needed to support multiple devices simultaneously. Support also needed to be added for newer communication technologies since the device was currently limited to plain old telephone service (POTS) as the only mode of data transfer to the cloud.

THE NEW DEVICE NEEDED TO:

- Collect health information via USB and Bluetooth from multiple PHM devices simultaneously (e.g. blood-glucose monitors, blood pressure monitors, pulse oximeters, etc.)
- Upload PHM device data to the cloud via Internet, cellular networks, and home phone line
- Be designed to meet North American and European EMC and Electrical Safety standards
- Use components with lifecycles that exceeded the planned product life
- Be manufactured at a price point that was well within the average home-care patient's budget

PHM DEVICE CONNECTIVITY STANDARDS

Standards for connected health monitoring devices used in the home are governed in part through collaboration between IEEE and the Continua Health Alliance, whose mandate is "to establish an eco-system [sic] of interoperable personal health systems that empower people and organizations to better manage their health and wellness."[1] Nuvation provided hardware and firmware solutions to help make the device compliant with Continua's special USB standard for PHM devices.

REGULATORY COMPLIANCE

The device had to undergo testing to ensure compliance with a range of medical and information technology equipment regulatory standards including:

- IEC 60601-01, 3rd Edition("IEC 60601" in North America, "EN 60601" in Europe[2]) – an internationally recognized standard for medical equipment performance, managed by the International Electrotechnical Commission (IEC)
- IEC 60950 – governs the safety of "information technology equipment"
- FCC Part 68 – a U.S. regulation that governs device connectivity to telephone lines[3]

- CS-03 – an Industry Canada guideline governing the operation of devices that connect to the telecommunications equipment of Canadian carriers[4]
- TBR21 – a European telecommunications standard published by ETSI and which applies to all telephone equipment being connected to Europe's public switched telephone network[5]
- CISPR-11, 22 – an IEC-managed standard governing how a device manages radio interference[6]

By the end of the project, Nuvation had conducted the compliance testing and certification required to meet all regulatory standards in the areas of Telecoms, Safety, and EMC, certifying the client's device to a combined total of twelve industry standards and their sub-parts.

RADIATED, CONDUCTED AND ELECTROSTATIC DISCHARGE

A variety of innovative approaches were required to design a product compliant with all applicable medical device, telecommunications and radio interference standards. Part of the challenge involved accommodating an innovative industrial design that required connecting three boards with flat-flex cables within a plastic enclosure. This increased the risk of radiated, conducted, and electrostatic discharge (ESD) because of the possibility of high-frequency noise radiation emanating from the flat flex-cables when devices were connected to the USB ports. Nuvation resolved this vulnerability by adding suppression components to the signal lines at every off-system connector and adding more filter capacitance to the signal lines.

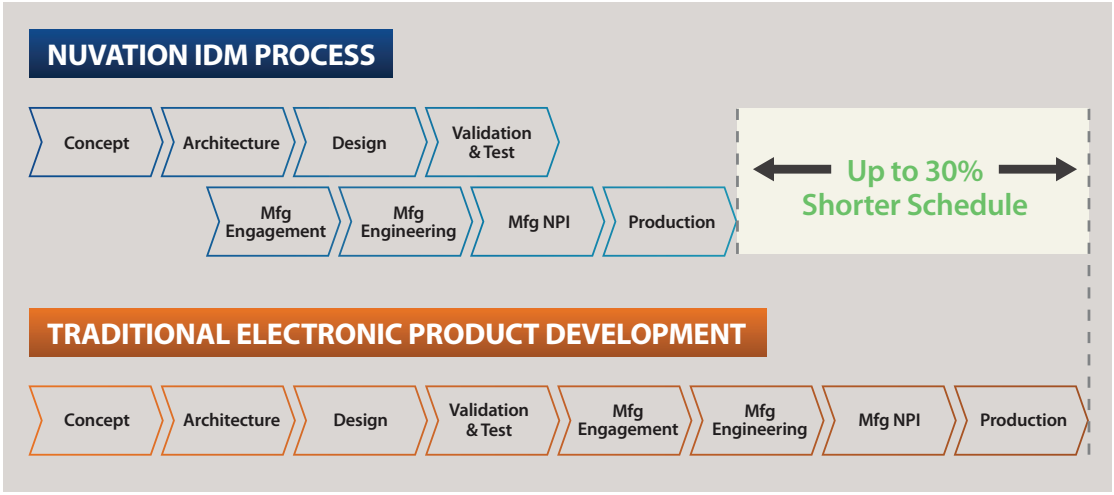
Selecting a power supply with a common mode noise level that does not exceed regulatory limits was a critical factor in meeting the IEC 60601-1 and FCC Part 68 standards for telecoms and radio interference. Power supply vendors do not state their products' common mode noise specifications on their datasheets, so Nuvation lab-tested various power supplies. Testing revealed that several low-cost power supplies from offshore suppliers exceeded the FCC-mandated limits despite claims of being "medical grade." After testing numerous power supplies one was found that was both compliant and within the target price range.

MITIGATING COMPONENT OBSOLESCENCE

The client's existing device utilized components that were nearing obsolescence. This was driving up production costs by requiring volume purchases of near end of life (EOL) components to support continued production. Nuvation leveraged their partnerships with component manufacturers to ensure that all components selected for the new device would be available well beyond the planned lifecycle of the new product.

MEETING TARGET PRODUCTION COSTS

The client was hoping this next-generation product could be produced at a lower price than its predecessor. During the discovery phase of the project however, Nuvation determined that the hardware and software components required to support the functional requirements would in fact make the product more expensive. Cost drivers included requirements for an Android operating system, a telephone line interface, color LCD screen, and the ability to power the device from both standard cell batteries and an AC adapter. The Android OS requirement for example, limited the type of CPU that could be selected and imposed a minimum memory requirement on the design, and supporting POTS required a telephone modem.



Nuvation's concurrent Integrated Design to Manufacturing (IDM) process can shorten the project schedule by as much as 30%.

After weighing the options of accepting the higher price point against reducing the functionality, the client determined that their customers would prefer the full functionality and still respond positively to the revised price. Nuvation managed to keep the new price within the client's budget by thoroughly reviewing the system architecture and negotiating with component suppliers on the client's behalf. They were able to find a newly developed integrated CPU and modem that cost 75% less than discrete components would have, and leverage their partner network to obtain extra discounts on components.

FROM DESIGN TO MANUFACTURE

With the product designed, tested, and meeting all regulatory requirements, it was time to take it to production. Where many design firms consider this the point of "hand-off" to the client, Nuvation's turnkey services include managing the transition to volume manufacturing. Nuvation designed a manufacturing test fixture to validate the product assembly process, creating a "bed of nails" style fixture and functional test program that verified the hardware and software functionality. They also wrote a test manual and provided onsite training to the contract manufacturer. When production began, Nuvation continued supporting and debugging issues during small pilot production runs until the transition to volume production was complete.

DESIGNING FOR THE END-USER

Nuvation worked with their industrial design partners to deliver a visually appealing and compact industrial design for this home-use medical device. The design included a 3" LCD screen that supported large fonts and colorful graphics for easy viewing and operation, and a small amount of large buttons with dedicated functions that made it very easy to use. They also engineered the product to deliver a battery life of 3-6 months, making it virtually maintenance-free.

CONCLUSION

KEY ELEMENTS THAT MADE THIS PROJECT A SUCCESS:

- Strong communication between the client and engineering team during all phases of the project
- Up-front "Phase 0" discovery phase that provided the client with full visibility into the project scope and "all-in" costs. This enabled the identification and resolution of potential issues before work began
- A diversely experienced software and hardware team supported by a collaborative workflow process
- A technology partner network that enabled the engineering team to source the best products and obtain the lowest available price points to meet the client's needs

CONTACT US

To learn more about how Nuvation can help your organization with your next engineering design project, contact **sales@nuvation.com** or call us at **888.669.0828**

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