

# Serena Dimensions RM: Accelerating definition of medical device interoperability



*We are collaborating with medical practitioners and device manufacturers to visualize, organize and prioritize the requirements that will define the future of device interoperability. For MDPnP.org the requirements are the product, and Serena has provided the perfect wrapper.*

Richard Schrenker  
Clinical Engineer

## Executive Summary

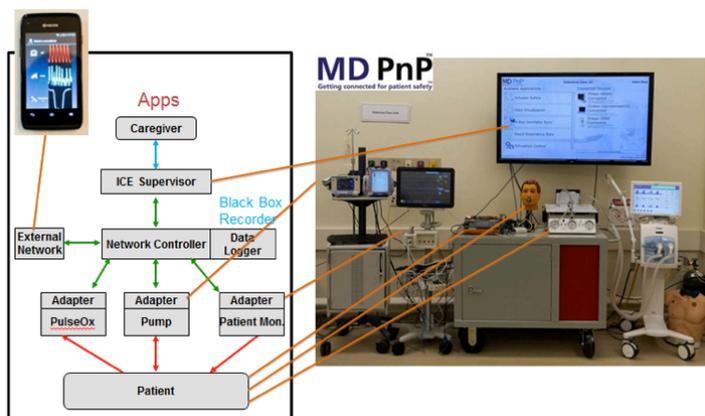
The MD PnP program (MdPnP.org), established in 2004, is a leader in the development of the concepts and capabilities necessary for the integrated clinical environments of the future. This team of biomedical and software engineers has been working with clinicians to accelerate the adoption of medical device interoperability by changing expectations through demonstration together with the adoption of a set of interoperability building blocks: use cases, standards, and open research conducted in a neutral lab environment.

For a decade the requirements for this program were managed by a brilliant and dedicated MD using what he hoped might be the latest version in a long line of Excel spread sheets. In 2013 the team began the search for a better requirements management solution; in March of 2014 MD PnP selected Serena Dimensions RM. Six months later, the team used RM to review, approve and to publish the first version of: 'System Requirements from a Clinical User Perspective'.

"Now," says Mr. Richard Schrenker, clinical engineer, "we know where our requirements are."

## Challenge

A patient lying in intensive care can be connected to as many as 15 devices, each one—individually—logging and interpreting data; some silently and some with a whoosh, a beep or a ping. Alerts bring clinical staff running, often for nothing, while the real alerts, those that might be raised by an immediate and automated reading of the combined data, do not come. The problem is that the ability to combine that data, the infamous 'patient black box', has not yet been realized. The 'Medical Device Plug and Play' interoperability program is working toward eliminating technology related issues through the definition and adoption of open standards and technologies that will result in ICE: 'Integrated Clinical Environments'.



Those involved realize that after years of building and testing - it is the requirements that will define their final product. They knew that they required a solution capable of collecting requirements, from high level clinical to technical system detail, using an application that would be both accessible and useful to doctors and nurses and software engineers.

## Solution

Most requirement management tools focus on document management. Typically, it is a document that is imported, broken down and segmented into information, requirements, and attributes before it is reviewed and managed—by analysts and software engineers. Such a solution would never work for MD PnP.

This team needed to define and maintain requirements that could be collected and reviewed using methods that would maintain accessibility to medical professionals,

regulatory and standards groups as well as hardware and software engineers. And that wasn't all; they needed to:

- Provide facilities for maintaining IP rights acceptable to device manufacturers,
- Support collaboration offline to meet the needs of international standards groups and online for the engineers and clinicians sitting in the lab in Cambridge, Massachusetts,
- Provide facilities for baselining publications and releases,
- Maintain traceability between use cases and test cases.

Someone said 'this is all so clear' just half-way through the first presentation, and before the month was out the decision was made.

With help from Serena RM professional services, the organization moved their requirements from Microsoft to Serena control in five days, at the end of 10 days team members were reviewing and updating requirements—basking in the ability to visualize the use case breakdown, to check history, and to show traceability.

Senior members of the MD PnP team presented their solution at Serena xChange 2015. They are now working with standards groups and medical partners to expand the use of Serena Dimensions RM in the medical device community.



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