How to create a medical device proof-of-concept prototype overnight

Roger Mazzella
Sr. Product Manager - Medical, TheQtCompany

Juhani Vanhala
Managing Director, Managing Director, SW Contracting, Siili Auto Oy

Bartosz Taczala
Technical Lead, Siili Auto Oy
What do Qt Medical Customers Value?

• Capability to Create Safe, Effective, Reliable and Intuitive User Experiences with uncompromising performance & reliability

• Develop the best, user-adopted, efficient User Experiences with Qt Design Tools and the ability to Rapidly Prototype on your Target Device

• Qt is a UI/UX cross-platform development environment

• Qt is the development platform, and is embedded into, FDA (Class I, II, and III) and EU Certified (Class I, IIa, IIb, and III) medical devices currently on the market

• Qt provides documentation and transparency into our development process, product performance, validation and testing to fully support of your device compliance needs

• Get to market faster with best-in-class technology, full tooling support and access to Qt’s industry-leading partnerships
What’s all the interest / hype in ventilators?

SARS-CoV-2 Symptoms
- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

SARS-CoV-2 Emergency Warning Signs
- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake or stay awake
- Bluish lips or face
Ventilator Needs: Current

**Current Evolving Situation:**
The Flattening of the curve throughout Asia, Europe and Americas means that ventilators are no longer in short supply.

The demand for ventilators is decreasing

**How was the need filled?**
Ventilator manufacturers increased manufacturing of ventilators already approved for market across the globe.

Additional manufacturing resources were leveraged from industries outside of the medical device industry (i.e. Automotive)

Why? The regulatory process for new devices takes time, even in expedited situations
Ventilator Needs: Future

So if the curve is flattened, why are we still talking about ventilators?

As demand for ventilators increased in response to the SARS-CoV-2, many of the ventilators were older technology, not very intuitive, somewhat difficult to use.

The majority of the ventilators were not very portable.

There is a need for more modern ventilators, that are truly portable, with intuitive UI/UX that mimics the experience on your smartphone.
What Keeps Medical Product Developers Up at Night?

Three main areas of concern when developers of medical products select COTS software:

- **Clinical Risk**: Risk a product will not work as intended.
- **Human Factors Risk**: Risk a product will be used as intended.
- **Cybersecurity Risk**: Risk a product will be hacked and compromised.

Qt works with our customers to support and create solutions for each.
What Keeps Medical Product Developers Up at Night?

Human Factors Risk

Risk a product will be used as intended
What is the value of a product working as intended if it is not **USED** as intended?

Human Factors is Critical!
Three main goals:

- Understand how the device will be used
- Drive a design that matches the capabilities and limitations of users
- Discover use errors and eliminate them
How is HFA Accomplished

✓ Use error and task analysis
✓ Early prototype usability evaluation
✓ Formal usability testing
✓ Post-market usability studies or surveys

Each is necessary but not sufficient. Together they form the foundation for the development of a safe and usable system.
HFA in Development – The Solution

- Realize value of investment in HFA
  - A development framework that facilitates UI/UX prototyping
  - Tools to make it easier to implement UI changes
  - Ensure the best overall user experience
How does Qt make it easier to iteratively prototype and re-design?

- Pre-built libraries enabling Drag and Drop / WYSIWYG development
- Qt Design Tools: Qt Design Studio
- Rapid prototyping on the target device
Rapid Prototyping on Target Device

Iterate quickly / Identify issues early and easily

Prototyping is in “Real Space” within actual environment

- Correct form factor
- Correct resolution
- Correct “look and feel”

Identify actual issues

Prioritize and Triage issues to be fixed
Accelerating product development

Fast prototyping as part of design process
Sudden need to vast amount of new ventilators in short period of time created high pressure for accelerating product development and shortening time to market.
High-level can’t be tested, high-fidelity can.

Building fast prototypes early in the design phase supports innovation by allowing the ideas to be put in front of users. This helps to get the details right and limit amount of iterations later in the development process. Hence reducing the total cost of innovation.

Key points:
- Incomplete experiences run the risk of highly biasing user reactions
- Rather than rapid and rough, we do rapid and right
- Amazing experiences emerge in the details
“Can Android look & feel match our brand identity?”

“What’s the best set of physical controls to operate the HMI in our device?”

“Will 3D help visualize data in my application?”

“Will a context display inside the rotary knob be usable in my device?”

“Can 3D content be streamed between different systems and displayed on different screen?”

“Can our existing HMI technology be mixed with Qt, Android, Unity, Unreal ...”

TYPES OF PROTOTYPES:

• UX of new features
• Technical feasibility
• Performance
• Workflow
Good prototypes should allow

- Change of the test scenarios
- Customizing of the displayed content per test user
- Fast iterations in max. 1-week cycles
- Recording of test user and the actions made (analytics & heat maps for eye gaze, clicks, interactions etc.)
A case example of fast prototyping with Qt for MCUs

Ventilator HMI POC
Building the first HMI prototype to enable UX testing

**Goal**

Enable Design Teams to experience their ideas on the target platform and make quick iterations on the created concepts. Get instant feedback from the tech (Qt for MCUs). Optimize for ability to experience the prototype quickly.

**Day 1**

**Setting the GOALS**

A Technology specialists skilled in fast prototyping joins the design team.

The team agrees goals what needs to be prototyped and what are the hypotheses to be verified.

**Days 2 - 4**

**Fast prototyping**

High fidelity prototype is built which can be tested on the target platform.

Design / Dev team works together to ensure fast iterations and tweak the prototype in real-time.

**Day 5**

**Demo review & alignment**

High-fidelity prototype review in a demo session.

Team reviews the results together and sets the expectations for the next iteration.
Thank you!

Next – how it was done
Links to videos:

› https://www.youtube.com/watch?v=CLba2K-l8io

› https://www.youtube.com/watch?v=Wdn14pxJiol
Qt for MCUs Training Program – Now available!

Official training course to hone your or your team's microcontroller development skills. Learn the basics and get your hands dirty with 'Qt for MCUs' online training.

In five hours, you will learn:

- Qt for MCUs package contents
- Building and running application using command line
- Qt for MCUs application build process
- CMake API
- Qt For MCU’s specific components
- Configuring Qt Creator
- Asset management
- Styling controls
- Internationalization
- C++/QML integration
- A Technology specialists skilled in fast prototyping joins the design team
- The team agrees goals what needs to be prototyped and what are the hypotheses to be verified.

Practice makes perfect – there will be live coding exercise included in the training. You’ll create your very first Qt for MCUs application.

What:
1st out of three session in Qt for MCUs program

When:
24-Jun-2020

Lecturer:
Jacek Nijaki, Software Architect C++, Siili Auto Oy as Qt Premium Partner

How much:
€308 / $350

Read more and sign up: https://marketplace.qt.io/
Thank you!

Have more questions?
Contact Qt at www.qt.io/contact-us/

Contact Siili at auto.siili.com/
Qt for MCUs: https://www.qt.io/qt-for-mcus
Qt for Medical: https://www.qt.io/medical

Follow us:
Twitter: @Qtproject
Facebook: /qt/
Linkedin: /company/theqtcompany/
Youtube: /Qtstudios/