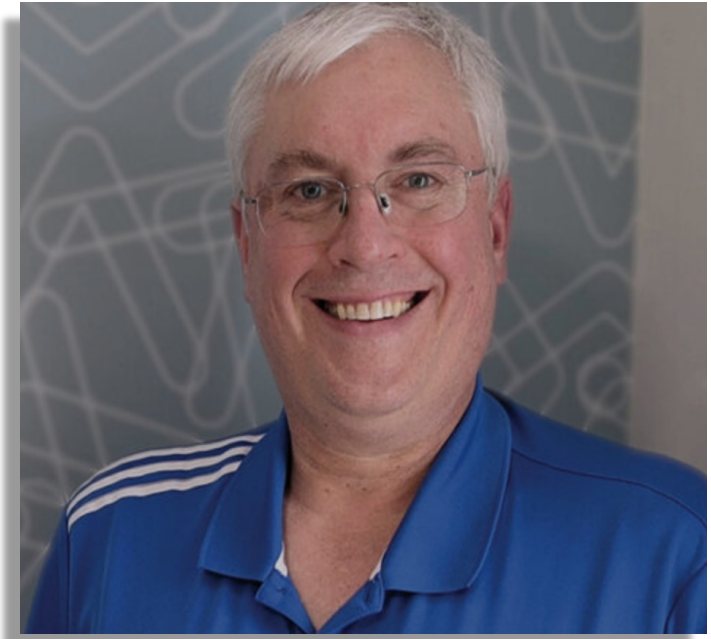

ROBOTICS
SUMMIT & EXPO
BOSTON CONVENTION AND EXHIBITION CENTER
MAY 1-2, 2024

Is a Medical Certifiable ROS Needed?



Tom Amlicke

Solutions Architect/
Systems Engineer

MEDACUITY

Medical Device Software

Robotics Practice – software for medical and non-medical robots

DISCUSSION POINTS

- What Do We Need to Build Safe Medical Devices?
- Robot Operating System (ROS) Qualities
- ROS 2 Qualities
- ROS and Safety
- ROS Safety Specializations
- Medical ROS Interest
- Benefits for the Medical Device industry
- Possible Features of Medical ROS
- Possible Roads to Medical ROS

MEDACUITY

WHAT'S NEEDED TO BUILD SAFE MEDICAL DEVICES?

ASSURANCE OF QUALITY

- Ability to inspect and review the code
- Run static and dynamic checkers
- Avoid Software of Unknown Provenance (SOUP)

ASSURANCE OF SAFETY

- Easy to evaluate risk
- Apply risk mitigations

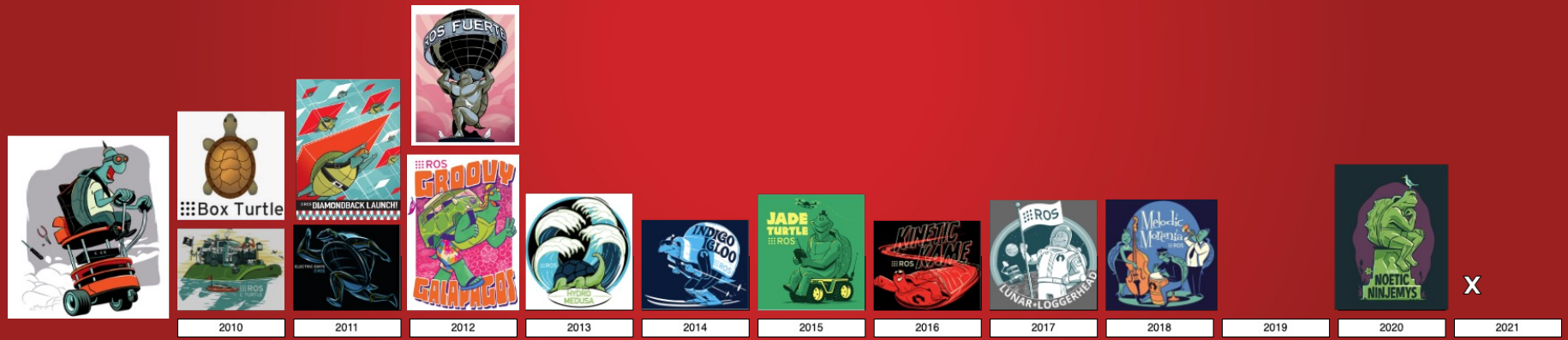
ASSURANCE OF SECURITY

- Easy to determine vulnerabilities
- Easy to secure
- Apply security mitigations

MEDACUITY

ROBOT OPERATING SYSTEM (ROS) QUALITIES

Idea to **working robot**



MEDACUITY

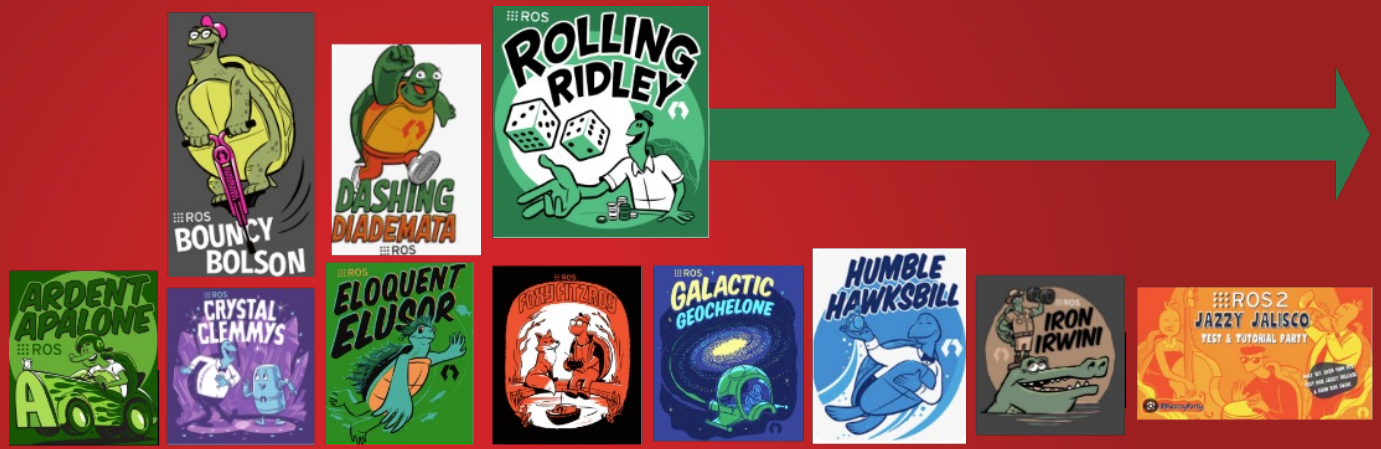
ROS 2 ARCHITECTURAL REDESIGN

- New network transport – DDS or others
- No single roscore limitation
- More platform support
- Client Libraries share a common C library (rcl)
- Support for multiple nodes per process
- New threading model
- Embedded support through micro-ROS
- Parameter support changes

MEDACUITY

ROS 2 QUALITIES

- Idea to commercial robot



MEDACUITY

ROS 2 QUALITY, SECURITY, AND SAFETY

- Package Quality Categories (REP-2004)
  - Level 1 – highest quality rclcpp, urdf, tf2
  - Level 5 – lowest and default level
- ROS 2 Security
  - Security provided through DDS with vendor security plug-ins
- ROS 2 Safety
  - See industry-specific solutions
  - ROS Safety Working Group in 2021

MEDACUITY

Specific industry safety concerns

THE AUTOWARE FOUNDATION

https://autoware.org

- ISO 26262
- APEX.AI Certified a feature set reduction of ROS2

spaceROS

https://space.ros.org

- DO-178C
- NPR7150.2
- Goal: space certifiable subset of ROS 2
- Static Checkers

https://rosindustrial.org

- ISO 13849-1
- IEC 62061
- Many more

MEDACUITY

MEDICAL ROS INTEREST

- 2023 ROSCON Birds of a Feather – 50 attendees
- Interest varies based on size of the company
- Potential Medical use cases
  - Prototyping
  - System and software verification
  - Baseline architecture for new robot design
  - Offline data processing and simulation

MEDACUITY

LARGE COMPANY PERSPECTIVE

- Legacy Problem
- ROS 2 as
  - A product/prototype accelerator
  - A baseline architecture for a next-generation robotic system
  - Post-procedure analysis and review

MEDACUITY

LARGE COMPANY PERSPECTIVE

”I like the idea of providing a concrete example/project as a blueprint for a successful “from idea to 510k clearance" journey. Big companies will feel comfortable making this tech shift only when there is a concrete example to testify to the feasibility and value of using such technology for new product introduction.”

Vincenzo Schettino

MEDACUITY

SMALL COMPANY PERSPECTIVE

- ROS provides a framework to get a prototype up and running quickly
- Getting that prototype over the chasm
- To turn the prototype into a product requires:
  - A process that creates the current prototype under design controls
    - ISO 14971
    - ISO 62304
    - ISO 60601 series
  - Possibly functional safety through ISO 61508

MEDACUITY

SMALL COMPANY PERSPECTIVE

"Our strength as startups is innovation; Vexev's resources are better directed at innovation in tomographic ultrasound, not developing common robotics libraries from scratch - we NEED to leverage SOUP to get our products out there and make an impact sooner. So, the ROS benefit is that it gives us more resources to work on our unique application domain, revolutionising haemodialysis treatment."

Deanna Hood, Vexev

MEDACUITY

BRIDGING THE VALLEY

How do you get design controls around ROS 2?

- Lock in your versions of ROS 2 libraries
- Document the quality of the libraries of ROS 2 you're using
  - *Are there static checkers running against code?*
- Trace user needs to system and subsystem requirements, including software requirements to test cases
- Document system and software architecture use of ROS 2 libraries
- Mitigate risk with additional system or subsystem requirements with traceability to test cases
- Validate tool and SOUP

MEDACUITY

POSSIBLE BENEFITS FROM A MEDICAL ROS

- Templates to help validate ROS 2 libraries
- Requirements and test cases with test run results are documented and easy to adapt to the intended use
- Software architecture document templates
- Risk assessment and failure modes and effects analysis (FMEA) templates

MEDACUITY

POSSIBLE FEATURES OF MEDICAL ROS

- Monitor Surgeon Attention
- Monitor Sterile Field
- Monitor the Operating Room
- Tool Swapping
- Surgical Port Kinematics
- Soft Tissue Modeling
- Medical Imaging Integration

- Algorithms for Teleop motions
- RT-safe tracing and logging
- Qualified Tooling
- Low latency and jitter
- Functional Safety architectures
- OTS OS support (QNX etc.)

MEDACUITY

POSSIBLE ROADS TO MEDICAL ROS

Create a Medical ROS Community Group

From this group, form a **working group** of volunteers to bootstrap Medical ROS efforts such as:

- Create a survey to determine what would make Medical ROS valuable to the community
- Create a roadmap to address the needs of the community
- Determine the level of effort needed and possible funding sources

MEDACUITY

NEXT STEPS

- Post your interest to ROS Discourse
- Reach out to me
  - tamlicke@medacuity.com
- Create *Birds of a Feather* sessions at upcoming conferences
  - Please see Shashank Sharma's talk "Enabling Software Defined Medical Robotics Using Open-Source Software" at the Hamlyn Symposium on Medical Robotics in June

MEDACUITY

SAVE THE DATE

First Medical ROS Community Group Meeting

Wednesday 15 May 2024

MEDACUITY

QUESTIONS

MEDACUITY

THANK YOU!

LET’S KEEP THE CONVERSATION GOING.

VISIT MEDACUITY - BOOTH 726

MEDACUITY