Corindus
Vascular Robotics

A Secure Robotics Platform for Remote Vascular Interventions

Including PCI and Stroke[1]

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Control Systems and The Quest for Autonomy
A Symposium in Honor of Professor Panos J. Antsaklis
10/28/2018

1 CorPath Systems are not indicated for neuro interventions, nor is it indicated for remote interventions.

Vascular Interventions

An overview for Coronary (PCI)

- Vascular Interventions
  - Physician gains access to the patient via an *introducer sheath*
  - Physician navigates *guide catheter* (GC) to opening of vascular region which requires treatment
    - Visualization is typically under X-Ray with a *fluoroscope* in which a radiopaque contrast is injected into the artery or vessel of interest in order to determine treatment options
  - Once diagnosis is complete, treatment of the vessel or artery is commenced using additional devices including
    - Micro-catheters
    - Guide wires to cross a lesion for example
    - Balloon catheters to perform *angioplasty*
    - Stent catheters to deliver a stent

- PCI
  - Access is typically via the radial (wrist) or femoral artery (groin)
  - Most interventions involve a GC which is seated in the left or right coronary ostium typically with the aid of a J-wire
  - Physician typically steers GW past lesion in order to allow delivery of *RX device*
  - RX device includes Semi compliant balloons for angioplasty, {bare metal, medicated} Stents, High pressure balloons for post dilatation of Stent.
  - During the procedure patient health is monitored via *Hemodynamics*

Remote Interventions

Motivation

PCI

- Time is Heart Muscle
- Reduce time to treatment in surrounding rural locations in states including:
  - Michigan (Ryan D. Madder, M.D., FACC – Spectrum Health)
  - MN (Eleid, Mackram F., M.D – Mayo Clinic)
- From 2001-2006, The number of US PCI capable hospitals increased by 44%; however, the increase of population within one hour only increased by 2%. Leaving over 20% of the US population being more than one hour from a PCI capable hospital[2].

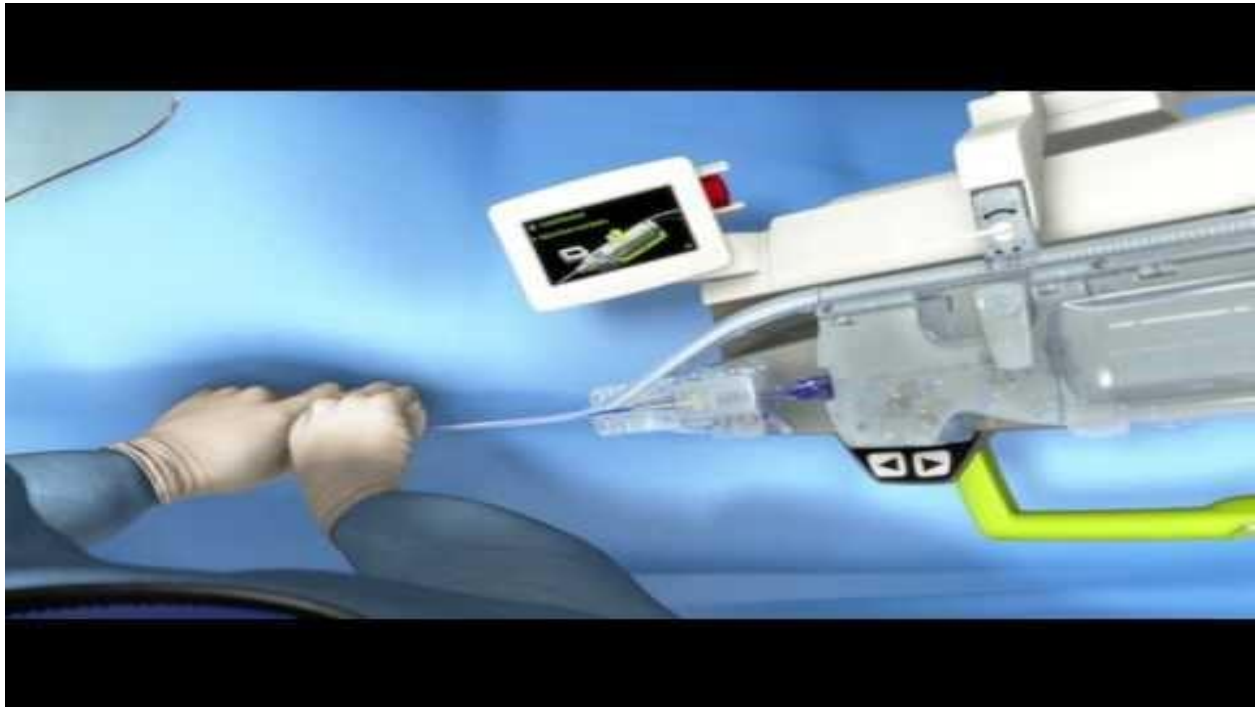
Stroke: Time to Treatment is Key

- Time is brain – Quantified, Jeffery Saver
  - Typical patients suffering large vessel acute ischemic stroke loose 120 million neurons, 830 billion synapses, and 447 miles of myelinated fibers per hour.
- Treating stroke via vascular interventions is an emerging field with improved benefits to patient outcome (~900k victims per year in US).
  - Lack of proximity to facilities (distance)
  - Limited number of specialists
    - Only 35k receiving treatment
  - Excellent opportunity for robotic intervention to increase access and reduce time to treatment.

2- Concannon TW, Nelson J, Goetz J, Griffith, "A percutaneous coronary intervention lab in every hospital?"' JL Circ Cardiovasc Qual Outcomes. 2012 Jan;5(1):14-20..

System Overview

CorPath GRX



Key Corpath GRX Features

- Guide Catheter Control & Management
  - Prismatic and rotational motion of guide catheter allows the IC to reseat GC during complex cases when GW and/or SC pushes back due to tortuous lesions.
  - Enclosing Sheath Allows us to drive the GC distal of the patient.
- Precise monitoring and control of GW and RX devices.
- Bedside Touchscreen
  - Instructs bedside technologist through device (GW, BSC) and GC exchanges.
- techniIQ^{TM} – Rotate on Retract
  - When physicians retracts a GW due to traveling off a the main path down a child vessel, the Robodrive rotates the GW in order to adjust the tips heading and get back on the main path.
- Radiation Shield & Power Vision Monitor
  - IC remains seated at console with capacitive JS interlocking system without 25 lb of lead in order to focus on treating patient.

Permanent magnet synchronous motor (PMSM) Control

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A Closed Loop Control Law of PMSMs Which Is Asymptotically Stable

PMSM is a motor in which the rotor consists of n_p in {1, 2, …} pole pairs and stator w/ *m* in {2, 3} phases.

<u>Assume</u> rotor is cylindrical so the stator inductances, L, are constant in the Direct Quadrature (DQ) frame.

<u>Define</u> *electrical angle* $\theta_e = n_p\theta$, torque constant K > 0

Park Transform: $\begin{bmatrix} f_d \\ f_q \end{bmatrix} = \begin{bmatrix} \cos(n_p\theta) & \sin(n_p\theta) \\ -\sin(n_p\theta) & \cos(n_p\theta) \end{bmatrix} \begin{bmatrix} f_\alpha \\ f_\beta \end{bmatrix}$

Therefore, $\begin{bmatrix} f_\alpha \\ f_\beta \end{bmatrix} = \begin{bmatrix} \cos(n_p\theta) & -\sin(n_p\theta) \\ \sin(n_p\theta) & \cos(n_p\theta) \end{bmatrix} \begin{bmatrix} f_d \\ f_q \end{bmatrix}$

Clarke Transform: $\begin{bmatrix} f_\alpha \\ f_\beta \end{bmatrix} = \begin{bmatrix} \frac{2}{3} & -\frac{1}{3} & -\frac{1}{3} \\ 0 & \frac{1}{\sqrt{3}} & \frac{-1}{\sqrt{3}} \end{bmatrix} \begin{bmatrix} f_a \\ f_b \\ f_c \end{bmatrix}, \begin{bmatrix} f_a \\ f_b \\ f_c \end{bmatrix} = \begin{bmatrix} 1 & 0 \\ -\frac{1}{2} & \frac{\sqrt{3}}{2} \\ -\frac{1}{2} & -\frac{\sqrt{3}}{2} \end{bmatrix} \begin{bmatrix} f_\alpha \\ f_\beta \end{bmatrix}$

<u>Define</u>: 'effective Q v': $\overline{v_q} = (v_q - K\omega)$

<u>Define</u>: DeQ voltage: $\bar{v}_{\mathrm{DQ}} = [v_d \quad \overline{v_q}]$

Denote the DQ current as: $i_{\mathrm{DQ}} = [i_d \quad i_q]$

<u>Recall</u> *skew symmetric* matrix as $S = \begin{bmatrix} 0 & 1 \\ -1 & 0 \end{bmatrix}$ in which $S = -S^{\mathrm{T}}$

PMSM Model:

$$L\dot{i}_{\mathrm{DQ}} = \bar{v}_{\mathrm{DQ}} - Ri_{\mathrm{DQ}} + n_P\omega LSi_{\mathrm{DQ}}$$

$$J\dot{\omega} = Ki_q - \tau_l - B\omega - K_{d4}\sin(4n_p\theta) - \tau_f \tanh\left(\frac{\pi\omega}{\omega_f}\right)$$

DQ Control Law for PI Control of PMSMs

$$e_{\mathrm{DQ}}(t) = i_{\mathrm{DQ-r}} - i_{\mathrm{DQ}}$$

$$\dot{i}_{\mathrm{DQ-I}}(t) = k_{\mathrm{DQ-I}}e_{\mathrm{DQ}}(t)$$

$$i_{\mathrm{DQ-c}}(t) = k_{\mathrm{DQ-P}}e_{\mathrm{DQ}}(t) + i_{\mathrm{DQ-I}}(t)$$

$$\bar{v}_{\mathrm{DQ}}(t) = Ri_{\mathrm{DQ-c}}(t).$$

The proof for stability involves passivity theory showing: i) that the mapping from the PMSM voltage input $\bar{v}_{\mathrm{DQ}}$ to the PMSM current output i_{DQ} is *strictly output passive*; ii) the PI control law (s.t. $k_{\mathrm{DQ-P}} > 0$ and $k_{\mathrm{DQ-I}} \geq 0$) is *strictly input passive*; and iii) from the *passivity theorem* the resulting system is asymptotically stable.

Passivity Based Control of PSMS

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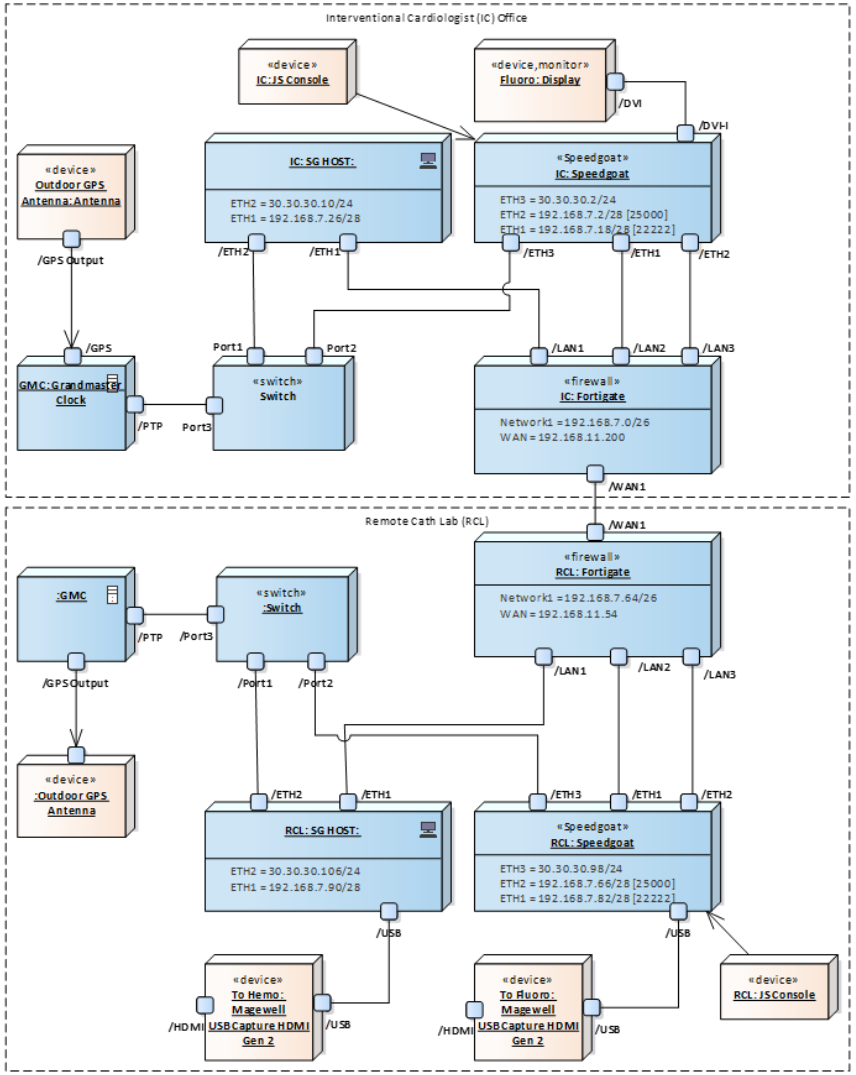
System Overview

Remote Architecture – C2 Corpath GRX, Navigation, and Patient Monitoring

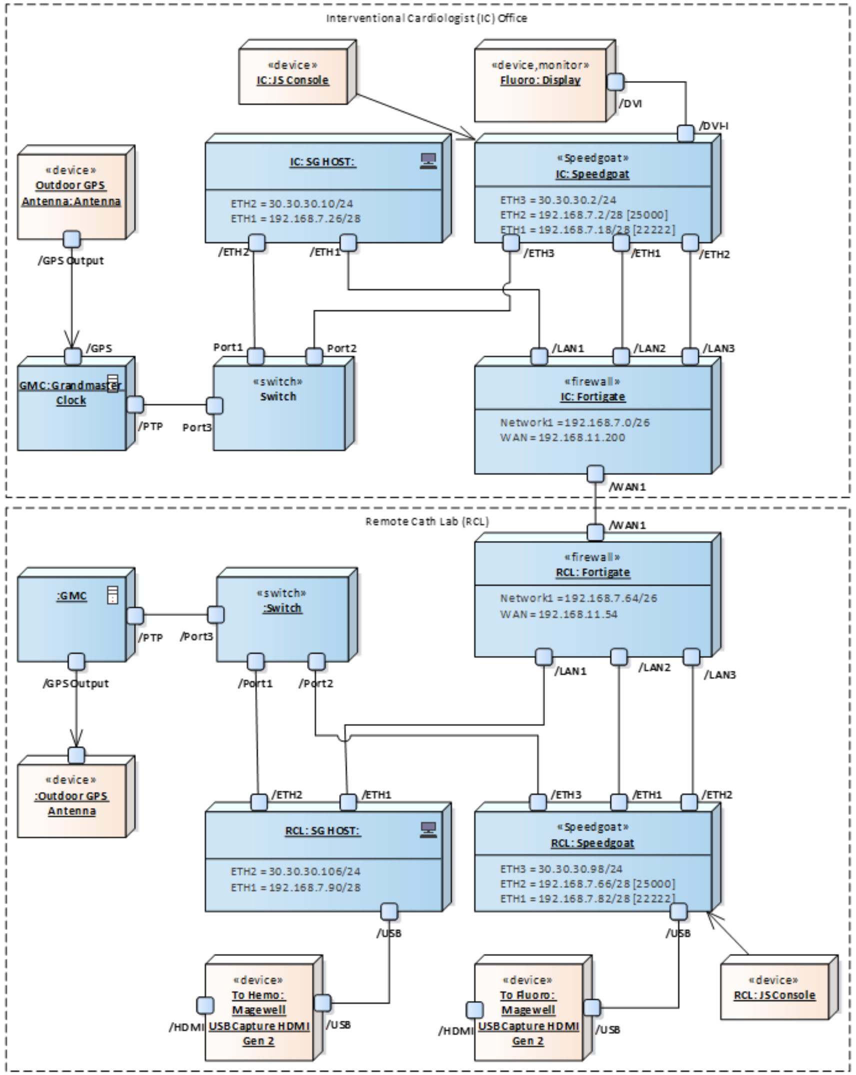


Remote Cath Lab

- Firewall with Real-Time Hardware Enabled IPSEC VPN (Gigabit, low latency)
- Simulink Real-Time speedgoat target
  - USB 3.0 based Image capture and compression of fluoro via. Magewell
  - PTP synchronization to GPS referenced Grandmaster Clock via ETH3
  - FPGA based IO for JS Console
  - High Speed CAN interface to GRX Robodrive
  - Image and C2 comm via ETH2 with IC
- Host machine
  - Console GUI for C2 via ETH1 to speedgoat
  - USB 3.0 based Image capture and compression of Hemodynamics

System Overview

Remote Architecture – C2



Intervention Cardiologist (IC) Office

- Firewall with Real-Time Hardware Enabled IPSEC VPN (Gigabit, low latency)
- Simulink Real-Time speedgoat target
  - Image decompression and display of fluoro
  - PTP synchronization to GPS referenced <u>Grandmaster Clock</u> via ETH3
  - FPGA based IO for <u>JS Console</u>
  - Image and C2 comm. via ETH2 with RCL
- Host machine
  - Console GUI for C2 via ETH1 to speedgoat
  - Image decompression and display of Hemodynamics
  - Capacative touchscreen for improved immersion and access

Remote Technology Development

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Achievements & Planned Milestones

2017 | 2018 | 2019

Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019

Q4 2017 – Remote Demonstration

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Q1 2018 – Technology Development

- Realtime fluoroscopy
- Realtime hemo
- Telepresence system
- Network monitoring tool

Q2 2018 – Product Development

MAYO CLINIC HEALTH SYSTEM

Q2 2018 – End User Testing

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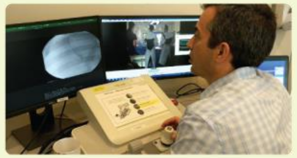
Q3 2018 – 100 Mile Remote PCI Case



SPECTRUM HEALTH

Q3 2018 – Preclinical Labs

MAYO CLINIC HEALTH SYSTEM

Q3 2018 – Live Remote Case

tct2018

Q4 2018 – First Human Use Case

APEX HEART INSTITUTE™

Q4 2018 – 5G Pilot

verizon

Q1 2019 – Initialize Remote Commercialization Process

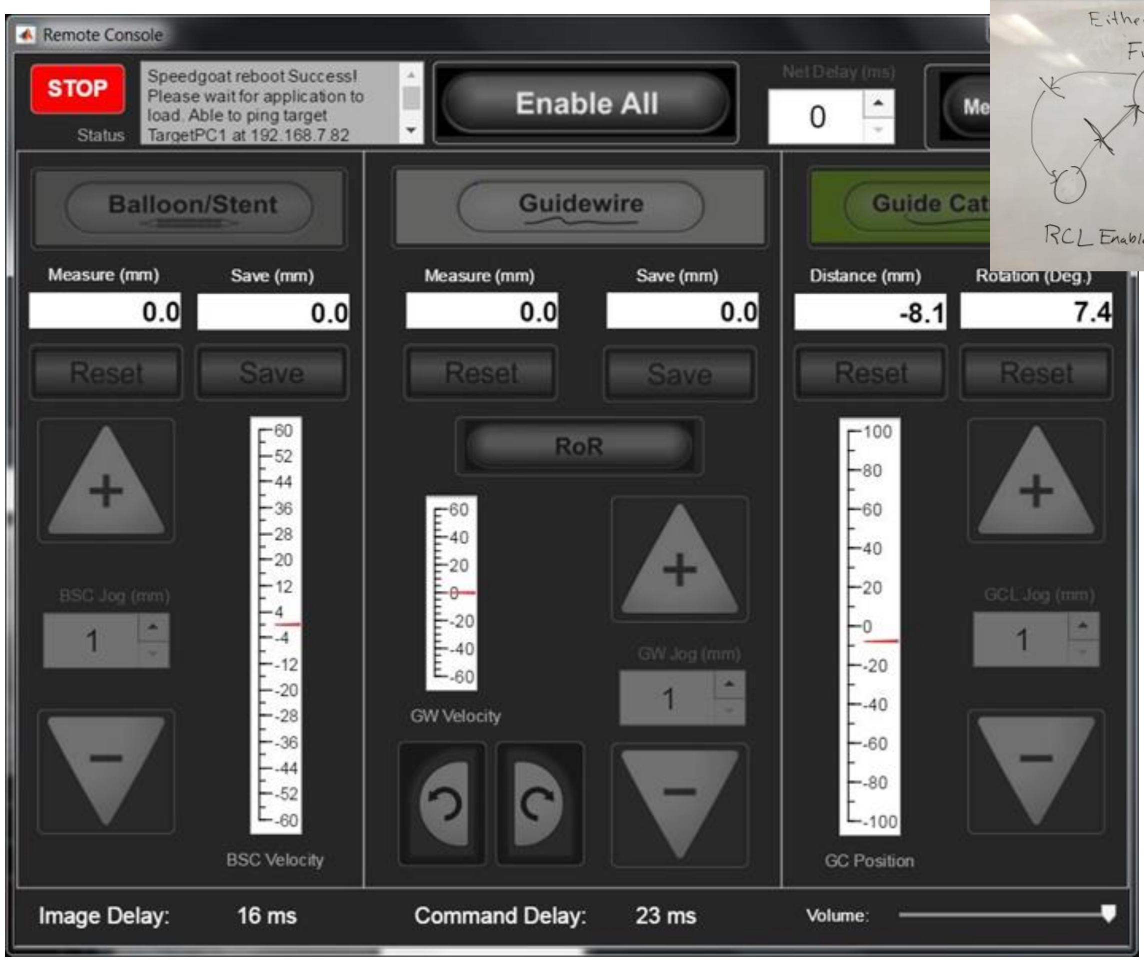
Videos & Presentations

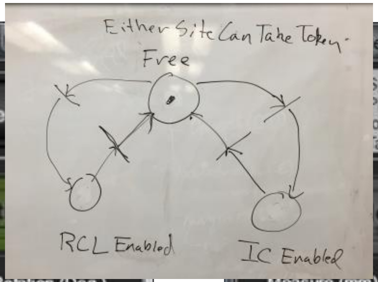
- TCT 2018 Presentations
- TCT 2018 Live Cases
- Corindus Channel

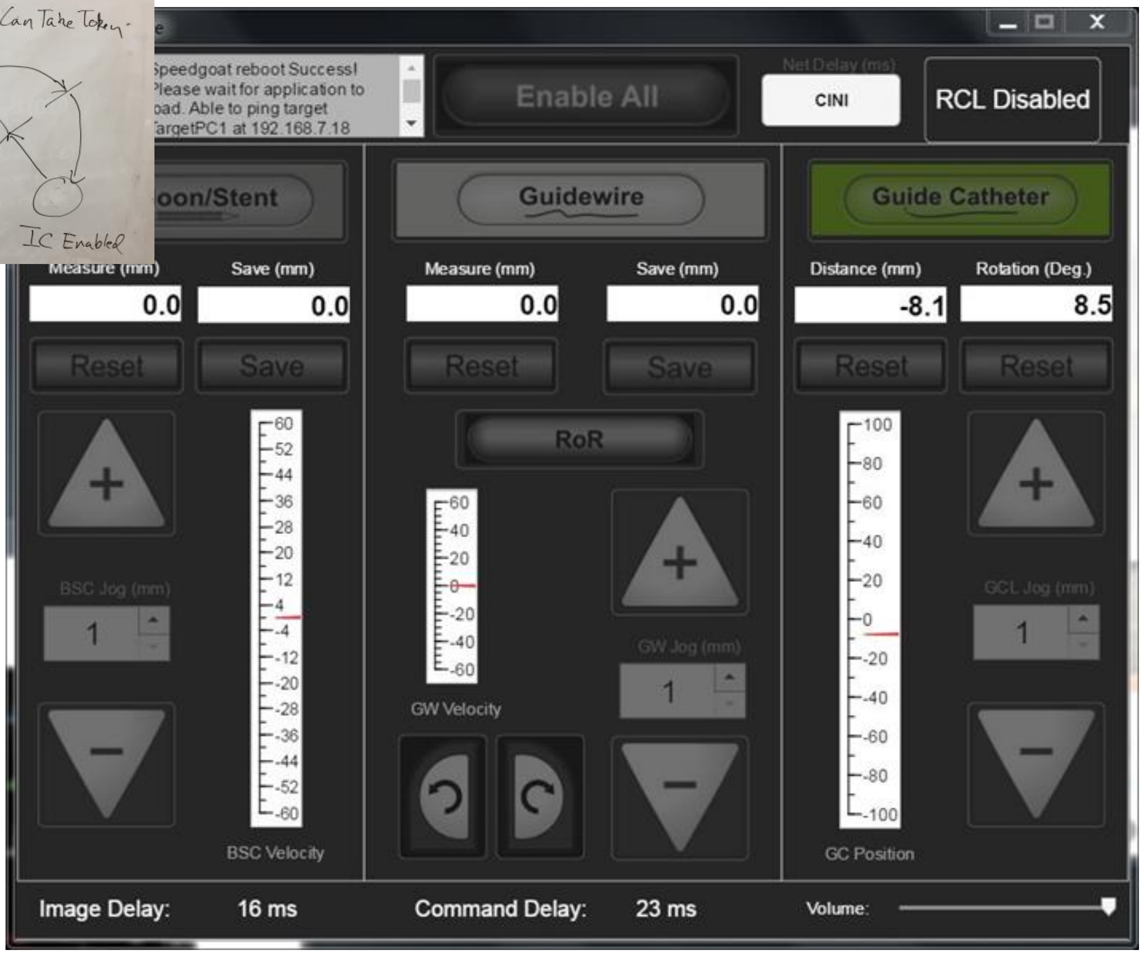
For Fun : Deadlock Free Petri Net For IC and RCL C2

RCL-IC Console Petri Net

RCL without Token & IC without Token





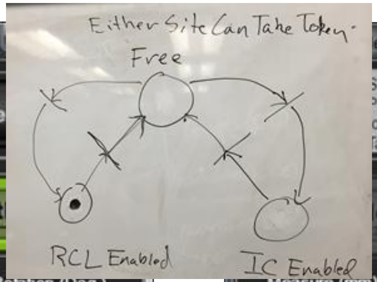


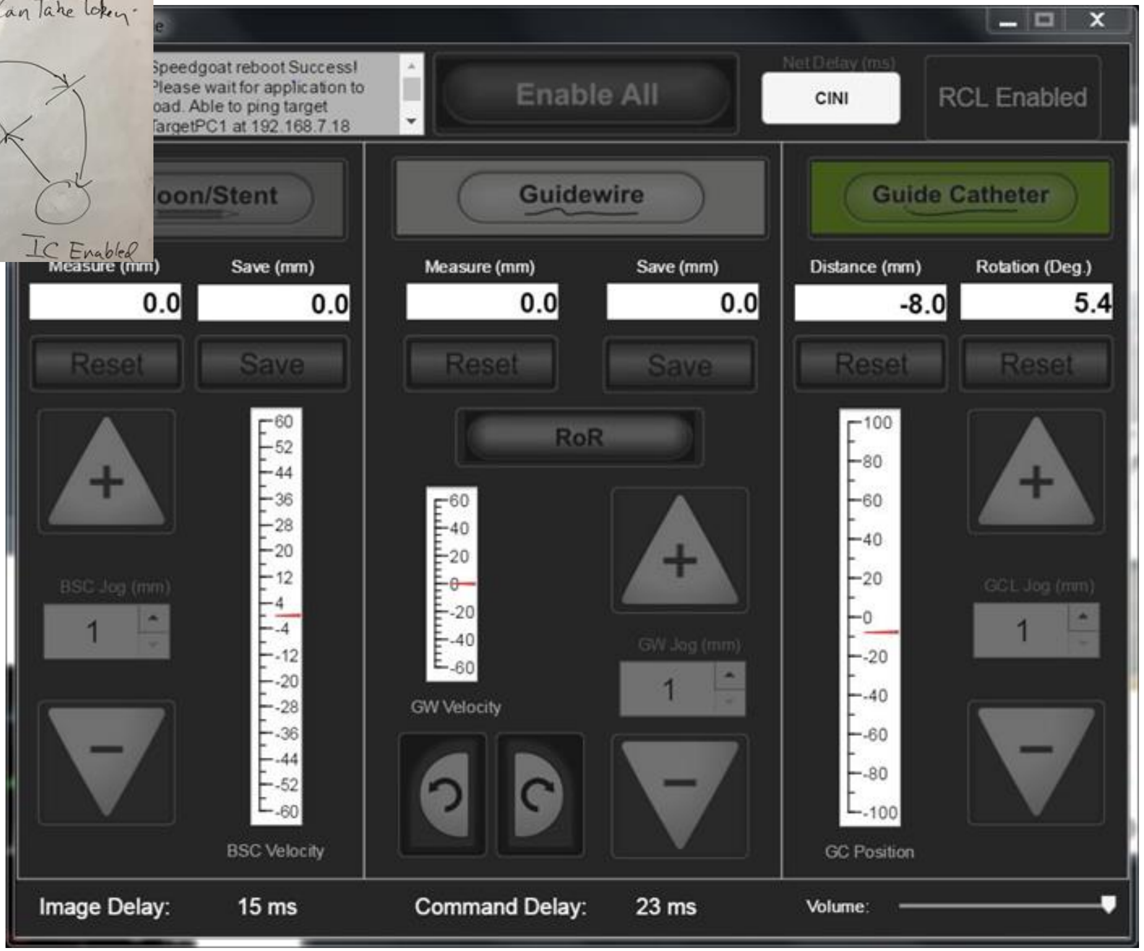
RCL Disabled (without Token)

IC Disabled (without Token)

RCL-IC Console Petri Net

RCL with Token & IC without Token





RCL Enabled (with Token)

IC Disabled (without Token)

RCL-IC Console Petri Net

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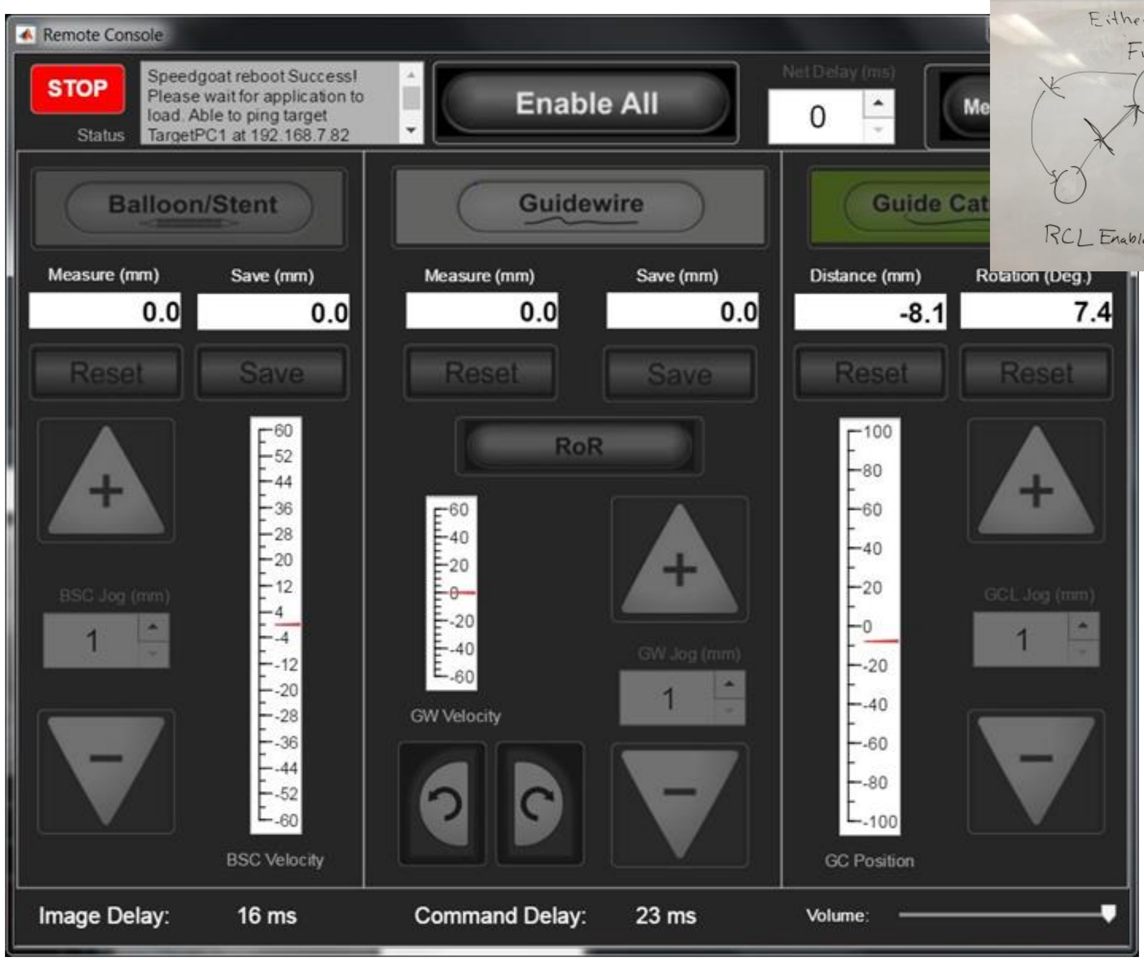
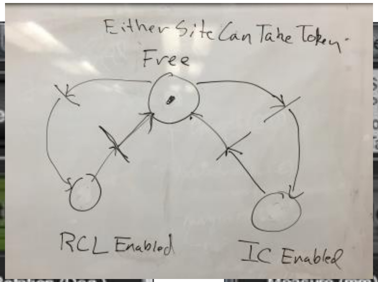
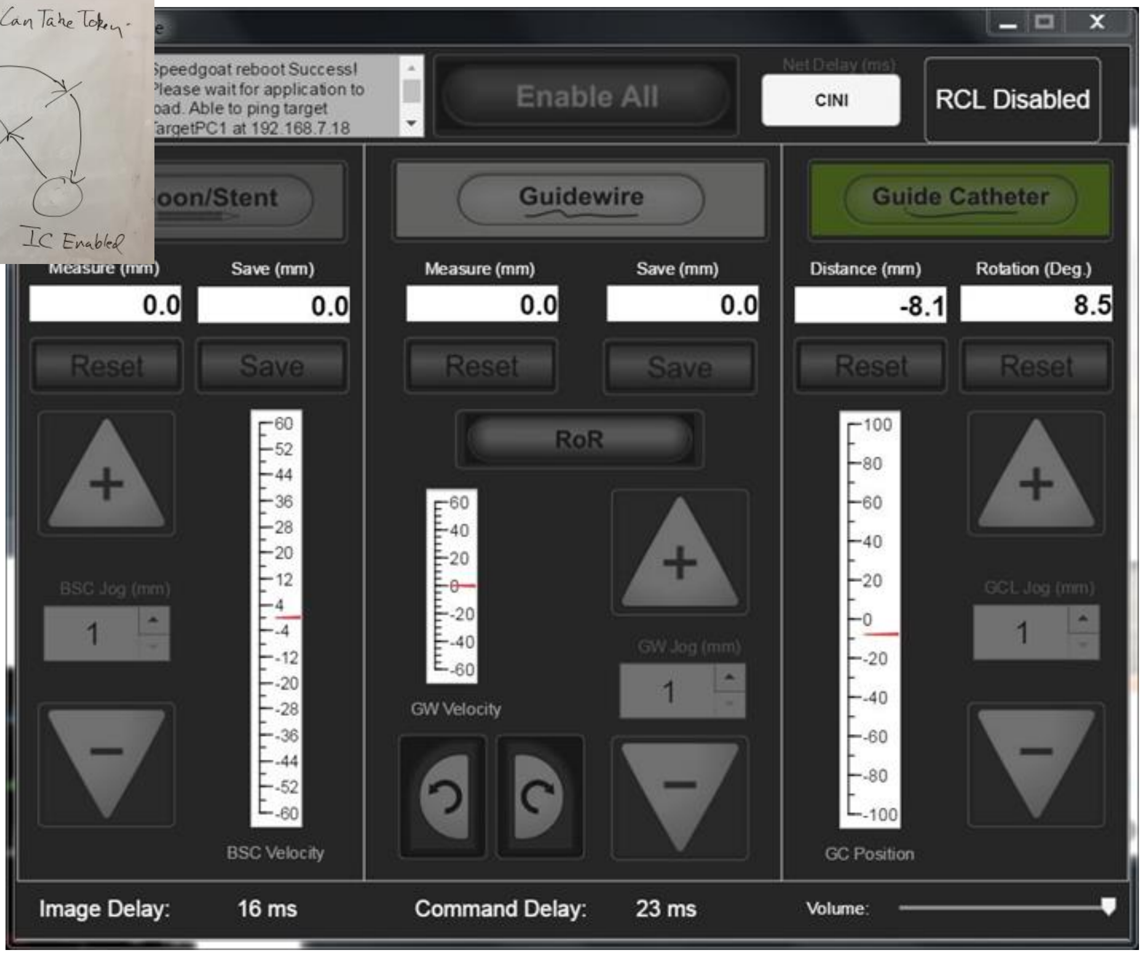
RCL without Token & IC without Token





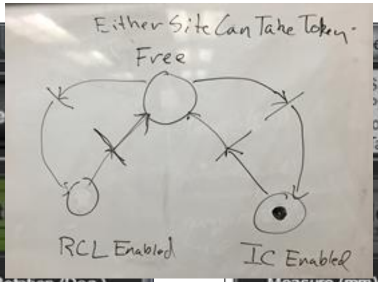


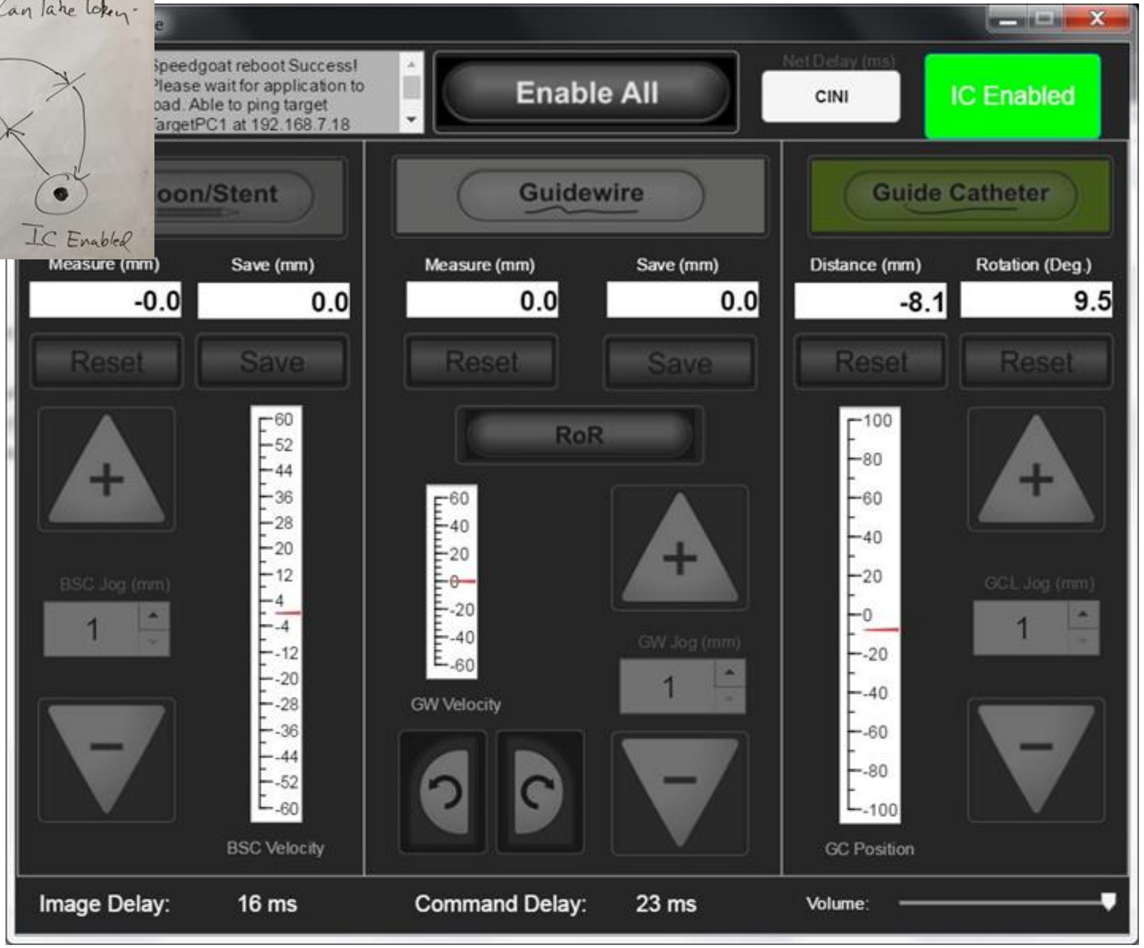
RCL Disabled (without Token)

IC Disabled (without Token)

RCL-IC Console Petri Net

RCL without Token & IC with Token





RCL Disabled (without Token)

IC Ready to Enable All (with Token)