

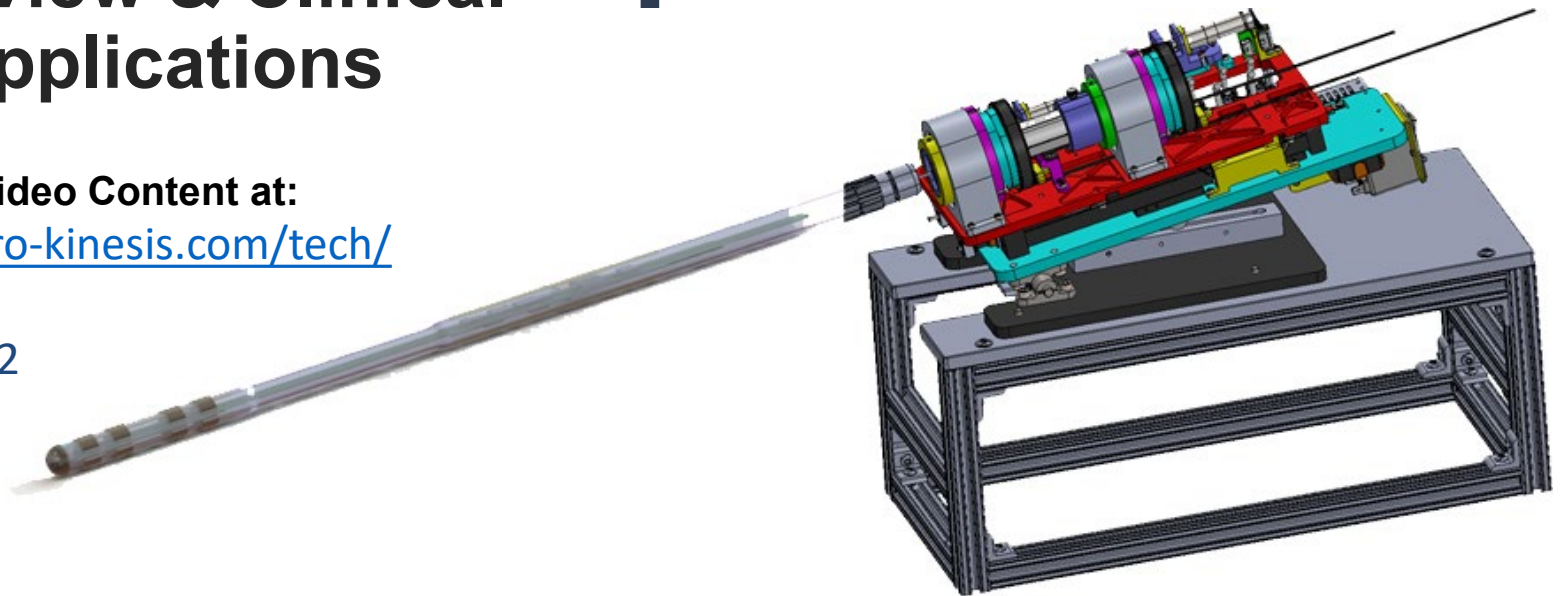
# NEUROKINESIS CORPORATION

## Huygens-Proteus-LAS Overview & Clinical Applications

Additional Video Content at:  
<https://neuro-kinesis.com/tech/>

PW: nkc2022

Prepared for Presentation:  
04/27/2022





# NKC Development Milestones

## Proteus Robotic Arm

The Robotic system hardware and software for 4x full systems has been completed.

## Huygens

The catheter validation is in progress, and all parameters have been verified for rev.5 (11French), and rev.6 (9fr) will be completed by May 10, 2022.

## Lorentz Active Sheath (LAS)

Will also be completed on May 10, 2022.

## Integrated Operating Room

Currently, the NKC Integrated Operating Room containing the Proteus/Huygens/LAS is scheduled for presentation to our potential strategic player on May 26<sup>th</sup>, 2022.

## Validation

Full System Installation at Inglewood lab facility, May 17-18, 2022.

## Animal Study

Term Sheet Signed with Rambam and Univ. of Haifa

Animal Testing at Rambam Hospital (Haifa, IL), July 15, 2022

# Regulatory Highlights

## ISO 1385 Highlights:

- Will be conducted with SAI Global
- Pre-Assessment beginning May 6, 2022
- Stage 1 out of 2 will be scheduled after Pre-Assessment (roughly 4 weeks after)



## Medical Device Regulation (MDR) Highlights:

- Will be conducted with DNV
- 5-Year certification estimate proposal has been agreed upon and signed by both parties
- In queue for MDR application process

# NKC Proprietary Technologies

## NKC Robotic Navigation Suite, comprised of Huygens™ Smart Catheter, Lorentz™ Active Sheath & Proteus™ Robotic Arm



US 20200375541A1

(19) **United States**  
(12) **Patent Application Publication** (10) **Pub. No.:** US 2020/0375541 A1  
**Shachar et al.** (43) **Pub. Date:** Dec. 3, 2020

(54) **OPTICALLY COUPLED CATHETER AND METHOD OF USING THE SAME** (52) **U.S. CL.**  
CPC: *A61B 5/0632* (2013.01); *A61B 5/04002* (2013.01); *A61B 2013/0166* (2013.01); *A61B 5/7435* (2013.01); *A61B 5/0084* (2013.01); *A61B 5/0017* (2013.01)

(71) Applicant: **Neurokines Corp.**, Los Angeles, CA (US)

(72) Inventors: **Josh Shachar**, Santa Monica, CA (US); **Marc Rockinger**, Marina del Rey, CA (US); **Eli Gong**, Los Angeles, CA (US)

(73) Assignee: **Neurokines Corp.**, Los Angeles, CA (US)

(21) Appl. No.: **16424,202**

(22) Filed: **May 28, 2019**

**Publication Classification**

(51) **Int. Cl.** (2006.01)  
*A61B 5/00* (2006.01)  
*A61B 5/04* (2006.01)

(57) **ABSTRACT**  
The embodiments include an apparatus used in combination with a computer for sensing biopotentials. The apparatus includes a catheter in which there is a plurality of sensing electrodes, a corresponding plurality of local amplifiers, each coupled to one of the plurality of sensing electrodes, a data, control and power circuit coupled to the plurality of local amplifiers, and a photonic device bidirectionally communicating an electrical signal with the data, control and power circuit. An optical fiber optically communicated with the photonic device. The photonic device bidirectionally communicates an optical signal with the optical fiber. An optical interface device provides optical power to the optical fiber and hence to the photonic device and receives optical signals through the optical fiber from the photonic device. The optical interface device bidirectionally communicates an electrical data, control and power signal to the computer.

(19) **United States**  
(12) **Patent Application Publication** (10) **Pub. No.:** US 2009/0253985 A1  
**Shachar et al.** (43) **Pub. Date:** Oct. 8, 2009



US 20090253985A1

(54) **APPARATUS AND METHOD FOR LORENTZ-ACTIVE SHEATH DISPLAY AND CONTROL OF SURGICAL TOOLS** (51) **U.S. CL.**  
CPC: *A61B 5/06* (2006.01)

(75) Inventors: **Yehoshua Shachar**, Santa Monica, CA (US); **Bruce Marx**, Ojai, CA (US); **Leslie Farkas**, Ojai, CA (US); **David Johnson**, West Hollywood, CA (US); **Laszlo Farkas**, Ojai, CA (US)

Correspondence Address: **KNORR, MARTENS OLSON & BEAR LLP**, 2040 MAIN STREET, FOURTEENTH FLOOR, IRVINE, CA 92614 (US)

(73) Assignee: **Magnetics, Inc.**, Inglewood, CA (US)

(21) Appl. No.: **12099,079**

(22) Filed: **Apr. 7, 2008**

**Publication Classification**  
(51) **Int. Cl.** (2006.01)  
*A61B 5/06* (2006.01)  
(52) **U.S. CL.** (2006.01)  
**680/424**

(57) **ABSTRACT**  
The Lorentz-Active Sheath (LAS) serves as a conduit for other medical devices such as catheters, balloons, biopsy needles, etc. The sheath is inserted through a vein or other body orifice and is guided into the area of the patient where the operation is to be performed. The position and orientation of the LAS is tracked via an industry standard position detection system which senses electrical signals that are emitted from several electrodes coupled to the LAS. The signals received from the LAS are used to calculate an accurate and reliable assessment of the actual position of the LAS within the patient. The electrode signals also serve to create a reference frame which is then used to act as a motion compensation filter and fiducial alignment system for the movement of the LAS-hosted medical tool.

(12) **United States Patent** (10) **Patent No.:** **US 9,220,425 B2**  
**Shachar et al.** (45) **Date of Patent:** **Dec. 29, 2015**



US 9220425B2

(54) **METHOD AND APPARATUS FOR MEASURING BIOPOTENTIAL AND MAPPING EPICARDIAL COUPLING EMPLOYING A CATHETER WITH MOSFET SENSOR ARRAY** (52) **U.S. CL.**  
CPC: *A61B 5/0632* (2013.01); *A61B 5/04002* (2013.01); *A61B 2013/0166* (2013.01); *A61B 5/7435* (2013.01); *A61B 5/0084* (2013.01); *A61B 5/0017* (2013.01)

(71) Applicants: **Yehoshua Shachar**, Santa Monica, CA (US); **Eli Gong**, Los Angeles, CA (US)

(72) Inventors: **Yehoshua Shachar**, Santa Monica, CA (US); **Eli Gong**, Los Angeles, CA (US)

(73) Assignee: **Magnetics Corp.**, Inglewood, CA (US)

\* Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 580 days.

(21) Appl. No.: **13821,727**

(22) Filed: **Sep. 17, 2012**

(5) **Prior Publication Data**  
US 2014-0081114 A1 Mar. 20, 2014

(51) **Int. Cl.** (2006.01)  
*A61B 5/04* (2006.01)  
*A61B 5/0428* (2006.01)  
*A61B 5/00* (2006.01)  
*A61B 5/042* (2006.01)  
*A61B 5/0478* (2006.01)

(52) **U.S. CL.** (2006.01)  
*A61B 5/0001* (2013.01); *A61B 5/042* (2013.01); *A61B 5/04284* (2013.01); *A61B 5/0658* (2013.01); *A61B 5/0478* (2013.01)

(58) **Field of Classification Search**  
CPC: *A61B 5/0402*; *A61B 5/0422*; *A61B 5/04284*; *A61B 5/0408*; *A61B 5/042*; *A61B 5/0478*; *A61B 5/72*; *5/7296*; *A61B 2562/0296*; *A61B 2562/36*; *A61B 2017/00053*; *A61B 2017/00044*; *A61B 2017/00026*; *A61B 2017/00022*

(10) **Patent No.:** **US 9,220,425 B2**  
(45) **Date of Patent:** **Dec. 29, 2015**

USPC ..... 600/372-374, 377, 378, 381, 393, 509, 600/544-545

See application file for complete search history.

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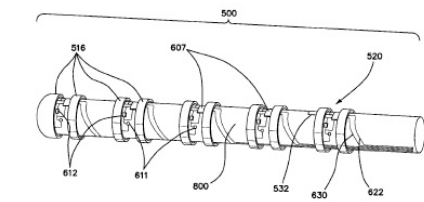
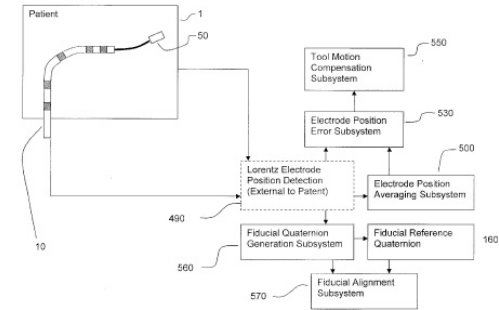
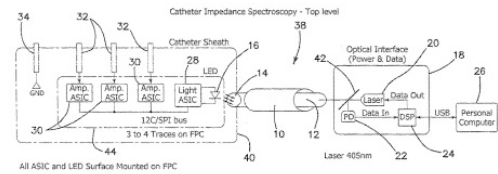
\* cited by examiner

**Primary Examiner** — Lee S Cohen  
**Assistant Examiner** — Erin M Cardinal  
(74) **Attorney, Agent, or Firm** — Marcus C. Dawes; Daniel L. Dawes

(57) **ABSTRACT**

This invention relates generally to electro-anatomical mapping method and an apparatus using a catheter and more particularly to mapping catheter having an embedded MOSFET sensor array for detecting local electrophysiological parameters such as biopotential signals within an excitable cellular matrix geometry, for determining physiological as well as electrical characteristics of conduction path and its underlying substrate within the endocardial and epicardial spaces, the arterial structure and its ganglionic plexus. The apparatus with its MOSFET sensor is geometrically configured as a decapolar linear array and optionally with an 8x8 sensor matrix placed on a balloon-like structure.

13 Claims, 25 Drawing Sheets



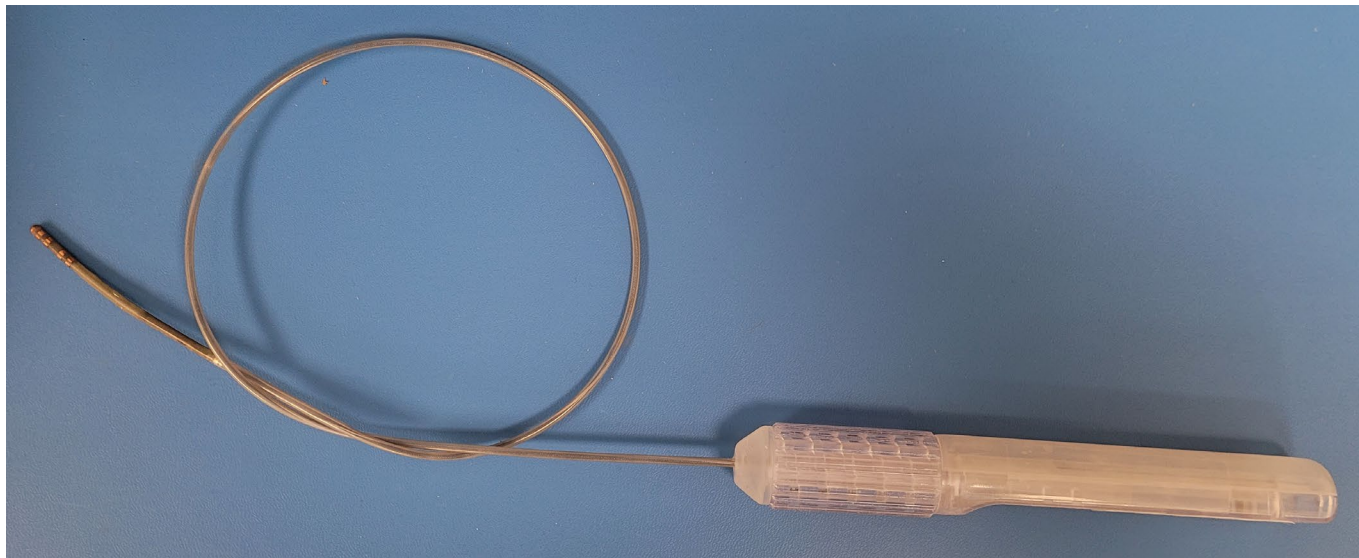
**Combined Patents and Applications  
for Patents assigned to Neuro-  
Kinesis Corp.**

#	Property Type	Number
1	Patent Number:	8986214
2	Patent Number:	9381063
3	Patent Number:	9220425
4	Application Number:	14797020
5	Application Number:	12475370
6	Patent Number:	9655539
7	Application Number:	13314273
8	Application Number:	13966526
9	Patent Number:	8684010
10	Patent Number:	7769427
11	Application Number:	11331781
12	Application Number:	11331944
13	Patent Number:	7873401
14	Patent Number:	7280863
15	Patent Number:	7873402

16	Patent Number:	8027714
17	Application Number:	13245310
18	Patent Number:	7869854
19	Application Number:	12480566
20	Application Number:	11697690
21	Application Number:	13440188
22	Application Number:	12103518
23	Application Number:	13464091
24	Application Number:	12099079
25	Application Number:	13450148
26	Application Number:	12113804
27	Application Number:	13491300
28	Patent Number:	8457714
29	Application Number:	12582588
30	Application Number:	13470084
31	Application Number:	12582621
32	Application Number:	13450323
33	Application Number:	12615176

# Introduction

Huygens™ Catheter is an endocardial diagnostic catheter that reads cardiac biopotential signals. Through local amplification and digitization at the catheter tip, Huygens Catheter provides superior signal quality over the current analog market catheters. Furthermore, this device contains impedance measuring capability that allows physicians to differentiate heart tissue from blood pool.

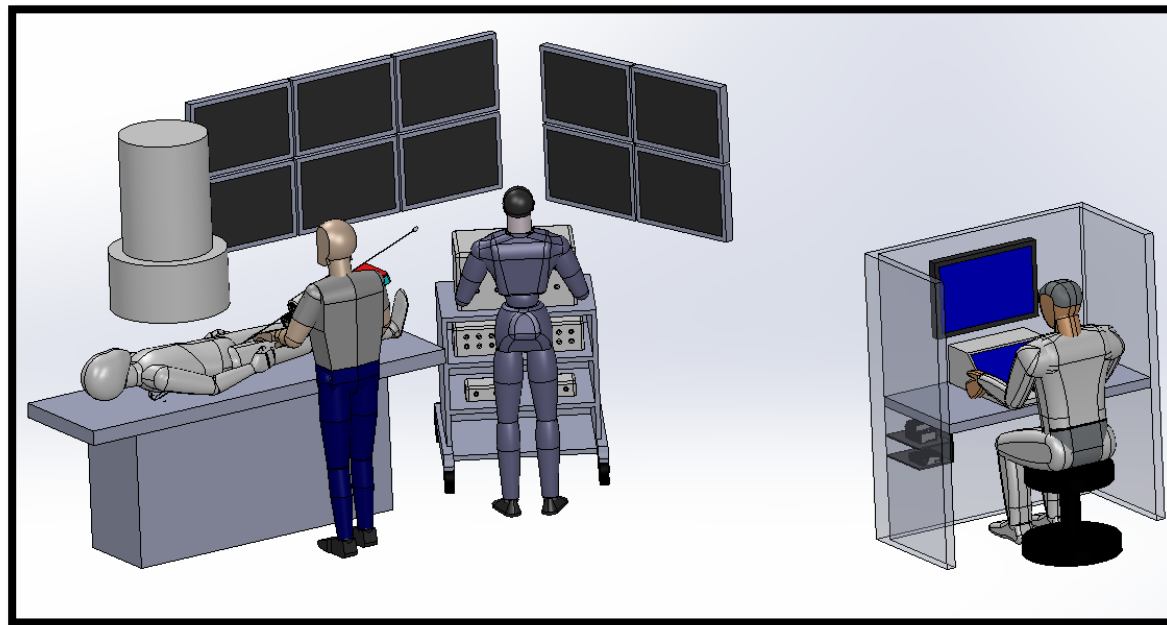


Huygens™ Catheter Prototype



# Introduction

The Huygens™ Catheter can pair with the Proteus™ Robotic Arm to enable navigational features. With artificial intelligence (AI) and 3 – axial coordinates of position and orientation of the catheter, the Proteus system can automatically maneuver around the patient heart and navigate the tip to the site of interest.



Simulated Proteus™ Robotic  
Armand Huygens™ Catheter Setup

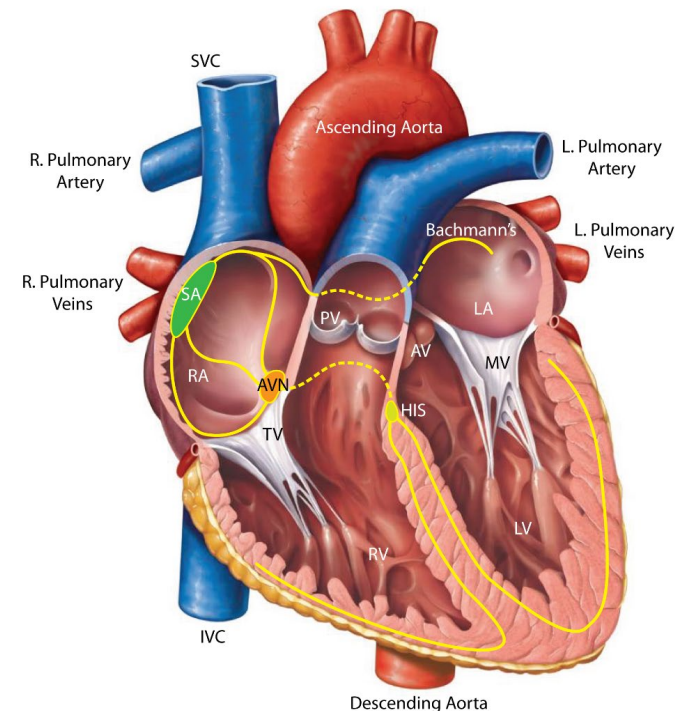
# Huygens & Proteus™ within EP Mapping Market

## EP Mapping Overview

Electrophysiologic testing and radiofrequency ablation have evolved as curative measures for a variety of rhythm disturbances.

- relatively straightforward arrhythmias (such as atrioventricular [AV] nodal reentry or tachycardias)
- complex arrhythmias, including atypical atrial flutter, atrial fibrillation, and ventricular tachycardia, often associated with significant underlying structural cardiac abnormalities, such as congenital, ischemic, and post-surgical heart disease.

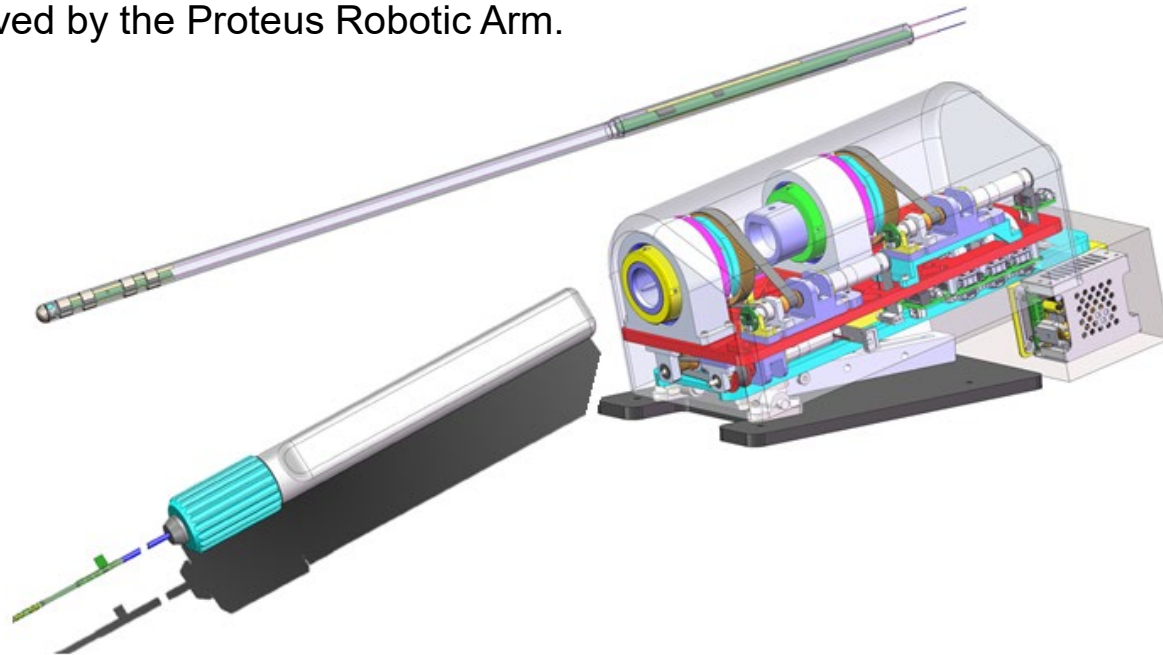
Broader use of EP testing and RFA in such individuals has been accompanied by technological enhancements such as Electroanatomic mapping (EAM), allowing operators to record intracardiac electrical activation in relation to anatomic location in a cardiac chamber of interest, during arrhythmia mapping.



# The Huygens Advantage

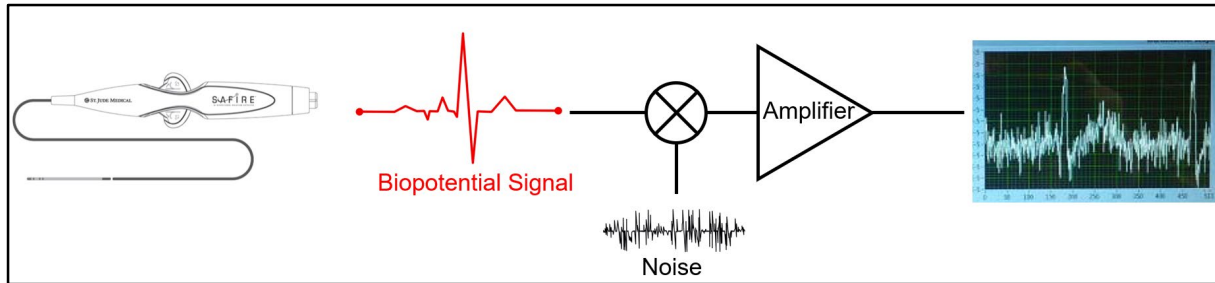
NKC understanding of the strengths and limitations of the use of EAM in treating pacing disturbances concentrated its effort in improving two areas of concern to EP physicians.

- **Accuracy and resolution** of the data-gathering from the electro-anatomical site, comprised of SNR and resolution by which the system can measure small electrical signals – the Huygens catheter solution.
- **Navigation.** While able to recreate an electro-anatomical map that captures chamber reconstruction, tagging of important anatomic landmarks and ablation lesions, display of diagnostic and mapping catheters without using fluoroscopy, activation mapping, and voltage (or scar) mapping, the other significant improvement NKC is concentrating on is to reduce the required dexterity of the physician to a machine language using robotics such as conceived by the Proteus Robotic Arm.



# Local Amplification

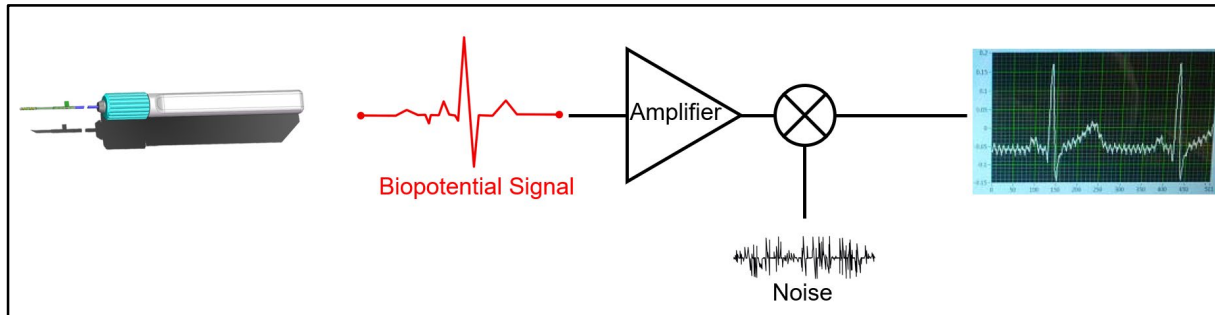
## Competitor Catheter System



Huygens™ catheter's local amplification feature allows the cardiac signals to be amplified before the noise is introduced to the system.

The diagram on the right shows the electrical flow chart of the biopotential signals.

## Huygens™ Catheter System

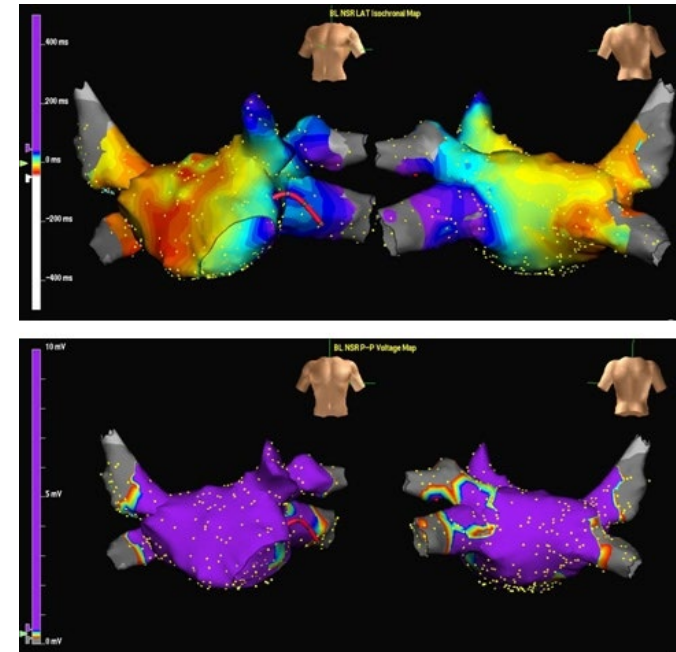


As the noise is added after the amplification stage, the raw and unfiltered signal quality of Huygens™ catheter is superior to the competitor's signal.

# Integration with Electro-Anatomical Mapping (EAM)

Huygens™ catheter has broad applications in EAM, and is compatible with standard mapping system such as Prucka CardioLab, EnSite NavX, and others, capable of displaying 3D positions of multiple catheters as follows:

- The Huygens catheter records voltage and impedance at the electrodes located on the catheter shaft, (using locator skin patches customarily employed during such procedures), thereby defining their location in space, triangulated with a reference CS catheter electrode.
- Three-dimensional images of the catheter can then be displayed.
- Respiratory motion artifact can also be eliminated to prevent confounding of actual catheter position.
- Chamber geometry can be determined thereafter by moving a mapping catheter along the endocardial surface.
- Creation of EAM and improvements of imaging reduces the need for X-ray imaging.



Electroanatomical maps acquired by the Ensite NavX system. A. Top. Activation map of the LA during sinus rhythm, AP and PA views. Bottom. Simultaneously-acquired voltage map of the LA, demonstrating low-amplitude EGMs in the PV ostia. B. Posteroanterior view of the LA and PVs.



# Noncontact Mapping

The noncontact mapping system utilizes a multi-electrode array (MEA) catheter to simultaneously record multiple areas of endocardial activation. Hence, relatively high-density mapping can be performed from even a single heartbeat.

A Huygens™ quadripolar catheter will reduce the need for multiple catheters.

**A “Smart” Catheter** – The electronics of Huygens catheter improves signal measurement quality of recorded data set where:

$$\langle t_o, x_p, y_p, z_p, x_o, y_o, z_o, \Omega, \bar{Z} \rangle$$

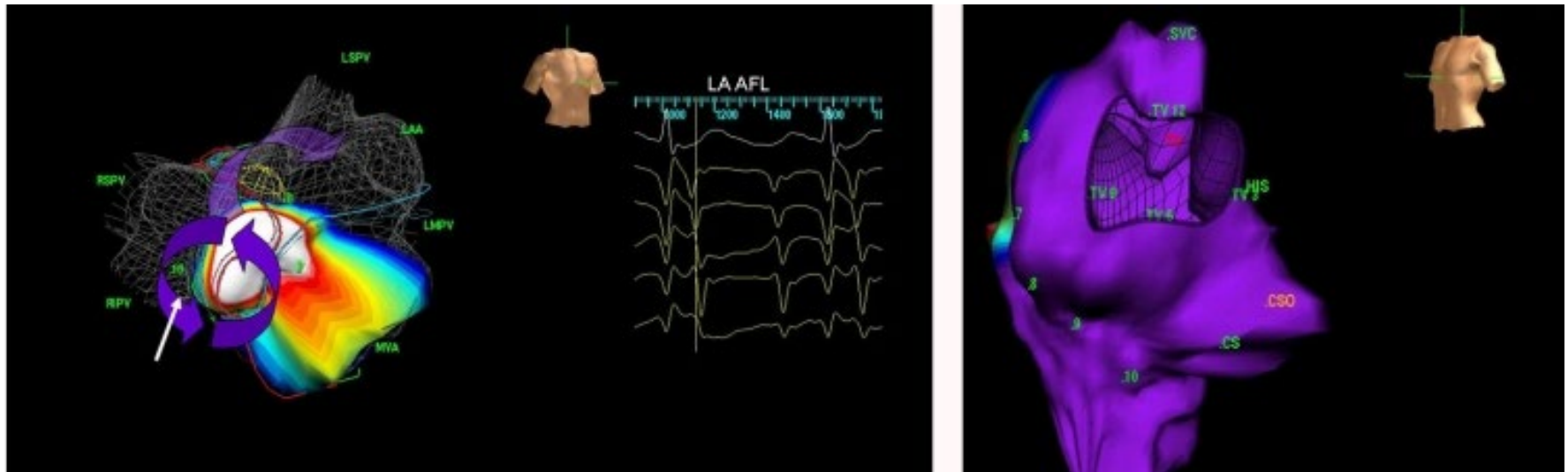
(time, position, orientation, DC potential, impedance)

- Position & orientation vectors are measured according to standard practice
- DC voltage potential is higher resolution than existing method (5μV as opposed to 50μV)
- Potential measurement is amplified 20x to provide a 1mV signal
- Signal is digitized at the source to preserve signal fidelity
- Sampling rate is higher than existing method (1kHz vs. 50Hz)

## 3D Localization

3D localization of surface electrodes is achieved by applying a low-level current between electrode on distal end of catheter and two ring electrodes along its shaft.

Chamber geometry is reconstructed by manipulating mapping catheter within the chamber of interest and the corresponding electrical isopotentials can be "plotted" on this geometric representation of the endocardial surface.



### Electroanatomic maps acquired by using a MEA.

Left: Activation map of macro-reentrant LA flutter. The arrows depict wavefront propagation within the flutter circuit.

Right: Anatomical reconstruction of the RA.

# Real-Time Position Management System

A Real-Time Position Management System (RTPMS) employs RF ranging to localize reference and mapping/ablation catheter positions.

## Reference

A reference catheter, typically situated in the Right Atrium at the Coronary Sinus, and the mapping/ablation catheter.

**Trilateralization** or position of the Catheter is accomplished via transmission of energy from the patches (5.6kHz), received by an outside source, where the reference catheter is used to gauge the dynamics of the diagnostic catheter on the Left Atrium.

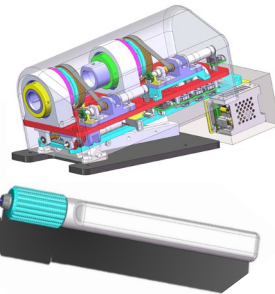
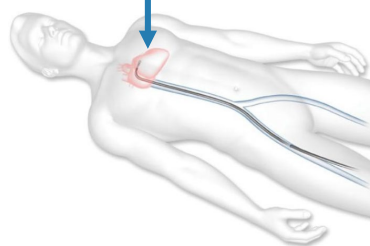
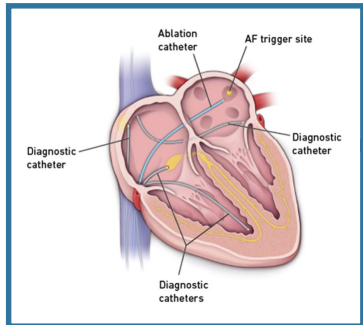
Transducers housed within the reference and ablation catheters; the time required to receive this signal by each transducer is converted to a distance and the position of each catheter is thereby determined, forming the relative position of the catheter on the endocardial surfaces.

Specific advantages of the Huygens™ system include

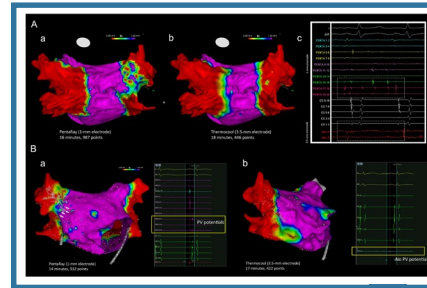
- Continuous real-time location of the catheters,
- Ability to demonstrate the degree of catheter deflection,
- Capability to reposition reference catheters to their original location should they become dislodged, as these locations can be stored.

# System Overview

## 1. Catheter Tip



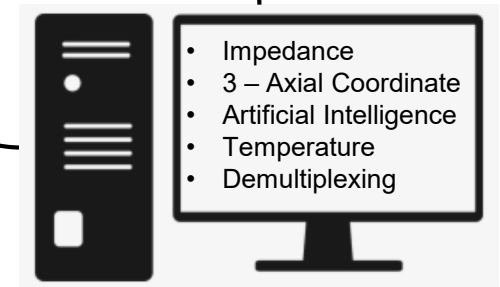
## 2. Handle + Proteus Arm



## 5. Mapping Station



## 4. Prucka System



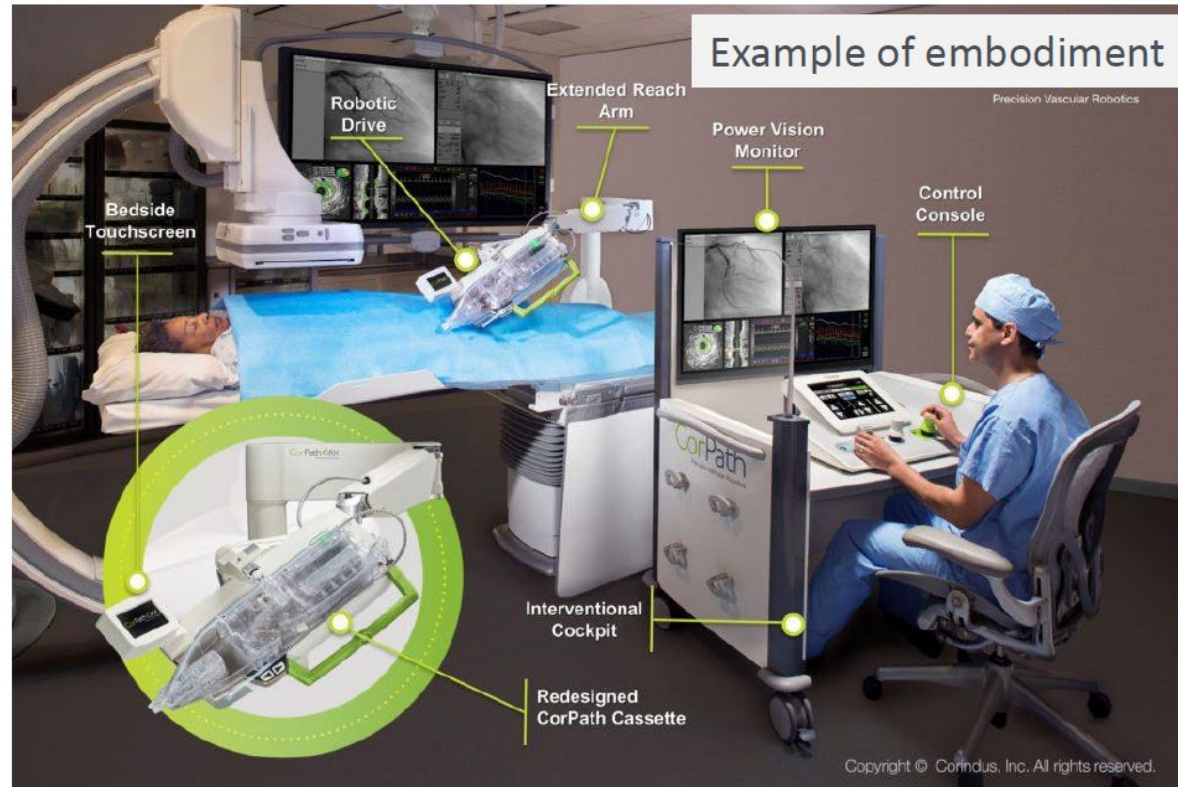
## 3. Industrial PC

- Impedance
- 3 – Axial Coordinate
- Artificial Intelligence
- Temperature
- Demultiplexing

# System Overview

The operation room of Huygens™ Catheter will contain:

- Huygens™ Catheter – Collect, amplify, and digitize the biopotential cardiac signal.
- Proteus™ Robotic Arm – Automatically maneuver the catheter to locate/ablate the targeted area.
- Industrial PC – Process the digitized biopotential signals and form a communication line between the catheter and the mapping station, as well as control and automate the Proteus™ Robotic Arm.
- Cardiolab (Prucka) – Display the demultiplexed biopotential signals to diagnose heart disease models.



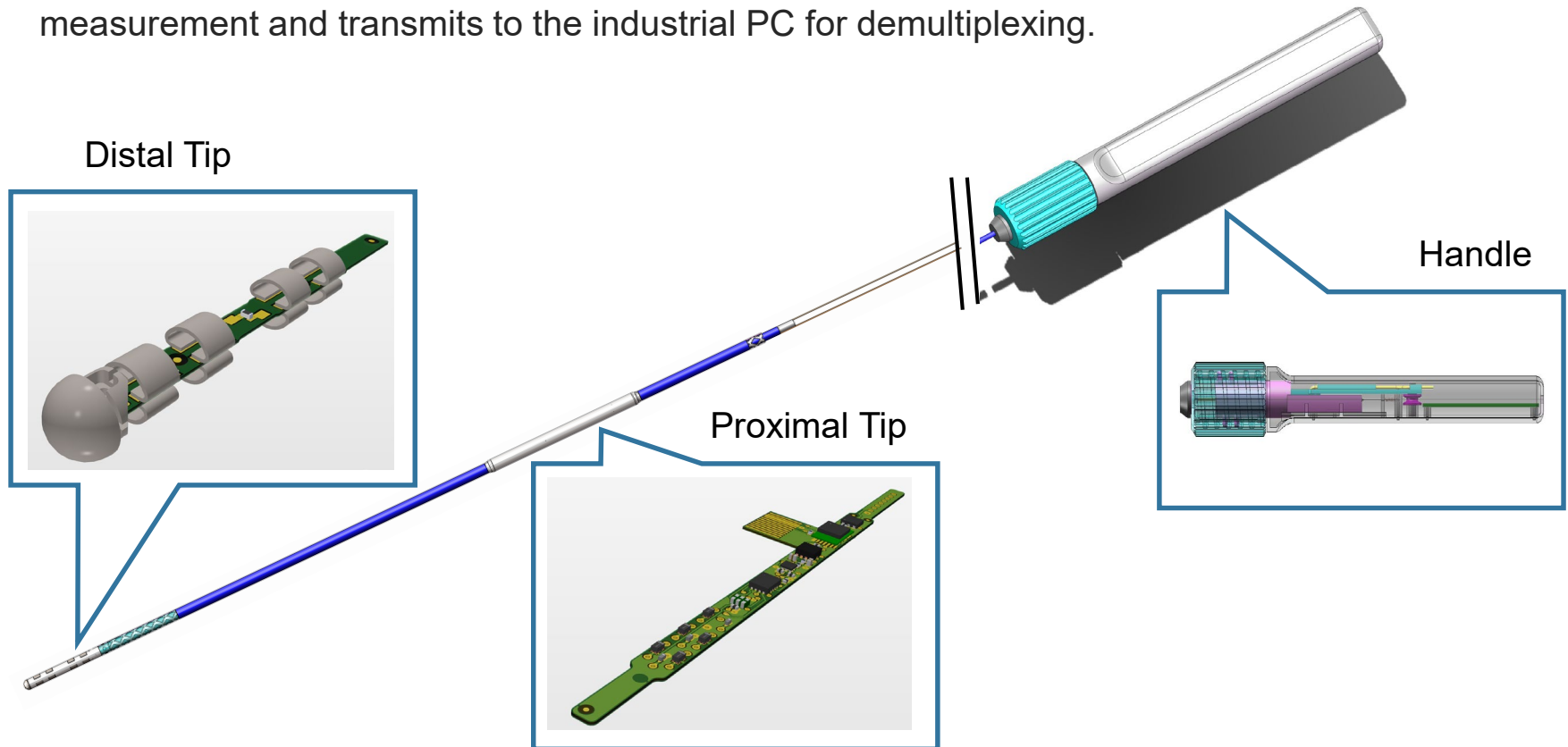
Simulated Operation room with catheter, robotic driven arm, monitor, and control console.



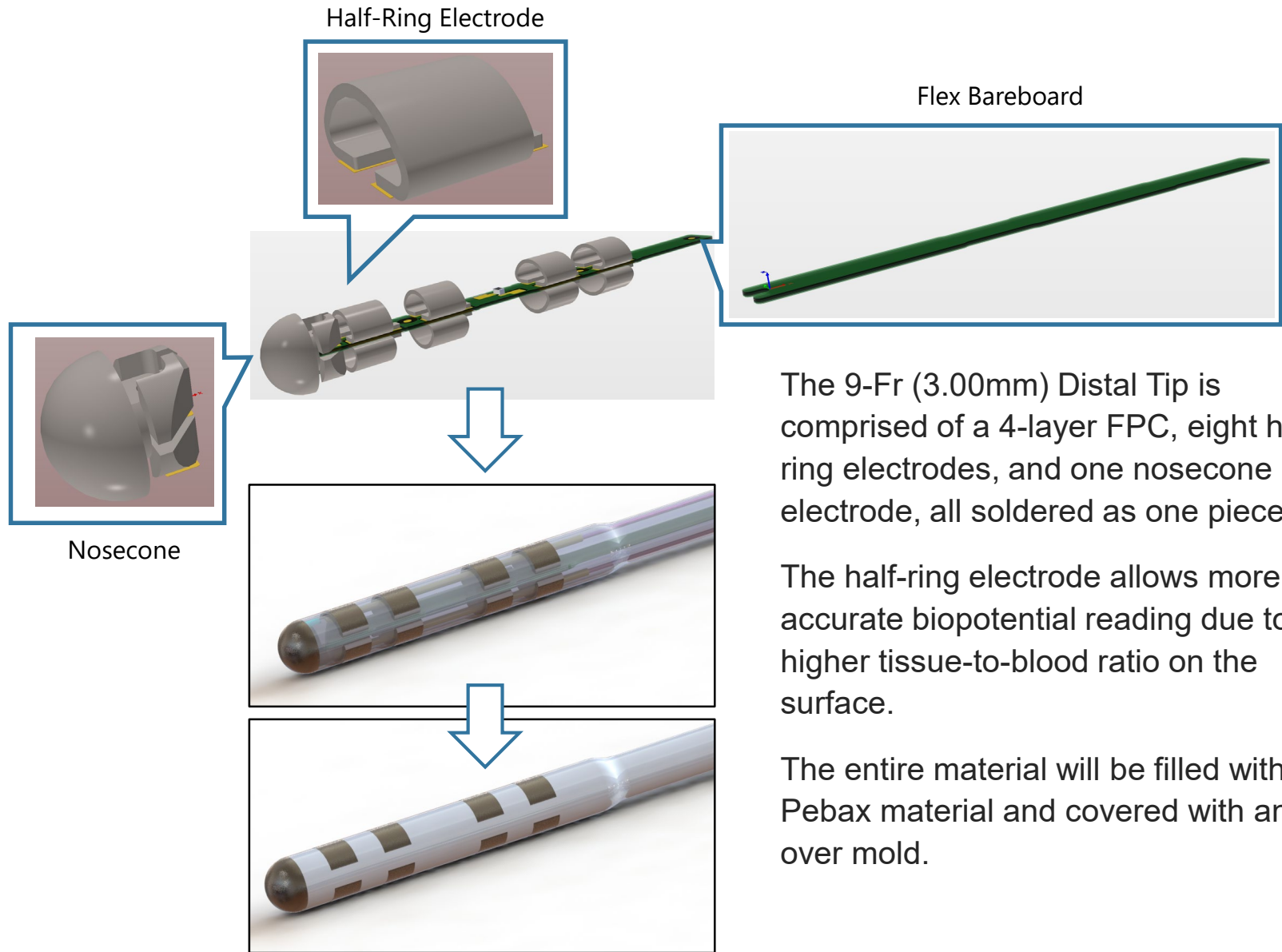
# Huygens™ Catheter Sectional Overview

Catheter is mainly divided into three sections, tip, sheath, and handle. The Huygens catheter further divides the tip into two sections: distal tip, which contains 9 electrodes (one nosecone and eight half-ring), and proximal tip, which contains electronics that allow local amplification and digitization.

The handle assesses digitized biopotential signals from the tip along with the impedance measurement and transmits to the industrial PC for demultiplexing.

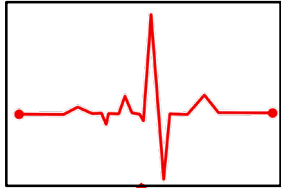


# Catheter Tip Overview



# Catheter Tip Function

Electrophysiological signal enters to the electrodes

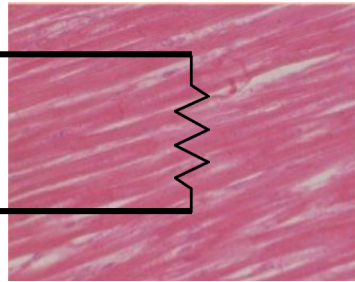


8 signals are multiplexed to 1

Multiplexed signal is amplified

Amplified signal is digitized and sent to handle

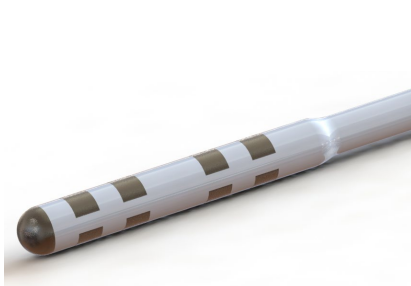
Impedance Measurement



Electrode sends small AC current to measure the impedance of its contact.

# Huygens™ Catheter Future

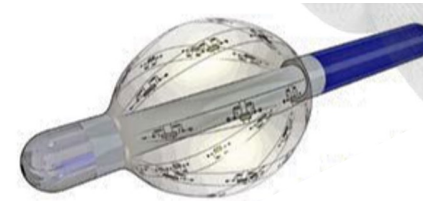
As the electronics are developed into one ASIC, a current quadripolar (4 half-ring electrodes) Huygens™ Catheter in development will further be improved as a decapolar (10 half-ring electrodes) and balloon (8 arrays of 8 half-ring electrodes).



Quadripolar Catheter

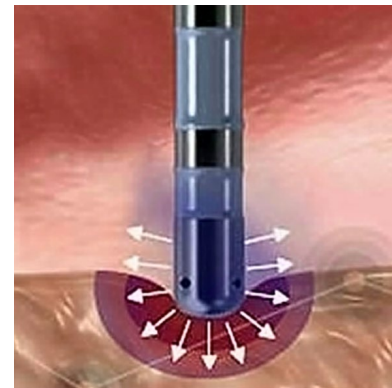


Decapolar Catheter



Balloon (64-Electrode) Catheter

Additional ablation feature that generates high RF frequency to the tip to ablate the cardiac tissues. Combined with impedance measurement feature, the ablation will be very efficient and accurate compared to the competing catheters.

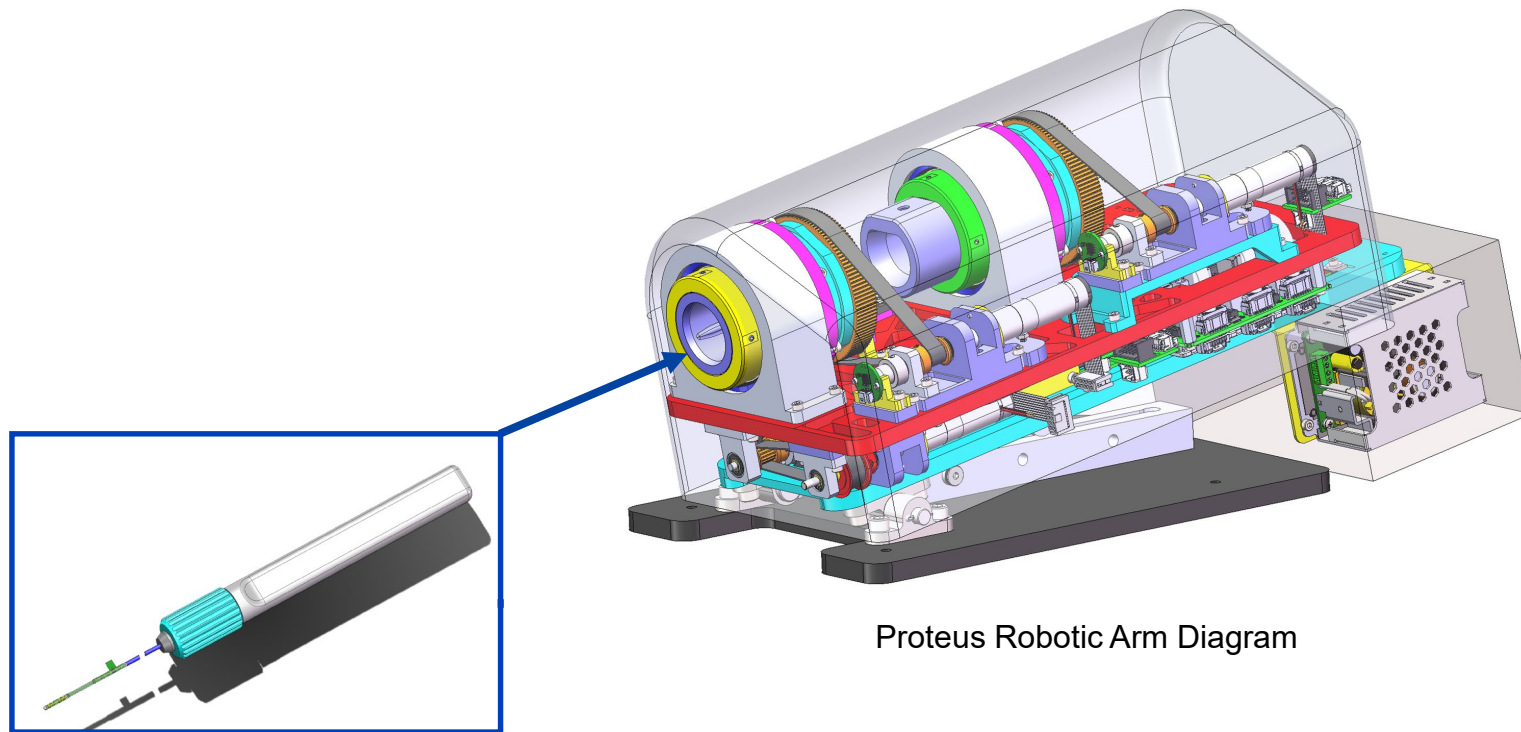


High RF Frequency Ablation  
Procedure onto Cardiac Tissue

# Robotic Arm Overview

The Proteus Robotic Arm contains three Maxon motors, each responsible for the corresponding 3-axial movement of deflection, translation, and rotation of the catheter.

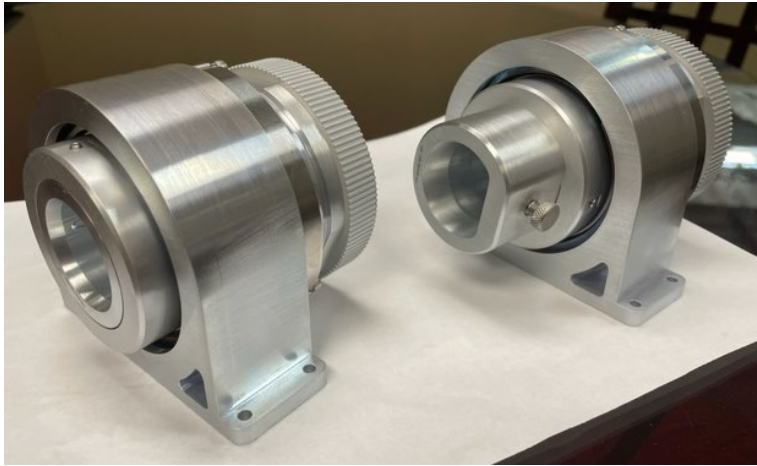
Once the catheter is locked into the robotic arm, it will automatically maneuver the catheter to the ablation region, which the data is gathered from the prior diagnostic procedure.



Proteus Robotic Arm Diagram

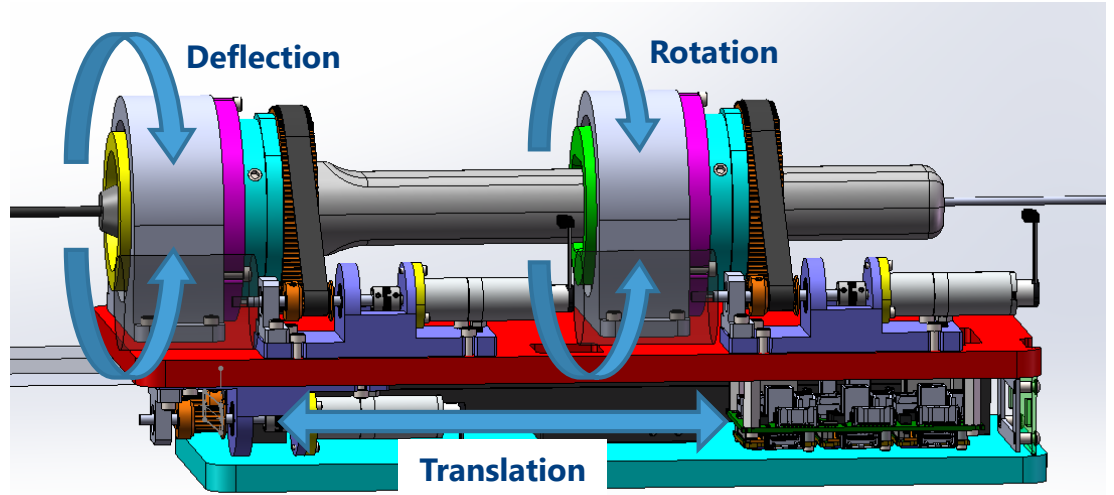


# Robotic Arm



Proteus™ Robotic Arm Mechanical Components

\* Three motors allow three axial movement: Deflection, rotation, and translation

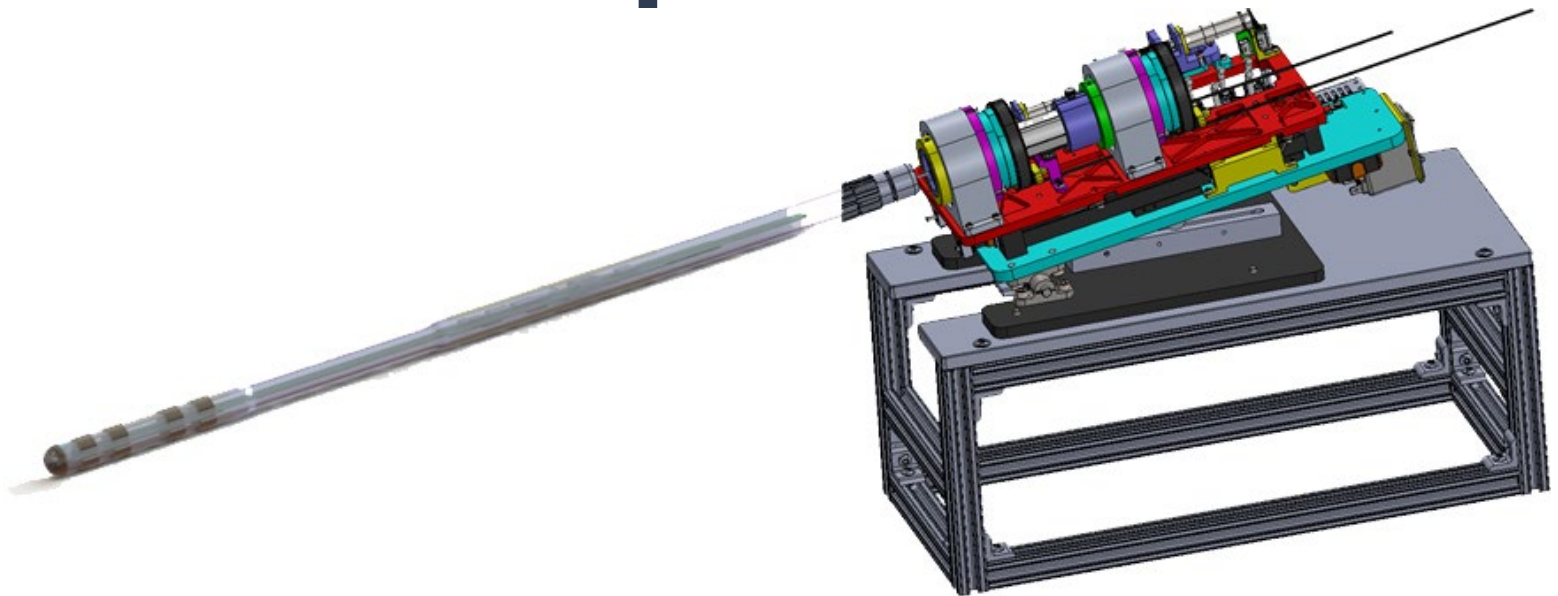


Proteus™ Robotic Arm Functional Overview

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## Software

- Catheter Tip microcontroller firmware
- Catheter handle microcontroller firmware
- Integration with GE CardioLab (Pruka) EP System

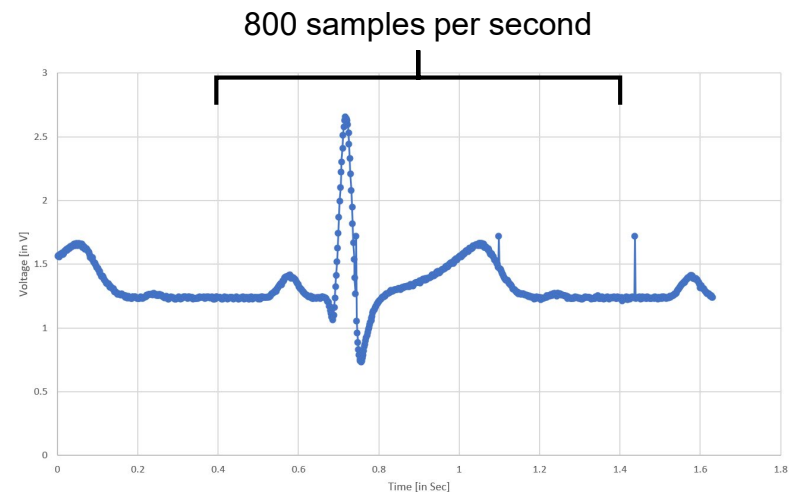


# Catheter Tip microcontroller firmware

- To gather cardio electro signals from 8 channels.
- To gather temperature measurement around the tip.
- To convert above analog signals to digital data in real time.
- To transmit digital data to the catheter handle.
- The speed of the data collection is greater than 800 samples per second per channel.

Time Stamp      8 Demultiplexed Electrode Reading      Temperature Reading

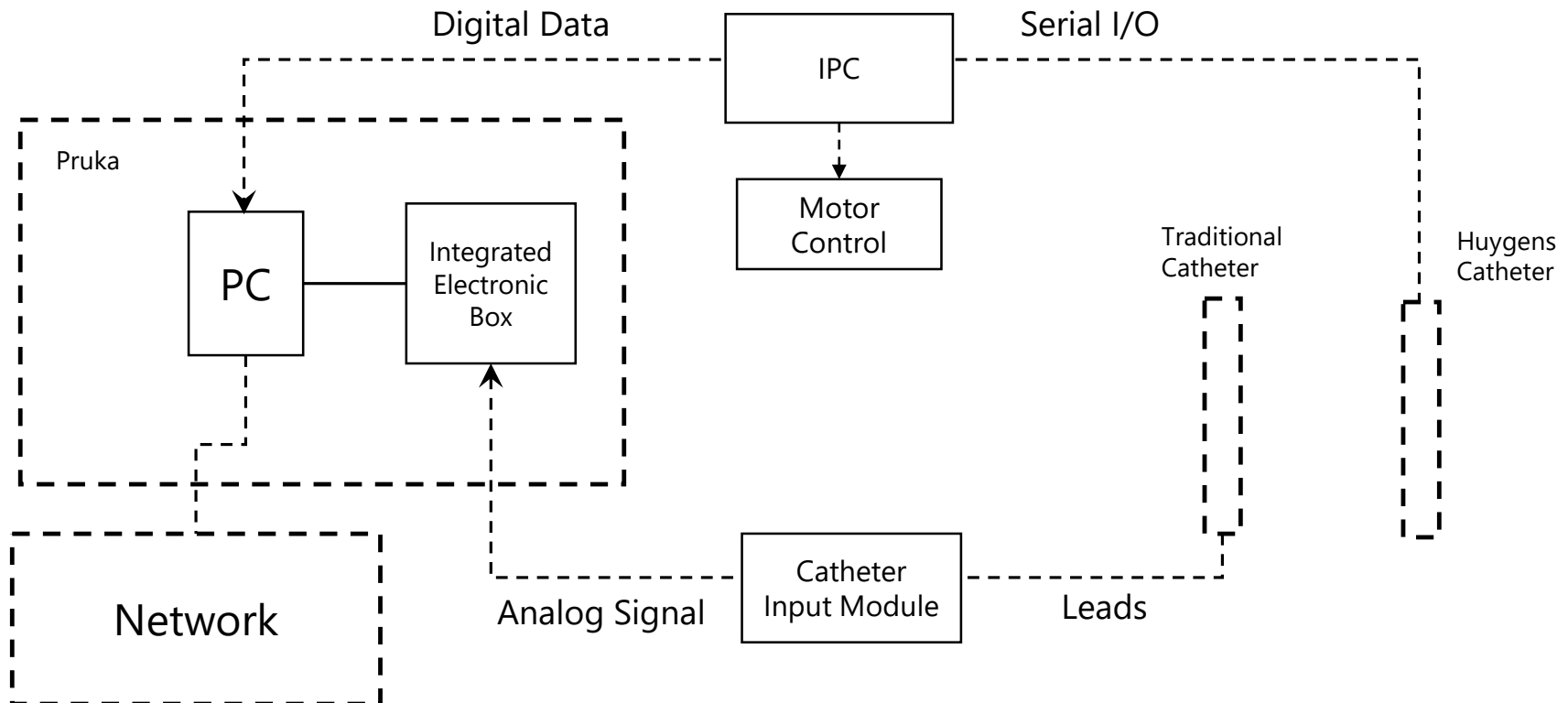
	A	B	C	D	E	F	G	H	I	J
1	0.001029	2058	1206	539	879	556	1985	1273	817	812
2	0.003036	2034	1157	547	872	480	1974	1228	754	780
3	0.003995	2013	1213	538	879	541	1954	1246	805	809
4	0.005982	1986	1110	502	856	497	1951	1271	843	848
5	0.007983	1947	1101	531	865	502	1929	1186	733	748
6	0.009993	1912	1122	475	870	411	1924	1148	607	715



Amplified QRS-Complex from One Electrode After Demultiplexing

# Integration with GE CardioLab (Pruka) EP System

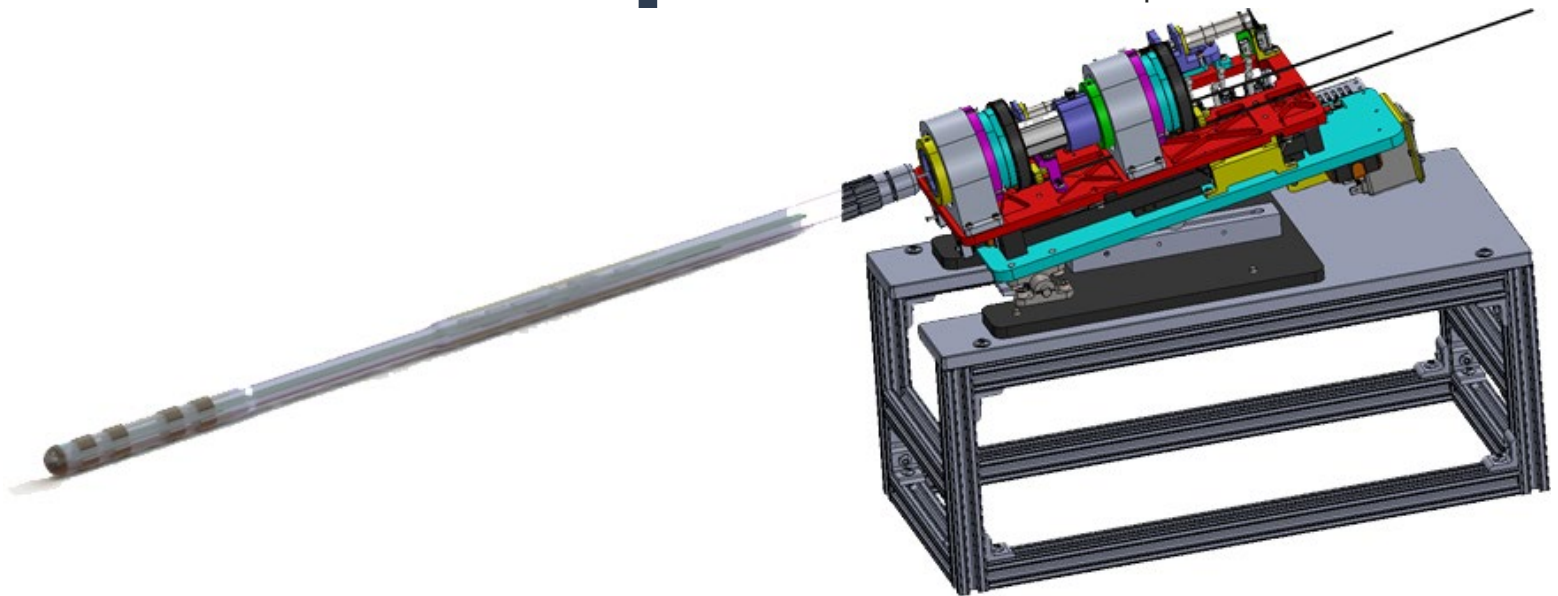
- Seamless addition to the existing PruKa EP system
- High speed data sampling and transmission of the high-quality digital cardio signals
- Data storage locally and in cloud for AI/ machine learning



# NEUROKINESIS CORPORATION

## Regulatory

- ISO 13485: Medical Devices - QMS
- European Union Medical Device Regulation
- ISO 10993: Biological Evaluation of Medical Devices
- IEC 60601: Basic Safety and Essential Performance of Medical Electrical Equipment
- CE Mark: Conformité Européenne



# Regulatory – ISO 13485: Medical Devices - QMS

- Neuro Kinesis' QMS creates a formalized system for all operations. The processes are intended to achieve and improve Neuro Kinesis' quality policies and objectives.
- It is designed to comply with ISO 13485 regulatory requirements with the guidance of the leading quality assurance provider, Intertek.
- QMS is planned to be recognized and certified by a Notified Body in 2022.



**intertek**  
Total Quality. Assured.





# Regulatory – European Union Medical Device Regulation

- Medical Device Regulation (MDR) Purpose:
  - Improve the quality, safety, and reliability of medical devices
  - Strengthen transparency and information for patients
  - Enhance vigilance and market surveillance
- Relies heavily on data collected from clinical investigations (animal and human studies), biocompatibility, mechanical, and electrical testing.



## Regulatory – ISO 10993: Biological Evaluation of Medical Devices

- This will determine if patient contacting materials can safely abide in a human body for the duration of operation (<24 hours).
- The experts at Intertek will assess the materials used, create a biological evaluation plan, test plan, and a biological report.
- Information from Intertek will be sent to UL for further biological testing.

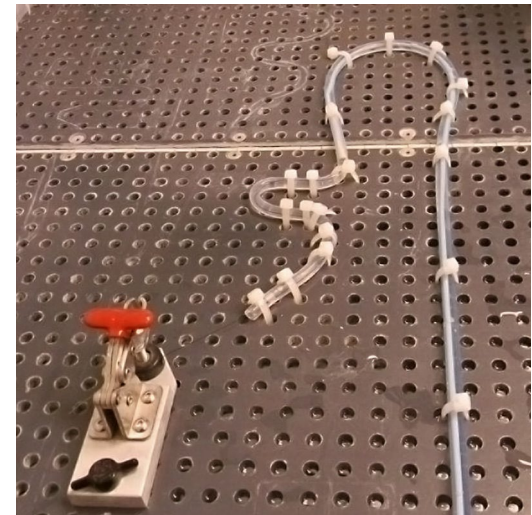


## Regulatory – IEC 60601: Basic Safety and Essential Performance of Medical Electrical Equipment

- Main areas of focus are electromagnetic compatibility (EMC), software, and basic safety and essential performance.
- Testing and evaluation be in accordance with IEC 60601 and the MDR. This will be conducted by Intertek's testing laboratories in both Menlo Park, CA and Lake Forest, CA.
- This includes, but are not limited to voltage surge, useability, and intravascular testing.



**intertek**  
Total Quality. Assured.



## Regulatory – CE Mark: Conformité Européenne

- All the information, certifications, and data collected from ISO, IEC, MDR, and applicable regulatory requirements will then be submitted to the European Commission for review.
- After acceptance, the Huygens™ Catheter will be available in the EU market.



# Animal Study at Rambam Hospital (Israel)

neuroKINESIS CORPORATION	Animal Trial Protocol	Confidential
	Title: Animal Protocol HUYGENS	
Document # HUYGENS-210923	Revision: 1.0.0	Page 1 of 63

neuroKINESIS CORPORATION	Animal Trial Protocol	Confidential
	Title: Animal Protocol HUYGENS	
Document # HUYGENS-210923	Revision: 1.0.0	Page 20 of 63

## Evaluation of the HUYGENS Intracardiac Catheter System Mapping, Target Acquisition Performance in the Porcine Heart - A GLP Study -



**Sponsor:** Neuro-Kinesis Corp.  
 Josh Shachar, Chief Technology Officer  
 10524 S. La Cienega Blvd. Inglewood, CA 90304  
 Phone: 310.649.9000 / Fax: 9004  
 Email: [josh@magnetecs.com](mailto:josh@magnetecs.com)

**Neuro-Kinesis Chief Medical Officer and Study Director:** Eli S. Gang, MD,  
 Clinical Professor of Medicine  
 Geffen School of Medicine at UCLA  
 Cedars Sinai Medical Center  
 Los Angeles, CA  
 Email: [gang@cvmg.com](mailto:gang@cvmg.com)

**Principal Investigators:** Professor Lior Gepstein, MD  
 Dr. Muhammand Sulliman, MD.

**Laboratory Facility (US):** Neuro-Kinesis Corp.  
 10524 S. La Cienega Blvd. Inglewood, CA 90304  
 Phone: 310.649.9000 / Fax: 9004

**Laboratory Facility (Israel):** Rambam Hospital, Department of Cardiology  
 HaAliya HaShnia St.8, Haifa Israel 3109601

**Additional Co-Investigators: (Optional\*)** Prof. Jose Luis Merino, MD\*  
 Prof. Petr Neuzil, MD\*  
 Dr. Reddy Vivek Y, MD\*

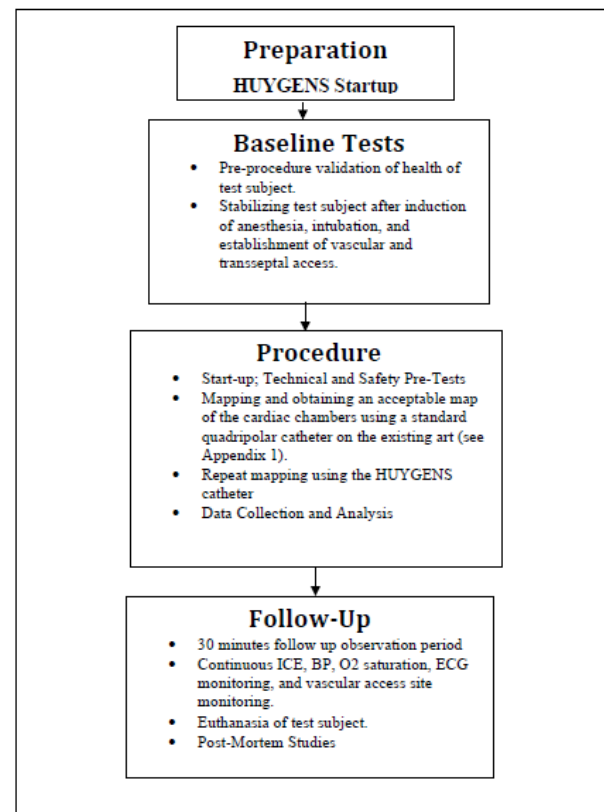
**GLP Compliance Coordinator:** Daniel Rastein, MD, MPH

**Neuro-Kinesis Technical Team:** Timothy Kim, Electrical Engineer  
 Marc Rocklinger, Electrical/Mechanical Engineer  
 Peter Yin, Software Engineer  
 Elissa Salceda, Quality Engineer

## 6. Study Structure and Procedure Flow-Diagram

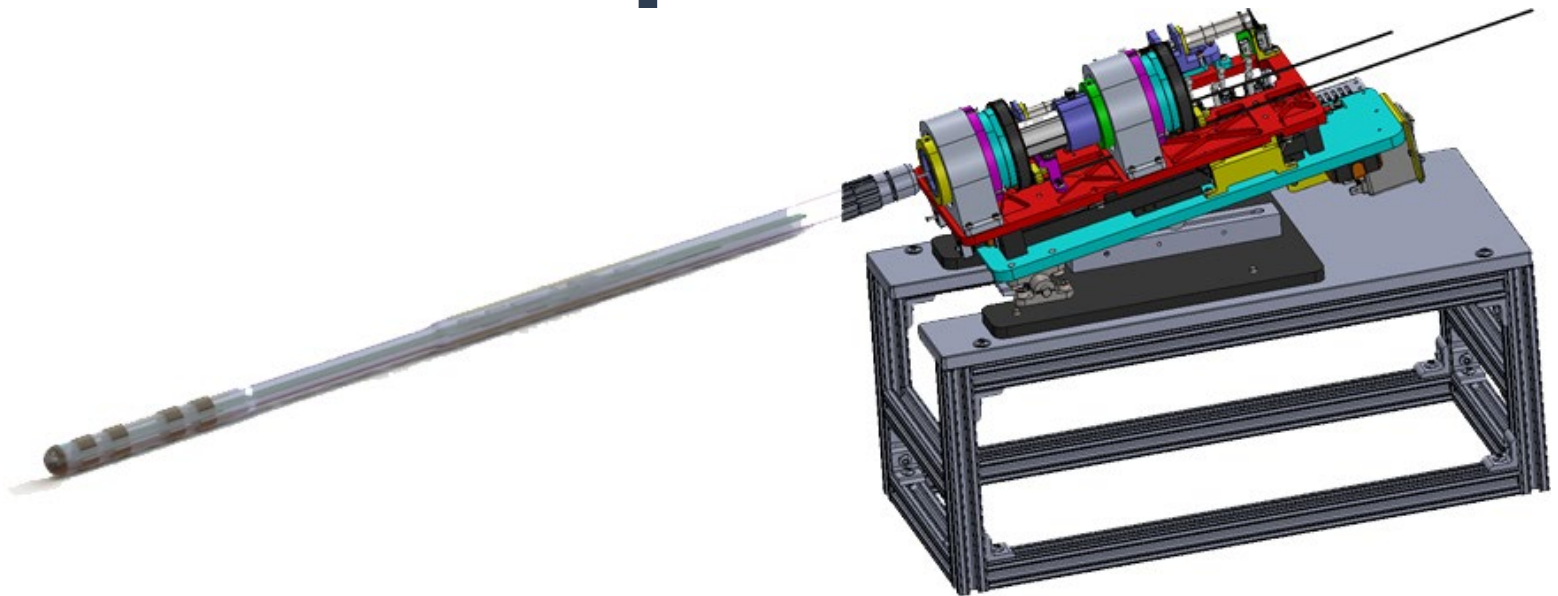
### 6.1. Study Flow Diagram

The following diagram is a simplified schematic of the study structure for evaluating the primary outcomes, as formally described in other sections of this protocol.



# NEUROKINESIS CORPORATION

Engineering





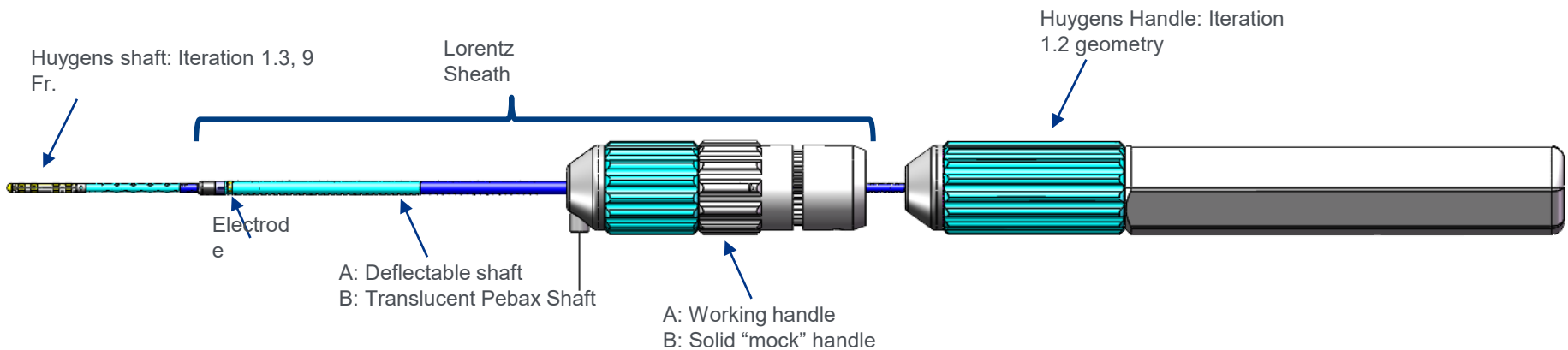
# HUYGENS™ CATHETER AND LORENTZ™ SHEATH

- **Huygens Catheter:**

- 9Fr. Shaft design, fit 1.2 handle to fit in MCS

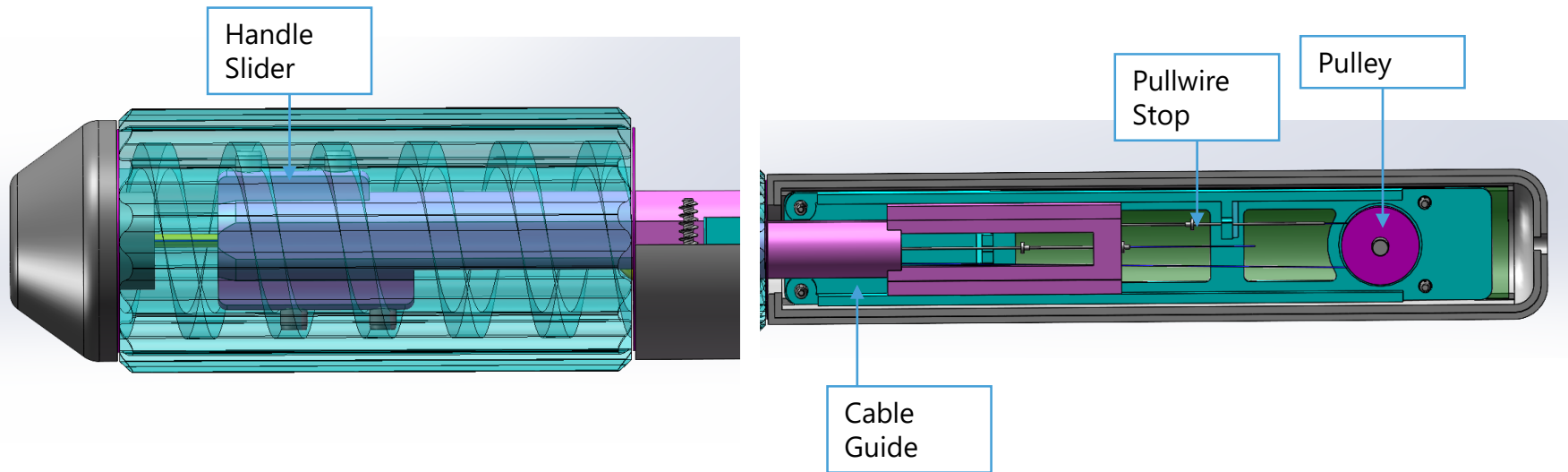
- **Lorentz Sheath:**

- Functional prototype of deflectable sheath with electrode at tip and handle





# Handle Mechanism 1.2

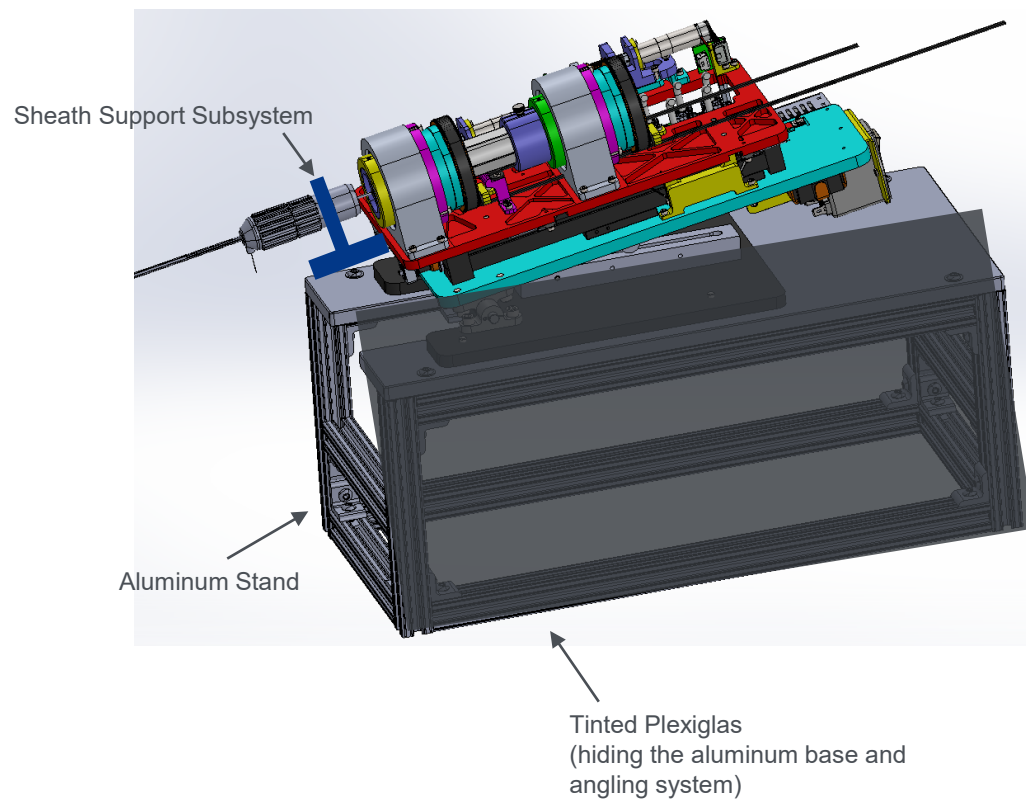


- Using a pulley system, when the knob is rotated, the Handle Slider and pullwires move linearly causing the catheter to deflect.
- A magnet is housed underneath the Cable Guide for communicating with the MCS Iteration 1.1 hall effect sensor

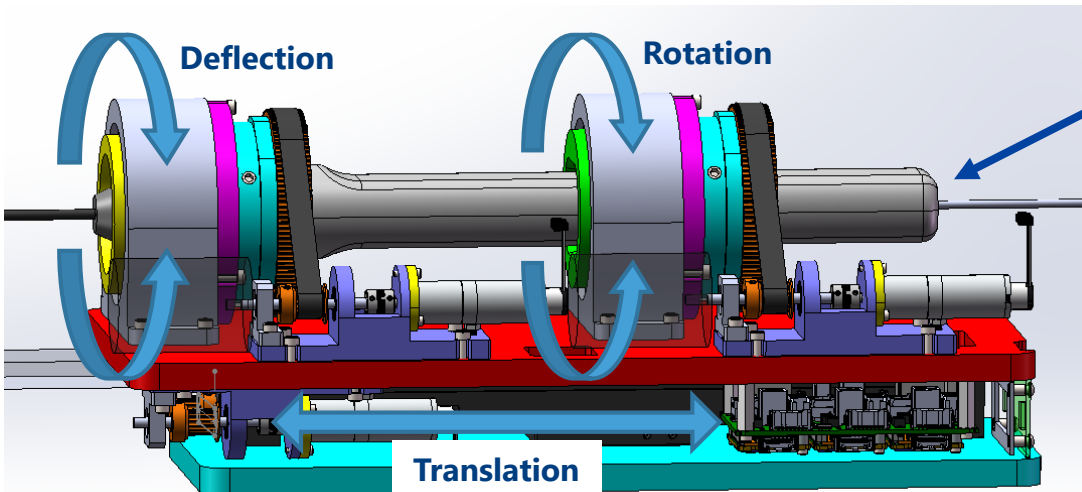
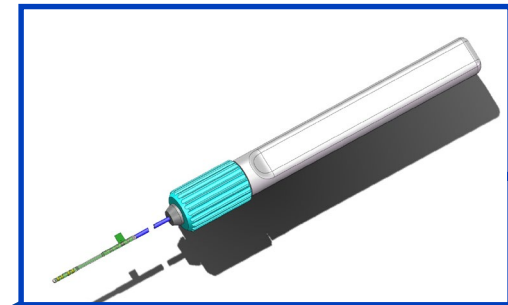
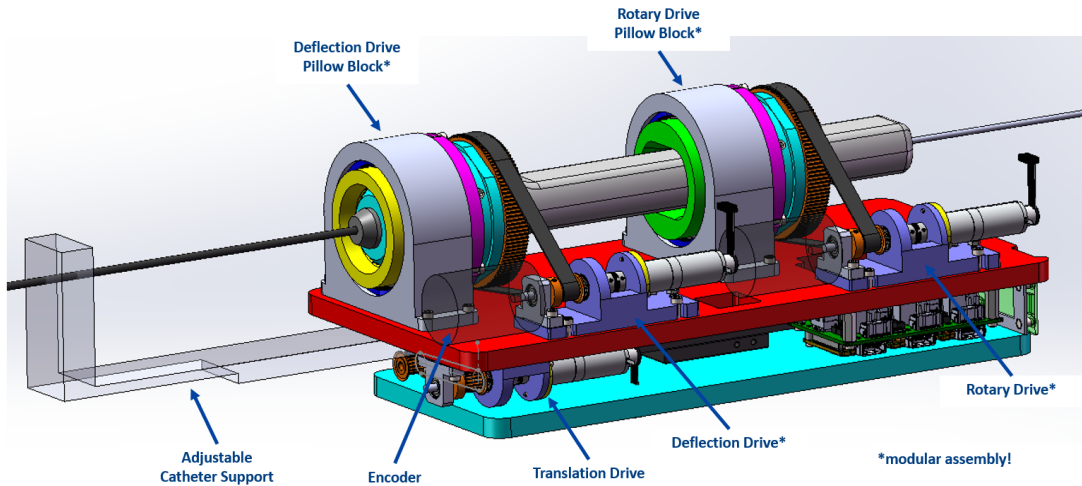
# MOTION CONTROL SUBSYSTEM

- **Motion Control Subsystem**

- MCS iteration 1.1
- Aluminum stand
- Sheath support subsystem

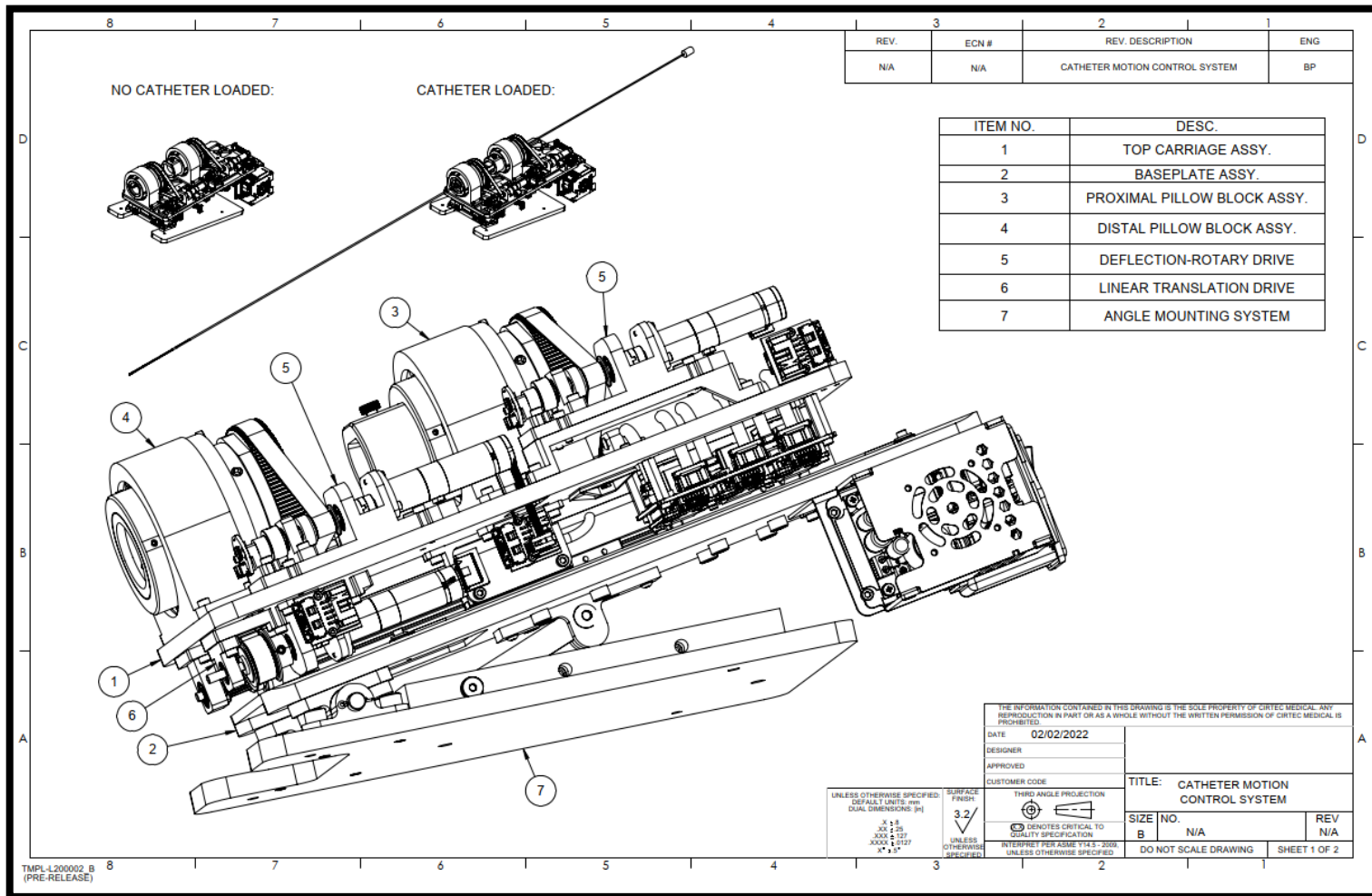


# Proteus™ Robotic Arm Construction



\* Three motors allow three axial movement: Deflection, rotation, and translation

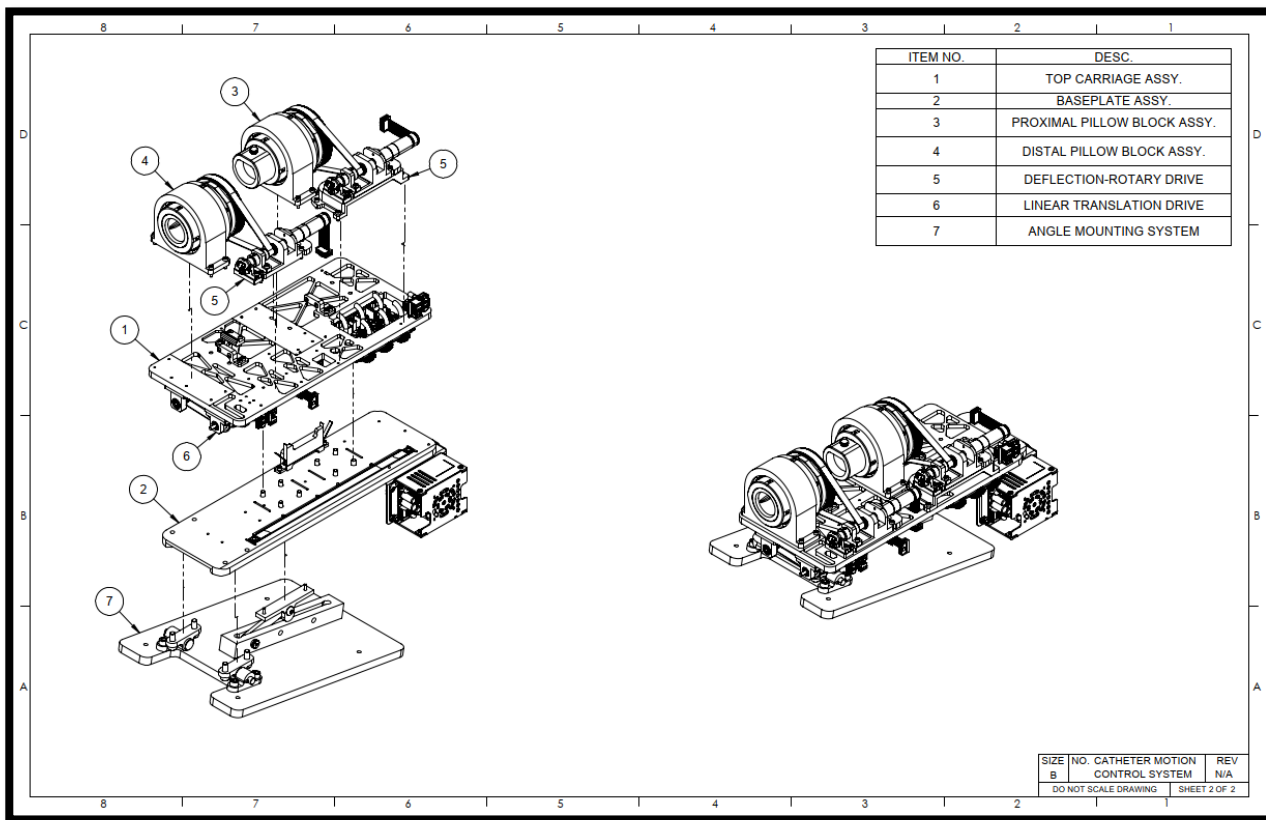
# PROTEUS™ ROBOTIC ARM DESIGN



Detail of the robotic navigation device mechanical components.

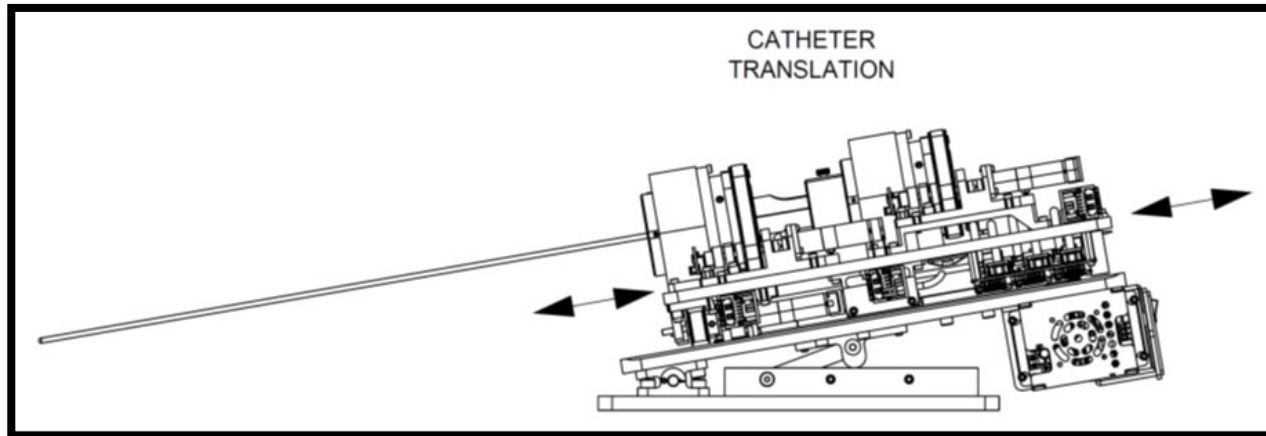


# PROTEUS™ ROBOTIC ARM DESIGN

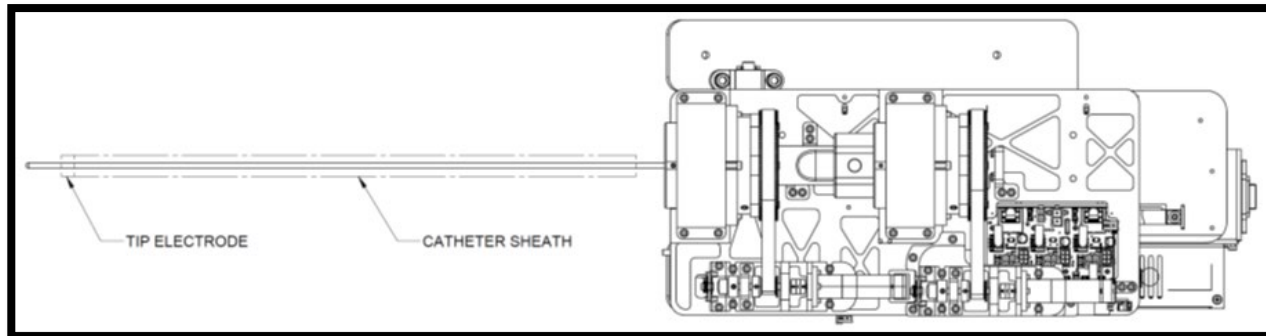


Exploded view of the robotic navigation device mechanical components.

# PROTEUS™ ROBOTIC ARM DESIGN

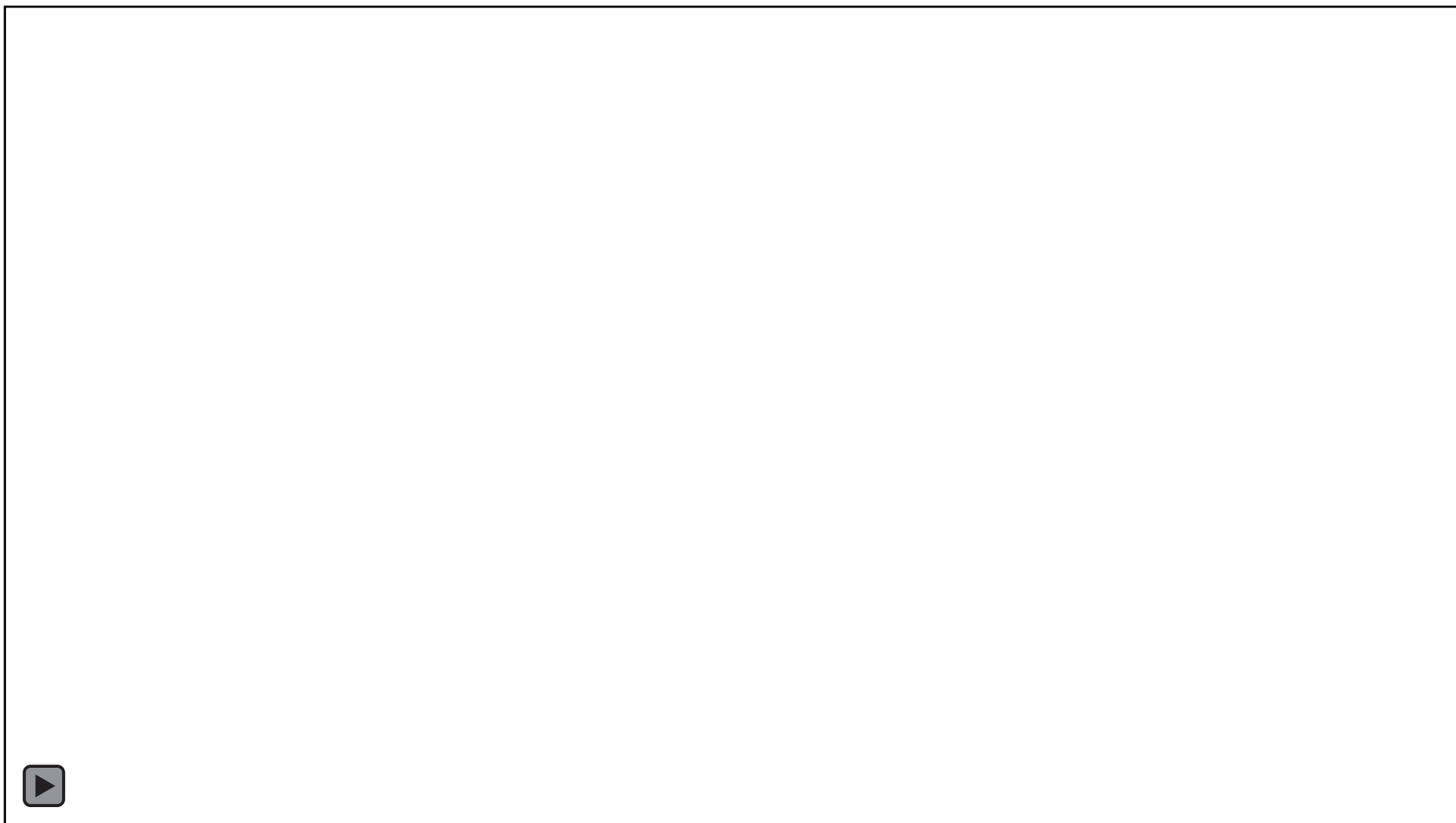


Depiction of catheter translation operations with the robotic navigation device.

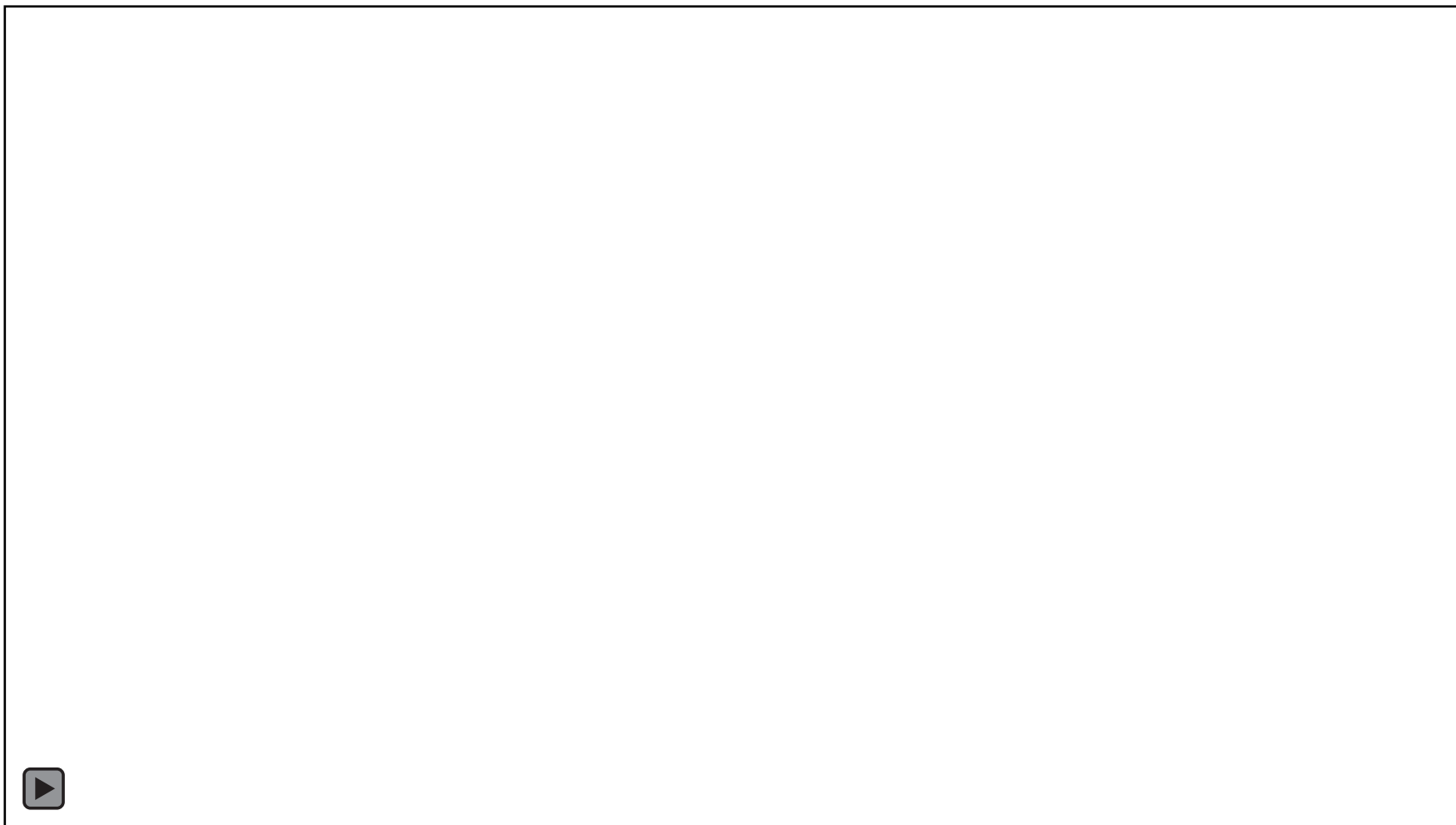


Robotic navigation device in relation to catheter and sheath.

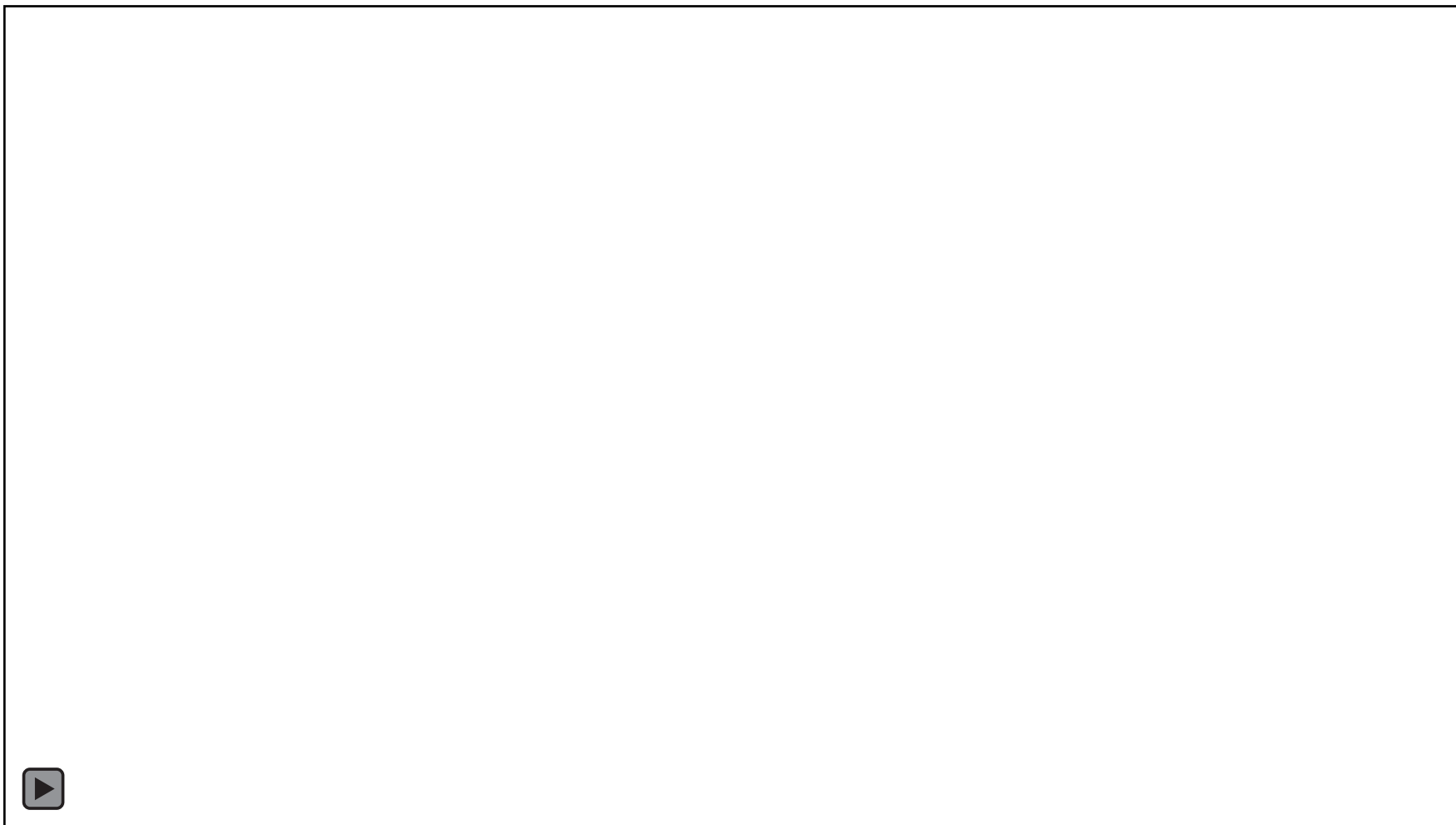
# PROTEUS™ ROBOTIC ARM OPERATIONS



# PROTEUS™ ROBOTIC ARM DEFLECTION CONTROL

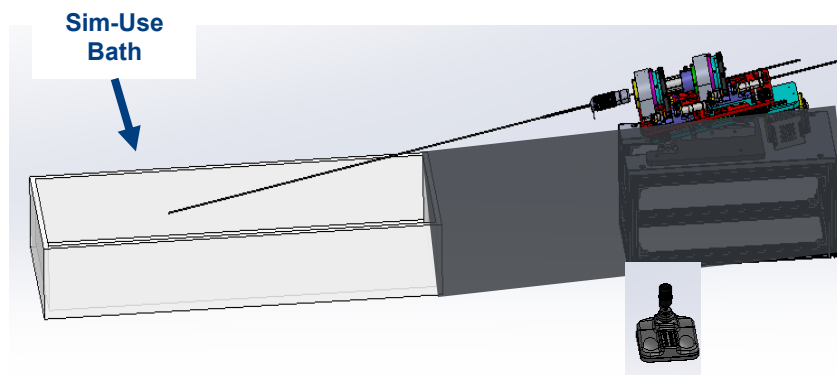
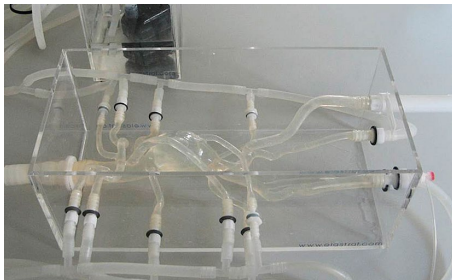


# PROTEUS™ ROBOTIC ARM LINEAR CONTROL



# SIM USE MODEL – WETLAB

- Vascular model
- Water circulator
- Water bath





# NEUROKINESIS CORPORATION

**Thank You for  
Watching**

Prepared for Presentation  
04/25/2022

