The 3.5D Ultrasound System

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Project Overview and Justification

The 3.5D Ultrasound Device is intended to be a class I accessory medical diagnostic device. The mechanical and software systems will work with a diagnostic ultrasound machine to improve the diagnostic performance of the instrument by creating 3D models of soft tissue in specified regions of patients. An articulated arm which acts as the mechanical system is intended to hold the ultrasound probe as it is moved about the 3D space to track the position at any time, which enables a software to take the images and compile them with their location data as they are accumulated over time. These data sets acquired from the ultrasound images are translated or rotated across the 3D volume based on the location data through affine space transformation to compile the data points into a final 3D model.

This project was developed to act as a cost-effective improvement to a widely used diagnostic technique for soft-tissue related conditions, pregnancy, assists image-guided procedures, blood flow monitoring, congenital vascular malformations, tumors etc. The device will allow healthcare providers to utilize 3D volume models of the scanned area to improve diagnostic accuracy and reliability.

Functional Requirements

For the mechanical system, the articulated arm needs to have the quality of strength, smooth movement, and accurate position tracking. These requirements are to be gauged by engineering standards ASME B89.4.22 for articulated arm assessments and ISO 10370-12 for CMM tracking. The software system, on the other hand, needs to have fast and accurate image construction which is assessed by ISO 12052. The FDA guidelines 21 CFR 820.30 outline the requirements necessary for a Class I medical device accessory to be deemed safe, which revolves around the device not altering the ultrasound function as well as biocompatibility which is outlined by ISO 10993-1. Each specification is pulled from the engineering standards to ensure efficiency and success.

Functional Requirements and Specifications

Requirement	Specification	Relevant Standard
No mechanical failure	Safety Factor of 5+	ASME B89.4.22
Smooth movement	Feedback average of 3/5+	ASME B89.4.22
Accurate position tracking	1% accurate to pre-existing device	ISO 10360-12
No adverse health effects	Compliance under biocompatibility guidelines	ISO 10993-1
HDMI Compatibility	Ultrasound image output that is readable on video card	VESA
Fast Image Acquisition	Image acquisition at 60 Hz	ISO 12052
Accurate Image Construction	Image construction data accurate within 5%	ISO 12052
Complies with medical device regulations	Device is biocompatible and does not interfere with ultrasound function	FDA 21 CFR 820.30

Assessment Data

Each assessment for the specification was designed according to the relevant standards, and the tables below depict the tests completed or to be completed in order to assess the quality of the system function. Smooth movement and biocompatibility were assessed as intended whereas other tests regarding software function and strength were not completed due to unforeseen circumstances. To assess position tracking and image stitching accuracy, a pre-approved CMM and evaluation software will be used to assess the accuracy of each respectively. For image acquisition, a simple speed test will be used when running the Matlab software to assess the speed of the system. All of the remaining tests can be completed using the full system fairly simply, and with evaluation software like Solidworks should run smoothly without any issues.

Smooth Movement Assessment

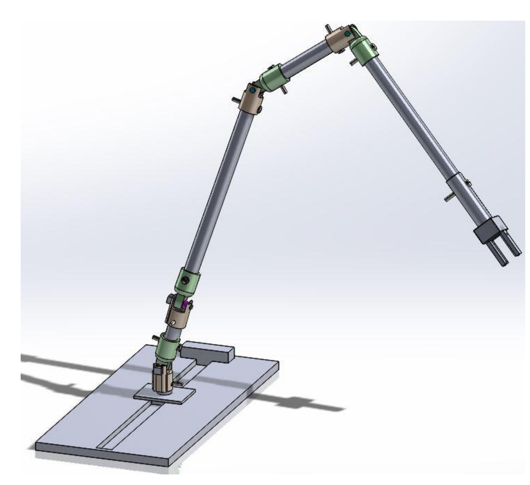
Test Number	Ease of Movement	Did it fall apart? Y/N
1	3	Y
2	3	N
3	3	N
4	2	Y
5	4	N
6	5	N
7	4	N
8	3	N
9	4	N
10	4	N

Biocompatibility Assessment

Test Number	Skin Irritant (Y = yes, N = no)	Time of exposure (s)
1	N	5
2	N	5
3	N	10
4	N	10
5	N	20
6	N	20
7	N	30
8	N	30
9	N	60
10	N	60

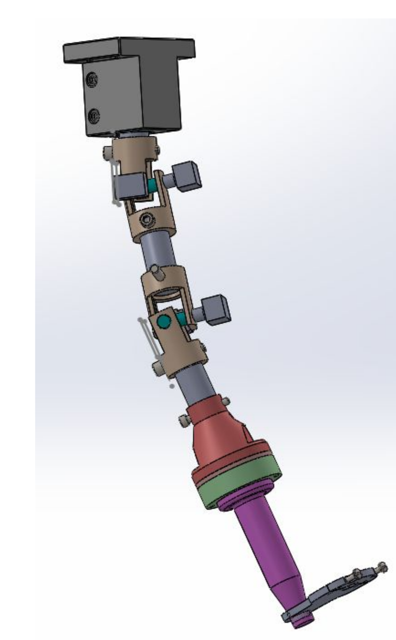
The Design Process

The design process was an iterative process that involved three major design pivots. Stage I shown below contained a base, sliding joint, two hinge joints, and a clamp. This design met user needs and would follow most of the standard for this design project, but not all. Ergonomics was highly neglected so a design pivot lead us to stage II. This included a base, a universal joint, two hinge joints, and a pivot joint, and a clamp. From here we wanted to add a counterbalance feature working toward the ergonomic portion of the design. This proved to be outside the scope of this project, so it was scrapped. The final design in stage III used portions from all previous designs to meet all required standards, be ergonomic, and provide a adequate volume to record images in.



Stage I

Stage II

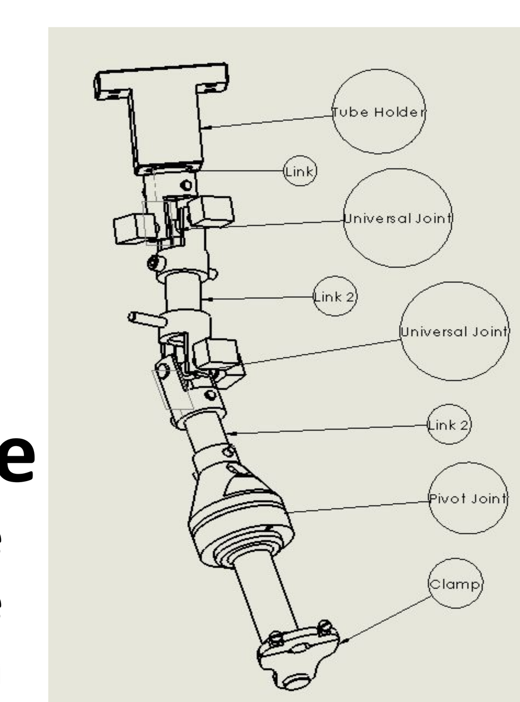


Stage III

Counterbalance Prototype

Position Tracking

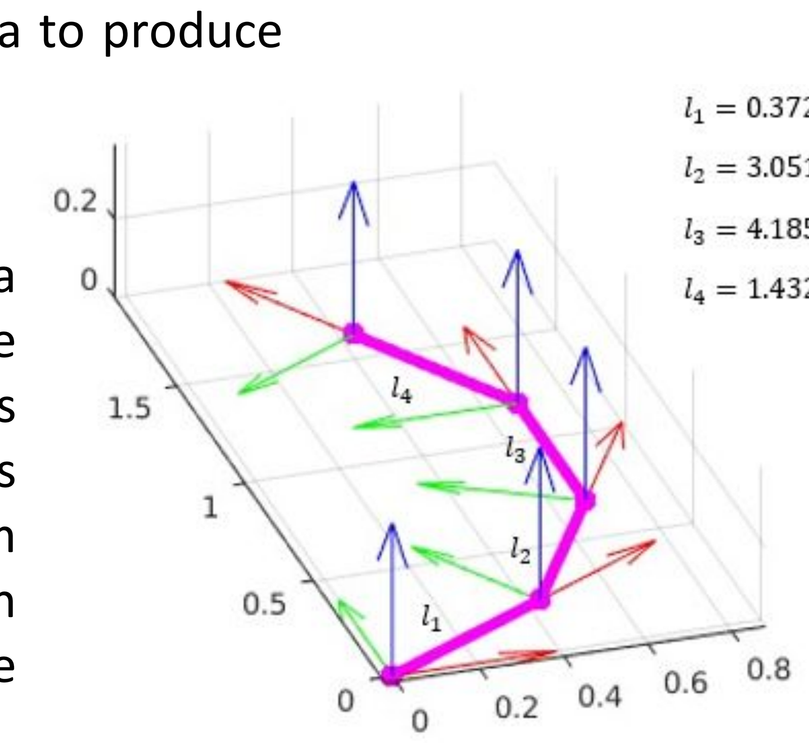
Optical encoders were placed in the rotation plane within each joint shown the the figure to the right. These joints were connected to an electrical system that transfers the data to a computer software system in order to track the position of the probe at any given time.



Final Design CAD drawing

Localization in Denavit-Hartenberg Space

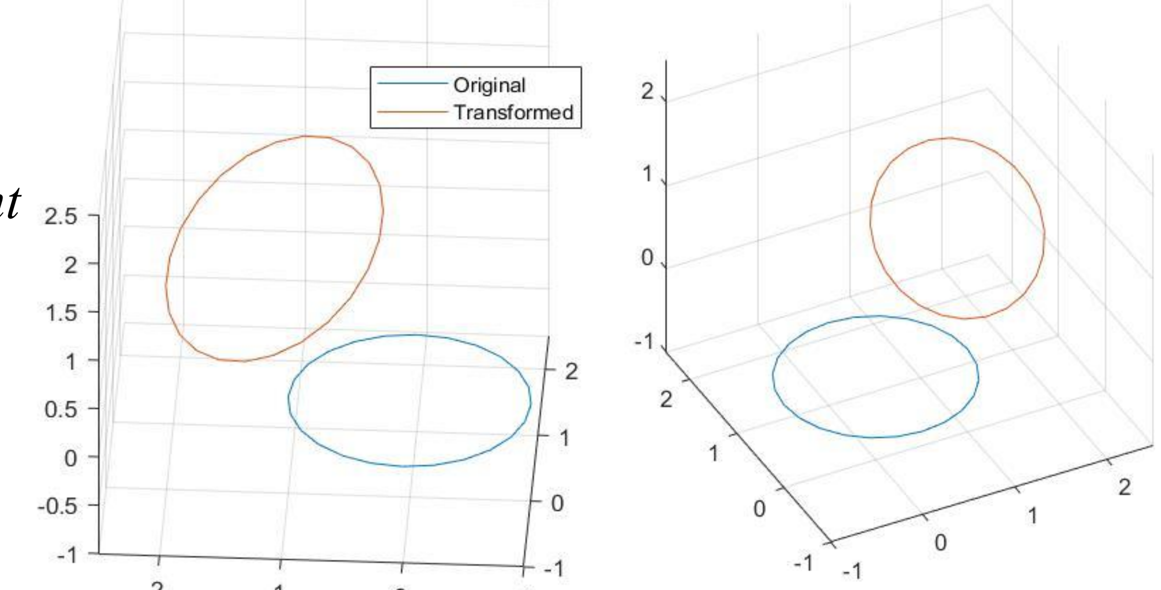
Using the data from each optical encoder and dimensions of the articulated arm, the point at which the transducer probe is can be represented in Denavit-Hartenberg space as a transformation matrix. This matrix contains both the rotational and translational difference between the base of the articulated arm and the probe at any given time, enabling the system to use this data to produce 3D images based on the location of the probe.



Localization Tracking in D.H. Space

Image Stitching in Affine Space

In order to rotate and translate entire sets of data points from a 2D image across a 3D space, affine transformation in Matlab is an ideal process that takes the coordinates of each data point in a set and applies the transformation matrix acquired from Denavit-Hartenberg space representation. With each data set from the ultrasound images, the matrix is applied to transform it as required based on the location of the probe in the 3D space. This produces a new data set that shows the location of the 2D ultrasound image with respect to the origin of the articulated arm. As more images are individually transformed and compiled into the 3D space, the data creates the surface of the scanned object in three dimensions.



Affine Transformation of a 2D circular data set

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