Project Acronym: PROSTASONIC (ENTERPRISES/0918/0012)

Prostate cancer ablation with a 4D robotic system using thermal ultrasonic waves under MRI guidance.

Deliverable number: 2.5

Title: Preparation of application for CE marking

Prepared by:

Marinos Giannakou (MEDSONIC)
Christakis Damianou (CUT)
Andria Philipou (CUT)

Date: 17/03/2021

Ευρωπαϊκή Ένωση
Ευρωπαϊκά Διαρθρωτικά και Επενδυτικά Ταμεία

Κυπριακή Δημοκρατία

Διαρθρωτικά Ταμεία
της Ευρωπαϊκής Ένωσης στην Κύπρο

Table of Contents

Executive Summary

A 4D robotic system was designed for accurate thermal ablation of prostate tumors by employing ultrasonic waves under MR-guidance. For commercialization of the robotic system in the European Economic Area (EEA), CE marking is needed. The CE mark is a certificate that verifies that the product has been assessed and meets high safety, health, and environmental protection requirements, and thus can be sold on the EEA market without any restrictions.

As part of the CE Marking process, a technical documentation of the product is required. The main purpose of the current deliverable is to provide any related pieces of information in this regard, thus assessing the system's conformity. Each individual part of all incorporated devices (robotic device, ultrasonic transducer, electronic system), that have been designed for proper operation of the robotic system, is described in detail. CAD drawings are available, indicating the design of each part, along with a short description of each part's function.

CE Marking application document

List of devices

1. Prostate Robotic Device
2. Ultrasonic Transducer
3. Electronic System

1. Prostate Robotic Device

The robotic device was designed with 5 motion axes. Specifically, the designed device incorporates 2 PC-controlled axes: 1) a linear axis for motion along the rectum (X-axis), and 2) an angular axis for rotation within the rectum (Θ-axis). The other three axes are manually controlled: 3) a linear axis to lift the robot up and down since the height of the rectum varies from patient to patient (Z-axis), 4) an angular axis to set the entry angle to the rectum (Φ-axis), and 5) a linear axis on the base of the device for left to right adjustment of the device. The parts of the robotic device were 3D printed on a Stratasys printer (FDM400, Stratasys, 7665 Commerce Way, Eden Prairie, Minnesota, USA) using Acrylonitrile butadiene styrene (ABS) plastic. All components were made from non-magnetic materials that can safely be used in the MR environment, thus preventing image artifacts. The completed version of the robotic device is shown in figure 1, in both front and rear views, while a description of each part's function is listed in table 1.

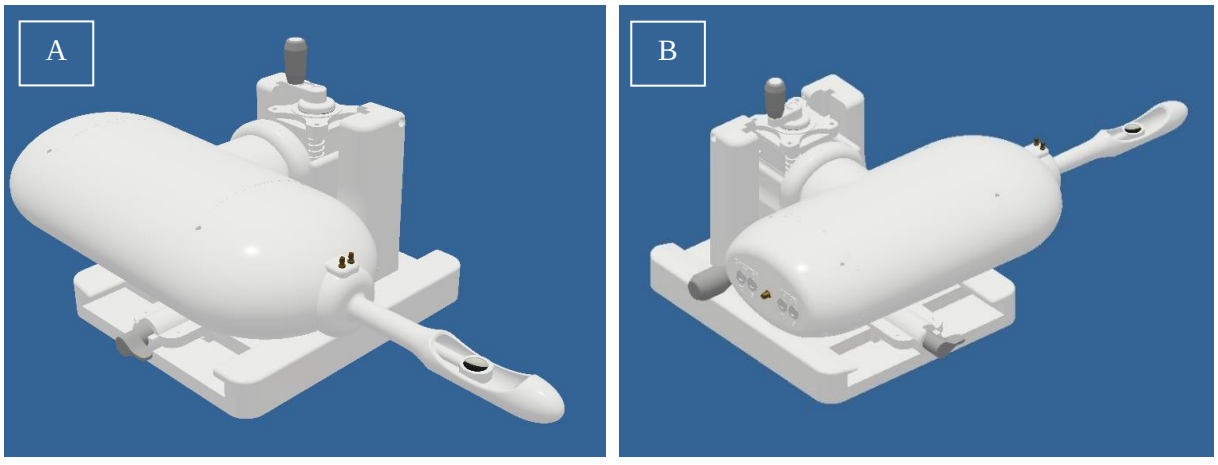
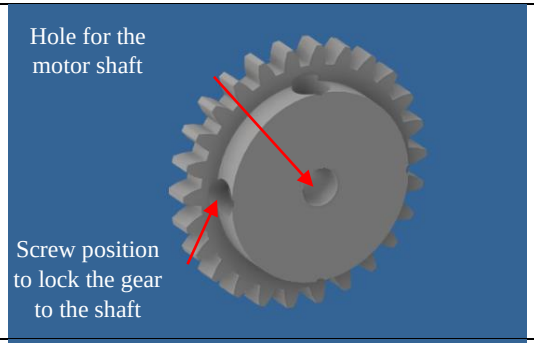
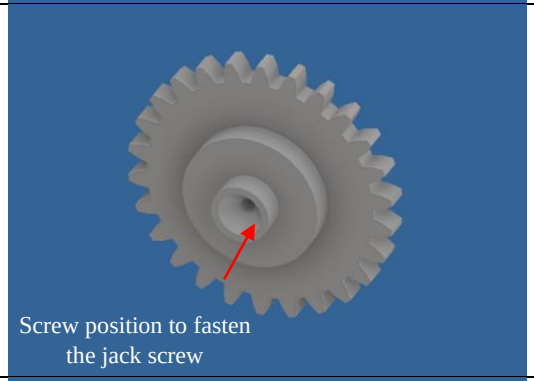
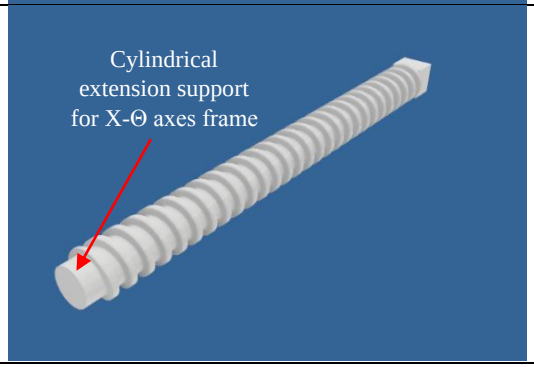
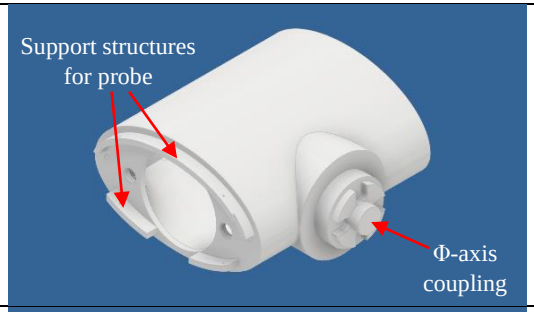
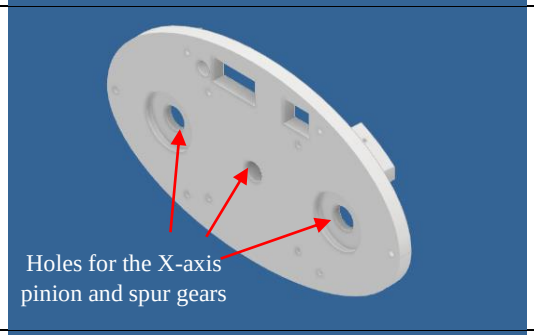
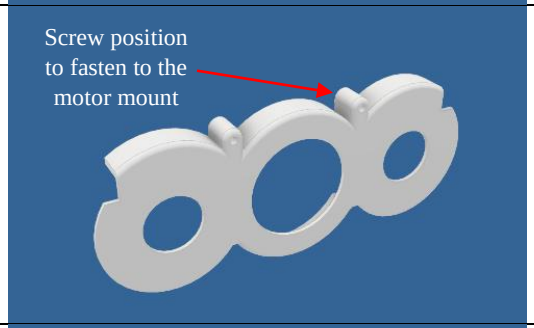
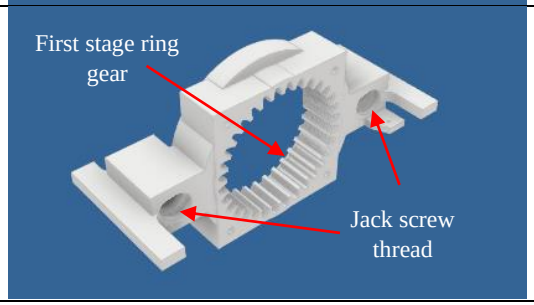
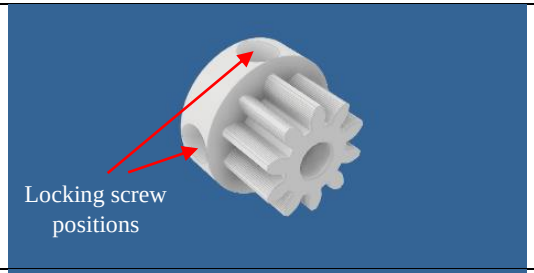
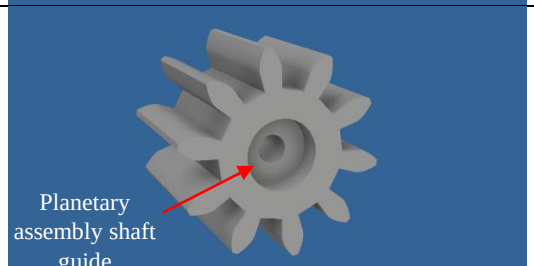
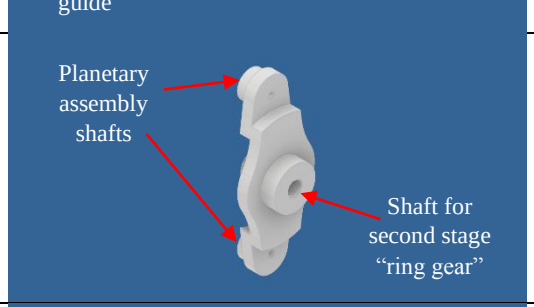
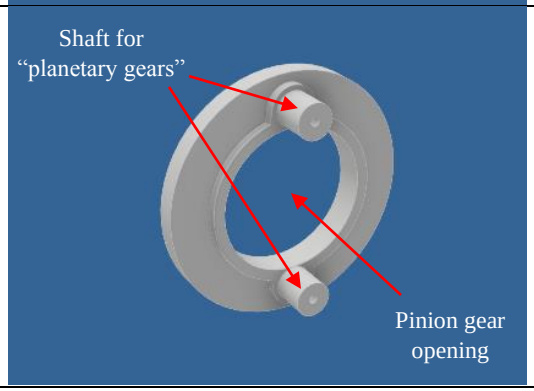


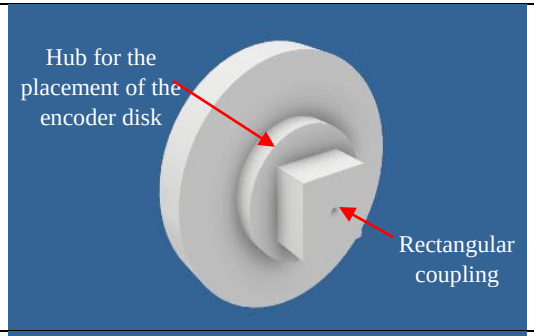
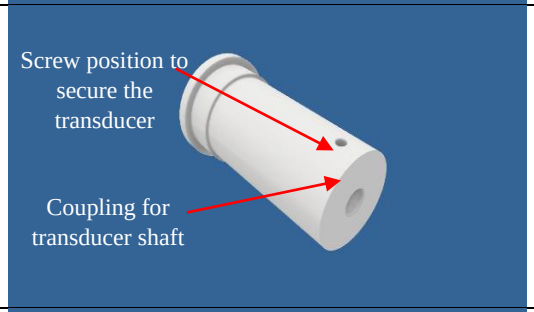
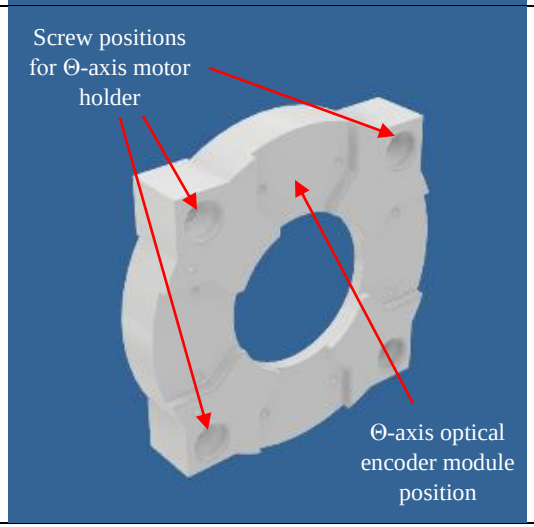
Figure 1: CAD drawing of the prostate robot A) Front view, and B) Rear view.

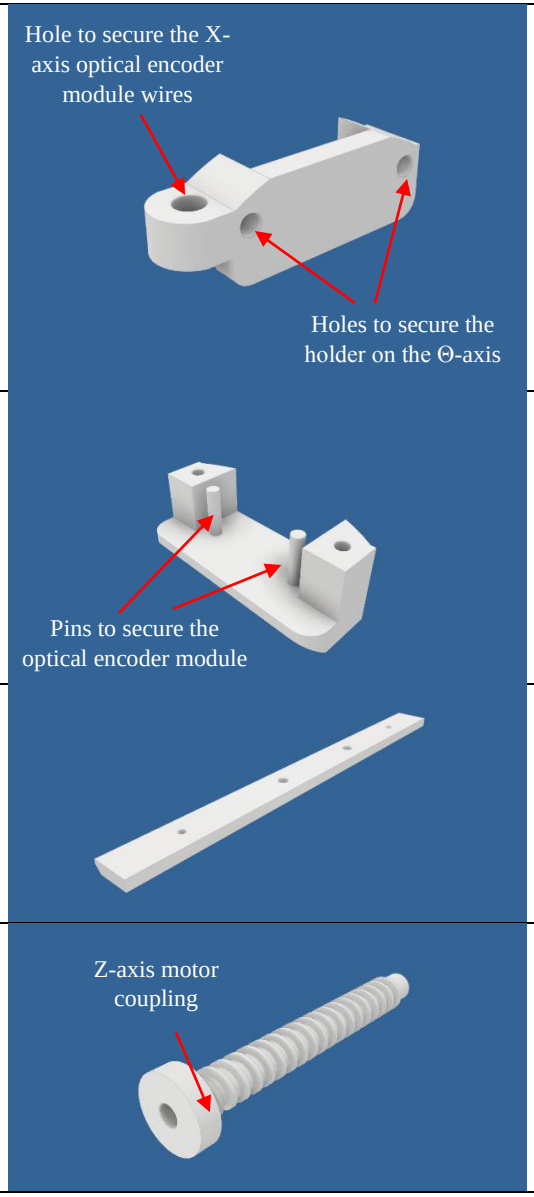
Table 1: Description of each part of the designed robotic system.

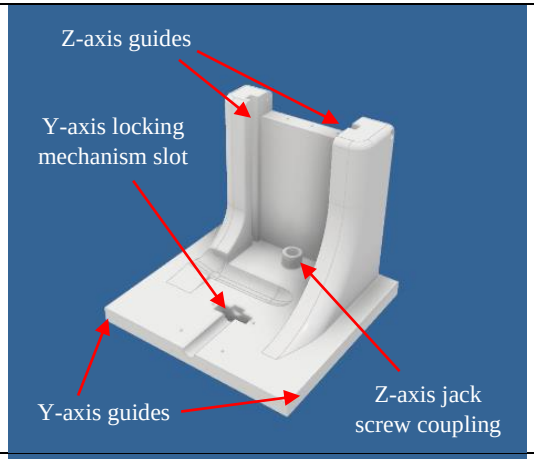
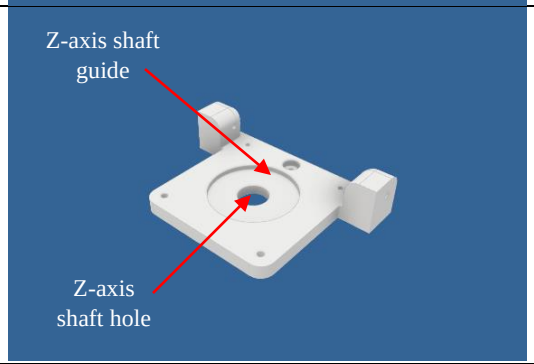
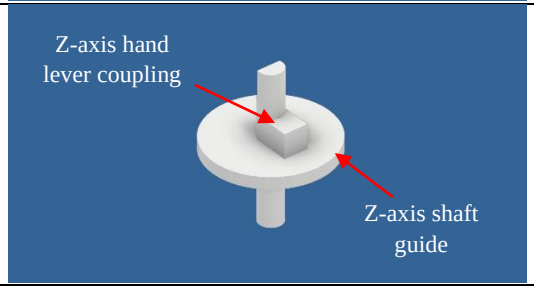
Part name	CAD drawing	File name	Purpose
X-axis pinion gear (26 teeth)		4D prostate Manual Z_lever4	The pinion gear is an essential component for actuating X-axis motion. It attaches to the ultrasonic motor for transmitting motion to the two coupled X-axis spur gears.
X-axis spur gear (26 teeth)		4D prostate Manual Z_lever3	Two gears of this type are required for robot assembly, with each coupled to the X-axis pinion gear. Each gear attaches to the end of each X-axis jack screw, thus enabling simultaneous rotation.
X-axis jack screw		4D prostate Manual Z_lever107	Two parts of this type are used to complete robot assembly. The X-axis jack screws attach to the X-axis spur gears. Their simultaneous rotation ensures the smooth motion of the X-axis.

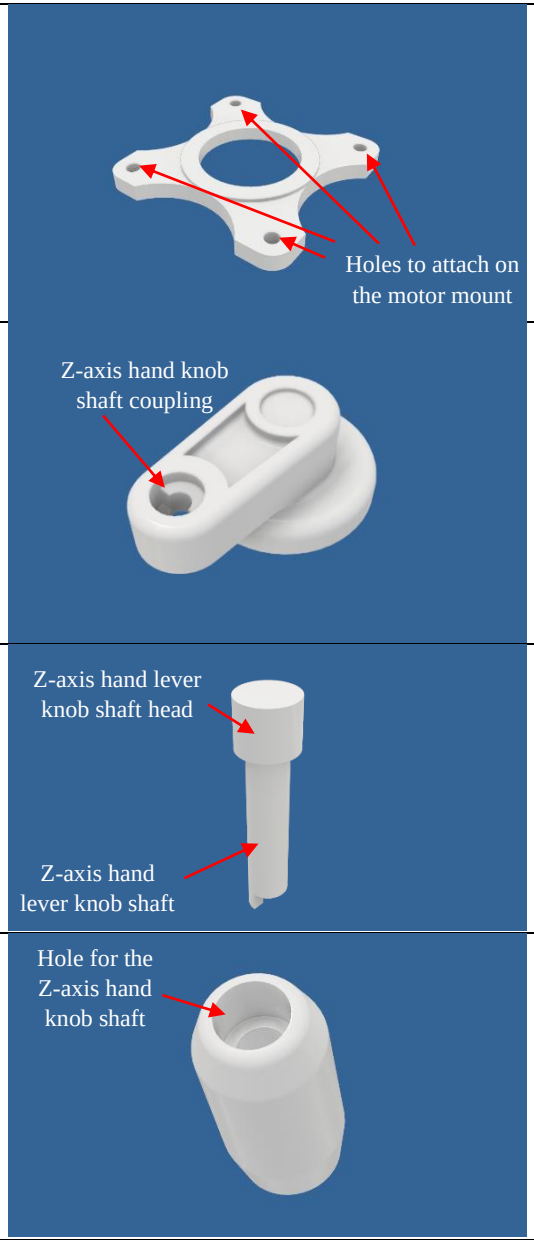
X-Θ axes frame		4D prostate Manual Z_lever57	This part encloses the mechanical assembly of the X and Θ-stage. It is also used to support the endorectal probe and the connectors. The cylindrical coupling on the side is used for connecting the X-Θ-axes to the Z and Φ axes.
X-axis motor holder		4D prostate Manual Z_lever36	On the X-axis motor holder, the X-stage motor is attached. Two holes were created on the front side of the holder to support the X-axis spur gears. The X-axis pinion gear is coupled to the X-axis motor through the hole in the center.
X-axis gear cover		4D prostate Manual Z_lever37	The X-axis gear cover fastens on the X-axis motor holder through brass screws, to protect the cables of the X and Θ-stage from the gears.
Θ-axis motor holder		4D prostate Manual Z_lever59	The Θ-axis motor holder includes the X-stage guides and a coupling for the X-stage optical encoder module. Teeth were added in the center to enable coupling with the first stage "ring gear". A guide for the second stage "ring gear" was added on the rear side of the motor holder.

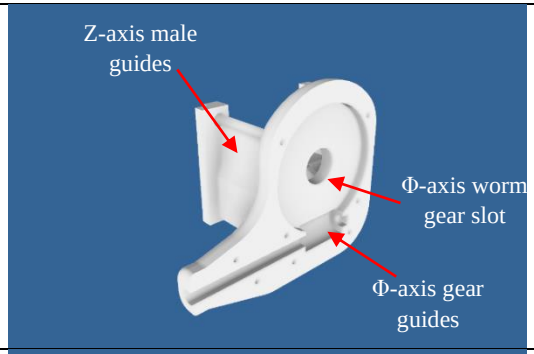
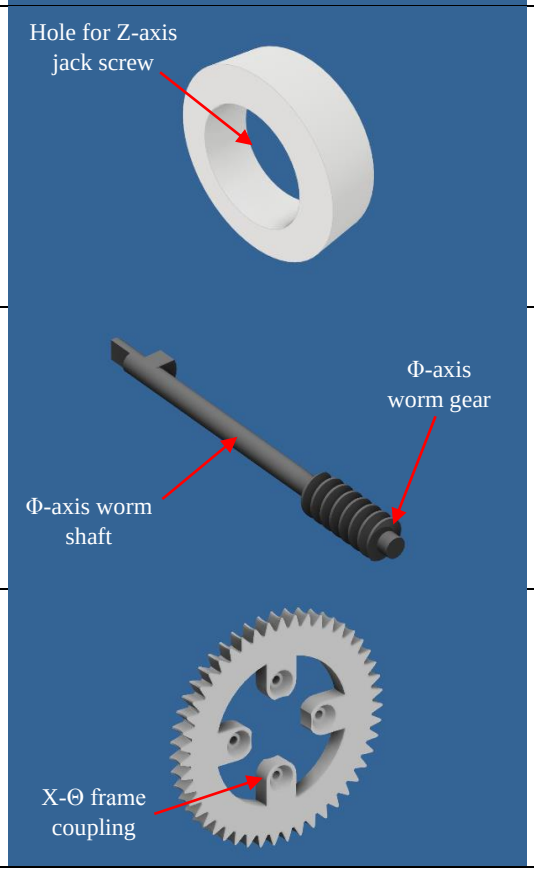
Θ-axis “sun gear” (10 teeth)		4D prostate Manual Z_lever77	The sun gear is located in the center of the Θ-stage gear assembly, coupled to the motor. It is secured to the motor shaft by two screws fastened to the coupling of the gear.
Θ-axis “planetary gear”		4D prostate Manual Z_lever111	The Θ-axis “planetary gear” couples to the Θ-axis “sun gear” and transmits motion to the second stage of the Θ-axis. Two of these parts are needed to complete the assembly.
Θ-axis front “planetary gear” holder		4D prostate Manual Z_lever115	The Θ-axis front “planetary gear” holder includes three shafts; two for the “planetary gear” alignment and one for coupling with the second stage “ring gear.” Its purpose is to hold together the “planetary gears” and “sun gear” during operation.
Θ-axis rear “planetary assembly” holder		Planetary assy rear1	Θ-axis rear “planetary assembly” holder is used to hold the two Θ-axis “planetary gears” coupled with the Θ-axis “sun gear”. The opening in the center allows space for the coupling with the “sun gear” and helps with the alignment of the gears with the motor shaft.

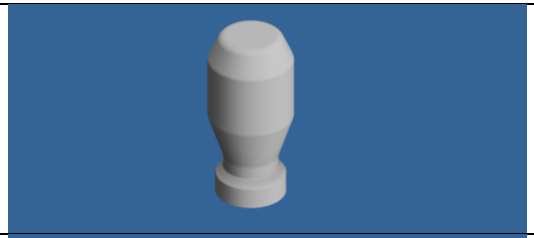
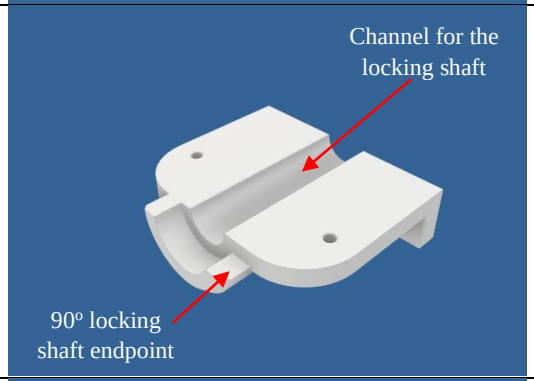
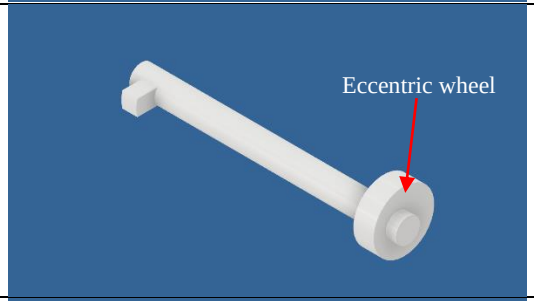
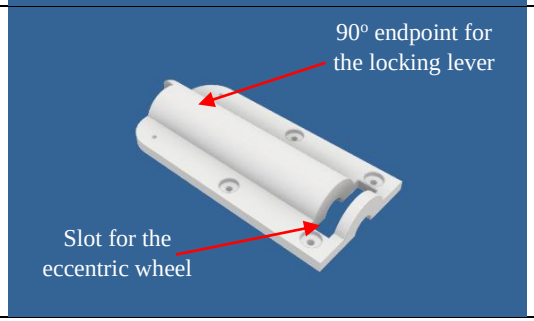
Θ-axis second stage "ring gear"		4D prostate Manual Z_lever110	This part represents the output of the Θ-axis, which delivers the angular motion to the transducer. The rectangular coupling at the front allows placement of the angular encoder disk. It also includes the 2nd stage ring gear (on rear side), which couples to the "planetary gears."
Encoder disc holder		4D prostate Manual Z_lever1	This part attaches to the rectangular coupling of the Θ-axis second stage "ring gear" to secure the optical encoder disk and connect the transducer shaft with the Θ-stage.
Θ-axis planetary gear cover		4D prostate Manual Z_lever78	This part covers the Θ-stage moving parts. It also includes means for enabling attachment of the optical encoder module. The opening in the center allows alignment of the Θ-axis second stage "ring gear."

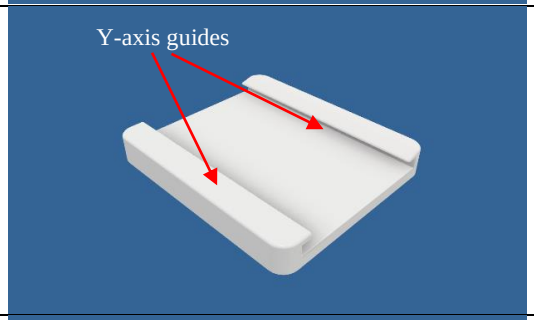
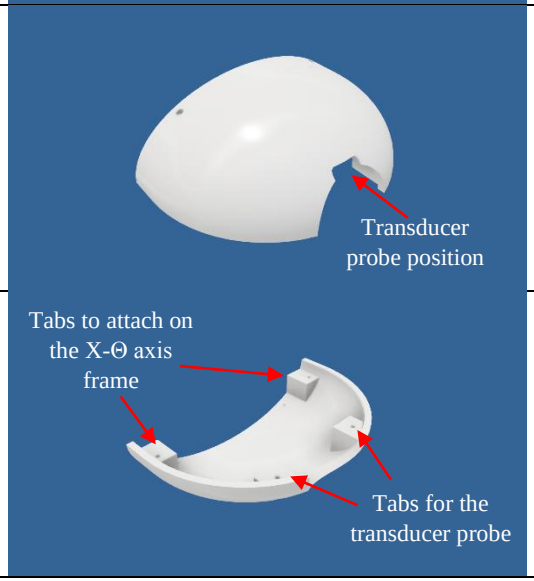
Θ-axis optical encoder module holder		4D prostate Manual Z_lever22	This part secures the Θ-axis optical encoder module to the Θ-axis planetary gear cover. The X-axis optical encoder wire is advanced through a hole located at the right side of the holder, in order to be protected from the rotating jack screws.
X-axis optical encoder module holder		4D prostate Manual Z_lever15	This part secures the optical encoder module of the X-axis motor under the Θ-stage motor holder.
X-axis optical encoder strip holder		4D prostate Manual Z_lever104	This holder is used to secure the optical encoder strip of the X-axis. It is fastened to the interior of the X-Θ axes frame.
Z-axis jack screw		4D prostate Manual Z_lever108	The Z-axis jack screw is used to convert the angular rotation of the motor to linear. When the jack screw rotates clockwise, the robot is lifted. When the jack screw rotates anti-clockwise, the robot moves down.

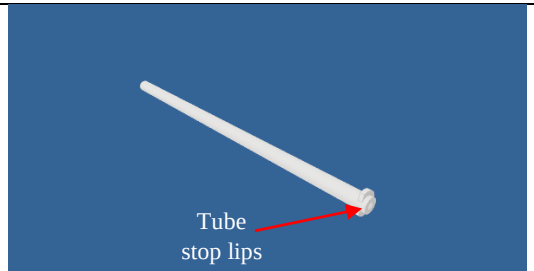
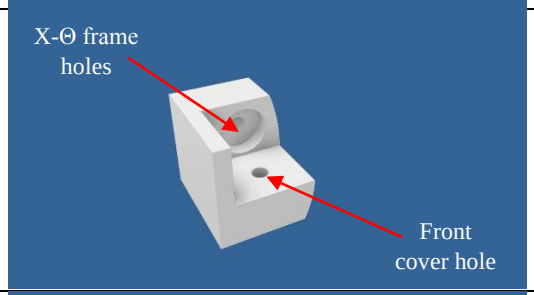
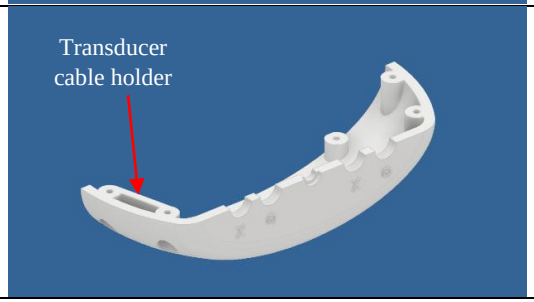
Z-axis frame		4D prostate Manual Z_lever32	The Z-axis frame supports both the X- and Θ-stage. It incorporates guides for the Θ-rear cover. The lower section includes guides for the Y-axis and a coupling for the Z-axis jack screw. In the center of the lower section there is a slot for securing the locking mechanism of the Y-stage.
Z-axis bottom shaft holder		4D prostate Manual Z_lever41	The Z-axis bottom shaft holder attaches to the Z-axis frame. It supports the Z-axis shaft, which in turn connects to the jack screw coupling on the Z-axis frame.
Z-axis shaft		4D prostate Manual Z_lever28	The Z-axis shaft connects to the Z-axis jack screw. The disk-shaped structure in the middle acts as a bearing. The top coupling attaches to the Z-axis lever.

Z-axis top shaft holder		4D prostate Manual Z_lever27	The Z-axis top shaft holder secures the Z-axis shaft between the top and bottom holder. It also includes a guide for the shaft holder. The opening in the middle allows the attachment of the Z-axis hand lever.
Z-axis hand lever		4D prostate Manual Z_lever74	The Z-axis hand lever attaches to the top of the Z-axis shaft. It enables the user to rotate the jack screw in order to control manually the Z-axis.
Z-axis hand knob shaft		4D prostate Manual Z_lever72	The Z-axis hand knob shaft is attached to the top part of the Z-hand lever through the coupling and secures by a brass screw located at the bottom of the lever. This secures the Z-axis hand knob and allows its rotation around the shaft.
Z-axis hand knob		4D prostate Manual Z_lever65	The hand knob is fitted to the hand knob shaft, thus enabling manual adjustment of the robot's height by the user.

Φ-axis rear cover		4D prostate Manual Z_lever25	This part hosts the Φ-axis mechanism, which includes the Φ-axis gear and the and the Φ-axis worm gear. It supports the Z-stage of the prostate robot assembly through male guides.
Z-axis endpoint collar		4D prostate Manual Z_lever76	The Z-axis endpoint collar is fitted around the Z-axis jack screw to limit the downward range. The size of the collar sets the low endpoint, thus preventing any motion beyond the effective range of the device.
Φ-axis worm gear		4D prostate Manual Z_lever35	The Φ-axis worm gear is coupled with the Φ-axis gear. The shaft on the rear is extended out of the Φ-axis cover and coupled with the Φ-axis knob thus allowing the user to drive the Φ-stage manually.
Φ-axis gear		4D prostate Manual Z_lever5	The Φ-axis gear is fastened to the X-Θ frame coupling. The rotation of the Φ-axis gear by the worm gear provides angular adjustment of the endorectal probe.

Φ-axis knob		Theta knob	The Φ-axis knob couples to the Φ-axis worm gear, allowing the user to make manual adjustments of the Φ-stage.
Y-axis locking mechanism extension		4D prostate Manual Z_lever31	This extension attaches to the side of the Z-axis frame. It extends the slot in order to house the shaft of the Y-axis locking shaft. An endpoint, which limits the rotation of the shaft to 90°, is also included.
Y-axis locking shaft		4D prostate Manual Z_lever30	The Y-axis locking shaft has an eccentric wheel attached to the shaft. With rotation of the shaft, the eccentric wheel is simultaneously rotated, pressing the Z-axis frame to the base of the device and allowing the user to lock the device (Y-axis) in the desired location.
Y-axis locking mechanism cover		4D prostate Manual Z_lever29	The Y-axis locking shaft is covered by the Y-axis locking mechanism cover. The cover secures the Y-axis locking shaft in the slot. The rear end of the shaft has a rectangular coupling for the attachment of the Y-axis locking lever, which is extended further to create a stop for the shaft.

Y-axis locking lever		4D prostate Manual Z_lever54	The locking lever attaches to the Y-axis locking shaft, allowing the user to lock the Y-axis manually.
Base of the device		4D prostate Manual Z_lever66	The base of the device includes guides for the Y-axis, which allows the left and right manual adjustment of the device. It also supports the robot on the MRI table.
Front top cover		4D prostate Manual Z_lever53	The front top cover is used to attach the endorectal probe to the X-Θ axes frame of the device and to protect the patient from the moving parts.
Front bottom cover		4D prostate Manual Z_lever43	The front bottom cover is used to attach the endorectal probe to the X-Θ axes frame of the device and to protect the patient from the moving parts.

Coaxial cable tube		4D prostate Manual Z_lever56	The coaxial cable tube is attached between the X-Θ axes frame and the X-axis motor holder. The tube protects the transducer cable from the moving parts.
Front cover detachable tabs		4D prostate Manual Z_lever48	The device requires two front cover detachable tabs to support the front top and front bottom cover.
Rear top cover		4D prostate Manual Z_lever50	The rear top cover is used to enclose the moving parts and cables of the robot and support the connectors for the motors, encoders, and transdcuer.
Rear bottom cover		4D prostate Manual Z_lever60	The rear bottom cover is used to enclose the moving parts and cables of the robot and support the connectors for the motors, encoders, and transducer. A cable holder is incorporated on the left side for better cable access.

2. Ultrasonic Transducer

A spherically focused ultrasonic transducer was developed. A piezoelectric transducer element hosted in a case with an integrated shaft, was placed inside the transducer probe. The piezoelectric top and bottom surfaces of the element were connected to a coaxial cable. Epoxy was used as the backing material for supporting the transducer inside the transducer case and electrically isolating the contacts of the transducer. The transducer was installed inside the endorectal probe and attached to the X- and Θ-axes to enable motion and targeting. A CAD drawing of the designed transducer system is shown in figure 2A, while a transparent view of the probe can be seen in figure 2B.

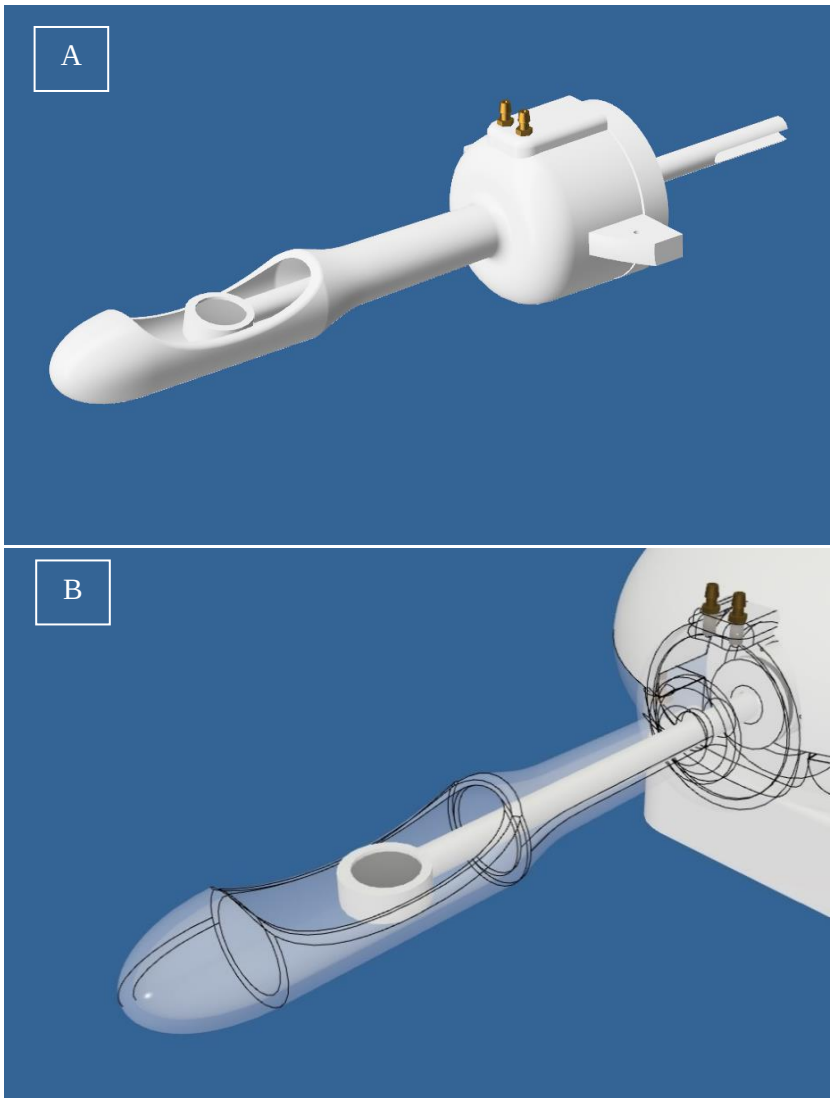
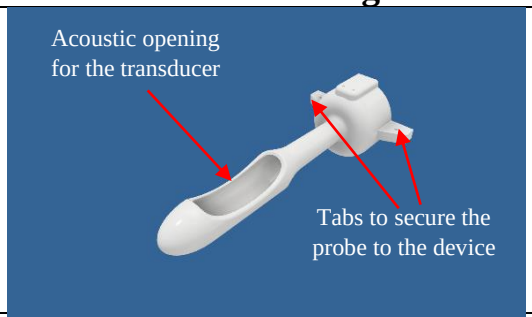
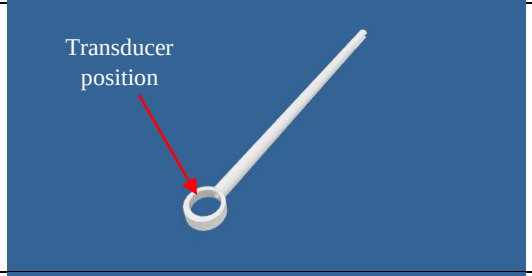
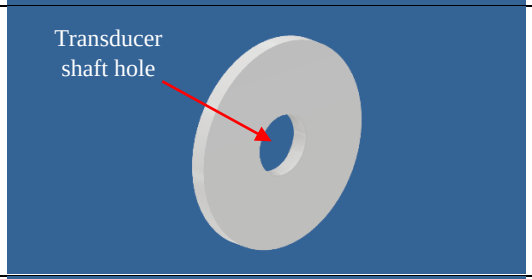
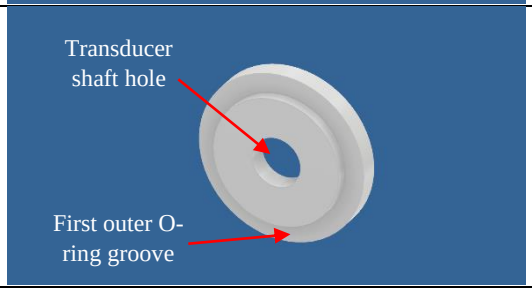
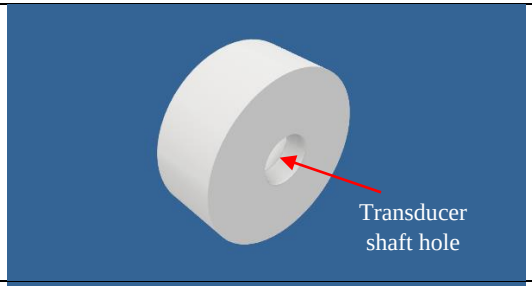
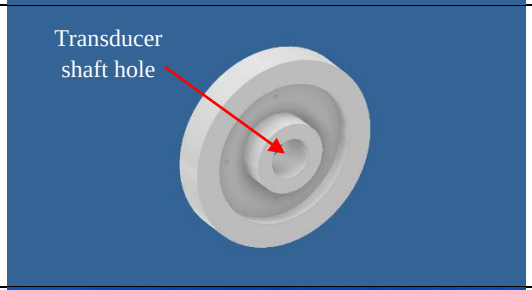


Figure 2: A) CAD drawing of the transducer probe assembly. B) Transparent view of the probe demonstrates the mechanism.

Table 2: Description of each part of the designed transducer system.

Part name	CAD drawing	File name	Purpose
Transducer probe		4D prostate Manual Z_lever42	The transducer probe hosts the transducer element. Ultrasound propagates through the acoustic opening (water-filled) at the front of the probe. Sideways two tabs are used to secure the probe to the device. At the top of the probe there are two holes, on which hoses for water circulation can be attached.
Transducer case		4D prostate Manual Z_lever69	The transducer case has an opening to accommodate the transducer element. It also includes a shaft that is connected to the X- and Θ-stage. The shaft is hollow to allow the transducer cable to exit from the rear.
Front O-ring holder		4D prostate Manual Z_lever63	The front part of the assembly secures the outer O-ring, which is used to prevent water leaking from the transducer shaft.
Rear O-ring holder		4D prostate Manual Z_lever62	The rear O-ring holder secures the outer O-ring on the front face and the inner O-ring on the rear face.

O-ring tension spacer		4D prostate Manual Z_lever61	A spacer is used to add tension to the O-rings, thus establishing optimal sealing of the probe.
Seal mechanism rear cover		4D prostate Manual Z_lever71	The seal mechanism rear cover is used to secure the O-ring assembly to the rear of the transducer probe. The rear cover is secured by four screws, which are used to adjust the tension of the O-rings.
Transducer element		Spherically focused transducer element	A spherically focused transducer element is used to generate the ultrasonic beam. The bowl-shaped element enables the focusing of ultrasonic waves.

3. Electronic system

The electronic system hosts all electronic devices into a compact unit. The system includes four motor drivers (USR60-S3N, Shinsei corporation, Tokyo Japan), a USB data acquisition card (DAQ) USB 6251 (National Instruments, Austin, Texas, USA), and a DC supply. The motor drivers powered by a 24 V power supply produce the appropriate sinewave signal that operates the piezoelectric motors. The DAQ card is connected to the computer via a USB port. It detects the signals from the robot encoders and controls the motors through commands inserted into the software by the user. The electronic system also controls the ultrasound system, according to the desired sonication parameters inserted by the user. The switches on the front of the electronic system allow the user to control the robot manually. A photo of the electronic system is shown in figure 3A, in which the switches enabling manual control of the robot can be seen. Figure 3B shows a photo of the electronic components incorporated into the system, including the motor drivers, the DAQ card, and the DC supply.

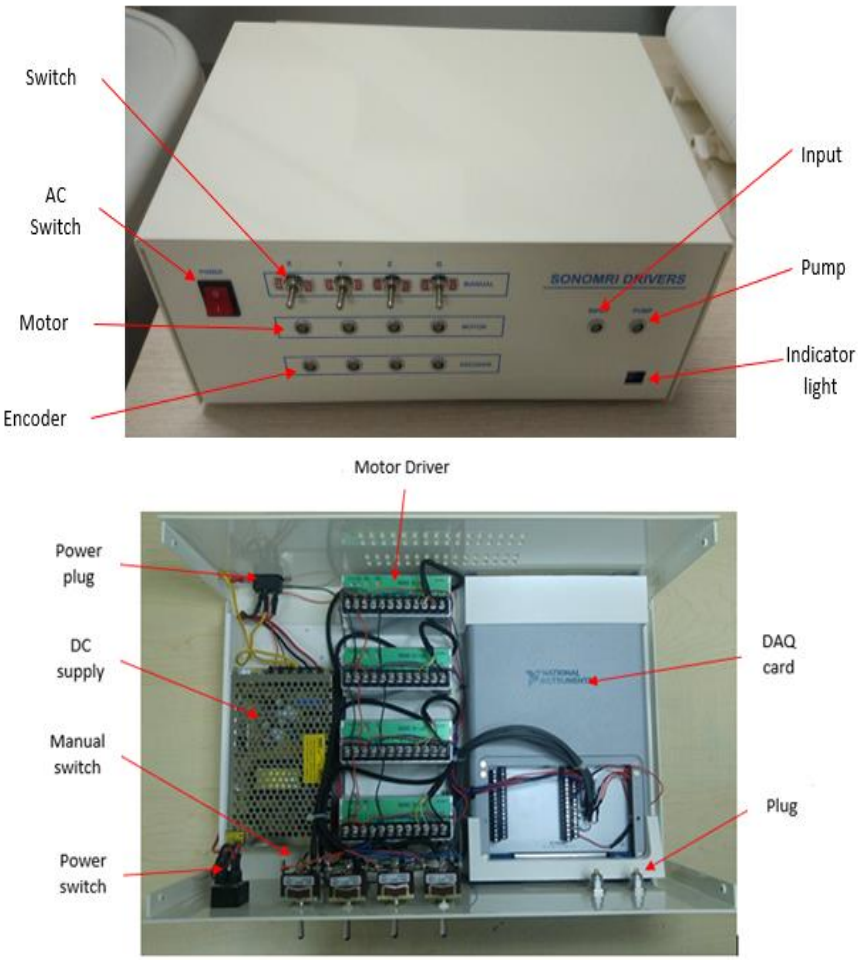
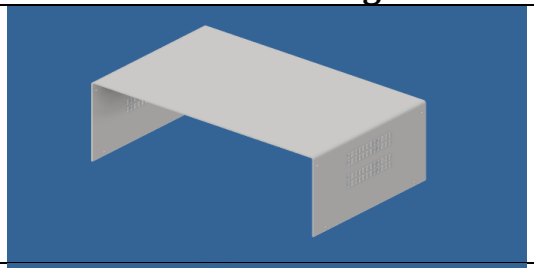
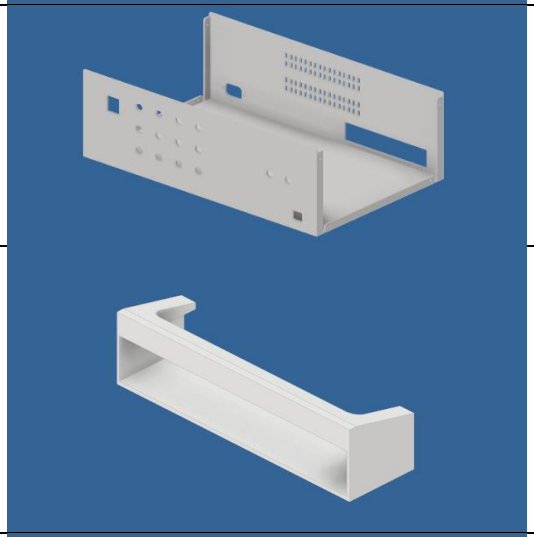
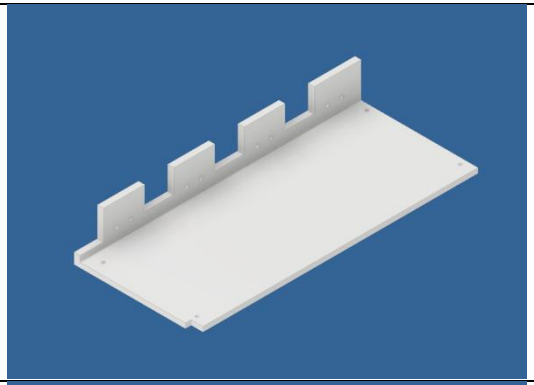
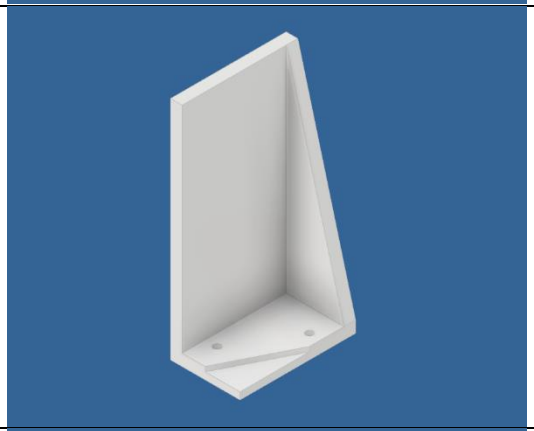
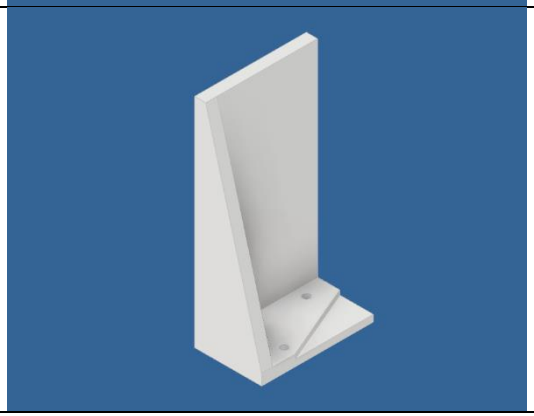
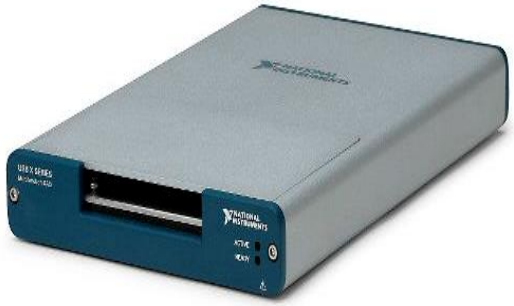


Figure 3: A) Photo of the electronic system. B) The electronic components installed in the system.

Table 3: Description of each part of the designed electronic system.

Part name	CAD drawing	File name	Purpose
Electronic enclosure cover		Electronic enclosure top cover	The cover of the electronic enclosure protects the user from the high voltage/current electricity sources. The arrays of rectangular openings on the sides allow air to circulate, thus cooling the electronic components.
Electronic enclosure base		Electronic enclosure bottom cover	The electronic components are mounted on the base of the electronic enclosure. The front and rear openings on the base allow placement of the connectors and switches. Additional openings were added to cool the electronic components.
USB interface card front holder		DAQ USB front holder	The holder supports the front of the USB interface card inside the electronic enclosure.
USB interface card rear holder		DAQ USB rear holder	The holder supports the rear of the USB interface card inside the electronic enclosure.

Ultrasonic motor drivers base		Motor driver base	The base is used to secure all motor drivers hosted in the electronic enclosure.
Power supply front holder		Power supply mount front	The front holder supports the power supply on the base of the electronic enclosure.
Power supply rear holder		Power supply mount rear	The rear holder supports the power supply on the base of the electronic enclosure.

Power Supply		DC power supply	The DC power supply converts the 230 V alternating current (AC) to 24 V direct current (DC). The power supply provides power to the motor drivers.
Motor driver		Ultrasonic motor driver	The ultrasonic motor driver is used to produce the appropriate sinewave signals for driving the ultrasonic motors.
USB data acquisition card		USB Data acquisition card	The data acquisition card connects to a computer via a USB port. The drivers and encoders are connected to the output and input terminals, respectively. It processes the user commands and the data from the encoders so as to navigate the transducer and activate ultrasound waves.

Electronic system wiring diagrams

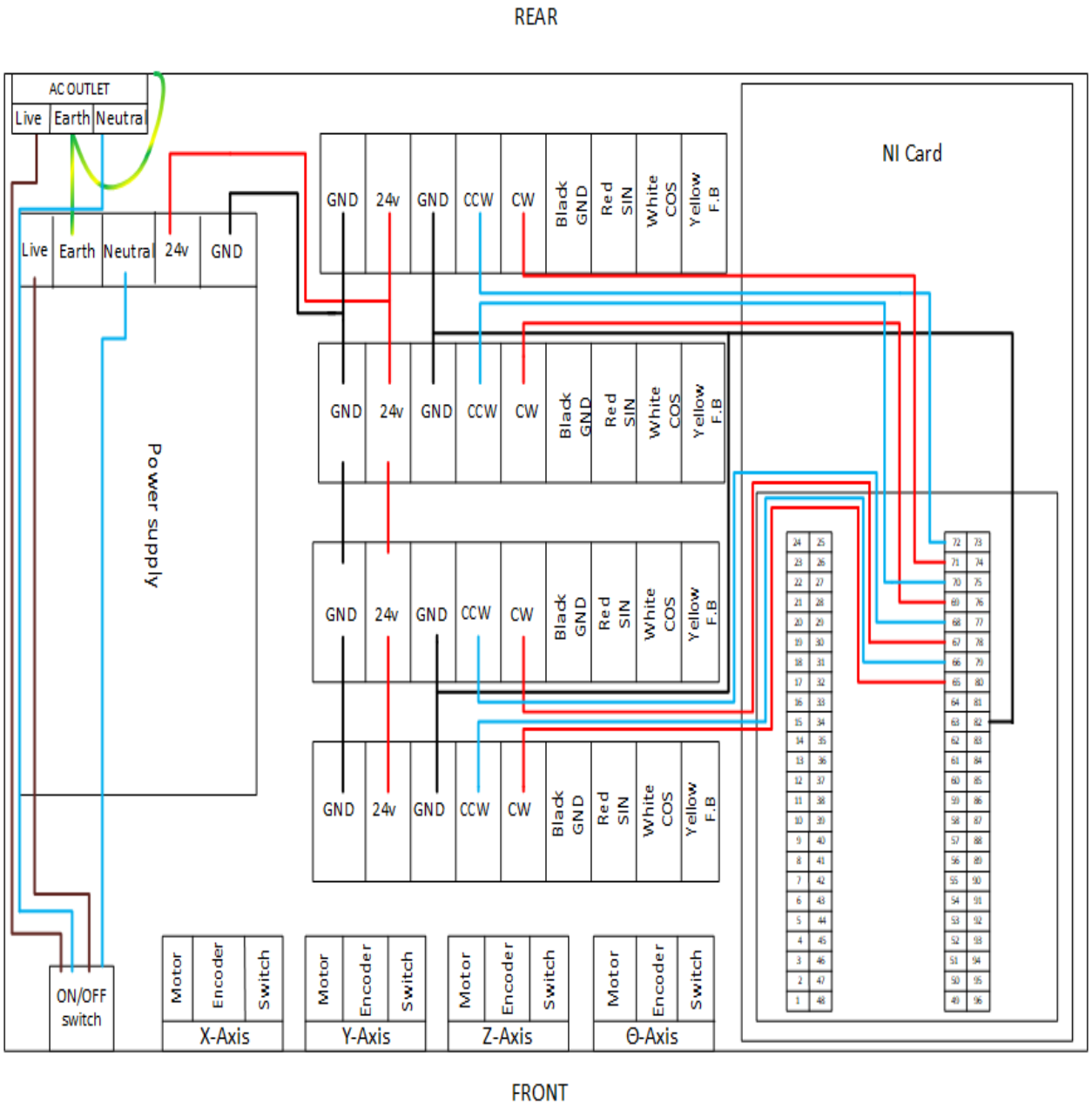


Figure 4: Connection between the motor driver and the data acquisition card.

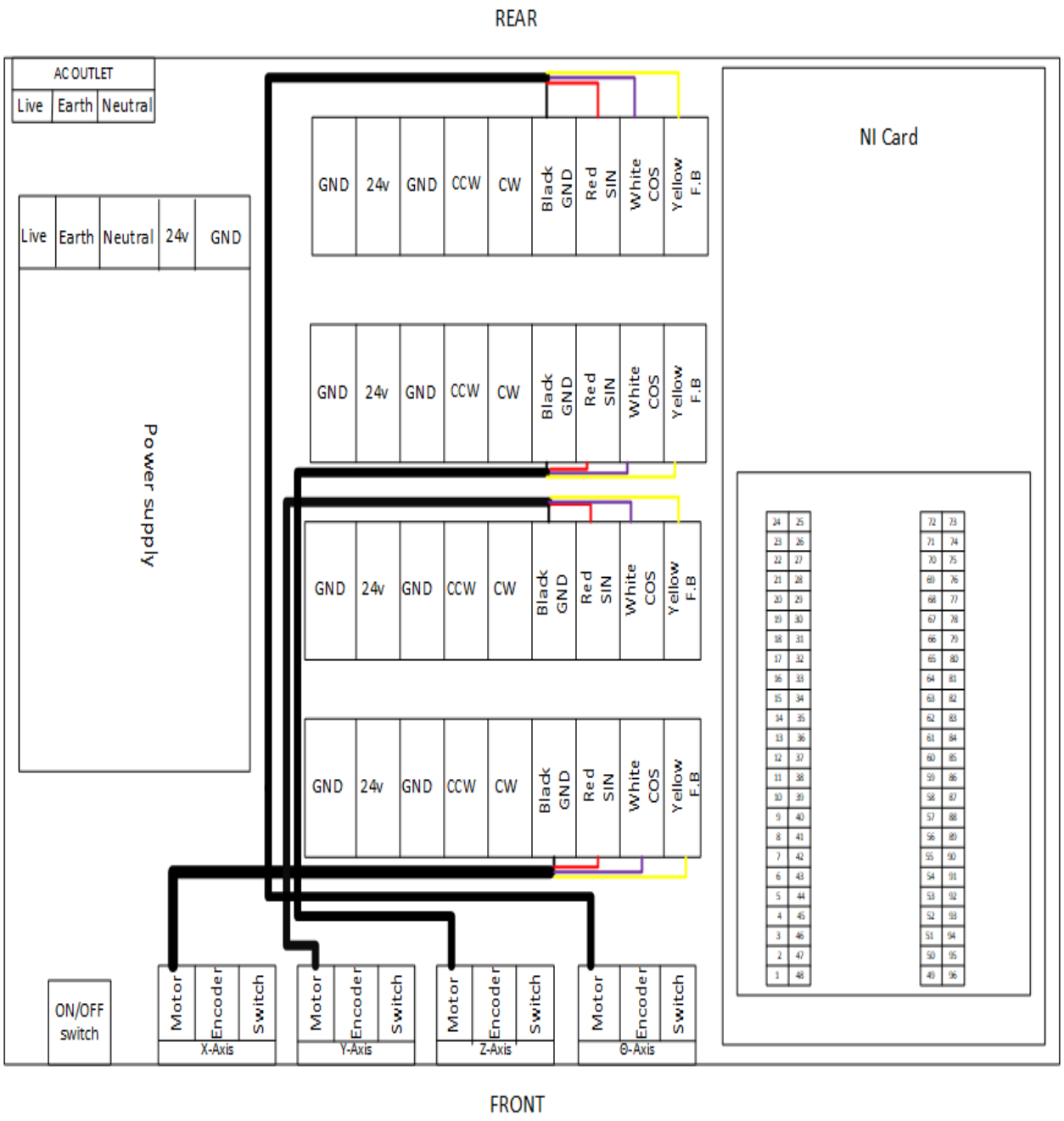


Figure 5: Connection between the motor driver and the motor.

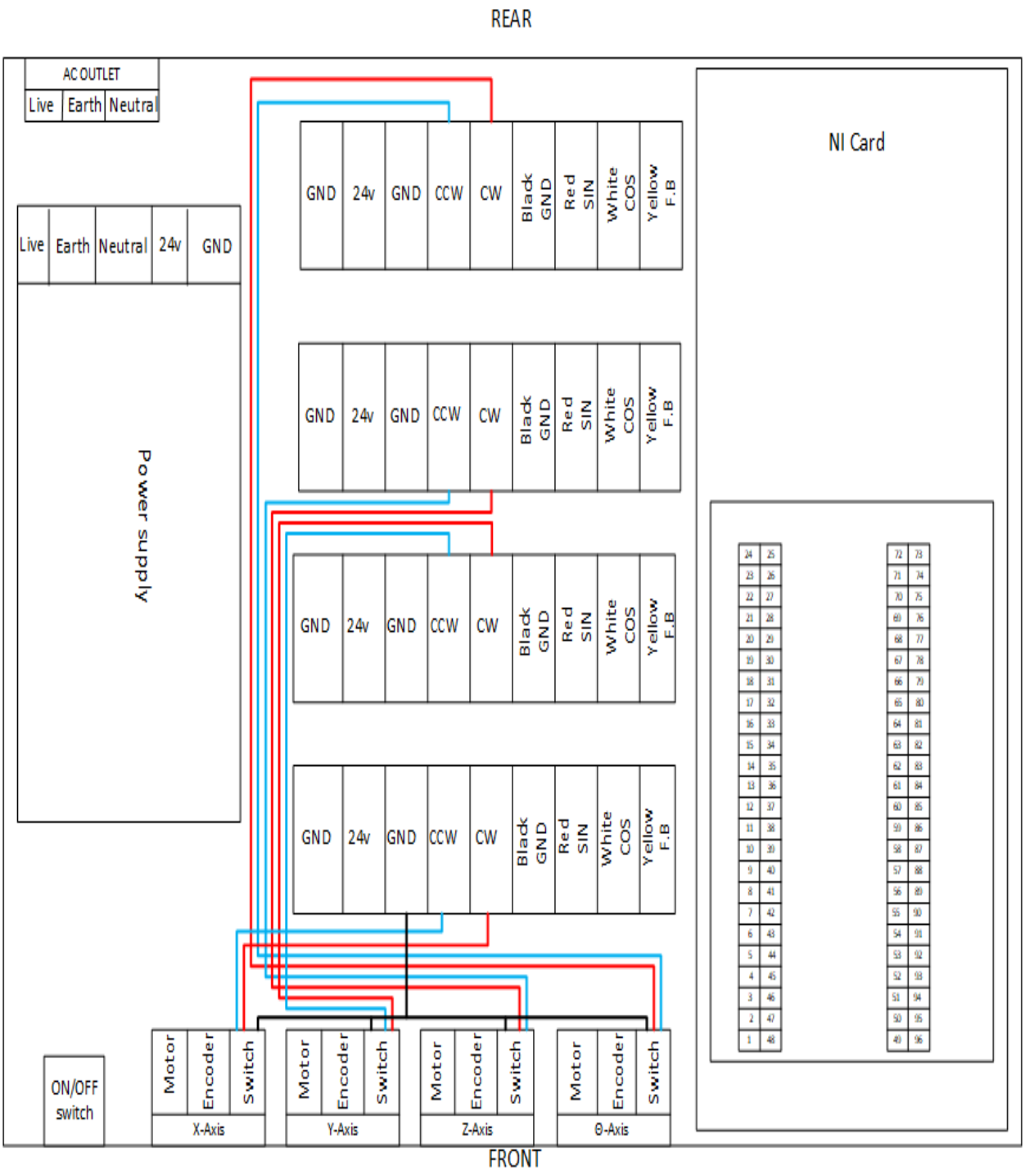


Figure 6: Connection between the manual switch and the motor driver.

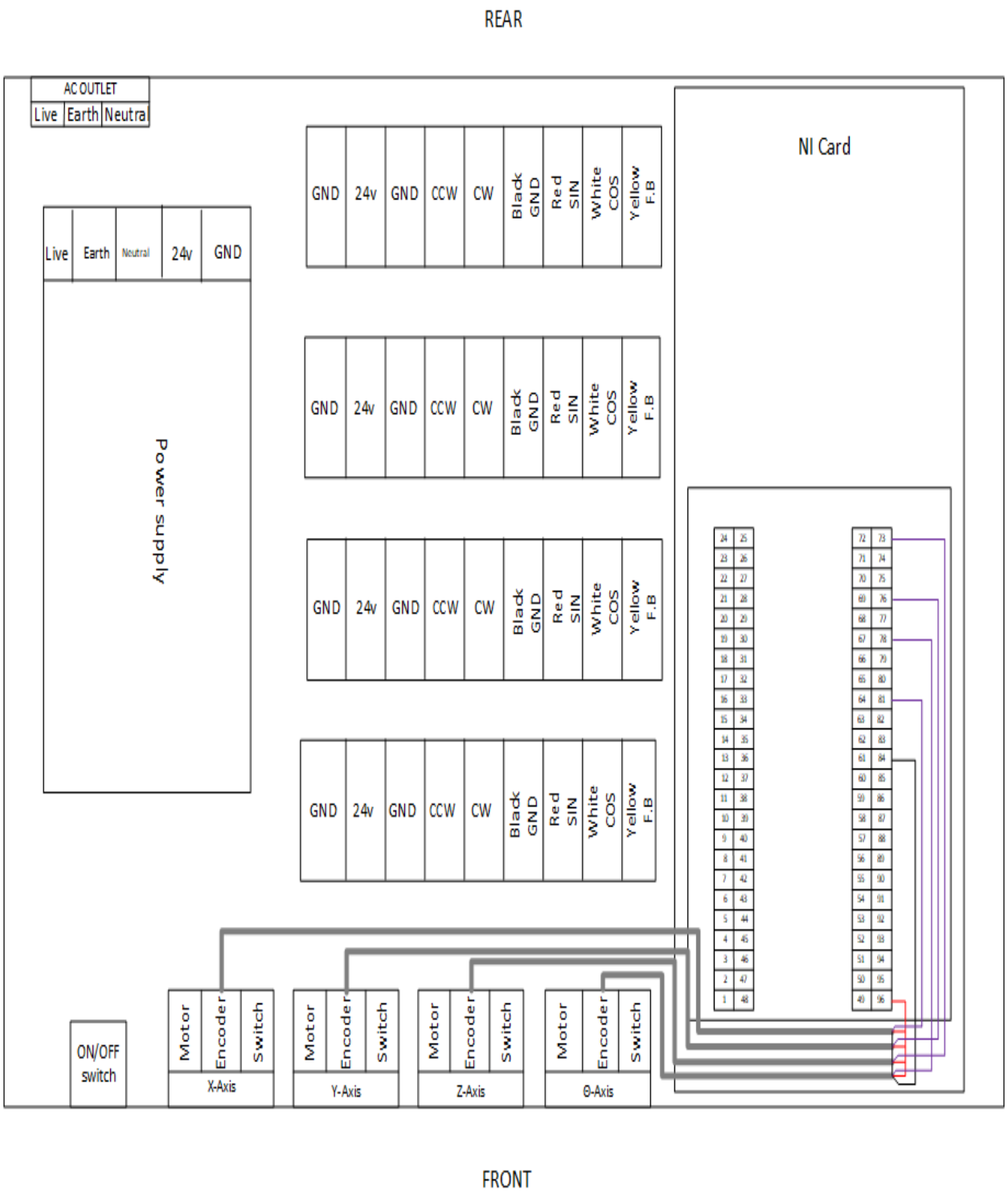


Figure 7: Connection between the encoder and the data acquisition card.