System Testing

Test: Place a bucket at the inlet and outlet port. Fill the inlet bucket with > 5 L of water. Pump the system for one minute. Measure the amount of water transferred to the outlet bucket and measure the amount of water leaked.

Specs Met: (Universal 1, 3)

Test: Seal/plug the system for 30 seconds. Build a water column out of PVC pipe that is greater than or equal to 1.63 m high. The sealed heart should be attached to the bottom of the water column via one of the ports. Fill with water and inspect for cracks, breaks, etc. after 30 seconds.

Specs Met: (Universal 5)

Test: Have 5 average adults between the ages of 18-40 pump the system for 5 minutes. After they have done this, have them rate their ease of gripping and their level of discomfort on a scale of 0-5.

Specs Met: (Universal 15, Design Specific 5)

Test: Give (printed) instructions to 5 individuals (ages 18-40) and allow them to read the instructions and assemble the external driver for practice. Once they have familiarized themselves with the process, all five individuals must repeat the setup procedure. The average time for all 5 individuals during the second setup must be less than or equal to 90 seconds.

Specs Met: (Universal 14)

Test: Place the internal portion (assembled) and the external portion (disassembled) in separate cardboard boxes filled with styrofoam or foam that has been shaped to the pieces. Subject the sealed boxes to drop, impact, compressions, and vibration tests as specified in the Fedex manual. Open the boxes when testing is completed and inspect the parts for damage.

Specs Met: (Universal 9, 18)

Test: Cycle the implantable portion (independent of the driver) from expanded to compressed and measure the volume expelled. Cycle the external portion (independent of the implantable portion) from expanded to compressed and measure the volume expelled. The external value divided by the implantable value must be between 0.9 and 1.0.

Specs Met: (Design Specific 1)

Test: Construct a box that is 6 cm x 15 cm x 10 cm in size. Place the device within the box and ensure that the entire implantable portion fits within the box. In addition, visually inspect the shape of the device. Ensure there are no sharp edges or corners on any of the exposed surfaces.

Specs Met: (Universal 2)

Test: Visually inspect each ventricle. Count the number of ports and initial that there are at least 2 ports on each ventricle.

Specs Met: (Universal 4)

Test: Inspect the device. Ensure that there are no batteries.

Specs Met: (Universal 6, 16)

Test: Dye water red to simulate blood. Pump the system and visually inspect to make sure that none of the red water is flowing through the inlet or outlet tubes, as these tubes exit the body.

Specs Met: (Universal 7)

Test: Assemble the implantable portion. Drop the implantable portion onto a padded rubber surface from 1 ft high. Repeat this 5 times. Visually and manually inspect the device after each drop for damage or cracks. Complete the same test for the external portion, but with the pieces disassembled.

Specs Met: (Universal 8, 17)

Test: Implant the device into an animal, such as a cow. Observe the effects of the device on the cow and the tissues surrounding the device for at least one year.

Specs Met: (Universal 10)

Test: Use typical sterilization procedures (utilizing steam/heat). Conduct at least 3 swab tests on different surfaces of the implantable portion and examine the swabs under microscopes for any microbial life.

Specs Met: (Universal 11)

Test: Obtain a backpack that is 45 cm x 43 cm x 22 cm. Place all of the required items for the external portion into the backpack. Make sure that all the items fit and that the backpack cans still be zipped. Place the backpack on a scale and weigh the bag with all of the necessary components inside.

Specs Met: (Universal 12, 13)

Test: Visually inspect the fluid used inside the external and implantable portions. Check to make sure that the fluid used is known to be incompressible.

Specs Met: (Design Specific 2)

Test: Wrap a 0.5 inch thick strip of colored tape around the rim of the flywheel. Spin the flywheel for 30 seconds and count the amount of times that the piece of tape completes a full revolution.

Specs Met: (Design Specific 3)

Test: Assemble the external driver. Spin the flywheel and visually inspect the piston to see if the piston is moving in sync with the flywheel's motion.

Specs Met: (Design Specific 4)

Test: Assemble the entire system. Fill the blood side of the implantable device with water. Pump the piston fully and measure the amount of water that is expelled from the blood side of the implantable device (via the outflow tubes). Conduct this test at least 5 times.

Specs Met: (Design Specific 6)