Parkinson’s Disease

**Exec Summary – 9**

* clear, thorough, concise, reimbursable = good value

**Background and Motivation – 9**

* I like the use of personal interviews in the background, as it provides a specific source from an expert and people who are directly affected by PD
* it solidifies the need in my mind, good clear concise description of RAS and PD with a good flow – easy to read
* well done research about reimbursing the product and how to follow the process to do that
* well thought out chart of needs

**Product Definition – 7.5**

* cool logo and nice description as to what each part does
* additional thoughts to section 3.3 The Market: another advantage is that it doesn’t require surgery unlike DBS, could be employed before DBS as it will probably cost less (as well as drugs)
* looking for a labeled picture of the overall system in the system level and module level description sections, but this is missing. Instead there are several individual pictures but it would be nice to see them all tied together in the overall system. i.e. in figure 2 in the sensor module box, insert a picture of the IMU
* Good description of the IMU limitations and how they were mitigated via assumptions
* In figure 5, show the Velcro and where/how exactly the sensor will be attached
* Page 16 last paragraph – mentions that they tested the sound module with input data, would like to see or have a reference to the proof of the testing (in an appendix or referenced elsewhere in the report)
* 3.5.3 – no picture of the fanny pack? No need to show the plastic box that was not used, would rather have seen the fanny pack that was the selected device casing

**Concept Exploration - 8**

* iteration 1 – good explanation, simple concise, and good proof of concept prototype and test
* page 24 – RMS error value of 17.45% (is this an acceptable error?) if it is, should there be a reference?

**Quality Analysis – 9**

**Risk Analysis - 9**

**Summary – 9**

**Overall Structure – 9** well organized and well written – easy to follow, thorough, clear, concise writing

**Overall Comment:** Great job! Impressive that the REB was completed to provide meaningful research to the project!

EnerCardio

**Executive Summary – 6.5**

* good hook but stick to Canadian stats
* not specific enough – if you mention risks and human factors considered, they should be briefly listed in the exec summary as it should read stand alone
* no cost analysis
* language is a bit too aggressive – instead of ‘our device proves’, it should read: ‘we present a proof of concept prototype that can use blood flow to….’

**Background and Motivation – 5**

* page 3 and in exec summary – it is obvious that children (and other patients) would want a pacemaker that lasts longer so this is not a strong reason to cite as the main motivation, consider cost of procedure, length of hospital stay, patient recovery times, etc. as motivators instead of this
* needs statement has a grammatical error
* why is it not possible to test an implantable device easily? Need to have solid reasons e.g. cost, REB, regulatory approval, time, resources, validated animal models, etc.
* background reads more as an opinion piece, rather than a factual section – e.g. “we realize it will be difficult to implement….” – this needs to have a reason as to why it will be difficult and what regulatory tests are you referring to?
* This section lacks a lot of research. It should provide the initial research for the problem (pacemaker, surgery, battery replacement surgery, patient recovery, wait times, etc., and the research on the technology (the turbine and how it can be used to harness energy))

**Product Definition – 6.5/7**

* Need an engineering paper or textbook to act as a reference for the proposed concept overview.
* Figure 1 - Avoid hand drawn – this could have been a CAD or a simple powerpoint drawing to make it look more professional
* Good logo
* Should still talk about the products on the market – even one or two sentences about each
* Good cost research about how expensive replacing the battery can be
* Post-surgery complications – these risks (as well as others) would be present after implantation of the turbine too. If the device will be implanted in patients who already have a pacemaker, then you’re still exposing them to another surgery with these post-surgery complications. Should have mentioned this as a limitation, not something that would be overcome with this device.
* ‘even though companies might reject…’ – need to explain why they would reject it. Don’t use ‘we believe’ your claims should all be backed up by evidence – could even use another device that has a similar solution as an example why companies might be attracted to this idea
* Figures 3 and 4 need to have an explanation and caption. Figures should always be accompanied by text.
* What is the number of doctor visits required by pacemaker patients currently? Use this number as a benchmark to determine whether patient care would be affected
* System-level – what is the widest artery? And if you have chosen that please list all factors that would go into selecting that artery
* Describe why you are prototyping a large artery (3cm in diameter) -> because of the scoping of the project, proof of concept phase, etc.
* Good picture and CAD of the propeller, would have liked to see labels
* Placement and holding section is good

**Concept Exploration - 7**

* Good first prototype
* How was it tested and how did you arrive to the conclusions as to why it didn’t work the first time? Need a link here, usually testing provides some insight but it is not included how it was tested
* What is a ‘high reluctance’? please provide a number/range and a reference for a high or low reluctance
* Figure 14/15 shows testing set up which is good, but the figures are not clearly labeled to fully understand clearly what is going on. Nevertheless, looks like a normal electrical engineering testing setup which is good. Looks like the manual rotation of the propeller was done using a electric screwdriver – should have mentioned that in text and explained what speeds of the screwdriver were used and how they correlate to the blood flow experienced by the body
* Table 1 is good and clearly summarizes the testing results and why they are relevant – description scoped out the initial test well and explained that this test was proof of concept that allowed advancement to the next phase
* Would delivering too much power be harmful? Would you need to reduce power? What range of power is required? Is there an upper limit?
* Wet testing – well done
* Blood coag. Due to turbulent flow – need to cite the reference!
* Page 23 – quantify “much impact on blood pressure”
* Good use of CFD but should also show CFD inside a normal vessel with nothing but blood flowing through
* Figure 23 – need to label where the magnets go, diameter label is hard to read
* Touched on many different design criteria, which is good, but they were not very well explained or linked to each other. Hard to follow.

**Quality Analysis - 7**

* Employing the camera and x-ray for the surgery increases surgery time, cost, training required, risk, etc. instead of relying on the surgeon, the design should be modified so that it doesn’t require such precise positioning during surgery
  + However, this was mentioned, so that is good thinking, if you had talked to the expert from before, they might have mentioned this to you
* Should have a picture accompanying this to show how it will be implanted
* Should have considered that requiring all this extra training and equipment for the surgery would hinder people from using the device as it’s too cumbersome

**Risk Analysis – 7**

* How to mitigate these human factor risks of the surgeon not implanting it properly!!
* Page 29 – talking about stenosis – mention the size of stents, if the design is comparable within a range then that is probably okay
* Would the magnet and pacemaker interfere with each other’s function? – this is mentioned but there is no reference or example to explain why it would not interfere
* Instead of saying “we will try our best to use insulating material” – use electrical requirements to spec out a good insulated wire to use – probably the wires used in the leads that go from the pacemaker to the heart are appropriate here
* Every artery is vital. Where is the axillary artery? How wide is it?
* Erythrocytes being destroyed – need numbers here. How much turbulence can they handle? How much turbulence does your device cause? This will give a definite answer about erythrocytes
* How can the infections be treated?
* Again, these are all very good points raised but are not thoroughly and/or clearly explained – ‘we will try our best’ is not enough to convince the FDA that your product is safe to use in patients.

**Summary - 7**

* This project was not enough to prove that a turbine will successfully generate power from blood flow as blood flow was not mimicked. Instead, it proved that a blood like fluid flowing through a large pipe and turbine can generate wattage and the turbine can be tweaked to generate desired power. This is a proof of concept, and that was attained.

**Overall – 5**

* Multiple grammar errors present
* Statements are missing references e.g. on page 5/6 when talking about the options to replace the battery
* Need to label figures and have accompanying text
* Figures need to be meaningful – crop them and have a meaningful caption
* Language – “we believe” and “we think” is inappropriate for a final report. Need to have factual and evidence based claims. Use references more.
* Writing was hard to follow and not thorough – missing references and critical thinking was lacking

Stool Diagnosis

**Exec Summary – 9**

* great, clear concise, thorough – I have a good idea of what will be discussed

**Background and motivation – 9**

* good use of interview sources

**Product definition – 9**

* good logo
* thorough understanding of market and users is demonstrated

**Concept Exploration – 9**

* fyi - the tests are called verification and validation tests (qualitative assessment is the validation test)
* table 1 is great – good, clear rationale as to the final product decision
* figure 4.3 is blurry and does not provide a clear representation of the test results
* good explanation of how the simulated stool is a limitation
* great needs table

**Quality Analysis- 8.5**

* additional to harming the user or contamination, another human factor to be considered would be proper use of the product to yield the sample by the technician and person providing the sample – what if the lid falls on the ground or gets stepped on, damaged, etc. how would you prevent or mitigate damage to the mechanism on the lid

**Risk Analysis – 9**

**Summary – 9**

**Overall – 9**

* very well written, flows well, organized, thorough, clear

EyeDiagnose

**Executive Summary – 9**

**Background and Motivation – 9**

**Product Definition - 9**

* good explanation of logo
* thorough, clear, concise, great overview of the product

**Concept Exploration – 9**

**Quality Analysis – 9**

**Risk Analysis – 9**

* thorough explanation of realistic risks identified

**Summary – 9**

**Overall - 10**