

ABET Addendum

1) Desired Needs

- Managing the heterogeneity nature of organoid batches in a way that is cost-friendly, and easy to implement into standard lab settings.
- Automated sorting device should classify and separate brain organoids, without human intervention, into two categories: good/healthy that offer further usage, and bad/unhealthy that should not be used in further research or experiments.
- Organoids are preserved through the entirety of the device.

2) Constraints

- a) Safety/ Regulatory Affairs: Device must be biocompatible to organoids such that they maintain viability through the entirety of the system from loading to exit flow/collection.
- b) Risks: Damaging the organoids within the system due to shear stress, and subsystem failures such as clogging or flow disruption, image classification errors, or sorting malfunctions.
- c) Global Impact: Organoid research and technology is being increasingly used in disease modeling, drug screening and personalized medicine.
- d) Manufacturability: The device must be manufacturable and reproducible using common, inexpensive biomaterials such as CAD design, resin 3D printing, and PDMS casting.
- e) Quality Control/Marketability: Quality control in our device is dictated by requiring a high success rate from the sorting algorithm and marketability for our device is dictated by the system integration and the automated nature of organoid flow within our system.

3) Engineering Standards:

- ISO 22916:2022: addresses interoperability, dimensions, and connections for microfluidic devices, guiding physical design and integration of system components.
- ISO 10993-1: covers biological evaluation of medical devices, governing material selection and cytotoxicity testing when the device contacts living organoids or culture media.

4) Ethical, Environmental, Societal Concerns

- Environmental concerns are found in our project through the use of various materials that require proper usage and disposal.

5) Active Teamwork and Leadership

- a) Collaboration – Establishing the subassemblies early provided opportunities for everyone to be involved and heard in design discussions.
- b) Delegation – Division of labor that aligned with our devices subassemblies was based on interest, previous experience. Cross-system discussion and planning was encouraged and utilized.
- c) Goals and Deadlines – We established goals around our project priorities list and applied them to design geometry, testing methods and prototyping.
- d) Constructive Feedback – Mentor feedback was invaluable and we saw it as a learning opportunity. Intergroup feedback was always constructive as we understood our unified goal.

6) Motivating Factors

Studying new concepts like organoid biology on our own and making design decisions surrounding constraints that didn't offer a clear, single solution was motivation in itself.

7) Most innovative and/or entrepreneurial ideas

The most innovative idea in our project was the real time imaging of the organoids combined with the flow-based sorting. On top of that, a future direction for our device would be integrating our entire system into one software would effectively automate the system and eliminate the need for manual input.