REQUIREMENTS SPECIFICATION: Environmental Enclosure for a Single-Cell Inkjet Printer

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PREFACE

Due to restrictions imposed as a result of the COVID-19 pandemic, we were not able to complete all elements of the project. The following document reflects the requirements for the intended design, with all elements fully assembled. The actual prototype is not fully integrated due to shipping and manufacturing delays , as well as an inability to access vital equipment. Without the fully assembled enclosure, we were unable to complete the testing required to validate the various performance specifications, particularly for the humidity control unit. Although we have collected data for smaller enclosure volumes, validation is required for the humidity control unit within the custom-designed BIOME enclosure. Fortunately, based on the previous prototype iterations, we were able to satisfy all the main requirements described for the temperature control unit. Integrated validation with all subsystems is still required to ensure the enclosure works as intended. Please note that Air Filtration was not implemented for this version of the product, however Air Filtration requirements have still been included in this document as a goal for future development.

CHANGELOG

Version	Date	Editor	Change
1.0	24/09/19	All	Document created.
1.1	11/20/19	LH, AY	Edited spec. numbers; added additional specifications.
1.2	09/02/20	NL,LH, AY	Reworded requirements for TCU and FEU materials/structure.
1.3	01/04/20	LH, AY	Updated budget, removed specifications for ambient temperature heating.

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LIST OF ACRONYMS AND ABBREVIATIONS

BioMEMS	Bio-Medical Micro Devices[1]
BIOME	Biological Metabolism Maintaining Environmental Enclosure[2]
Cx.x	Constraint x.x
Fx.x	Functional Requirement x.x
NFx.x	Non-functional Requirement x.x
RH	Relative Humidity
Spec.	Specification

[1] This abbreviation is defined by the laboratory of our client. The colloquial definition of BioMEMS is "Biomedical Micro-Electrical-Mechanical Systems"

[2] BIOME is the product name of the Environmental Enclosure, chosen by the Capstone team

1 BACKGROUND AND CONTEXT

The Bio-Medical Micro Devices (BioMEMS) Laboratory is a research group at UBC that focuses on the miniaturization of systems and devices, particularly for biomedical applications. Currently, the BioMEMS Lab is developing a novel inkjet printing system for isolation of single cells. Inkjet printing technology provides a flexible, cost-effective, and efficient means of micropatterning living cell samples and can be used for a variety of applications including genomic sequencing, antibody discovery, and stem cell research. While existing cell printers struggle to balance the high accuracy necessary for single-cell isolation with sufficient throughput, the BioMEMS' system uses machine vision and deep learning to facilitate a single-cell dispensing process at high rates.

One challenge with single-cell isolation processes is that they must be performed within meticulously controlled environments. External factors such as temperature, humidity, and sterility (i.e. airborne particles and bacteria) can be detrimental to the health and usability of cell samples; without proper regulation, downstream analysis cannot be performed. In order to evolve the current single-cell inkjet printer from a proof of concept to a practical technology for end users, a controlled environmental enclosure must be designed.

2 DOMAIN

The project is classified as an integrated control system. The application of the project is to enable the single cell inkjet printer for end-use by various research groups that would like to perform analysis on samples produced by the printer. Once the enclosure has been developed and integrated with the BioMEMS inkjet printer, the printing system will be a better alternative for single-cell inkjet printing in comparison to current market options, attributed to the high throughput and isolation accuracy of the printer.

3 GOAL

The main goal of this project is to design and build a strictly controlled environmental enclosure to complement the existing single-cell inkjet printing system of the BioMEMS Lab. This is necessary to mitigate the negative impacts of the environment on biological samples and to allow downstream analysis for future end-users. Upon completion, this project will serve as an initial prototype with fully integrated humidity, temperature, and sterility control systems; it will act as supporting equipment for the single-cell isolation printer.

4 FUNCTIONAL SPECIFICATIONS

Functional specifications describe the services, capabilities or functions delivered by the product. The tables below consist of the functional specifications for different parts of the system. Table 1 consists of the functional specifications for Temperature Control of the 5184 Nanowell and 96-Well plates, while Table 2 is for Humidity control and Filtration control.

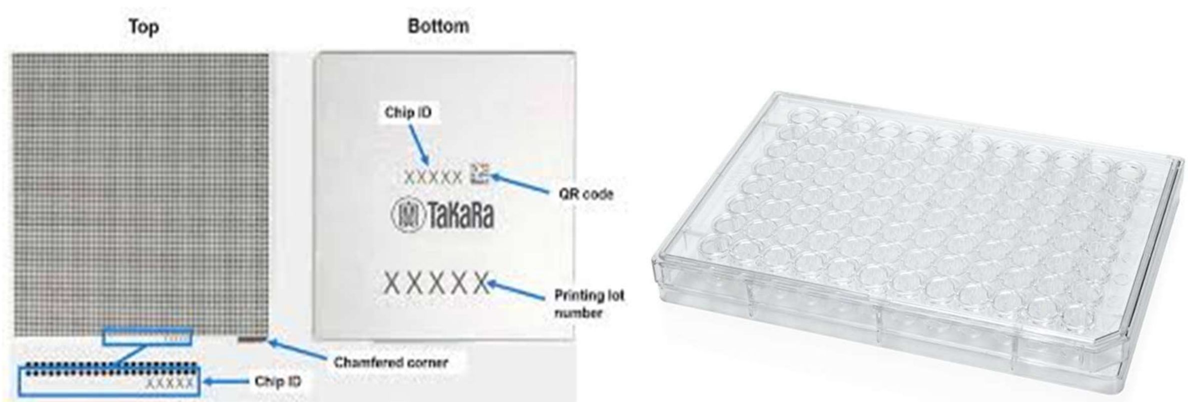

Figure 1: (a) 5184 Nanowell Plate [1] (b) Standard 96-Well Plate [2]

System	Specification		Reason	Spec. Number
Temperature Control for 5184 Nanowell and 96-Well Plates	The temperature of the plate must be controlled for a variety of setpoints	2.0 °C - 4.0 °C	This will allow the user to put the cells in stasis	F1.0
		37.0 °C	This will allow the user to use the system for cell incubation	F1.1
		80.0 °C	This will allow the user to sterilize the well plate	F1.2
	The system must report the temperature with a certain degree of precision	+/- 0.2 °C	This is to ensure that the well plate is at the temperature that the system indicates	F1.3
	The steady-state temperature must remain within a certain range of the setpoint	+/- 0.5 °C	This is the temperature range that the plate can fluctuate without damage to the cells	F1.4
	The system must reach a setpoint within a certain amount of time	> 5 °C per minute	This specification is to ensure that the user does not need to wait for a long period of time before printing	F1.5

Table 1: Functional Specifications for Temperature Control of the 5184 Nanowell and 96-Well

System	Specification		Reason	Spec. Number
Humidity Control	The enclosure must be controlled to 95.0% RH to prevent evaporation of samples at temperature setpoints	2.0 °C - 4.0 °C	This will allow the user to put the cells in stasis	F2.0
	This system must have a certain degree of precision	+/- 0.1 %	This is to ensure that the relative humidity in the enclosure is at the relative humidity that the system indicates	F2.2
	The system must have a certain degree of accuracy	+/- 2.0 %	This is the relative humidity range that will not result in cell evaporation	F2.3
	The system must reach the RH for a setpoint within a certain amount of time	< 5 minutes	This specification is to ensure that the user does not need to wait for a long period of time before printing	F2.4
Air Filtration[3]	The air within the enclosure must be sterilized prior to the start of printing by the built-in filtration system to catch 99.97% of the 0.3-micron particles. This is the standard for HEPA filtration.		This will prevent contamination of samples due to contaminants in the air	F3.0
	The system must sterilize the air of the enclosure within a certain period of time	< 5 minutes	This specification is to ensure that the user does not need to wait for a long period of time before printing	F3.1

Table 2: Functional Specifications for Humidity Control and Air Filtration

[3] Air Filtration is not implemented for this version of the product

5 NON-FUNCTIONAL SPECIFICATIONS

Non-functional specifications describe the various qualities and attributes the product needs to exhibit. The non-functional requirements that have been identified for this project are outlined in Table 5

Type	Specification	Reason	Spec. Number
Access	The enclosure must have an access door at least 210 mm x 160 mm and have a latch that indicates that the door is sealed.	This is required so that the user can perform maintenance on the mechanical and electronic systems. This is also required to allow the user to load chips and plates.	NF1.0
	The enclosure must have sealed conduits to allow cables and tubes of the single cell inkjet printer to pass into the external environment.	The conduits will limit the number of locations in the enclosure that will break isolation.	NF1.1
	The door-hinges must be able to bear up to 12kg.	The hinges need to support the weight of the doors.	NF1.2
	The doors must have the ability to lock in-place in an open position of up to 85 degrees from the closed position.	The user must be able to safely open the enclosure and access the printing system without the doors falling upon them.	NF1.3

Sizing	The enclosure must be at least 85 cm x 70 cm x 50 cm (L x W x H).	The enclosure must be big enough to include printer extrusions and moving components	NF2.0
	The temperature control platform must be at least 127.71 mm x 85.43 mm x 14.10 mm (L x W x H) to secure the 96 well plate	This is to ensure the well plate does not fall out while printing is occurring	NF2.1
	The temperature control platform must be at least 60 mm x 60 mm x 3.97 mm (L x W x H) to secure the 5184 nanowell plate.	This is to ensure the well plate does not fall out while printing is occurring	NF2.2
Power	The system must be powered from a standard 120 V, 60 Hz wall outlet.	The client requested this as the method to power the system	NF3.0
Enclosure Materials	The material must not dissolve when sterilized with ethanol.	The enclosure needs to be easily sterilizable without dissolving	NF4.0
	The material must not release particulates or off-gas.	The enclosure materials cannot contaminate the sample	NF4.1
	The material must not be hygroscopic.	Droplets from the air cannot be absorbed by the enclosure, which could lead to bacterial growth	NF4.2
	The total weight of the enclosure should not exceed 50kg.	This ensures that the enclosure can be reasonably lifted from ground level to a lab bench 60 cm in height by ~4 average-strength people.	NF4.3

Operation	The enclosure must operate separately from printer electronics and software.	This was a suggestion from the client	NF5.0
	The system will have buttons to set the relative humidity and temperature setpoints.	This will allow the user to change the setpoints without using an external system	NF5.1
Display	The enclosure must display the current relative humidity to the nearest 0.1% and temperature to the nearest 0.1 °C.	This allows the user to monitor enclosure conditions in real-time	NF6.1

Table 3 : Non-functional Specifications for the Enclosure System

6 CONSTRAINTS

Constraints are any aspects of the project that restrict design choices and overall implementation of the product. Table 6 summarizes some of the key constraints identified for this project.

Type	Summary	Spec. Number
Contamination	The enclosure material must not contribute to contamination.	C1.0
	The humidity system cannot produce condensation on the well plates.	C1.1
	The humidity system cannot produce aerosols that will interfere with the sample.	C1.2
	The humidity system must not contribute to contamination.	C1.3
Budget	The project is limited to the $1000[4] provided by capstone and the resources that the BioMEMS lab can provide.	C2.0
Dimensions	The maximum height between the print bed and nozzle is 50 mm, therefore any temperature control platform height must be less than this.	C3.0
	The maximum width of the print bed is 120 mm, therefore any temperature control platform solution must be smaller than this.	C3.1

Table 4: Constraints for the Enclosure System

[4] An increase in the Capstone budget was requested by the Capstone team

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