Product Design Specifications: Microscope cell culture incubator

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Problem Statement

This project team serves to develop a low cost cell culture incubation chamber that is compatible with an inverted microscope and capable of live cell imaging. This incubation chamber must be able to maintain an internal environment of 37 C, 5% CO2, and 95-100% humidity over a long duration of time, without compromising the integrity of the microscope's optics or functionality. Special consideration should be taken to maintain even heating and humidity across the chamber as gradients can result in evaporation from low volume cultures such as microfluidic devices. Current commercially available systems are prone to these issues and are extremely expensive. Commercial systems also tend to be large and enclose the entire microscope making it difficult to assemble and remove and between uses. Because of their size, they also hinder use of the microscope in general.

Client Requirements

- No condensation can form on the viewing screen of the incubator
- Cannot hinder the optics of the microscope
- Must be able to be cleaned with ethanol
- Make the temperature across the incubator and cell culture as uniform as possible
- Limit the amount of wires if possible

Design requirements

This device description should be followed by list of all relevant constraints, with the following list serving as a guideline. (Note: include only those relevant to your project):

1. **Physical and Operational Characteristics**

a. *Performance requirements*: The device must fit on the inverting microscope used by the client, have a window that allows the user to see the cell culture as well as if there was no incubating chamber there. The device must maintain an internal environment of 37℃, 5% CO2, and 95-100% humidity. Condensation build up due to humidity must be removed in order to preserve clarity for the user.

b. *Safety*: The device should operate without harming the user in any way. Some issues that we may encounter include the heat of the object surface coming into contact with the user, improper gas connections leaving CO2 gas to fill the room, and breaking of glass due to improper usage or drastic changes in temperature.

c. *Accuracy and Reliability*: The device must be able to maintain a temperature of 37°C ± 0.5°C [1] throughout the entire internal environment. The humidity must be kept above 95% humidity [2]. CO_2 levels must be 5% ± 0.1%. The incubator must be able to maintain these conditions constantly for at least two weeks. The device must also be able to reach these conditions after the incubator has been opened and exposed to the external environment within five minutes of interruption.

d. *Life in Service*: The device should be able to sustain two weeks of active use with a viable cell culture. This includes humidity, CO_2 levels, and temperature that are all within the optimal range. Optimal use will be for one week at a time as part of a tissue engineering lab.

e. *Shelf Life*: The shelf life of this device will be ten years.

f. *Operating Environment*: The device will be used in a clean room and there are no adverse effects caused by this environment. The incubation chamber will contain internal conditions of 37 °C, 5% CO2, and 95-100% humidity over a long duration of time.

g. *Ergonomics*: This device is being reinvented in part due to the lack of ergonomics for devices that are currently on the market. In the other devices, our client described difficulties in setting up the microscope to work with the cell cultures despite being experienced with microscope usage. Therefore, our device must function in such a way that it is easy to take on and off of the microscope while still maintaining its primary function. The device must also be easy to set up and start the process so that it can be done by a user with minimal experience [3].

h. *Size*: The device must have a maximum size of 310x300x45mm [4]. This size constraint will allow the device to effectively interface with the current set up used by the client. In general, this device needs to fit with all inverting microscopes.

i. *Weight*: The device must have a maximum weight of 30kg [4]. This weight will allow for the device to be put on the microscope without damaging it.

j. *Materials*: The device may use stainless steel as its core and incorporate copper wirings as a variety of sensors. The device may use a water heater as its heating source and may thus also use a water pump.

k. *Aesthetics, Appearance, and Finish*: The device may look rectangular in shape, with a water heater pipe running along its perimeter. The device may be filled with water, with a glass window for the microscope to see through.

2. Production Characteristics

a. *Quantity*: Only one device is necessary. However, two would be preferable for the tissue engineering class it is designed for. The device should ideally be able to be produced at a larger scale if required.

b. *Target Product Cost*: The target cost for the whole project is under $100. The goal is to utilize other models, previous prototypes, and used sensors to minimize cost so that we can effectively accomplish the tasks we set out to accomplish. It is currently estimated by the client that most of the budget for this project will be allocated to sensors and the devices needed to make use of the sensor functions.

3. Miscellaneous

a. *Standards and Specifications*:

i. Product should follow the standards and regulations set by the FDA in CFR Title 21

1. The incubator must have multiple chambers or compartments filled with water in which controlled environmental conditions, particularly temperature, are maintained [5].
2. As a class one medical device, the device is exempt from premarket notification procedures and good manufacturing practice requirements [5].

b. *Customer*: The primary customer is John Puccinelli, professor at UW-Madison using this for the education of future BMEs. It may also be used by other professors and researchers that are looking for a more affordable option for a microscope cell culture incubator.

c. *Patient-related concerns*: It is recommended that the incubator be sterilized with ethanol occasionally, approximately one or two times a month [6]. There is no storage of patient data that must be safeguarded for confidentiality. The main concern of the patient is the accuracy of the temperature, CO_2, and humidity levels.

d. *Competition*:

i. Current inverted microscope incubators and standard incubators are priced from around $500-$40000. These prices are costly in comparison to the client's demands. [4]

ii. Previous UW-Madison BME design team designed an incubator with a copper tube heating element that had water flowing through the copper tube. The design also had a solenoid valve to manage the CO2 levels. One main issue with the design was the humidity impaired visibility of the microscope.

Work Cited

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