Product Design Specifications

Microscope Cell Culture Incubator

BME 200/300
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Function: Develop a low cost cell culture incubation chamber with interchangeable culture plates that is compatible with an inverted microscope and capable of live cell imaging.

Client requirements:

- Incubation chamber must be able to maintain an internal environment of 37℃, 5% CO_2, and 95-100% humidity
- Microscope's optics and functionality must not be damaged
- Maintain even heating and humidity across the chamber
- Create device that stays within a budget of $100
- Ensure that the device can be easily assembled and removed between uses

Design requirements:

1. Physical and Operational Characteristics

a. ***Performance requirements:*** The device must be able to sit on a microscope stand, be transparent on the top and bottom to allow for optical visualization with an inverted microscope, and maintain an internal environment of 37℃, 5% CO_2, and 95-100% humidity.

b. ***Safety:*** The incubator and the cell culture environment must be in corporation with BioSafety Level 1 Standards [1]. Any material and electrical or mechanical machinery must be sterilizable and waterproof.

c. ***Accuracy and Reliability:*** The device must be able to maintain a temperature of 37°C ± 0.05°C throughout the entire internal environment. The humidity must be kept above 95% humidity. CO_2 levels must be 5% ± 0.1%. The incubator must be able to maintain these conditions for extended periods of time and be able to reach these conditions after the incubator has been opened and exposed to the external environment in an efficient manner.

d. ***Life in Service:*** The device must be able to be used for two weeks, but optimal usage will occur for one week at a time for teaching purposes in the client's tissue lab.

e. ***Shelf Life:*** The shelf life of this product should be ten years.

f. ***Operating Environment:*** The operating environment is a clean room. The incubation chamber must be able to maintain an internal environment of 37°C, 5% CO_2, and 95-100% humidity over a long duration of time, without compromising the integrity of the microscope's optics or functionality. Even heating and humidity across the chamber must be maintained to ensure that evaporation does not occur.

g. ***Ergonomics:*** The device should be portable in that one should be able to carry and store the device easily. Wires should not be hanging freely out of the device, and it should be easy to pick up and put away when needed.

h. ***Size:*** The size constraints for this device are that it must sit on the microscope stage and hold a well plate that also doesn't interfere with the optics or functionality of the microscope. It would be ideal if all sides are transparent, but it is a requirement that the bottom and top are transparent. Overall, the product must be compatible with an inverted microscope.

i. ***Weight:*** There are no specific weight requirements. However, minimizing weight would be ideal to promote incubator mobility and usability.

j. ***Materials:*** There are no specific materials that are required for development of this device. However, it is important to examine different material properties to determine which materials hold heat effectively and have a transparent appearance.

k. ***Aesthetics, Appearance, and Finish:*** The client does not have a preference in color. Well plates are clear, black (to stop contamination), and white (to increase light). Using materials that would block out external light sources would be ideal, but this is not a requirement for the device. Finish should exclude messy elements, such as long wires, and be transparent on both the top and bottom.

2. Production Characteristics:

a. ***Quantity:*** Only one device is necessary to produce, but ideally, it would have the capacity to be produced on a larger scale to be used repeatedly in the teaching labs.

b. ***Target Product Cost:*** The target product cost for this device is $100. It will be paid for via UW BME Departmental teaching funds.

3. Miscellaneous

a. ***Standards and Specifications:*** The incubator would need to adhere to the ISO 13485 regulation which outlines requirements for regulatory purposes of Medical Devices [2]. The incubator would also need to follow the FDA's Code of Federal Regulations Title 21, Volume 8 where it outlines the requirements for Cell and Tissue Culture products [3].

b. ***Customer:*** The client, Dr. John Puccinelli, is an undergraduate advisor in the Biomedical Engineering Department at the University of Wisconsin - Madison. Dr. Puccinelli is asking for the cell culture incubator in order to amplify the teaching curriculum in his classroom environment. Having an incubator that is easy to disassemble and compatible with an inverted microscope would result in efficient classroom lessons.

c. ***Patient-related concerns:*** The accuracy of the temperature, humidity, and CO_2 concentration is of utmost concern for the client. Humidity must be 95-100%, otherwise cells will begin to dry out. Having a set temperature of 37°C will

replicate optimal cellular environments. Lastly, ease of disassembly and disinfecting of the incubator was of concern.

d. ***Competition:*** There are currently multiple inverted microscopes and cell culture incubators on the market ranging from $500-$40,000 [4]. ThermoFisher, NuAire, and New Brunswick all have incubators currently on the market. ThermoFisher and NuAire are more popular as they have both direct heat and water jacketed incubators. The most popular ThermoFisher design is the Heracell VIOS 160i CO2 Incubator with Copper Interior Chambers, which has HEPA filtration for ISO Class 5 air quality and an overnight Steri-Run for total sterilization [5]. Others have also attempted to design low-cost live-cell imaging platforms using 3D printed and off the shelf components. A team of researchers from Australia were able to successfully design a portable low-cost long-term live-cell imaging platform for biomedical research and education for under $1750 [6]. This low-cost incubator also monitored and regulated temperature, CO_2, and humidity as per the parameters for successful mammalian cell culture. Past BME 200/300 design projects have attempted to build incubators for this client, but none have been completely successful.

References

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