*An embedded system for microscope-based, real-time image capture of cancer cells*

Product Design Specification

Version *<1.0>*

*<12/24/2018 >*

VERSION HISTORY

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| **Version #** | **Implemented**  **By** | **Revision**  **Date** | **Approved**  **By** | **Approval**  **Date** | **Reason** |
| 1.0 | Alfred, Angeline | 12/24/2018 |  |  | Initial Design Definition draft |
|  | Bontrager, Ashten |  |  |  |  |
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# Introduction

## Purpose

The goal of this project is to implement a software/hardware prototype system that provides automated, and real-time, selective acquisition of microscope images based on pre-set user-established intensity thresholds.

## GENERAL OVERVIEW

Hematologic malignancies, such as lymphoma, leukemia or myeloma, are the fifth most common type of cancer and fourth most common form of cancer-related death. In the U.S. alone, there are more than 1 million people who suffer from hematologic malignancies, with approximately 150,000 more patients diagnosed every year. Targeted drugs are a driving focus of drug development, but the majority of patients eventually develop resistance even to these new drugs. As a result, many leukemia patients eventually succumb to their diseases due to resistance to both conventional chemotherapies and newer targeted agents.

As a response to this issue, the Oregon Health and Science University along with members of the Knight Cancer Center developed the CytoScreen to help identify novel drugs that produce complete kill of drug-resistant cancer cells. The CytoScreen is a miniaturized single-cell assay that is performed in multi-well chambers on a fluorescent microscope-imaging platform. It is an ultra-sensitive system that enables imaging of patient blood samples with single-cell granularity.

This is a process requiring time-intensive scanning and acquisition of large numbers of images. Because the drug-resistant cells that underlie cancer recurrence are often present at low frequency (<0.1%) in an individual patient, the majority of scanned images are not used.

The implementation of a software/hardware prototype system that provides automated, and real-time, selective acquisition of microscope images containing drug-resistant cells would significantly increase the speed of the drug screening process and potentially impacting treatment decisions and benefiting lives.

# Design Guidelines/Approach

## Requirements / Standards

1. Implementation of open source automated microscopy software (https://micro-manager.org/) to perform rapid microscope-based scanning of patient samples.
2. Implementation of open source imaging software (https://imagej.nih.gov/ij/) to rapidly evaluate and detect microscope-scan of clinical interest in real-time.
3. Implementation of software that uses decision-making, feedback-based microscope scanned information to control acquisition of microscope images.
4. Benchmarking the speed and accuracy of the integrated working prototype.

## Assumptions / Constraints

[Describe any general design assumptions / constraints / standards related to any of the project’s design]

# Architecture Design

## Software Architecture

[Insert any software architecture documents or provide a reference to where they are stored.]

## Hardware Architecture

[Insert any related security architecture documents or provide a reference to where they are stored.]

# System Performance

## Data Analysis

[Insert any documents describing any necessary database design guidelines or provide a reference to where they are stored.]

## Performance analysis (speed and accuracy)

[Insert any performance documents or provide a reference to where they are stored.]

# Approval

The undersigned acknowledge they have reviewed the **Product Design Specification** document and agree with the approach it presents. Any changes to this Requirements Definition will be coordinated with and approved by the undersigned or their designated representatives.

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Appendix A: References

[Insert the name, version number, description, and physical location of any documents referenced in this document. Add rows to the table as necessary.]

The following table summarizes the documents referenced in this document.

|  |  |  |
| --- | --- | --- |
| **Document Name and Version** | **Description** | **Location** |
| *<Document Name and Version Number>* | *[Provide description of the document]* | *<URL or Network path where document is located>* |

Appendix B: Key Terms

*[Insert terms and definitions used in this document. Add rows to the table as necessary. Follow the link below to for definitions of project management terms and acronyms used in this and other documents.*

*http://www2.cdc.gov/cdcup/library/other/help.htm*

The following table provides definitions for terms relevant to this document.

|  |  |
| --- | --- |
| **Term** | **Definition** |
| *[Insert Term]* | *[Provide definition of the term used in this document.]* |
| *[Insert Term]* | *[Provide definition of the term used in this document.]* |
| *[Insert Term]* | *[Provide definition of the term used in this document.]* |