

Tuberculosis Detection by Purified Protein Injection Product Requirements Document Team TB

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Customer: Arnulfo Torres

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Revisions Level

D

Date

12-15-2017

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Authentication Block

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Revision History

Revision	Description	Date	Authorization
A	Release	Oct 31 2017	All
B	Release	Nov 15 2017	All
C	Release	Dec 1 2017	All
D	Release	Dec 15 2017	All

The customer for this project is Arnulfo Torres, registered nurse based out of Rochester, NY. He approved the final PRD revision D on December 15, 2017. And email confirmation is attached in the Appendix section.

The motivation behind the TB detection test is to assist nurses for improving accuracy in medical procedures and diagnosis. The senior design group would identify optical specifications along with source and detector design system.

Vision:

The ideal system has a source and detector connected to a data processing device. The user would place the detector and source above the spot of skin with PPD injection. The device would be able to calculate the surface topography of the bleb after injection, and provide a volume measurement in milliliters. This includes, cross sectional area and height of the bleb. After the patient returns for a follow up meeting 48hr to 72hr later, the device would be able to calculate the cross sectional area, most importantly the width perpendicular to the arm, of the physical reaction on the dermis. We are exploring a profilometry method, an approach that meets the basic criteria requested by the customer. This approach explores the physical traits such as area and volume of the skin reaction to the PPD injection. This solution is similar to that of the current medical procedure, but will eliminate the subjectivity of measuring the spot by hand or simply judging size via the human eye.

Environment:

As a device intended for clinics, it needs to operate in the following environment:

Temperature

59-77 °F – operation range

Relative Humidity

40-50%~ room temperature

It will operate under outlet/battery power.
Building and testing will be done in a lab in Wilmot 536.

Budget:

Currently all cost should be under \$1000

Regulatory Issues:

None

Fitness for use:

The scanner system will:

- Low Signal/Noise, high contrast
- Write code (MATLAB) to take the 2D image obtained and render a height to construct a 3D image, giving us a volumetric measurement.
- Need a stationary stand to elevate and angle source and detector
- System will be portable and lightweight, about weight of laptop
- Create calibration technique for system to assure accurate and consistent measurements
 - Including a calibration sample of known size (possibly use 3D printer in Rettner)
- Stand to hold source/detector instrument, exploring tripod and small C arm designs, must be stationary
- Currently operating under \$1000 budget
- Be able to reliably categorize patients and keep their before and after test results separate

Schematics

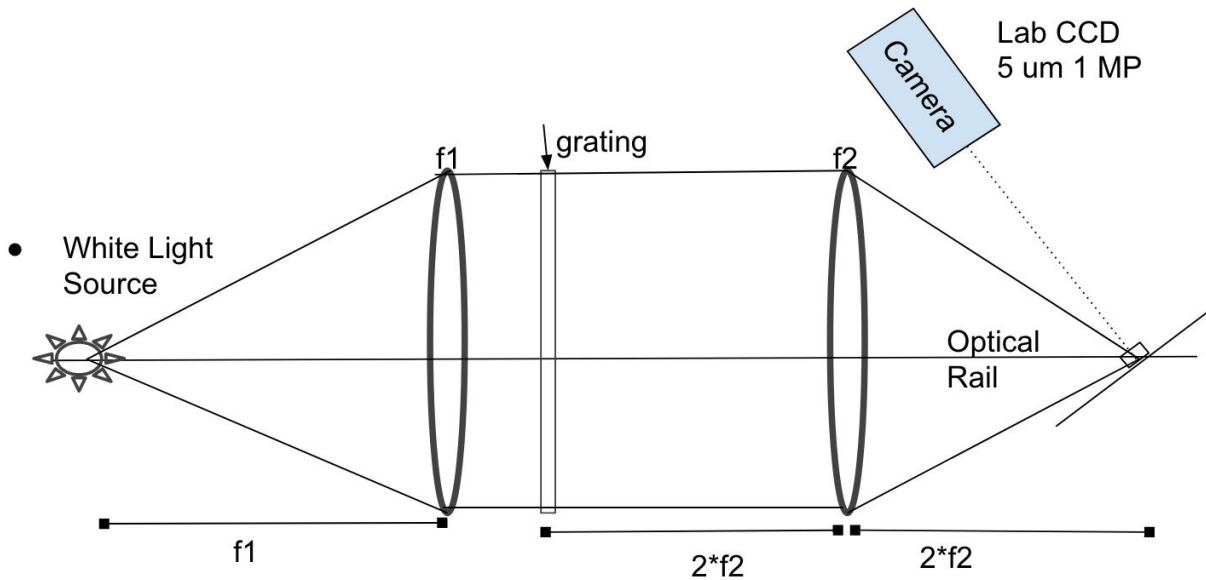


Figure 1: Lens 1 would be a collimating lens. Grating would be placed in the collimated beam path. The second lens is placed 2 focal lengths away from the grating and thus imaged at $2f$ away the lens with 1x magnification. The camera would detected perpendicular to the image plane.

Requirements	
Collimator Lens Diameter	~ 20mm
Object FOV	≥ 20mm
Magnification	1 X
Overall system length	< 300 mm
Weight	< 5 lbs
Light Source	LED or White Light
Sensor CCD Resolution	1 MP at 5 um per pixel
Grating Spacing and Dimension	1 ot 2 lp/mm ; 20 x 20 mm
Response time	< 5 minute

It is desirable that:

- Both problems (correct injection depth and reading results) should be solved in one instrument
- Instrument must be portable, easy to operate, low cost

If there is time and/or team resources available:

- Be able to charge and use without continuous power source
- Plug into phone and use with app

We are not responsible for

- False negatives and positives diagnosis
- Accuracy of the physical injection
- Getting our product approved by the FDA

Next Steps and Upcoming challenges

- Lab space has been acquired, PPD samples to be picked up today
- 3D print volume sample to test profilometry method
- PPD sample has been acquired
- Test PPD sample to determine reflectivity and transmission
- Test reflectivity and transmission of different color types of skin.
- Solve the problem that skin will diffuse light and might cause noticeable scatter.
- Consider the curvature of the “reference plane” in the calculation of the height since the tested skin is not perfectly flat.
- Consider the diffraction limit and aberration of the system.

Team Member Responsibilities

Sze Wah Lee (Project Coordinator)

- Reinforce Schedules
- Gating Spacing
- Code V modelling of Optical System with known aberrations

Rebecca Silver (Customer Liaison)

- Create and running MATLAB code
- Communicate with customer

Madilyn Beckman (Scribe)

- Create and running MATLAB Code
- Maintain meeting notes with clarity and concision

Coco Yang (Document Handler)

- CAD drawing of the 3 3-D bumps (Make sure its STL file, <https://www.tinkercad.com/>)
- Lab equipments tracking and finding
- Ensure all official documents includes all the requirements, specifications and correct format.

Fall Semester 2017 Timeline

October

- Meet with customers and address scope of problem
- Brainstorm Preliminary design solutions
- Meet with faculty advisor

November

- Decided on a design solution
- Suggest solutions to customer and readdress scope of problem
- Design setup and understand the mathematical algorithm for solution
- Lab space confirmation
- Preliminary lab demonstration

December

- Final PRD and presentation
- Plan for next semester

Spring Semester 2018 Timeline

January

- Write a functional MATLAB program
- Obtain system components and assemble in lab
- 3D print bumps with known volume, width and height

February

- Implement our code and test with 3D bump in lab
- Revise and improve code
- Design a final packaging prototype

March

- Finalize Prototype
- IA Presentation

April

- Probability to test device on store bought chicken
- Design Day

Appendix:

Anticipated Lab Internal Equipment Borrowing

CCD Camera (Per's Lab)

Optical Rail and Len's Mount (Per's Lab)

BME TB Team Info

Group Members:

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Progress:

Our plan is to measure the modulus of skin tissue in order to quantify the induration of the tissue. We have several approaches in mind, including ultrasound elastography and compressive force sensors, but haven't narrowed it down yet.

Basic Lab SetUp Implementation

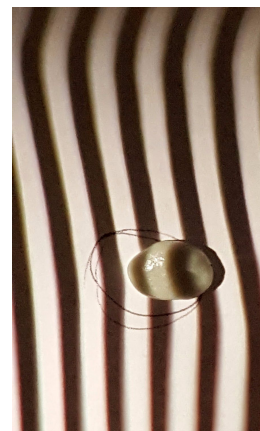
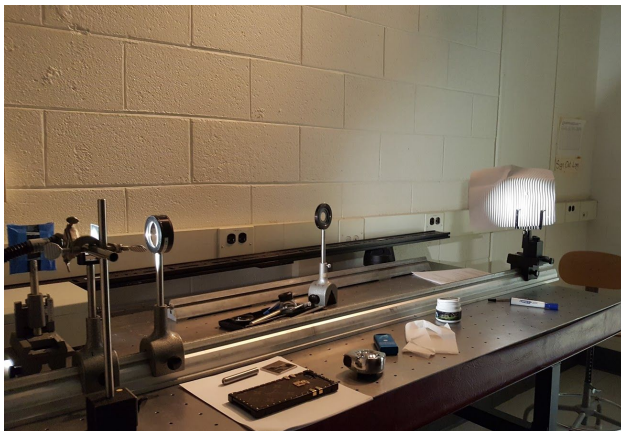


Figure (a)Left. Grating pattern is imaged onto an angled flat surface. (b) Right. Image seen by the phone camera positioned perpendicular to the flat surface. The object with unknown height on the flat surface distorts the grating pattern as expected from the theory.

Equations for data analysis

$$(a) g_o(x, y) = a(x, y) + b(x, y)\cos[2\pi f_o x + \Phi_o(x, y)]$$

$$(b) \Phi_o(x) = 2\pi f_o \overline{BD}$$

$$(c) g_s(x, y) = a(x, y) + b(x, y)\cos[2\pi f_o x + \Phi_s(x, y)]$$

$$(d) \Phi_s(x) = 2\pi f_o \overline{AD}$$

$$(e) \Delta\Phi = 2\pi f_o \overline{AB} = \mathfrak{I}\{\log[F^{-1}(G_s(u, v)G_o^*(u, v))]\}$$

$$(f) h(x, y) = \frac{L}{\frac{2\pi L^2 d \cos\theta}{P_o \Delta\Phi (L + x \cos\theta \sin\theta)^2} - \frac{d \cos\theta \sin\theta}{L + x \cos\theta \sin\theta} + 1}$$

$$(g) P_o = \frac{1}{f_o} = \frac{P}{\cos\theta}$$

G_o and G_s are the fourier transforms of the reference and object fringe pattern, given by g_o and g_s . Together they are the change in phase due to height, and h gives the height of the object at all points (x, y) of an image. P is the the projected grating. All other variables are givens from the setup.

Customer Approval Email Confirmation

Arnulfo Torres
to me

10:07 AM (2 hours ago) ☆ ↶ ↷

To the PPD reading team,

Thank you very much for your design, it looks promising and helpful to eradicate Tuberculosis. Precision in the test will benefit finally all the patients that may need these test.

Arnulfo Torres

...

Rebecca Silver <rsilver8@u.rochester.edu>
to Arnulfo

12:05 PM (5 minutes ago) ☆ ↶ ↷

Thank you! We will be in contact with you over our winter break and hope to meet up again sometime in January to show you our progress.

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