Low Resource Bronchoscope

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Project Importance

Within the last two decades there has been a rapidly increasing demand for healthcare services in low-income countries.

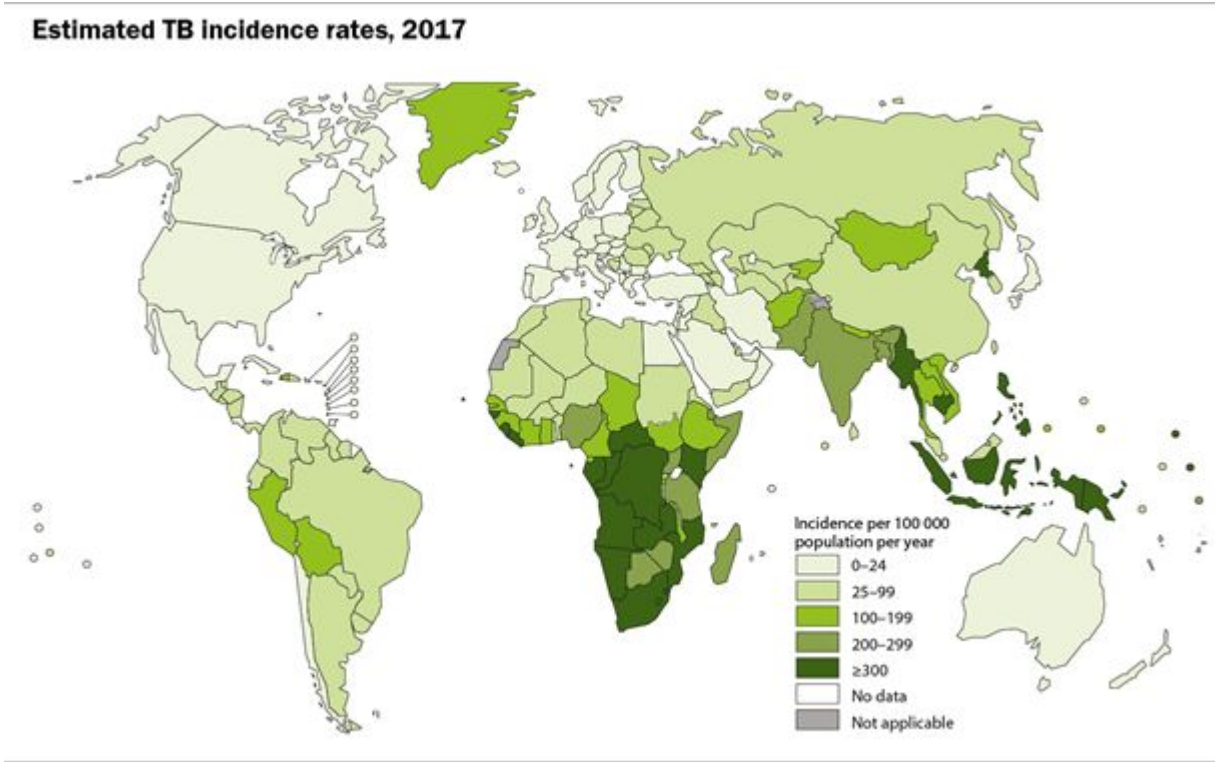
1. Geopolitical reasons: natural and manmade disasters
2. Burden of illness exceeding existing healthcare capacity
3. Lack of healthcare infrastructure
    a. Scarcity of medical facilities, shortage of medication and medical equipment

Respiratory diseases are leading causes of death in low resource areas

The burden of Tuberculosis (TB) is the highest in low-resource areas and was one of the top 10 leading killers in 2018

Estimated 10.6M new cases and 1.5M deaths

Treatment success rate is 85% in 2018



Bronchoscope collects a purer sample and better identifies origin of bacteria

- More than one third pulmonary TB patients cannot produce sputum
- Even when produced, there is an inadequate volume or quality in up to 20% of the case

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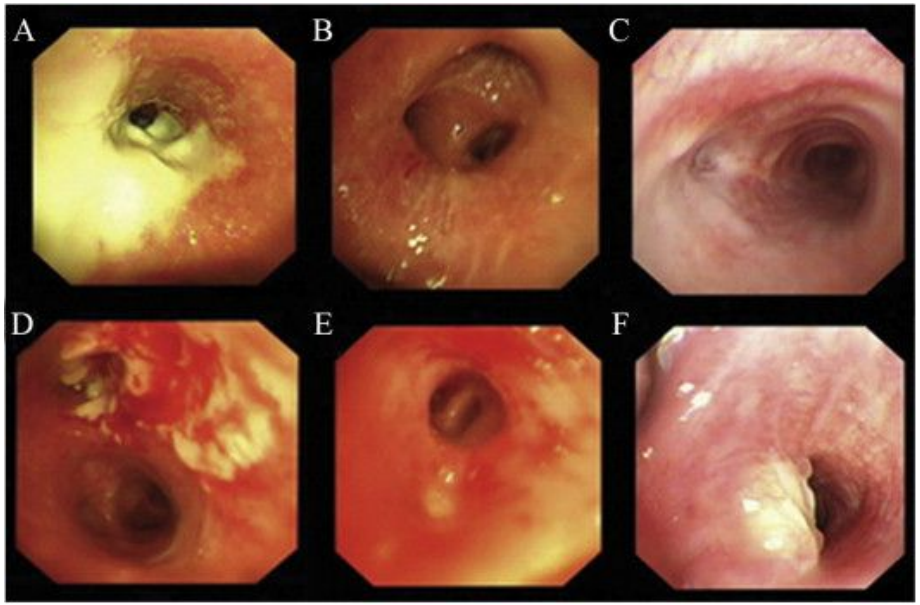

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- Bronchoscope allows sputum to be collected at the suspected TB source
  - Allows doctors to explore airways and collect adequate volume/quality
  - 2015 Review: 83% - 92% sensitivity and 91% - 98% specificity

Current Market

- Two major players in the reusable bronchoscope field
  - Olympus - high baseline cost: 7,000-15,000 USD
  - Pentax - lower base cost: 4,000 USD

Additional Cost Factors

Cleaning costs between 100 and 300 USD

Reusable vs Single Use probes

- Single use probes are easier to use
- Reusable probes have lower cost per procedure

Key Differences

Our Device

1. Decreased Video Quality

800x800 pixel resolution at 60 fps

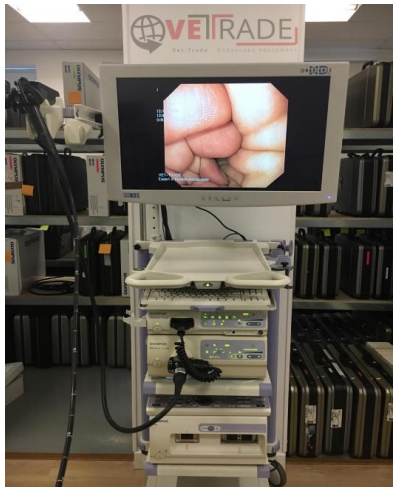
Capable of edge detection

Current Devices

1. HD Video Quality

26-inch full HD LCD Panel

Built in software for blood vessel visualization



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   800x800 pixel resolution at 60 fps

   Capable of edge detection

Essential Specifications

Monitor standards have not been established in digital pathology

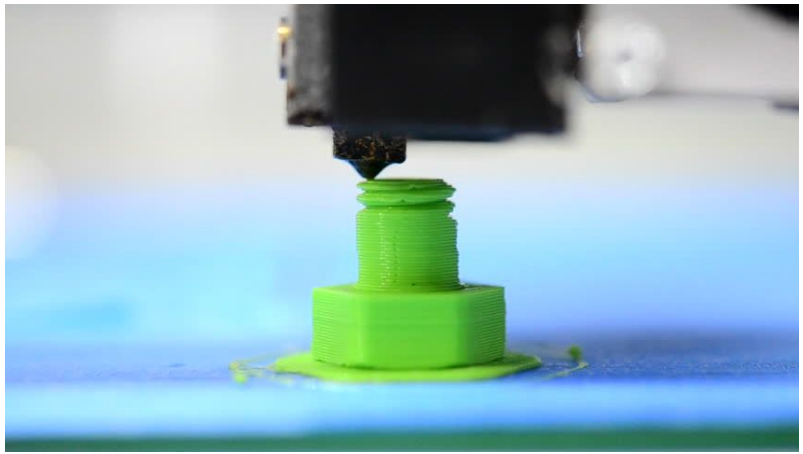
- Current monitors on the market range from 640x480 pixels to 6400x4800 pixels
- The lower end resolution allows us to save cost while remaining in market range

Key Differences

Our Device

1. Decreased Video Quality
2. Lower Material Quality

ABS or PLA (plastic) body



Current Devices

1. HD Video Quality
2. Higher Material Quality

Proprietary body material with polymer coating (polycarbonates, polypropylene, polyethylene)

- Versatile plastics with low moisture absorption
- Heat resistance
- Chemical and bacteria resistant

Key Differences

Our Device	Current Devices
1. Decreased Video Quality 2. Lower Material Quality 3. Reduced Functionality	1. HD Video Quality 2. Higher Material Quality 3. More Functionality
Max angulation: 90°/90° (up/down) 90°/90° (left/right)	Maximum angulation: 210°/130° (up/down) 120°/120° (left/right)
Available Functions: suction and camera	Available Functions: biopsy/suction, air channel, water channel, fiber optic image bundle

Problem Statement

Current bronchoscope devices on the market face a number of issues that make them unfavorable for providers in low resource environments. The high up-front cost of a bronchoscope, coupled with bulky recording equipment, impairs both purchase and sharing of these devices. As a result, most healthcare providers in low resource environments do not own bronchoscopes, greatly exacerbating the difficulty in diagnosis of millions of TB patients.

Needs Assessment

Functionality
- Match competitor specifications as closely as possible
- Equipped with a companion application with integrated IP modules

Cost Reduction
- Materials and hardware shall be selected to reduce cost without large sacrifices to performance
- The main probe shall be reusable with a single use outer sheath to eliminate reprocessing fees

Ease of Use
- Intuitive control system that non-professionals can learn to operate
- Integrated IP modules shall aid non-professionals in point-of-care diagnostics
- Parts will be easily replaceable in case of failure

Portable
- Powered using single cell batteries
- Coiled to save space during transport

Durable
- Electronics and optics shall be properly insulated within the main probe
- Parts shall be optimized for durability for lower replacement costs

Camera Functionality

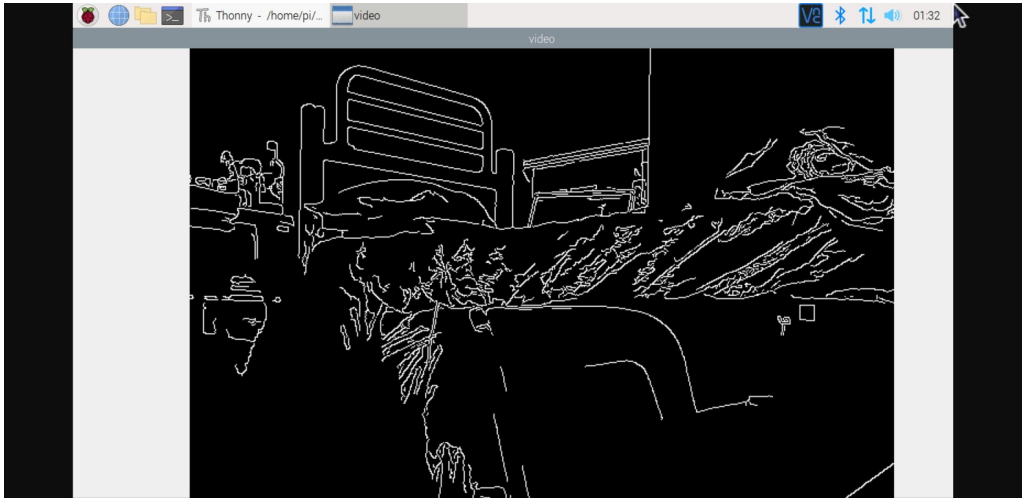
Logitech C922

- Used for the purpose of prototyping, since small camera has not arrived yet.
- USB camera connects directly to the Raspberry Pi
- Allows real-time video that can be processed.

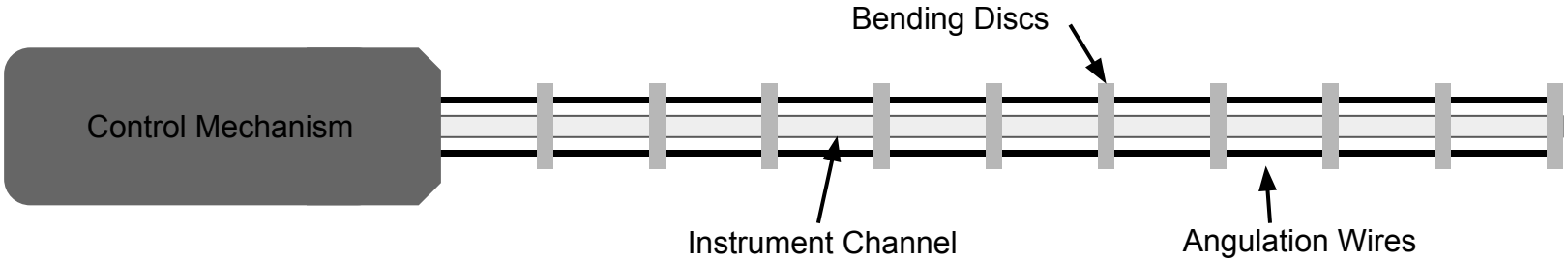
Camera Functionality

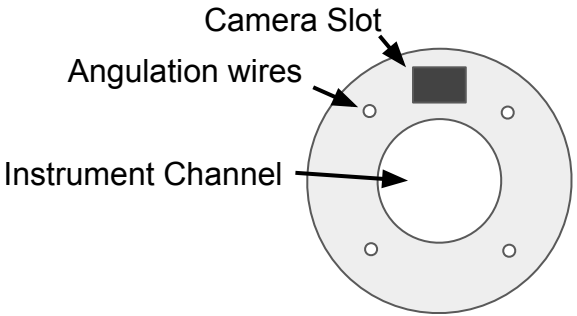
VNC Server / Secure Shell (SSH)

- Accessing a remote server (microcontroller) with a mobile device (client) requires SSH.
- Once the connection is established, the mobile device can run programs and scripts.
- So far, we have edge detection and isolation working.



Design Overview

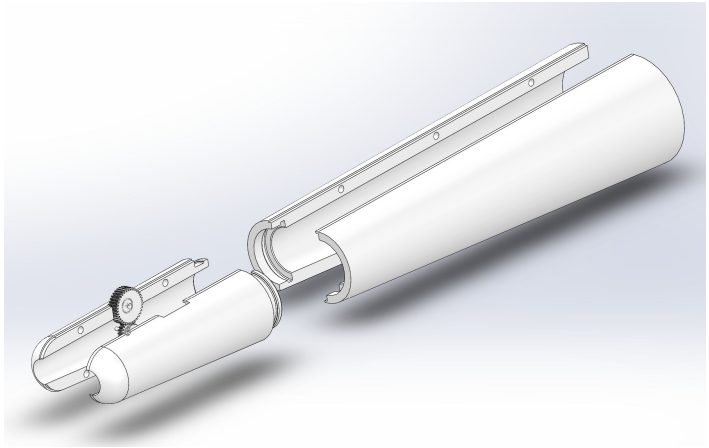


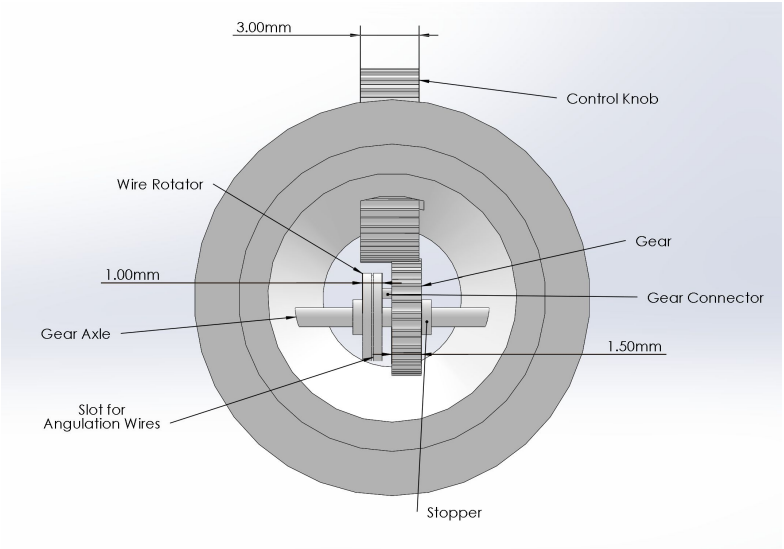


End Disc Cross Section

Mechanical Design #1 Review

- Stationary Handle with Rotational End Piece
  - Split in half for assembly and easy repair
- Control Knob interlocks with Gear to rotate Wire Rotator
- Wires connected to Wire Rotator run through Discs in Insertion Tube
  - When moving Wire Rotator with Control Knob, the wires pull the Discs to angulate the Insertion Tube
- Rotational End Piece can be rotated manually to rotate Insertion Tube
- Angulation and rotation allow for navigation through airways





Mech. Design #1 Potential Design Flaws

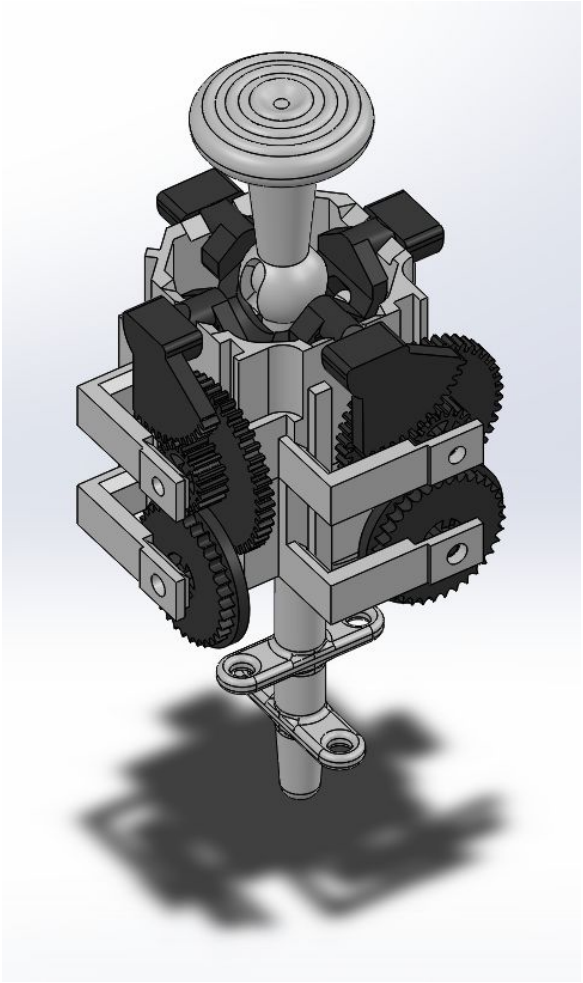
- Simultaneous rotation of the Rotational End Piece and manipulation of the Control Knob may be cumbersome
- Internal parts such as the Control Knob and Gear are too small to be 3D printed at target scale
- Pegs and holes connecting 2 halves of Rotational End Piece and Stationary Handle cannot be optimally 3D printed
    - Results in either too loose or too tight attachment

Mech. Design #1 Potential Failures

Problem	Solution
Internal parts may break or be faulty after manufacturing	● Manufactured devices must be tested for proper functionality before deployment ● Device is split in half to allow easy access to internal parts for replacement
Use of low cost materials may cause device to wear down over time after extensive use	● Determine required durability factor of materials during testing ● Provide extra parts that are most susceptible to wear and tear (control knob, gear, etc.)

New Mechanical Design #2

- Joystick design
  - Modified N64 joystick taken from GrabCAD
    - First layer “encoder wheel” changed to a step-up gear
    - Second layer added with a second step-up gear which attaches to angulation wires
    - Double step-up system ensures amplification of input movements
    - Added custom insertion tube attachment
- Design concept
  - Joystick in “bowl” operating 2 arms controlling gears for both axes
  - Allows for 2 axis control with one joystick



Mechanical Design #2 Design Flaws

- Insertion tube attachment too large to easily slot tubing
  - Reduce diameter of central tube
- Wire guides on insertion tube attachment work poorly: they angled the wires away from the second gear, causing slippage
  - Add several wire bending points to relieve strain
- Bowl attached gear restricts range of motion
  - Increase arc length of toothed gear

Critical Marketing Pathway Overview

We have split our marketing model into seven steps and are currently on the second step

1. Concept & Feasibility
2. Device Development
3. Clinical Validation
4. Regulatory Approvals - FDA approval
5. WHO Evaluation - results in WHO endorsement
6. Country Transition to Scale (Pre-Launch) - Civil society engagement, cost analysis and procurement, distribution plan, training
7. Country Adoption - procurement for widespread use

Completed Concept and Feasibility

Identified Problem Statement and developed corresponding Needs Assessment

Assessed current devices on the market and identified characteristics needed for a low-cost bronchoscope

Defined intended product use and scope compared to current devices

Completed Device Development

Stakeholder consultations with VUMC mentor for initial design brainstorming

Developed SolidWorks models for design visualization

Scaled up functional component prototyping through Lego modeling and SolidWorks fabrication using 3D printing

Marketing Pathway Moving Forward

Safety Analysis of Diagnostic Medical Device

Design verification and validation with VUMC Mentor

Produce a “to-scale” prototype

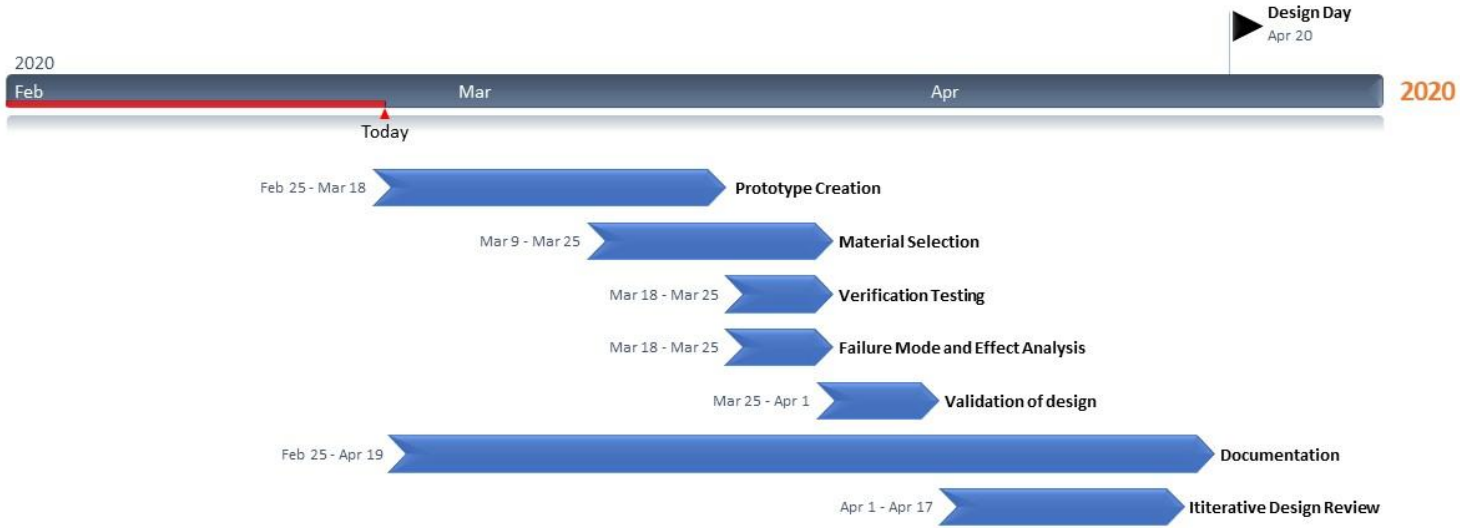
Determine possible ways device could fail and potential corrections

Anticipated Regulatory Approvals

To determine our device classification, we searched for pre-existing bronchoscopes within the FDA product classification database. Based on our preliminary research we found that our device will likely fall under the following classifications

Device	Regulatory Description	Medical Specialty	Regulation Number	Submission Type	Device Class	GMP Exempt
Bronchoscope (Flexible or Rigid)	Bronchoscope (flexible or rigid) and accessories.	Ear Nose & Throat	874.4680	501K	2	No

Gantt Chart


Design Day
Apr 20
2020
Feb
Mar
Apr
2020
Today
Feb 25 - Mar 18
Prototype Creation
Mar 9 - Mar 25
Material Selection
Mar 18 - Mar 25
Verification Testing
Mar 18 - Mar 25
Failure Mode and Effect Analysis
Mar 25 - Apr 1
Validation of design
Feb 25 - Apr 19
Documentation
Apr 1 - Apr 17
Ititerative Design Review

Sources

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