.decimal Proton Therapy Device Manager

The benchmark for custom radiation therapy

Team Number:	14
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1 Product Specification Deliverable

1.1 Need Statement

The sponsor for this project is .decimal. .decimal is a medical device manufacturing company in North Orlando. They manufacture patient specific devices for various types of cancer treatments including proton, photon, and electron beam treatment. The need that they have expressed to the senior design team has been that the apertures, or patient specific devices, take too long to load into a Mevion S250 Proton Therapy System. For the technician to come into the room, the machine must be off and then they have to navigate through a long hallway before getting to the treatment room. Also the apertures can be up to 25 pounds and the technicians have complained about having to lift the heavy apertures repeatedly throughout the therapy session.

It takes too long and too much effort for a technician to load and unload apertures during a patient's treatment.

1.2 Goal Statement & Objectives

Goal Statement: Provide proof of concept by developing a functioning scaled model of an automation device that will load and unload .decimal's apertures and range compensator relative to the nozzle of the Mevion S250.

Objectives:

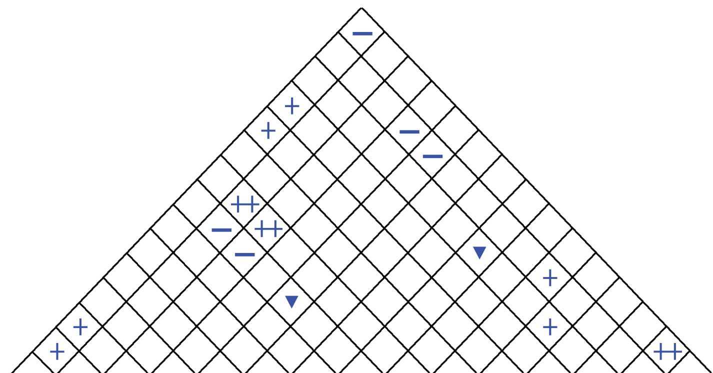
- Decrease the time a patient is in the treatment room
- Eliminate manual process for technician

1.3 Constraints

- Automation device must lift up to 25 lbs.
- Automation device must not interfere with proton beam or the patient couch
- Automation device must scan apertures to identify patient specific aperture
- Automation device must be installed in the same room as the Mevion S250
- Automation device must load apertures and range compensator
- Automation device must unload apertures and range compensator

Below in Table 1 is a House of Quality, which helped determined which customer requirements and engineering characteristics will be focused on when developing the design and final deliverables.

Table 1- House of Quality for Proton Therpay Device Manager



Row #	Max Relationship Value in Row	Relative Weight	Weight / Importance	Demanded Quality (a.k.a. "Customer Requirements" or "Whats") / Quality Characteristics (a.k.a. "Functional Requirements" or "Hows")	1 Aperture loading time	2 Scanning Sensors	3 Mechanical Sensors	4 Installation Time	5 Energy usage	6 User Interface	7 Wear on proton therapy machine	8 Cost	9 Scanning	10 Weight	11 Structural Integrity	12 Gripping Device	13 Materials	14 Size	15 Motion Range	Our Company	Competitor 1	Competitor 2	Competitor 3	Competitor 4	Competitor 5
				Direction of Improvement: Minimize (▼), Maximize (▲), or Target (x)	▼	x	x	▼	▼	x	▼	▼	▲	▼	▲	x	x	▼	x						
1	9			Reliability of Loading	Θ		Θ				▲					Θ									
2	9			Cost Estimate								Θ					O	Θ							
3	9			Treatment Time	Θ				▲		▲								O						
4	1			Technician Effort	▲													▲	▲						
5	9			Scanning System		Θ				▲			Θ												
6	9			Reliability of Operation	O	Θ	Θ			▲	O					Θ									
7	9			Non-obtrusive				O	O		O			Θ				Θ							
8	3			Scalability								O			O			O	O						
9	9			Software		O	O			Θ			Θ												
10	9			Patient Safety	O	Θ	Θ						Θ		Θ	Θ	▲		▲						
				Target or Limit Value																					
				Difficulty (0=Easy to Accomplish, 10=Extremely Difficult)																					
				Max Relationship Value in Column	9	9	9	3	3	9	3	9	9	9	9	9	3	9	3						
				Weight / Importance																					

Competitive Analysis (0=Worst, 5=Best)

Our Company, Competitor 1, Competitor 2, Competitor 3, Competitor 4, Competitor 5

0 1 2 3 4 5

Legend		
Θ	Strong Relationship	9
O	Moderate Relationship	3
▲	Weak Relationship	1
++	Strong Positive Correlation	
+	Positive Correlation	
—	Negative Correlation	
▼	Strong Negative Correlation	
▼	Objective Is To Minimize	
▲	Objective Is To Maximize	
x	Objective Is To Hit Target	

1.4 Methodology

The team plans on spending a week or two brainstorming and narrowing down possibilities. Then, the team will create a few rough prototypes made out of cardboard or foam to create a general proof of concept before finalizing designs and ordering parts. By December, the goal is to have an initial prototype. From there, further improvements and refinement can be made during the spring semester as the group prepares for the final deliverable.

1.5 Schedule and Work Breakdown

We plan to have one, very basic prototype built in mid- October and then our first major prototype built by the beginning of December. This will allow the team to utilize the spring semester to refine the design and take the necessary measures to correct the design to make it the best it can be. Our schedule can be seen in the Gantt Chart in Figure 1. The work breakdown structure is in Table 2. The team will be referring to our defined roles when delegating who will do the tasks. Since the team is so small, most aspects will be completed together.

Table 2 Work Breakdown Structure for Fall 2015

Task Name	Duration	Start	Finish
Brainstorming	**12 days**	**Sun 9/20/15**	**Sat 10/3/15**
Create many ideas	6 days	Sun 9/20/15	Fri 9/25/15
Narrow it down to 3	0 days	Fri 9/25/15	Fri 9/25/15
Select Initial idea to begin designing	2 days	Mon 9/28/15	Tue 9/29/15
Initial Prototype	**11 days**	**Wed 9/30/15**	**Wed 10/14/15**
Buy cheap supplies	3 days	Wed 9/30/15	Fri 10/2/15
Build very basic and cheap prototype	3 days	Mon 10/5/15	Wed 10/7/15
Evaluate if chosen design is a good concept	3 days	Thu 10/8/15	Mon 10/12/15
Design 2nd Prototype	**6 days**	**Thu 10/15/15**	**Thu 10/22/15**
Create CAD Files	3 days	Thu 10/15/15	Mon 10/19/15
Reasearch Parts for purchase	3 days	Tue 10/20/15	Thu 10/22/15
Build 2nd prototype	**29 days**	**Thu 10/22/15**	**Tue 12/1/15**
Order parts needed	4 days	Thu 10/22/15	Tue 10/27/15
Create Software to operate device manager	16 days	Mon 10/26/15	Mon 11/16/15
Assembly Prototype as parts are delivered	20 days	Mon 11/2/15	Fri 11/27/15
Evaluate quality of design and prototype	3 days	Fri 11/27/15	Tue 12/1/15

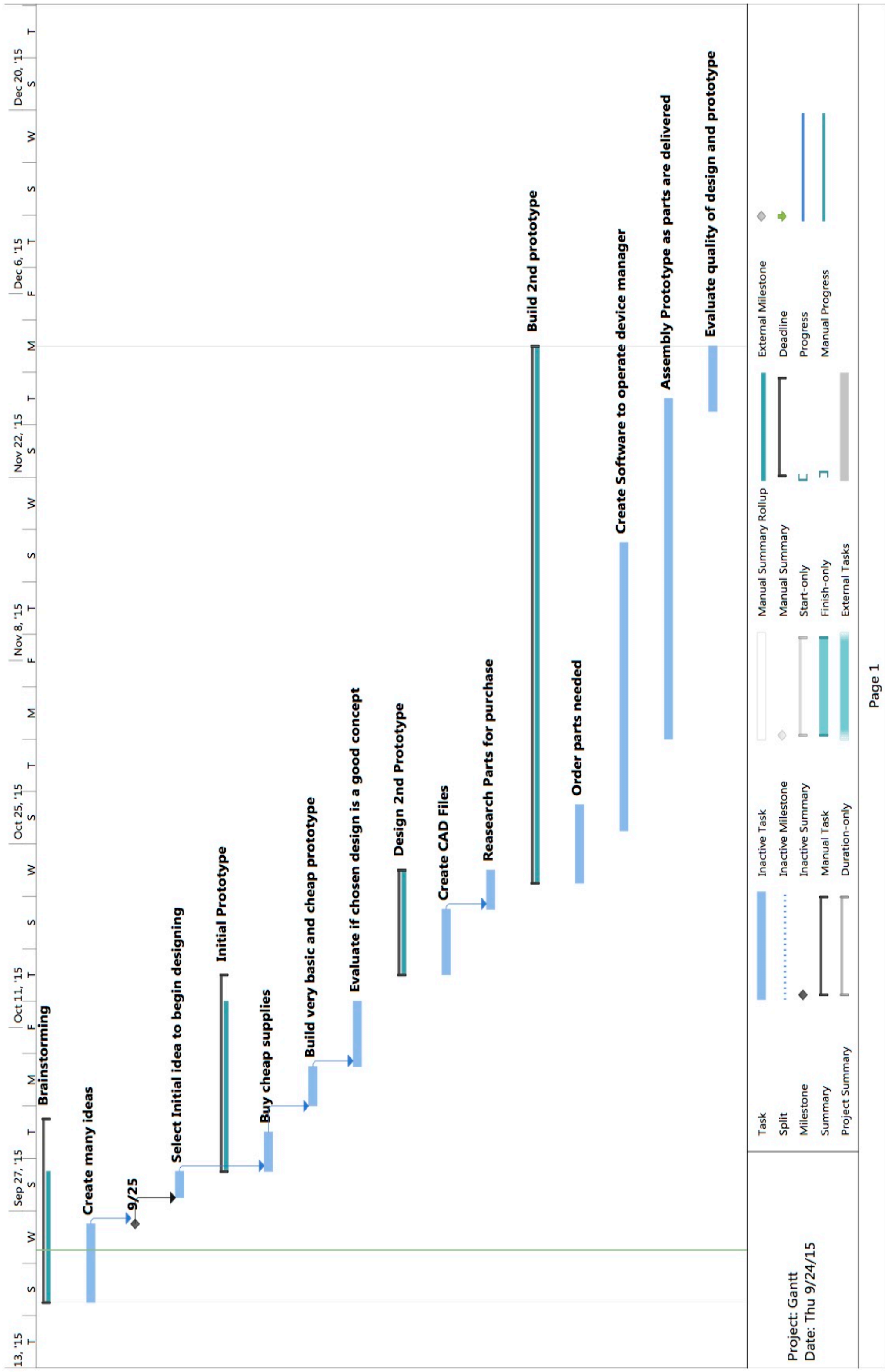


Figure 1 – Gantt Chart for Fall 2015

1.6 Product Specifications

1.6.1 Design Specifications

The design must be fully automated and fit inside the proton therapy room. It must not interfere with the 6 degree of freedom robotic couch, which positions the patient for treatment. The automation device must not interfere with the movement of the electron therapy system's nozzle. The device must repeatedly and reliably be able to identify, pick up, and load an aperture. The design must incorporate a device that releases a spring-loaded safety latch. The purpose of this is to enable the aperture to be unloaded from the nozzle of the Mevion S250. Preliminary discussion with Dot Decimal has established that a secondary device can be designed to perform this operation. An integrated safety system for identifying the order of each aperture should be created. The system must return to its original position after a full cycle of loading and unloading has occurred. After unloading, the cycle must repeat. . A life cycle will need to be developed to ensure a re-design is in line with the latest market requirements of the Mevion S250. Design for manufacturability must be considered. One Mevion S250 Proton Therapy System is clinically active and 6 are under installation and architectural planning in the United States.

1.6.2 Performance Specifications

The system must perform the loading and unloading process faster than a human technician. The goal for operation time of one complete cycle (unloading and loading) is under one minute. Patient safety is of utmost importance. The apertures must be rigidly secured to the automation device during loading and unloading. The system should be able to lift up to 25 lbs. The device's deflection under load must be minimized and accounted for to ensure the aperture is able to be secured in the nozzle. Failure mode analysis must be performed on all components of the system in order to identify any safety concerns. Safety factors should be considered to ensure failure does not occur during operation. Additionally, the automation device must be manufactured from materials that are anticorrosive. Additionally, the cycle progress and state will be continuously monitored and outputted to the technician. Data transmission will be wired and should not affect the room.