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Team 102: Exactech Bone

Quality Indenter

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Abstract

Exactech, a manufacturer of replacement shoulder joints, wants to create a tool to measure bone quality quantitatively. Exactech asked the FAMU-FSU College of Engineering to make such a device. Bone quality is an important factor in shoulder replacement surgery.

Age, injury, disease, or a combination of these, can cause damage to the shoulder joint. When a joint is damaged, shoulder replacement surgery is a treatment option. The surgery removes the damaged joint, replacing it with an artificial joint. These artificial joints fall into two general categories, stemmed and stemless implants. Stemless implants provide shorter recovery times and less invasive surgeries. However, these need a sufficient humeral bone quality. If the bone quality is not acceptable for a stemless implant, the surgeon uses a stemmed implant.

To determine the quality of the bone the surgeon uses a "Thumb Test." The humeral head is cut off, then the surgeon places their thumb on the cut plane of the bone. The surgeon then uses their thumb to apply pressure to the bone. Based on the bone's deflection, the surgeon discovers the bone quality and implant type. However, this is a qualitative measurement based only on the surgeon's experience.

The team designed a tool that replaces the subjective "Thumb Test" with a handheld indenter which creates a quantitative score of bone quality. The indenter uses a spring to accelerate an indenting pin. This causes the pin to strike the cut face of the bone. The tool measures the maximum distance the pin penetrates the bone. The distance the indenter traveled identifies the bone quality. The pin enters the portion of the bone that is removed as part of the surgery, which prevents interference between the measurement and the replacement joint.

Keywords: Shoulder replacement surgery, bone quality, bone density

Acknowledgement

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- Our sponsor Exactech through our point of contact Mr. Tom Vanasse have been instrumental in making this project possible. His willingness to answer questions and provide direction have been critical in making this project a success.
- Our advisor Dr. Arce, provide constant guidance, support and challenged the team to achieve more. Without his support this project would not have achieved the results it has.
- The ME senior design instructor Dr. McConomy, was an important source of guidance and constructive criticism that helped refine the project.
- The FAMU-FSU College of Engineering machine shop, provided the expertise and time to transform the materials acquired to into the finished project presented on engineering design day.

To those mentioned above and everyone else who has made contributions that made this project possible thank you.

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Notation

in.	Inch
lbs.	pound
A40	Back Angle
A42	Hip Angle

Chapter One: EML 4551C

1.1 Project Scope

Project Description

The objective of the project is to provide Exactech a device to quantitatively measure the bone quality of the proximal humerus during shoulder replacement surgery. The density of the bone determines where a stemmed or stemless replacement can be used. Surgeons currently make this decision by using their thumb to qualitatively determine the quality. The project attempts to produce a device that will provide the surgeon a quantitative measurement, during surgery, with a production cost of less than $2,500.

Key Goals

The key goal of this project is to develop a device that can measure human bone quality. The device should provide surgeons instant results that assist them in recognizing osteoarthritic bones. Since the device would be replacing a fast qualitative “thumb test”, the device must provide results in a similar time frame. The device should also be compatible with both sterilization methods and human tissue. Sterilization temperatures of 121ºC or 132ºC (250ºF and 270ºF) are standard; therefore, at a minimum, the part in contact with the bone should be able to withstand these temperatures. Additionally, the device should not damage the bone or negatively affect the procedure. The device should be a size that is accessible and easily used during surgery.

Markets

Surgeons currently use a qualitative thumb test for measuring bone density, which the device is intended to replace. The surgeons will be the ones who will use the device, making them a primary market. However, surgeons do not generally do their own purchasing, meaning the hospitals and offices that make the purchasing decisions would be considered a primary market with the surgeons. Additionally, the sponsor of the project will need to approve the device, and potentially provide it to its customers. Therefore, the sponsor is a second primary market.

Secondary markets for the device include research facilities and universities. The ability of the tool to quantitatively measure bone density would be useful in studies related to the humerus where bone density is a factor.

Assumptions

The first assumption made for this project is that the surgeon using it will be willing and capable of using their hands. This was done because there is a possibility the design will be handheld and may require use of simple mechanisms, such as buttons or levers. If the device requires any electrical power, it was assumed that the surgeon/hospital will have a power supply. It was also assumed that the device will be sterilized using standard sterilization temperatures and will be cleaned with standard isopropyl alcohol. Besides sterilization, it is assumed that the device will not encounter severe environments, because it will be packaged during the transportation portion of its life span and then will be stored in a medical facility. When the device is being operated, environment factors such as lighting, temperature, pressure, and moisture will

be assumed to be constant because it will be used during surgery in a surgical room where this is necessary.

Stakeholders

Key stakeholders in this project are Exactech, Inc. and our connection to the company, Tom Vanasse. Patients are stakeholders because their health and safety are dependent on the compatibility and accuracy of the device. Additional stakeholders would be the surgeons and nurses who will be handling and operating the device. The FAMU-FSU College of Engineering and our advisor, Dr. Stephen Arce, are stakeholders because the work done reflects the school and the faculty who have guided the team. Lastly, the members of the development team are stakeholders in this project because their time and effort will be contributed to the development of the device.

1.2 Customer Needs

Contacting the Customer

To understand our customer's needs an interview was held with Mr. Tom Vanasse, a representative from our sponsor Exactech Inc. Exactech, Inc., makes medical devices including the shoulder replacement components Mr. Vanasse works with. The interview provided insight into the needs of Exactech and the physicians Mr. Vanasse has worked with in his role with Exactech.

Needs Analysis

After talking to Mr. Vanasse, the team gained a better understanding of the customer needs. Question 2 was essential in understanding that the customers expect the device to accomplish. The initial project description stated the density of the bone was to be measured. However, the customers use PCF (pounds per cubic feet) to grade bone quality. This changes the way the team will approach the device.

In the medical device field, there are many regulations devices must follow to be approved. Through question 4 the team learned that the customer needs the device to be approved by the FDA. This must be accomplished before it can be used for surgery. The FDA classifies medical devices based on the risk to the customer, Class I being the lowest risk and Class III the highest. The customer responded to question 1 stating a Class I device is preferred. This would make approval for the device easier, but there are a few additional requirements the design must meet with to fall within this category. These requirements relate the device to existing devices, and the simpler the design is the easier it is to fall within this category. This aligns with the first question we asked, because the customer stated the device may have electrical components, but this is not a requirement. To satisfy these needs, the device can be mechanically operated.

Questions 5, 7, and 8 related to the material and expected use of the device. Since the device is intended to touch the patient in an operating environment, questions of sterilization and reusability are important for considering physical constraints of the product. The device will be used multiple times, as noted in the answer to question 8. This means it will need to be sterilized between uses, which he confirmed in question 7.

Additionally, the device will touch the patient directly and it must be nontoxic as confirmed in question 8.

The team also asked Mr. Vanasse about size requirements for the device. Specifically, how big the indentation in the bone can be and the size of the device. As for the indentation, it was stressed that the device should not create an indentation larger than the stemless implant. The customer also expressed that the device should be handheld and easy to handle during surgery, which indicates that the device should not be large or bulky.

Conclusion

From interactions with the customer, the team has gained a better understanding of the need that are to be incorporated in the design. The main takeaways from the interview are that the customer expects the design to be mechanical, measure bone PCF on the humorous, not interfere with the stemless implant, follow FDA regulations, be nontoxic, and be reusable. The team will do its best to understand and incorporate these needs into the design.

Table 1 *Customer Needs Q&A*

Customer Needs Q&A			
Number	Questions	Customer Statement	Needs Interpretation
1	Does the device need to be purely mechanical, or can it have electrical components?	Old studies used purely mechanical methods, but there would be no problem if the device had electrical components.	The device is mechanically operated
2	What should the device measure?	The device should measure the PCF of the bone.	The device measures the PCF of the bone
3	Are there any size constraints for the indentation?	The indentation should not be bigger than the stemless implant.	The device can create an indentation smaller than the implant fin 1/8”

4	Does the device need to be approved by the FDA?	Yes.	The device is compliant with FDA regulations
5	Does the device need to be sterilized?	Yes.	The device can be sterilized.
6	What class medical device should the device be classified as.	Hopefully, it would be a Class I device.	The device can be classified as a Class I device.
7	What kind of output should the device have?	There is some freedom to this. You can do a number scale, but a color scale would also be adequate.	The device outputs a scale recognizable by the user
8	Can the device be disposable?	The device should be reusable.	The device can be reused
9	Does the material of the device matter?	The device should not be toxic and will be used in a surgical room.	The device is non-toxic
10	How is the device supposed to be handled?	The device should be handheld.	The device is handheld
11	Are there any size preferences for the device as a whole?	It should be easy to handle during surgery.	The device is easily handled during surgery
12	Where should the indentation be taken?	The measurement should be taken at the center of the where the stemless would go	Device takes the measurement at the center at the humorous
13	What range of values should we expect?	Bones will range from 15 PCF, for marginal bones to 30 PCF for healthy bones.	Device can take measurements between 15 to 30 CF

1.3 Functional Decomposition

Introduction

Within our customer needs, we identified what the customer requires of the device. From these needs, key goals were developed. The most important goal is to make the device safe for use. The other goals were to measure properties of the bone and make the device operable in a surgical environment.

Our preferred outcome is a device which is safe, provides measurements of bone density and works well in a surgical environment.

Our customer emphasized the need for the device to be compatible with FDA regulations and not damage the bone. These were interpreted to be an issue of safety. The customer also described the device as being capable of distinguishing between different bone densities which falls under the goal of measurement. The goal of surgical operability does not relate to a specific idea mentioned by the customer but incapsulates several requirements mentioned.

Continuing the functional decomposition of our project and its subsequent systems, a functional decomposition hierarchy chart was developed to graphically represent how each aspect was broken down into components until a base level of detail was reached. The project was divided into systems, then into subsystems, then into functions which were then systematically divided until it was impossible to divide them anymore. These functions were then inserted into a cross-reference table to show which systems were impacted by each function.

Results and Discussion

After careful analysis of our project and the functions we need to fulfill, we created a hierarchy chart. This represents the different systems involved in our designs broken into the smallest functions.

Figure 1 Functional Decomposition Hierarchy Chart

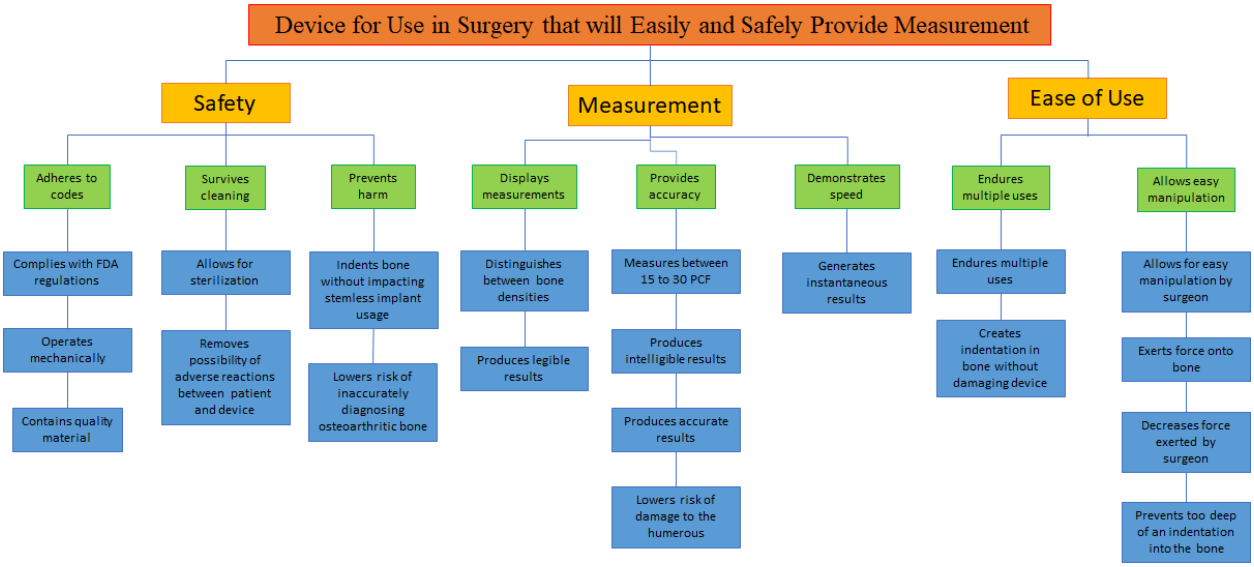


Figure 1 shows how each function is part of a broader system. With our key goals broken into systems and then into subsystems, we were able to define what the basic functions of our designs would be and what specific functions those are made of. The main goal of our project is to create a device for use in surgery that will easily and safely provide measurement. Then we broke this goal were safety, measurement and ease of use.

We chose safety as a system because the device will be used in surgery. The health and wellbeing of the patient is our highest priority.

We then divided this system into more specific subsystems: adheres to codes, prevents harm, and survives cleaning. Complying with FDA regulations is a good first step

to ensuring the safety of the device. Additionally, designing the device to use nontoxic components and to avoid mechanically causing damage to the bone are also necessary.

The next critical system is measurement. Providing the surgeon with a quantified measure of bone quality is the purpose of the device. This means the device must have a subsystem that displays measurements. Interviewing the customer provided that the range and granularity of the measurements expected creating the subsystem provides accuracy. Additionally, these measurement s must be provided to the surgeon quickly so a subsystem for demonstrates speed is created.

Our final system is ease of use. The customer will need to use the device inside of an incision, this means the device musts be allows easy manipulation. The customer would also prefer the device to be easily accessible, which is why another subsystem of functions for the device is endures multiple uses, so the surgeon does not to reorder the part. The design must also not be a burden on the user.

Table 2 *Functional Decomposition Cross Reference Table*

Function	Systems		
	Safety	Measurement	Ease of Use
Complies with FDA regulations	X		
Operates mechanically	X		X
Produces legible results		X	X
Produces intelligible results	x	X	
Generates instantaneous results		X	
Allows for easy manipulation by surgeon			X
Indents bone without impacting stemless implant usage	X		
Lowers risk of damage to the humerous	X		
Endures multiple uses			X
Produces accurate results		X	
Distinguishes between bone densities		X	

Measures between 15 to 30 PCF		X	
Conatains quality materials	X		
Lowers risk of inaccurately diagnosing osteoarthritic bone	X		
Removes possibility of adverse reactions between patient and device	X		
Decreases force exerted by surgeon			X
Prevents too deep of an indentation into the bone			X
Allows for sterilization	X		
Exerts force onto bone			X
Creates indentation in bone without damaging device			X

From figure 2, the ranking of priority for the project's different systems from most to least important: safety, measurement, and ease of use. Safety is our largest concern as this device will be used in an operating environment. The second priority was measurement, as the function of the device is to take a measurement. Additionally, the device must be easy to use. This requirement is important both due to the nature of the operating room and so the surgeons will adopt the product.

Analysis

Systems that have the greatest impact on our product's design were prioritized. For example, the safety of the design is paramount, and as such, adhering to FDA regulations, provide the framework the device bust be built within. Additionally, the device must avoid damage to the humorous that would prevent the use of a stemless implant. Such damage would result in longer healing times and discomfort for the patient, violating the goal of safety. There are also many more of these functional relationships that can be found in figure 2.

Several functions also serve multiple purposes, with the more purposes served showing the more integral that function may be in the final design. For example, the function

"produces intelligible results" falls under both safety and measurement functions. Providing an intelligible result is a key purpose of any measurement. However, the surgeon will choose the treatment based on this result affecting the patient's outcomes to this function.

These functional requirements will guide the product design. Some functions can be solved using existing information, for example being nontoxic can be solved by selecting from a list of nontoxic materials. Other functions, such as ease of manipulation by the surgeon, will require prototyping, testing, and additional research. However, the creation of the design will be structured around these functions.

1.4 Target Summary

The functional decomposition outlines what the device must do. However, to ensure the device preforms these functions they must be converted to targets with testable metrics for success or failure. The complete catalog of functions and their associated targets and metrics is attached in Appendix B. The critical targets and metrics shown in the table below are discussed in detail in this section.

Table 3 *Targets and Metrics*

Function	Target	Metric
Complies with FDA regulations	Compliant with FDA regulations	Complete 510k approval process
Produces intelligible results	Reports results with 95% percent accuracy	Measure PCF of multiple samples with known PCFs using device and measure accuracy
Allows for easy manipulation by surgeon	Weighs less than or equal to 5 lbs.	The device when weighed is equal to or less than 5 lbs.
Indents bone without impacting stemless implant usage	Creates indentation less than or equal to 2 cm	Use the device on samples and measure the indentation created to check it is equal to or less than 2 cm

Endures multiple uses	Lifespan greater than 50 uses	The device will be repeatedly tested against bone blocks, checking for accuracy in measurement.
Produces accurate results	Measures to an accuracy of .5 PCF	The provided sawbones are provided in grades of .5 PCF and the device will be tested against sawbones of various densities
Allows for sterilization	Device withstands temperatures up to 140 C	Materials will be exposed to high temperatures until the device has a reaction or begins to deform
*Does not come into contact with incision	Width of device is smaller than 6 inches (size of standard incision)	A model of an incision will be made and the device will be checked to ensure it will not come into contact with the incision walls

Note: * Entries were not part of the functional decomposition.

The objective of the project is a medical device. As a medical device it must comply with FDA regulations. The requirements of the approval vary by device, and the devices currently approved by the FDA. This approval process requires the use of a 510K application. This document will be completed through the BME class. The targets and the relevant metrics will be explored in the 510K application. They will then be tested by Dr. Arce's review of the 510K.

The customer will need to read and understand the measurement taken. The results will begin at 15 PCF and extend to 20 PCF. By confining the results to this range, the display will be able to provide the user with the density readings that are important. This range is where the surgeon will need to determine whether a stemmed or stemless implant is needed. Since there is no defined density at which a stemless implant can be used, providing an accuracy of .5 PCF

is assumed to be acceptable. This will be tested by asking people to take measurements from saw-bone blocks and tell us the results.

The device must avoid damaging the bone while taking the measurement. This means the device must use biocompatible materials. Additionally, the device cannot indent the bone more than 2 cm. This indentation should be in the part of the bone which will be replaced by the implant. This will be tested by taking measurements in the saw-bones and measuring the indentation, if any, left on the block.

Since the device will be coming into direct contact with the patient, the device must be sterilized. Sterilization of medical equipment is done bey chemical disinfectants and through the use of an autoclave. In an autoclave the device will be subjected to temperatures above 131 degrees C and 15 pounds per square inch. The device must be able to withstand these temperatures, and not react when exposed to common cleaning chemicals such as alcohol. The materials used will be chosen from materials where this will not be an issue. However, the device will be exposed to these conditions to confirm these properties.

The device will need to take a measurement within an incision. The device will have infinite space from the cut face of the humeral head, however, area beyond the face is very limited. Therefore, the device must be easily manipulated by the surgeon to allow them to make the measurement within this confined space. This will be tested by asking multiple people to take a measurement, without touching the walls of a model incision we will create.

The device must be reusable both between surgeries and within the operation room. This means the device will be built to survive 100 uses and sterilizations (will probably change based

on the number we expect the device to handle). The device must also be able to take multiple measurements during a single surgery, so the device must be able to be reset in less than a minute.

1.5 Concept Generation

Concept 1.

The most rudimentary way to measure density is mass divided by volume. This concept would really take advantage of this simple idea. This device would need to include at least two systems. The first would be an extraction tool to cut the bone at the center of the humerus. This cut would need to extract the same volume every time. After the tool extracts this piece, it would have a very precise scale that measure the mass of the bone. The device would then display the calculated density for a piece based on the volume that was extracted.

Concept 2.

There were two main inspirations for this concept. The first of which was the reflex test performed during a checkup. The second of which are the impact and hardness tests done for material testing. This device would have a method of attaching to the humerus, most likely by griping the outside of the bone to create stability. It would also consist of a pendulum with a mechanism that allows release from the same distance for each use. The doctor would release the pendulum and indent the bone. The device would also push into the indent created to measure the depth. The device would be calibrated to output a quality reading dependent on the set height of the swing when measuring the indent.

Concept 3.

Surgeons sometimes test the quality of the bone by feeling the force needed to ream the bone, when implanting the device. This concept would create a handle for the reamer that would measure the torque needed to turn the reamer. This would operate by the handle and reamer being connected through a mechanism like that of a torque wrench. This will result in the applied torque being displayed. The torque read can then be correlated to the density of the bone from a conversion table to be developed later.

Concept 4.

Exactech's current surgical procedure for the stemless implant also includes a guidewire called the Stienmann pin to decide which size stemless implant to use. Since the surgeon is already pushing into the bone and creating an indent/tunnel, another concept favored by the team is to create an applicator for the pin that would measure the force needed to push through the bone.

Concept 5.

The rate of heat transfer is dependent on density. Therefore, another concept the team thought of was a device that could use this relationship to estimate bone density. This device would use a constant heat source and put it into contact with the humerus. A temperature sensor would be pushed into the bone and the device would measure the rate of temperature change. After a set amount of time, the device would output a bone density.

Concept 6.

A linear spring collapses a set distance for the force applied. Additionally, force acts equally in opposite directions. This concept replies on these fundamental concepts to function. The device has an applicator head which will be pressed against the bone. The applicator has a long shaft which slides linearly into and out of the handle. A linear spring is compressed as the surgeon presses the handle towards the bone. Since the force is the same at both ends of the device and the spring compresses linearly with the force the length of the compression will relate to the force applied. The handle will include a gauge that displays the force applied at the current level of spring compression. The surgeon will be providing the force and deciding when to stop, allowing the surgeon to be the sensor that is responsible for preventing bone damage.

Concept 7.

Another approach the team considered another use of the guidewire. Instead of a sensor measuring the force used to push, this concept would involve a loaded spring. The doctor would place the opening of the device against the flat cut of the humerus and pull a trigger. The trigger would release the spring and push the guidewire into the bone. The depth that the guidewire goes in the bone will be calibrated to a bone quality scale. The surgeon can then make the decision to either continue with the stemless implant or switch to the more conservative option.

Concept 8.

A saw is used to remove the head of the humorous from the patient. The density of the bone will impart the force the saw needs to apply to make this cut. More dense bones will require

more force and the saw will draw more amps as the cut is made. This device will measure the amps pulled by the saw while the cut is made. This measurement will be recorded to a computer screen over time. A software will then use the provided measurements of the bone and the thickness of the exterior bone material to determine the force needed to cut the internal bone material. This force will then be converted to density at a rate to be determines by experimentation later.

1.6 Concept Selection

The most promising concepts were selected from the concepts generated. However, one of these concepts must be selected. To this end the customer's needs were evaluated in a pairwise comparison to provide the relative weights of the customer's needs. The device being approved by the FDA was determined to be the most important need. This was followed closely by safety factors such as being nontoxic and being able to measure the bone density. The full pairwise comparison table can be found in Appendix D.

House of Quality

The customer needs were then compared to the engineering characteristics of the device. Engineering characteristics were then rated 1, 3, or 9 based on how strongly they relate to each customer need. By multiplying the relative weight of the need, by how strongly the characteristic effects the need the relative importance of each characteristic can be determined. This comparison is shown in the house of quality table shown below.

Table 4 *House of Quality*

House of Quality										
		Engineering Characteristics								
Improvement Direction		↑	↓	↓	↑	↑	↑	↓		↑
Units		%	lb	cm	uses	PCF	deg	in.	n/a	ft
Customer Requirements	Importance Weight Factor	Result Repeatability	Device Weight	Indentation Depth	Reusability	Measurement Accuracy	Withstands High Temperatures	Device Width	Results in under 10 seconds	Readability Distance
Mechanically operated	0		1		3				3	
Measures PCF of bone	8	3		1		3				
Indentation smaller than 1/8"	3			9						
Compliant with FDA	11	9		9		3	1			
Sterilizable	10				3		9	3		
Class 1 device	4			1	9					
Recognizable scale	5					9				9
Reusable	2	3			9		3			
Non-toxic	9				1		1			
Handheld	7		9					9		9
Measure at center of Humerous	2			3					3	
Measure between 15-30 PCF	5	9				3				
Raw Score	914	174	63	144	93	117	116	93	6	108
Relative Weight %		0.190	0.068	0.157	0.101	0.128	0.126	0.101	0.006	0.118
Rank Order		1	8	2	6	3	4	6	9	5

Based on the house of quality the most important engineering characteristic was the repeatability of results. This was followed by the indentation depth. These relate to the ability of the device to take a precise measurement and minimizing the risk of the most likely harm to the patient. The next two highest values also delt with safety and measurement, as measurement accuracy and withstanding high temperatures were next respectively.

The lowest weighted value was results in under 10 seconds. The minimal importance of the customer requirements it effected resulted in this characteristic being dropped from use in

concept selection. This leaves the device weight as the lowest remaining factor that will be considered.

Pugh Charts

Once the importance of the engineering characteristics was determined the concepts were compared to each other based on how well they included each engineering characteristic. Each concept was rated on its ability to meet the characteristic as good (+), satisfactory (S), or unsatisfactory (-). The number of good and unsatisfactory results was tallied for each concept at the bottom allowing the concepts to be compared.

The concepts compared in the Pugh Chart were selected as the most promising concepts form the concept generation. However, the descriptions were too long to fit on the Pugh Chart so they were abbreviated as show in the table below.

Table 5 *Concepts Evaluated*

Concept	**Short name**
Place a torque wrench on the reamer and measure force needed to turn it	Torque Wrench
A force sensor on the guidewire that measures how much force was applied	Sensor
Spring linear applicator	Linear Spring
Spring load the guidewire, and measure how far it goes in	Loaded Guidewire
Amps pulled by saw making cut	Amp meter

in each Pugh Chart the concepts are arrayed along the top and the engineering concepts are shown along the left. The first Pugh Chart uses the current state of the art, the surgeon's thumb as a means of comparison. Each concept is then compared to this datum for every engineering characteristic. The first of these Pugh Charts is shown below.

Table 6 *Pugh Chart 1*

Pugh Chart 1						
	Concepts					
Selection Criteria	**Thumb test**	**Torque Wrench**	**Sensor**	**Linear Spring**	**Loaded Guidewire**	**Amp Meter**
Result Repeatability	Datum	+	+	+	+	+
Device Weight		-	-	-	-	-
Indentation Depth		-	S	S	-	S
Reusability		S	S	S	S	S
Measurement Accuracy		+	+	+	+	+
Withstands High Temperatures		+	-	+	+	-
Device Width		S	S	S	S	S
Readability Distance		S	S	S	S	S
# of Pluses		3	2	3	3	2
# of Minuses		2	2	1	2	3

As shown above, the concepts were compared to the thumb test which is currently used by surgeons. Based on this comparison the torque wrench concept, had three pluses and two minuses making it a moderate choice and a good datum for the next pugh chart.

In the second Pugh Chart, the concepts were again compared this time to the torque wrench. This resulted in the Amp meter concept being dropped, because it had no pluses and three minuses compared to the datum. From the remaining concepts the loaded guidewire was

selected as the new datum. This concept had a good balance of pluses and minuses being almost evenly split between them.

The last Pugh Chart compared the loaded spring to the torque wrench, sensor, and linear spring concepts. This chart is shown below.

Table 7 *Final Pugh Chart*

Pugh Chart 3				
	Concepts			
Selection Criteria	**Loaded Guidewire**	**Torque Wrench**	**Sensor**	**Linear Spring**
Result Repeatability	Datum	+	+	+
Device Weight		-	-	+
Indentation Depth		+	+	+
Reusability		-	+	+
Measurement Accuracy		S	+	+
Withstands High Temperatures		S	-	S
Device Width		-	-	S
Readability Distance		+	+	+
# of Pluses		3	5	6
# of Minuses		3	3	0

The Torque wrench was comparable to the guidewire. However, the Sensor and Linear spring concepts were superior. While it is close to the sensor in the number of pluses, the linear spring is superior in terms of withstanding high temperatures which is a heavily weighted attribute. Therefore, the linear spring was selected as the concept to proceed with.

To ensure the values were consistent, a criteria comparison matrix was used. In the matrix, a pairwise comparison of the engineering criteria was done. The resulting values were then processes to provide a consistency ratio of 0.10. The relevant spreadsheets are shown in Appendix D.

Additionally, the top three concepts were compared with respect to each of the engineering characteristics in an analytical hierarchy process. These tables resulted in a consistency ratio of 0.00. The spreadsheet showing these values can be found in Appendix D.

These resulted in the final rating matrix shown below. This rating matrix confirms the selection of the Linear spring as the concept to move forward with.

Final Rating Matrix

Table 8 *Final Rating Matrix*

Final Rating Matrix			
	Concepts		
Selection Criteria	Torque Wrench	Sensor	Linear Spring
Result Repeatability	0.14	0.43	0.43
Device Weight	0.20	0.20	0.60
Indentation Depth	0.07	0.47	0.47
Reusability	0.20	0.20	0.60
Measurement Accuracy	0.14	0.43	0.43
Withstands High Temperatures	0.43	0.14	0.43
Device Width	0.20	0.20	0.60
Readability Distance	0.14	0.43	0.43
Total	1.52	2.50	3.98

Additionally, the rating matrix gives a priority to the other two concepts placing the sensor as the second ranked concept and the torque wrench as the third. This is consistent with the earlier selection, and the linear spring concept will be used moving forward.

1.8 Spring Project Plan

Table 9 *Spring Timeline*

Spring Project Plan								
Start date	Info	Action	Progress	Assigned to	Results	Status	Due	Date Completed
1/5/2022	First day of classes	Show up do first day assignement	Not Started	All	N/A	Not Started	1/5/2022	
1/2/2022	Background research completed	Speak to more surgeons and get numbers related to the force applied with different qualities of bone (good/bad)	Not Started	All	N/A	Not Started	1/11/2022	
1/9/2022	Compression Testing of Saw Bones	Use equipment to characterize force needed to indent blocks	Not Started	All	N/A	Not Started	1/11/2022	
1/10/2022	Forces Converted to Spring Strengths	Calculate spring force required using data from Compression Testing	Not Started	All	N/A	Not Started	1/14/2022	
1/14/2022	Pick a Mechanical Amplifier	Research and test mechanical amplifiers to find the kind that would work best for this application	Not Started	All	N/A	Not Started	1/15/2022	
1/14/2022	Design 1 Completed	Create CAD for protoype and drawings for each piece	Not Started	All	N/A	Not Started	1/18/2022	
1/18/2022	Identify All Parts and Vendors	Research vendors to find parts at lowest high quality cost	Not Started	All	N/A	Not Started	1/21/2022	
1/18/2022	Order Parts	Order parts from selected vendors through the school's purchasing department	Not Started	All	N/A	Not Started	1/22/2022	
1/29/2022	Test Spring Properties Post Sterilization	Find springs' coefficients, sterilize them and then find springs' coefficients to see if there are any changes	Not Started	All	N/A	Not Started	2/1/2022	
1/31/2022	Prototype Completed	Once all parts are recieved assemble prototype	Not Started	All	N/A	Not Started	2/9/2022	
2/1/2022	Test Size Targets	Check the size and weight of the prototype and compare to targets. Also simulate using device to test within a mock incision	Not Started	All	N/A	Not Started	2/10/2022	
2/2/2022	Test Temperature Targets	Introduce prototype to high temperature enviroments to see if it survives	Not Started	All	N/A	Not Started	2/11/2022	
2/3/2022	Test Indentation Targets	Test prototype on multiple saw bones to ensure it does not make an indentation larger than the target	Not Started	All	N/A	Not Started	2/12/2022	
2/4/2022	Test Accuracy Targets	Test prototype on sawbones to check accuracy of measurement	Not Started	All	N/A	Not Started	2/13/2022	
2/10/2022	Identify Shortcomings	Using data from tests, identify relevant failures	Not Started	All	N/A	Not Started	2/14/2022	
2/14/2022	Revisions Completed	Redesign to fix failures found in prototype testing	Not Started	All	N/A	Not Started	2/21/2022	
2/21/2022	Design 2 Completed	Create CAD for protoype and drawings for each piece	Not Started	All	N/A	Not Started	2/22/2022	
2/22/2022	Order Parts	Order parts from selected vendors through the school's purchasing department	Not Started	All	N/A	Not Started	2/23/2022	
2/22/2022	Final Prototype Completed	Once all parts are recieved assemble prototype	Not Started	All	N/A	Not Started	3/1/2022	
2/23/2022	Test Size Targets	Check the size and weight of the final prototype and compare to targets. Also simulate to test whether the device fits with the incision	Not Started	All	N/A	Not Started	2/10/2022	
2/24/2022	Test Temperature Targets	Introduce final prototype to high temperature enviroments to see if it survives	Not Started	All	N/A	Not Started	2/11/2022	
2/25/2022	Test Indentation Targets	Test final prototype on multiple materials to ensure it does not make an indentation larger than the target	Not Started	All	N/A	Not Started	2/12/2022	
2/26/2022	Test Accuracy Targets	Test final prototype on sawbones to check accuracy of measurement	Not Started	All	N/A	Not Started	2/13/2022	
2/28/2022	Create Poster	Design poster for Engineering Design Day	Not Started	All	N/A	Not Started	2/15/2022	
4/1/2022	Engineering Design Day	Present project to the College of Engineering	Not Started	All	N/A	Not Started	2/16/2022	
4/25/2022	Finals		Not Started	All	N/A	Not Started	4/25/2022	
4/30/2022	Graduation		Not Started	All	N/A	Not Started	4/30/2022	

Chapter Two: EML 4552C

2.1 Restated Project Definition and Scope

Project Description

The objective of the project is to provide Exactech a device to quantitatively measure the bone quality of the proximal humerus during shoulder replacement surgery. The density of the bone determines where a stemmed or stemless replacement can be used. Surgeons currently make this decision by using their thumb to qualitatively determine the quality. The project attempts to produce a device that will provide the surgeon a quantitative measurement, during surgery, with a production cost of less than $2,500.

Key Goals

The key goal of this project is to develop a device that can measure human bone quality. The device should provide surgeons instant results that assist them in recognizing osteoarthritic bones. Since the device would be replacing a fast qualitative “thumb test”, the device must provide results in a similar time frame. The device should also be compatible with both sterilization methods and human tissue. Sterilization temperatures of 121ºC or 132ºC (250ºF and 270ºF) are standard; therefore, at a minimum, the part in contact with the bone should be able to withstand these temperatures. Additionally, the device should not damage the bone or negatively affect the procedure. The device should be a size that is accessible and easily used during surgery.

Markets

Surgeons currently use a qualitative thumb test for measuring bone density, which the device is intended to replace. The surgeons will be the ones who will use the device, making them

a primary market. However, surgeons do not generally do their own purchasing, meanign the hospitals and offices that make the purchasing decisions would be considered a primary market with the surgeons. Additionally, the sponsor of the project will need to approve the device, and potentially provide it to its customers. Therefore, the sponsor is a second primary market.

Secondary markets for the device include research facilities and universities. The ability of the tool to quantitatively measure bone density would be useful in studies related to the humerus where bone density is a factor.

Assumptions

The first assumption made for this project is that the surgeon using it will be willing and capable of using their hands. This was done because there is a possibility the design will be handheld and may require use of simple mechanisms, such as buttons or levers. If the device requires any electrical power, it was assumed that the surgeon/hospital will have a power supply. It was also assumed that the device will be sterilized using standard sterilization temperatures and will be cleaned with standard isopropyl alcohol. Besides sterilization, it is assumed that the device will not encounter severe environments, because it will be packaged during the transportation portion of its life span and then will be stored in a medical facility. When the device is being operated, environment factors such as lighting, temperature, pressure, and moisture will be assumed to be constant because it will be used during surgery in a surgical room where this is necessary.

Stakeholders

Key stakeholders in this project are Exactech, Inc. and our connection to the company, Tom Vanasse. Patients are stakeholders because their health and safety are dependent on the compatibility and accuracy of the device. Additional stakeholders would be the surgeons and nurses who will be handling and operating the device. The FAMU-FSU College of Engineering and our advisor, Dr. Stephen Arce, are stakeholders because the work done reflects the school and the faculty who have guided the team. Lastly, the members of the development team are stakeholders in this project because their time and effort will be contributed to the development of the device.

2.2 Results

Through the concept selection process the linear spring concept, discussed above, was selected. However, through discussions with Exactech and the FAMU-FSU College of Engineering machine shop, a few modifications were made. Since the force applied by each surgeon and each use would vary and the point defined as “deflection” would be an objective call the team decided to use the spring in a different way. The concept that made is to design day can be found in Figure 2.

Figure 2 Final Machined Prototype

In this iteration of the design the surgeon would pull the handle back until they felt it lock into place. This is the locked, or compressed position. This would compress the spring in the same position each time, with the same potential energy. The face of the device is then placed on the face of the humerus. The surgeon then pushes the button, and this creates an indentation on the bone. The depth of the indentation is related to the quality of the bone and can be measured to assist the surgeon in choice of implant during surgery. The inside of the device is pictured in more detail in Figures 3 and 4.

Figure 3 Final Prototype: Free Position

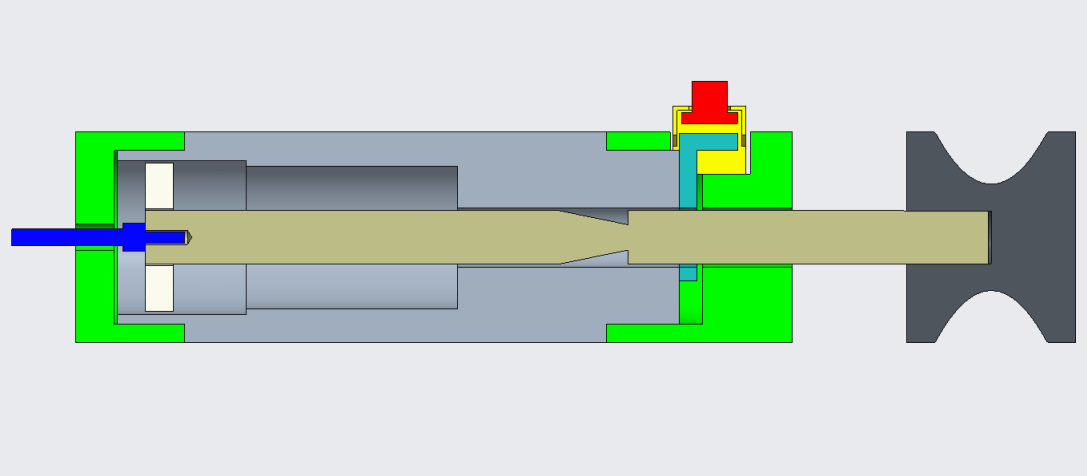
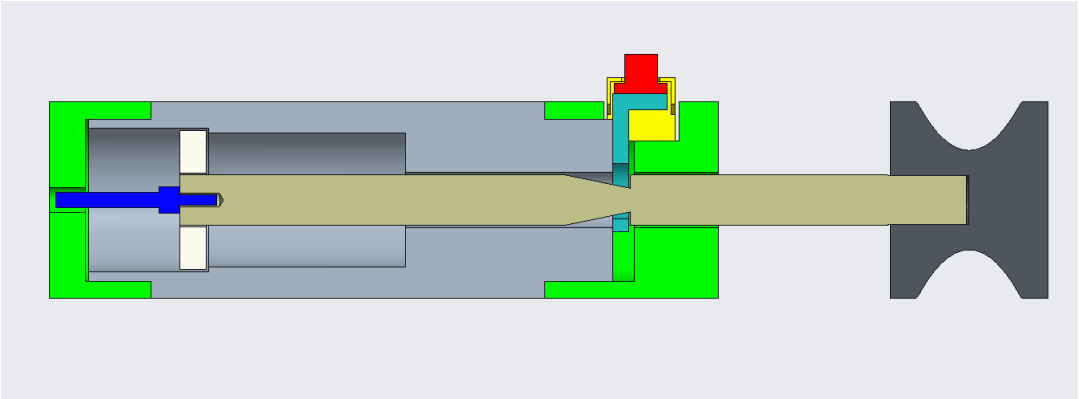


Figure 4 Final Prototype: Locked Position



The first prototype designed by the team was 3D printed to learn any kinks or faults of the design. That iteration held the device in the locked position using pegs on the side of the indenter rod that would slide up the device as the handle is pulled and then rest on a shelf when the handle was twisted. When the user was ready, they would twist the handle in the opposite direction allowing the spring to push the indenter tip into the bone. The team found that the twist

method was difficult to use and the transition between the free and locked position was very rough. This is when the team design a new locking mechanism which can be shown in Figures 3 and 4.

This design utilizes an extra spring located under a plate. The plate has a hole large enough for the indenter rod to move freely when it is aligned with the largest section of the rod. When the handle is pulled and the plate passes the shelf located on the rod, the constant force supplied by the spring pushes the plate underneath the shelf holding the larger spring in the housing to be locked in a compressed position. When the surgeon is ready to use the device they press the button which aligns the hole on the plate with the largest cross section of the rod allowing the main spring to push the indenter tip into the bone.

2.3 Discussion

The completed device began validation testing upon completion. This was done to ensure the device met all targets outlined earlier in the design process. The results are shown in Table 10 below.

Table 10 *Validation Results*

Target	Validation
Compliant with FDA regulations	Exempt or 510k
Device withstands temperatures up to 284 °F	Yes
Creates indentation less than or equal to 1 in.	Yes
Weighs less than or equal to 5lbs	Yes
Length of device is smaller than 6 in.	Yes
Lifespan greater than 50 uses	Yes
Reports results with 95% accuracy	Yes

The FDA approval target is not possible to test without applying for and receiving this approval. This approval was not sought as part of the project, because the FDA approval process is very timely and costly, and ultimately not in the scope of what Exactech asked us to complete. However, research was done on the path required to get the approval. The FDA provides that devices which are significantly similar to existing medical devices may be approved without an analysis, exempt devices, or with a filing explaining the similarity to existing devices, a 510k. A review of existing devices, leads to the belief the device could be classified as a Class I medical device, meaning approval would be achieved with the device qualifying as exempt or with a 510k.

The physical requirements were also compared to the targets initially set. These targets included a weight of less than 5 lbs. and a width of less than 5 inches. The device has a measured diameter of 1.5 inches at its maximum width. When placed on the scale the device weighed 2.7

lbs., just over half of the target maximum weight. To prevent damage to the part of the bone that would not be removed during surgery, the maximum distance the device could indent the bone was set at 1 inch. The final device was designed to prevent the tip exceeding 1 inch of indentation, the indenter tip extends less than 1 inch past the front face of the device. This was confirmed by allowing the device to indent in the air and confirming the tip was less than 1 inch past the front of the device. The stainless-steel design of the device was selected for its durability and biocompatibility. However, this material also provides the device an ability ot endure temperatures of 284°F, without damage. The device was placed in an autoclave that reached this temperature and functioned reliably after the process. This confirms the device's ability to survive this temperature target and the more general target of sterilization of the device.

Due to the high variation in the number of surgeries performed by surgeons, a target based on use was difficult to determine. Therefore, the target was chosen based on an assumption of one year with one surgery a week and two weeks for holidays. The device did not show signs of deterioration at the resulting target of 50 uses. Instead, the device did not encounter a malfunction until use 92. The deterioration consisted of slight rounding of the indenter tip, and the tip becoming loose in the rod. However, the production version of the device would use a welded indenter tip preventing it becoming loose. Additionally, the rounding of the tip did not affect the indentation depth to a level beyond that of normally occurring variation in the results. The resulting durability exceeded the target number of uses, and based on discussions with the machine shop the wear on the indenter tip could be reduced by changing to a hardened stainless steel further improving device durability.

The most important test of the device was its ability to determine the bone density. Since the surgeon my not create a perfectly level or perpendicular plane by respecting the humeral head the accuracy testing was conducted at multiple angles: vertical, horizontal and 45 degrees. The results are shown in Figures 5 and 6.

Figure 5 Validation Testing: Angled Indentations

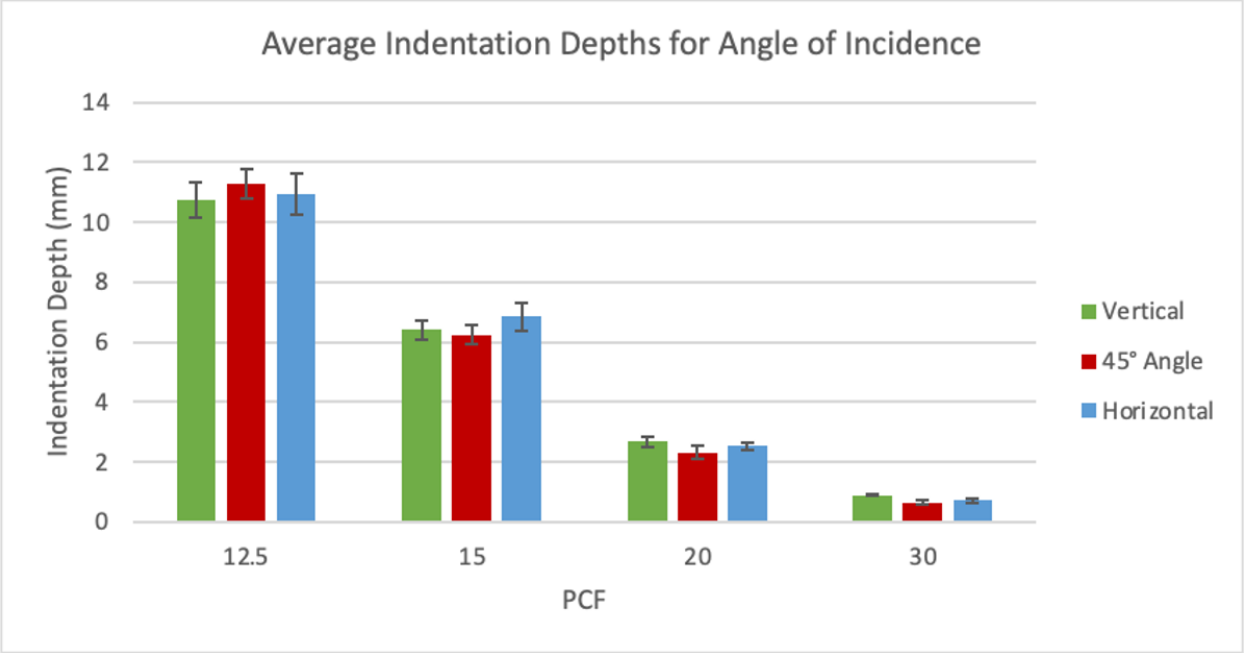
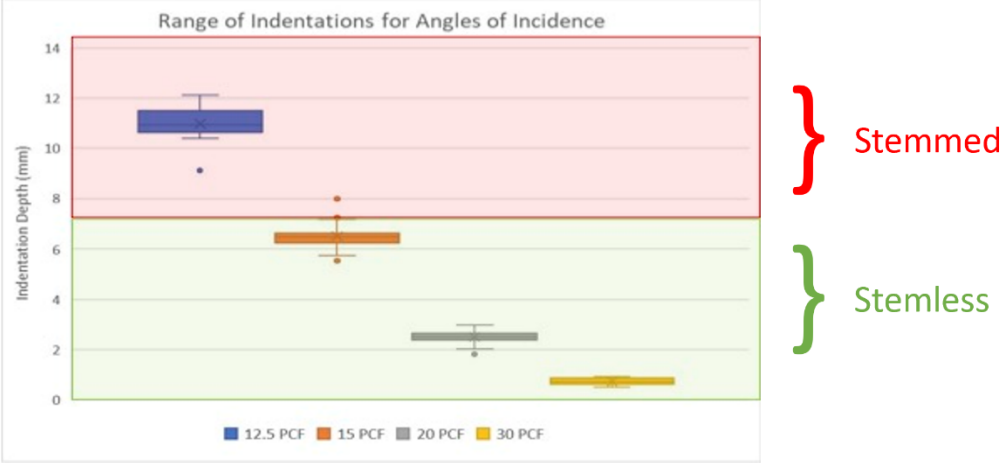


Figure 6 Validation Testing: Stemmed vs Stemless



The figures above show the device read stemmed versus stemless correctly 91 of 92 tests/ this is a reporting accuracy of 98.9%. This exceeds the accuracy target set; however, the device requires further testing because all of this was done with one prototype. This limits the ability to determine if the device when mass produced can replicate these results. It needs to be validated that these results are repeatable dependable, but this is not within the scope of the project.

2.4 Conclusions

With the exception of FDA approval which exceeded the scope of the project, the device successfully met all targets. This confirms the device meets its intended purpose of distinguishing bone qualities that will or will not support a stemless shoulder implant. This removed a subjective thumb test and provides consistent results without regard to the force applied by the surgeon.

2.5 Future Work

While the device has met all the provided targets, it is a prototype. To fully replace the thumb test large numbers of the device will need to be produced. This will require changes in the design to improve the efficiency of manufacturing, and the ensure the accuracy of every device manufactured. Following changes such as a perinatally fixed hardened stainless steel indenter tip, and welded end caps, the device will need to repeat the validation testing.

Additionally, an operating room calibration test should be developed. This will provide a way for surgery personnel to confirm the device is functional an accurate prior to use on the patient. Prior to any use on any patient the production device will need to apply for and receive

approval from the FDA. While these improvements and goals exceed the scope of this project, they provide a necessary next set in the development of the device and replacement of the thumb test.

Appendices

Appendix B Code of Conduct

Team 102 was not required to do a code of conduct due to the unprecedented circumstances of collaboration between the ME and CBE department.

Appendix B: Functional Decomposition

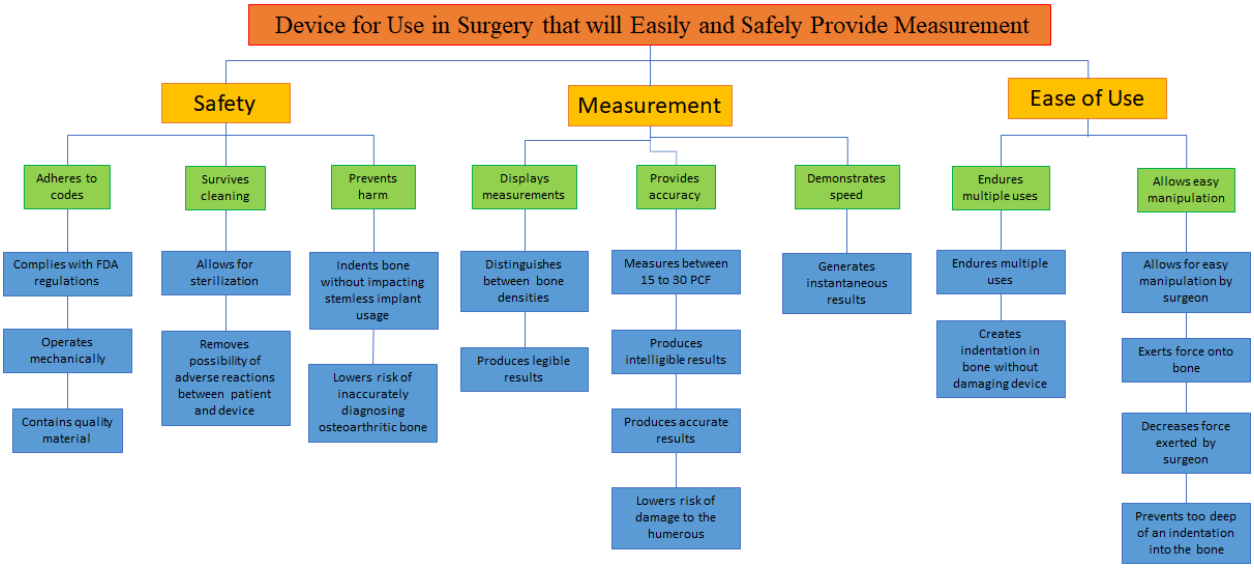


Fig 1. Functional Decomposition Hierarchy Chart of Functions

Function	Systems		
	Safety	Measurement	Ease of Use
Complies with FDA regulations	X		
Operates mechanically	X		X
Produces legible results		X	X
Produces intelligible results	x	X	
Generates instantaneous results		X	
Allows for easy manipulation by surgeon			X
Indents bone without impacting stemless implant usage	X		
Lowers risk of damage to the humerous	X		
Endures multiple uses			X
Produces accurate results		X	
Distinguishes between bone densities		X	
Measures between 15 to 30 PCF		X	
Conatains quality materials	X		
Lowers risk of inaccurately diagnosing osteoarthritic bone	X		
Removes possibility of adverse reactions between patient and device	X		
Decreases force exerted by surgeon			X
Prevents too deep of an indentation into the bone			X
Allows for sterilization	X		
Exerts force onto bone			X
Creates indentation in bone without damaging device			X

Table 2. Functional Decomposition Cross Reference Table

Appendix C: Target Catalog

Function	Target	Metric
Complies with FDA regulations	Compliant with FDA regulations	Complete 510k approval process
Operates mechanically	0 Electrical components	Make a list of all parts and check any contain electrical components
Produces legible results	Readable at 1 ft distance	Multiple people with 20/20 vision will be asked to read the results from a 1ft distance
Produces intelligible results	Reports results with 95% percent accuracy	Measure PCF of multiple samples with known PCFs using device and measure accuracy
Generates Instantaneous results	Generates results in under 10 seconds	Use a timer to measure the time between using the device and when the results are produced
Allows for easy manipulation by surgeon	Weighs less than or equal to 5 lbs.	The device when weighed is equal to or less than 5 lbs.
Indents bone without impacting stemless implant usage	Creates indentation less than or equal to 2 cm	Use the device on samples and measure the indentation created to check it is equal to or less than 2 cm
Lowers risk of damage to the humorous	Can measure less than 15 PCF without causing the bone to split or crack	Bone saw-blocks and animal bones will be tested with the device and examined for splitting or cracking
Endures multiple uses	Lifespan greater than 50 uses	The device will be repeatedly tested against bone blocks, checking for accuracy in measurement.
Produces accurate results	Measures to an accuracy of .5 PCF	The provided sawbones are provided in grades of .5 PCF and the device will be tested against sawbones of various densities
Distinguishes between bone densities	Reports with 95% accuracy when bone is below 15 PCF or above 20 PCF	The provided sawbones will be tested using the device and record the accuracy of taking multiple measurements
Measures between 15 to 30 PCF	Measures between 15 to 20 PCF	The device will be tested against saw-bone blocks that fall in this range and compare its results to the blocks' densities
Contains quality materials	Device is 100% made of non-toxic materials	Device materials will be compared to materials used for implants

Lowers risk of inaccurately diagnosing osteoarthritic bone	Accurately identifies osteoarthritic bone 95% of the time	Device will be used to measure sawbones of known densities and results will be compared to the known densities
Removes possibility of adverse reactions between patient and device	Creates negative reaction with tissue less than 1% of the time	Device materials will be compared to materials used for implants and allergies in the US
Decreases force exerted by surgeon	Device will require the surgeon to use less than 10 lbf to measure bone	Will have a surgeon apply force to a scale similar to that applied to the bone and compare the result to the force the device needs to make that measurement.
Prevents too deep of an indentation into the bone	Mechanism that stops indentation at 2 cm	Will test the device on sawbones and measure indentation.
Allows for sterilization	Device withstands temperatures up to 140 C	Materials will be exposed to high temperatures until the device has a reaction or begins to deform
Exerts force onto bone	Device exerts equal or more force onto the bone than the surgeon applies	Will set the device between two scales and apply pressure outside, and compare results
Creates indentation in bone without damaging device	The device material is not scratched or worn by contact with the bone 90% of the time	The indenter head is tested against saw-bone blocks and animal bones then examined for scratched wear.
*Does not come into contact with incision	Width of device is smaller than 6 inches (size of standard incision)	A model of an incision will be made and the device will be checked to ensure it will not come into contact with the incision walls
*Notes densities over 20 PCF	Device will indicate density is in excess of 20 PCF	Device will be tested on a sawbones block with a PCF of 30 and will be checked to ensure that it notes the density is in excess of its range
*Devie will note the density is under 15 PCF	Device will indicate density is in less than 15 PCF	Device will be tested on a sawbones block with a PCF of 12.5, and will be checked to ensure that it notes the density is less than the range
*Needs not listed in functional decomposition		Critical targets and metrics

Appendix D: Operations Manual

Product Overview

The indenter is designed for use as part of a total shoulder replacement surgery. The surgeon can use a stemmed or stemless implant during the surgery. Stemless implants require better bone quality than stemmed implants but offer several advantages. The indenter can be used to determine if the bone quality is sufficient to use a stemless implant.

Component Description

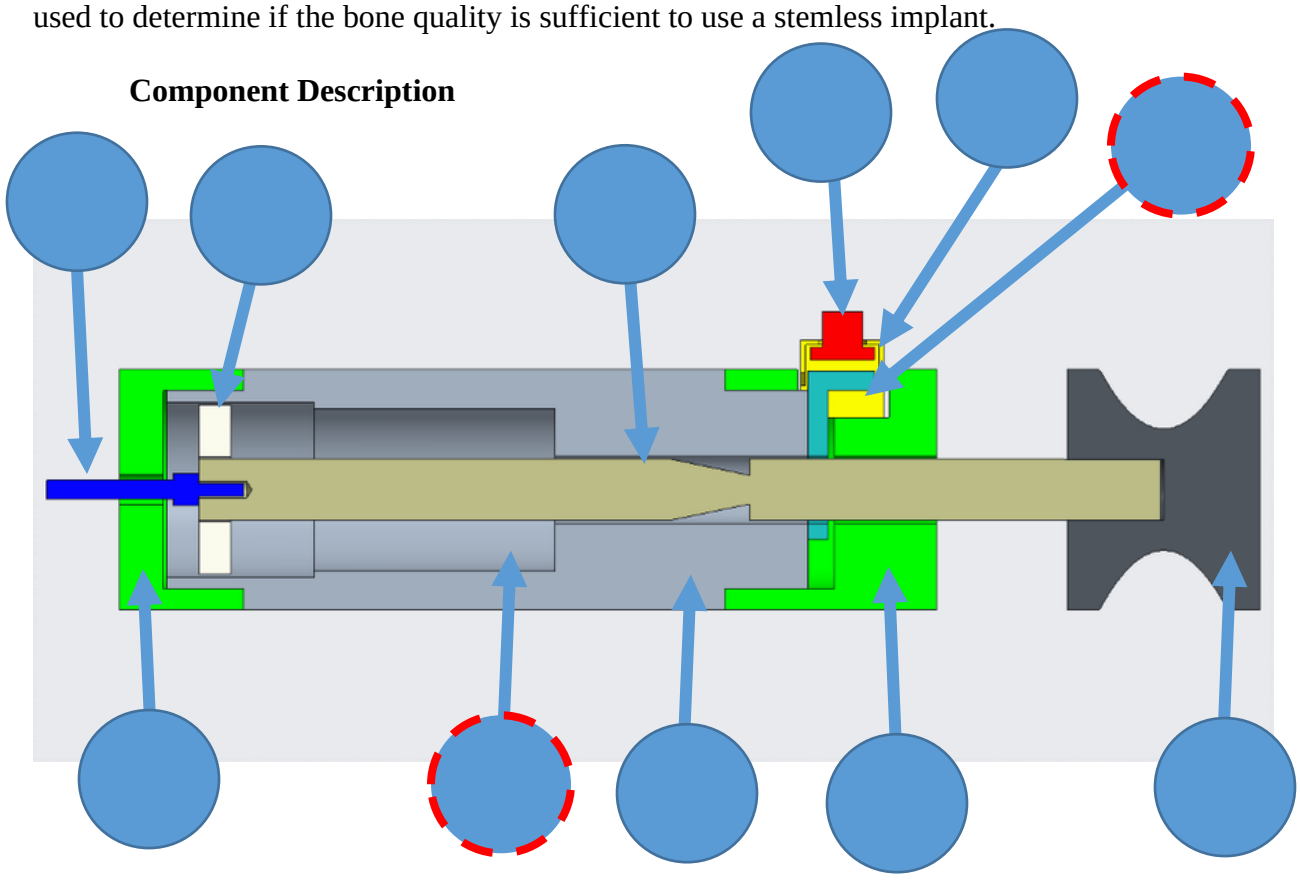


Fig 1. Functional Decomposition Hierarchy Chart of Functions

1. Handle: This portion provides a grip for the operator to compress the spring by pulling the rod back.

2. Rear cap: This houses the locking mechanism and provides a plane where the readings are taken.
3. Button and locking mechanism: The component catches on the shoulder of the rod passing through it. When the button is pressed, the hole in the mechanism aligns with the rod allowing it to move freely.
4. Buton cover: This part holds the button and locking mechanism and the supporting spring into the rear cap.
5. Button spring (not pictured): This component sits between the button mechanism and housing. The spring provides a force on the button mechanism so that the mechanism will catch on the rod's shoulder.
6. Housing: This portion connects the caps and rod. It also aligns the rod, holds the mainspring, and provides one of the faces the mainspring is compressed against.
7. Rod. This part runs through the device connecting the spring to the handle and the indenter tip to the bone quality markings made on the rod itself.
8. Washer. Part connects to the rod and provides the second face that the mainspring is compressed against.
9. Mainspring (not pictured): This part provides the device's force for making the indentations.
10. Indenter tip: This is the point of the device that impacts the bone.
11. Front cap: this part holds the internal components in and provides a flat plane set against the bone when the measurement is taken. This part also ensures the internals stay inside the indenter.

Integration

1. The handle is screwed onto the rod.
2. The secondary spring is placed in a recess inf the rear cap.
3. The button and locking mechanism are placed into the secondary spring's rear cap.
4. The button cover is placed over the button and screwed into place to maintain compression on the secondary spring,
5. The rear cap is screwed onto the rear of the housing.
6. The button is pressed, and the rod is inserted through the hole in the rear cap. The rod is shoved forward until the base of the handle sits flush against the back of the rear cap.
7. The device is on the back of the handle with the open front end facing up.
8. The mainspring is placed in the open end of the housing.
9. The washer is placed on the rod and slid to the marked position on the rod. Once in position, the set screws are tightened.
10. The indenter tip is placed in the hole at the rod's end. Once the tip of the rod is in contact with the back of the widest part of the indenter tip, the set screw in the rod is tightened.
11. The front cap is then aligned with the indenter, so the indenter tip passes through the hole, and the cap threads are aligned with the housing threading.
12. Lift the indenter by the housing and thread the front cap onto the body.

Operation

1. Grab the body of the indenter firmly in the non-dominant hand.

2. Using the free hand, grab the handle, and while maintaining a firm grip on the indenter body, pull the handle away from the indenter body. Pull the handle until it reaches the maximum distance from the indenter body.
3. Gently reduce tension on the indenter handle. The handle should travel no more than an inch before stopping movement. If the handle continues moving more than an inch, repeat this step. If the issue continues, see troubleshooting.
4. CAUTION! The indenter is now ready for use. If the button is pressed, the indenter tip can spring forward, indenting whatever is in front of it.
5. Change the grip on the indenter's body so the face of the indenter can be comfortably placed against the cut surface of the humeral head.
6. Ensure the indenter is placed firmly and levelly on the cut surface, that it is centered with the center of the humorous.
7. CAUTION! A pinch point is created between the indenter handle and rear cap when the button is pressed. Ensure nothing is between the handle and rear cap when pressing the button.
8. Maintaining a firm pressure between the indenter and humorous, press the button.
9. Continue maintaining the pressure against the humorous as the indenter stops and the measurement is read. Once the handle stops moving, look at the marking on the rod. The measurement at the edge of the rear cap is the quality measured by the indenter.

Troubleshooting

Button sticking

Ensure the springs are decompressed, then disassemble and clean the device. Once clean, reassemble the device and test its function and if problems persist, contact the manufacturer.

"Gritty" feeling when pulling rod.

Ensure the springs are decompressed, then disassemble and clean the device. Contact the manufacturer if there are signs of foreign matter, corrosion, or problems persist after cleaning.

Indentations are not round holes/indenter pulls to side during indentation

These are indentations that the indenter tip is bent. With the indenter tip in the extended position, place the device on a table with the button housing off the edge. With one hand, slowly roll the indenter along the table's edge. If the tip appears to "wiggle" as it turns, the indenter tip is bent, and the manufacturer should be contacted for a replacement.

Appendix E: Engineering Drawings

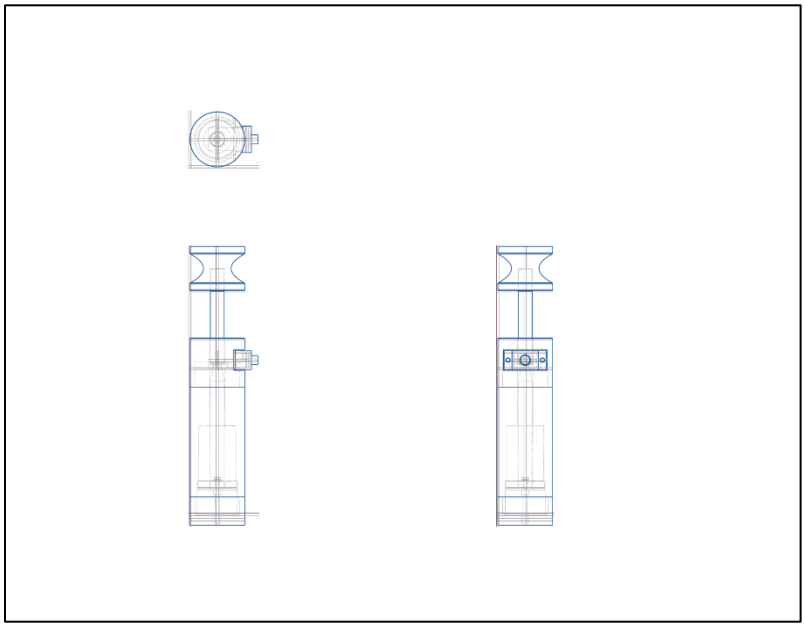


Fig 2. Assembly

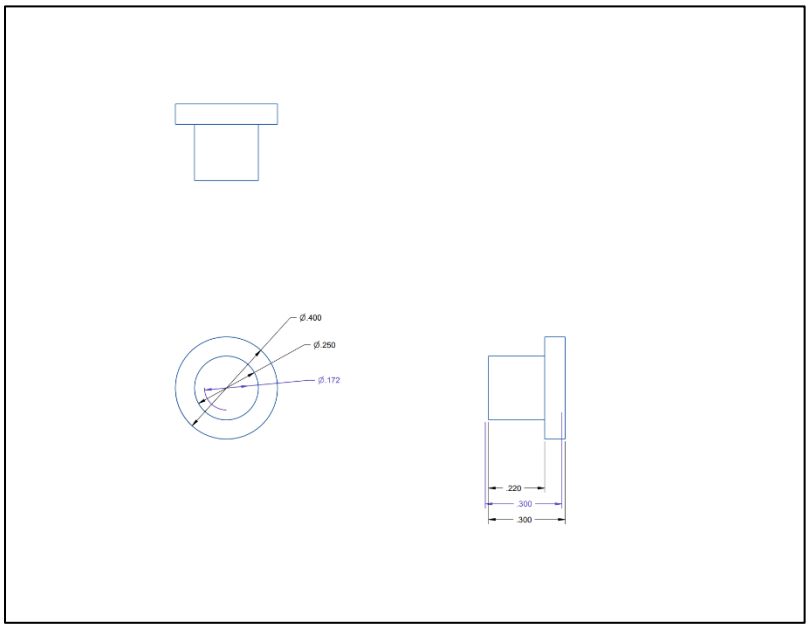


Fig 3. Button

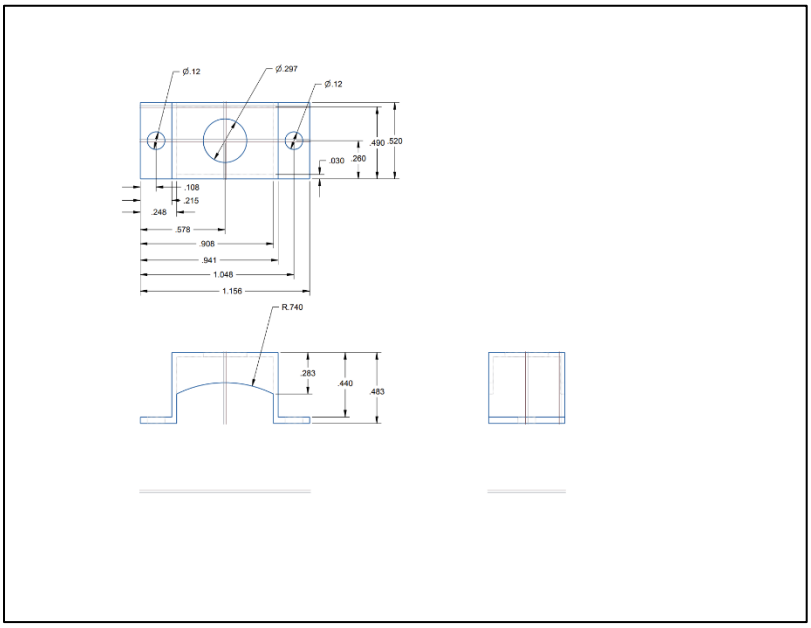


Fig 4. Button Housing

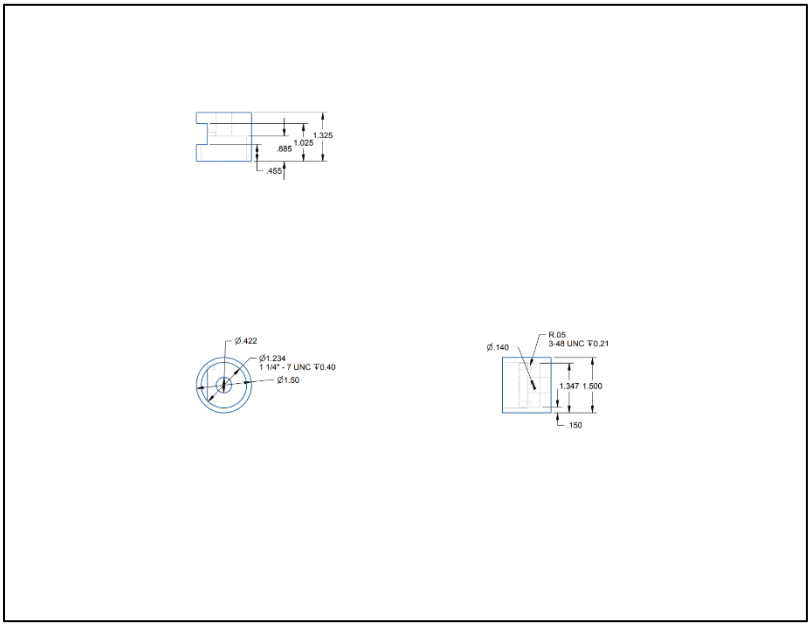


Fig 5. End Cap

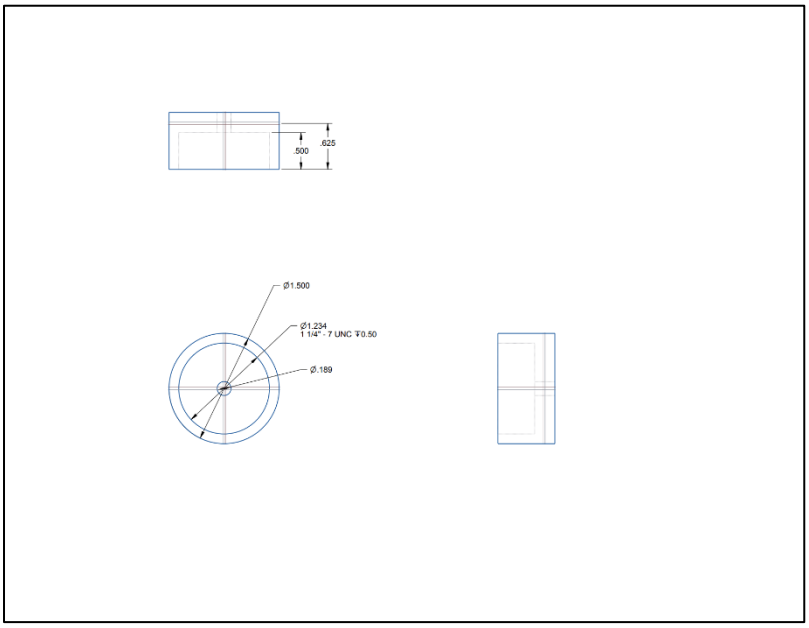


Fig 6. Front Cap

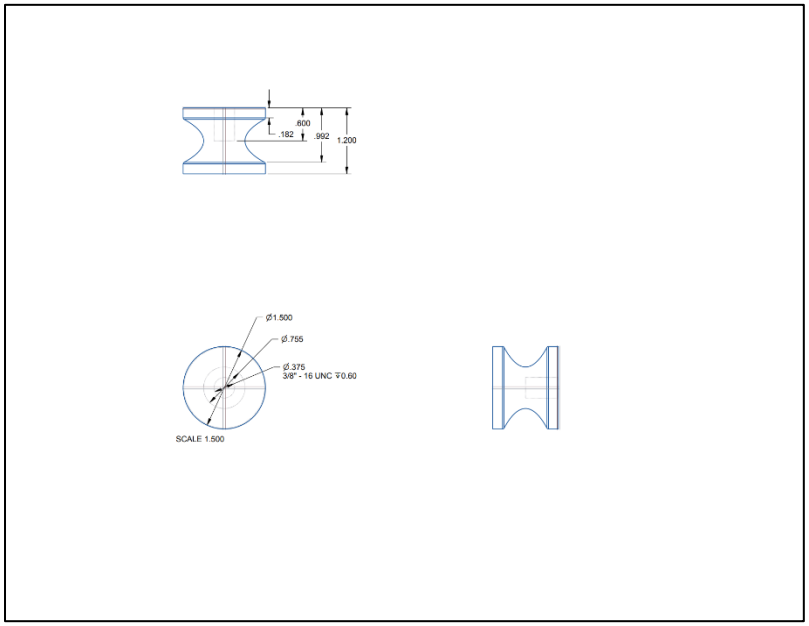


Fig 7. Handle

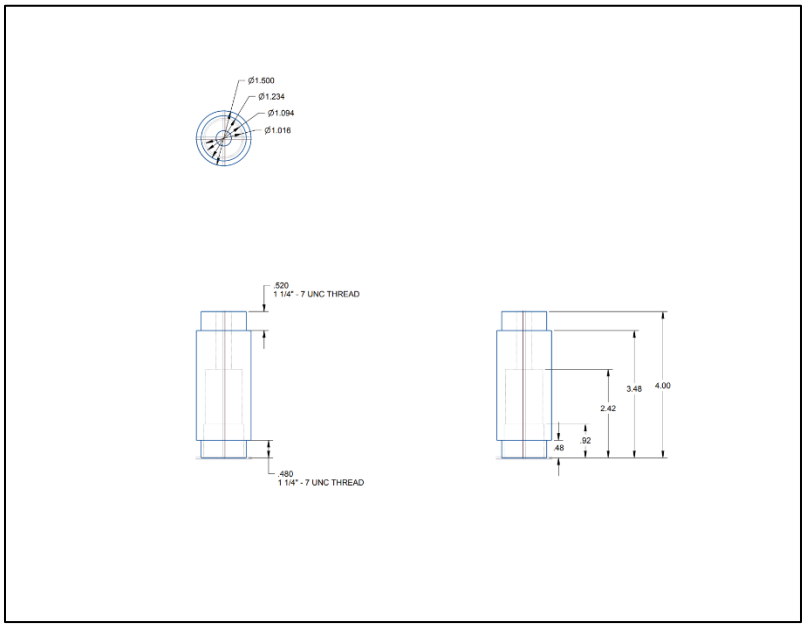


Fig 8. Housing

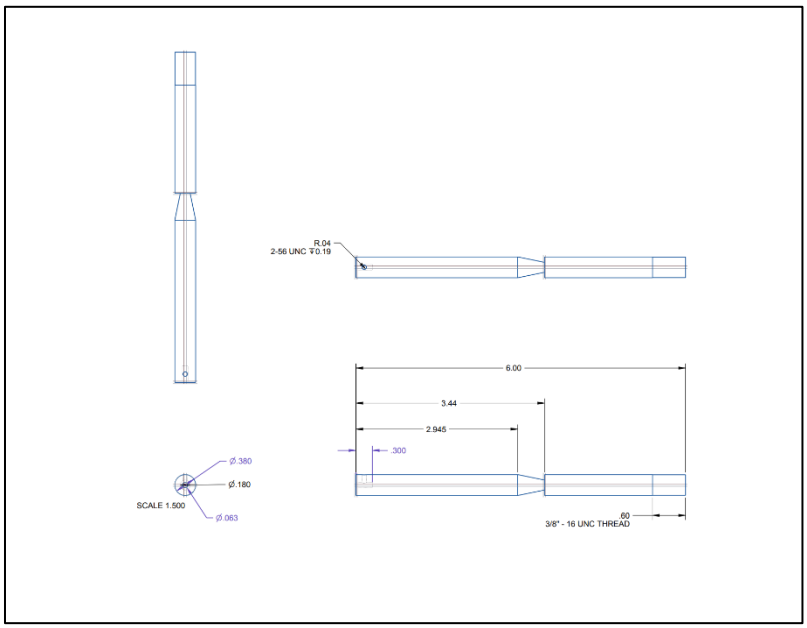


Fig 9. Indenter Rod

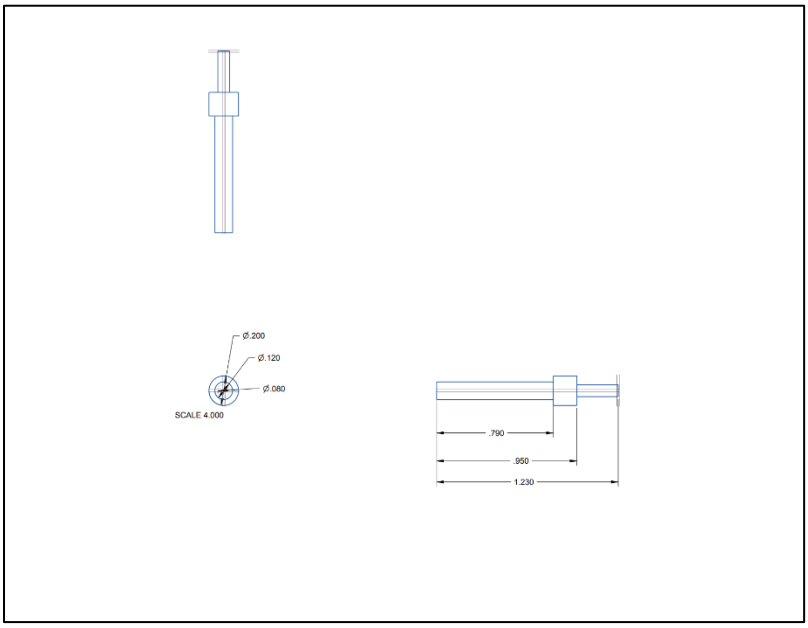


Fig 10. Indenter Tip

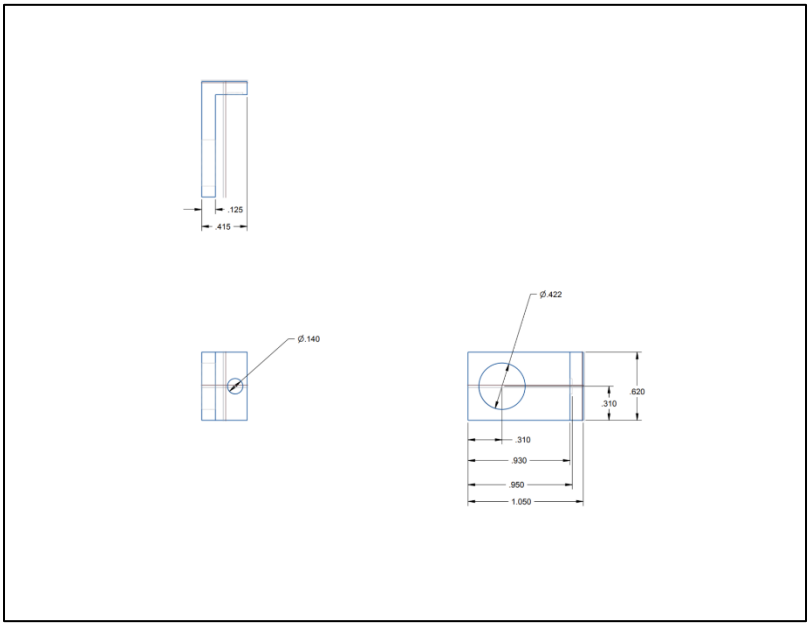


Fig 11. Plate

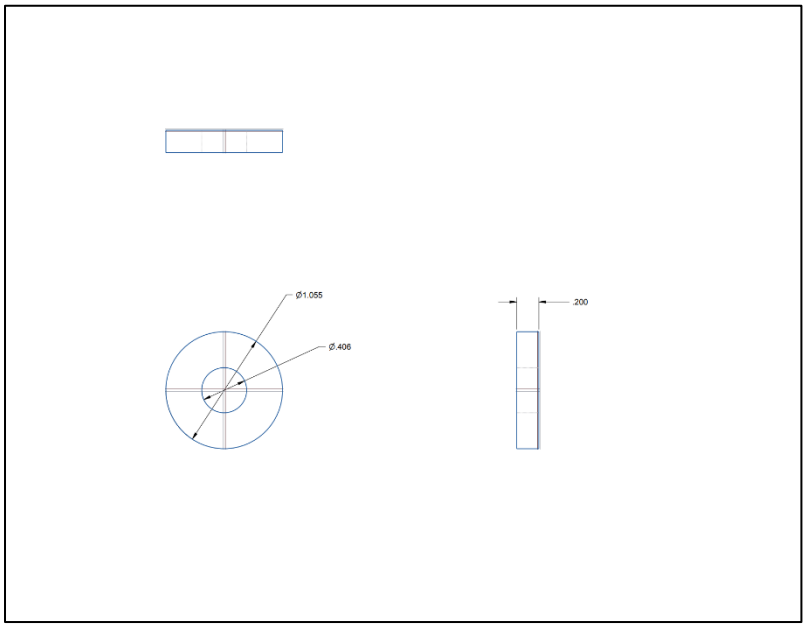


Fig 12. Washer

Appendix F: Calculations

Drop Testing																E* (15 PCF)	72.53333
Height	50.75 in.		PE (kg*m2	1.099001		Polyurethane Foam Possion's ratio				0.25						E* (20 PCF)	146.1333
Weight	87 g															E* (30 PCF)	0
Indentation Depth (mm)																	
PCF	Drop 1	Drop 2	Drop 3	Drop 4	Drop 5	Drop 6	Drop 7	Drop 8	Drop 9	Drop 10	Drop 11	Drop 12	Drop 13	Drop 14	AVG	STDEV	Force (N)
7.5																	
12.5	5.16	6.1	4.8	4.06	5.32	5.7	6.35	5.19							5.335	0.7282464	756.0513
15	5.35	3.21	4.3	4.01	4.54	3.95	4.75	4.63	4.01	4.09	4.15	4.32	4.05	4.06	4.24429	0.5047581	692.3133
20	2.05	3.12	2.71	2.65	2.78	2.88	2.56	2.19	2.81	2.92	2.85	2.46	2.54	2.63	2.65357	0.2856735	545.2136
30	1.02	0.96	0.66	0.75	1.04	0.9	0.74	1.15	0.74	0.77	1.07	1.03	0.53	0.78	0.86714	0.181931	1267.382
Surface Area and Volume of Indentation																	
PCF 30	Drop 1	Drop 2	Drop 3	Drop 4	Drop 5	Drop 6	Drop 7	Drop 8	Drop 9	Drop 10	Drop 11	Drop 12	Drop 13	Drop 14			
Diameter	3.06	3.12	3.06	3.54	3.41	3.13	2.75	3.86	3.53	4.04	4.57	3.8	4.05	4.38			
SA	20.61725	21.16434	19.56125	26.14178	25.24869	21.09828	16.15065	32.24368	25.97269	33.7888	43.9462	30.86532	33.35749	39.54928			
Volume	3.183624	3.115008	2.059992	3.1329	4.031075	2.93907	1.865417	5.711513	3.073689	4.189211	7.448948	4.957733	2.897775	4.987944			
PCF 20	Drop 1	Drop 2	Drop 3	Drop 4	Drop 5	Drop 6	Drop 7	Drop 8	Drop 9	Drop 10	Drop 11	Drop 12	Drop 13	Drop 14			
Diameter	3.8	3.79	4.24	3.32	3.57	3.84	3.83	4.24	3.1	4.71	4.22	4.23	5.35				
SA	35.68265	42.03414	47.15484	31.78565	36.33352	41.32861	39.15794	43.82491	29.50669	57.52156	47.73722	45.33882	68.09263	0			
Volume	9.867333	14.93866	16.23977	9.736453	11.81027	14.15578	12.51746	13.12365	9.001367	21.59252	16.91798	14.67218	24.23372	0			
PCF 15	Drop 1	Drop 2	Drop 3	Drop 4	Drop 5	Drop 6	Drop 7	Drop 8	Drop 9	Drop 10	Drop 11	Drop 12	Drop 13	Drop 14			
Diameter	6.31	5.42	5.08	6.03	5.48	5.07	5.18	5.15	5.1	5.38	5.39	5.17	4.95	5.2			
SA	118.1989	74.91498	76.54703	96.86596	88.14858	73.29676	82.88239	81.09066	74.48158	81.61809	82.39461	78.78402	71.49166	77.18008			
Volume	71.00538	31.43275	36.98917	48.6024	45.44601	33.84479	42.48463	40.93306	34.7667	39.46087	40.18874	38.48962	33.07838	36.59413			
PCF 12.5	Drop 1	Drop 2	Drop 3	Drop 4	Drop 5	Drop 6	Drop 7	Drop 8	Drop 9	Drop 10	Drop 11	Drop 12	Drop 13	Drop 14			
Diameter	5.56	6.02	5.78	5.72	5.3	5.67	5.81										
SA	96.09046	118.139	98.17752	89.53179	91.09084	104.3405	114.8979	0	0	0	0	0	0	0			
Volume	53.17139	73.68881	53.45344	44.2789	49.81293	61.08291	71.45041	0	0	0	0	0	0	0			

Appendix G Risk Assessment

FAMU-FSU College of Engineering
Project Hazard Assessment Policy and Procedures

INTRODUCTION

University laboratories are not without safety hazards. Those circumstances or conditions that might go wrong must be predicted and reasonable control methods must be determined to prevent incident and injury. The FAMU-FSU College of Engineering is committed to achieving and maintaining safety in all levels of work activities.

PROJECT HAZARD ASSESSMENT POLICY

Principal investigator (PI)/instructor are responsible and accountable for safety in the research and teaching laboratory. Prior to starting an experiment, laboratory workers must conduct a project hazard assessment (PHA) to identify health, environmental and property hazards and the proper control methods to eliminate, reduce or control those hazards. PI/instructor must review, approve, and sign the written PHA and provide the identified hazard control measures. PI/instructor continually monitor projects to ensure proper controls and safety measures are available, implemented, and followed. PI/instructor are required to reevaluate a project anytime there is a change in scope or scale of a project and at least annually after the initial review.

PROJECT HAZARD ASSESSMENT PROCEDURES

It is FAMU-FSU College of Engineering policy to implement followings:

1. Laboratory workers (i.e. graduate students, undergraduate students, postdoctoral, volunteers, etc.) performing a research in FAMU-FSU College of Engineering are required to conduct PHA prior to commencement of an experiment or any project change in order to identify existing or potential hazards and to determine proper measures to control those hazards.
2. PI/instructor must review, approve and sign the written PHA.
3. PI/instructor must ensure all the control methods identified in PHA are available and implemented in the laboratory.
4. In the event laboratory personnel are not following the safety precautions, PI/instructor must take firm actions (e.g. stop the work, set a meeting to discuss potential hazards and consequences, ask personnel to review the safety rules, etc.) to clarify the safety expectations.
5. PI/instructor must document all the incidents/accidents happened in the laboratory along with the PHA document to ensure that PHA is reviewed/modified to prevent reoccurrence. In the event of PHA modification a revision number should be given to the PHA, so project members know the latest PHA revision they should follow.
6. PI/instructor must ensure that those findings in PHA are communicated with other students working in the same laboratory (affected users).
7. PI/instructor must ensure that approved methods and precautions are being followed by :
    a. Performing periodic laboratory visits to prevent the development of unsafe practice.
    b. Quick reviewing of the safety rules and precautions in the laboratory members meetings.
    c. Assigning a safety representative to assist in implementing the expectations.
    d. Etc.
8. A copy of this PHA must be kept in a binder inside the laboratory or PI/instructor's office (if experiment steps are confidential).

Project Hazard Assessment Worksheet				
PI/instructor: Dr. Shayne McConomy	Phone #:850-410-6624	Dept.: Mec. Eng.	Start Date: 11/19/2021	Revision number: Original
Project: T102 Exactech Human Bone Density Measurement			Location(s): Material Lab, BME Lab, ME Senior Design Lab	
Team member(s): Timothy Surface Tessany Schou			Phone #: 850-510-7223 786-259-4907	Email: tjs11f@my.fsu.edu tas18d@my.fsu.edu

Experiment Steps	Location	Person assigned	Identify hazards or potential failure points	Control method	PPE	List proper method of hazardous waste disposal, if any.	Residual Risk	Specific rules based on the residual risk
Machining the device	COE machine shop	Tim & Tessany	The turning parts and cutting tools could cut the operator. The operator could get caught in the turning parts. The machined part will have sharp edges. Process will generate sharp chips. Operator should wear safety glasses consistent with OSHA safety standard 1910.133(a)	Following established safety protocols, hold a cutting oil bottle in operator's free hand to avoid it being placed near turning parts. (Administrative Control and PPE)The machines need to be properly guarded and secured to teh floor per OSHA rule 29 CFR 1910.147.	Safety glasses	No hazardous waste.	HAZARD: 3 CONSEQ: Severe Residual: Med High	-After approval by the PI, the Safety Committee and/or EHS must review and approve the completed PHA. -A written Project Hazard Control is required and must be approved by the PI and the Safety Committee before proceeding. -Two qualified workers must be in place

								before work can proceed. -Limit the number of authorized workers in the hazard area.
Indenter Tip Testing	BME Lab	BMEs	The indenter tip could break. The saw bone blocks could break when indented. Possible pinch point between indenter tip and saw bone.	Keep hands away from contact surface. Wear appropriate PPE. (PPE)	Safety goggles	No hazardous waste.	HAZARD: 1 CONSEQ: Minor Residual: Low Med	Safety controls are planned by both the worker and supervisor. Proceed with supervisor authorization.
Assembling the device	ME Senior Design Lab	Tim & Tessany	Potential sharp edges on machined part. Strong spring under compression during assembly.	Wearing appropriate PPE. File corners to avoid sharp edges. (PPE) Should wear safety glasses consistent with OSHA safety standard 1910.133(a)	Safety glasses	No hazardous waste.	HAZARD: 1 CONSEQ: Negligible Residual: Low	Safety controls are planned by both the worker and supervisor. Proceed with supervisor authorization.
Testing the device accuracy	BME Lab	BMEs	A piece may break off during an indentation. Device may release when against peron not bone.	Wearing appropriate PPE. (PPE) Should wear safety glasses consistent with OSHA safety	Safety glasses, Operating instructions	No hazardous waste.	HAZARD: 3 CONSEQ: Moderate Residual: Low	Safety controls are planned by both the worker and supervisor.

				standard 1910.133(a) Follow operating instrucion to avoid device being left in an active condition. Clean lab after testing.				Proceed with supervisor authorization.
Sterilization Testing (device)	BME Lab	BMEs	The machine could break. The is risk of being burnt. The device may break from high temperature	Use sterilization machine according to instructions. Wait appropriate time before touching device. Wear appropriate PPE. (PPE) Should wear safety glasses consistent with OSHA safety standard 1910.133(a) The PPE should aso include gloves per SHA standard 1910.138.	Safety glasses, gloves	No hazardous waste.	HAZARD: 1 CONSEQ: Negligible Residual: Low	Safety controls are planned by both the worker and supervisor. Proceed with supervisor authorization.
Testing device durability	BME Lab	Tim & Tessany	The device could indent someone's hand. The device could break releasing the spring.	Only compress spring when applicator is against testing material. Only remove after indenter deployed. Wearing appropriate PPE. (PPE)	Safety glasses	No hazardous waste.	HAZARD: 2 CONSEQ: Negligible Residual: Low	Safety controls are planned by both the worker and supervisor. Proceed with supervisor authorization.

				Should wear safety glasses consistent with OSHA safety standard 1910.133(a)				
Operating the device	BME Lab	Entire Team	The device could indent someone's hand. Device could pinch hand between handle and body.	Only compress spring when applicator is against testing material. Only remove after indenter deployed. Keep fingers clear of pinch point. Wearing appropriate PPE. (PPE) Should wear safety glasses consistent with OSHA safety standard 1910.133(a)	Safety glasses	No hazardous waste.	HAZARD: 2 CONSEQ: Negligible Residual: Low	Safety controls are planned by both the worker and supervisor. Proceed with supervisor authorization
Transporting the device	COE	Entire Team	Device may be dropped	Reasonable care in transporting.	Closed toed shoes	No hazardous waste.	Hazard 1 CONSEQ: Negligible _____ Residual: Low	Firm grip on device, and reasonable care.

Principal investigator(s)/ instructor PHA: I have reviewed and approved the PHA worksheet.

Name	**Signature**	**Date**	**Name**	**Signature**	**Date**

Team members: I certify that I have reviewed the PHA worksheet, am aware of the hazards, and will ensure the control measures are followed.

Name	Signature	Date	Name	Signature	Date
Timothy Surface	*Timothy Surface*	03/10/2022	Tessany Schou	*Tessany Schou*	03/10/2022

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DEFINITIONS:

Hazard: Any situation, object, or behavior that exists, or that can potentially cause ill health, injury, loss or property damage e.g. electricity, chemicals, biohazard materials, sharp objects, noise, wet floor, etc. OSHA defines hazards as "*any source of potential damage, harm or adverse health effects on something or someone".* A list of hazard types and examples are provided in appendix A.

Hazard control: Hazard control refers to workplace measures to eliminate/minimize adverse health effects, injury, loss, and property damage. Hazard control practices are often categorized into following three groups (priority as listed):

1. **Engineering control:** physical modifications to a process, equipment, or installation of a barrier into a system to minimize worker exposure to a hazard. Examples are ventilation (fume hood, biological safety cabinet), containment (glove box, sealed containers, barriers), substitution/elimination (consider less hazardous alternative materials), process controls (safety valves, gauges, temperature sensor, regulators, alarms, monitors, electrical grounding and bonding), etc.
2. **Administrative control:** changes in work procedures to reduce exposure and mitigate hazards. Examples are reducing scale of process (micro-scale experiments), reducing time of personal exposure to process, providing training on proper techniques, writing safety policies, supervision, requesting experts to perform the task, etc.
3. **Personal protective equipment (PPE):** equipment worn to minimize exposure to hazards. Examples are gloves, safety glasses, goggles, steel toe shoes, earplugs or muffs, hard hats, respirators, vests, full body suits, laboratory coats, etc.

Team member(s): Everyone who works on the project (i.e. grads, undergrads, postdocs, etc.). The primary contact must be listed first and provide phone number and email for contact.

Safety representative: Each laboratory is encouraged to have a safety representative, preferably a graduate student, in order to facilitate the implementation of the safety expectations in the laboratory. Duties include (but are not limited to):

- Act as a point of contact between the laboratory members and the college safety committee members.
- Ensure laboratory members are following the safety rules.
- Conduct periodic safety inspection of the laboratory.
- Schedule laboratory clean up dates with the laboratory members.
- Request for hazardous waste pick up.

Residual risk: Residual Risk Assessment Matrix are used to determine project's risk level. The hazard assessment matrix (table 1) and the residual risk assessment matrix (table2) are used to identify the residual risk category.

The instructions to use hazard assessment matrix (table 1) are listed below:

1. Define the workers familiarity level to perform the task and the complexity of the task.
2. Find the value associated with familiarity/complexity (1 – 5) and enter value next to: HAZARD on the PHA worksheet.

Table 1. Hazard assessment matrix.

		Complexity		
		Simple	Moderate	Difficult
Familiarity Level	Very Familiar	1	2	3
	Somewhat Familiar	2	3	4

	Unfamiliar	3	4	5

The instructions to use residual risk assessment matrix (table 2) are listed below:

1. Identify the row associated with the familiarity/complexity value (1 – 5).
2. Identify the consequences and enter value next to: CONSEQ on the PHA worksheet. Consequences are determined by defining what would happen in a worst case scenario if controls fail.
    a. Negligible: minor injury resulting in basic first aid treatment that can be provided on site.
    b. Minor: minor injury resulting in advanced first aid treatment administered by a physician.
    c. Moderate: injuries that require treatment above first aid but do not require hospitalization.
    d. Significant: severe injuries requiring hospitalization.
    e. Severe: death or permanent disability.
3. Find the residual risk value associated with assessed hazard/consequences: Low –Low Med – Med– Med High – High.
4. Enter value next to: RESIDUAL on the PHA worksheet.

Table 2. Residual risk assessment matrix.

Assessed Hazard Level	**Consequences**				
	Negligible	Minor	Moderate	Significant	Severe
5	Low Med	Medium	Med High	High	High
4	Low	Low Med	Medium	Med High	High
3	Low	Low Med	Medium	Med High	Med High
2	Low	Low Med	Low Med	Medium	Medium
1	Low	Low	Low Med	Low Med	Medium

Specific rules for each category of the residual risk:

Low:
- Safety controls are planned by both the worker and supervisor.
- Proceed with supervisor authorization.

Low Med:
- Safety controls are planned by both the worker and supervisor.
- A second worker must be in place before work can proceed (buddy system).
- Proceed with supervisor authorization.

Med:
- After approval by the PI, a copy must be sent to the Safety Committee.
- A written Project Hazard Control is required and must be approved by the PI before proceeding. A copy must be sent to the Safety Committee.
- A second worker must be in place before work can proceed (buddy system).
- Limit the number of authorized workers in the hazard area.

Med High:
- After approval by the PI, the Safety Committee and/or EHS must review and approve the completed PHA.
- A written Project Hazard Control is required and must be approved by the PI and the Safety Committee before proceeding.
- Two qualified workers must be in place before work can proceed.
- Limit the number of authorized workers in the hazard area.

High:

- The activity will not be performed. The activity must be redesigned to fall in a lower hazard category.

Appendix A: Hazard types and examples

Types of Hazard	**Example**
Physical hazards	Wet floors, loose electrical cables objects protruding in walkways or doorways
Ergonomic hazards	Lifting heavy objects Stretching the body Twisting the body Poor desk seating
Psychological hazards	Heights, loud sounds, tunnels, bright lights
Environmental hazards	Room temperature, ventilation contaminated air, photocopiers, some office plants acids
Hazardous substances	Alkalis solvents
Biological hazards	Hepatitis B, new strain influenza
Radiation hazards	Electric welding flashes Sunburn
Chemical hazards	Effects on central nervous system, lungs, digestive system, circulatory system, skin, reproductive system. Short term (acute) effects such as burns, rashes, irritation, feeling unwell, coma and death. Long term (chronic) effects such as mutagenic (affects cell structure), carcinogenic (cancer), teratogenic (reproductive effect), dermatitis of the skin, and occupational asthma and lung damage.
Noise	High levels of industrial noise will cause irritation in the short term, and industrial deafness in the long term.
Temperature	Personal comfort is best between temperatures of 16°C and 30°C, better between 21°C and 26°C. Working outside these temperature ranges: may lead to becoming chilled, even hypothermia (deep body cooling) in the colder temperatures, and may lead to dehydration, cramps, heat exhaustion, and hyperthermia (heat stroke) in the warmer temperatures.
Being struck by	This hazard could be a projectile, moving object or material. The health effect could be lacerations, bruising, breaks, eye injuries, and possibly death.
Crushed by	A typical example of this hazard is tractor rollover. Death is usually the result
Entangled by	Becoming entangled in machinery. Effects could be crushing, lacerations, bruising, breaks amputation and death.
High energy sources	Explosions, high pressure gases, liquids and dusts, fires, electricity and sources such as lasers can all have serious effects on the body, even death.
Vibration	Vibration can affect the human body in the hand arm with `white-finger' or Raynaud's Syndrome, and the whole body with motion sickness, giddiness, damage to bones and audits, blood pressure and nervous system problems.
Slips, trips and falls	A very common workplace hazard from tripping on floors, falling off structures or down stairs, and slipping on spills.
Radiation	Radiation can have serious health effects. Skin cancer, other cancers, sterility, birth deformities, blood changes, skin burns and eye damage are examples.
Physical	Excessive effort, poor posture and repetition can all lead to muscular pain, tendon damage and deterioration to bones and related structures

Psychological	Stress, anxiety, tiredness, poor concentration, headaches, back pain and heart disease can be the health effects
Biological	More common in the health, food and agricultural industries. Effects such as infectious disease, rashes and allergic response.

Project Hazard Control- For Projects with Medium and Higher Risks

Name of Project:		**Date of submission:**
Team member	**Phone number**	**e-mail**
Timothy Surface	850-510-7223	tjs11f@my.fsu.edu
Tessany Schou	786-259-4907	tas18d@my.fsu.edu
Faculty mentor	**Phone number**	**e-mail**
Dr. Shayne McConomy	850-410-6624	smcconomy@eng.famu.fsu.edu
Dr. Steven Arce	(352) 246 6433	sarce@eng.famu.fsu.edu

Rewrite the project steps to include all safety measures taken for each step or combination of steps. Be specific (don't just state "be careful").

Machining
Milling the housing and turning the indenter. This will be done based on the drawings for the device. Safety glasses will be worn during both processes, consistent with OSHA standard 1910.133(a). Operator will follow established safety protocols. The operator will hold the cutting oil in the free hand to prevent placing it in way of the tool. The cut depth and feed rate will be matched to the material being machined. The machines need to be properly guarded and secured to teh floor per OSHA rule 29 CFR 1910.147.

Thinking about the accidents that have occurred or that you have identified as a risk, describe emergency response procedures to use.

In response to a piece of machinery breaking, we would turn off power immediately and call the supervisor in charge.
For serious injuries call 9-1-1.

List emergency response contact information:

- Call 911 for injuries, fires or other emergency situations
- Call your department representative to report a facility concern

Name	Phone number	Faculty or other COE emergency contact	Phone number
Timothy Surface	850-510-7223	Dr. Shayne McConomy	850-410-6624
Tessany Schou	786-259-4907	Grace Busch	850-377-0725

Safety review signatures

Team member	Date	Faculty mentor	Date
Timothy Surface	03/10/2022		
Tessany Schou	03/10/2022		

Report all accidents and near misses to the faculty mentor.

Revised 08-2019

Appendix H: Concepts Generated

1. Spring linear applicator
2. Stress element
3. Hydraulic
4. Displacement sensor
5. Force sensors
6. Ultrasonic
7. Extract small block of bone then measure volume and mass
8. X-ray
9. MRI
10. Use a spring to impact bone and measure bounce
11. Use powerful microscope to count atoms in a certain area
12. Hardness test -impact and debone
13. Strike w/ball and measure indent
14. Strike w/flat rod and measure indent
15. Drill core of humorous and measure torque
16. Rubber mallet like knee test
17. Strike something with the humorous
18. Break/fracture arm to see how it heals
19. (Thinking about a woodpecker) strike and measure bounce of object in attached fluid container.
20. Break of piece and see how it floats
21. Replace entire humorous
22. Liquid penetrant testing
23. Comparing density w/out putting into contact
24. Pass current through it
25. Radiographic testing
26. Dissolve in solvent and measure viscosity
27. Install test as part of spike tool measures as spike goes in
28. Above but measuring the force as spike removed
29. Pass gamma rays through
30. Measure reflectiveness
31. Visual inspection w/microscope
32. Force needed to cut bone
33. Amps pulled by saw making cut
34. Dye & radio graphic test (eg x-ray contrast)
35. Physically crush the ball that was removed
36. Resurface cut grinding and measuring force needed
37. Resurface face and measure amps need to grind away material
38. Detect heat (infrared) from bone

39. Damage the simulate growth making irrelevant
40. Transplant from healthy patient and do none of this
41. Splice into bone lower down grafting on a heathier portion of bone
42. Use larger implant so the bone is attached at a lower less stressed point
43. Pressurize bone marrow see how much absorbed
44. Pull on bone at cut and elbow
45. Flex bone at two points
46. Apply heat and measure rate of change of temperature
47. Change temps and measure change in dimension
48. Pneumatic indenter
49. Send signal down cut similar to vision
50. Send die down arm to see how fast it moves
51. Remove and see how it floats in fluid
52. Epoxy new joint so irrelevant
53. Fill bone with epoxy to make more dense
54. Constrain to shoulder
55. Scratch it and see how it wants to split
56. Longer arm on indenter less force more accuracy
57. See how bone transmits sound
58. Freeze “ball” of humorous and see how much force need to break
59. Use soft tipped indenter and measure deflection
60. Use soft tipped indenter and measure compression
61. Use fine needle indenter and measure compression of fluid compressed by it.
62. Pressurize bone to see how much it will hold
63. Pressurize bone and see how much comes out
64. Pull vacuum on bone and see rate of fluid loss
65. Cut sample to see how much it weighs
66. A needle and an indenter that tests prior to surgery
67. Use a model of a thumb with a grip that the surgeon applies to the bone
68. A force sensor on the guidewire that measures how much force was applied
69. Spring load the guidewire, and measure how far it goes in.
70. Place a torque wrench on the reamer and measure force needed to turn it.
71. A scraper that measures force as it is scrapped across the bone
72. A hammer that records accelerations and how far bone indents when hit
73. Glue a part to the bone and see force needed to pull it off
74. Put a screw in and see force needed to pull out
75. Apply a light and measure reflectivity
76. Apply a radio wave and measure refraction
77. Apply and x-ray and measure refraction
78. Take a sample of the interior bone and break it to see density
79. Take a sample of interior bone and x-ray it.
80. Place a transmitter in the bone and measure the signal from it

81. Pull sample form the bone and measure force needed to tear it
82. Place corrosive on the bone and see how fast and far the bone dissolves
83. Place light inside the bone at a set depth and measure light detected at surface
84. Place speaker in the bone and measure sound at surface
85. Apply heat and see how fast moisture level drops
86. Apply moisture and measure how fast the bone returns to normal moisture
87. Make a device that smells the cut determining the health of the bone
88. Make a device that "licks" the bone and uses enzymes to breakdown contents to give a reading of the bone quality.
89. Make a device that uses the stemless implant to measure bone density while being placed and set stemmed if the bone is not good enough.
90. Apply an open flame to the bone and measure discoloration
91. Apply a hot probe and measure how it chars the bone
92. Apply a probe and measure the way the heat disperses with infrared camera
93. Apply a chilled probe and measure how fast it freezes
94. Apply a chilled probe and measure change int temp with an Infrared camera
95. Apply a static weight and see if the weight sinks in at all
96. A drill that only applies enough force to cut osteoporotic bone, is it will drill hole for stemmed implant if stemless will not work.
97. Apply chemical that changes color as it binds with calcium, and us a spectrometer to measure color change.
98. Use a spectrometer to measure color of the bone at cut and determine the density
99. Modified Steinmann pin currently used in surgery
100. Drag pin along surface and measure vibration

Appendix I Concept Selection

Binary Pairwise Comparison

Pairwise Comparison													
Customer Requirements	**Mechanically operated**	**Measures PCF of bone**	**Indentation smaller than 1/8"**	**Compliant with FDA**	**Sterilizable**	**Class 1 device**	**Recognizable scale**	**Reusable**	**Non-toxic**	**Handheld**	**Measure at center of Humerous**	**Measure between 15-30 PCF**	**Total**
Mechanically operated	-	0	0	0	0	0	0	0	0	0	0	0	0
Measures PCF of bone	1	-	1	0	0	1	1	1	0	1	1	1	8
Indentation smaller than 1/8"	1	0	-	0	0	1	0	0	0	0	1	0	3
Compliant with FDA	1	1	1	-	1	1	1	1	1	1	1	1	11
Sterilizable	1	1	1	0	-	1	1	1	1	1	1	1	10
Class 1 device	1	0	0	0	0	-	0	1	0	0	1	1	4
Recognizable scale	1	0	1	0	0	1	-	1	0	0	1	0	5
Reusable	1	0	1	0	0	0	0	-	0	0	0	0	2
Non-toxic	1	1	1	0	0	1	1	1	-	1	1	1	9
Handheld	1	0	1	0	0	1	1	1	0	-	1	1	7
Measure at center of Humerous	1	0	0	0	0	0	0	1	0	0	-	0	2
Measure between 15-30 PCF	1	0	1	0	0	0	1	1	0	0	1	-	5
Total	11	3	8	0	1	7	6	9	2	4	9	6	

House of Quality

House of Quality										
		Engineering Characteristics								
Improvement Direction		↑	↓	↓	↑	↑	↑	↓		↑
Units		%	lb	cm	uses	PCF	deg	in.	n/a	ft
Customer Requirements	Importance Weight Factor	Result Repeatability	Device Weight	Indentation Depth	Reusability	Measurement Accuracy	Withstands High Temperatures	Device Width	Results in under 10 seconds	Readability Distance
Mechanically operated	0		1		3				3	
Measures PCF of bone	8	3		1		3				
Indentation smaller than 1/8"	3			9						
Compliant with FDA	11	9		9		3	1			
Sterilizable	10				3		9	3		
Class 1 device	4			1	9					
Recognizable scale	5					9				9
Reusable	2	3			9		3			
Non-toxic	9				1		1			
Handheld	7		9					9		9
Measure at center of Humerous	2			3					3	
Measure between 15-30 PCF	5	9				3				
Raw Score	914	174	63	144	93	117	116	93	6	108
Relative Weight %		0.190	0.068	0.157	0.101	0.128	0.126	0.101	0.006	0.118
Rank Order		1	8	2	6	3	4	6	9	5

Pugh Charts

Pugh Chart 1						
	Concepts					
Selection Criteria	Thumb test	Torque Wrench	Sensor	Linear Spring	Loaded Guidewire	Amp Meter
Result Repeatability	Datum	+	+	+	+	+
Device Weight		-	-	-	-	-
Indentation Depth		-	S	S	-	S
Reusability		S	S	S	S	S
Measurement Accuracy		+	+	+	+	+
Withstands High Temperatures		+	-	+	+	-
Device Width		S	S	S	S	S
Readability Distance		S	S	S	S	S
# of Pluses		3	2	3	3	2
# of Minuses		2	2	1	2	3

Pugh Chart 2					
	Concepts				
Selection Criteria	Torque Wrench	Sensor	Linear Spring	Loaded Guidewire	Amp Meter
Result Repeatability	Datum	+	+	-	-
Device Weight		+	+	+	-
Indentation Depth		+	+	-	S
Reusability		-	+	+	S
Measurement Accuracy		S	S	S	-
Withstands High Tempertaures		-	S	S	-
Device Width		S	S	+	-
Readability Distance		+	+	-	S
# of Pluses		4	5	3	0
# of Minuses		2	0	2	3

Pugh Chart 3				
	Concepts			
Selection Criteria	**Loaded Guidewire**	**Torque Wrench**	**Sensor**	**Linear Spring**
Result Repeatability	Datum	+	+	+
Device Weight		-	-	+
Indentation Depth		+	+	+
Reusability		-	+	+
Measurement Accuracy		S	+	+
Withstands High Tempertaures		S	-	S
Device Width		-	-	S
Readability Distance		+	+	+
# of Pluses		3	5	6
# of Minuses		3	3	0

Criteria Comparison

Criteria Comparison Matrix								
	Result Repeatability	**Device Weight**	**Indentation Depth**	**Reusability**	**Measurement Accuracy**	**Withstands High Temperatures**	**Device Width**	**Readability Distance**
Result Repeatability	1.000	1.000	0.111	0.333	0.143	0.143	0.333	0.200
Device Weight	1.000	1.000	0.111	1.000	0.200	0.143	0.333	0.143
Indentation Depth	9.000	9.000	1.000	1.000	1.000	0.333	1.000	1.000
Reusability	3.000	1.000	1.000	1.000	0.200	0.143	0.333	1.000
Measurement Accuracy	7.000	5.000	1.000	5.000	1.000	0.200	1.000	0.333
Withstands High Temperatures	7.000	7.000	3.000	7.000	5.000	1.000	1.000	1.000
Device Width	3.000	3.000	1.000	3.000	1.000	1.000	1.000	1.000
Readability Distance	5.000	7.000	1.000	1.000	3.000	1.000	1.000	1.000
Sum	36.000	34.000	8.222	19.333	11.543	3.962	6.000	5.676

Normalized Comparison Matrix									
	Result Repeatability	Device Weight	Indentation Depth	Reusability	Measurement Accuracy	Withstands High Temperatures	Device Width	Readability Distance	Criteria Weights{W}
Result Repeatability	0.028	0.029	0.014	0.017	0.012	0.036	0.056	0.035	0.028
Device Weight	0.028	0.029	0.014	0.052	0.017	0.036	0.056	0.025	0.032
Indentation Depth	0.250	0.265	0.122	0.052	0.087	0.084	0.167	0.176	0.150
Reusability	0.083	0.029	0.122	0.052	0.017	0.036	0.056	0.176	0.071
Measurement Accuracy	0.194	0.147	0.122	0.259	0.087	0.050	0.167	0.059	0.136
Withstands High Temperatures	0.194	0.206	0.365	0.362	0.433	0.252	0.167	0.176	0.269
Device Width	0.083	0.088	0.122	0.155	0.087	0.252	0.167	0.176	0.141
Readability Distance	0.139	0.206	0.122	0.052	0.260	0.252	0.167	0.176	0.172
Sum	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000

Consistency Check		
{Ws}	{W}	Cons
0.24	0.03	8.46
0.29	0.03	8.91
1.30	0.15	8.68
0.62	0.07	8.73
1.25	0.14	9.25
2.63	0.27	9.77
1.26	0.14	8.94
1.58	0.17	9.19
	λ	8.99
	CI	0.14
	RI	1.4
	CR	0.10

Result Reusability Comparison

Result Repeatability			
	Torque Wrench	Sensor	Linear Spring
Torque Wrench	1.00	0.33	0.33
Sensor	3.00	1.00	1.00
Linear Spring	3.00	1.00	1.00
Sum	7.00	2.33	2.33

Normalized Comparison Matrix				
	Torque Wrench	Sensor	Linear Spring	Design Alternative Priorities {Pi}
Torque Wrench	0.14	0.14	0.14	0.14
Sensor	0.43	0.43	0.43	0.43
Linear Spring	0.43	0.43	0.43	0.43
Sum	1.00	1.00	1.00	1.00

Consistency Check		
{Ws}	{W}	Cons
0.43	0.14	3.00
1.29	0.43	3.00
1.29	0.43	3.00
	λ	3.00
	CI	0.00
	RI	1.4
	CR	0.00

Device Weight Comparison

Device Weight			
	Torque Wrench	Sensor	Linear Spring
Torque Wrench	1.00	1.00	0.33
Sensor	1.00	1.00	0.33
Linear Spring	3.00	3.00	1.00
Sum	5.00	5.00	1.67

Normalized Comparison Matrix				
	Torque Wrench	Sensor	Linear Spring	Design Alternative Priorities {Pi}
Torque Wrench	0.20	0.20	0.20	0.20
Sensor	0.20	0.20	0.20	0.20
Linear Spring	0.60	0.60	0.60	0.60
Sum	1.00	1.00	1.00	1.00

Consistency Check		
{Ws}	{W}	Cons
0.60	0.20	3.00
0.60	0.20	3.00
1.80	0.60	3.00
λ		3.00
CI		0.00
RI		1.4
CR		0.00

Indentation Depth Comparison

Indentation Depth			
	Torque Wrench	Sensor	Linear Spring
Torque Wrench	1.00	0.14	0.14
Sensor	7.00	1.00	1.00
Linear Spring	7.00	1.00	1.00
Sum	15.00	2.14	2.14

Normalized Comparison Matrix				
	Torque Wrench	Sensor	Linear Spring	Design Alternative Priorities {Pi}
Torque Wrench	0.07	0.07	0.07	0.07
Sensor	0.47	0.47	0.47	0.47
Linear Spring	0.47	0.47	0.47	0.47
Sum	1.00	1.00	1.00	1.00

Consistency Check		
{Ws}	{W}	Cons
0.20	0.07	3.00
1.40	0.47	3.00
1.40	0.47	3.00
	λ	3.00
	CI	0.00
	RI	1.4
	CR	0.00

Reusability Comparison

Reusability			
	Torque Wrench	Sensor	Linear Spring
Torque Wrench	1.00	1.00	0.33
Sensor	1.00	1.00	0.33
Linear Spring	3.00	3.00	1.00
Sum	5.00	5.00	1.67

Normalized Comparison Matrix				
	Torque Wrench	Sensor	Linear Spring	Design Alternative Priorities {Pi}
Torque Wrench	0.20	0.20	0.20	0.20
Sensor	0.20	0.20	0.20	0.20
Linear Spring	0.60	0.60	0.60	0.60
Sum	1.00	1.00	1.00	1.00

Consistency Check		
{Ws}	{W}	Cons
0.60	0.20	3.00
0.60	0.20	3.00
1.80	0.60	3.00
λ		3.00
CI		0.00
RI		1.4
CR		0.00

Measurement Accuracy Comparison

Measurement Accuracy			
	Torque Wrench	Sensor	Linear Spring
Torque Wrench	1.00	0.33	0.33
Sensor	3.00	1.00	1.00
Linear Spring	3.00	1.00	1.00
Sum	7.00	2.33	2.33

Normalized Comparison Matrix				
	Torque Wrench	Sensor	Linear Spring	Design Alternative Priorities {Pi}
Torque Wrench	0.14	0.14	0.14	0.14
Sensor	0.43	0.43	0.43	0.43
Linear Spring	0.43	0.43	0.43	0.43
Sum	1.00	1.00	1.00	1.00

Consistency Check		
{Ws}	{W}	Cons
0.43	0.14	3.00
1.29	0.43	3.00
1.29	0.43	3.00
	λ	3.00
	CI	0.00
	RI	1.4
	CR	0.00

Withstands High Temperatures Comparison

Withstands High Temperatures			
	Torque Wrench	Sensor	Linear Spring
Torque Wrench	1.00	3.00	1.00
Sensor	0.33	1.00	0.33
Linear Spring	1.00	3.00	1.00
Sum	2.33	7.00	2.33

Normalized Comparison Matrix				
	Torque Wrench	Sensor	Linear Spring	Design Alternative Priorities {Pi}
Torque Wrench	0.43	0.43	0.43	0.43
Sensor	0.14	0.14	0.14	0.14
Linear Spring	0.43	0.43	0.43	0.43
Sum	1.00	1.00	1.00	1.00

Consistency Check		
{Ws}	{W}	Cons
1.29	0.43	3.00
0.43	0.14	3.00
1.29	0.43	3.00
λ		3.00
CI		0.00
RI		1.4
CR		0.00

Device Width Comparison

Device Width			
	Torque Wrench	Sensor	Linear Spring
Torque Wrench	1.00	1.00	0.33
Sensor	1.00	1.00	0.33
Linear Spring	3.00	3.00	1.00
Sum	5.00	5.00	1.67

Normalized Comparison Matrix				
	Torque Wrench	Sensor	Linear Spring	Design Alternative Priorities {Pi}
Torque Wrench	0.20	0.20	0.20	0.20
Sensor	0.20	0.20	0.20	0.20
Linear Spring	0.60	0.60	0.60	0.60
Sum	1.00	1.00	1.00	1.00

Consistency Check		
{Ws}	{W}	Cons
0.60	0.20	3.00
0.60	0.20	3.00
1.80	0.60	3.00
λ		3.00
CI		0.00
RI		1.4
CR		0.00

Readability Distance Comparison

Readability Distance			
	Torque Wrench	Sensor	Linear Spring
Torque Wrench	1.00	0.33	0.33
Sensor	3.00	1.00	1.00
Linear Spring	3.00	1.00	1.00
Sum	7.00	2.33	2.33

Normalized Comparison Matrix				
	Torque Wrench	Sensor	Linear Spring	Design Alternative Priorities {Pi}
Torque Wrench	0.14	0.14	0.14	0.14
Sensor	0.43	0.43	0.43	0.43
Linear Spring	0.43	0.43	0.43	0.43
Sum	1.00	1.00	1.00	1.00

Consistency Check		
{Ws}	{W}	Cons
0.43	0.14	3.00
1.29	0.43	3.00
1.29	0.43	3.00
	λ	3.00
	CI	0.00
	RI	1.4
	CR	0.00

Final Rating Matrix

Final Rating Matrix			
	Concepts		
Selection Criteria	Torque Wrench	Sensor	Linear Spring
Result Repeatability	0.14	0.43	0.43
Device Weight	0.20	0.20	0.60
Indentation Depth	0.07	0.47	0.47
Reusability	0.20	0.20	0.60
Measurement Accuracy	0.14	0.43	0.43
Withstands High Temperatures	0.43	0.14	0.43
Device Width	0.20	0.20	0.60
Readability Distance	0.14	0.43	0.43
Total	1.52	2.50	3.98

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