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**ZEPHYR**

**QUALITY MANUAL**

FALL 2019

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# COMPANY PROFILE

## our mission

Zephyr aids people suffering from muscular dystrophy in increasing quality and quantity of sleep through our revolutionary oscillating vesicle mattress.

## our policy

On customers: We will pay attention to our customers needs, be sensitive to their abilities and limitations, and balance their expectations with those of our suppliers, investors, and employees.

On our team: Zephyr works cohesively and inclusively.

On processes and systems: We reward transparency between management and employees. We strive to maximize efficiency and be a lean company.

On continual improvement: We will invest in our employees learning, success, and independence.

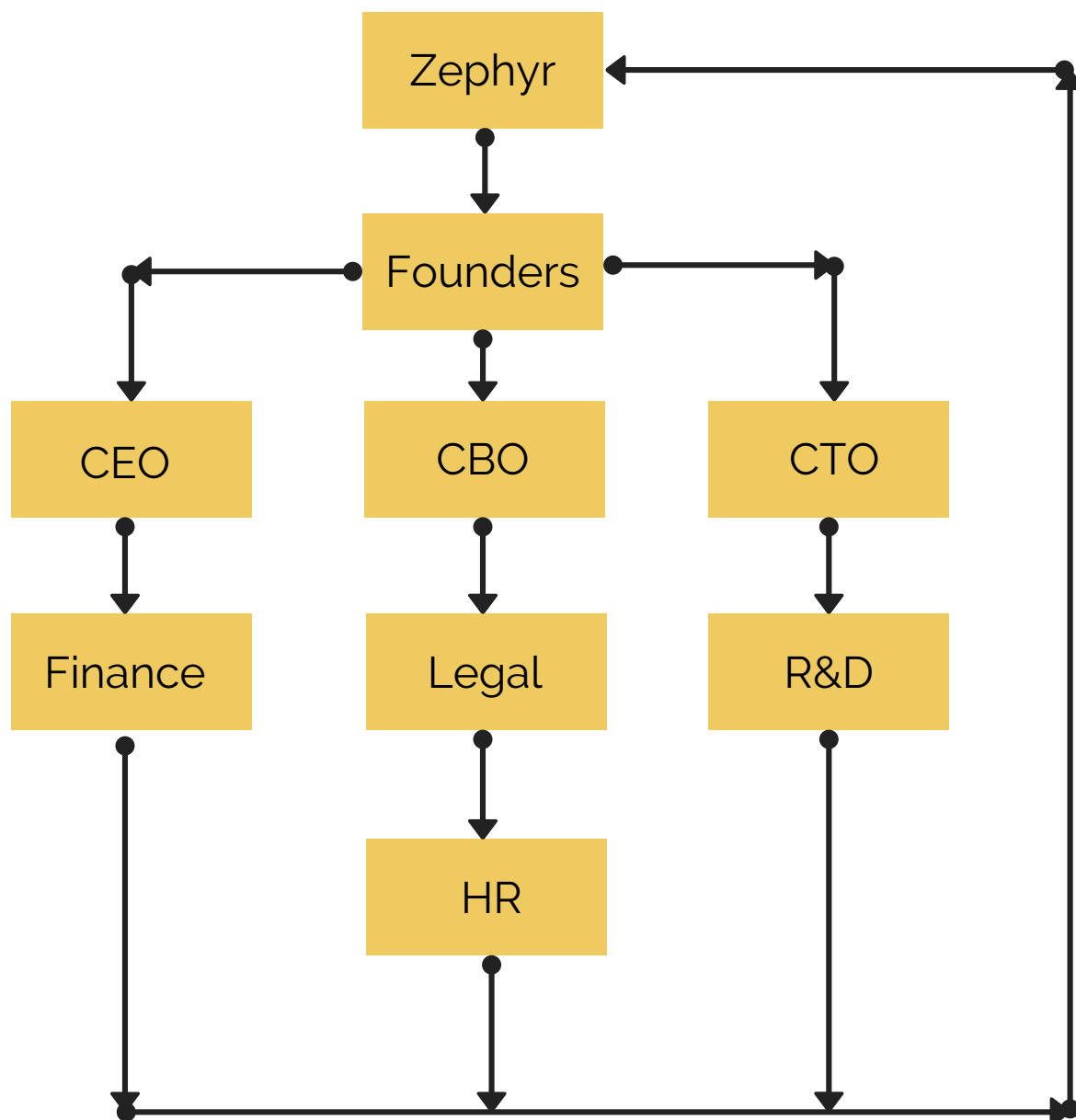
On decisions: We will weigh the pros and cons of each important decision and come to educated conclusions that benefit our company, customers, and employees.

On supplier relationships: We will develop long standing alliances with suppliers and maintain transparency.

On profits: We will reinvest a portion of profits back into the company to further achieve our mission statement. We will satisfy our investors and improve relationships with stakeholders.

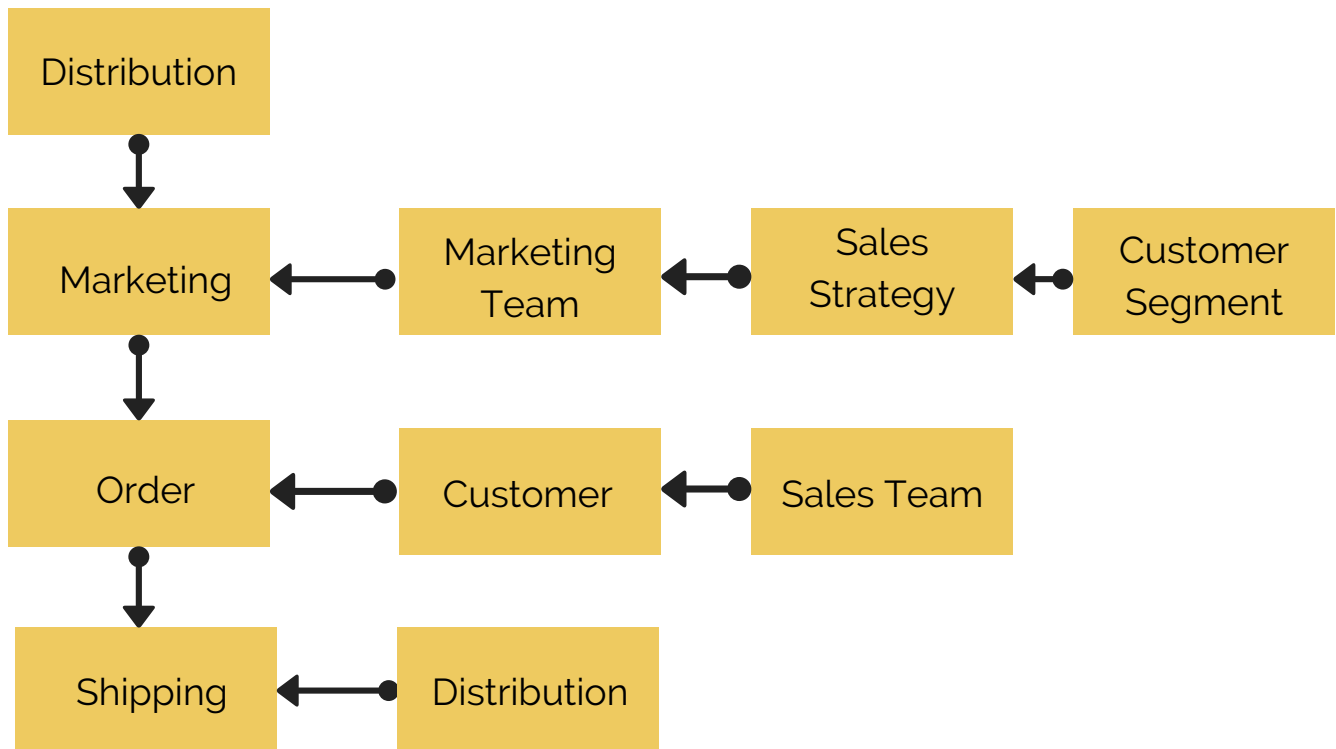
On society, the environment, health, and safety: We will conduct our company in a way that exemplifies sustainable practices, improve quality of life, and abide by federal regulations.

# COMPANY HIERARCHY

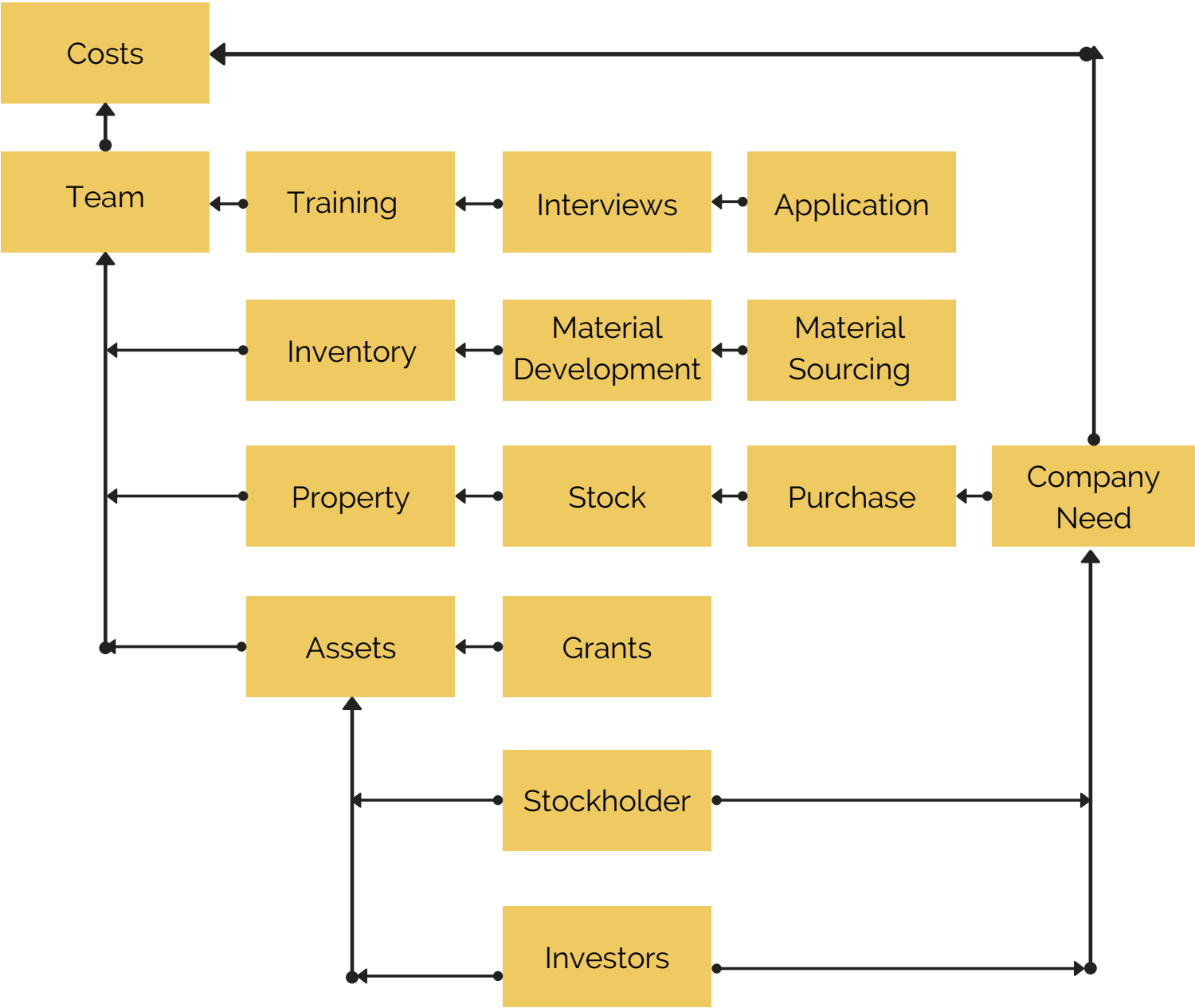




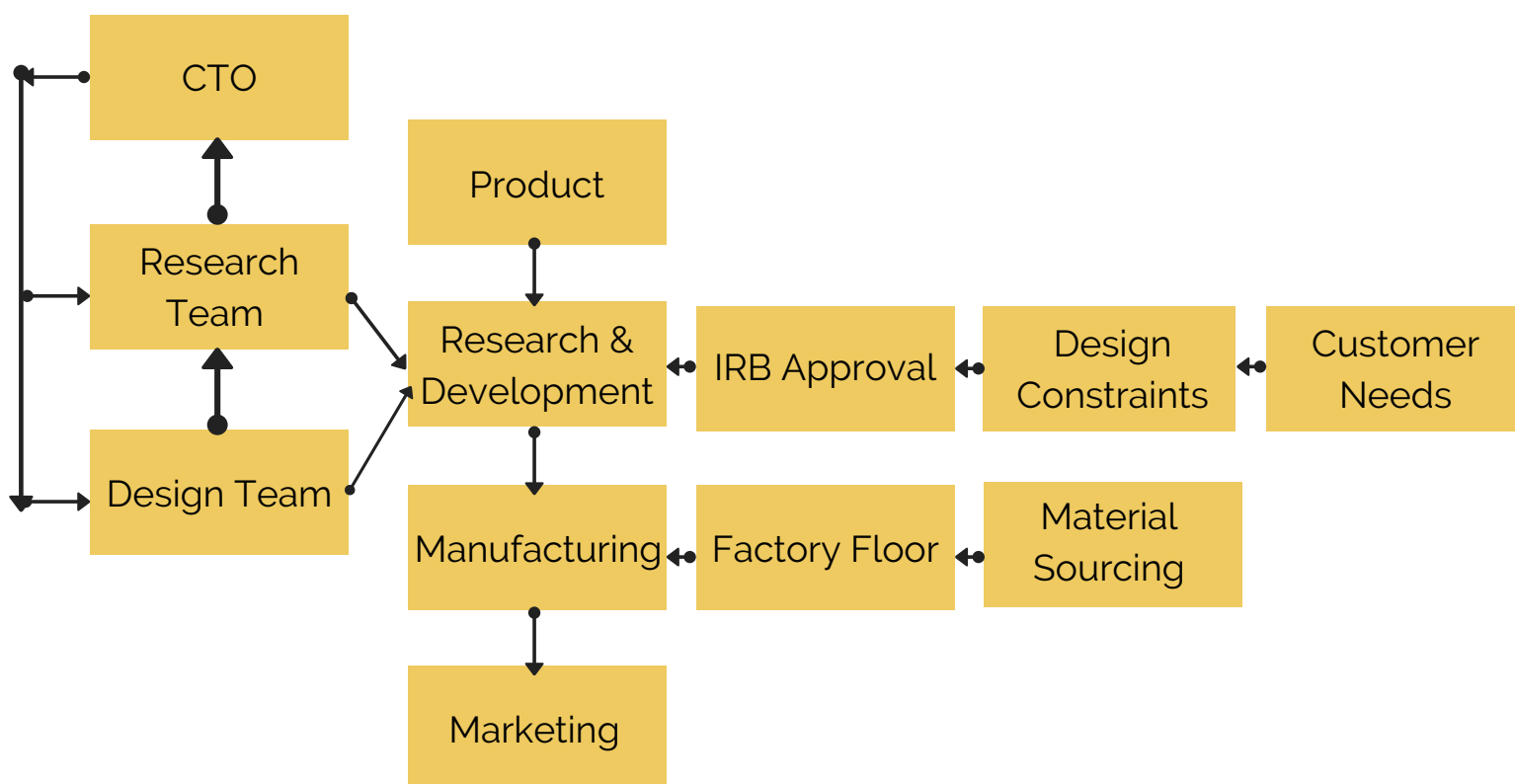
# COMPANY HIERARCHY



# COMPANY HIERARCHY



# COMPANY HIERARCHY



# REGULATORY PLAN

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# REGULATORY PLAN

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# REGULATORY PLAN

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# FAILURE MODE AND EFFECTS ANALYSIS

Potential Failure Mode and Effects Analysis in Design (Robust Design FMEA) I - Support Bar										
Product Number: 1 Project Name: Zephyr		II - Mattress III - Electrical								
No.	Item/ Function	Potential Failure Mode	Potential Effects of Failure	SEV	Potential Causes of Failure	OCC CLASS	Current Mitigations	Verification	DET	Recommended Actions
1	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	vesicles can rupture	mattress will deflate, patients may be electrocuted	8	Vesicles not made of material that can withhold pressure necessary to maintain comfort and mobility	3% III, I	Material analysis of vesicle material and filling, material compatibility testing	analytical testing, preproduction tests	100%	visual inspection, pressure test detection
2	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	Mattress collapses on patient	Patients could suffocate	10	user sending continued signal or false signal to the servo responsible for collapsing the mattress or lacking mechanical stops that prevent the mattress from fully collapsing	1% II	structural analysis, framework testing, weight limit testing	analytical testing, preproduction tests, human testing	100%	strength test, visual inspection
3	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	failure to inflate vesicles	patients will be uncomfortable	6	compressor motor burns out, compressor lacks power to create sufficient pressure, or there is a leak in the inflation system	3% II	vesicle filling material compatibility testing, pressure testing	analytical testing, preproduction tests, visual functional inspection	97%	pressure test detection, calibration
4	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	failure to bend at the knees	patient stuck in bed	5	motor failure or failure to send signal to the motor responsible for bending at the knees	3% II	Material testing of frame and mattress together, parameter design study	analytical testing, preproduction tests, visual functional inspection, human testing	95%	strength test, visual inspection
5	Support bars on either side of bed and overhead to assist in manual readjustment or positioning	support bars can break	patient stuck in bed	7	material and shape of the support bars aren't strong enough to support the patients weight	5% I, III	Material testing of frame and mattress together, parameter design study, strength study on frame	analytical testing, preproduction tests	98%	strength test, bending test
6	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	mattress catches fire	patient catches on fire causing severe burns	10	mattress material is not reasonably flame retardant and electrical components are not insulated well enough	2% III	Flammability testing	analytical testing, preproduction tests	100%	heat resistance test
7	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	failure to raise person to seated position		6	fails to send signal to motor responsible for putting the patient in a seated position or motor failure	2% II	Parameter testing, human testing for preferences	analytical testing, preproduction tests, human testing, visual functional inspection	95%	strength test, visual inspection
8	Touchscreen component that allows user to control mattress pressure and oscillation pattern with option to preset conditions	AC/DC converter failure	Bed will not inflate, patient will be uncomfortable	5	AC/DC converter fails to convert wall power to usable power within the bed	3% I	Study to determine whether or not a fail safe is necessary	analytical testing, preproduction tests	95%	pressure test detection, calibration
9	Touchscreen component that allows user to control mattress pressure and oscillation pattern with option to preset conditions	computer interface doesn't work	can't have presets, patient will be stuck in one position all night	6	interface fails to receive input or receives input but fails to send the proper outgoing signal	4% II	Long term storage testing, type of computer analysis, test for memory need	analytical testing, preproduction tests	95%	No inspection needed
10	Touchscreen component that allows user to control mattress pressure and oscillation pattern with option to preset conditions	touchscreen for controlling mattress doesn't interface with beds	Bed will not inflate or modulate	6	touch screen fails to send signals to the rest of the bed that can then affect the correct portions of the bed	3% II	Test for touchscreen use, text size, ease of use	analytical testing, preproduction tests, human testing	95%	calibration
11	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	pumps to inflate mattress don't work	mattress doesn't inflate	6	leak in the compressor, failure to get signal to the compressor, or compressor motor fails	4% II, I	Study to determine whether or not a fail safe is necessary	analytical testing, preproduction tests, visual functional inspection	95%	pressure test detection, calibration



# FAILURE MODE AND EFFECTS ANALYSIS

12	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	drop resistant protocols do not engage	bedframe collapses on ground	10 not having mechanical stops that would prevent the mattress from going all the way to the ground if the motors lose power	2% II	Study to determine whether or not a fail safe is necessary	analytical testing, preproduction tests	100%	strength test, bending test	2.7
13	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	mattress is not water resistant and sterile	patients may be electrocuted, bacteria may grow on mattress	8 using materials in the electronic components that are not reasonably water resistant. Using bedding materials that prove difficult to maintain cleanliness.	2% III	Test for waterproof materials, test for sterile and easily cleaned materials, material analysis	analytical testing, preproduction tests	99%	Sterility test	3.2
14	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	overheating of electrical components	patients may burn themselves	9 improper use of heatsinks for electrical components	2% III	Circuit built to meet current standards, material flammability is tested for	analytical testing, preproduction tests	99%	flammability analysis	3.3
15	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	Bedding being stuck in mechanical components	stragulation or abrasions	9 failure to mechanically isolate the motors to prevent bedding from becoming stuck in them (e.g. chain guard)	3% I, III	Study to determine whether or not a fail safe is necessary	analytical testing, preproduction tests, human testing	99%	strength test, bending test	1.3.3
16	Support bars on either side of bed and overhead to assist in manual readjustment or positioning	patient hits head on support bar	patient suffers small head injury	6 support bar was too low and could not retract	3% I	Study to determine if there should be an emergency contact function	analytical testing, preproduction tests, human testing	99%	strength test, bending test	1.2
17	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	only one side of lift mechanism deploys	patient gets dumped off the bed onto the floor	10 improper signal sent to the motor responsible for raising mattress sides	2% II	Study to determine whether or not a fail safe is necessary	analytical testing, preproduction tests, visual functional inspection	100%	strength test, bending test	2.8
18	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	vesicles fail to maintain pressure	bed slowly deflates	6 material used to create vesicles is too porous or does not make a proper seal	3% II	Study to determine whether or not a fail safe is necessary	analytical testing, preproduction tests, human testing, visual functional inspection	90%	pressure test detection, calibration	2.9
19	Mattress that creates oscillating pressure and movement to provide enhanced comfort to patients with muscular atrophy	uneven use of mattress	more wear and tear of features on one side of mattress	3 using materials that wear out to easily and/or cannot be replaced without replacing the entire unit	5% I, III	Structural standards and analysis over time	analytical testing, preproduction tests, human testing	85%	strength test, bending test	1.3.4
20	Touchscreen computer component that allows user to control mattress pressure and oscillation pattern with option to preset conditions	inability to store presets	patient will need to manually change mattress settings every time	6 lack of memory capability or inability to code memory set	2% II	Study to determine whether or not a fail safe is necessary. Test for touchscreen use, text size, ease of use	analytical testing, preproduction tests	90%	calibration	2.10

## DESIGN AND DEVELOPMENT PLAN

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### VOICE OF CUSTOMER

#### **Characteristic 1 - Quality**

Our mattress having a long life is an important aspect of the device. While the life expectancy of ALS patients varies drastically and some customers may only use our device for less than a year before succumbing to the disease, there are many device sharing systems in place where if our mattress has good longevity, it could get passed on to another individual. Other individuals may use the mattress for 5+ years and should expect the same quality sleep for all of those years. It is also important for the device to be robust, as ALS patients spend a lot of time in a stagnant position, and need a comfortable and reliable place to rest.

#### **Characteristic 2 - Safety**

It is important for our device to be safe as it is meant to bring peace of mind to the customer, not inspire doubts. One of the main fears of our customer segment is losing mobility, whether it be from a fall they can't get up from and can inherently harm them in the process, or sleeping on a mattress that lacks the means for them to get out of on their own. With an adjustable bed, there is a risk of one of the sections moving in a way that could eject the patient, and while this may be desired at times, there must also be checks in place to prevent this from happening accidentally.

#### **Characteristic 3 - Cost**

Cost is always a concern in any design process, and while the medical field is known to be an expensive market, that doesn't mean our device should cost tens of thousands of dollars and should still be an affordable piece of equipment people can reasonably acquire and add to their homes.

#### **Characteristic 4 - Function**

Our mattress should improve the quality and quantity of sleep while reducing fears of getting stuck and subsequently improving overall quality of life for patients affected by muscular atrophy. An ideal mattress would allow the patient to have the capability to have the softness and comfort they need to sleep comfortably while having the stiffness and support they need to move themselves and relieve stress points.

## DESIGN AND DEVELOPMENT PLAN

# SYSTEM REQUIREMENTS SPECIFICATIONS

### Functional Requirements

#### Requirement 1.1.0 - Movement of the Mattress - General

The mattress must be able to move patient to seated position, to raise and lower knees, and to inflate and deflate air vesicles as programmed.

*Req. 1.1.0 - <0.2% failure rate*

#### Requirement 1.1.1 - Movement of the Mattress - Additional Needs

The mattress should be able to inflate and deflate individual air vesicles to a predetermined pressure and oscillate as determined by the patient.

*Req. 1.1.1 - < 0.05 psi error*

#### Requirement 2.1.0 - Computer Interface - General

The computer interface must connect the pump, motor, and mattress to the touch screen feature used to control mattress oscillations.

*Req. 2.1.0 - <0.1% failure rate*

### Physical Requirements

#### Requirement 3.1.0 - Mattress Vesicle Pressure - Maintaining Presets

Mattress vesicle must maintain the pressure preset by the user for the duration of the required time, regardless of added weight and/or shifting.

*Req. 3.1.0 - <0.05 psi error for up to 100 lbs applied*

#### Requirement 3.1.1 - Mattress Vesicle Pressure - Maximum Pressure

Mattress vesicles must not be at risk for rupture, and as such cannot exceed a dangerous pressure level.

*Req. 3.1.1 - must not exceed 3 psi*

#### Requirement 3.1.2 - Mattress Vesicle Pressure - Oscillatory Abilities

Mattress vesicles must be able to change pressure based on preset conditions every 15 minutes.

*Req. 3.1.2 - must change position by pressure change every 15 mins.*

#### Requirement 3.2.0 - Mattress Longevity and Wear

Mattress must be able to maintain its shape and conformation for a considerable amount of time. The wear on either side of the mattress should not become such that it is not functional for many years.

*Req. 3.3.0 - mattress must not show functional hindering wear for <5 years*

## DESIGN AND DEVELOPMENT PLAN

### **Requirement 3.2.1- Mattress Usability**

Mattress must be comfortable and easy for all consumers to use regardless of ability to maneuver themselves, muscle mass, or protrusion of bony prominence's. Consumers of the mattress will need to self report how they slept on the mattress over a period of time and answer a questionnaire on the quality of sleep they received while using the mattress.

*Req. 3.2.1- must have favorable results reported by consumer tests (over 6/10 average for sleep quality)*

### **Requirement 4.1.0 - Bed frame Weight Requirement**

Bed frame must support at least 450 lbs per person for a twin, full, queen, or king sized mattress. Assuming a twin will support one person, and full - king will support two.

*Req. 4.1.0 - bed frame must support 450 lbs per person*

### **Requirement 4.1.1 - Bed Frame and Mattress Size Requirements**

Bed frames and mattresses must come in sizes twin, full, queen, and king.

*Req. 4.1.1 - Bed frames and mattresses must come in 4 standard sizes*

### **Requirement 5.1.0 - Support Bar Function - General**

Support bars should be able to support the action of a person shifting their position in bed.

*Req. 5.1.0- must support 50N of force*

## **Safety and Reliability**

### **Requirement 6.1.0 - Mattress Material Sterility**

Mattress must be sterilized before being packaged and shipped out to consumers. This must be done by applying an antiseptic spray on the top, bottom, and sides of the completed mattress.

*Req. 6.1.0 - must kill 99% of surface bacteria*

### **Requirement 6.1.1 - Mattress Material Flammability**

Mattress material must fall within acceptable flammability standards as set by the Electronic Code of Federal Regulations in Title 16, chapter III, subchapter D, number 1632. (Pass the cigarette test.)

*Req. 6.1.1- must pass federal regulations on flammability*

### **Requirement 7.1.0 - Drop Resistant Protocols**

Should the mattress give way to the weight applied, drop resistant protocols must engage to prevent falling from bed frame. These protocols must ensure that the consumer never falls through the bed frame.

*Req. 7.1.0- protocols must have <1% failure rate*

### **Requirement 8.1.0 - Emergency Shutdown Protocol**

Should any bedding or loose materials get caught in the mechanical components of the mattress and/or bed frame, emergency shutdown protocols must engage to prevent any electrical overheating, damage to the machinery, or injury to the consumer.

*Req. 8.1.0 - emergency shutdown must have <1% failure rate*

## DESIGN AND DEVELOPMENT PLAN

### Interface Requirements

#### Requirement 9.1.0 - Touchscreen Interface - Ease of Use

To get to the desired output, the system should only require 5 keystrokes.

*Req. 9.1.0 - must use < 5 keystrokes*

### Software Requirements

#### Requirement 10.1.0 - Computer - Storage

The computer interface must retain pressure and configuration presets for the mattress.

*Req. 10.1.0 - must store > 4 presets of 10 hour periods*

## DESIGN AND DEVELOPMENT PLAN

# SYSTEM ARCHETECTURE

## SYSTEM ARCHITECTURE

### BED FRAME

Bed frame allows users to raise and lower themselves into a seater position and laying down position.



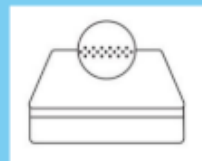
### SUPPORT BARS



Support bars can be used to assist users in shifting positions and raising themselves into a standing position.

### MATTRESS

The mattress is composed of vesicles filled with air. The vesicles inflate and deflate in response to computer programming. This allows users to shift positions during sleep.



### INTERFACE

User interface is a touchscreen. The internal computer can store preset mattress settings for users. These presets adjust mattress position and pressure.

## DESIGN AND DEVELOPMENT PLAN

### DESIGN PLAN

#### Inputs

- Research into the target customer segment will drive development of overall product and features.
- Funding will be sourced from the Harold Frank Engineering Entrepreneurship Institute, WSU Bioengineering Capstone, and the Gleason Institute.

#### Business Constraints and Timelines

- Budget will be determined for the initial stage by the involved parties. Funding will drive project to the next stage.
- Business model will be developed. Marketing team will start advertising product for additional funding.
- Begin obtaining IP.
- R&D will recommend steps moving forward:
  - Potential technologies for vesicle supports in mattress
  - Summary of pressure sensors
  - Biomechanical assessment of bending points and support bar

#### Overall Product Goal

Provide a product that assists in increasing sleep in people suffering from muscular atrophy.

#### Stage 1

- Input: \$500 - Output: assessment of desired features and necessary components
  - Marketing team will provide initial survey of target customer segment
    - Prepare a presentation detailing needs and gains for potential investors
    - Bring assessment of components back to a focus group for analysis
  - R&D team will assess components
    - Provide a detailed summary of all necessary features and options for components needed to successfully integrate necessary features
  - Financial team will advertise to investors
    - Find funding to move to Stage 2
  - Management will oversee all processes and advise steps moving forward
    - Will require formal review board of founders and investors

DESIGN AND DEVELOPMENT PLAN

DESIGN PLAN

Things to do

	Owner	Status	Due Date	Priority
Round 1 Funding	KL	Waiting for review	Oct 22	Medium
Component Assessment		Working on it	Oct 31	High
Seek Investors		Waiting for review	Dec 31	Low
Initial Product to Focus Group		Stuck		Low
+ Add				

Done

	Owner	Status	Due Date	Priority
Initial Customer Interviews		Done	Apr 18	High
+ Add				





## DESIGN AND DEVELOPMENT PLAN

# Testing Specifications

### Spec 1.3.1 - Vesicle Max Pressure

Vesicle must hold 10 psi within +/- 0.05psi; based on pressure maps' maximum being around 2psi with a safety factor of 5.

#### Testing Protocol 1.3.1

- Grainger Hydrostatic Test Pump, Hand Operated, 1000psi Item # 6GDU5 Mfr. Model # 29201 Catalog Page # 2631 UNSPSC # 40151533
- Herco Liquid Filled Hydraulic Pressure gauge 0-100 psi (npt)

Although air will be used to fill these vesicles eventually, testing procedures are safer to conduct in a hydrostatic environment. The hydrostatic test utilizes a liquid to fill and pressurize the vessel. Water is the most commonly used liquid. The hydrostatic pressure is raised inside the vessel until the pressure reaches at least the minimum hydrostatic test pressure which is: Minimum Hydrostatic Test Pressure =  $1.3 \times \text{MAWP} \times \text{LSR}$

Where LSR is the smallest ratio of the allowable stress at test temperature to the allowable stress at design temperatures of materials used in vessel construction and MAWP is the maximum pressure based on the design codes that the weakest component of a pressure vessel can handle. For the hydrostatic test the Code recommends that the temperature of the vessel and its contents are the same and between a range of 30°F and 120°F above the operating temperature. After the pressure reaches the test pressure (10 psi +/- 0.05psi), the pressure is reduced until it reaches a value equal to the test pressure divided by 1.3. A visual examination or gas leak test is used to check for cracks or leaks in all connections and joints.

### Spec 3.2 - Electrical Components' Water Resistivity

Mattress' electrical components should have a reasonable water resistivity of IPX4

Testing Protocol 3.2 Lab PLC Controlled IPX4 / IPX 5 / IPX6 Waterproof Rain Test Equipment  
IPX4 testing protocol - can survive splashes of water from any direction. The water is sprayed at different angles up to 60° measured from the vertical axis. The pressure of the water is 50-150kPa and the amount of the sprayed water during 5min testing is 50 liters.

### Spec 1.3.2 - Rigidity of Support Bars

Support Bars should be able to support the full weight of a reasonably sized individual and should be able to hold ~450lbs

## DESIGN AND DEVELOPMENT PLAN

Testing Protocol 1.3.2

- Instron 3340 Series Universal Testing Systems up to 5 kN (1,125 lbf) Force Capacity

Tests will be conducted to test the weight the bar is able to support, using the Instron 3340, at key points that the bar is expected to support that weight.

### **Spec. 3.2.1- Mattress Useability**

Mattress must be comfortable and easy for all consumers to use regardless of ability to maneuver themselves, muscle mass, or protrusion of bony prominences.

Testing protocol 3.2.1

- Mattress prototype complete with computer interface and bed frame
- 10 human subjects

Preliminary tests will be conducted over the span of 5 days, where the 10 human subjects will sleep 5 nights on the mattress prototype and self report on their quality of sleep after every night. This will take the form of a brief questionnaire including questions on how they rate the quality of their sleep, how many times they woke up per night on average, if anything was not working properly, how easy the interface was to use, if their presets were comfortable, and if they were able to use each component on the mattress/ bed frame. Question responses will be recorded and used to validate design goals.

Upon completion of 5 day trial data will be recorded and tabulated, a satisfaction rating of >80% will be acceptance level.

## DESIGN AND DEVELOPMENT PLAN

### Testing Validation

#### Validation test for Spec. 1.3.1- Max Pressure

Vesicle must hold 10 psi within +/- 0.05psi

Equipment: Grainger Hydrostatic Test Pump, Herco Liquid Filled Hydraulic Pressure gauge 0-100 psi

Hydrostatic pressure testing will ensure that the pressure sensors at work in the mattress are meeting specifications and protecting against over inflating. 20 randomly selected mattresses will be subjected again to the specification testing protocols to maintain that mattresses vesicles are filling to the specified pressure range. Mattresses will be tested to hold pressures of 2, 5, and 10 psi pressures as controlled by the computer interface. Upon completion of all 20 tests, data will be recorded and tabulated, a mean score of <0.05 psi error will be acceptance level.

Validation test for Spec. 3.2 - Electrical Components' Water Resistivity

Reasonable water resistivity of IPX4

Equipment: Lab PLC Controlled IPX4 / IPX 5 / IPX6 Waterproof Rain Test Equipment

A randomly selected 20 mattresses will be chosen and subjected to the specification testing protocols to determine whether the electrical components are water resistant enough to be safe. The components will need to achieve a resistivity of at least IPX4 to maintain a safe rating. Upon completion of all 20 tests, data will be recorded and tabulated, a mean score of at least IPX4 will be acceptance level.

#### Validation test for Spec. 1.32 Rigidity of Support Bars

Support Bars should be able to support the full weight of a reasonably sized individual (~450lbs)

Equipment: Instron 3340 Series Universal Testing Systems up to 5 kN (1,125 lbf)

Structural testing will ensure that the support bars meet weight requirements. 20 randomly selected support bars will be placed individually in the instron machine and will need to pass the specification testing. Bars will need to be able to withstand the force of up to 450 lbs being applied to 3 points without structural failure. Upon completion of all 20 tests, data will be recorded and tabulated, a score of <1% structural failure for <450lbs will be acceptance level.

## DESIGN AND DEVELOPMENT PLAN

### **Validation test for Spec. 3.2.1- Mattress Usability**

Mattress must be reasonably comfortable for all consumers.

Equipment: Mattress prototype complete with computer interface and bed frame, 10 human subjects

Human testing will be performed per IRB standards once preliminary testing has concluded. 10 subjects will each sleep on a mattress for 30 nights and report via a survey twice a week detailing their experience. This will include how they rate the quality of their sleep, how many times they woke up per night on average, if anything was not working properly, how easy the interface was to use, if their presets were comfortable, and if they were able to use each component on the mattress/ bed frame. Question responses will be recorded and used to validate design goals. Along with weekly surveys, subjects will also meet with a design team after their trial period to further discuss any potential alterations to the product. Upon completion of 30 day trial, data will be recorded and tabulated, a satisfaction rating of >80% will be acceptance level.

DOCUMENT CONTROL

Document Control Index

Index #	Title	Type	Initials	Date of Approval	Storage Location	Security Level
1	Quality Assurance Protocol	Policy	SES	10/31/2019	DMR	2
2	Equipment Instructions	Policy	JR	10/31/2019	DMR	2
3	Employee Conduct Manual	Policy	SES	10/31/2019	Master records	1
4	Mechanical Testing	R&D	JR	10/31/2019	TDF, DHF	6
5	Electrical Testing	R&D	JR	10/31/2019	TDF, DHF	6
6	Material testing	R&D	JR	10/31/2019	TDF, DHF	6
7	Report on IP potential	Legal	SES	10/31/2019	Master records	7
8	Minutes from design meetings	Memo	JR	10/31/2019	DHF	3
9	Instructions for use	R&D	SES	10/31/2019	DMR	1
10	Customer feedback	R&D	KML	10/31/2019	DHF	2
11	Market research	Marketing	KML	10/31/2019	Master records	4
12	Marketing plan	Marketing	KML	10/31/2019	Master records	4
13	Monthly sales report	Sales	KML	10/31/2019	Master records	4
14	Patent	Legal	SES	10/31/2019	Master records	10
15	Design output	R&D	SES	10/31/2019	DMR	3
16	10 year financial projection	Sales	KML	10/31/2019	Master records	4

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**DOCUMENT CONTROL**

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## Device History Record

The DHR contains all production records for the Zephyr Mattress product. It traces each product through processing to packaging to demonstrate product manufacturing compliance with the DMR.

The following information is included below:

Dates of manufacture

Quantity manufactured

Quantity released for distribution

Acceptance records which demonstrate the device is manufactured in accordance with DMR

Primary identification and labeling used for each production unit

Any device identification or control number used

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## DOCUMENT CONTROL

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### Design History File

The Design History File (DHF) is updated monthly and exists as a digital copy on the OneDrive and as a physical copy, where all records describing the history of the design of a finished device is compiled. The DHF must reference records if they are in a different format (e.g. physical vs. digital) or contain records that are necessary to show that the device followed an approved design plan.

The DHR includes:

#### **Design Planning**

Design plans

Sketches, blueprints, FBD, photos

#### **Design Inputs**

System Specifications

Component Specifications

Product Specifications

#### **Design Outputs**

Design implementation documentation

Production methods

Testing equipment specifications

Production procedures

Assembly methods

Quality assurance specifications and procedures

#### **Design Review**

FMEA

Acceptance Criteria

Materials testing

Component testing

System testing

#### **Design Validation**

Customer surveys

Validation report

#### **Design Transfer**

Training methods and materials

Manufacturing processes

Inspection methods

Testing methods

#### **Design Changes**

Documentation of design iterations

Design change queries

Design alteration control procedures

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**DOCUMENT CONTROL**

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## Device Master Record

The Device Master Record (DMR) is updated monthly and exists as a digital copy on the OneDrive and as a physical copy and contains all of the procedures and specifications for a commercially ready Zephyr Mattress.

Contains a compilation of records containing the procedures and specifications for a finished device, references to locations of documents for manufacturing and processing, information on the design formulation, complete manufacturing procedures, quality assurance requirements, acceptance criteria, packaging procedures, and labeling procedures.

- System specifications
- Component specifications
- Device specifications
- Characteristic diagrams
- Material specifications
- Manufacturing procedures
- Testing specifications
- Testing procedures
- Employee training procedures
- System audit procedures
- Standard operating procedures (SOP)
- Labeling and packaging requirements
- Software specifications
- Production equipment specifications
- Quality assurance procedures
- Quality assurance equipment specifications
- Installation, maintenance, and servicing procedures

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## DOCUMENT CONTROL

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# Quality Assurance

### **Quality Statement:**

The teams at Zephyr strive to maintain the highest quality of our product. We reach this standard by continuous testing, feedback from product testing to development, continuous communication between branches of the company, and listening to customer feedback. If our products do not meet our standards as outlined in our design and development plan, we will discard the under-performing product and ensure our process is equipped to produce fully performing mattresses.

### **Quality Assurance Procedures:**

To ensure quality, regular testing is conducted to verify our product is meeting our standards. These standards are outlined in our system requirement specifications, and our verification and validation protocols can be found under testing specifications. These tests include those for vesicle pressure, water resistivity, mattress usability, and more.

### **Quality Management System:**

Quality starts with our team members and our materials sourced. In this document you will find the standards that we have set for our employees and suppliers. We also include standards for our completed products in our design and development plan, and standards for IRB testing of the commercially available mattress. The system we have in place sets clear and concise standards for every aspect our Zephyr Mattress as a company as well as our product. We have elected to exclude information regarding FDA approval, as our mattress is not considered a medical device.

### **Testing of system:**

Quarterly quality reports will be generated and subjected to review. If quality standards (outlined in FMEA report and design and development plan) are not met for any section of design, production, or management, that team will need to present documentation justifying the failure to meet requirements. The processes in question will then be reviewed by management for possible improvements and adjustments. This team will then have one quarter to improve their output to meet standards. If they are unable to do so, a third party consultant will be brought in to streamline the process and remedy the problem.

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**DOCUMENT CONTROL**

## Quality Test Results for 12/1/19

On 12/1 quality testing for max vesicle pressure was conducted on 10 randomly sampled mattresses. As written in testing specification, max pressure must be  $10 \pm 0.05$  psi. The results of the test are shown below.

Mattress supply number	Max pressure recorded (psi)	Pass/fail quality test
156	10.01	Pass
178	10.03	Pass
194	9.99	Pass
226	10.04	Pass
237	10.01	Pass
255	10.00	Pass
282	10.02	Pass
298	10.03	Pass
305	9.98	Pass
321	10.01	Pass

**DOCUMENT CONTROL**

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**MEMO**

To: Sarah Schroeder, Jackson Rieb

From: Katie Lober

Subject: Marketing Venture

Date: 28 October 2019

All,

I believe the main point in our campaign should be that the mattress adds to the aesthetic of a room - no more hospital feel in your household! I'm excited to launch this campaign because we are able to give some independence back to our customers. I'm excited to meet with you all soon regarding some of the fun things our marketing team has up their sleeves.

Thanks,  
Katie Lober

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**DOCUMENT CONTROL**

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## 191029- Zephyr Mattress Meeting

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In attendance: Katie, Sarah, Jackson

Start Time: 10:35

End Time: 11:50

Goals: Finish financials, publish

### Agenda

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- Go over financial model
- OKR's
  - Dr. Davis emphasized that OKR's should have data driven results
  - Follow the why/how/what strategy to define goals
  - Submit Document Control

### Notes

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#### Executive Summary

- Virtual meetup over break
- Katie can design formatting
  - Sections
    - Meet the team
    - Problem
      - Customer segment research
    - Concept/product
    - Marketing strategy
    - Competitors
    - Timeline/graphic
- Do they understand your plan?
- Go to market is weak.
- How do you make money
  - Number of sales on a timeline and what is the margin

### To Do

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**Sarah** - submit documents

**Katie** - brand everything

**Jackson** - finish prototype

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## DOCUMENT CONTROL

# Document Filing

### Document Creation

Documents are created within the company by employees, suppliers, or customers. All documents fall under NDA. Company documents include all bodies of writing that includes the title Zephyr Mattress or any IP belonging to Zephyr Mattress regardless of when or where the document is produced.

Customer complaints and reviews will be filed along with documents.

### Document Review and Approval

Documents must be approved up the chain of command; the head of a department must approve documents for official review. The author and the head of the department of interest must agree on initial revisions before sending the document to the Document Review Board.

The document in question will then be read through by the Document Review Board. The Document Review Board is composed of at least one founder, one stakeholder, and one project manager outside of the department where the document originated. The Document Review Board may suggest revisions.

### Document Revisions

Document revisions suggested by the Document Review Board must be tended to by the author within one week of initiation. From there the document must be approved by one member of the Document Review Board for publishing.

### Document Publishing

Documents may be published to the database by the author after official approval after following document filing procedure.

### For Obsolete Documents

Obsolete documents will be archived and held for at least ten years. A document may be ruled obsolete only after approval by all three founders.

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## DOCUMENT CONTROL

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### Supplier Qualification

Suppliers are defined as an entity that provides either a suitable good or a qualified service to Zephyr Mattress.

All suppliers are subject to NDA.

Zephyr Mattress may agree to partnerships after extensive work with specific suppliers. Partners of Zephyr Mattress may benefit from substantial sales and purchases.

#### Verification Protocol

Buyers must request company details and create a company profile for approval. Company profile must include the company in question's latest financial statement, an organizational chart, a product process flow chart, and machinery list with capacity. Buyers must also assess reliability of shipping, packaging, and product.

After approval of company profile, buyers may request a quote and product samples with specifications.

#### Validation Protocol

Samples and initial product will be handed over to R&D QA for initial testing and evaluation.

Zephyr Mattress's quality assurance team is responsible for validating all goods and services from external suppliers (outsourced products). These may include but are not limited to: stress and strain testing, strength testing, flammability testing, water resistance testing, durability testing, finite element analysis, reliability, etc.

It is the job of Zephyr Mattress's quality assurance team to ensure that all product from suppliers conforms to regulations outlined in Zephyr Mattress's FMEA.

Each product sample will be subject to an individualized series of tests before Zephyr Mattress will move forward with official purchases for production.

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## DOCUMENT CONTROL

### Product Release Procedure

#### Storage Requirements and Specifications

Zephyr Mattress requires a space that has a production floor, R&D department, and logistic offices.

Zephyr Mattress is strictly confidential. All assembly and product information is property of the company. Only employees with key card access will be allowed onto the factory floor.

No unsold stock is to leave the factory floor unless there is unanimous approval by founders. This may be the case for meetings with investors, special marketing campaigns, and promotional events.

Missing stock will result in an in depth investigation.

#### Sterilization Procedure

Mattress is to be sterilized as the last step in production. Sterilizing spray will be used on all components before final assembly. Packaging must be vacuum sealed to ensure no contamination during shipping and transport.

#### Defective and Contaminated Equipment Procedure

Routine auditing of the production equipment will take place biweekly or if a defect is found by the production manager, possibly resulting in replacement or maintenance of equipment.

Mattress will be assessed by QA before leaving manufacturing facility for shipment.

Mattress will be deemed defective if it fails testing and validation specifications outlined in FMEA.

When a sample is defective, it will be sent back to R&D for analysis. Once a failed component is isolated, R&D will contact receiving. Receiving will ultimately decide whether or not the failed component was fault of the supplier. Based off of this decision, two paths may be taken.

Supplier Fault: Supplier will be contacted for replacement. If the supplier is unable to produce replacement, it is possible that the supplier in question will lose contract with Zephyr Mattress.

Component Failure: Receiving will contact R&D. R&D will perform production analysis to define point of failure during assembly. Actions will be taken to streamline production.

#### Packaging Procedure

Amount of product ordered and distance travelling will determine what packaging and shipping method should be used.

Appropriate material must be used in shipping to ensure mattress integrity: bubble wrap, air pillow, support, stability, etc.

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**DOCUMENT CONTROL**

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Once appropriately packaged, shipping containers will be branded with designs designated by marketing team.

Labels should clearly list the product name, customer information, customer support contact information, identification number, etc.

All shipments will be documented fully.

**Maintenance**

Zephyr Mattress personnel will be available to service any Zephyr Mattress should there be any malfunction within the warranty time. Such issues may include any breakage of the mattress, bed frame, pump, or computer interface; problems with storage function of computer; or problems with the general set up of the mattress.



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**DOCUMENT CONTROL**

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## Technical Documentation File

The Technical documentation file (TDF) is a subset of the DMR and includes the following documents:

- Product description
- Intended use
- Labeling
- Product Specifications
- Parts list
- Component drawings
- Material specifications
- List of applicable standards
- Instructions for use
- Product verification
- Testing data and reports
- Lab journals
- Functionality testing
- Risk analyses
- Warnings
- FMES analysis

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## DOCUMENT CONTROL

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# Technical Documentation File

**Product description:**

The Zephyr Mattress is a comprehensive mattress and bed frame complete with oscillating pressure vesicles within the mattress controlled by a touchscreen interface, and supports bars located on the bed frame for easy self adjustment. The Mattress is composed of small air vesicles that can individually inflate or deflate to a desired pressure to offer the user variety in their mattress surface.

**Intended use:**

The Zephyr Mattress is intended to be used by consumers with muscular atrophy and have a more difficult time becoming comfortable enough to sleep. Our mattress can change the surface of the mattress by oscillating pressures to become the most appealing surface to sleep upon.

**Labeling:**

Each mattress will arrive almost fully assembled, with the mattress, air pump, touchscreen interface, bed frame, and support bars clearly labeled.

**Product specifications:**

Our product meets the product specifications laid out in the Design and Development Plan, attached.

**Parts List:**

- Bed frame (sizes full-king)
  - Attached 3 support bars located on either side of the bed and one above the head of the bed
- Mattress with air vesicles and attachments to pump and computer interface
  - Pressure sensors embedded into the mattress
- Air pump
- Computer touch screen interface

**Material specifications:**

Materials must meet the sterility, flammability, and water resistant specifications laid out in the Design and Development Plan, attached.

**List of applicable standards:**

See Regulatory Plan.

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## DOCUMENT CONTROL

**Product verification:**

Products must be verified through procedures listed in the Design and Development plan, attached before they are released to consumers.

If products fail to meet required specifications for verification, they must be reviewed by Zephyr's quality assurance team before re-release and re-testing. Quality assurance's rework must be documented as per our documentation standards, and reworked product must then pass the same verification tests it previously failed.

**Testing data and reports:**

In order to pass our regulations, mattresses and related components must pass the testing procedures outlined in the Design and Development Plan.

**Lab journals:**

Laboratory journals detailing the testing protocols, results, and research done on improving our product are documented digitally as well as with physical copies.

**Functionality testing:**

To ensure the highest quality of our products, testing is continuously conducted on each shipment of mattresses. This testing ensures our specifications and safety standards are being met. The testing procedures are outlined in the Design and Development Plan.

**Risk analyses:**

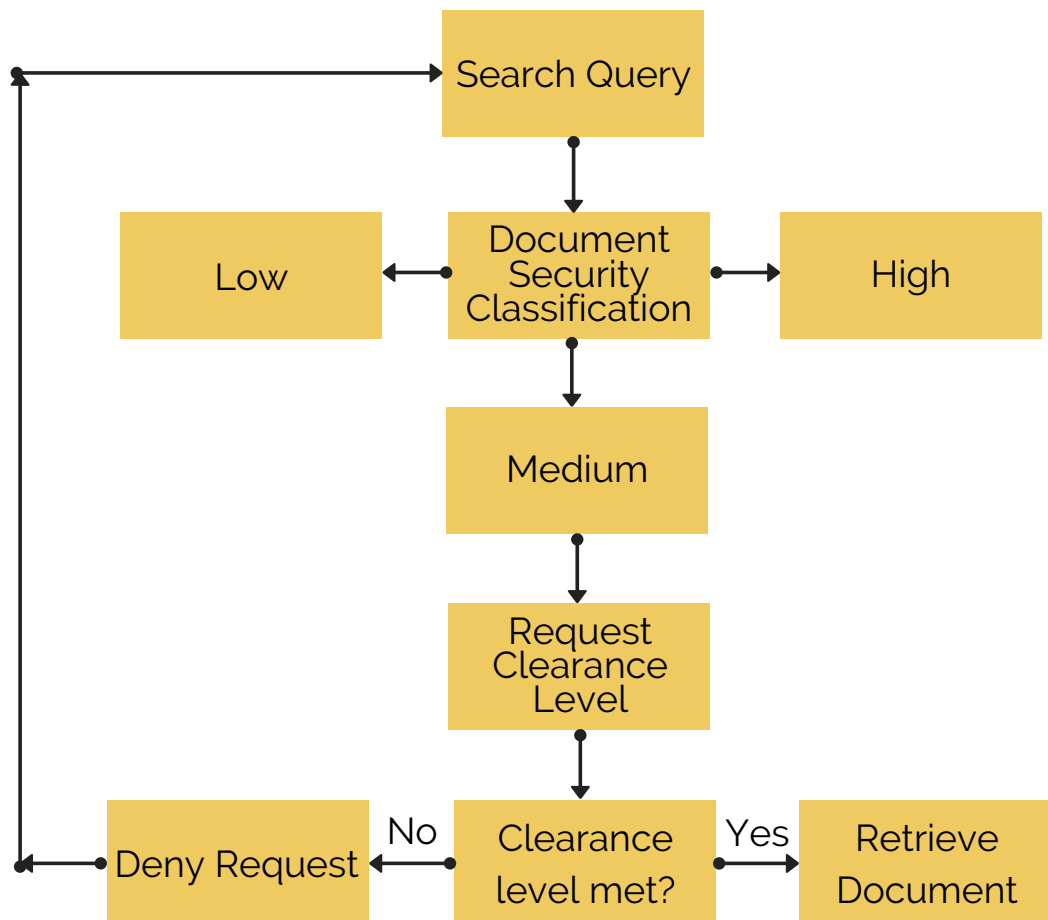
Risk analysis for each component of the Zephyr Mattress has been assessed and documented in our product FMEA report.

**Warnings:**

Warnings associated with our product have been addressed and adequate testing protocols have been designed to ensure the safety of our consumers. Specific hazards and warnings can be found in the FMEA report.

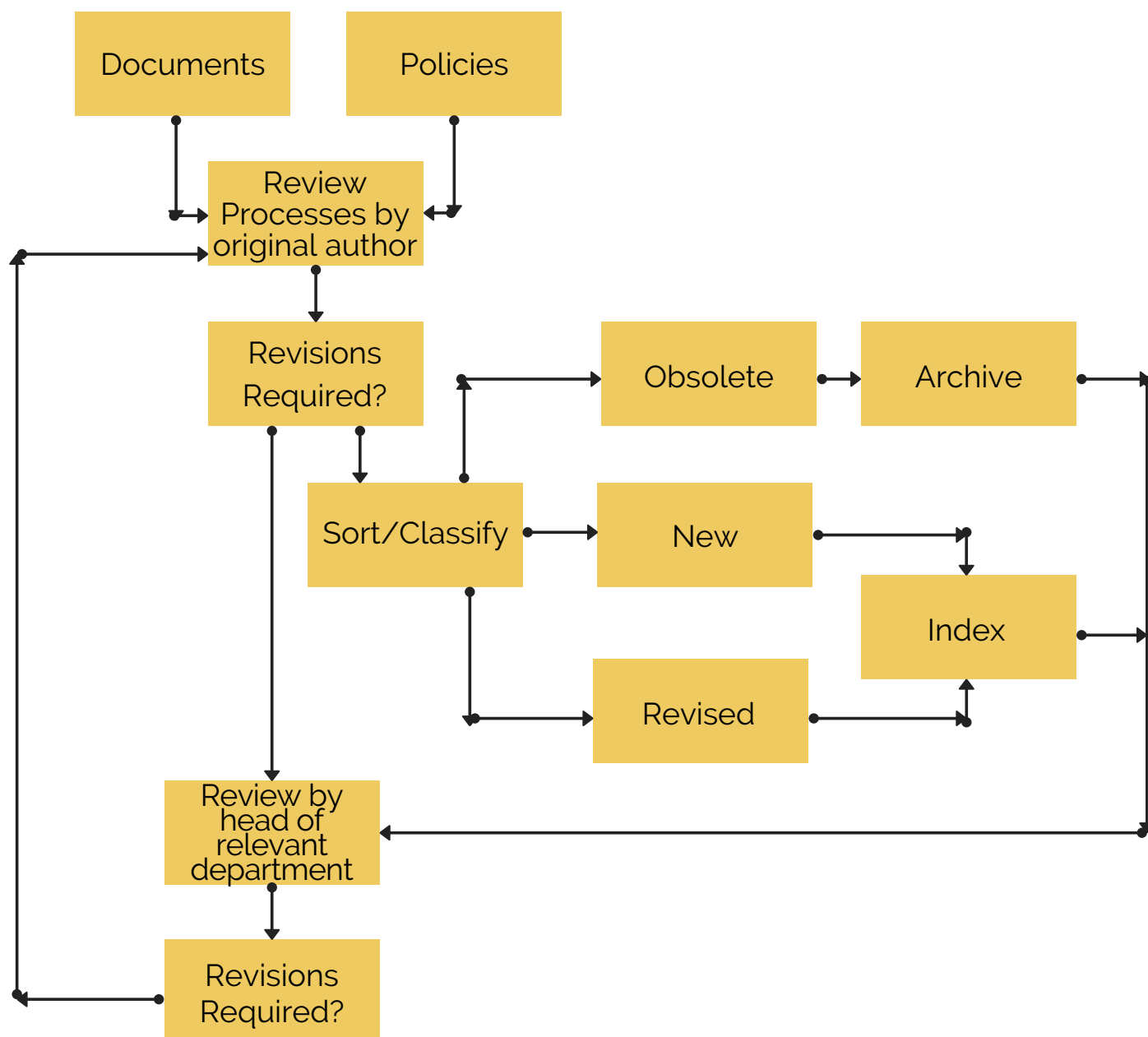
## DOCUMENT CONTROL

### Document Retrieval Process



## DOCUMENT CONTROL

### Document Control Process



**DOCUMENT CONTROL****Sample IRB Document****PROTOCOL TITLE:** *Mattress Comfort Study***PRINCIPAL INVESTIGATORS:***Sarah Schroeder, Katie Lober, Jackson Rieb**Washington State University**(509)942-9305**Sarah.e.schroeder@wsu.edu***VERSION DATE:***10/27/19***Study Summary:**

Investigational Agent(s) (Drugs or Devices)	Pressure Oscillating Mattress
IND / IDE / HDE #	
Indicate Special Population(s)	
Sample Size	50
Funding Source	Grants
Indicate the type of consent to be obtained	Written
Site	Lead Site ( For A Multiple Site Research Study)
Research Related Radiation Exposure	No
DSMB / DMC / IDMC	No

## DOCUMENT CONTROL

**Objectives:**

The purpose of this study is to determine whether the mattress we create is comfortable for consumers and identify any areas for improvement in the design. We will be gauging the quality of sleep that participants receive while using our mattress.

**Background:**

People with muscular atrophy find it difficult to be comfortable on normal mattresses and as such often do not get quality sleep. After conferring with a panel of ALS patients and family, we have determined that an oscillating air vesicle mattress may alleviate any discomfort by changing the sleeping surface multiple times throughout the night.

Not only is the oscillating surface good for alleviating any pressure sore type injuries, it also gives individuals with limited mobility the sensation of changing sleeping positions without the need to physically move themselves. This change could be instrumental in restoring the feeling of natural sleeping tendencies.

**Study Endpoints:**

The endpoints for this study will be to reveal how well participants slept on our mattress compared to on a standard mattress. We will also ask participants to give feedback on certain design components ease of use, including the touchscreen interface and the pre-set conditions feature.

We will also ensure that there are no gross malfunctions of the product and eliminate any final safety concerns.

**Study Intervention(s) / Investigational Agent(s):**

The device being evaluated is a mattress that inflates with an air pump, and the related bed frame. The mattress is controlled by a computer with a touchscreen interface.

**Procedures Involved:**

The study involves an individual sleeping on a standard mattress for 10 days, and then sleeping on the Zephyr Mattress for 30 days. The participants will be asked to fill out questionnaires twice weekly describing their quality and amount of sleep, the ease of use of the mattress components, and any difficulties they may have had.

**Data and Specimen Banking**

Questionnaire results/data will be stored electronically within our company's master records. Subject personal information will be encrypted, only responses will be made available to the R&D division.

DOCUMENT CONTROL

Sharing Results with Participants

Results are self-reported by the participants and copies of their submission can be made available upon request.

Study Timelines

The study will cover 10 days of sleep on a normal mattress and 30 days of sleep on the Zephyr Mattress. 40 days in total with results available within 7 days of the study completion.

Inclusion and Exclusion Criteria

Participants must be adults able to consent to participation in this study without a history of muscular atrophy or other muscle related conditions. Participants cannot have muscular conditions coming into this study as we are looking to see how this mattress works on an individual with average health and body composition. Later studies will include how the mattress effects participants with low muscle density and degenerative conditions.

Participant Population(s)

Accrual Number:	Category/Group: (Adults/Children Special/Vulnerable Populations)	Consented:  Maximum Number to be Consented or Reviewed/Collected/Screened	Enrolled:  Number to Complete the Study or Needed to Address the Research Question
Local	50	0	0
Study-wide	50	0	0
Total:	50	0	0



## DOCUMENT CONTROL

### **Recruitment Methods**

Participants will be recruited from the area around our main operations and may include family and friends of employees. Participants must be a consenting adult able to participate in all 40 days of our study and be able to communicate through a written survey.

Participants will be recruited by word of mouth and by advertising in our immediate area through social media and through posters/flyers.

### **Compensation for Participation in Research Activities**

Participants will be compensated with a \$100 amazon gift card after completion of the study.

### **Withdrawal of Participants**

Participants may be withdrawn from the study if they do not complete the twice weekly reports or if the researchers suspect that they are falsifying their reports (ie. not sleeping on the mattress).

### **Risks to Participants**

There is very low risk to participants, the most being that the mattress may deflate during the night causing mild discomfort.

### **Potential Benefits to participants**

The potential benefits would be a better night sleep and less aches and pains after sleeping.

### **Data Management and Confidentiality**

Data from the patient surveys will have personal information removed before being sent for analysis of results. The Research and development team will only have access to personal data if deemed relevant to the results and will only be provided to those with clearance.

## DOCUMENT CONTROL

### **Consent Process**

Consent will be obtained in writing before the beginning of the research. The individual is free to leave the study at any time but will not be compensated unless they complete the study.

- *Setting*

The study will be conducted in the participant's own home. We will provide a trial mattress for them to use for 30 days, they will fill out surveys and send them electronically back twice a week, and after the study we will recover the trial mattress.

- *Lead Coordinating Center:*

The lead coordinating center will be at Washington State University.

### **Qualifications to Conduct Research and Resources Available**

The number of participants that we want to recruit is 50, which is not very many. We have access to friends, family, classmates, and other students that can all be consenting adults and take part in this study. This study will be held in each participant's own home and will only require that we have a trial mattress available for each participant at the time of their study.

## PROJECT FINANCIALS

It has been assumed that the price of our product should range between \$3000 and \$6000 based on competitor's prices. Our product is similar to already existing hospital beds and specialty mattresses that are priced in this range. As such, we have priced our product at \$5000.

From customer interviews, it has been made clear that they are willing to pay within this range for a comprehensive solution to their sleeping issues. Our price is competitive with other mattress and bed frame combinations that offer fewer benefits and features.

It has been assumed that in stage one of development it will cost \$2500 per product to produce. This estimate was made based off of cost of parts included in the design (see Appendix), and the cost of labor in assembling the components. This value is a rough estimate based on component research and estimated time to complete construction of product.

Based on the price and cost of production assumptions listed above, we will gross \$2500 per each mattress sold. This, multiplied by our estimated sales for stage 2, ~500 mattresses, will give an estimated \$1,207,500 to use in funding our company (ie. paying employees, fixed costs in rent, etc.)

## **PROJECT FINANCIALS**

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Our financial estimates at this time rely heavily on online research on mattress components and comparisons to competitor's pricing. Our cost of production is estimated to be \$2500 per mattress. Our initial estimate cost of material is \$1518, leaving \$982 for labor costs per mattress. By partnering with suppliers and ordering parts in bulk we should be able to reduce the cost of materials, thereby reducing the COGS and allowing us to either decrease the price of our product or just increase revenue.

## PROJECT FINANCIALS

Component	Quantity based on King Size Mattress	Cost Per	Total Cost of Component
Vesicle material	4.2 m <sup>2</sup>	\$0.38/m <sup>2</sup>	\$11
Mattress Topping material	3.9 m <sup>2</sup>	\$12.82/m <sup>2</sup>	\$50
Raspberry pi microcontroller	1	\$48.00	\$48.00
Touch Screen Display	1	\$69.00	\$69.00
Bed frame	1	\$1,340	\$1,340
Total Cost of Device Materials	\$1,518		

## PROJECT FINANCIALS

sales model by year	0	1	2	3	4	5
N sales	0	250	500	750	1000	1500
Price	\$5,000.00	\$5,000.00	\$5,000.00	\$5,000.00	\$5,000.00	\$5,000.00
Gross Revenue	0	\$1,250,000.00	\$2,500,000.00	\$3,750,000.00	\$5,000,000.00	\$7,500,000.00
total COGS by year	0	2500	2500	2500	2500	2500
fixed costs	0	\$512,500.00	\$1,025,000.00	\$1,537,500.00	\$2,050,000.00	\$3,075,000.00
net revenue	0	\$735,000.00	\$1,472,500.00	\$2,210,000.00	\$2,947,500.00	\$4,422,500.00
cash flows	-1,000,000	-\$265,000.00	\$1,207,500.00	\$3,417,500.00	\$6,365,000.00	\$10,787,500.00

sales model by year	6	7	8	9	10
N sales	1500	1500	1000	750	500
Price	\$5,000.00	\$5,000.00	\$5,000.00	\$5,000.00	\$5,000.00
Gross Revenue	\$7,500,000.00	\$7,500,000.00	\$5,000,000.00	\$3,750,000.00	\$2,500,000.00
total COGS by year	2500	2500	2500	2500	2500
fixed costs	\$3,075,000.00	\$3,075,000.00	\$2,050,000.00	\$1,537,500.00	\$1,025,000.00
net revenue	\$4,422,500.00	\$4,422,500.00	\$2,947,500.00	\$2,210,000.00	\$1,472,500.00
cash flows	\$15,210,000.00	\$19,632,500.00	\$22,580,000.00	\$24,790,000.00	\$26,262,500.00

R&D Investment	\$1,000,000.00
Total ROI	26.2625
AROI	0.3917350597
Discount Cost of Money	8%
NPV	\$66,970,705.27
IRR	130%

## GAP ANALYSIS

ISO 9001	Description	Found on Page	Reviewer	Date of Review	Action Needed	Action Taken	Date
4.1.1	The standard requires the organization to implement and maintain a quality management system in accordance with the requirements of ISO 9001. This includes insurance of control of any outsourced processes that affect product conformity with requirements and to identify such control within the quality management system (QMS)	38	MA	11-20-19	good		12-1-19
4.1.1a	The standard requires the organization to identify the processes needed for the quality management system and their application throughout the organization.	49-50	MA	11-20-19	good		12-1-19
4.1.1b	The standard requires the organization to determine the sequence and interaction of the identified processes.	49-50	MA	11-20-19	good		12-1-19
4.1.1c	The standard requires the organization to document the role(s) undertaken by the organization under the applicable regulatory requirements.	51-52	MA	11-20-19	good		12-1-19
4.1.3a	For each quality management system process, the organization shall determine criteria and methods needed to ensure that both the operation and	51-52	MA	11-20-19	good		12-1-19
4.1.3b	For each quality management system process, the organization shall ensure the availability of resources and information necessary to support the operation and monitoring of these processes	49-52	MA	11-20-19	good		12-1-19
4.1.3c	For each quality management system process, the organization shall implement actions necessary to achieve planned results and maintain the effectiveness of these processes	49-52	MA	11-20-19	good		12-1-19
4.1.3d	For each quality management system process, the organization shall monitor, measure as appropriate, and analyse these processes	49-52	MA	11-20-19	good		12-1-19
4.1.3e	For each quality management system process, the organization shall establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5)	49-52	MA	11-20-19	good		12-1-19
4.1.4	The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be: evaluated for their impact on the quality management system; controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.	51-52	MA	11-20-19	good		12-1-19
4.1.5a	The standard requires that if the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes.	21	MA	11-21-19	more clear information needed	reviewed and sustained	12-1-19
4.1.5b	The standard requires that controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements. The controls shall include written quality agreements.	38	MA	11-21-19	good		12-1-19
4.1.6	The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.	45	MA	11-21-19	good		12-1-19
4.2.1a	The quality management system documentation (see 4.2.4) shall include documented statements of a quality policy and quality objectives	20	MA	11-21-19	More information needed about the quality management	Added section on quality assurance to document control	12-1-19



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4.2.1b	The quality management system documentation (see 4.2.4) shall include a quality manual	21	MA	11-21-19	More information needed about the quality management	entire document is quality manual	12-1-19
4.2.1c	The quality management system documentation (see 4.2.4) shall include documented procedures and records required by this International Standard	20,21	MA	11-21-19	More information needed about the quality management	Added section on quality assurance to document control	12-1-19
4.2.1d	The quality management system documentation (see 4.2.4) shall include documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes	20,21	MA	11-21-19	More information needed about the quality management	quality test results document was added	12-1-19
4.2.1e	The quality management system documentation (see 4.2.4) shall include other documentation specified by applicable regulatory requirements	20,21	MA	11-21-19	More information needed about the quality management	we have attached IRB forms for those regulatory requirements	12-1-19
4.2.2a	The organization shall document a quality manual that includes the scope of the quality management system, including details of and justification for any exclusion or non-application	20,21	MA	11-21-19	More information needed about the quality management	Added section on quality assurance to document control	12-1-19
4.2.2b	The organization shall document a quality manual that includes the documented procedures for the quality management system, or reference to them	20,21	MA	11-21-19	More information needed about the quality management	Added section on quality assurance to document control	12-1-19
4.2.2c	The organization shall document a quality manual that includes a description of the interaction between the processes of the quality management system. The quality manual shall outline the structure of the documentation used in the quality management system.	34	MA	11-21-19		covered on 34, document control flowchart	12-1-19
4.2.3	For each medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements. The content of the file(s) shall include, but is not limited to: general description of the medical device, intended use/purpose, and labelling, including any instructions for use, specifications for product; specifications or procedures for manufacturing, packaging, storage, handling and distribution; procedures for measuring and monitoring; as appropriate, requirements for installation; as appropriate, procedures for servicing.	23	MA	11-21-19	it needs more details	reviewed comprehensive purpose, instructions for setup and use, manufacturing, packaging, sterilization, shipping, and handling procedures. Servicing protocol was added.	12-1-19



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4.2.4	Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.5.A documented procedure shall define the controls needed to: review and approve documents for adequacy prior to issue; review, update as necessary and re-approve documents; ensure that the current revision status of and changes to documents are identified; ensure that relevant versions of applicable documents are available at points of use;e)ensure that documents remain legible and readily identifiable; ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled; prevent deterioration or loss of documents;h)prevent the unintended use of obsolete documents and apply suitable identification to them.The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions.The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable regulatory requirements.	missing	MA	11-21-19		document control specifications were reviewed and sustained in their entirety.	12-1-19
4.2.5	Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements.Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization	23	MA	11-21-19	needs more details	document control specifications were reviewed and sustained in their entirety.	12-1-19
5.1	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by: communicating to the organization the importance of meeting customer as well as applicable regulatory requirements; establishing the quality policy; ensuring that quality objectives are established; conducting management reviews; ensuring the availability of resources.	23,34,41	MA	11-21-19	good		12-1-19
5.2	Top management shall ensure that customer requirements and applicable regulatory requirements are determined and met.	23,34,41	MA	11-21-19	good		12-1-19

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5.3	Top management shall ensure that the quality policy: is applicable to the purpose of the organization; includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system; provides a framework for establishing and reviewing quality objectives; is communicated and understood within the organization; is reviewed for continuing suitability.	23,34,41	MA	11-21-19	good		12-1-19
5.4.1	Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.	23,34,41	MA	11-21-19	good		12-1-19
5.4.2	Top management shall ensure that: the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives; the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented	23,34,41	MA	11-21-19	good		12-1-19
5.5.1	Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization. Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.	23,34,41	MA	11-21-19	good		12-1-19
5.5.2	Top management shall appoint a member of management who, irrespective of other responsibilities, has responsibility and authority that includes: ensuring that processes needed for the quality management system are documented; reporting to top management on the effectiveness of the quality management system and any need for improvement; ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.	23,34,41	MA	11-21-19	good		12-1-19
5.5.3	Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.	23,34,41	MA	11-21-19	good		12-1-19
5.6.1	The organization shall document procedures for management review. Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.5)	23,34,41	MA	11-21-19	good		12-1-19
5.6.2	The input to management review shall include, but is not limited to, information arising from: feedback; complaint handling; reporting to regulatory authorities; audits; monitoring and measurement of processes; monitoring and measurement of product; corrective action; preventive action; follow-up actions from previous management reviews; changes that could affect the quality management system; recommendations for improvement; applicable new or revised regulatory requirements.	41,47	MA	11-21-19	good		12-1-19



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5.6.3	The output from management review shall be recorded (see 4.2.5) and include the input reviewed and any decisions and actions related to: improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes; improvement of product related to customer requirements; changes needed to respond to applicable new or revised regulatory requirements; resource needs.	34, 51-52	MA	11-21-19	good		12-1-19
6.1a	The organization shall determine and provide the resources needed to implement the quality management system and to maintain its effectiveness	34	MA	11-21-19	good		12-1-19
6.1b	The organization shall determine and provide the resources needed to meet applicable regulatory and customer requirements.	34	MA	11-21-19	good		12-1-19
6.2.1	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.	3	AS	11-19-19	good		12-1-19
6.2.2	The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.	3	AS	11-19-19	good		12-1-19
6.2.3a	The organization shall determine the necessary competence for personnel performing work affecting product quality	3	AS	11-19-19	good		12-1-19
6.2.3b	The organization shall provide training or take other actions to achieve or maintain the necessary competence	3	AS	11-19-19	good		12-1-19
6.2.3c	The organization shall evaluate the effectiveness of the actions taken	4	AS	11-19-19	good		12-1-19
6.2.3d	The organization shall ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives	2	AS	11-19-19	good		12-1-19
6.2.3e	The organization shall maintain appropriate records of education, training, skills and experience	25	AS	11-19-19	good		12-1-19
6.3	The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product.	34	AS	11-19-19	good		12-1-19
6.3.1	Infrastructure includes, as appropriate: buildings, workspace and associated utilities; process equipment (both hardware and software); supporting services (such as transport, communication, or information systems)	23	AS	11-19-19	explain further	Added information on workspace and utilities	12-1-19
6.3.2	The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement.	23	AS	11-19-19	more detail	Added information on the maintenance procedure	12-1-19
6.4.1	The organization shall document the requirements for the work environment needed to achieve conformity to product requirements. If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment. The organization shall: document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance; ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person. NOTE Further information can be found in ISO14644 and ISO14698	42	AS	11-19-19	good		12-1-19

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6.4.2	As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.	44	AS	11-19-19	good	12-1-19
7.1	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5). In planning product realization, the organization shall determine the following, as appropriate: quality objectives and requirements for the product; the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment; required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance; records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5). The output of this planning shall be documented in a form suitable for the organization's method of operations. NOTE Further information can be found in ISO14971.	43	AS	11-19-19	good	12-1-19
7.2.1	The organization shall determine: requirements specified by the customer, including the requirements for delivery and post-delivery activities; requirements not stated by the customer but necessary for specified or intended use, as known; applicable regulatory requirements related to the product; any user training needed to ensure specified performance and safe use of the medical device; any additional requirements determined by the organization.	23	AS	11-19-19	good	12-1-19
7.2.2	The organization shall review the requirements related to product. This review shall be conducted prior to the organization's commitment to supply product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that: product requirements are defined and documented; contract or order requirements differing from those previously expressed are resolved; applicable regulatory requirements are met; any user training identified in accordance with 7.2.1 is available or planned to be available; the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.5). When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.			11-19-19	good	12-1-19

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7.2.3	The organization shall plan and document arrangements for communicating with customers in relation to: product information; enquiries, contracts or order handling, including amendments; customer feedback, including complaints; advisory notices. The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.	missing	AS	11-19-19		12-1-19
7.3.1	The organization shall document procedures for design and development.	43	AS	11-19-19	good	12-1-19
7.3.2	The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses. During design and development planning, the organization shall document: the design and development stages; the review(s) needed at each design and development stage; the verification, validation, and design transfer activities that are appropriate at each design and development stage; the responsibilities and authorities for design and development; the methods to ensure traceability of design and development outputs to design and development inputs; the resources needed, including necessary competence of personnel.	43	AS	11-19-19	good	12-1-19
7.3.3	Inputs relating to product requirements shall be determined and records maintained (see 4.2.5). These inputs shall include: functional, performance, usability and safety requirements, according to the intended use; applicable regulatory requirements and standards; applicable output(s) of risk management; as appropriate, information derived from previous similar designs; other requirements essential for design and development of the product and processes. These inputs shall be reviewed for adequacy and approved. Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other. NOTE Further information can be found in IEC62366-1.	44	AS	11-19-19	good	12-1-19
7.3.4	Design and development outputs shall: meet the input requirements for design and development; provide appropriate information for purchasing, production and service provision; contain or reference product acceptance criteria; specify the characteristics of the product that are essential for its safe and proper use. The outputs of design and development shall be in a form suitable for verification against the design and development inputs and shall be approved prior to release. Records of the design and development outputs shall be maintained (see 4.2.5).	55	AS	11-19-19	good	12-1-19
7.3.5	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and documented arrangements to: evaluate the ability of the results of design and development to meet requirements; identify and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel. Records of the results of the reviews and any necessary actions shall be maintained and include the identification of the design under review, the participants involved and the date of the review (see 4.2.5).	44	AS	11-19-19	good	12-1-19



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7.3.6	Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements. The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced. Records of the results and conclusions of the verification and necessary actions shall be maintained (see 4.2.4 and 4.2.5)	47	AS	11-19-19	good	12-1-19
7.3.7	Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. The organization shall document validation plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. Design validation shall be conducted on representative product. Representative product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded (see 4.2.5). As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements. A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced. Validation shall be completed prior to release for use of the product to the customer. Records of the results and conclusion of validation and necessary actions shall be maintained (see 4.2.4 and 4.2.5).	missing	AS	11-19-19		12-1-19
7.3.8	The organization shall document procedures for transfer of design and development outputs to manufacturing. These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements. Results and conclusions of the transfer shall be recorded (see 4.2.5).	missing	AS	11-19-19	good	12-1-19
7.3.9	The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use. Design and development changes shall be identified. Before implementation, the changes shall be: reviewed; verified; validated, as appropriate; approved. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes. Records of changes, their review and any necessary actions shall be maintained (see 4.2.5)	20	AS	11-19-19	good	12-1-19

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7.3.10	The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.	20	AS	11-19-19	good	12-1-19
7.4.1	The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information. The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be: based on the supplier's ability to provide product that meets the organization's requirements; based on the performance of the supplier; based on the effect of the purchased product on the quality of the medical device; proportionate to the risk associated with the medical device. The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process. Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements. Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (see 4.2.5).	20	AS	11-19-19	good	12-1-19
7.4.2	Purchasing information shall describe or reference the product to be purchased, including as appropriate: product specifications; requirements for product acceptance, procedures, processes and equipment; requirements for qualification of supplier personnel; quality management system requirements. The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier. Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements. To the extent required for traceability given in 7.5.9, the organization shall maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5).	44	AS	11-19-19	good	12-1-19
7.4.3	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product. When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device. When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information. Records of the verification shall be maintained (see 4.2.5).	44	AS	11-19-19	good	12-1-19

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7.5.1	Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: documentation of procedures and methods for the control of production (see 4.2.4); qualification of infrastructure; implementation of monitoring and measurement of process parameters and product characteristics; availability and use of monitoring and measuring equipment; implementation of defined operations for labelling and packaging; implementation of product release, delivery and post-delivery activities. The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved	44	AS	11-19-19	elaborate on post delivery	Covered more in depth in product release procedure	12-1-19
7.5.2	The organization shall document requirements for cleanliness of product or contamination control of product if: product is cleaned by the organization prior to sterilization or its use; product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use, and its cleanliness is of significance in use; product is supplied to be used non-sterile, and its cleanliness is of significance in use; process agents are to be removed from product during manufacture.	23	AS	11-19-19	good		12-1-19
7.5.3	The organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate. If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation. Records of medical device installation and verification of installation performed by the organization or its supplier shall be maintained (see 4.2.5).	23	AS	11-19-19	good		12-1-19
7.5.4	If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met. The organization shall analyse records of servicing activities carried out by the organization or its supplier: to determine if the information is to be handled as a complaint; as appropriate, for input to the improvement process. Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5).	missing	AS	11-19-19		Covered in product release procedure	12-1-19
7.5.5	The organization shall maintain records of the sterilization process parameters used for each sterilization batch (see 4.2.5). Sterilization records shall be traceable to each production batch of medical devices.	23	AS	11-19-19	good		12-1-19



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7.5.6	The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results consistently. The organization shall document procedures for validation of processes, including: defined criteria for review and approval of the processes; equipment qualification and qualification of personnel; use of specific methods, procedures and acceptance criteria; as appropriate, statistical techniques with rationale for sample sizes; requirements for records (see 4.2.5); revalidation, including criteria for revalidation; approval of changes to the processes. The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications. Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).	23	AS	11-19-19	good	12-1-19
7.5.7	The organization shall document procedures (see 4.2.4) for the validation of processes for sterilization and sterile barrier systems. Processes for sterilization and sterile barrier systems shall be validated prior to implementation and following product or process changes, as appropriate. Records of the results and, conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5). NOTE Further information can be found in ISO11607-1 and ISO11607-2.	23	AS	11-19-19	good	12-1-19
7.5.8	The organization shall document procedures for product identification and identify product by suitable means throughout product realization. The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed. If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device. The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.	26	AS	11-19-19	good	12-1-19
7.5.9.1	The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (see 4.2.5).	28	AS	11-19-19	good	12-1-19

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7.5.9.2	The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements. The organization shall require that suppliers of distribution services or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained (see 4.2.5).	28	AS	11-19-19	good	12-1-19
7.5.10	The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.5).	29	AS	11-19-19	good	12-1-19
7.5.11	The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: designing and constructing suitable packaging and shipping containers; documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded (see 4.2.5)	23	AS	11-19-19	good	12-1-19

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7.6	<p>The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization shall document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. As necessary to ensure valid results, measuring equipment shall: be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.5); be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded (see 4.2.5); have identification in order to determine its calibration status; be safeguarded from adjustments that would invalidate the measurement result; be protected from damage and deterioration during handling, maintenance and storage. The organization shall perform calibration or verification in accordance with documented procedures. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action in regard to the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.5). The organization shall document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications. Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5). NOTE Further information can be found in ISO10012</p>	23,43	AS	11-19-19	good	12-1-19
8.2.2	<p>The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements. These procedures shall include at a minimum requirements and responsibilities for: a) receiving and recording information; b) evaluating information to determine if the feedback constitutes a complaint; c) investigating complaints; d) determining the need to report the information to the appropriate regulatory authorities; e) handling of complaint-related product; f) determining the need to initiate corrections or corrective actions. If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented. If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved. Complaint handling records shall be maintained (see 4.2.5).</p>	23	JR	11-19-19		12-1-19



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8.2.3	If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities. Records of reporting to regulatory authorities shall be maintained (see 4.2.5).	23		11-19-19			12-1-19
8.2.4	The organization shall conduct internal audits at planned intervals to determine whether the quality management system: conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements; is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results. NOTE Further information can be found in ISO19011.	3	AS	11-19-19	more detail about who specifically will audit	Added to product release procedure	12-1-19
8.2.5	The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.	3	AS	11-19-19	again I'd make obvious in charts	Covered in product release procedure	12-1-19
8.2.6	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures. Evidence of conformity to the acceptance criteria shall be maintained. The identity of the person authorizing release of product shall be recorded (see 4.2.5). As appropriate, records shall identify the test equipment used to perform measurement activities. Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed. For implantable medical devices, the organization shall record the identity of personnel performing any inspection or testing.	43	AS	11-19-19	good		12-1-19
8.3.1	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product. The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity. Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained (see 4.2.5)	43	AS	11-19-19	good		12-1-19

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8.3.2	The organization shall deal with nonconforming product by one or more of the following ways:	23	AS	11-19-19	maybe put these all under one so they are more intentional	Addressed in product release procedure	12-1-19
8.3.2a	a) taking action to eliminate the detected nonconformity;	23	AS	11-19-19	" "	Addressed in product release procedure	12-1-19
8.3.2b	b) taking action to preclude its original intended use or application	23	AS	11-19-19	" "	Addressed in product release procedure	12-1-19
8.3.2c	c) authorizing its use, release or acceptance under concession	23	AS	11-19-19	" "	Addressed in product release procedure	12-1-19
8.3.2	The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained (see 4.2.5).	Missing	AA	11-19-19		Addressed in product release procedure	12-1-19
8.3.4	The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure. After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements. Records of rework shall be maintained	missing	AA	11-19-19		clause added to product verifications in document control	12-1-19
8.4	The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from:	34	AA	11-19-19	It will be better if you can describe the flow chart in words	added section in quality assurance to describe process	12-1-19
8.4a	a) feedback	34	AA	11-19-19	Document retrieval process doesn't have feedback	document retrieval process does not need feedback	12-1-19
8.4b	b) conformity to product requirements	34	AA	11-19-19	good		12-1-19
8.4c	c) characteristics and trends of processes and product, including opportunities for improvement;	34	AA	11-19-19	It will be better if you can describe the flow chart in words		12-1-19
8.4d	d) suppliers	34	AA	11-19-19	It will be better if you can describe the flow chart in words		12-1-19
8.4e	e) audits	34	AA	11-19-19	It will be better if you can describe the flow chart in words		12-1-19

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8.4f	f) service reports, as appropriate.	34	AA	11-19-19	It will be better if you can describe the flow chart in words		12-1-19
8.4	If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5. Records of the results of analyses shall be maintained	34	AA	11-19-19	It will be better if you can describe the flow chart in words		12-1-19
8.5.1	The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, postmarket surveillance, analysis of data, corrective actions, preventive actions and management review.	34,38	AA	11-19-19	good		12-1-19
8.5.2	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered. The organization shall document a procedure to define requirements for:	34,38	AA	11-19-19	good		12-1-19
8.5.2a	a) reviewing nonconformities (including complaints)	42and 37	AA	11-19-19	the study may help to receive the complaints but it should also include in your daument control	Added to document filing	12-1-19
8.5.2b	b) determining the causes of nonconformities;	missing	AA	11-19-19		Not missing. FMEA spreadsheet.	12-1-19
8.5.2c	c) evaluating the need for action to ensure that nonconformities do not recur	missing	AA	11-19-19		Not missing. FMEA spreadsheet.	12-1-19
8.5.2d	d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation	34	AA	11-19-19	good		12-1-19
8.5.2e	e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device	42	AA	11-19-19	good		12-1-19
8.5.2f	f) reviewing the effectiveness of corrective action taken	23	AA	11-19-19		Present in product release specifications.	12-1-19
8.5.3	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems. The organization shall document a procedure to describe requirements for:	missing	AA	11-19-19		Added to QM5 in product verification.	12-1-19
8.5.3a	a) determining potential nonconformities and their causes;	missing	AA	11-12-19		Present in FMEA spreadsheet	12-1-19
8.5.3b	b) evaluating the need for action to prevent occurrence of nonconformities	missing	AA	11-12-19		Added to QM5 in product verification.	12-1-19
8.5.3c	c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;	16	AA	11-12-19	good		12-1-19
8.5.3d	d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device	16	AA	11-19-19	good		12-1-19