

FMEA of Final Design Concept – Balance Training Bicycle

NOTE: Risk Priority = Severity x Occurrence x Detection

Failure	Effect	Severity	Occurrence	Detection	Risk Priority	Corrective or Preventative Measure	Severity	Occurrence	Detection	Risk Priority
<u>Tilt Resistance Mechanism:</u>										
Mechanism fails (cable or connections break).	Bike falls to ground resulting in patient/PT injury.	9	3	3	81	Second backup cable attached between handlebars and pulley stand.	9	1	1	9
Pinch points.	Injury to PT/patient.	3	2	1	6	Place cover/guard over entire tilt resistance mechanism.	3	1	1	3
Power to winch is shut off.	Winch locks at the current position. Unable to change tilt resistance level.	1	1	1	1	None needed.	1	1	1	1
Winch exceeds range limit of spring compression.	Damage to handlebar post. Damage to pulley system.	3	5	1	15	Use travel limit switch on winch to cut off power when specified point in cable is exceeded. Or, place “winch stopper” on cable to make audible noise and to stop pull of cable when specified point on cable is reached.	3	1	1	3
<u>Axle:</u>										
Axle could shift forward if kicked, or during transportation.	Bike could become unstable while patient is riding. Result in patient injury. Premature wear and rubbing between bearings and seat/handlebar posts.	9	3	3	81	Turn a groove into the axle that the set screw in the bearing will rest in, to prevent axle from sliding forward/backward.	9	1	1	9
Cross member is a trip hazard.	Patient trips and falls.	9	7	1	63	Keep cross member as low as possible. (Below 12 inches.)	9	2	1	18
<u>Handlebars:</u>										
Handlebars could fall when angle is being adjusted.	Injure patient by bruising. Strike and damage part of bike. Break adjustment hinge.	7	5	1	35	Handlebar hinge rotates to 65 degrees max.	7	1	1	7
Bacteria growth on handle grips.	Spread of germs between patients/PT.	3	9	7	189	Use grips that are made out of material that is able to be wiped down / cleaned (rubber/plastic/nylon/leather).	3	1	7	21
<u>Portability:</u>										
Heavy weight of bike.	PT injures them self trying to lift bike (even with wheel barrow design).	9	2	2	36	Ensure the force necessary to lift the rear of the bike is no more than 35 pounds.	9	1	1	9

Failure	Effect	Severity	Occurrence	Detection	Risk Priority	Corrective or Preventative Measure	Severity	Occurrence	Detection	Risk Priority
<u>Steel Frame:</u>										
Rusting/deterioration of surface on steel assembly.	Rough surface, weakened strength of material resulting in bike frame failure.	9	3	2	54	Anodize/protective coating (paint) on metal frame materials.	9	1	2	18
Entire bike frame becomes unstable on falls over while in use.	Patient and PT injury.	9	3	2	54	Support legs extend out far enough to counteract the moment created by the heaviest (300 lbs) patient.	9	1	1	9
<u>Spring Loaded Pin Adjustments:</u>										
Pin does not fully engage when making adjustments.	Handlebars/seat – unexpected movement when weight applied. Patient could be startled, fall.	7	5	5	175	Use spring plunger pin that automatically engages into accessible slot. Use of color, i.e. red when not fully seated, click in place (sounds and feel). Tube to guide pin through entire shaft (may not be necessary with small diameter shaft).	7	1	2	14
<u>Human Error:</u>										
Recommended weight limit is exceeded.	Bike fails under patient weight.	9	1	5	45	Place highly visible Weight Limit warning label/sticker (front of handlebars).	9	1	1	9
Patient attempts to mount bike while it is not in the Upright Locked Position.	Patient instability resulting in injury.	5	5	2	50	Warning Label/sticker on side of seat: "Place bike in Upright Locked Position BEFORE mounting" (possibly use picture illustration).	5	2	2	20
PT trips over back support legs.	Annoyance, injury to PT/patient from fall.	5	7	2	70	Place anti-fatigue rubber mat with cutouts around support legs to provide flat standing platform.	5	1	1	5
Hand slipping off handlebar.	Patient instability.	1	5	1	5	Use ergonomic rubber grips, and place tear-away hand straps on handlebars.	1	1	1	1
Foot slipping off pedal.	Patient instability.	3	5	1	15	Use pedals fitted with rubber foot straps to allow foot to slide back, but not forward or side-to-side.	3	1	1	3
Patient slipping off seat.	Patient falls resulting in injury.	9	1	1	9	It is assumed that the PT will use the Velcro Belt on all patients, and will have control of patient at all times. Use textured seat to increase friction.	9	1	1	9