

# P15001 - Active Ankle Foot Orthotic

## **Customer Requirement**

### *Fruition Plan - MSD ii*

Updated: 5/7/15 - Week 14 - Phase 5

# Customer Requirements

Customer Requirements Status & Fruition Plan | P15001 5/7/15

Category	Customer Rqmt. #	Importance	Description	Comments/Status
Safe	S1	9	safe for daily operation	
	S2	9	energy stored safely	
Functional	FT1	9	hold foot up when stepping forward	
	FT2	3	range of motion to allow full dorsiflexion and plantar flexion	Based on no spasticity
	FT3	3	operate smoothly/simulate normal muscle behavior	
	FT4	9	allow for extended use without straining leg from weight	
	FT5	1	Low battery alert	
Portable	P1	3	last for a full day without recharging/refueling	
	P2	3	stay secure throughout the day	
Comfortable	CF1	9	Tolerable to wear for full day use	
	CF2	9	Not constrict blood flow	
	CF3	3	allow wide size range of users	
	CF4	1	allow normal cooling of leg	
	CF5	9	allow bending of knee	
	CF6	1	aesthetically pleasing	
	CF7	3	low noise	
Durable	D1	3	reliable for day to day usage	
	D2	1	usable in rain/shower	
Sense Terrain	ST1	9	allow natural movement up and down stairs and ramps	
	ST2	9	adapt to different terrains	
	ST3	3	fast system response between sensing and doing	
	ST4	3	correctly interprets sensor information	
	ST5	9	support foot drop over obstacles	
Convenient	C1	9	fit into normal shoe size	
	C2	1	reduce time and cost of custom fitting process	
	C3	3	easy to take off and put on	
	C4	1	easy patient interface with sensing system	

Legend	Complete
	Pending
	Problematic

# Phase 3 Week 8 Status

Customer Requirements Status & Fruition Plan | P15001 5/7/15

Category	Customer Rqmt. #	Importance	Description	Comments/Status
Safe	S1	9	safe for daily operation	
	S2	9	energy stored safely	
Functional	FT1	9	hold foot up when stepping forward	
	FT2	3	range of motion to allow full dorsiflexion and plantar flexion	Based on no spasticity
	FT3	3	operate smoothly/simulate normal muscle behavior	
	FT4	9	allow for extended use without straining leg from weight	
	FT5	1	Low battery alert	
Portable	P1	3	last for a full day without recharging/refueling	
	P2	3	stay secure throughout the day	
Comfortable	CF1	9	Tolerable to wear for full day use	
	CF2	9	Not constrict blood flow	
	CF3	3	allow wide size range of users	
	CF4	1	allow normal cooling of leg	
	CF5	9	allow bending of knee	
	CF6	1	aesthetically pleasing	
	CF7	3	low noise	
Durable	D1	3	reliable for day to day usage	
	D2	1	usable in rain/shower	
Sense Terrain	ST1	9	allow natural movement up and down stairs and ramps	
	ST2	9	adapt to different terrains	
	ST3	3	fast system response between sensing and doing	
	ST4	3	correctly interprets sensor information	
	ST5	9	support foot drop over obstacles	
Convenient	C1	9	fit into normal shoe size	
	C2	1	reduce time and cost of custom fitting process	
	C3	3	easy to take off and put on	
	C4	1	easy patient interface with sensing system	

Legend	Complete
	Pending
	Problematic

# Phase 4 Week 9

Customer Requirements Status & Fruition Plan | P15001 5/7/15

Category	Customer Rqmt. #	Importance	Description	Comments/Status
Safe	S1	9	safe for daily operation	
	S2	9	energy stored safely	
Functional	FT1	9	hold foot up when stepping forward	
	FT2	3	range of motion to allow full dorsiflexion and plantar flexion	Based on no spasticity
	FT3	3	operate smoothly/simulate normal muscle behavior	
	FT4	9	allow for extended use without straining leg from weight	
	FT5	1	Low battery alert	
Portable	P1	3	last for a full day without recharging/refueling	
	P2	3	stay secure throughout the day	
Comfortable	CF1	9	Tolerable to wear for full day use	
	CF2	9	Not constrict blood flow	
	CF3	3	allow wide size range of users	
	CF4	1	allow normal cooling of leg	
	CF5	9	allow bending of knee	
	CF6	1	aesthetically pleasing	
	CF7	3	low noise	
Durable	D1	3	reliable for day to day usage	
	D2	1	usable in rain/shower	
Sense Terrain	ST1	9	allow natural movement up and down stairs and ramps	
	ST2	9	adapt to different terrains	
	ST3	3	fast system response between sensing and doing	
	ST4	3	correctly interprets sensor information	
	ST5	9	support foot drop over obstacles	
Convenient	C1	9	fit into normal shoe size	
	C2	1	reduce time and cost of custom fitting process	
	C3	3	easy to take off and put on	
	C4	1	easy patient interface with sensing system	

Legend	Complete
	Pending
	Problematic

# Phase 4 Week 10

Customer Requirements Status & Fruition Plan | P15001 5/7/15

Category	Customer Rqmt. #	Importance	Description	Comments/Status
Safe	S1	9	safe for daily operation	
	S2	9	energy stored safely	
Functional	FT1	9	hold foot up when stepping forward	
	FT2	3	range of motion to allow full dorsiflexion and plantar flexion	Based on no spasticity
	FT3	3	operate smoothly/simulate normal muscle behavior	
	FT4	9	allow for extended use without straining leg from weight	
	FT5	1	Low battery alert	
Portable	P1	3	last for a full day without recharging/refueling	
	P2	3	stay secure throughout the day	
Comfortable	CF1	9	Tolerable to wear for full day use	
	CF2	9	Not constrict blood flow	
	CF3	3	allow wide size range of users	
	CF4	1	allow normal cooling of leg	
	CF5	9	allow bending of knee	
	CF6	1	aesthetically pleasing	
	CF7	3	low noise	
Durable	D1	3	reliable for day to day usage	
	D2	1	usable in rain/shower	
Sense Terrain	ST1	9	allow natural movement up and down stairs and ramps	
	ST2	9	adapt to different terrains	
	ST3	3	fast system response between sensing and doing	
	ST4	3	correctly interprets sensor information	
	ST5	9	support foot drop over obstacles	
Convenient	C1	9	fit into normal shoe size	
	C2	1	reduce time and cost of custom fitting process	
	C3	3	easy to take off and put on	
	C4	1	easy patient interface with sensing system	

Legend	Complete
	Pending
	Problematic

# Phase 4 Week 11

Customer Requirements Status & Fruition Plan | P15001 5/7/15

Category	Customer Rqmt. #	Importance	Description	Comments/Status
Safe	S1	9	safe for daily operation	
	S2	9	energy stored safely	
Functional	FT1	9	hold foot up when stepping forward	
	FT2	3	range of motion to allow full dorsiflexion and plantar flexion	Based on no spasticity
	FT3	3	operate smoothly/simulate normal muscle behavior	
	FT4	9	allow for extended use without straining leg from weight	
	FT5	1	Low battery alert	
Portable	P1	3	last for a full day without recharging/refueling	
	P2	3	stay secure throughout the day	
Comfortable	CF1	9	Tolerable to wear for full day use	
	CF2	9	Not constrict blood flow	
	CF3	3	allow wide size range of users	
	CF4	1	allow normal cooling of leg	
	CF5	9	allow bending of knee	
	CF6	1	aesthetically pleasing	
	CF7	3	low noise	
Durable	D1	3	reliable for day to day usage	
	D2	1	usable in rain/shower	*Not desiged for shower
Sense Terrain	ST1	9	allow natural movement up and down stairs and ramps	
	ST2	9	adapt to different terrains	
	ST3	3	fast system response between sensing and doing	
	ST4	3	correctly interprets sensor information	
	ST5	9	support foot drop over obstacles	
Convenient	C1	9	fit into normal shoe size	
	C2	1	reduce time and cost of custom fitting process	
	C3	3	easy to take off and put on	
	C4	1	easy patient interface with sensing system	

Legend	Complete
	Pending
	Problematic

# Phase 5 Week 12

Customer Requirements Status & Fruition Plan | P15001 5/7/15

Category	Customer Rqmt. #	Importance	Description	Comments/Status
Safe	S1	9	safe for daily operation	
	S2	9	energy stored safely	
Functional	FT1	9	hold foot up when stepping forward	
	FT2	3	range of motion to allow full dorsiflexion and plantar flexion	Based on no spasticity
	FT3	3	operate smoothly/simulate normal muscle behavior	
	FT4	9	allow for extended use without straining leg from weight	
	FT5	1	Low battery alert	
Portable	P1	3	last for a full day without recharging/refueling	
	P2	3	stay secure throughout the day	
Comfortable	CF1	9	Tolerable to wear for full day use	
	CF2	9	Not constrict blood flow	
	CF3	3	allow wide size range of users	
	CF4	1	allow normal cooling of leg	
	CF5	9	allow bending of knee	
	CF6	1	aesthetically pleasing	
	CF7	3	low noise	
Durable	D1	3	reliable for day to day usage	
	D2	1	usable in rain/shower	*Not desiged for shower
Sense Terrain	ST1	9	allow natural movement up and down stairs and ramps	
	ST2	9	adapt to different terrains	
	ST3	3	fast system response between sensing and doing	
	ST4	3	correctly interprets sensor information	
	ST5	9	support foot drop over obstacles	
Convenient	C1	9	fit into normal shoe size	
	C2	1	reduce time and cost of custom fitting process	
	C3	3	easy to take off and put on	
	C4	1	easy patient interface with sensing system	

Legend	Complete
	Pending
	Problematic

# Phase 5 Week 13 Imagine RIT

Customer Requirements Status & Fruition Plan | P15001 5/7/15

Category	Customer Rqmt. #	Importance	Description	Comments/Status
Safe	S1	9	safe for daily operation	
	S2	9	energy stored safely	
Functional	FT1	9	hold foot up when stepping forward	
	FT2	3	range of motion to allow full dorsiflexion and plantar flexion	Based on no spasticity
	FT3	3	operate smoothly/simulate normal muscle behavior	
	FT4	9	allow for extended use without straining leg from weight	
	FT5	1	Low battery alert	
Portable	P1	3	last for a full day without recharging/refueling	
	P2	3	stay secure throughout the day	
Comfortable	CF1	9	Tolerable to wear for full day use	
	CF2	9	Not constrict blood flow	
	CF3	3	allow wide size range of users	
	CF4	1	allow normal cooling of leg	
	CF5	9	allow bending of knee	
	CF6	1	aesthetically pleasing	
	CF7	3	low noise	
Durable	D1	3	reliable for day to day usage	
	D2	1	usable in rain/shower	*Not desiged for shower
Sense Terrain	ST1	9	allow natural movement up and down stairs and ramps	
	ST2	9	adapt to different terrains	
	ST3	3	fast system response between sensing and doing	
	ST4	3	correctly interprets sensor information	
	ST5	9	support foot drop over obstacles	
Convenient	C1	9	fit into normal shoe size	
	C2	1	reduce time and cost of custom fitting process	
	C3	3	easy to take off and put on	
	C4	1	easy patient interface with sensing system	

Legend	Complete
	Pending
	Problematic



# Phase 5 Week 14

Customer Requirements Status & Fruition Plan | P15001 5/7/15

Category	Customer Rqmt. #	Importance	Description	Comments/Status
Safe	S1	9	safe for daily operation	
	S2	9	energy stored safely	
Functional	FT1	9	hold foot up when stepping forward	
	FT2	3	range of motion to allow full dorsiflexion and plantar flexion	Based on no spasticity
	FT3	3	operate smoothly/simulate normal muscle behavior	Small known hang-up
	FT4	9	allow for extended use without straining leg from weight	
	FT5	1	Low battery alert	
Portable	P1	3	last for a full day without recharging/refueling	
	P2	3	stay secure throughout the day	
Comfortable	CF1	9	Tolerable to wear for full day use	
	CF2	9	Not constrict blood flow	
	CF3	3	allow wide size range of users	
	CF4	1	allow normal cooling of leg	
	CF5	9	allow bending of knee	
	CF6	1	aesthetically pleasing	
	CF7	3	low noise	
Durable	D1	3	reliable for day to day usage	
	D2	1	usable in rain/shower	*Not desiged for shower
Sense Terrain	ST1	9	allow natural movement up and down stairs and ramps	
	ST2	9	adapt to different terrains	
	ST3	3	fast system response between sensing and doing	
	ST4	3	correctly interprets sensor information	
	ST5	9	support foot drop over obstacles	
Convenient	C1	9	fit into normal shoe size	
	C2	1	reduce time and cost of custom fitting process	
	C3	3	easy to take off and put on	
	C4	1	easy patient interface with sensing system	

Legend	Complete
	Pending
	Problematic

# Week 15

Customer Requirements Status & Fruition Plan | P15001 5/7/15

Category	Customer Rqmt. #	Importance	Description	Comments/Status
Safe	S1	9	safe for daily operation	
	S2	9	energy stored safely	
Functional	FT1	9	hold foot up when stepping forward	
	FT2	3	range of motion to allow full dorsiflexion and plantar flexion	Based on no spasticity
	FT3	3	operate smoothly/simulate normal muscle behavior	Small known hang-up
	FT4	9	allow for extended use without straining leg from weight	
	FT5	1	Low battery alert	
Portable	P1	3	last for a full day without recharging/refueling	
	P2	3	stay secure throughout the day	
Comfortable	CF1	9	Tolerable to wear for full day use	
	CF2	9	Not constrict blood flow	
	CF3	3	allow wide size range of users	
	CF4	1	allow normal cooling of leg	
	CF5	9	allow bending of knee	
	CF6	1	aesthetically pleasing	
	CF7	3	low noise	
Durable	D1	3	reliable for day to day usage	
	D2	1	usable in rain/shower	*Not desiged for shower
Sense Terrain	ST1	9	allow natural movement up and down stairs and ramps	
	ST2	9	adapt to different terrains	
	ST3	3	fast system response between sensing and doing	
	ST4	3	correctly interprets sensor information	
	ST5	9	support foot drop over obstacles	
Convenient	C1	9	fit into normal shoe size	
	C2	1	reduce time and cost of custom fitting process	
	C3	3	easy to take off and put on	
	C4	1	easy patient interface with sensing system	

Legend	Complete
	Pending
	Problematic