P15001 - Active Ankle Foot Orthotic

Customer Requirements Status & Fruition Plan Updated 3/18/15 Week 8

Customer Requirements

| 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 | |
| Confortable | 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

| 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 | |
| Confortable | 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

| 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 | |
| Confortable | 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

| 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 | |
| Confortable | 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

| 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 | |
| Confortable | 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 5 Week 12

| 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 | |
| Confortable | 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 5 Week 13 Imagine RIT

| 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 | |
| Confortable | 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 5 Week 14

| 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 | |
| Confortable | 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 |

Week 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 | |
| Confortable | 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 |