Medical HAL Lower Limb Type (HAL-ML07 & 08)
Summary Information for EU/MDR

1. About this document

This document is a product summary of safety and clinical performance for Medical HAL Lower Limb Type, EU/MDR model.

Scope of product models of this document: HAL-ML07 and HAL-ML08 EU model.

2. Manufacturer Information

Company Name	CYBERDYNE, INC.
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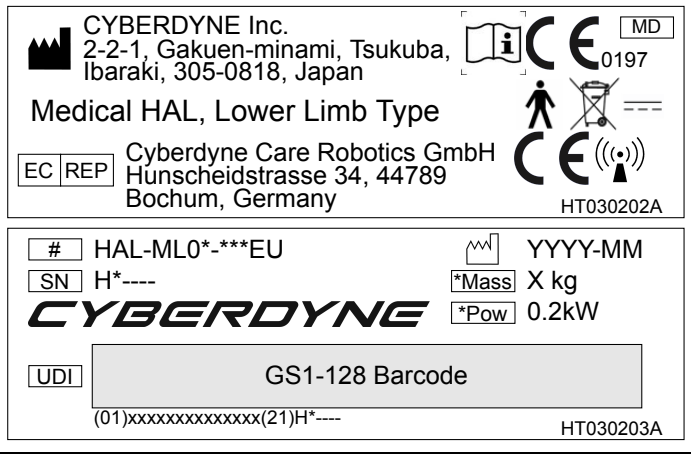
SRN	JP-MF-000026131

3. Authorized Representative Information

Company Name	Cyberdyne Care Robotics GmbH
Address	Hunscheidtstrasse 34, 44789 Bochum, Germany
SRN	DE-AR-000025326

4. Device Information

Applicable Regulation	Regulation (EU) 2017/745 (Medical Device Regulation)
Device Name	Medical HAL Lower Limb Type
Model	HAL-ML07-A2NEU (3 configuration types) HAL-ML08-AMBEU (3 x 2 configuration types) A = D/L/R, B = M/W
Basic UDI-DI	04560340093354
Device Class:	IIa
EMDN	Z12069002
Device label sample	

5. Device Description

5.1. Use Purpose

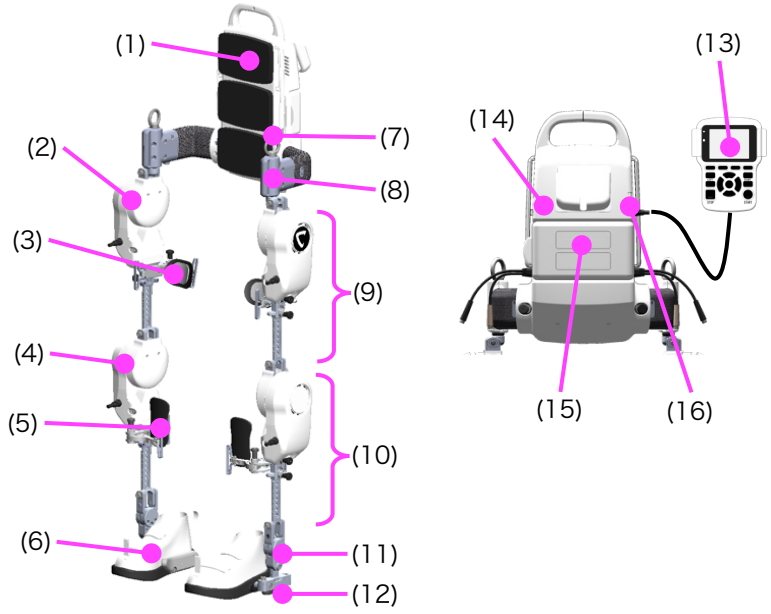
Medical HAL Lower Limb Type is a battery powered wearable cyborg device that provides assistive torque at the knee and hip joints for gait training.

HAL is intended to be used in conjunction with regular physiotherapy. HAL is intended to be used inside a medical facility under the supervision of trained medical professionals who have successfully completed the HAL training program.

The device must be used in combination with comprehensive fall prevention systems (e.g. Body Weight Support systems).

5.2. Device Structure and Variations

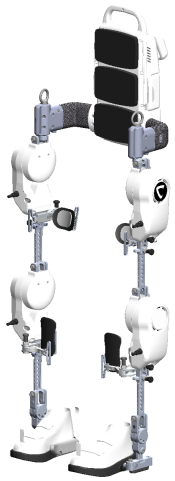
< Device Structure >



(1) Back Module
(2) Hip Power Unit
(3) Upper Leg Cuff
(4) Knee Power Unit
(5) Lower Leg Cuff
(6) Sensor Shoes
(7) Hip Hook
(8) Hip Frame
(9) Upper Leg Frame
(10) Lower Leg Frame
(11) Ankle Joint
(12) Stabilizer pad
(13) Controller
(14) Battery Level Indicator
(15) Battery Pack
(16) Power Switch

< Device Variations >

– Double leg, Right leg, and Left leg configurations.
– Different size variations: different leg lengths, different waist widths.
– Sensor shoes are available in sizes of 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30cm.

	HAL-ML07	HAL-ML08
Patient Height	Approx. 100 - 150cm	Approx. 150 - 190cm
Patient Weight	15 - 50kg	40 - 100kg
Size Variations	Leg length: 2 (=2S, Extra short) Waist width: N (Narrow)	Leg length: M (Medium) Waist width: M/W (Medium / Wide)
Device Weight	9.5kg (Double leg) 6.5kg (Single leg)	13kg (Double leg) 9kg (Single leg)
Maximum Torque	20Nm	40Nm
Appearance (double-leg type)		

5.3. Operation Principle

The device uses legally marketed cutaneous electrodes (up to 18 electrodes) to detect bioelectrical signals of the hip and knee extensor and flexor muscles when the device is used in Cybernic Voluntary Control (CVC) mode. This mode provides assistive torque at the corresponding joint (e.g., hip or knee) using surface bioelectrical signals that are processed using a propriety signal processing algorithm. The propriety processing algorithm allows the device to detect surface bioelectrical signals to control the HAL device in CVC mode and provide visualization of the surface bioelectrical signals during biofeedback training. The device can also provide two additional modes: Cybernic Autonomous Control (CAC) mode and Cybernic Impedance Control (CIC) mode. CAC mode provides assistive torque leg trajectories based on postural cues and sensor shoe measurements. CIC mode provides torque to compensate for frictional resistance of the motor based on joint motion. CIC mode does not provide torque assistance for dictating joint trajectories.

5.4. CYBERNIC Treatment

It is thought that one of the causes of diseases of the brain, nerves, and muscles lies in an abnormality of the signal transmission loop of the brain/nervous system between the brain and the peripherals that normally allows the body to function appropriately.

All of our Medical Cybernic Systems are intended to reconstruct the neural connectivity network (including the connectome of the brain) and improve/regenerate the patient's brain-neuro-physical function by promoting the improvement/strengthening of synaptic connections between the brain, nerves, and muscles. This is achieved by adjusting the patient's neurological information in a way that allows the body to appropriately function, activating the neural loop, which importantly includes the sensory nerves, through synchronization of the sensory feedback signal with the neural signal of the motor intent generated by the brain.

More specifically, in order to allow the body to function appropriately even if the signal detected at the periphery is too faint to elicit actual muscle movement, an MD can intervene by tuning the parameters embedded in the Medical Cybernic System. This intervention enables the Medical Cybernic System to realize the movement intended by the patient in place of the patient's muscles. Even if the muscles barely function, the sensory receptors such as those found in muscle spindle fibers get activated by the device's movement, and this sensory information is fed back to the brain in real-time. Because this flow/loop of information between the brain/CNS and the periphery can be established repeatedly without putting much load on the muscles, synaptic connections can be improved/strengthened through neuronal plasticity, reconstructing the neural connectivity network and thereby promoting functional improvement / regeneration. In this way, the technological characteristics of the Medical Cybernic Systems were designed with the intent to promote the reconstruction of the patient's neural connectivity network (including the connectome of the brain), and improve/regenerate the patient's brain-neuro-physical functions.

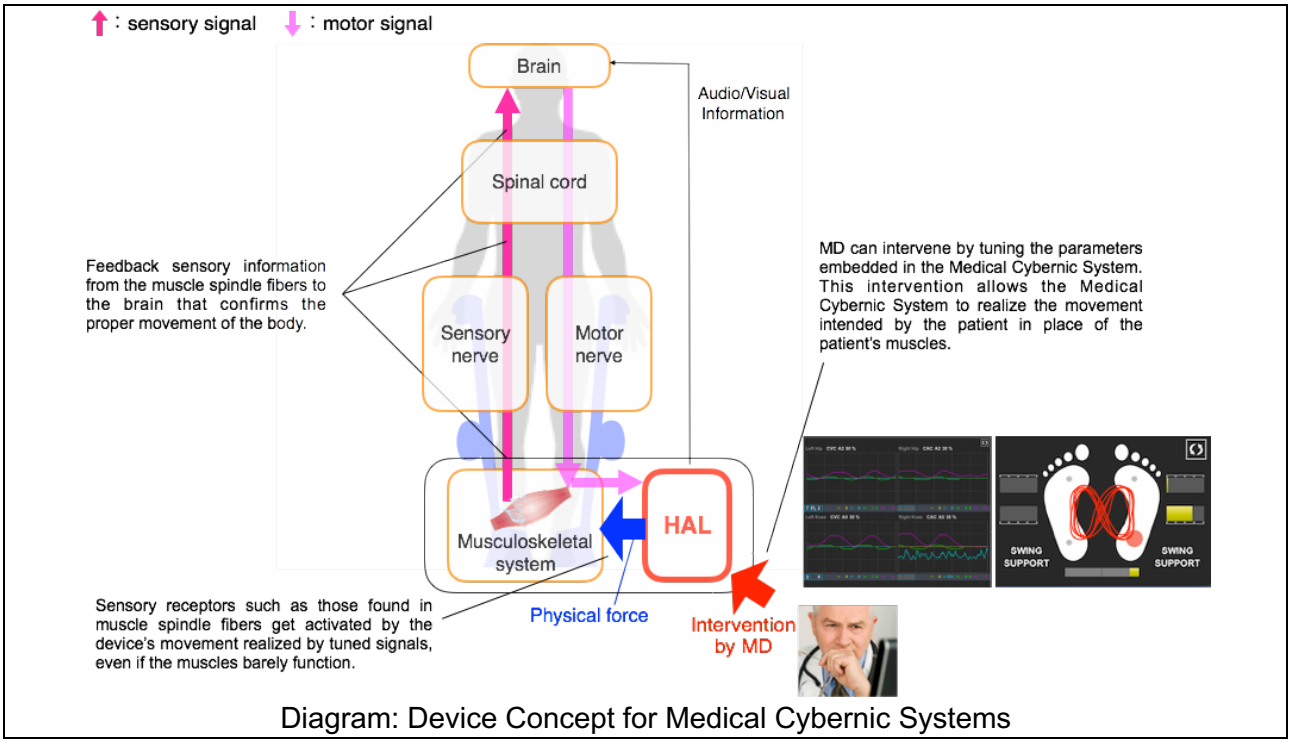


Diagram: Device Concept for Medical Cybernic Systems

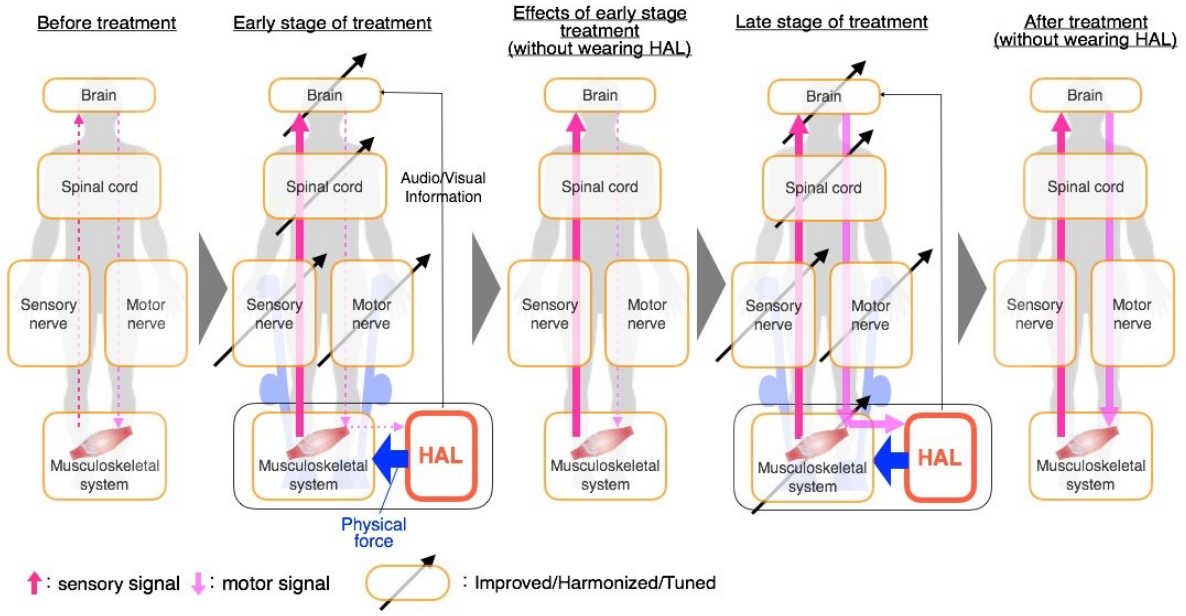


Diagram: Illustration of changes in transmission loop of the brain / nervous system with the use of Medical Cybernic Systems

In this way, the main theme of the Medical Cybernic Systems is to promote the improvement / strengthening of synaptic connections between the brain, nerves, and muscles. The physical force it delivers is merely a mechanism it uses to feedback sensory information from the muscle spindle fibers to the brain that confirms the proper movement of the body.

6. Intended Use and Indication for Use

6.1. Indications for Use

Medical HAL Lower Limb Type orthotically fits to the lower limbs and trunk.
HAL is a gait training device intended to temporarily help improve ambulation upon completion of the HAL gait training intervention. HAL must be used with a Body Weight Support system. HAL is not intended for sports or stair climbing. HAL gait training is intended to be used in conjunction with regular physiotherapy.

The device is intended for individuals with:

(A) Spinal cord injury (SCI).
(B) Post stroke paresis.
(C) Paraplegia due to progressive neuromuscular diseases (spinal muscular atrophy, spinal and bulbar muscular atrophy, amyotrophic lateral sclerosis, Charcot-Marie-Tooth disease, distal muscular dystrophy, inclusion body myositis, congenital myopathy, muscular dystrophy).
(D) Cerebral palsy.
(E) Spastic paraplegia caused by either HTLV-1 Associated Myelopathy (HAM) or hereditary spastic paraplegia (HSP).

who exhibit sufficient residual motor and movement-related functions of the hip and knee to trigger and control HAL.

In preparation for HAL gait training, the controller can be used while the exoskeleton is not donned to provide biofeedback training through the visualization of surface electromyography bioelectrical signals recorded.
HAL is intended to be used inside medical facilities while under trained medical supervision in accordance with the user assessment and training certification program.

<Supplementary Information>
When used for HAL Treatment, it must be used in combination with BWS systems:
In order to prevent falls that may lead to serious harm with certainty, combined use of comprehensive fall prevention systems that do not depend on the wearer is required.
The patient must be supported by the BWS before donning the device. The BWS must not be detached from the patient before doffing this device.

The target wearer's height and weight conditions are as follows:

Model	HAL-ML07 (2-N)	HAL-ML08 (M-M/W)
a) Height Guideline [cm] *1	100 - 150	150 - 190
b) Weight [kg]	15 - 50	40 - 100

Note *1: The product can be worn if the body size such as upper leg length, lower leg length and hip width fit, even if their height is outside this range. Conversely, even if the height is within the range, if the body size does not fit, the product cannot be worn.

6.2. Intended User (Operator)

Operators (Users) of this device are limited to the following people:

(a) Medical doctors, physiotherapists, nurses, engineers, and other medical staff who participated in the training established by CYBERDYNE Inc. and received the certificate of completion of the training.

(b) Operators other than medical doctors should use this product under the instruction of medical doctors.

Operators other than medical doctors must be under the supervision of medical doctors.
To apply for the training, contact the Call Center.

6.3. Intended Environment of Use

In order to operate this product, the battery pack, the battery charger and other supplementary components safely and correctly, ensure the following environmental conditions are satisfied.

Conditions on operating places:

- indoors
- ambient temperature: 10 - 30°C
- ambient humidity: 30 - 80% (no dew condensation)
- atmospheric pressure: standard atmospheric pressure at sea level (ref. 80kPa or higher), do not use in a flight.

Conditions on storage places:

- indoors
- ambient temperature: 0 - 40°C
- ambient humidity: 20 - 80% (no dew condensation)

Combination use with BWS:

- This device must be used in combination with BWS. The patient must be supported by the BWS before donning the device. The BWS must not be detached from the patient before doffing this device.

6.4. Limitations

Patients to whom the device is applied must meet the following conditions.

(1) Healthy bone density.
(2) In general good health.
(3) Candidates of the device should have the following characteristics:
– Hip width and leg segment lengths are within the range of adjustability.
– Height and weight of the patient should be within the range identified in the supplementary information to the indication for use.
(4) Judgment of whether this device is suitable for a person with an unusual body shape (such as deformation of the leg) shall be made after comprehensive consideration of leg length, hip width, positions of cuffs and belts, sizes of sensor shoes, and fit of the joint positions and frame to the person's body.
(5) Physical and cognitive ability to use a BWS. Use does not need to be independent of clinical support.
(6) Ability to communicate pain and need to cease session, verbally or nonverbally.
(7) Ability to acknowledge communication from the therapist, verbally or nonverbally.

6.5. Contraindications

The device shall not be applied to patients who meet the following conditions.

(1) Persons whose body dimensions such as weight, upper leg length, lower leg length and hip width, are not suitable for this device.
(2) Persons whom physicians have judged unsuitable for the implementation of therapeutic exercise such as standing and walking treatment.
(3) Persons who cannot have electrodes affixed to any part of their body due to a skin disease or any other reason. If there are target body parts that cannot have electrodes affixed due to skin disease or any other reason, Cybernic Voluntary Control (CVC) Mode cannot be used for the corresponding joints.
(4) Severe spasticity (Ashworth4).
(5) Unstable spine or unhealed limbs or pelvic fractures.
(6) Heterotopic ossification.
(7) Significant contractures.
(8) Psychiatric or cognitive situations that may interfere with:
– Proper operation of the device.
– Physical and cognitive ability to use a BWS. Use does not need to be independent of clinical support.
– Ability to communicate pain and need to cease session, verbally or nonverbally.
(9) Cognitive impairments resulting in inability to follow directions.
(10) History of severe neurological injury other than those listed in the indication for use.
(11) Persons with severe concurrent medical diseases: infections, circulatory, heart or lung, pressure sores.
(12) Persons with colostomy.
(13) Persons with uncontrolled hypertension/hypotension or decreased standing tolerance due to orthostatic hypotension.
(14) Persons with strict range of motion (ROM) restrictions that cannot tolerate the entire ROM of HAL, or that would prevent a patient from achieving a normal, reciprocal gait pattern.
(15) Persons with unresolved deep vein thrombosis.
(16) Persons with uncontrolled Autonomic Dysreflexia.
(17) Persons with lower limb prosthesis.
(18) Persons who require ventilators.
(19) Persons with epilepsy.

6.6. Warnings

Please note the following Warnings when using this device.

(1) If a BWS system is not used in conjunction with the device, the user may fall, and as a result there is a risk of death or major injury.
(2) Autonomic dysreflexia (also called autonomic hyperreflexia) is a serious medical condition associated with spinal cord injury at or above the sixth thoracic vertebral level (T6 and higher) and can affect individuals with complete or incomplete injuries. Common signs include sudden increase in blood pressure, severe headache, excessive sweating, goosebumps, blurred vision, flushed skin, nasal congestion, slow pulse, tightness in chest, and anxiety.
Autonomic dysreflexia is considered a medical emergency requiring immediate medical attention. If symptoms of autonomic dysreflexia occur while using the HAL device, immediately cease use and remove the device. The user should sit up or raise head and remain upright,

empty bowel or bladder, loosen or remove tight clothing, and monitor blood pressure until normal. If symptoms persist, seek medical attention immediately.

(3) The blood pressure and heart rate of the patient should be monitored at the following time points:
   (a) In the sitting position prior to standing
   (b) After standing up and donning the device; and
   (c) 1-2 minutes after starting to walk

(4) If there are any unsafe changes in the patient's blood pressure or heart rate, the session should be immediately terminated.

(5) Please obtain Vital Capacity (VC) before and after HAL use to assess changes in respiratory function. (for cervical patients with C4 or C5 ASIA C/D injury)

(6) Please obtain pulse oximetry readings before and after HAL use. (for cervical patients with C4 or C5 ASIA C/D injury)

(7) Please ensure that those with pulse oximetry readings of <90% prior to testing are excluded from participation. (for cervical patients with C4 or C5 ASIA C/D injury)

6.7. Precautions

Sufficient attention must be paid when this device is worn by the following type of wearer.

(1) Persons at a risk of fainting or dizziness.
   – Be careful about falls.

(2) Persons whom a physician has deemed would have problems when the belts are fastened.
   – If the belt is fastened too tightly, pinching, loss of circulation or other pain may occur.
   – If the belt is too loose, there is a risk of failure in transmitting torque to assist the wearer's motion, and a risk that the device may detach during the assistance.
   – Please be alert in order to catch early symptoms of autonomic dysreflexia. (i.e. anxiety and apprehension, irregular or racing heartbeat, nasal congestion, high blood pressure with systolic readings often over 200 mm Hg, a pounding headache, flushing of the skin, profuse sweating (particularly on the forehead), lightheadedness. dizziness, confusion, dilated pupils)

(3) Additional caution and close monitoring is recommended for the following patients:
   – patients with high risk of deep vein thrombosis.
   – patients who may not be able to safely use the device due to psychiatric disorders and cognitive dysfunction.
   – patients with significant involuntary movement in the lower extremities.
   – patients whose attending physician determines that there is a possibility that use of the device may present issues for any other reason.

(4) Significant osteoporosis that prevents safe standing or may increase the risk of fractures caused by standing or walking. Patients should be evaluated by their physician to assess severity of osteoporosis and whether they can tolerate walking and standing prior to using the device.

(5) Use of the device should be paused immediately if patient complains of pain or muscle spasms. If the muscle spasm does not resolve, treatment should be aborted.

(6) Hip dysplasia or hip axis abnormalities. Use of the device should be paused and checked for fit if the patient complains of hip discomfort or pain. If despite ensuring good fit of the device, the patient still experiences significant discomfort with the device, this device may not be appropriate for use in this patient.

(7) Patients with spatial neglect should not use the HAL device.

(8) Impulsive behavior that may lead to unsafe turns, walking or HAL use that may lead to injury to patient and trained medical professional supervision.

(9) Patients that require special physical protection during exercise shall use necessary protective equipment such as a helmet.

(10) The device must be fitted over clothing to prevent skin abrasions.

(11) Skin integrity should be assessed before and after each use to ensure tolerance is sufficient.
(12) Persons with skeletal deformations such as coxarthrosis, knee osteoarthritis, degenerative spondylosis, or lateral curvature of the spine. There is a chance that the device cannot be used properly due to the skeletal deformation. If it is orthopedically sufficiently controlled the device may be used.
(13) Women who are pregnant or want to become pregnant. Because the abdomen may be tightly fastened with the belt, consult with a doctor and only use the device if it is determined that there are no problems with its use.

If used incorrectly, there is a possibility of unintended movements, falls, injuries and damages to the device. A healthy person may wear the device to check its movements or for user training.
When using this product, always refer to its attached documents.

7. Known Adverse Events

(1) Muscle aches
(2) Pain
(3) Abrasion
(4) Light bruise (due to physical contact)

8. Conformed Standards Data

The subject devices demonstrate conformance with the following standards:

Standard number	Name of standard
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 13485:2016 +AC:2018 +A11:2021	Medical devices - Quality management system - Requirements for regulatory purposes
EN ISO 14971:2019 +A11:2021	Medical devices - Application of risk management to medical devices
EN ISO15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN 60601-1:2006 +A1:2013 +AC:2014 +A12:2014 +A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 +A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010 +A1:2015 +A2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62304:2006 +A1:2015	Medical device software - Software life cycle processes
EN 62366-1:2015 +AC:2015 +AC:2016 +A1:2020	Medical devices - Application of usability engineering to medical devices
EN IEC 80601-2-78:2020	Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation
EN IEC 80001-1:2021	Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities
EN IEC 81001-5-1:2022	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle

9. Summary of Clinical Performance Data

The clinical data for the device has been assessed by reviewing information in literature and data held by the manufacturer for each disease group.
Each study differ in terms of treatment method (frequency and total number of treatment sessions) and subjects (disease, inclusion criteria) and cannot be directly compared with each other, so they were subject to screening and appraisal to enable a thorough assessment.

9.1. Spinal Cord Injury

A: Spinal cord injury (SCI).

(a) There are 6 studies conducted on spinal cord injury subjects used for assessment of effectiveness.
(b) All studies were non-comparative and non-randomized. One study had 2 groups with different treatment frequencies.
(c) Subjects were mostly chronic SCI patients
(d) The sample size range of the studies are 8 ~ 55.
(e) Results on effectiveness is primarily measured by 10 meter walk tests, 6 minute walk tests, and WISCI-II tests, all measured without wearing the HAL device. The results suggest a statistically significant improvement in gait related outcome measures.
(f) One study showed that gains made from treatment with the HAL device were maintained for a year with continued treatment at the same treatment frequency as during the intervention, as well as with continued treatment at a much lower frequency.
(g) There were no SAEs reported, and all adverse events were minor incidents. AEs included reports of minor incidents that included: pain due to pressure from device parts that were managed by adjusting a better fit, skin irritation from electrodes and chafed feet due to wrong shoe size.
(h) Adverse events that occurred with use of other devices is unlikely to occur with the use of the HAL because falls are mitigated with a mandatory combined use with a BWS system, use on patients with low bone density is labeled as a limitation, and a swollen ankle has never been reported in our global market experience. It is assumed that the sensor shoes, which is an essential component of the HAL, protects the ankle from making physical contact with the rigid parts of the device.
(i) Long term use of the device has been tested, and the result supports long term effects of treatment even with decreased treatment frequency.

9.2. Post Stroke Paresis

B: Post stroke paresis.

(a) There are 14 studies conducted on stroke subjects used for assessment of effectiveness. Of these, 5 were studies for patients of over 6 months post stroke and 7 were for patients of less than 6 months post stroke. The remaining 2 studies monitored weekly 10MWT results during conventional physical therapy/rehabilitation after stroke, and started the intervention with HAL when the walk speeds stopped showing improvements.
(b) Some studies were comparative with a control group receiving conventional physical therapy.
(c) The sample size range of the studies are 8 ~ 53.
(d) The effectiveness is primarily measured by the 10MWT and 6MWT, all measured without wearing the HAL device. Overall, the results suggest a statistically significant improvement in gait related outcome measures. Results from studies that could not rule out the effects of

spontaneous recovery early after the onset of stroke still trended toward improvement of gait related outcome measures, and the studies that addressed spontaneous recovery, either through intervention timing or with a control group, suggest that the treatment with the device show statistically and clinically significant improvements in gait related outcome measures while conventional physical therapy does not.

(e) Results on safety suggest that there are no adverse events typical of the disease. No SAEs are reported.

(f) Though limited, there are some studies that support either lasting or long term effects.

9.3. Progressive Neuromuscular Disease

C: Paraplegia due to progressive neuromuscular diseases (spinal muscular atrophy, spinal and bulbar muscular atrophy, amyotrophic lateral sclerosis, Charcot-Marie-Tooth disease, distal muscular dystrophy, inclusion body myositis, congenital myopathy, muscular dystrophy).

(a) There are 3 studies (1 literature, 1 clinical trial and 1 post market survey) conducted on patients with diseases belonging in the group.

(b) The sample size range of the studies are 3 ~ 207.

(c) The effectiveness is primarily measured by the 10MWT and 2MWT, all measured without wearing the HAL device. Results suggest that treatment with the HAL device shows improvement in gait related outcome measures despite the progressive nature of the diseases. Since the literature and clinical trial have such small sample sizes, the findings from the post market survey bears significant weight and are quickly summarized below:
   (1) Participants showed improvement in gait related outcome measures comparing pre-post intervention of the first cycle of treatment (9 sessions).
   (2) Even after 1.5 years from the measurement of baseline, with intermittent treatment cycles participants showed about +20% difference from the baseline function, despite the progressive nature of their disease.
   (3) Blood creatine kinase data was collected from a total of 100 participants and results show a decreasing trend when comparing pre-post HAL treatment measurements. The lack of rise in CK levels suggests that HAL treatment does not damage the muscles through overuse.

(d) The safety of the device is primarily measured by SAE occurrences. No device caused SAEs are reported.

(e) Long term effects are evident from post market survey results.

9.4. Cerebral Palsy

D: Cerebral palsy.

(a) There are 4 studies (1 RCT and 3 single arm studies) conducted on patients with diseases belonging in the group.

(b) The sample size range of the studies are 6 ~ 25.

(c) The effectiveness is primarily measured by the 10MWT and total score for the GMFM (Gross Motor Function Measure), all measured without wearing the HAL device. Results suggest that treatment with the HAL device shows improvement in gait related outcome measures.

(d) The RCT reported a statistically significant intergroup difference for the GMFM total score, with the HAL group showing higher improvements compared to the control group.

(e) The safety of the device is primarily measured by SAE occurrences. No device caused SAEs are reported.

9.5. Spastic Paraplegia

E: Spastic paraplegia caused by either HTLV-1 Associated Myelopathy (HAM) or hereditary spastic paraplegia (HSP).

(a) There was a clinical trial conducted on patients with diseases belonging in the group.
(b) The sample size of the RCT trial was 41 (FAS).
(c) The effectiveness is primarily measured by the 2MWT and the main secondary measures included 10MWT and OMDS (Osame Motor Disability Score), all measured without wearing the HAL device.
(d) The 2MWT and 10MWT both showed inter group differences that were statistically significant, a results that suggests that treatment with the HAL device shows improvement in gait related outcome measures.
(e) The safety of the device is primarily measured by SAE occurrences. No device caused SAEs are reported.