HAL-ML05

Battery pack

External Appearance and Specifications

Outer Dimensions	L 43 cm (16 in) x W 48 cm (18.9 in) x H 123 cm (49 in) *1
Weight	Approximately 14 kg (30 lbs) including batteries
Range of Motion	Knee Joint: extension 6°, flexion 120° Hip Joint: extension 20°, flexion 120°
Operating Time	60 minutes *2

Knee power unit

*1 For Size S
*2 Operating Time varies depending on the operating conditions

Units: cm (in)

Size	S	M	L	X
Recommended Body Height	150-160 (59-63)	160-175 (63-69)	170-185 (67-73)	180-190 (71-75)
Upper Length	36-38 (14.2-14.9)	38-41 (15.0-16.1)	40-45 (15.8-17.7)	43-48 (17.0-18.8)
Lower Leg Length	35-38 (13.8-14.9)	37-41 (14.6-16.1)	39-45 (15.4-17.7)	42-48 (16.6-18.8)

* HAL® for Medical Use (Lower Limb Type) is full of adjustable elements that allow the device to fit to the patient's body size and shape.

Ankle joint

CYBERDYNE

Development, Manufacturing, and Sales

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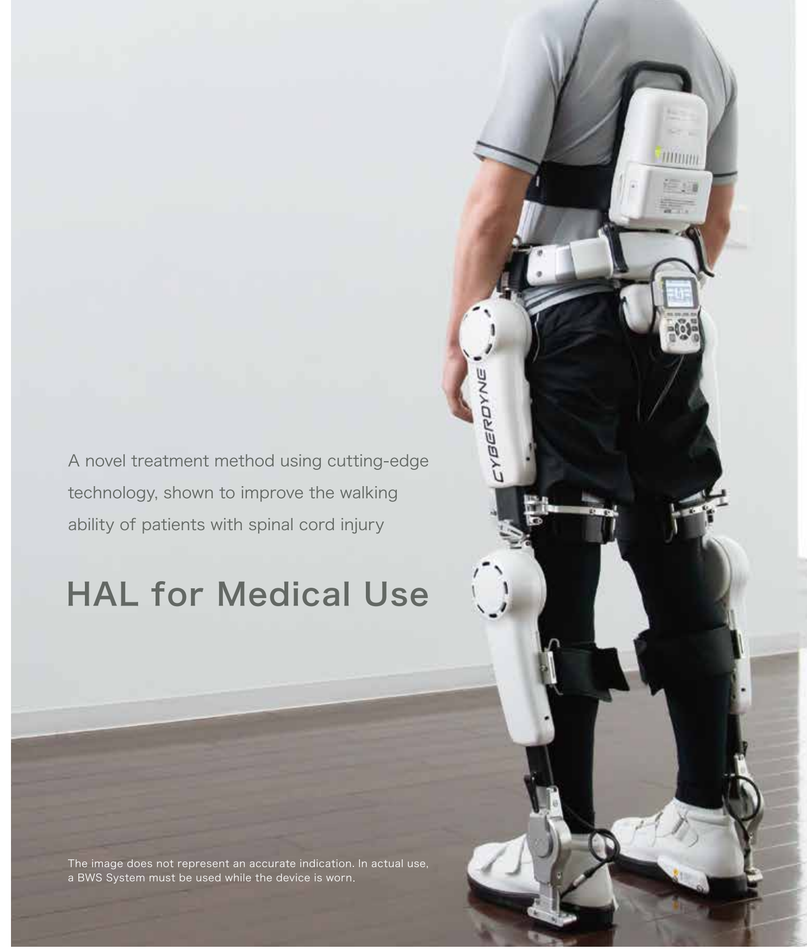
FOMPG-242-02 rev.1

A novel treatment method using cutting-edge technology, shown to improve the walking ability of patients with spinal cord injury

HAL for Medical Use



The image does not represent an accurate indication. In actual use, a BWS System must be used while the device is worn.

ROBOT SUIT
HAL®
Hybrid Assistive Limb

HAL® for Medical Use (Lower Limb Type)

CYBERDYNE

HAL for Medical Use (Lower Limb Type)

Product Model: HAL-ML05-D□□US
FDA 510(k) Number: K171909
Regulation Name: Powered Lower Extremity Exoskeleton (21 CFR 890.3480, PHL), Biofeedback Device (21 CFR 882.5050, HCC)
Regulatory Class: Class II General Controls and Special Controls

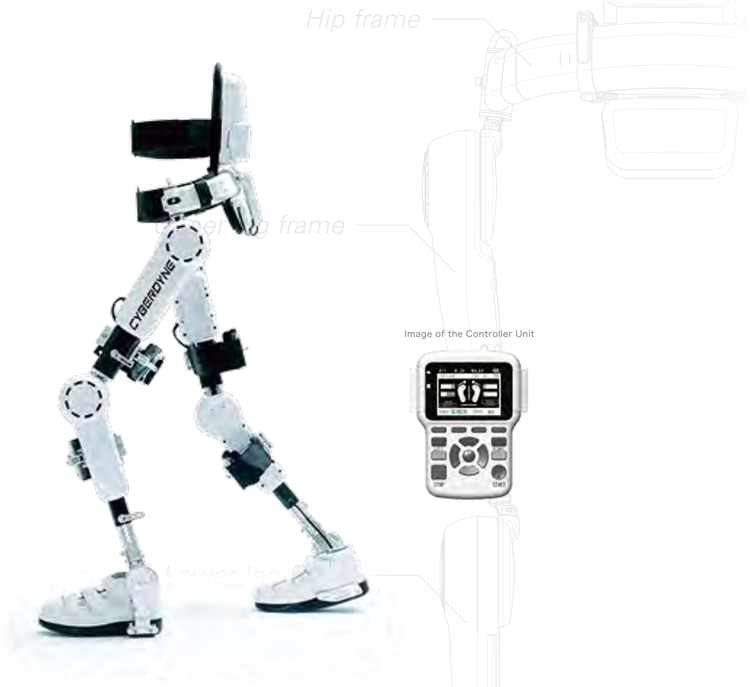


Image of the Controller Unit

Control Modes Selected at Each Joint Based on Patient Needs and Treatment Course

Cybernic Voluntary Control (CVC) Mode	Assistance Based on Bio-Electrical Signals
Cybernic Autonomous Control (CAC) Mode	Assistance Based on Previously Programmed Leg Trajectory
Cybernic Impedance Control (CIC) Mode	Minimal Assistance to Allow for Fluid Movement of the Joints

Product Characteristics

HAL for Medical Use (Lower Limb Type) is a treatment robot that is designed to improve the patient's ambulatory function outside of the robot, upon completion of the HAL gait training intervention. With the goal of leading the patient toward less dependence on mobility aids and caregivers, HAL for Medical Use (Lower Limb Type) received FDA clearance in December 2017 for the treatment of incomplete and complete spinal cord injuries. When a patient attempts to move their body, a nerve signal is sent from the brain toward the muscles via the spinal cord and motor neurons. Due to the spinal cord injury, these signals are often too weak to elicit the proper movement of the musculoskeletal system. However, HAL for Medical Use (Lower Limb Type) can detect faint bio-electrical signals in response to the brain and nervous system command at the skin surface of the target muscles. These bio-electrical signals are used to drive power units located at the hip and knee joints, allowing the patient to realize the intended movement voluntarily. By combining different Control Modes and other settings at each joint, the operating therapist or physician can customize the assistance provided by HAL for Medical Use (Lower Limb Type) to meet the patient's particular needs and cater the treatment course toward the functional improvement of problem areas.

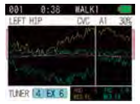
*See "Indications and Considerations" for the appropriate patient population

The operator can easily perform all operations near the patient undergoing treatment by using a controller that is easy to reach.
The many different settings can be easily adjusted, and by changing the screen it is possible to verify the patient's bio-electrical signal level at all joints (Fig. 1), the amount of load on the soles of the feet (Fig. 2), and the bio-electrical signal waveform over time (Fig. 3).

Fig. 1

Fig. 2

Fig. 3



HAL for Medical Use (Lower Limb Type) is full of adjustable elements that allow the device to fit to the patient's body size and shape.
Use of the step-less adjustable mechanisms for the thigh, the lower leg, and the hips makes for a seamless fitting process. The sensor shoes have a mid top cut so that the feet do not come out easily when fastened, and each HAL unit comes with three pairs of shoes*3.
The ankle joints can be locked or allowed to move freely.

*3 Shoe sizes can be selected from among 23, 24, 25, 26, 27, 28, 29, and 30 cm.

Indications and Considerations

To use this device, a sufficient understanding of the user manual and related guides is necessary, as well as attendance and completion of the safety training program designated by Cyberdyne and on-site hospital training.

[Indications *1]

HAL for Medical Use (Lower Limb Type) is intended for individuals with spinal cord injury at levels C4 to L5 (ASIA C, ASIA D) and T11 to L5 (ASIA A with Zones of Partial Preservation, ASIA B), who exhibit sufficient residual motor and movement-related functions of the hip and knee to trigger and control HAL. It must be used with a Body Weight Support system inside medical facilities while under trained medical supervision in accordance with the user assessment and training certification program. A patient must also satisfy the following requirements:
(1) A body weight from 40 to 100 kg (89 to 220 lbs)
(2) A height of approximately 150 to 190 cm (60 to 74 in), or a body size such as thigh length, lower leg length, or hip width that fits the device, and therefore can put on this device.

[Contraindications and Prohibitions *1]

(1) A patient who has severe deformities of body parts that limit proper fitting of the device.
(2) A patient whom physicians have judged unsuitable for the implementation of therapeutic exercise such as standing and walking treatment.
(3) A patient with severe spasticity (Ashworth 4)
(4) A patient who cannot have electrodes affixed to any part of their body due to a skin disease or any other reason.

[Warnings *1]

(1) A BWS system must be used in conjunction with the device, otherwise the patient may fall which could result in major injuries or death.
(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). If symptoms of autonomic dysreflexia occur while using the HAL device, immediately cease use and remove the device. The patient should sit up or raise head and remain upright, empty bowel or bladder, loosen or remove tight clothing, and have blood pressure monitored until normal. If symptoms persist, seek medical attention immediately.
(3) This product cannot prevent falling on its own, and may automatically power down to prevent unintended movements when it detects an abnormality.
(Consult user manual for complete description of [Warnings])

*1 Consult user manual for a complete description of the Indications for Use, Indication, Contraindication and Prohibitions and Warnings.

[Electrodes]

Only use snap type electrodes that are cleared or legally marketed in the United States per 21 CFR 882.1320 (product code GXY, Cutaneous electrode) or 21 CFR 870.2360 (product code DRX, Electrocardiograph electrode). Ensure they comply with the following conditions:

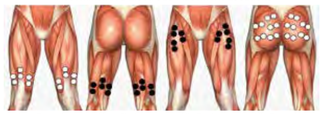
(1) The diameter of the conductive gel area should be in the range of approximately 15 – 25 mm (0.6 - 1.0 in).

(2) The electrodes are compatible to connect to the product's patient cables.

(3) Adhesive faces do not accidentally peel off, even with sweat and movements from training.

(4) Do not use electrodes of different types simultaneously.

Recommended Electrode Placement Locations



Knee Extension Muscle Groups | Knee Flexion Muscle Groups | Hip Flexion Muscle Groups | Hip Extension Muscle Groups

Information About Related Software

The related software is not a medical product. The appearance and specifications of the software may change without notice.

▪ "HAL Monitor" Software

Wirelessly displays the contents of the controller on a larger screen in real time.

Switch the contents on the main view and sub-view screens independent of the controller.
Displays task selection and elapsed time
Bio-electrical signal display
Model image that shows posture
Weight-bearing load and center of balance

Note: A Mac computer with Mac OS X 10.10 or later and a wireless LAN environment are required.
Mac and OS X are trademarks of Apple Inc., registered in the U.S. and other countries.