GEMS-H

Instructions for Use

Publishing details

GEMS-H Powered Lower Extremity Exoskeleton, Instructions for use

Document No.: SAIT-IFU-GEMS-H

Revision No.: 1.1

Revision date: 2019. 11. 05

Application version: 1.4

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Chapter 1. General

1.1. About these instructions for use

These instructions for use provide the information necessary to operate the GEMS-H device**. PLEASE READ THESE INSTRUCTIONS FOR USE BEFORE OPERATING THE SYSTEM.** If any part of these instructions for use is not clear, please contact Customer Support for assistance.

1.2. Explanation of symbols

Safety notes

Safety notes in these instructions for use are introduced with a symbol and a signal word to describe the severity of the hazard.

Follow these safety notes and proceed with caution to avoid accidents, personal injury, damage to property, and to ensure patient safety.

Safety notes	Meaning
⚠ WARNING	**This symbol and the word "WARNING" indicate a possible hazardous situation that, if not avoided, could cause death or serious injury.**
⚠ CAUTION	**This symbol and the word "CAUTION" indicate a possible hazardous situation that, if not avoided, could result in minor or moderate injury.**
NOTICE	**This symbol and the word "NOTICE" indicate a possible hazardous situation that, if not avoid, could result in damage to property or the environment.**

Hints, recommendations

Symbol	Meaning
ⓘ Note	**This symbol emphasizes useful tips and recommendations as well as information for the efficient and trouble-free use of the product.**

Chapter 2. Introduction

2.1. Indications for use

The GEMS-H is a robotic exoskeleton that fits orthotically on the wearer's waist and thigh, outside of clothing. The device is intended to help assist ambulatory function in rehabilitation institutes under the supervision of a trained physical therapist for the following population:

- Individuals with stroke who have gait deficits and exhibit gait speeds of at least 0.4 m/s and are able to walk at least 10 meters with assistance from a maximum of one person.

The trained physical therapist must successfully complete a training program prior to use of the device. The device is not intended for sports.

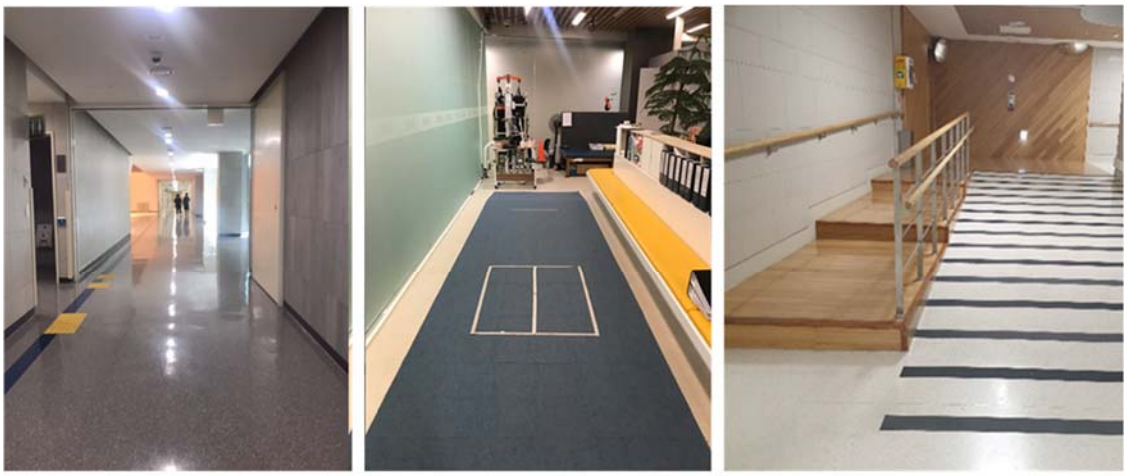
2.2. Training

The GEMS-H should be used only by medical personnel who have received specific training provided by Samsung, Inc. in the use of this device. Training provided by Samsung is limited to the use of the GEMS-H and does not replace the necessary medical training and experience required to perform rehabilitation.

2.3. Safe environments

The GEMS-H is intended to be used under the supervision of a trained physical therapist in all use environments. Suitable use environments include:

- Hospital's internal facilities (indoor only): a rehabilitation treatment room, hospital hallway, or gait analysis lab
- Surface type: smooth, cement, carpet, transitions, thresholds
- Stairs of height less than nine (9) inches
- Surfaces inclined at 5 degrees or fewer
- Treadmills



Hallways and stairs

2.4. Intended user profile

Occupation	• Physical therapists
Education	• Earned a degree in physical therapy and obtained a current physical therapist license.
Experience / Abilities	• Familiar with the application of the tablet PC. • Be able to set up the Bluetooth communication between the device and the tablet PC. • Complete a training program provided by Samsung on how to use the device.

2.5. Operating principle

GEMS-H is a wearable powered exoskeleton that actively assists individuals to walk. The GEMS-H consists of snap-together components weighing 4.7 lbs (2.1 kg) in total. The waist part houses two actuator modules, a Bluetooth module, and a control pack. Each actuator module houses a motor as well as an embedded angular position sensor and controller. In the control pack, there is a central processor, an IMU sensor, a rechargeable battery pack and a power switch.

The GEMS-H has the ability to assist wearers' walking. The GEMS-H has only one Walk Assist mode, which is operated based on the DOC (Delayed Output Control) algorithm. In the DOC algorithm, an on-board microprocessor receives signals from integrated sensors which provide information on the patient's joint angles. The sensors in the device detect the hip joint angle and associated angular velocity from the patient's gait, based on which the central processor determines the optimal assistive torque output. The actuator module then transmits the assistive force to the patient's hip joint to reduce the physical effort in walking.

FCC information:

- Frequency range & Number of channels: 2 402 ㎒ ~ 2 480 ㎒_Bluetooth (79 ch)
- Modulation: GFSK, π/4DQPSK, 8DPSK
- Max. Tune-up power: 0.5 dBm

2.6. Contraindications

- Severe concurrent medical diseases: infections, circulatory, heart or lung, pressure sores
- Lower extremity fracture
- Heterotopic ossification or severe osteoporosis
- Psychiatric or cognitive situations that may interfere with proper operation of the device
- Pregnancy

For patients with a weight of 100 kg (220 lb) or more, or BMI ≥ 35 kg/ m^2, use of the GEMS-H is not prohibited, but the GEMS-H may only be used for those patients after careful consultation with medical professionals.

Note

For further information with regard to the clinical studies, refer to “Chapter 11. Clinical studies”.

Chapter 3. Safety

3.1. Symbols

Symbol	Meaning
SN	Serial number
	Manufacturer information
	Manufacture date
	Type B applied part
	Follow instructions for use
	Non-ionizing electromagnetic radiation
IP20	Degree of protection against particulate matter
Rx only	Caution: Federal law restricts this device for sale by or on the order of a physician
C US	This mark is a Nationally Recognized Testing Lab (NRTL) marking and indicates conformance with UL 60601-1.
	Fragile
	Keep dry
	Temperature limit
	Atmospheric pressure limitation
	Humidity limitation

3.2. Safety

⚠ WARNING

Risk of electrical shock hazard and performance degradation if this equipment is modified!

Unauthorized modification of this equipment can affect the safety and effectiveness of the equipment.

- **Do not modify this equipment without authorization of the manufacturer.**

⚠ WARNING

Risk of serious injury due to misuse!

Use of the device without training can result in serious injury to the patient.

- **Users must successfully complete a training program provided by Samsung prior to use of the GEMS-H.**

⚠ WARNING

Risk of serious injury due to use of the device in improper environments!

Use of the device in environments not recommended by the manufacturer may result in injury to the patient.

- **Do not use in improper environments (e.g., on the sand, in stony areas, or any surface that is not recommended by manufacturer). Refer to section 2.3 Safe environments.**

⚠ WARNING

Risk of serious injury to the patient who is distracted or cannot pay attention to tasks!

If the patient is distracted or uses the device without caution, it could result in loss of balance and possible injury.

- **The GEMS-H must be used under supervision of a trained physical therapist.**
- **The user should cease using this device with patients who are distracted or cannot pay attention to the tasks.**

⚠ WARNING

Risk of serious injury due to misuse!

Use of the device without fitting and customizing can result in serious injury (e.g., fracture) to the patient.

- **The GEMS-H must be fitted to each patient properly by a trained physical therapist.**
- **Software settings must be customized for each patient by a trained physical therapist.**

⚠ WARNING

Risk of serious injury to the patient due to loss of control!

Should the therapist lose control of the device, or if a device is used without the supervision of the trained physical therapists, this may result in the patient having difficulty balancing and potentially falling while using the device.

- **At least one therapist should monitor patients at all times while the devices are turned on and/or while the patients are walking.**

⚠ WARNING

Risk of serious injury to the patient by potentially falling due to a device malfunction!

Should the device malfunction, the 12 Nm torque provided by the device may suddenly stop. This may result in the patient having difficulty balancing, and potentially falling.

- **In order to prevent malfunctions, users should make sure that the device has been maintained according to specifications and that the software is in working order prior to use.**
- **Users may conduct rehabilitation with a gait belt or a harness (e.g., body weight support system) and assistive devices such as cane or a walker as needed.**

⚠ WARNING

Risk of serious injury to the patient due to improper fitting or fitting too tightly!

Skin abrasions, including discomfort, skin pressure/friction, bruising, pain, or unusual swelling, may result from the device being improperly fitted or fitted too tightly.

- **The device must be fitted over clothing to prevent skin abrasions.**
- **When putting on the device, the thigh support straps should be fitted with the knees slightly bent to avoid excessive tightening or pressing.**
- **Users should examine the discomfort and skin pressure of the patient.**
- **Care should be taken to avoid pinching skin when fitting the device.**

⚠ CAUTION

Risk of muscle soreness to the patient due to excessive rehabilitation!

Should the patient perform dynamic and complex training at the first time of use, this may result in muscle soreness after the training session.

- **Patients should start with simple activities, then increase the intensity of the training including more dynamic and complex activities.**
- **Patients should be provided with adequate rest periods and asked about discomfort regularly.**

⚠ CAUTION

Risk of injury to the patient and device damage due to pressing on the patient's body!

If the patient opens the leg excessively to the side while wearing, it may cause discomfort, skin pressure, and/or device damage.

- **Do not open the leg excessively to the side while wearing.**

⚠ CAUTION

Risk of injury to the patient and device damage due to sitting and leaning backward on a surface while wearing the device!

If the patient wearing the device sits and leans back onto a surface (e.g., chair), it may cause discomfort, skin pressure, and/or device damage.

- **Do not lean backward onto a surface while wearing the device and sitting.**

⚠ CAUTION

Risk of injury to the patient due to skin pressure!

If the patient has something in their pockets or is wearing a belt while wearing the device, this may cause discomfort and pressure on the patient's body.

- **Belts should be removed prior to putting on the device.**
- **Pockets should be emptied prior to putting on the device.**

⚠ CAUTION

Risk of potentially falling due to using discharged battery!

Use of the device with a low battery may result in the device may suddenly turning off during rehabilitation which stops the assistive force. This may result in the patient having difficulty balancing and potentially falling.

- **To ensure continuous power during use, always charge the battery at the end of each training session.**
- **When the battery level is below 20 %, charge the battery within 5 minutes.**

⚠ CAUTION

Risk of electrical shock hazard and performance degradation when the device is dropped!

Should the device be dropped during use, it can affect the safety and effectiveness of the equipment.

- **Stop using it immediately and report the situation to the manufacturer.**

3.3. Safety standards

The GEMS-H conforms to the following international standards:

- IEC 60601-1:2005+A1:2012
- IEC 60601-1-2:2014
- IEC 60601-1-6:2010+A1:2013
- IEC 62366-1:2015
- IEC 62304:2006
- ISO 15223-1:2012
- ISO 14971:2007
- ISO 13485:2016

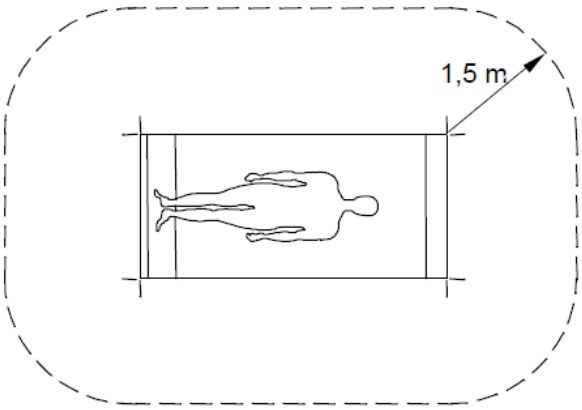
3.4. Environmental conditions

	Operation	Storage & Transport
Temperature	32 ℉ to 86 ℉ (0 ℃ to 30 ℃)	- 77 ℉ to 158 ℉ (- 25 ℃ to 70 ℃)
Humidity	30 to 85 % (non-condensing)	10 to 94 % (non-condensing)
Pressure	700 hPa to 1060 hPa	500 hPa to 1060 hPa

3.5. Disposal

This device contains electrical and electronic equipment waste, which must be disposed of separately from unsorted municipal waste. Please contact the manufacturer or an authorized disposal company to decommission your equipment according to local regulations.

3.6. Patient environment



Part within the patient environment	Device, Tablet PC
Part outside the patient environment	Device charger, Tablet PC charger

Note

The device charger that supplies the power separately is specified as a ME(Medical Electrical) system.

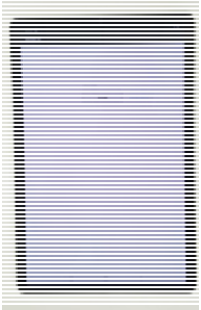
Chapter 4. Device description

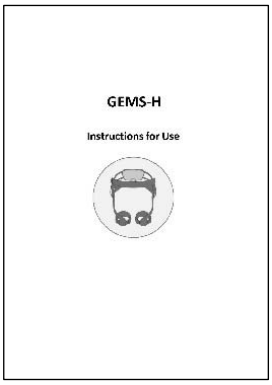
4.1. Package contents

The GEMS-H sales package contains the following items:

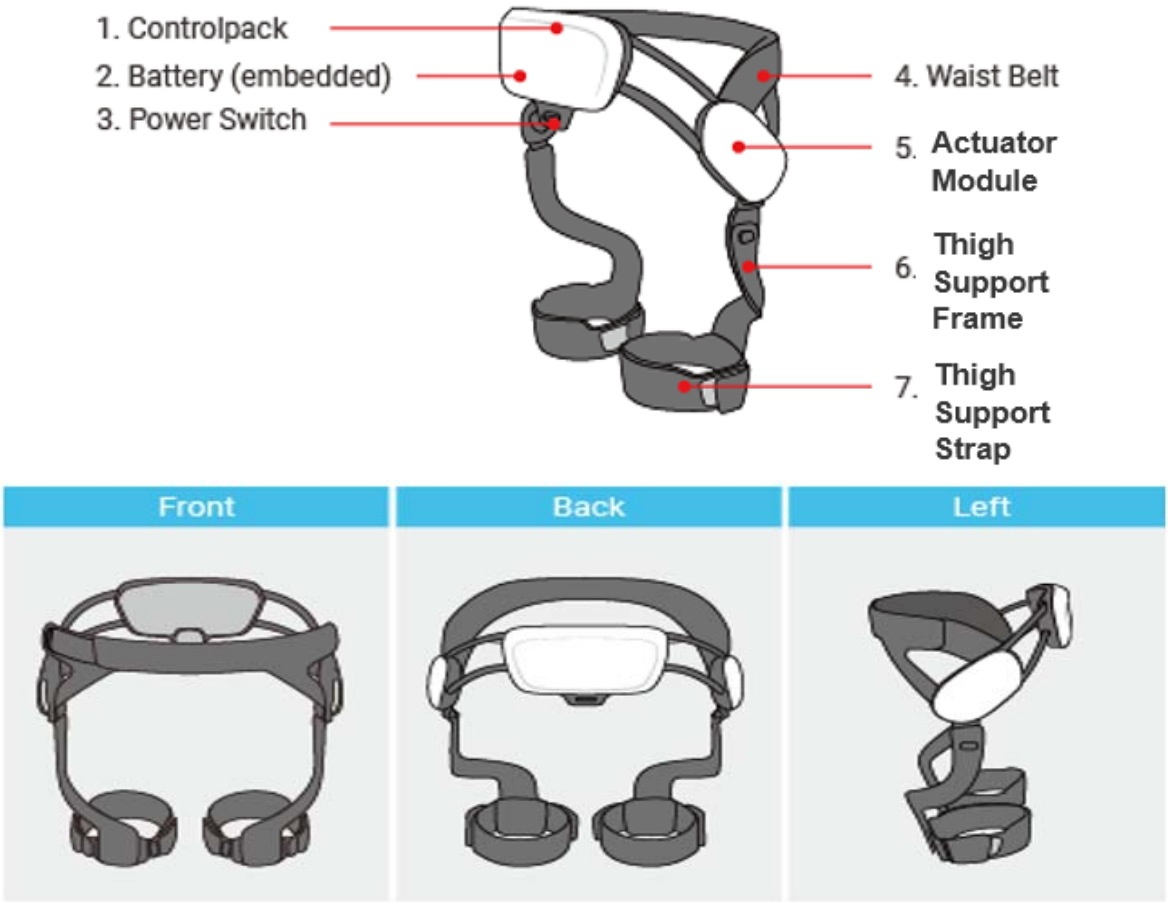
- Waist part (Sizes: S, M, L)
- Thigh support frame (Sizes: S, M)
- Thigh support strap with buckles (Sizes: S, M, L)
- Tablet PC
- Tablet PC case
- Device charger
- Tablet PC charger
- Hip width ruler
- Extension belt
- Torque wrench
- Storage case
- Instructions for use

Depending on the wearer's size, these components are used in combination. For safe storage, place the GEMS-H in the case after each use.

Waist part (Sizes: S, M, L)	Thigh support frame (Sizes: S, M) – left/right
Thigh support strap with buckles (Sizes: S, M, L) – left/right	**Tablet PC**
	

Device charger	Tablet PC charger
Hip width ruler	**Extension belt**
Torque wrench	**Storage case**
Tablet PC case (optional)	**Instructions for use**
	

4.2. Device overview



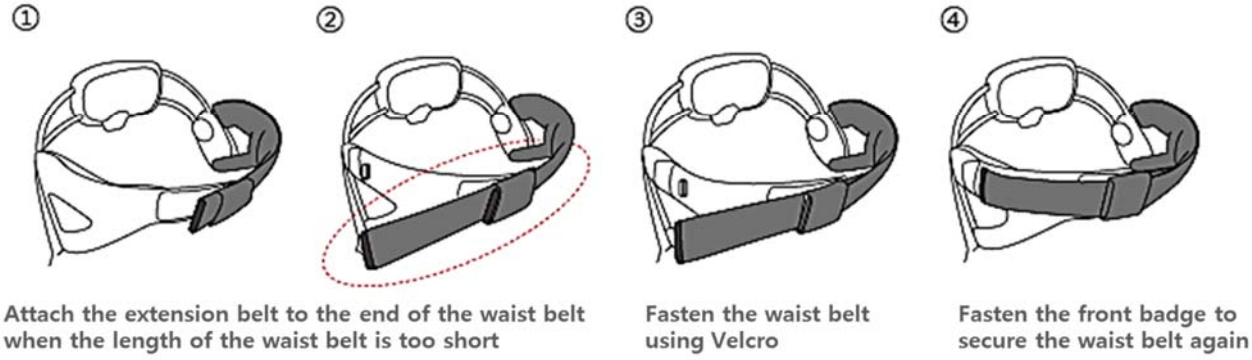
No.	Parts	Description
1	Control pack	Computing unit and built-in battery
2	Battery	Power supplier
3	Power switch	Power ON/OFF switch (switch up: ON, switch down: OFF)
4	Waist belt	Waist belt
5	Actuator module	Motor and reduction gears for generating the assistive force
6	Thigh support frame	Rigid frame delivering the assistive force to the wearer's thigh
7	Thigh support strap	Fastening strap connecting the thigh support frame and to the wearer's thigh

4.3. Accessory: waist extension belt

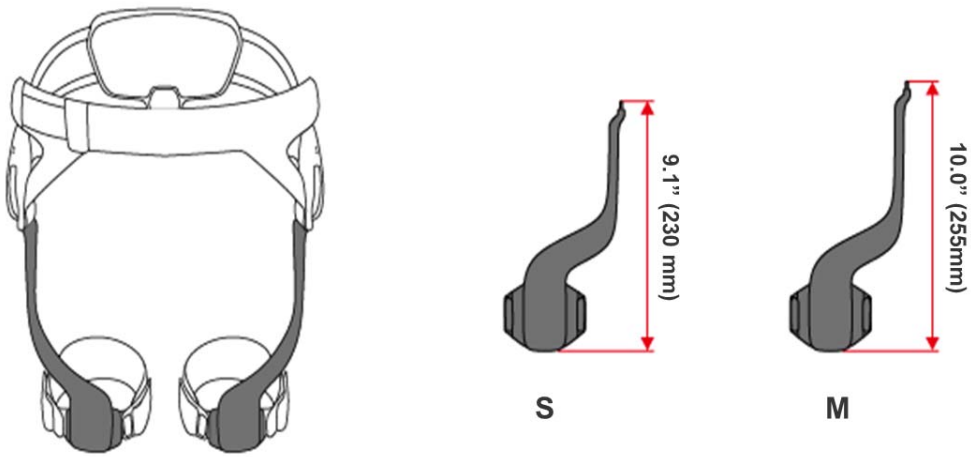
The extension belt may be used to increase the length of the waist belt by 5.9 inches (150 mm). It is used when the waist belt of the device is too short to fasten completely and comfortably around the patient's waist.

Increasing the length of the waist belt by 5.9 inches (150 mm)

Waist Extension Belt

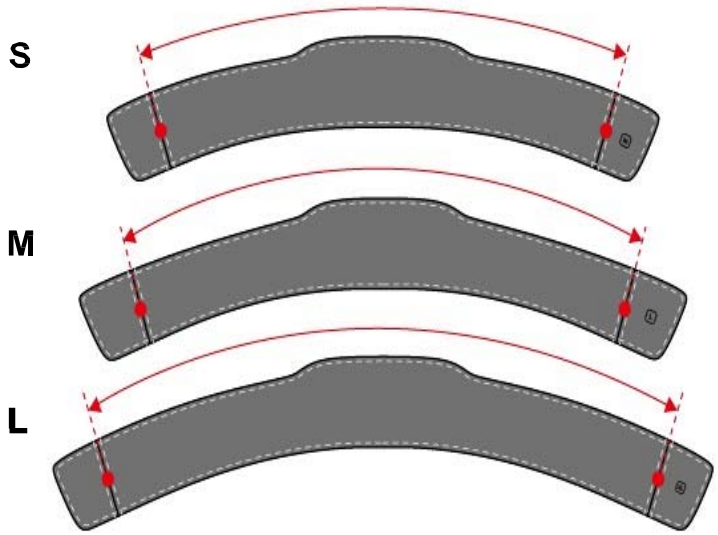


4.4. Accessory: thigh support frame



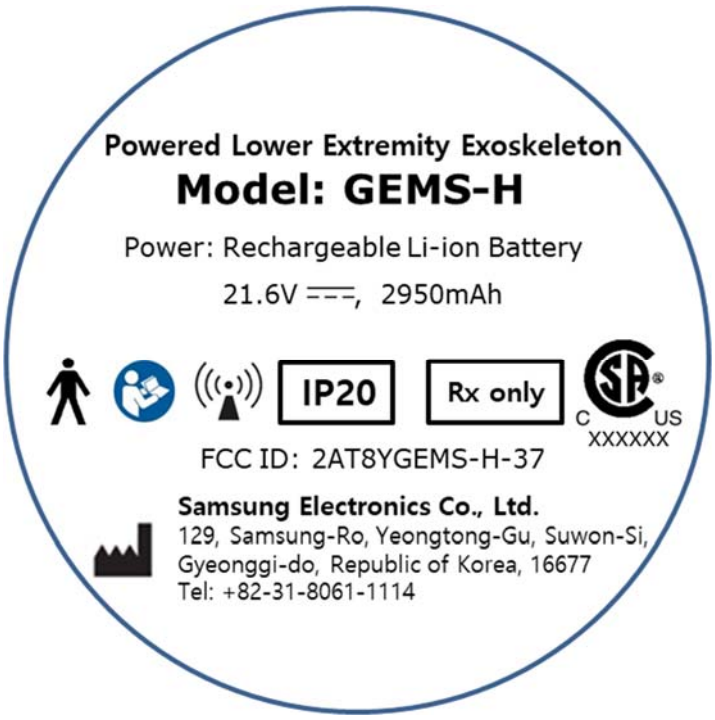
	Small size	Medium size
Length, inches (mm)	9.1 (230)	10.0 (255)

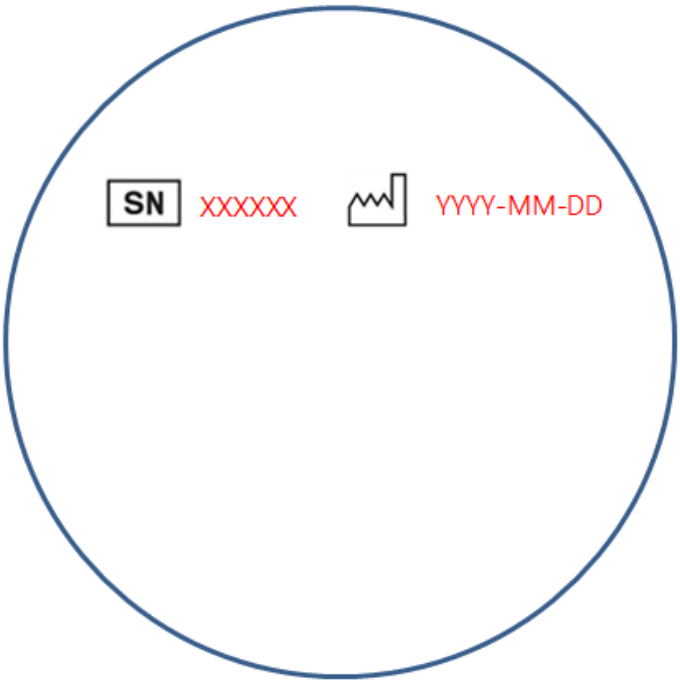
4.5. Accessory: thigh support strap



	Small size	Medium size	Large size
Length, inches (mm)	14.2 (360)	16.1 (410)	17.7 (450)

4.6. Marking plate





Chapter 5. Preparation

5.1. Device fitting procedure

① Measure the wearer's hip width using the provided hip width ruler.

② Select the appropriate waist part size according to the wearer's hip width.

- hip width: 12.4 ~ 14.4" (315 ~ 365 mm) → Small
- hip width: 14.0 ~ 15.9" (355 ~ 405 mm) → Medium
- hip width: 15.9 ~ 17.9" (405 ~ 455 mm) → Large

③ Use the torque wrench provided to adjust the waist part width according to the wearer's hip width. Details of the waist part adjustment are shown in section 5.3 Adjust the waist part width.

④ Use the extension belt if the length of the waist belt is too short.

- The extension belt may be used to increase the length of the waist belt by up to 5.9 inches (150 mm).

⑤ Use a Medium-size thigh support frame initially. If the thigh support frame area comes in contact with the knee cap, then use the Small-size thigh support frame.

⑥ Use the thigh support strap size which fits the wearer's thigh.

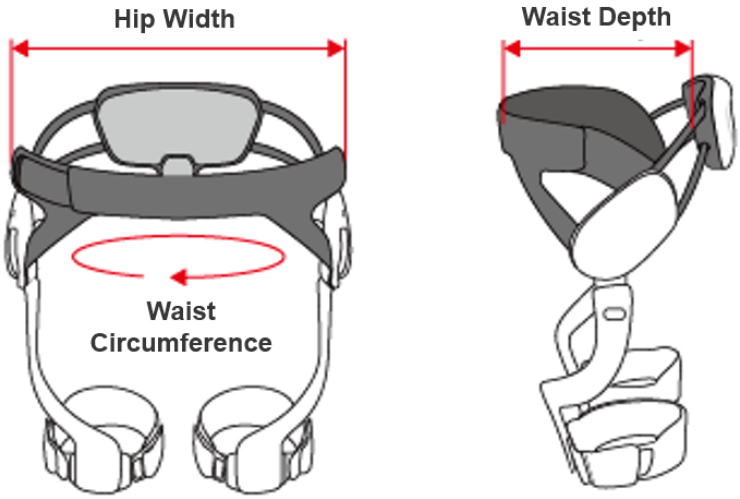
- Choose the strap size adequately, so that the Velcro can be securely fastened.

5.2. Determine the waist part size

5.2.1. Waist part size

Note

The device width can be adjusted within a range of about 2 inches (50 mm) by adjustment of the waist part.



	Small [inches (mm)]	Medium [inches (mm)]	Large [inches (mm)]
Hip width	12.4 ~ 14.4 (315 ~ 365)	14.0 ~ 15.9 (355 ~ 405)	15.9 ~ 17.9 (405 ~ 455)
Waist depth	5.7 ~ 6.7 (145 ~ 170)	7.9 ~ 9.8 (200 ~ 250)	9.4 ~ 12.2 (240 ~ 310)
Waist circumference	30.7 ~ 34.3 (780 ~ 870)	32.3 ~ 36.2 (820 ~ 920)	36.2 ~ 43.3 (920 ~ 1100)

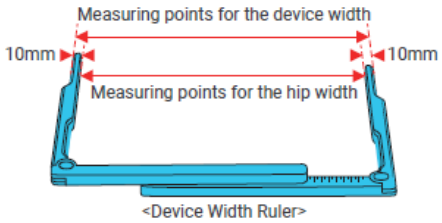
5.2.2. Hip width measurement

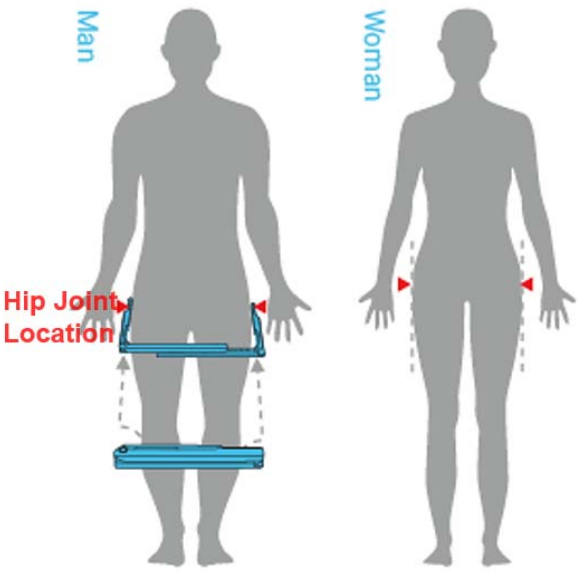
Note

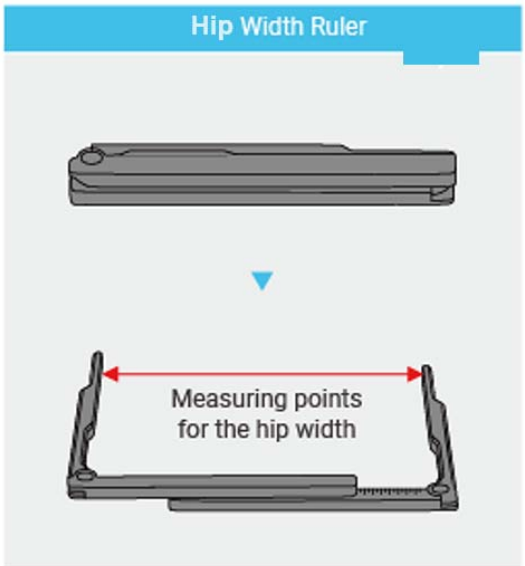
When the measured hip width falls between the applicable size ranges of two different devices, it is recommended that the device of the bigger size be selected.

Note

A 10 mm margin of safety is automatically included on each side by the hip width ruler provided, as shown below, and is usually suitable if the measurement is taken loosely. If the device is still too tight, the user should adjust the device for patient comfort at their discretion.







① Identify the hip joint location.

② Measure the hip width using the ruler provided, as shown above.

③ Select the waist part size which fits the wearer's hip width.

- hip width: 12.4 ~ 14.4" (315 ~ 365 mm) → Small
- hip width: 14.0 ~ 15.9" (355 ~ 405 mm) → Medium
- hip width: 15.9 ~ 17.9" (405 ~ 455 mm) → Large

5.2.3. Size markings

The size of the waist part is indicated on the front clasp (S, M, and L).

5.3. Adjust the waist part width

NOTICE

Property damage when the screws are over tightened!

The product may be damaged if the screws are over tightened or continuously tightened after clicking sounds are emitted from the torque wrench provided.

- **Do not tighten further after clicking sounds emit from the torque wrench provided.**

NOTICE

Property damage when the screws are not fully tightened!

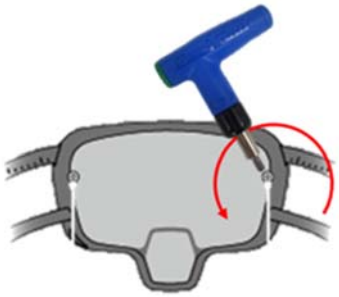
If the screws are not fully tightened, the screws will be too loose during walking and the waist part may be damaged.

- **Before putting the device on the patient, check that the screws are tightened securely enough that noise is not made, as the screws loosen during walking.**

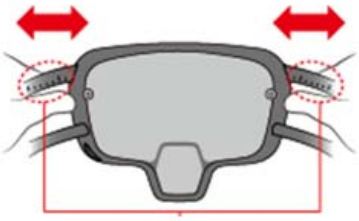
① Ensure the Velcro on the waist belt is unfastened.

② Adjust the device width by loosening the two screws, one on each side of the control pack.

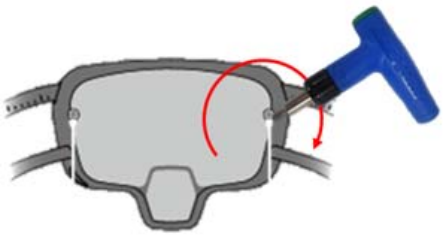
③ Use the provided torque wrench to loosen both screws. Turn counter-clockwise (CCW) to loosen.



④ Check the ruler scale on the upper beams (metric-based, one tick mark indicates 10 mm), and adjust the width by holding the lower beams and applying a gentle force.



⑤ Once the waist part has been adjusted to the appropriate size, use the provided torque wrench to tighten (turn clockwise) the screws until the wrench clicks.



5.4. Wear the waist belt & fasten thigh support frames

⚠ WARNING

Risk of serious injury due to improper device sizing to the patient!

Improper sizing of the waist part and thigh support frames could cause skeletal fractures and injury to the patient.

- **The therapists must determine the proper size of the waist part and thigh support frames to suit the patient.**

⚠ CAUTION

Risk of potentially falling due to the loosened waist belt!

If the device is used frequently, Velcro on the waist belt may lose its adhesion. If the patient wears the thigh support strap loosely during rehabilitation, this may result in the patient having difficulty balancing, and potentially falling.

- **Check whether the waist belt is fastened before walking.**

⚠ CAUTION

Risk of potentially falling due to loosening the thigh support frame during walking!

When the therapist attaches the thigh support frames loosely, the thigh support frames may be disconnected during walking. This may result in the patient having difficulty balancing, and potentially falling.

- **Make sure that the thigh support frame fastening hook is securely fastened before walking. (Check whether the release button had popped out and also try pulling out the thigh support frame)**

① Open the waist belt and place the device around the wearer's waist.

② Position the device such that the center of the actuator coincides with the wearer's hip joint.

③ Fasten the waist belt using the Velcro.

④ Use the extension belt if the length of the waist belt is too short.

⑤ Attach both thigh support frames.

⑥ Use a Medium-size thigh support frame initially, and use a Small-size if the length of the wearer's thigh is somewhat short (i.e., if the thigh support frame comes in contact with the knee cap).

⑦ The size is indicated on the release button of the thigh support frame (S, M).

5.5. Fasten both thigh support straps

⚠ WARNING

Risk of serious injury to the patient due to excessive tightening!

Excessive tightening may cause discomfort, skin pressure/friction, bruising, pain, or unusual swelling caused by the exoskeleton which has the potential to lead to skin breakdown or abrasions.

- **When putting on the device, the thigh support straps should be fitted with the knees slightly bent to avoid excessive tightening or pressing.**
- **The therapist should check for discomfort and check the skin pressure of the patient.**

⚠ CAUTION

Risk of falling due to broken buckle!

If you insert the buckle while pulling sideways, the buckle may be broken. This may result in the patient having difficulty balancing, and potentially falling.

- **When inserting the buckle into the hook, insert it while tilting it by 90 degrees and pull the strap out perpendicular to the surface of the leg.**

⚠ CAUTION

Risk of injury due to the straps unfastened during walking!

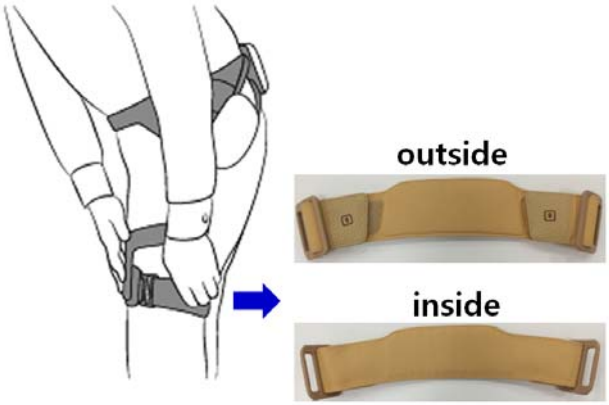
If the straps are not securely fastened to the buckles, the straps may become unfastened during walking. This may result in the patient having difficulty balancing.

- **Be sure to connect the straps with the buckles securely and to make sure that the buckles are securely connected with the thigh support frame.**

Note

The therapist can use a different size selection for the waist part, thigh support frame, and thigh support strap for each patient. For example, the therapist can select the Medium waist part, the Small thigh support frames, and the Large thigh support straps, and so on.

① Use a Medium-size thigh support strap initially. Switch to Small or Large-size if needed.



② Fasten both thigh support straps by attaching the buckles on the strap to the thigh support frame.

③ Make sure the strap Velcro is securely fastened around the wearer's leg.

Here is how to connect the strap with buckles.

	Step 1	Step 2	Step 3	Step 4
Front View				
Top View				
Buckle		Hole of #1	Hole of #2 (outside)	

5.6. Waist part position

⚠ WARNING

Risk of serious injury due to incorrect waist part positioning!

Incorrect waist part positioning on the patient could cause discomfort, skin pressure/friction, bruising, pain, or unusual swelling.

- **Before turning the device on, ask the patient to walk in place to check for any discomfort. If so, reposition the device or try donning the device again. The therapist may need to re-adjust the waist part width or the tightness of the waist belt.**

1) Examples of correct and incorrect waist part positioning:

- The rotation axis of the actuator should align with the greater trochanter.
- The control pack should rest directly below the lumbar curve near the sacrum.

2) Examples of correct and incorrect thigh support frame positioning:

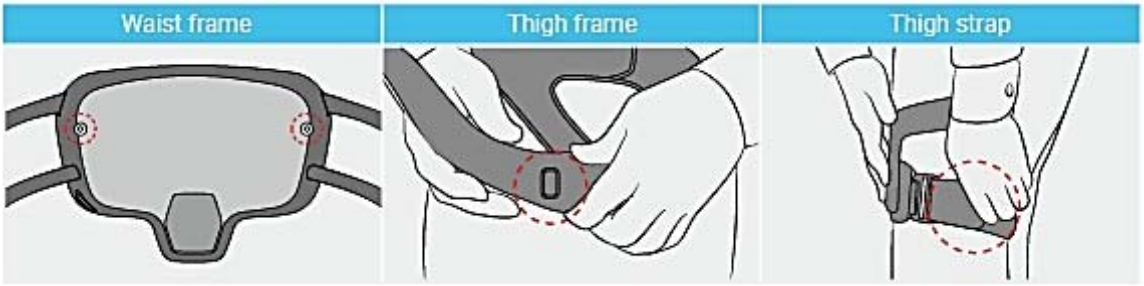
5.7. Check prior to use/operation of the device

5.7.1. Check for before use

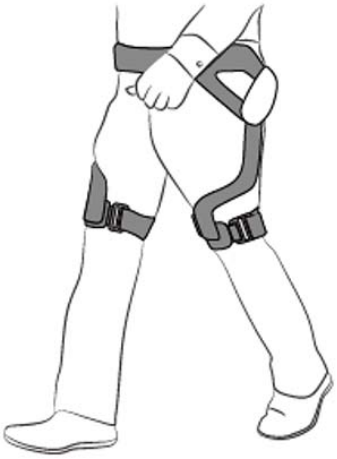
① Check that the screws for adjusting the hip width of the waist part are not loose.

② Check that the thigh support frame fastening hook and strap Velcro are securely fastened.

③ Use the device after it is fully charged. Monitor the battery level and if the battery level is below 20 %, charge the device before use.



5.7.2. Check for any discomfort while walking



① Before turning the device on, make the wearer walk around to check for any discomfort. If there is discomfort, reposition the device or try donning the device again. You may need to readjust the width of the waist part or the waist belt tightness.

② Confirm with the patient that there is no pinching of the skin. If the patient is comfortable then the measurement is acceptable.

③ Check if the greater trochanter area is making contact with the hard surface of the device. This could cause discomfort after walking for some time. If this is the case, the device width may need to be widened.

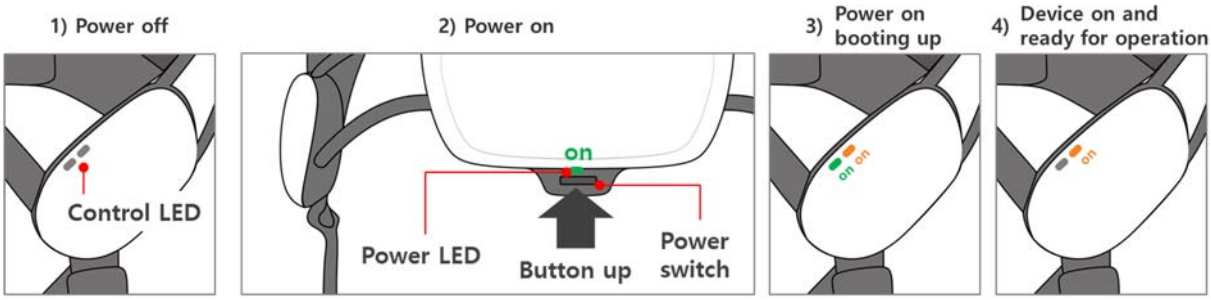
④ Avoid wearing the device with short pants where the skin is exposed to the thigh support strap area. When walking a long time, this could cause skin chafing.

Chapter 6. Operating the device

6.1. Turn on the device

Turn on the power switch by pushing it up. The indicator light (Power LED) will turn green. Then check that the front left and right LEDs (Control LED) are ON, which indicates that the device is booting up. This may take up to 15 seconds. When device is ready for operation, only the orange light is on.

Sequence of LED (control LED and power LED) Lighting



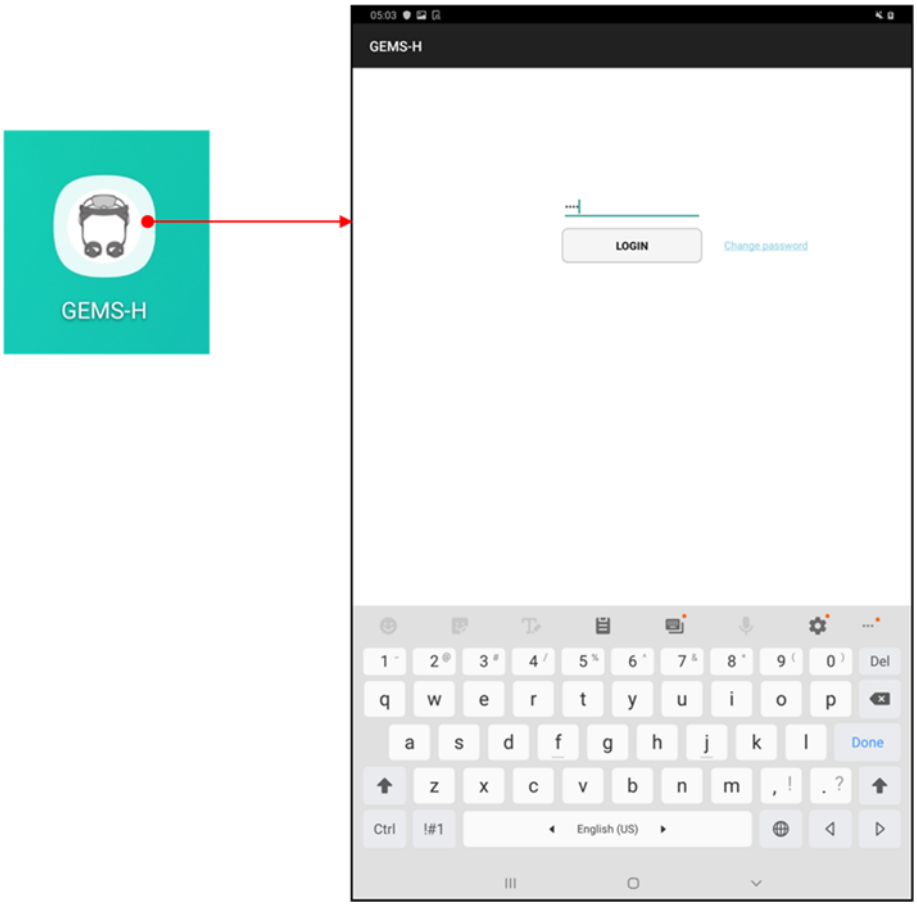
Situation	LED state	Example	
1) Power off	Both light off	Control LED	OFF OFF
2) Power on	Power light on	Power LED	ON
3) Power on booting up	Green and orange light on	Control LED	ON ON
4) Device on and ready for operation	Orange light only on	Control LED	ON OFF

6.2. Opening and closing the GEMS-H application

6.2.1. Opening the GEMS-H application

An android application controls and monitors the GEMS-H using Bluetooth communication.

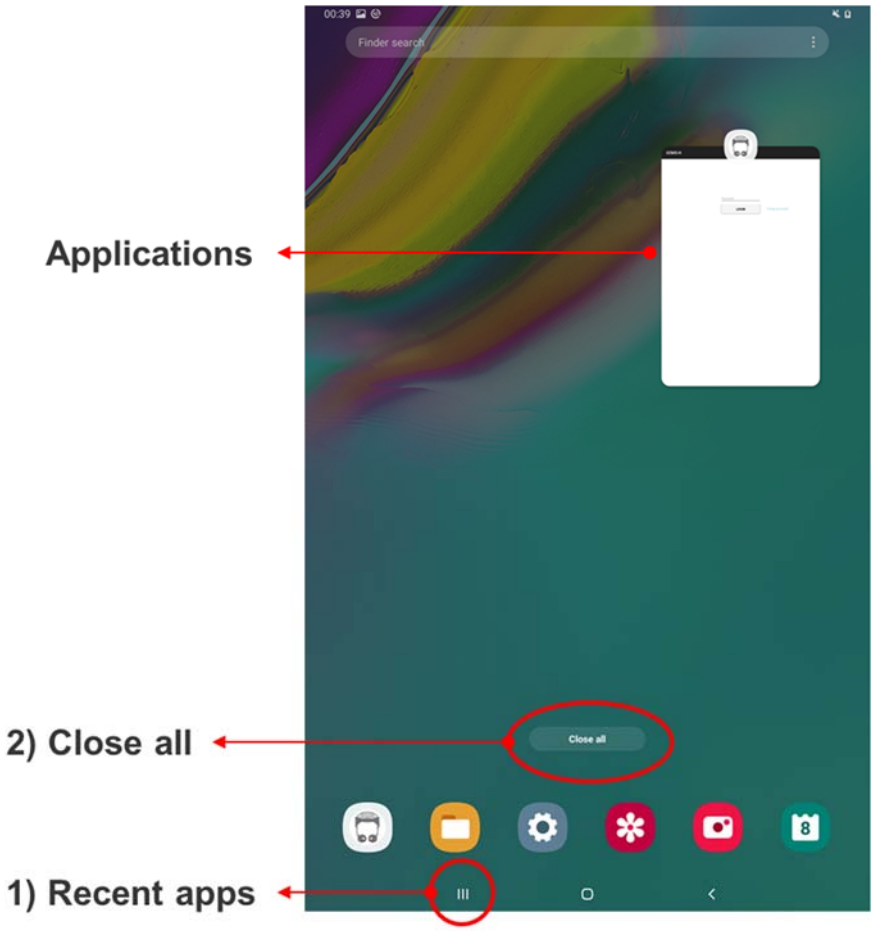
Press the “GEMS-H” icon on the home screen of the tablet PC to execute the application and it will show the login screen.



6.2.2. Closing the GEMS-H application

If you want to close the application,

1) Press the “Recent apps” button at the bottom left of the home screen, as shown below.
2) Press the “Close all” button.



Note

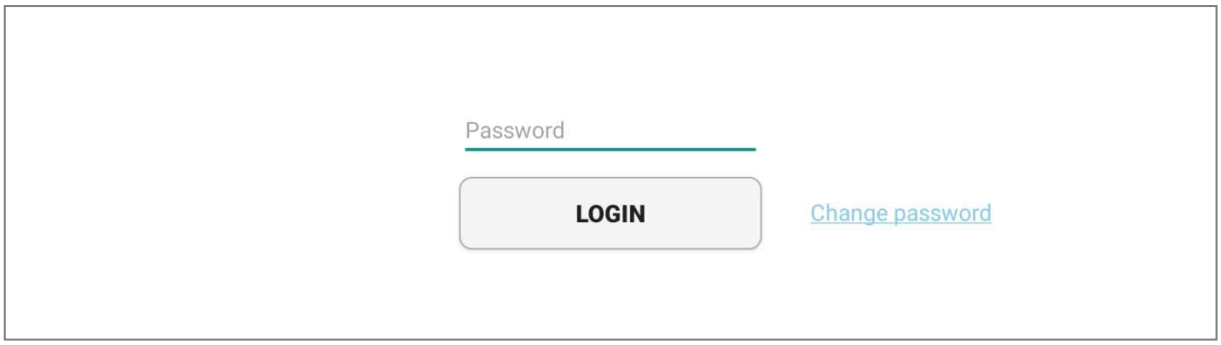
If the user does not close the application properly, the following message will appear when the application is run again. Please press the “RESTART” button to start the application anew, or press the “CONTINUE” button to continue using the current application.

6.3. Login screen

Note

The user and the administrator passwords should be managed by the authorized administrator. In particular, the administrator password should not be exposed to patients and non-administrators.

6.3.1. Logging in



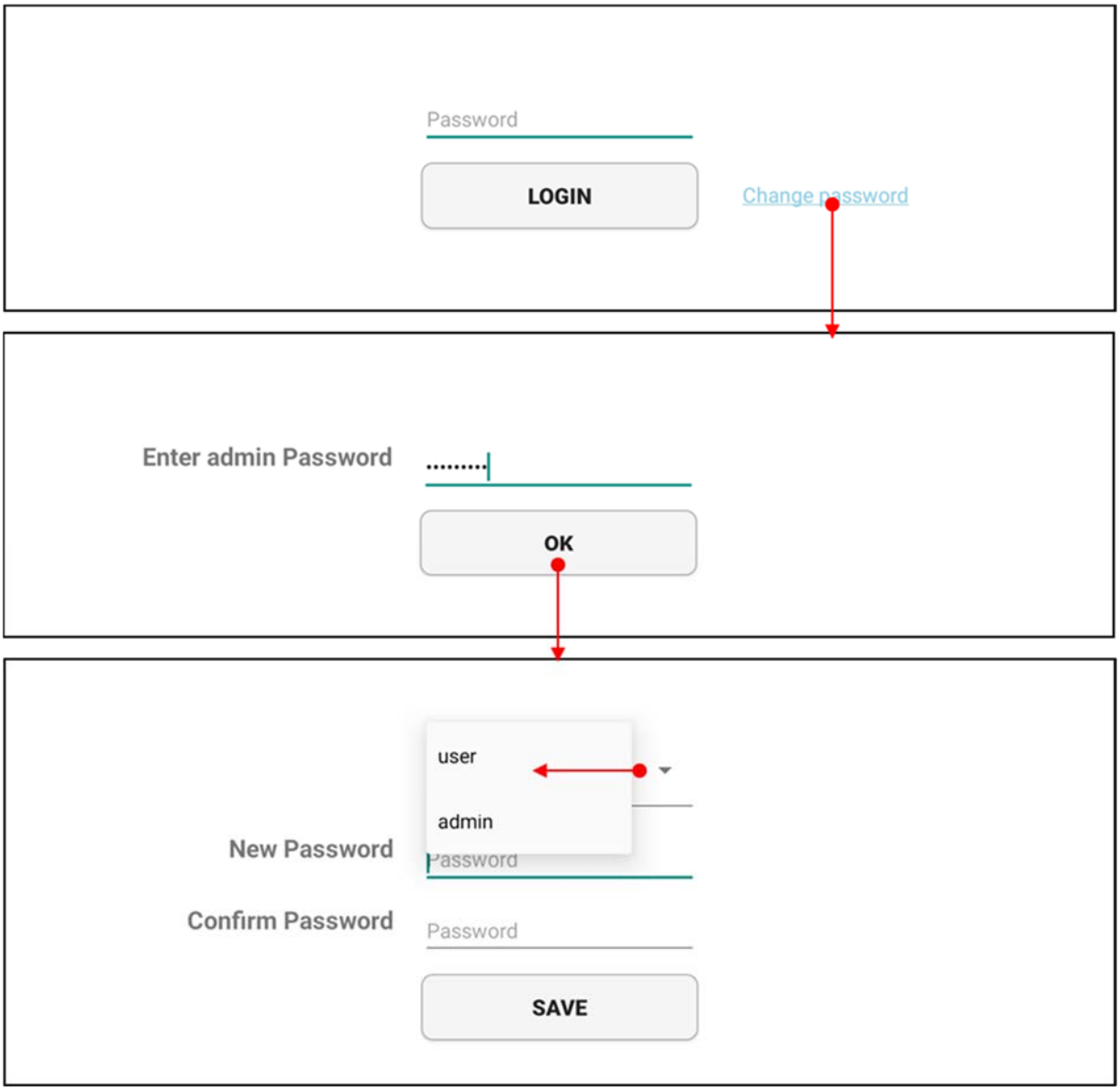
① A physical therapist may use the app as a general user by using a password given by an administrator.

② Administrators can change the user password with admin password in order to manage authorized users.

6.3.2. Changing the user and admin password

Note

The initial admin password will be given by the manufacturer, and the administrator can later change the password as needed. If you forget the admin password, you will need to contact the manufacturer to reinstall the application, which will erase your stored patient information.

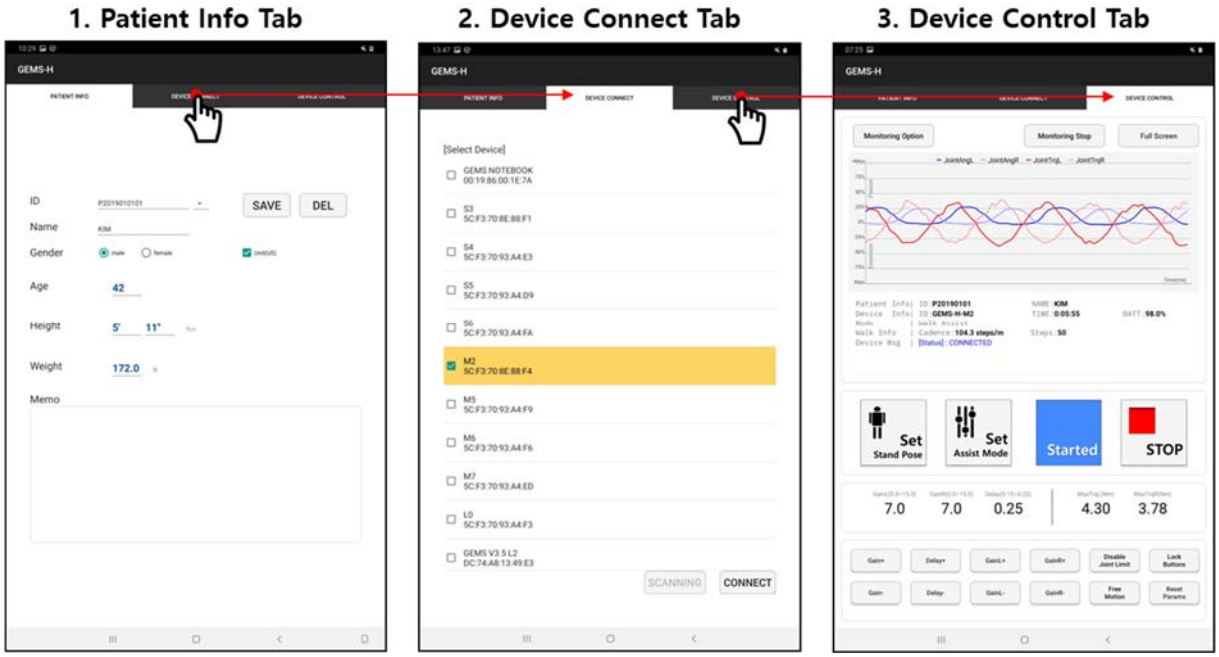


① Click “Change password”.

② Enter the admin password.

③ Select “user” or “admin” and save the new password.

6.4. Overall GEMS-H user interface



1) **Patient Info Tab**

   User interface to manage patient information (See section 6.5 The 'Patient Info' tab for details).

2) **Device Connect Tab**

   User interface for connecting the device using Bluetooth (See section 6.6 The 'Device Connect' tab for details).

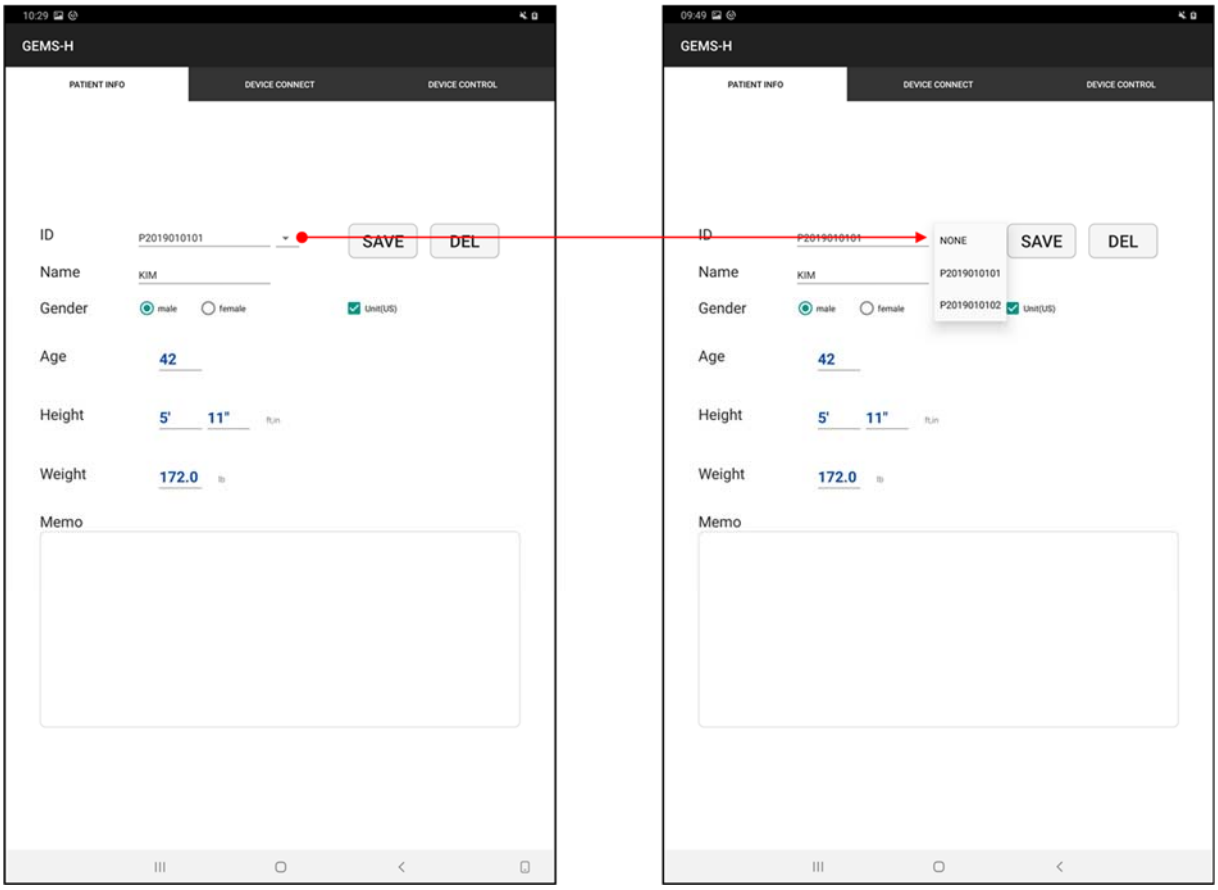
3) **Device Control Tab**

   User interface to control the device (See section 6.7 The 'Device Control' tab for details).

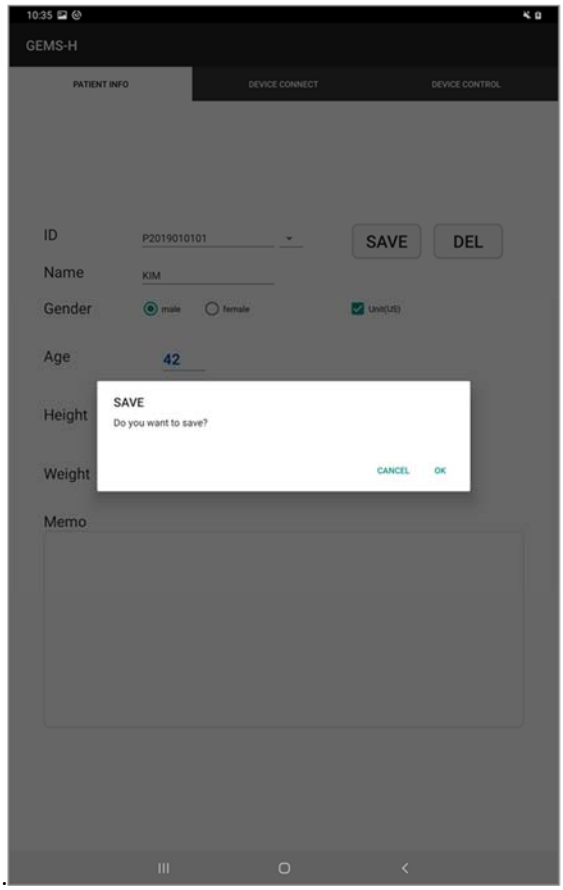
6.5. The 'Patient Info' tab

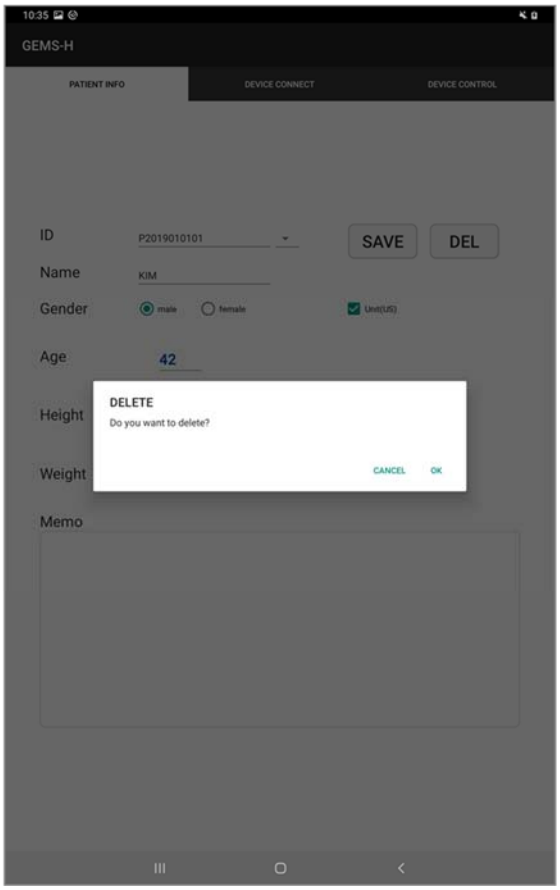
Note

Be sure to ask the patient whether the information is correct or not.

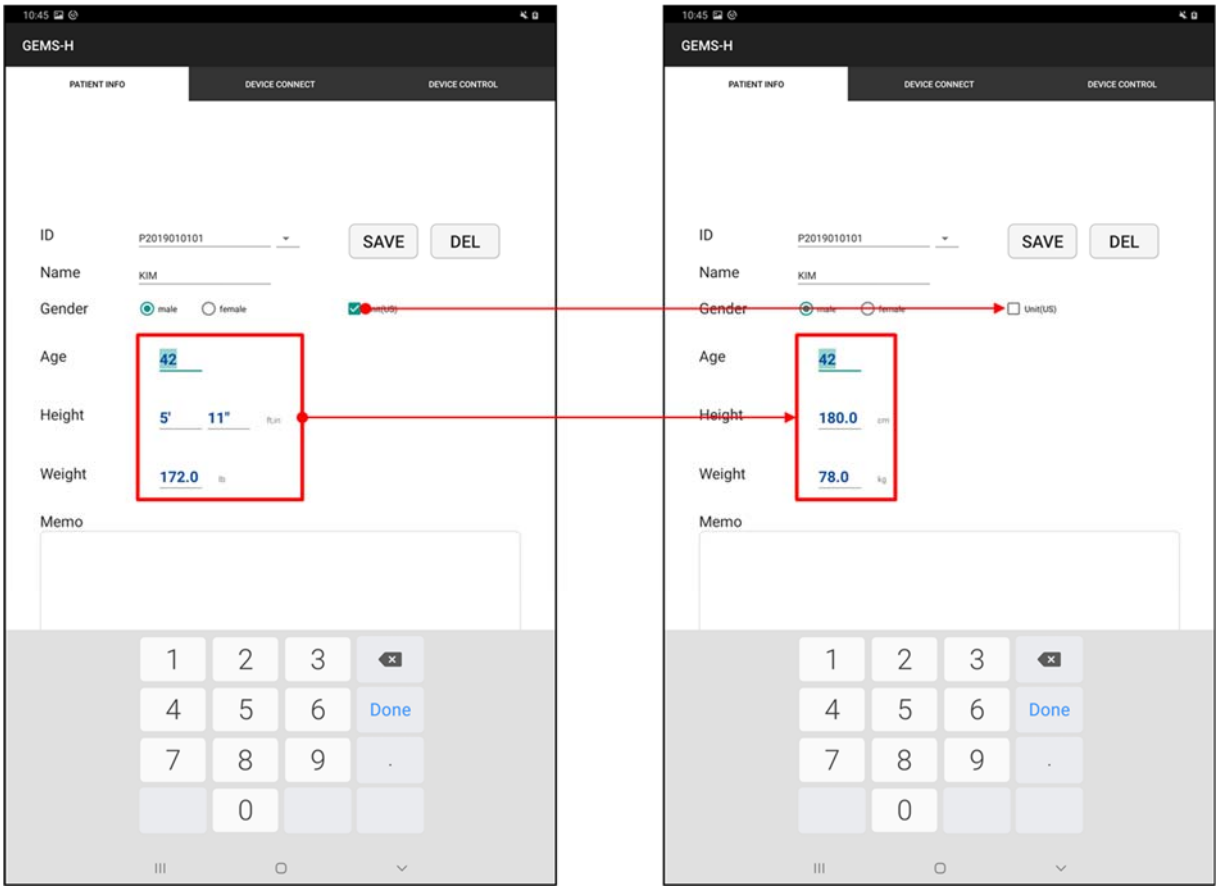


- Select the patient ID from the list and load the information accordingly.
- Give a new patient ID for the first-time patients and specify name, gender, age, height, weight, and note associated with a patient ID.
- Patient information is only for user reference and does not affect any functions of the device. Therefore, input of patient information can be skipped.



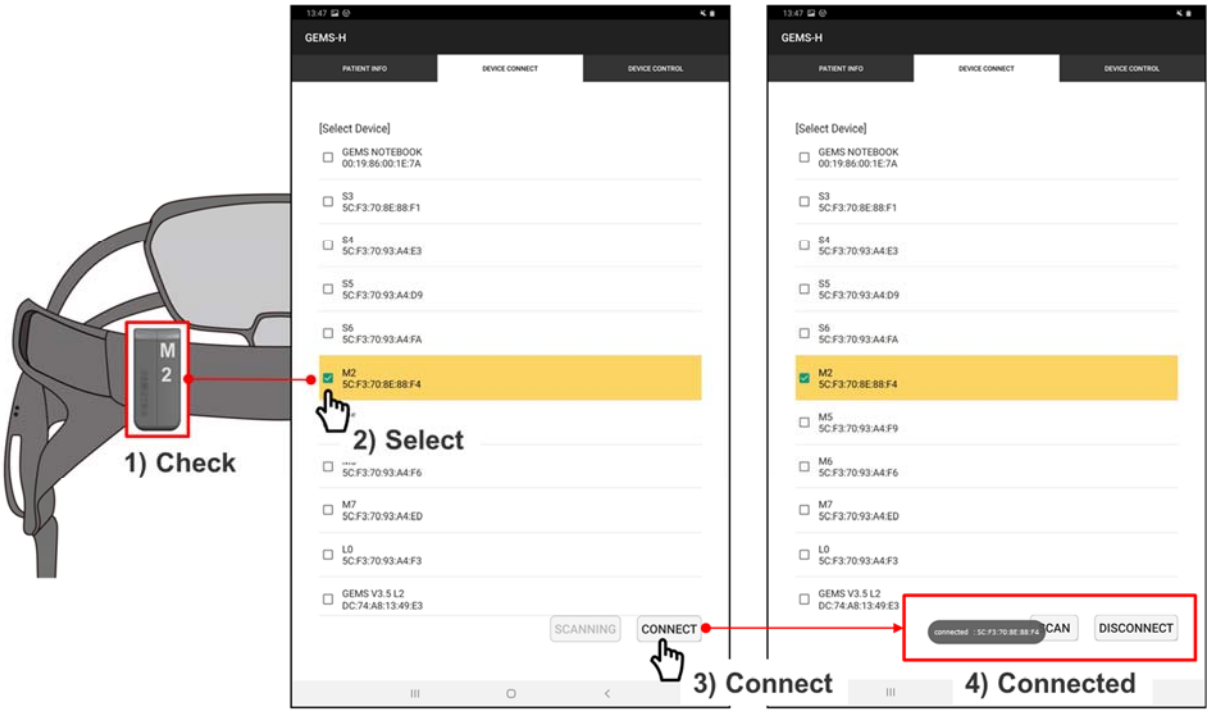


- Press the “SAVE” button to save the patient ID and associated patient information.
  If you use a patient ID that already exists, all previous information will be updated with the new information.
- Press the “DEL” button to delete patient ID and associated information.



- Uncheck “Unit (US)” in order to use SI Units instead of US Units.

6.6. The ‘Device Connect’ tab



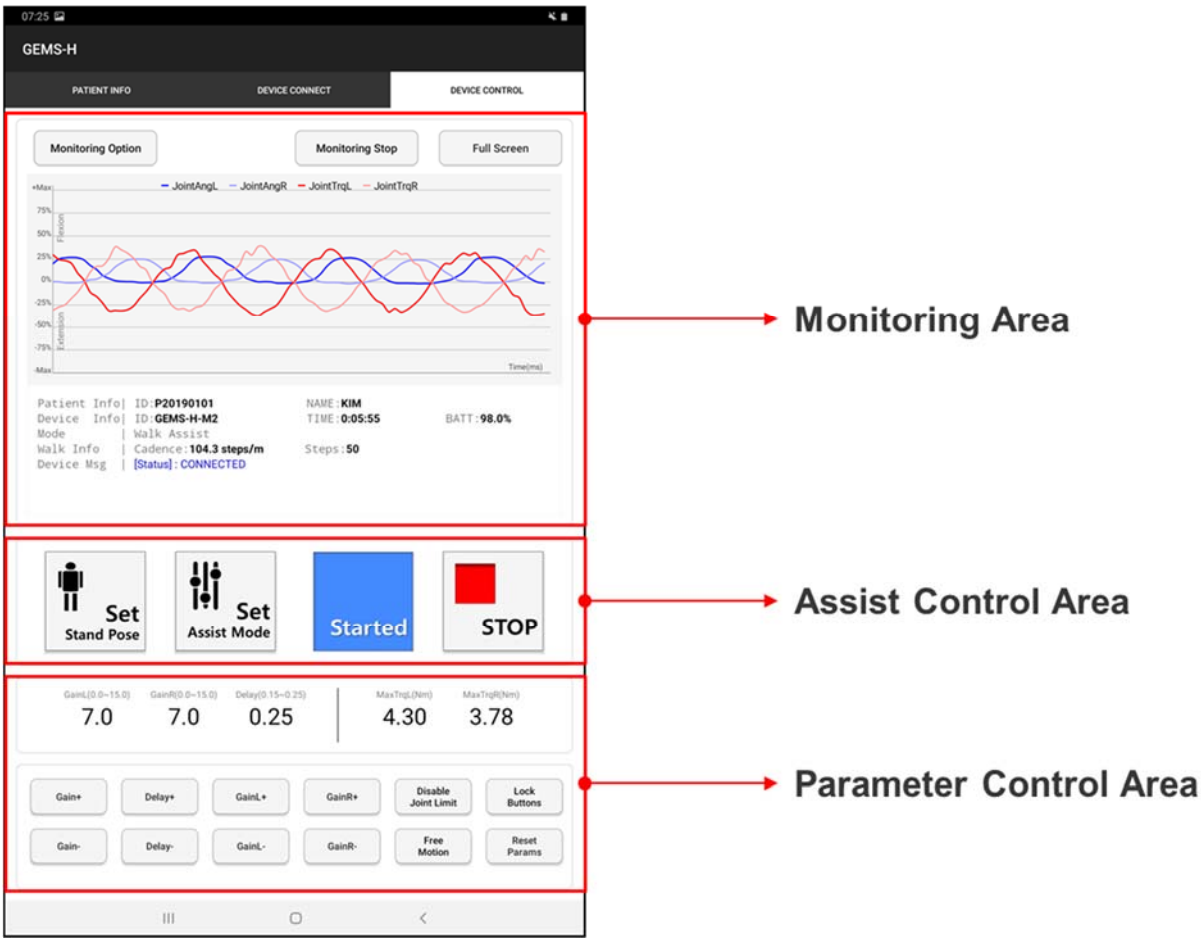
① Check the device name on the top of the clasp.

② Select the name of the device to enable so that it is highlighted in yellow. Press the “SCAN” button again if the desired device is not found.

③ Connect the selected device by pressing the “CONNECT” button. message will appear and the text on the button will changed to “DISCONNECT”.

6.7. The 'Device Control' tab

The screen configuration of the 'Device Control' tab is shown below.

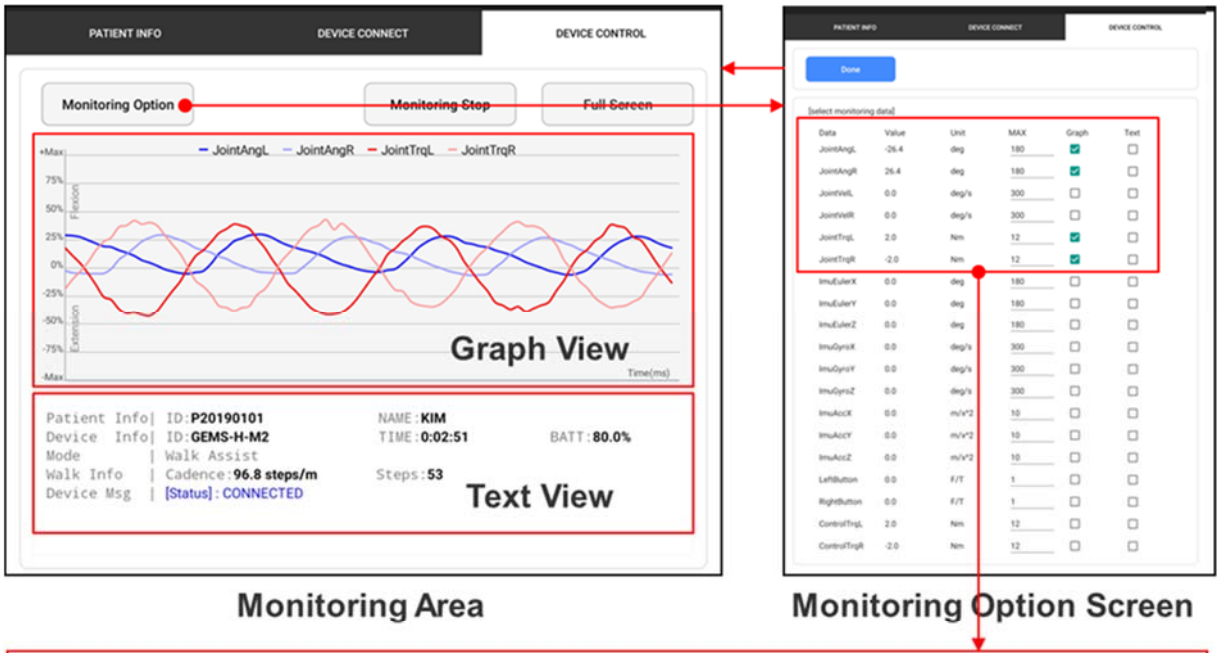


6.7.1. Monitoring area

1) Monitoring option

Device and patient information may be monitored as a graph or as text.

Press the “Monitoring Option” button to open the “Monitoring Option Screen”.

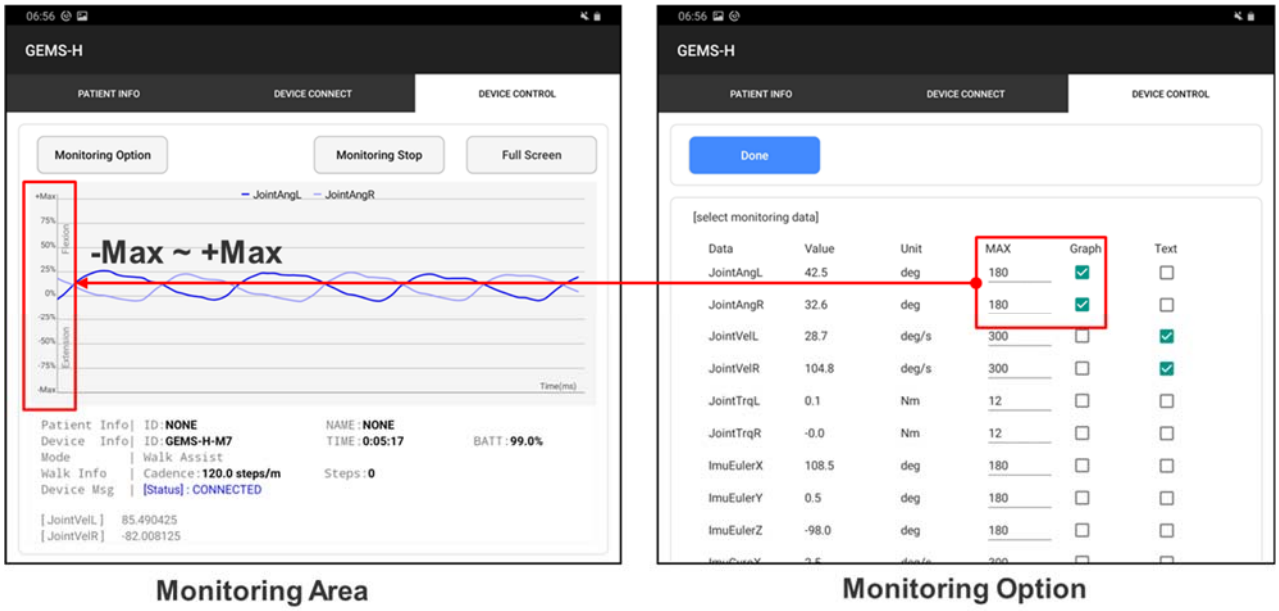


Data	Value	Unit	MAX	Graph	Text
JointAngL	-26.4	deg	180	☑	☐
JointAngR	26.4	deg	180	☑	☐
JointVelL	0.0	deg/s	300	☐	☐
JointVelR	0.0	deg/s	300	☐	☐
JointTrqL	2.0	Nm	12	☑	☐
JointTrqR	-2.0	Nm	12	☑	☐

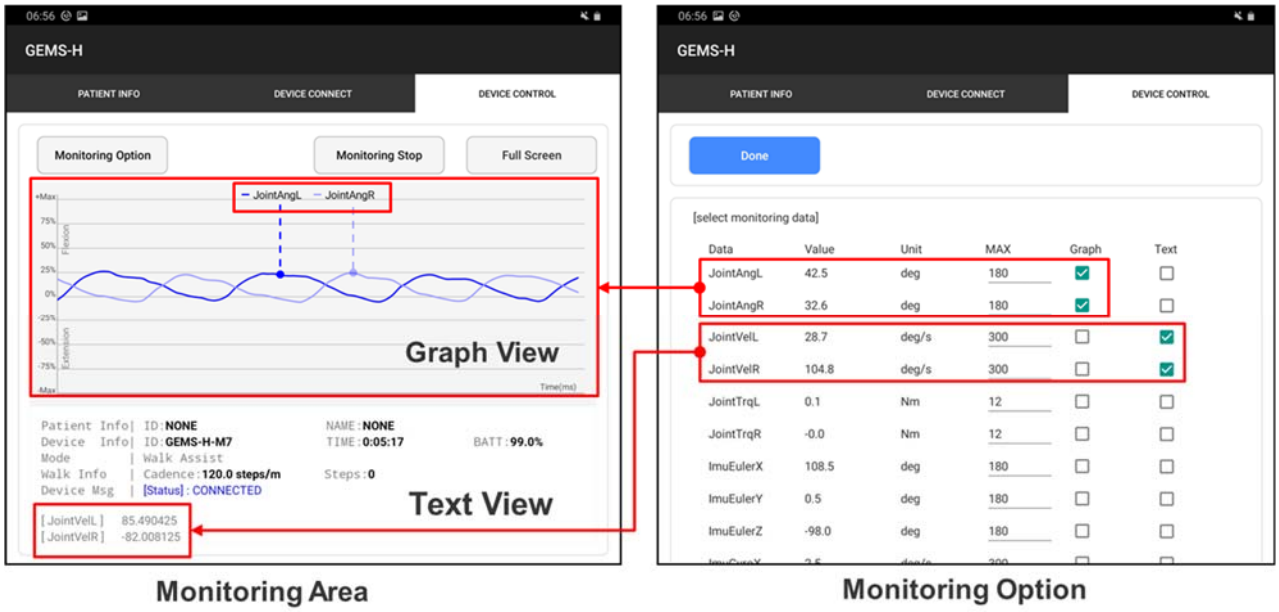
Default selections of monitoring data for graph view

In the monitoring option screen, the user may select data to be displayed on the main screen graphically or textually. These selections may be made by checking “Graph” or “Text” in the relevant row of the monitoring option screen. The “MAX” column shows the graph range for each monitoring data. The default settings of the monitoring option screen are shown below / above.

① The “Max” label on graph view refers to the max value in the monitoring option screen as shown below:



② Legend of selected data as shown below:



③ The following table explains the meaning of the possible monitoring data variables:

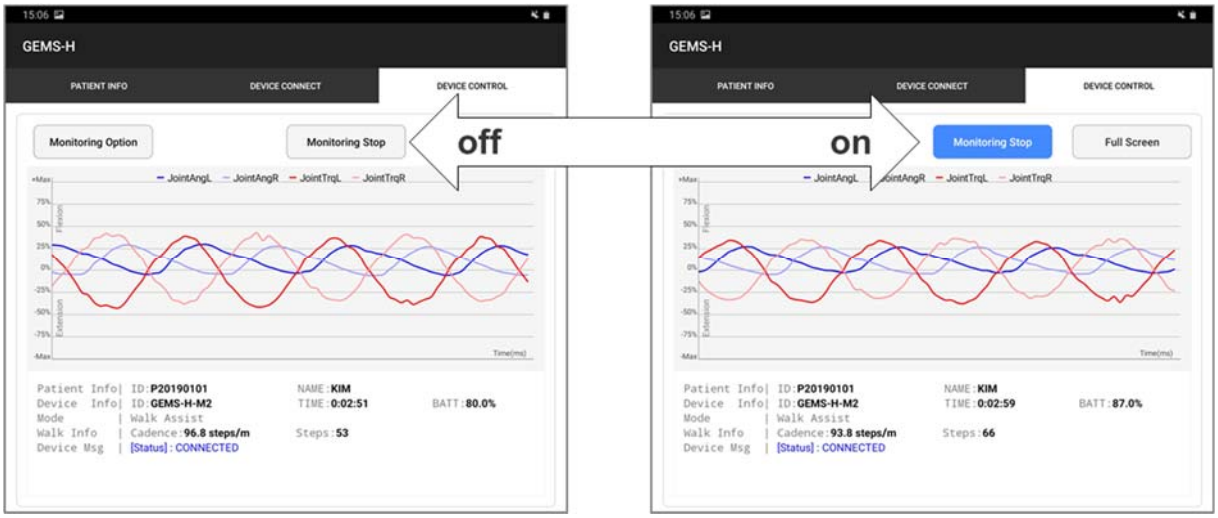
JointAngL	left hip joint angle
JointAngR	right hip joint angle
JointVelL	left hip joint angular velocity
JointVelR	right hip joint angular velocity
JointTrqL	left hip assist torque, measured
JointTrqR	right hip assist torque, measured
ImuEulerX	Euler angle of X axis from the IMU sensor
ImuEulerY	Euler angle of Y axis from the IMU sensor
ImuEulerZ	Euler angle of Z axis from the IMU sensor

ImuGyroX	angular velocity of X axis from the IMU sensor
ImuGyroY	angular velocity of Y axis from the IMU sensor
ImuGyroZ	angular velocity of Z axis from the IMU sensor
ImuAccX	acceleration of X axis from the IMU sensor
ImuAccY	acceleration of Y axis from the IMU sensor
ImuAccZ	acceleration of Z axis from the IMU sensor
LeftButton	currently not available
RightButton	currently not available
ControlTrqL	left hip torque goal from the algorithm
ControlTrqR	right hip torque goal from the algorithm

Description of monitoring data

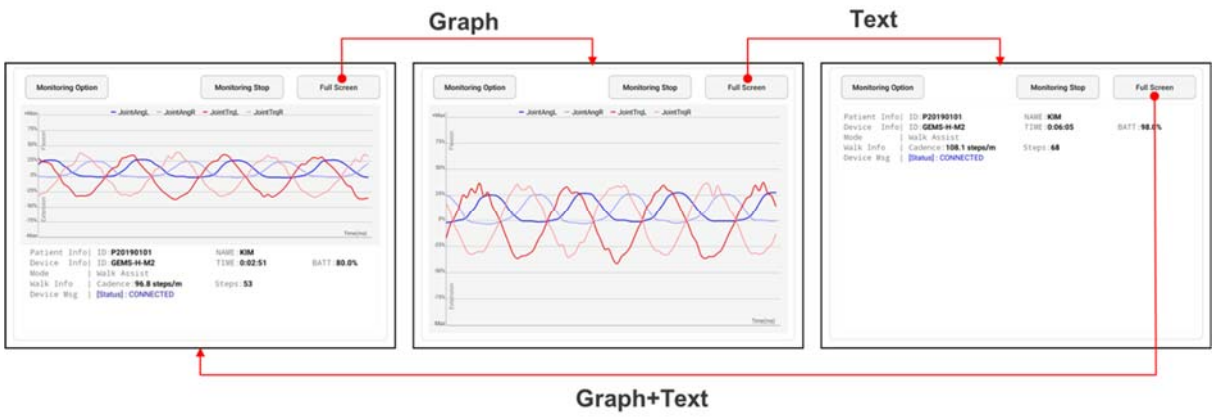
2) Monitoring Stop

If you want to look at the graph in detail, you can freeze the monitoring data by pressing the "Monitoring Stop" button and zoom in on the graph.



3) Full Screen

Press the "Full Screen" button to cycle between graphical, text, and mixed graph/text full-screen layouts.



4) Text Screen

```
Patient Info| ID:P20190101              NAME:KIM
Device  Info| ID:GEMS-H-M2              TIME:0:02:51          BATT:80.0%
Mode        | Walk Assist
Walk Info   | Cadence:96.8 steps/m      Steps:53
Device Msg  | [Status] : CONNECTED
```

[Patient Info]	Patient ID and name.
[Device Info]	Device ID, time duration since power on and battery level.
[Mode]	Operation mode. Currently only the Walk Assist mode is available.
[Walk Info]	Cadence: The number of steps per minute. This value is updated every two steps. Steps: The number of steps. This value is reset to 0 when the "STOP" button is pressed.
[Device Msg]	Messages from the device. There are three types of messages and each type of message has own color: Status messages are shown in blue, warning messages are in orange, and error message are in red. Please see "Chapter 9 Troubleshooting" for details.

6.7.2. Assist control area

6.7.2.1. Set the stand pose

Note

Make sure that hip angle is as close to neutral as possible with the patient standing naturally. If the patient is walking with their back bent, their neutral posture will also be standing with back bent.

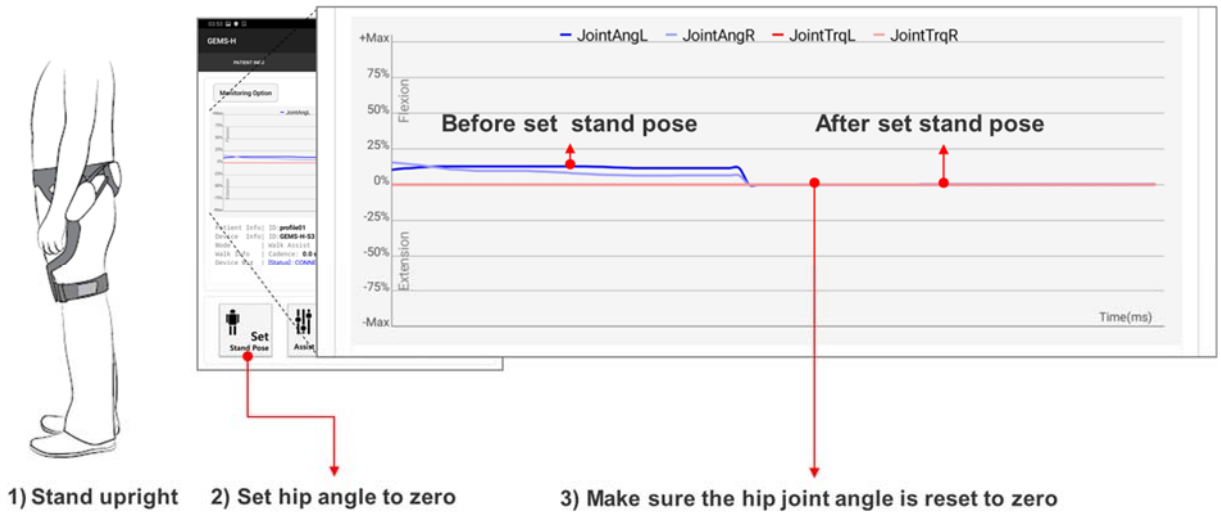
Incorrect setting of the stand pose may cause uncomfortable assistance or degrade clinical effectiveness.

Note

Make sure that both the left and right joint angle options are selected within the monitoring option dialog.

[select monitoring data]

Data	Value	Unit(US)	MAX	Graph
JointAngL	-15.3	deg	180	☑
JointAngR	15.3	deg	180	☑



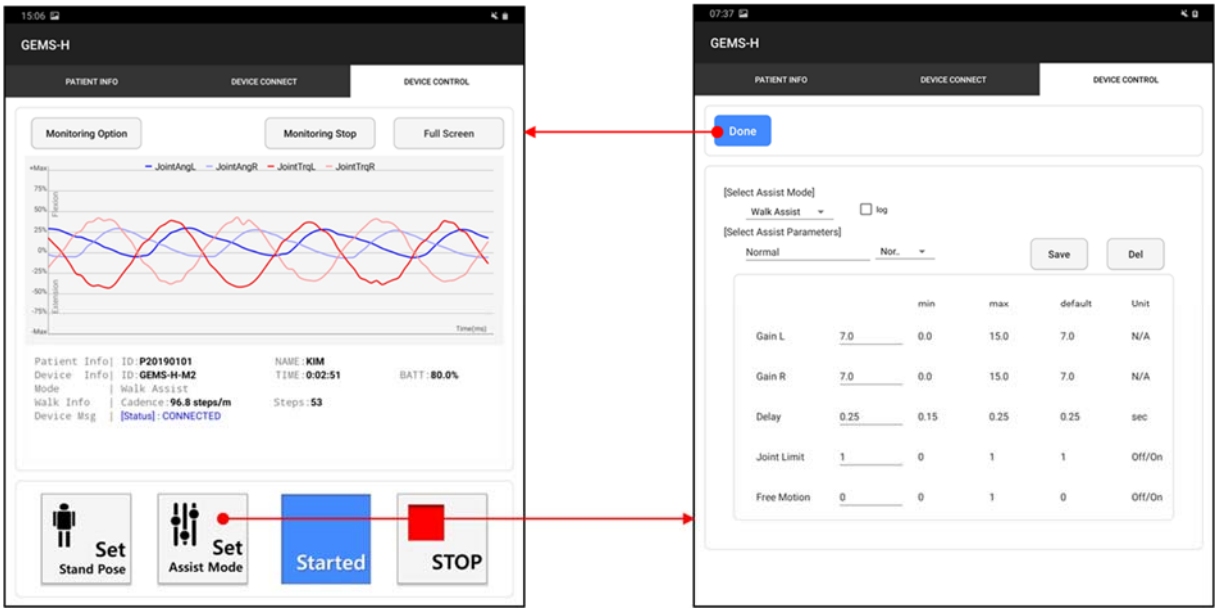
① Reset the hip angle sensor while the patient is standing in a neutral posture with hips straight if possible, or with comfortable posture otherwise. This will be used as the reference position for calculating flexion and extension.

② Press the “Set Stand Pose” button to reset the hip angle to zero and to calibrate the reference posture.

③ If the stand pose is not set, the “START” button will not be activated.

④ Make sure that both left the right joint angles are selected in the monitoring option dialog to see both joint angles in the graph.

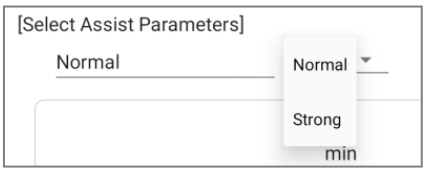
6.7.2.2. Set assist mode



① By pressing the “Set Assist Mode” button, the therapist can change the assist mode and parameters.

② At present, only the Walk Assist mode is provided.

③ Pre-saved assist parameters can be selected. The default parameters are available as “Normal,” and an additional saved parameter set called “Strong” is available by default.



④ Assist parameters can be saved with a user-defined name using the “Save” button.

⑤ Parameters that are no longer needed can be deleted with the “Del“ button. The default parameters cannot be deleted.

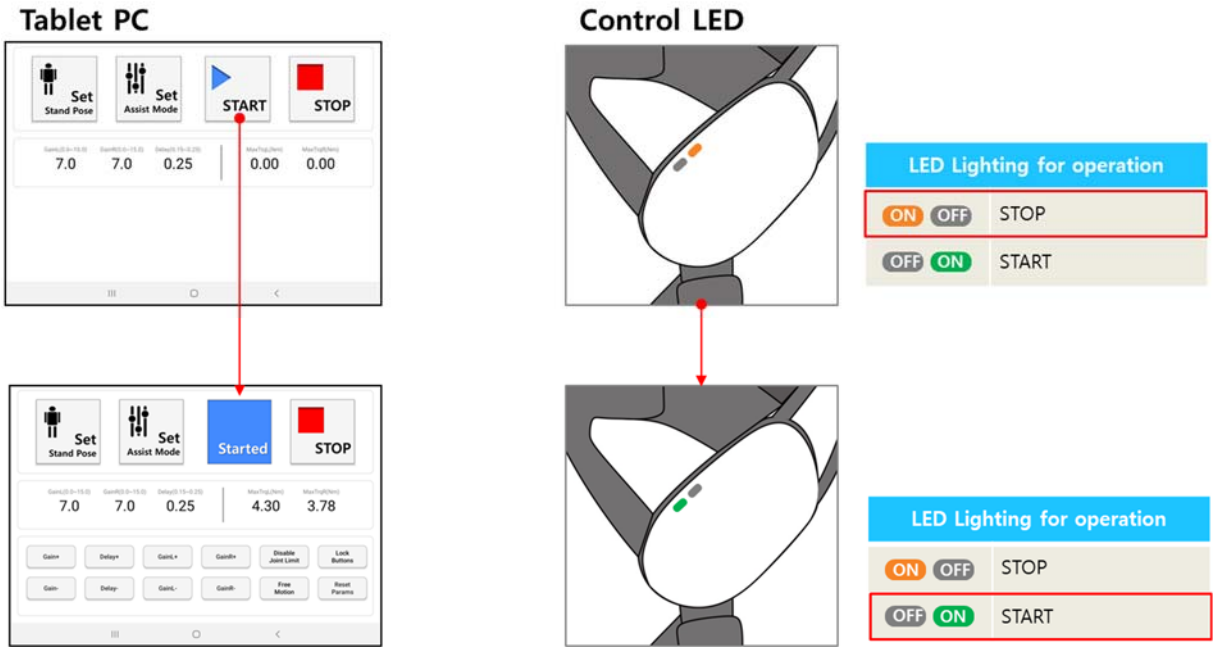
⑥ Select the “log” check box to automatically log data when the assist starts. If you are interested in using your log data for research or other purposes, please contact the manufacturer.

6.7.2.3. Start/Stop assistance

1) Start assistance

① Press the “START” button to run the assistance algorithm.

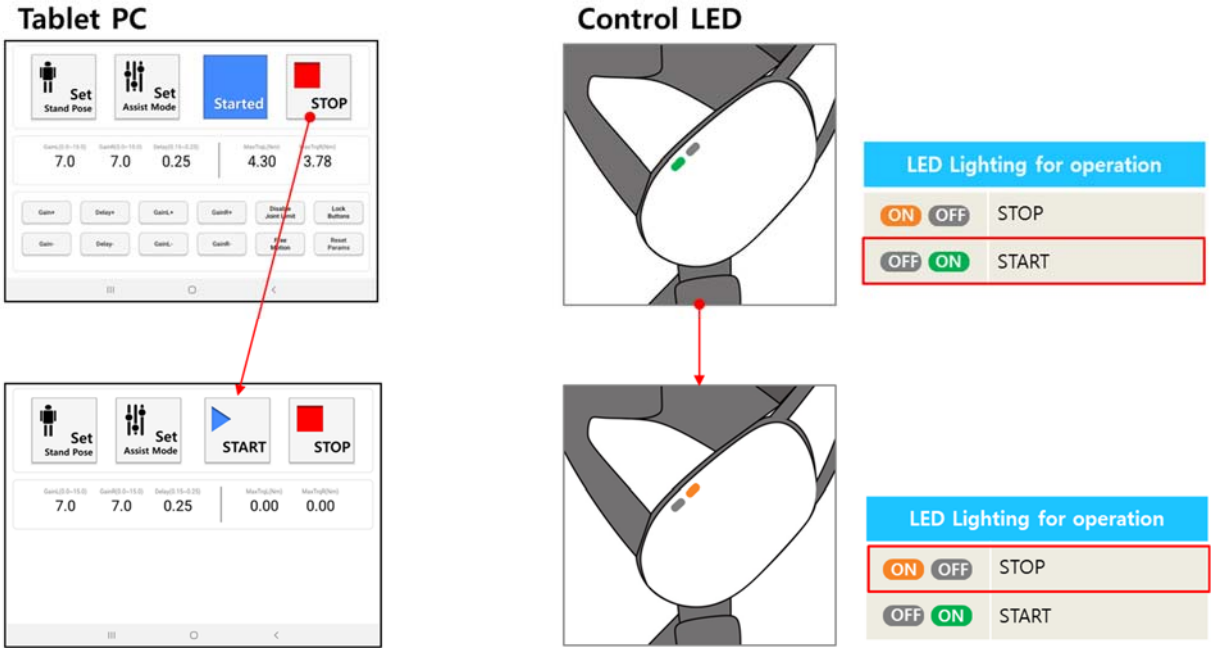
② If the algorithm runs properly, the tablet PC interface and the LEDs on the device will change as shown below.



2) Stop assistance

① Press the “STOP” button to stop the assistance algorithm.

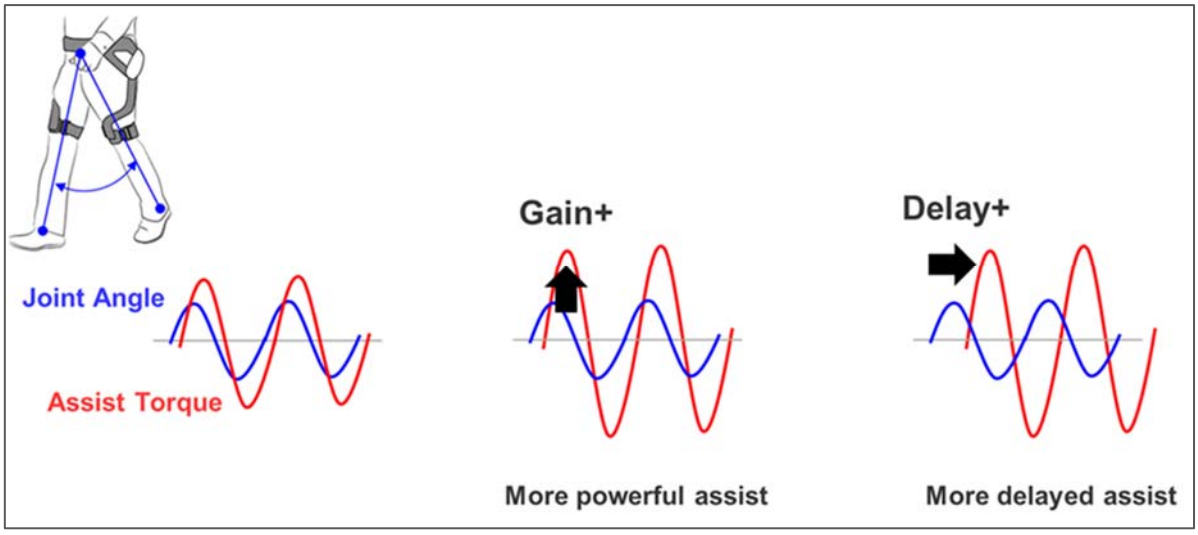
② If the algorithm stops properly, the tablet PC interface and LEDs on the device will change as shown below.



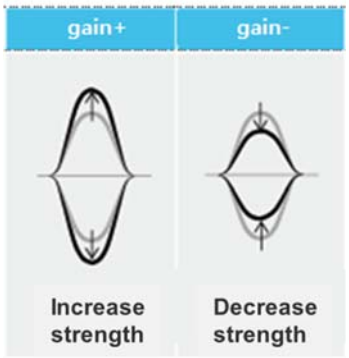
6.7.3. The parameter control area

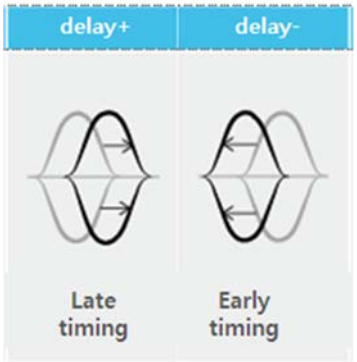
6.7.3.1. Parameter control descriptions

The parameter control area contains a number of parameters that can be controlled by the user while therapy is in progress. The following illustrations and table describe the use of the parameter control area.



Assist pattern changes by controlling parameters

<table>
<tr><th>Parameter</th><th>GUI element</th><th>Function</th></tr>
<tr><td>Gain +/-</td><td>Gain+
Gain-</td><td>Adjust assist strength to be weak or strong. Gradually increase the gain after confirming that the torque is not too strong for the wearer. Each press will change the parameter by 0.2. This parameter ranges from 0 to 15. The default setting is 7 and usually assists around 5 Nm.
 

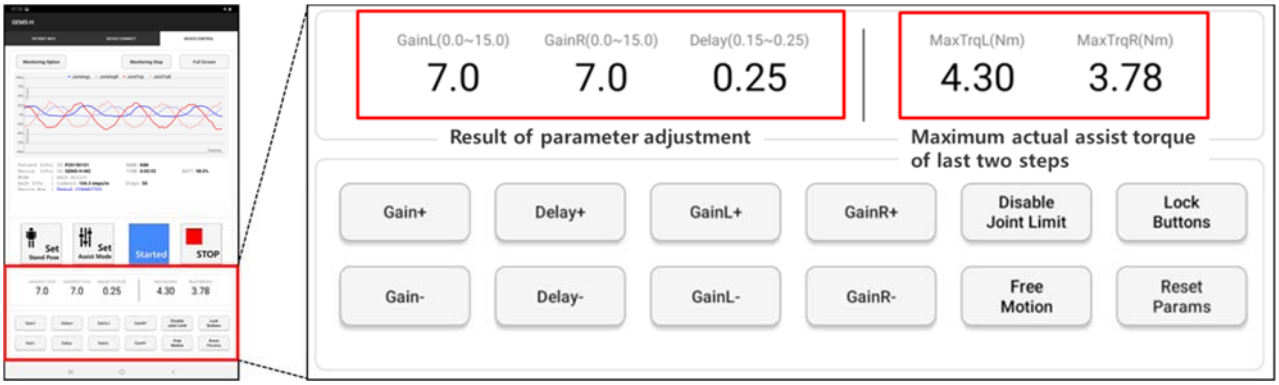
Guide Line
• Slow step time/weak step pattern → increase gain
• Heavy patient weight or small step length → increase gain
• Light patient weight or too much assistive force → decrease gain</td></tr>
<tr><td>Delay +/-</td><td>Delay+
Delay-</td><td>Adjust timing to be early or late. Each press will change the parameter by 0.1. This parameter ranges from 0.15 to 25. The default setting is 2.5.
 

Guide Line
• Slow walk (≤1 m/s) → 0.25
• Fast walk (>1 m/s) → 0.2 or 0.15</td></tr>
</table>

Parameter	GUI element	Function
GainL +/-	GainL+ GainL-	Adjust assist strength of left leg only.
GainR +/-	GainR+ GainR-	Adjust assist strength of right leg only.
Disable Joint Limit	Disable Joint Limit off ⇔ on Disable Joint Limit	Turn off joint limit monitor (extension 40 degree ~ flexion 100 degree) which is used for safety functions.
Free Motion	Free Motion off ⇔ on Free Motioin	The device gives no assistive force, and moves itself just enough to follow the patient as the patient moves.
Lock Buttons	Lock Buttons off ⇔ on Lock Buttons	Disable all buttons to prevent accidental button presses.
Reset Params	Reset Params	Reset all assist parameters back to initial values of the START point.

6.7.3.2. Parameter control monitoring

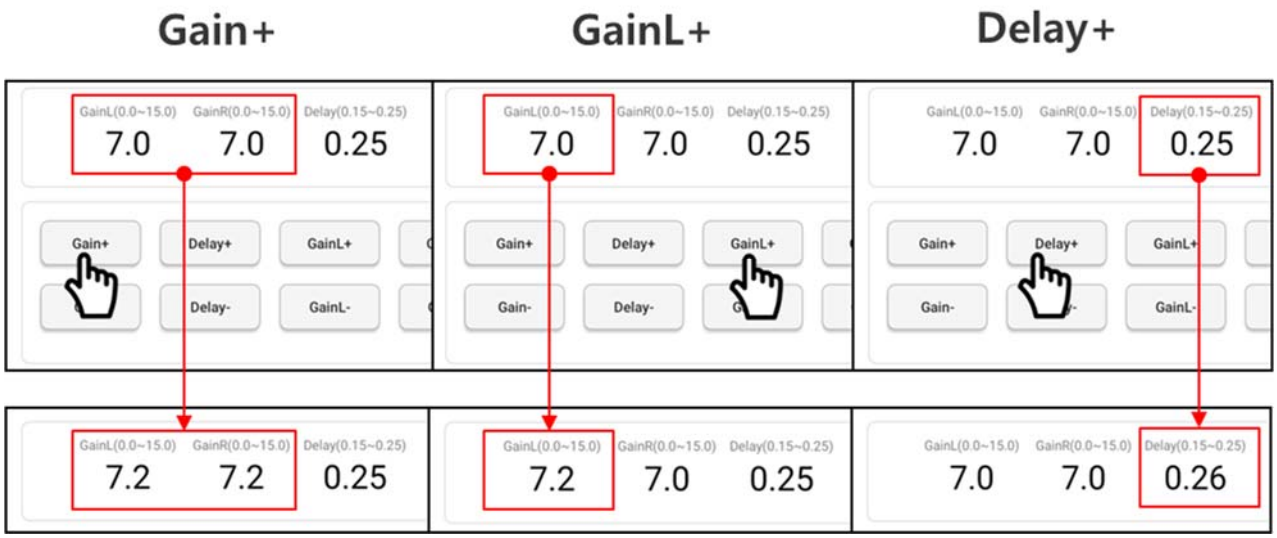
The therapist can monitor the control parameters and assist torque.



1) Control parameters: Gain, Delay parameters

As shown in the figure below, the user can monitor parameter adjustments.

If a parameter is adjusted beyond the defined parameter range, the parameter will not change.



2) Monitor parameter: Maximum Torque Parameters (MaxTrqL, MaxTrqR)

Users can monitor the maximum assistive torques that the device delivers to the patient as the user changes the assist gain. The maximum assistive torques MaxTrqL and MaxTrqR indicate the maximum values of assistive torques provided by the device for the last two steps. Even with parameters fixed, the assistive strength will vary based on the patient walking condition such as step length, walking speed, and other factors.

6.7.3.3. Example of parameter control

	GEMS-H	DESCRIPTION	CAR
Monitoring	**Max torque** 0 ~ 12 Nm	Peak torque info updated every stride Torque (rotational force) = Radius * Force To get 5 Nm, use 5 kgs of weight or increase length to 50 cm.	**Speedometer**
Control 1	**Gain** (default = 7) 0 ~ 15	Adjust **strength** to be weaker or stronger (or adjust peak torque) Recommended target max torque: 4 ~ 8 Nm (up to 12 Nm is possible) Gradually increase the gain after confirming that the torque is not too strong from the wearer	**Accelerator Pedal**
Control 2	**Delay** (default = 0.25) 0.15 ~ 0.25 sec	Adjust **timing** to be earlier or later (or adjust response to be faster or slower) Slow walk (0 ~ 1 m/s): 0.25 s Fast walk (1 m/s or more): 0.2 s or 0.15 s	**Gear Stick or Drive Mode**

6.8. Safety features

6.8.1. Mitigation of risks related to a fully discharged Lithium Ion battery

The Li-ion battery used in this device has a risk of explosion and of material leakage when completely discharged. To prevent this, the power control module (PCM) circuit is designed to fundamentally cut off the power before the battery discharges fully. In addition, the battery level is continuously measured and displayed on the application.

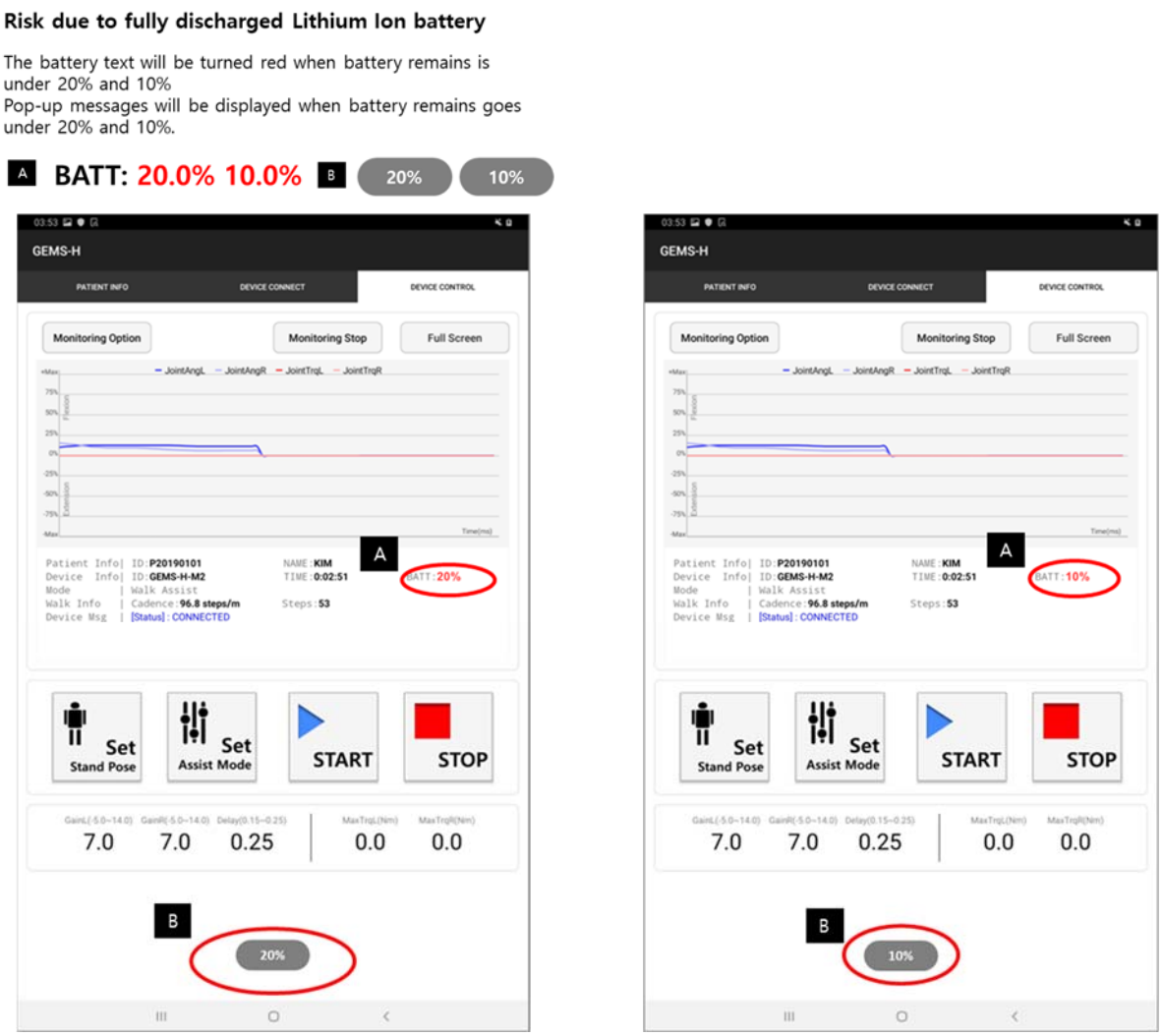
Status of the device and recommended user action

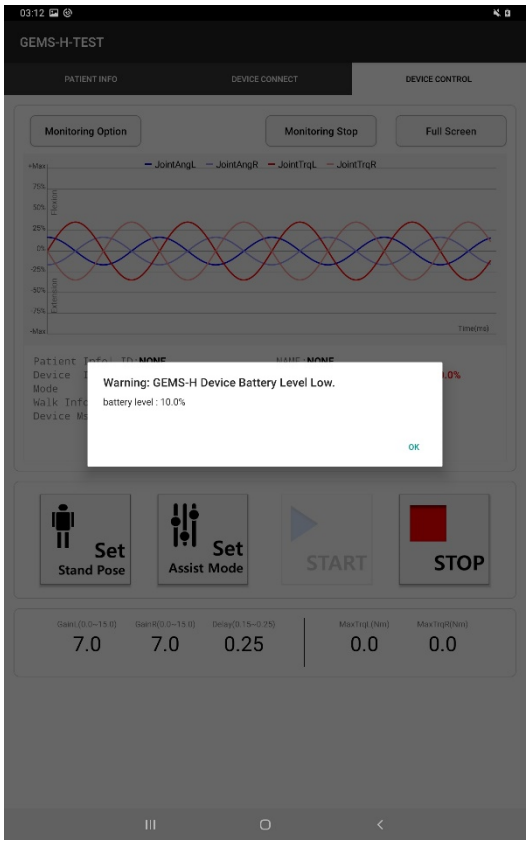
An alert will appear on the associated tablet PC if the battery level is below 20 % and 10 %, and the battery level will be shown in red.

When the battery level is below 20 %, the physical therapist is recommended to charge the battery within 5 minutes.

When the battery level is below 10 %, it is recommended that device operation be stopped immediately, and that the device be charged before further use.

As a final warning, if the battery level is almost zero, then without further warning messages, the low battery warning sound will be played from the device speaker, and device assistance will be stopped immediately.

Error message examples


Error message examples


6.8.2. Mitigation of risks due to excessive power output

In order to avoid an excessive torque being applied to the patient, the device is designed to not to transmit a torque of more than 12 Nm ±15 % to the patient. When the assistive force reaches the predetermined maximum force, then the device will cease applying the assistive force.

Status of the device and recommended user action:

If assistive force is ceased due to an over-torque situation, the associated tablet PC will display an error message of "**EXCEEDED TORQUE LIMIT**."

When this message is displayed and the device is stopped, the physical therapist may try to start the device again by pressing the "START" on the tablet PC. If the problem persists, reboot the device and the tablet PC. If there is still the problem with the device, turn off the device immediately and contact the manufacturer.

Error message examples
Risk due to excessive power output A [Error] EXCEEDED TORQUE LIMIT

6.8.3. Mitigation of risks due to excessive joint angle movement

The GEMS-H joints have mechanical stoppers to restrict over-extension of joints, as well as software limits on joint movement. The mechanical stoppers are designed to ensure that the hip joints stay within the specified range even in the case of a malfunctioning device. The mechanical stoppers are set to a maximum of 110 degrees for flexion and a maximum of 45 degrees for extension. The delayed output controller (software) is limited to a maximum of 100 degrees for flexion and a maximum of 40 degrees for extension in normal use.

Status of the device and recommended user action:

When the joint angle reaches the joint angle limit, the device alerts the physical therapist by displaying a warning message of "**EXCEED JOINT LIMIT**". When the joint angle reaches these joint limits, the device ceases applying assistive force. Thereafter, the physical therapist may reset the device by asking the patient to stand with upright posture and tapping the "Set Stand Pose" button on the tablet PC. Pressing the "START" button will then cause the device to start providing assistive force again.

Error message examples
Risk due to excessive joint angle movement A [Warn] EXCEEDED JOINT LIMIT

6.8.4. Mitigation of risks due to disconnection from the tablet PC

When using the GEMS-H, status monitoring and operation are done through a tablet PC via Bluetooth wireless communication. If the Bluetooth communication is interrupted, the monitoring and control of the GEMS-H are designed to cease, but the device will continue operation.

Status of the device and recommended user action:

In the case that communication ceases, the tablet PC alerts the physical therapist by displaying the "**DISCONNECTED**" warning message on the application.

For safety, when such an event occurs, the GEMS-H continues at the current assistance setting. The physical therapist should stop the current treatment and reconnect the tablet PC. When the tablet PC is reconnected to the GEMS-H, the application will display the message "**CONNECTED**", and the tablet PC resumes operation.

Error message examples

Risk due to disconnection from the mobile computing device

A [Warn] DISCONNECTED

[Warning message]

[Screen of connected situation]

6.8.5. Mitigation of risks due to abnormal actuator module status

If the actuator module does not work properly during use, the controller may generate abnormal power. The actuator module is monitored continuously during treatment, and when an abnormality is detected, the assistive force is turned off.

Status of the device and recommended user action:

Should abnormal actuator status be detected, the tablet PC will display the error "**DETECTED ABNORMAL ACTUATOR**" The actuator status is considered abnormal when data transmitted from the actuator does not match the expected signals, for example, when the device detects patient movement, but actuator readings are constant. This may result from disconnected communication lines, actuator faults, and/or software failure. The physical therapist should attempt to fix the problem by rebooting both the device and the tablet PC. If this corrects the error, the tablet PC will display "**NORMAL OPERATION**".

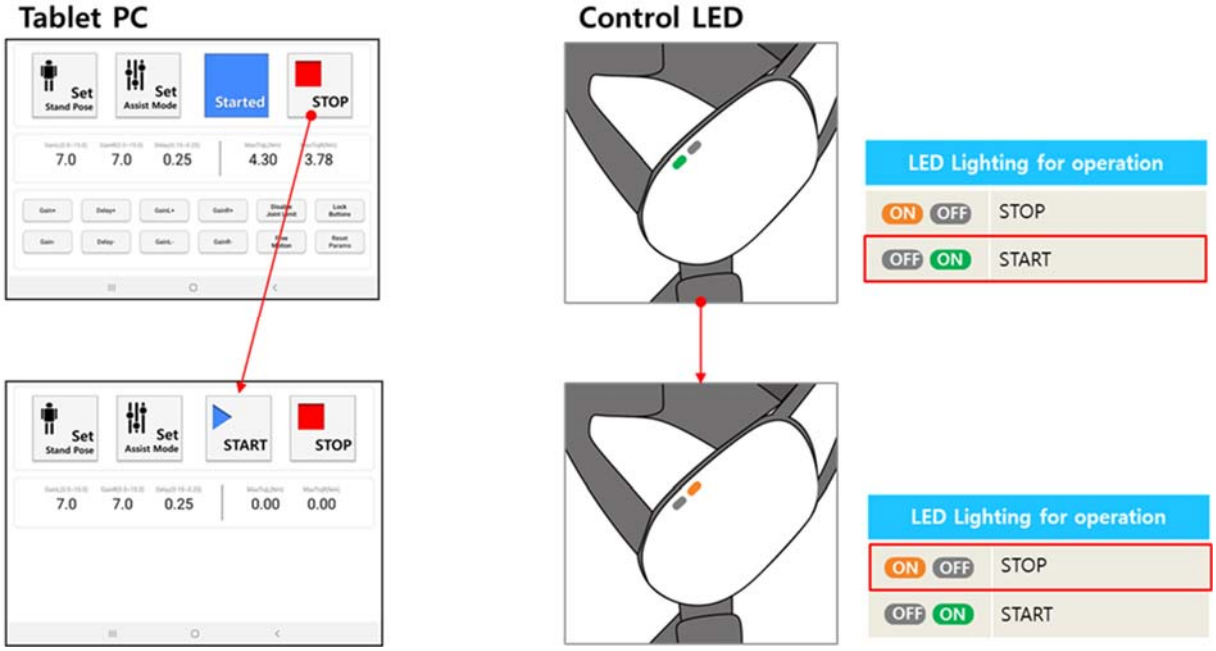
If rebooting the device and the tablet PC do not clear the problems, please contact the manufacturer.

Error message examples
Risk due to abnormal status of the actuator module A [Error] DETECTED ABNORMAL ACTUATOR **[Warning message]** **[Screen of normal operation]**

Chapter 7. Shutdown

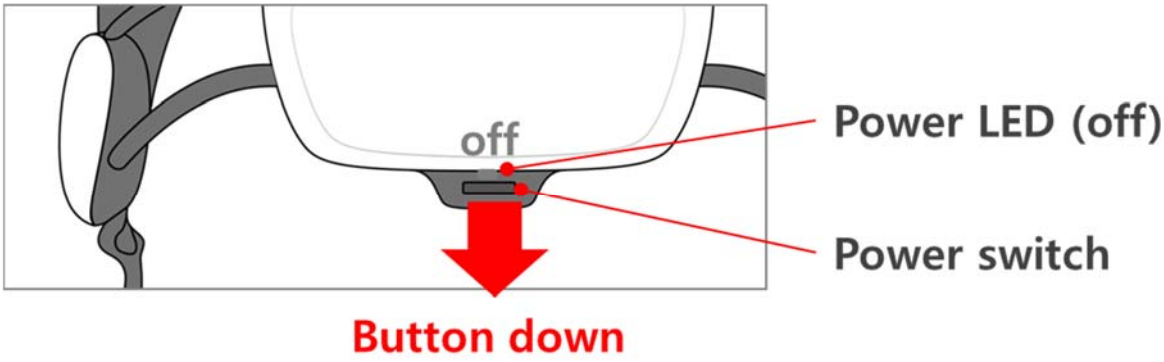
7.1. Stop the assistance

When the “STOP” button is touched on the tablet PC, the device will cease applying assistive force and buttons in the Assist Control Area will deactivate.



7.2. Turn off the device

Turn off the power switch by pushing it down. The green power LED indicator will turn off.



7.3. How to take off the device

① Unfasten the thigh support straps.

② Push the release button on the thigh support frame to unhook the thigh support frame.

③ Detach both thigh support frames.

④ Unfasten the waist belt Velcro.

⑤ Open the waist belt and remove the device from the wearer's waist. Be careful not to let the device fall.

⑥ Charge the device before its next use and place it in the storage case provided if use is not anticipated.

Chapter 8. Maintenance

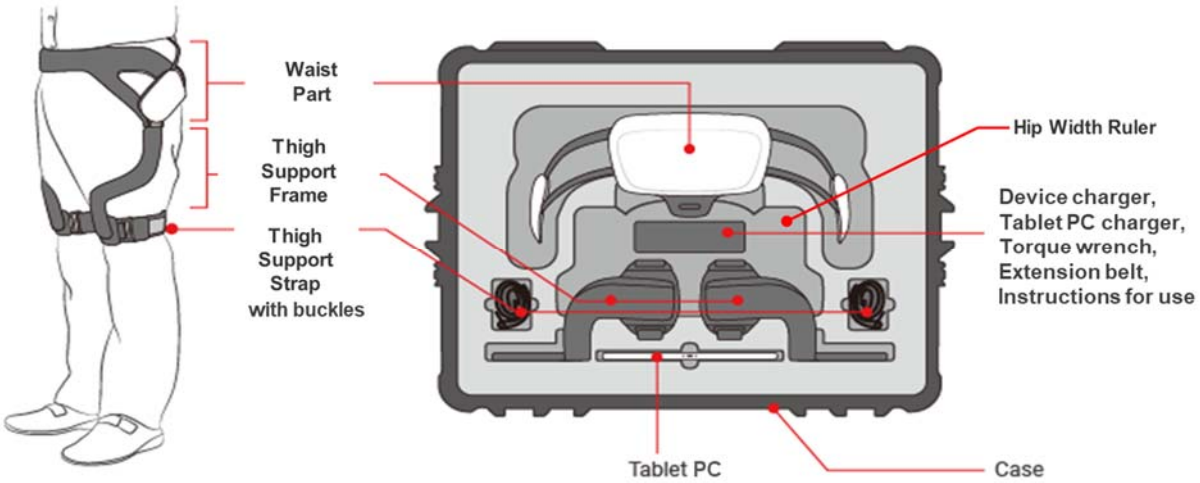
8.1. Storage

To prevent damage during storage, it is recommended that the thigh support frames and the waist part are disconnected prior to storage.

The device should be stored under the following recommended environmental conditions:

	Storage & Transport
Temperature	- 77 ℉ to 158 ℉ (- 25 ℃ to 70 ℃)
Humidity	10 to 94 % (non-condensing)
Pressure	500 hPa to 1060 hPa

When the device is not in use, it is recommended that the device be stored in the shock-resistant case, as shown below:



8.2. Regular maintenance (Weekly Checklist)

- Check that the bolts on the actuator cover are not loose.
- Check that the bolts on the battery cover are not loose.
- Check that the bolts on the thigh support frame are not loose.

8.3. Cleaning

⚠ WARNING

Risk of electrical shock hazard due to moisture!

Electrical shock may be delivered to the patient and the user due to excessive moisture when the device is turned on while cleaning.

- **Do not clean while in use.**
- **Be sure to turn off the power before cleaning.**

NOTICE

Property damage may occur due to improper cleaning procedures or agents!

The product may be damaged if it is cleaned and disinfected with improper procedures or agents.

- **Use only this procedure for cleaning.**

Note

If the device is used by more than one patient, it is essential to clean the device with disinfectant before use.

To prevent cross-infection between patients, the device (i.e., waist part, thigh support frames, and thigh support straps) should be cleaned after each use. The device should be disinfected as follows:

① Dampen (but do not soak) a lint-free cloth with purified water.

② Wipe the surface of the device for at least five (5) minutes.

③ Wipe the surface of the device with an (isopropyl) alcohol-based disinfectant for at least five (5) minutes.

- Recommended Disinfectant: Cavi-Wipes (Metrex Research, Kerr) or equivalent

④ Dampen (but do not soak) a lint-free cloth with purified water.

⑤ Wipe the surface of the device for at least five (5) minutes.

⑥ Let the device dry completely in air.

⑦ Store the device in its storage case provided until the next use.

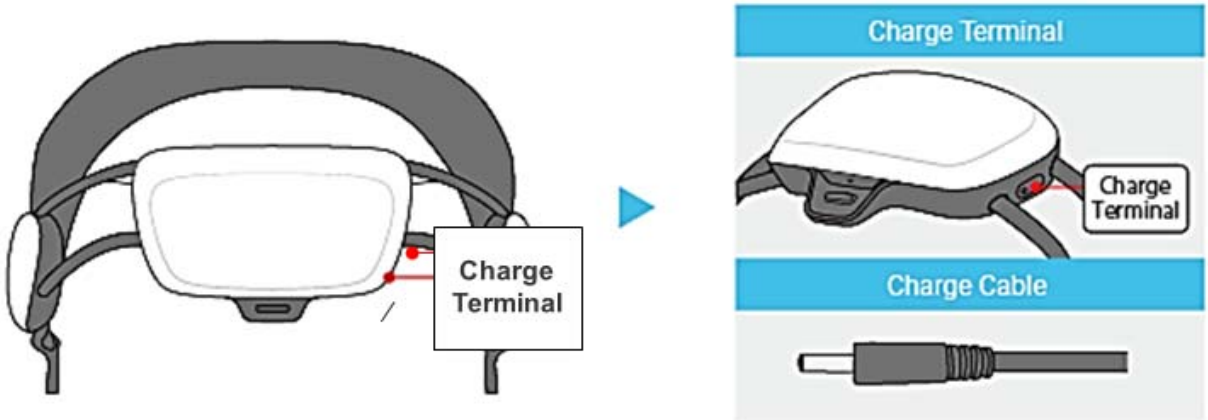
8.4. How to charge the GEMS-H

NOTICE

Property damage may occur when the charger cable receives any force!

If the charger cable receives any force when the terminal pin is plugged in, the connector of the charger cable can be damaged beyond repair.

- **Make sure that the charge cable does not receive any force when the terminal pin is plugged in.**



① There is a terminal for charging on the right side of the control pack.

② Charging begins automatically when the charger cable is plugged in.

③ When charging, the LED lights on the charger are illuminated (see image below).

④ After the device is fully charged, the green charger LED will come on.

⑤ It takes about two hours to fully charge the device (50 minutes with a high-speed charger), and the device may be used for about two hours on a full charge.

⑥ The device may be left on while charging, but the user should not use the device while charging.

charging

fully charged

Chapter 9. Troubleshooting

NOTICE

Property damage may occur due to improper repair.

If personnel other than authorized by the manufacturer carries out the repair, it may irreversibly damage the device.

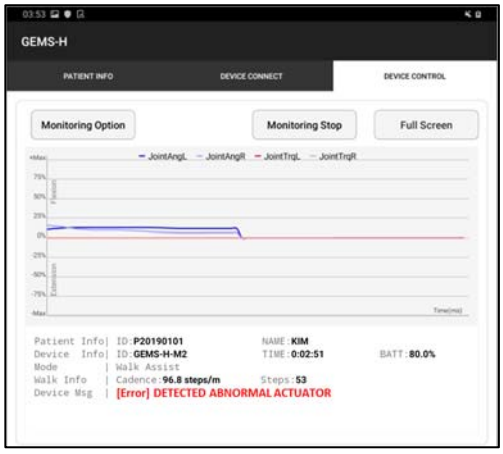
- **Repair should only be performed by the manufacturer.**

9.1. Troubleshooting

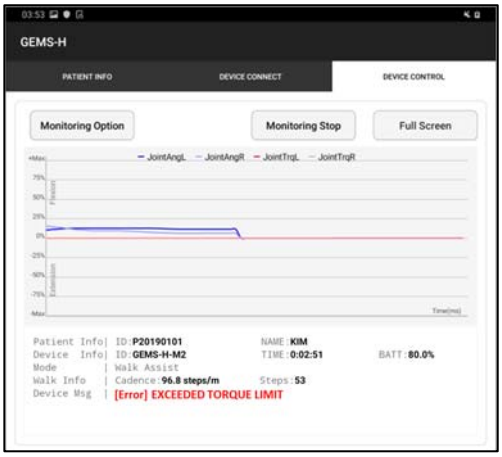
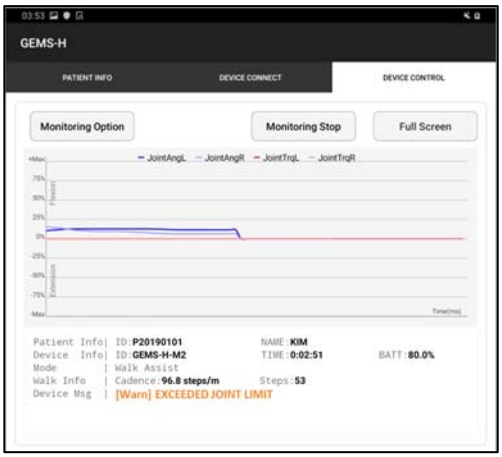
Issue	Recommended action(s)
The hip joint of the device becomes stuck during operation.	• If the actuator becomes stuck during operation, do not apply excessive force to the device. • First, turn off and then take off the device. • Check what the problem is while gently moving the corresponding joint. • If the problem persists or occurs repeatedly, please contact the manufacturer.
Case / Frame / Fastener breaks	• If the hardware is damaged, do not operate the device. Contact the manufacturer.
There is unusual noise coming from the device.	• If you hear noise from the device that is not associated with normal use, please contact the manufacturer.
No Bluetooth connection.	• Make sure that Bluetooth is activated on the tablet PC. (Check this from Quick Settings on the top of the tablet screen). • Restart the GEMS-H App. (Press the button left of the home button on the bottom of the tablet screen to completely close the app). • Restart the GEMS-H Device. (Use the power switch located at the bottom of the control pack). • Restart the associated tablet PC.
Assistance is uncomfortable or the patient cannot feel the assistive force.	• Make sure the LED indicator is not indicating a “STOP” state. • Repeat the procedure for resetting the Stand Pose to zero when the patient is stationary and standing upright. This procedure may be found in section 6.8.3, under “Mitigation of risks due to excessive joint angle movement.” • Restart the assistance algorithm with default control parameter values (or quit the GEMS-H and run it again). • Check whether the hip angle/torque value during walking is normal or not.

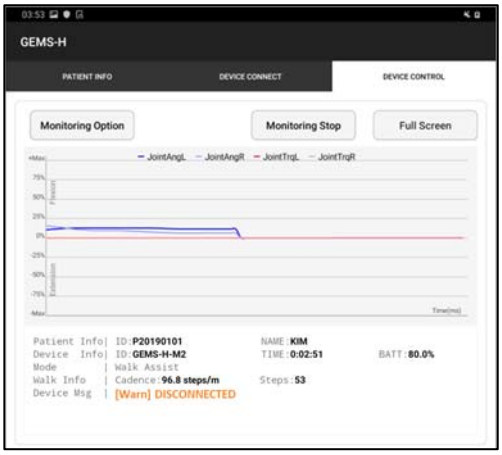
Issue	Recommended action(s)
	• Restart the GEMS-H Device. (Use the power switch located at the bottom of the control pack). • If the above procedure does not solve the problem, the actuator may not be in a normal state. Please contact the manufacturer of the device.
The following malfunctions: - The assistive force suddenly ceases without any reasons. - The assistive forces are being delivered to the patient, but hip angles and torques are not displayed on the connected tablet PC. - The device turns off unexpectedly.	• First, turn off and then take off the device. • Restart the GEMS-H Device. (Use the power switch located at the bottom of the control pack). • If the problem persists or occurs repeatedly, please contact the manufacturer.

9.2. Device messages

Messages	Causes	Recommended action(s)
[Error] DETECTED ABNORMAL ACTUATOR  	**Abnormal communication with actuator**	The physical therapist should attempt to fix the problem by rebooting both the device and the tablet PC. If this corrects the error, the tablet PC will display "**NORMAL OPERATION**". If rebooting the device and the tablet PC do not clear the problems, please contact the manufacturer.
[Error] DETECTED ABNORMAL IMU* *IMU is used for the patient's posture estimation	**Abnormal communication with an inertial measurement unit (IMU)**	Restart the GEMS-H device by using the power switch located at the bottom of the control pack. If restarting the device does not resolve the problem, please contact the manufacturer.

03:53 GEMS-H PATIENT INFO DEVICE CONNECT DEVICE CONTROL Monitoring Option Monitoring Stop Full Screen JointAngL JointAngR JointTrqL JointTrqR +Max 75% 50% 25% 0% -25% -50% -75% -Max Flexion Extension Time(ms) Patient Info| ID:P20190101 NAME:KIM Device Info| ID:GEMS-H-M2 TIME:0:02:51 BATT:80.0% Mode | Walk Assist Walk Info | Cadence:96.8 steps/m Steps:53 Device Msg | [Error] DETECTED ABNORMAL IMU		

Messages	Causes	Recommended action(s)
[Error] EXCEEDED TORQUE LIMIT 	Over the limit value of assist torque	When this message is displayed and the device is stopped, the physical therapist may try to start the device again by pressing the “START” button on the tablet PC. If the problem persists, reboot the device and the tablet PC. If there is still a problem with the device, turn off the device immediately and contact the manufacturer.
[Warn] EXCEEDED JOINT LIMIT 	Over the limit value of joint angle	When the joint angle reaches these joint limits, the device ceases applying assistive force. Thereafter, the physical therapist may reset the device by asking the patient to stand with upright posture and tapping the “Set Stand Pose” button on the tablet PC. Pressing the “START” button will then cause the device to start providing assistive force again.
[Warn] EXCEEDED ASSIST LIMIT	Over the limit value of assist command	Restart the GEMS-H device by using the power switch located at the bottom of the control pack. If restarting the device does not resolve the problem, please contact the manufacturer.

Messages	Causes	Recommended action(s)
[Warn] DISCONNECTED  	**Disconnected Bluetooth communication**	The physical therapist should stop the current treatment and reconnect the tablet PC. When the tablet PC is reconnected to the GEMS-H, the application will display the message "**CONNECTED**", and the tablet PC resumes operation.
[Status] NORMAL OPERATION 	**Recovered from Warn/Error situation**	n/a
[Status] CONNECTED 	**Connected Bluetooth communication with device**	n/a

Chapter 10. Technical specifications

10.1. Specifications

Device Sizes	S, M, and L size
Battery	Rechargeable lithium ion, 21.6 V, 2950 mAh, 2 hrs charge time
Working time	Minimum 2 Hr. of continuous walking* (with gain = 7, delay = 0.25 s) Minimum 1 Hr. of continuous walking* (with gain = 8, delay = 0.25 s) * at a walking speed of about 1.9 ~ 2.5 MPH (0.8 ~ 1.1 m/s)
Device Weight	4.7 lbs (2.1 Kg)
Range of Motion	Hip: 100° flexion to 40° extension
Actuator Spec.	2 motors, 12 Nm ±15 % max torque
Failsafe Feature	Motor torque disables; device becomes passive
Bluetooth	Frequency range: 2402-2480 MHz Bluetooth version: V2.1 + EDR Modulation type: Frequency hopping spread spectrum Transmit power: 4.61 dBm (Peak) Dwell time: <=0.4 s
Product compliance	The GEMS-H is classified in the following categories for compliance with IEC 60601-1: Internally powered, Type-B applied part For continuous operation Not suitable for use in the presence of flammable anesthetics Not for use in the presence of an oxygen-enriched atmosphere Degree of protection against particulate matter: IP20
Essential Performance	Safety related to the range of motion Torque tracking at maximum angular velocity Maximum torque Providing assistive torques at operation for walking and stopping Generation of assistive torque patterns according to the change of control parameters Continuous use time Noise

Device Charger*	Model: JBL7451251700002FJ Manufacturer: BRIDGEPOWER CORP. Input: 100 - 240 Vac, 50 - 60 Hz, 1.0 A Output: 25.2 Vdc, 1.7 A
Tablet PC*	Model: Galaxy Tab S5e Manufacturer: Samsung Electronics Co., Ltd. Battery: 7040 mAh CPU: Octa-Core, 2 GHz, 1.7 GHz Display: Super AMOLED, 2560 x 1600, 10.5 inch(267.2 mm) Network: 2G GSM, 3G UMTS, 4G FDD LTE, 4G TDD LTE
Tablet PC Charger*	Model: EP-TA20JBE Manufacturer: Samsung Electronics Co., Ltd. Input: 100 - 240 Vac, 50 - 60 Hz, 0.5 A Output: 9.0 Vdc, 1.87 A or 5.0 Vdc, 2.0 A

* Evaluated as a ME system in safety test.

Note

For details of the tablet PC and its charger, refer to the relevant user's manual.

10.2. EMC (Electromagnetic Compatibility)

⚠ WARNING

Risk of serious injury due to radiation!

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ WARNING

Risk of serious injury due to radiation!

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING

Risk of serious injury due to radiation!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the GEMS-H, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ WARNING

Risk of serious injury due to radiation!

If you are going to have an X-ray, CT scan, MRI, or be exposed to other types of radiation, remove the GEMS-H, and leave them outside the radiation area. The GEMS-H is designed and tested to tolerate common electromagnetic interference.

Note

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

EMC Table – Guidance and manufacturer's declaration

Electromagnetic emissions		
The GEMS-H is intended for use in electromagnetic environments, as specified below. The customer or the user of the GEMS-H should ensure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR11	Group 1	The GEMS-H uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class A	The GEMS-H is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning! The GEMS-H is intended for use by physical therapists only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the GEMS-H or shielding the location.**

Guidance and manufacturer's declaration - electromagnetic immunity			
The GEMS-H is intended for use in the electromagnetic environment specified below. The customer or the user of the GEMS-H should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment- guidance**
Electrostatic discharge (ESD) IEC61000-4-4	±8 kV contact ±2,4,8,15 kV air	±8 kV contact ±2,4,8,15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity of at least 30% is recommended.
Electrical fast Transient/burst IEC61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	The main power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	The main power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short Interruptions and voltage variations on power supply input lines IEC61000-4-11	0% U_T (100% dip in U_T) for 0.5/1 cycles 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 250/300 cycles	0% U_T (100% dip in U_T) for 0.5/1 cycles 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 250/300 cycles	The main power quality should be that of a typical commercial or hospital environment. If the user of the GEMS-H requires continued operation during power mains interruptions. It is recommended that the GEMS-H be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment
NOTE : U_T is the a.c. mains voltage prior to application of the test level.			
a For example, 10/12 means 10 cycles at 50 Hz or 12 cycles at 60 Hz.			

Guidance and manufacturer's declaration - electromagnetic immunity

The GEMS-H is intended for use in the electromagnetic environment specified below. The customer or the user of the GEMS-H should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment- guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz Outside ISM bands [c] 6 Vrms 150 kHz to 80 MHz in ISM bands [c]	3 Vrms 6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the GEMS-H, including cable. Then the recommended separation distance calculated from the equation appliance to the frequency of the transmitter. Recommended separation distance d=1.2$\sqrt{p}$
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	IEC 60601-1-2:2014 d=2.0$\sqrt{p}$ 80 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations; Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the GEMS-H is used exceeds the applicable RF compliance level above, the GEMS-H should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the GEMS-H.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

c The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz: 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Recommended separation distance between portable and mobile RF communications equipment and the GEMS-H		
The GEMS-H is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. **The customer or the user of the GEMS-H can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GEMS-H as recommended below, according to the maximum output power of the communications equipment.**		
Rated a maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]	
	IEC 60601-1-2:2014	
	150 kHz to 80 MHz d=1.2$\sqrt{p}$	80 kHz to 2.7 GHz d=2.0$\sqrt{p}$
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0
10	3.8	6.3
100	12	20
For transmitters rated a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter. where is the p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refection from structures, objects and people.		

Guidance and manufacturer's declaration - electromagnetic immunity					
The GEMS-H is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the GEMS-H. Otherwise, degradation of the performance of this equipment could result.					
Immunity test	**Band a**	**Service[a]**	**Modulation**	**IEC 60601 test level**	**Compliance level**
Proximity fields from RF wireless Communications IEC61000-4-3	380 - 390 MHz	TETRA 400	Pulse modulation 18 Hz	27 V/m	27 V/m
	430 – 470 MHz	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	28 V/m	28 V/m
	704 – 787 MHz	LTE Band13, 17	Pulse modulation 217 Hz	9 V/m	9 V/m
	800 – 960 MHz	GSM800:900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	28 V/m	28 V/m
	1700 – 1990 MHz	GSM 1800 CDMA 1900 GSM 1900 DECT	Pulse modulation 217 Hz	28 V/m	28 V/m

		LTE Band 1,2,4,25 UMTS			
	2400 – 2570 MHz	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	28 V/m	28 V/m
	5100 – 5800 MHz	WLAN 802.11a/n	Pulse modulation 217 Hz	9 V/m	9 V/m
NOTE : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.					
a For some services, only the uplink frequencies are included.					

10.3. FCC

10.3.1. FCC Compliance Statement

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

10.3.2 FCC Interference Statement

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense. Change or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment under FCC rules.

10.3.3 FCC Caution

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

10.3.4 FCC Radiation Exposure Statement

This equipment complies with RF exposure requirements set forth for an uncontrolled environment.

Chapter 11. Clinical studies

11.1. Introduction

In 2019, Samsung conducted a clinical study of the GEMS-H device primarily to evaluate the safety and efficacy of using the GEMS-H device in the outpatient setting for post-stroke rehabilitation. In addition, the effects on functional ambulation are also being investigated in this project.

The primary objectives are:

1) To determine safety and efficacy of Samsung GEMS-H during physical therapy care in an outpatient setting for post stroke individuals.
2) To determine the effect on gait speed, as assessed by the 10 meter walk test, after gait training using Samsung GEMS-H device in an outpatient setting for post stroke individuals.

11.2. Adverse events

There was no serious device related adverse events during the course of the clinical studies. The adverse events reported were all skin related, such as abrasions and were all resolved with adjustments to the fit of the device.

11.3. Summary of studies

Clinical trial summary (Pivotal study) – from 2019.11

Title	Safety and Efficacy of Samsung GEMS-H Device to improve Functional Walking Ability in Outpatient Stroke Rehabilitation.
Protocol Number	STU00210372
Methodology	Interventional study
Study Duration	1 year
Study Center(s)	Single site, multiple clinics within SRAL's flagship hospital and its outpatient clinics
Objectives	**Primary objectives** 1) To determine safety and efficacy of Samsung GEMS-H hip assist exoskeleton during physical therapy care in an outpatient setting for post stroke individuals. 2) To determine the effect on gait speed, as assessed by the 10 meter walk test, after gait training using Samsung GEMS-H device in an outpatient setting for post stroke individuals. **Secondary objectives** 1) To determine the effect on functional walking endurance, as assessed by the 6 minute walk test, of task specific training with the Samsung GEMS-H device in an outpatient setting for post stroke individuals. 2) To determine the effect on functional balance, as assessed by the Berg Balance Scale, Functional Gait Assessment and Five Times Sit to Stand, of task specific training with the Samsung GEMS device in an outpatient setting for post stroke individuals.
Endpoints	The outcome measures will be assessed prior to the start of the training, after 9 sessions, after 18 sessions, and a 1 month follow up testing visit, which will be the endpoints of the study. Measures related to safety will be assessed at the start and end of each session. The outcome measures will be collected without using the GEMS-H device.
Number of Subjects	30
Diagnosis and Main Inclusion Criteria	Cerebrovascular accident (CVA), post 30 days, gait speed between 0.4 m/s and 0.8 m/s, MMSE > 17, unsupported sitting >30 s, walk at least 10m with assistance from a maximum of one person, follow instructions, physician clearance for participation
Study Product(s), Dose, Route, Regimen	Samsung GEMS-H device in outpatient physical therapy
Duration of administration	18 Sessions of Outpatient Physical Therapy + 4 Sessions of testing + 2 TMS sessions
Environment of use	Hospital's internal facilities (hallways) – stairs, ramps, curbs, uneven surfaces, indoors. All the training conditions are ADA compliant with slopes less than 5 degrees.

Statistical methods	Multiple ANOVAs
Summary conclusions	**Performance results:** Primary performance endpoints Secondary performance endpoints **Safety results:** Primary safety endpoints Secondary safety endpoints Conclusions:
NCT number	