USER MANUAL

Exo-H3

Read carefully this user manual before using the *Exo-H3* and keep it for future reference.

Updated: October 15th, 2019

TECHNAID

EXO-H3

Please, read and understand this user manual before starting the exoskeleton Exo-H3.

All information related to optimal use of the Exo-H3 is provided in this user manual. It contains important safety and maintenance information; it also describes the potential problems related to use.

It is recommended to keep the user manual in the vicinity of the Exo-H3, in order to always have access to information about its right use, maintenance and safety. All information, illustration and specifications are based on the available information of the product at the time when this manual was printed; it could occur that your individual product may differ from the illustration shown here, however the operation is the same.

The user manual can be requested at Technaid S.L. or viewed online at www.technaid.com. If you have question after reading the manual, please feel free to get in touch with us.

Important notice:

Any responsibility that result from the faulty maintenance, improper repair, unauthorized service or alteration by any third party other than Technaid will fall over the owner of the product.

The reliability of this product can only be assured in case that:

1. The user follows this manual
2. All the readjustments, changes or reparations are carried out by Technaid Staff

Enjoy the Exo-H3.

Technaid S.L.

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1. Introduction

1.1. About this User Manual.

This user guide provides the information necessary to operate the Exo-H3 device. It contains important safety and maintenance information; it also describes the potential issues related to its use. Please read this user guide before operating the device. If any part of this user guide is not clear contact the support department of Technaid for assistance (support@technaid.com).

It is recommended to keep the manual user in the vicinity of the Exo-H3, in order to always have access to information about its right use, maintenance and safety. All information, illustration and specifications are based on the available information of the product at the time when this manual was printed; it could occur that your individual product may differ from the illustration shown here, however the operation is the same.

If you have questions after reading the manual, please feel free to get in touch with us.

1.2. Glossary and Abbreviations

Exoskeleton	A powered lower extremity exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis that is placed over a person's paralyzed or weakened limbs for medical purposes**.**
User interface	Mobile app used to control de Exo-H3.
User	A specially-trained person who prepares, adjusts and installs the Exo-H3 to the end-user, and who teaches him how to use it.
End-user	The person wearing the Exo-H3.
Companion	A person who can provide assistance to the end-user when the device is being used.

Table 1. Glossary of terms.

CAN	Control Area Network
MC	Main Controller

UI	User Interface
L1	Led 1
L2	Led 2

Table 2. Abbreviations used on this manual.

2. Product description

The Exo-H3 can completely emulate the process of human walking. In this way, a person with total or partial cerebral palsy of the lower limbs can walk by using his/her own legs, when wearing the Exo-H3, with the aid of crutches or similar support asset and/or aid of a health professional person.

The Exo-H3 is a device designed for research, usually on neurorehabilitation, robotic control, etc. Under that framework, the system can be used by patients with partial walking. That means, the patient must have trunk control to use the device without problems. SCI injured subjects under Th8 are able to use the system too.

The Exo-H3 is mainly indicated to assist in walking to those people that have partially lost the capacity of walking or to those people that need to "learn how to walk anew" after suffering a brain accident or neurological disease, such as medullar lesions, cerebrovascular accidents and in general for any cerebral damage acquired that limit the ability to walk.

It is also very useful for maintaining the tone of the legs and to activate the circulation in the legs of persons that have lost mobility in the legs or have muscle weakness.

What make the Exo-H3 attractive with respect to similar exoskeletons is that it is designed with an open architecture that allows the user (being a therapist, professor or researcher) to modify and adjust the control parameters of the system, getting the best performance for the patient needs, as opposed to other exoskeletons which are systems with completely closed architecture.

The Exo-H3 has been the result of many years of research in the Bioengineering Group CSIC, whom is the proprietary of the Know-How rights and has conceded an exclusive license to Technaid.

3. Indications and Safety instructions

For your safety, basic precautions should always be followed when using this device. Read all indications and instructions, especially safety warnings, before using the device. Please, remember to keep the user manual in the vicinity of the Exo-H3.

THE USER MANUAL MUST BE FOLLOWED TO AVOID INJURY

3.1. Indications and Contraindications

Note: This exoskeleton device is limited by European legislation to be used for research purposes only. Consequently, the team in charge of the device shall not use the system for clinical applications. This limitation of use extends to any third party users.

3.1.1. Indications before its use:

- A trained user must supervise the complete installation process.
- The end-user must have trunk-control.
- The end-user must use at least crutches to maintain balance. Walkers, parallel bars or cranes (for end-users with no trunk control) can also be used.
- The end-user should have sufficient passive range of motion at the hip (at least 90 deg. flexion, 15-20 deg. extension), knee (90 deg. flexion, complete extension) and ankle (15 deg. dorsiflexion, 15 deg. plantarflexion);
- The end-user should be between 1,10 m. and 2.10 m. height
- The end-user must weigh less than 100 kg.

3.1.2. Contraindications for use:

The Exo-H3 should not be used with individuals with:

- Unhealed bone fractures or at risk to fracture.

- Open wounds, fragile skin, deep vein thrombosis, incontinence, or those who are on contact precautions for infections.
- Concurrent circulatory disease, heart disease, infections or chronic obstructive pulmonary disease
- Skin lesions that may hinder or prevent the application of exoskeleton
- Joint contractures of any extremity that limits normal range of motion during ambulation with assistive devices;
- Pregnant women.
- Severe sensory deficit.

3.2. Warnings

- This product may be used only for its intended design and only as it is described in this manual.
- Consider a good clinical judgment and be careful when using the Exo-H3.
- Always make a visual inspection of the device for damage detection before use it.
- Do not use the device, if there are any sign of damage in the device or accessories.
- Use the Exo-H3 considering the motion range and level of assistance safe for the end-user's condition.
- If the end-user presents open lesions, fragile skin, or blisters in the vicinity of where the device will be placed, do not use the Exo-H3.
- While the Exo-H3 is being used, footwear must be worn. Otherwise, the performance of the device may be affected and/or cause injury to the end-user.
- Avoid over-tightening any part of the device around the end-user's lower extremities. This may reduce blood circulation to the limbs and potentially cause swellings, paresthesia, tissue death, or other symptoms.
- If the end-user experiences irritation, swelling, pain, or other similar symptoms when the Exo-H3 is wearing, suspend the use of the device.
- Consider to discontinue use of the device if the end-user has sustained an injury related to their ability to use the device safely.

- If the end-user experiences any unusual cardiovascular responses or feels dizzy, lightheaded or nauseated, do not use, or discontinue use of the device.
- Consider to remove obstruction from the path of the end-user's motion.
- The device should not be turned off while end-user is ambulating.
- While end-user is ambulating, the battery is not to be removed.
- Always follow and practice basic safety precautions when using electrical products to avoid electric shock, burns, or fire.
- The battery charger or the power supply should not be used if either appears damaged or is not working properly.
- When using the battery charger, attach only the power supply provided with the device.
- It is common for the battery charger to become warm, during charging. The charger should place in a cool spot, away from external heat sources.
- The battery charger's power cord has to be kept away from heat sources.
- Do not expose the charger or power supply to water or liquids.
- When the device is shipped via air or ground transport, always remove the battery.
- Use the system indoors only.
- The Exo-H3 should be placed over the end-user's clothes or suitable protective barrier.
- End-users should wear appropriate, comfortable and supportive shoes while using the device. Low profile athletic shoes or walking shoes are best.
- The end-user should be closely monitored when he/she walks even in a simple surface or non-level surface such as gravel, sand or rocks while wearing the device.
- Continuous activity with the device will cause the cable system to naturally loosen over time. The cables and connectors should be frequently checked to maintain a proper functionality

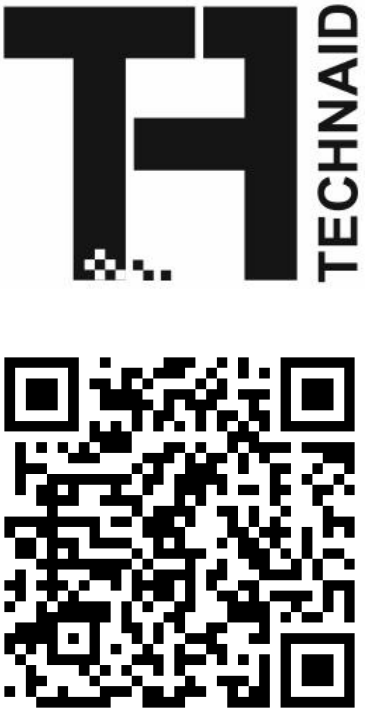
3.3. Cautions

- If the device is not fitted properly, it may be unable to gather correct information from the sensors and therefore may not perform as expected.
- Handle this product with care. Avoid dropping or hitting the device against hard surfaces.

- Store the device in its protective trunk in a clear, dry location.
- Avoid storage locations subject to excessive temperatures or humidity.
- To ensure the correct voltage power supply, recharge the battery at the end of each use day. The battery must be disposed of, or recycled, in accordance with local regulations. Do not dispose of the battery in the trash or fire.
- If you are considering to open, to disassemble, to modify, or to repair any component of the Exo-H3, you should contact the support service of Technaid for all service related concerns.

3.4. List of symbols used.

Symbol	Symbol Meaning
	This symbol represents the existence of entrapment risk. On Exo-H3, the six motorized joint modules are marked with this symbol.
	This sticker is placed in the battery of Exo-H3. It indicates where the emergency stop button of the inner circuit of battery is.

	Each Exo-H3 has an associated QR code with the reference number of the device. This QR code is glued to some parts of the device to work as seal. A broken seal will avoid the warranty conditions agreed.
	This sticker located on each "Main Controller" identifies each Exo-H3 unit and warns the user that the device is valid for research use only.

Note: At the end of the useful life of the Exo-H3, please contact us for instructions on proper disposal or return the product.

4. Breakdown of System Components

Exo-H3 system consist in five main elements:

- Mechanical parts
- Electronics
- Battery
- Control Software.
- Tool Case

4.1. Mechanical Parts

Within the mechanical parts of the device we can found motors, gears, bars, hip attachments straps and insoles

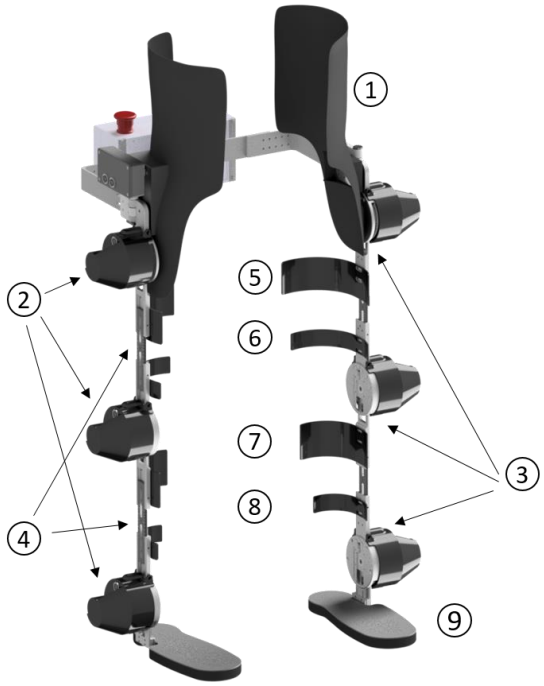
Exoskeleton	Mechanical Parts
	1. Hips attachment 2. Motors 3. Gears 4. Bars 5. Thigh Strap 6. Upper Knee Strap 7. Lower Knee Strap 8. Shank Strap 9. Insole

Table 3. Mechanical parts placement.

- Motors: DC brushless motors
- Gears: Strain Wave Gears

- Hips Attachments: Ergonomic attachment
- Bars: each Exo-H3 comes with 16 bars (4 types of bars, 4 bars of each type) that allows different configurations in order to obtain different height sizes for the exoskeleton's end-user (see section 4.1.)
- Straps: Every strap is designed to maximize the fastening and the comfort of the device.
- Insoles: Exoskeleton uses insoles to attach the feet of the end-user.

4.2. Electronics.

The electronics in the Exo-H3 considers the following:

1. Main controller.
2. Joint controllers.
3. Sensors.
4. Communication protocols.

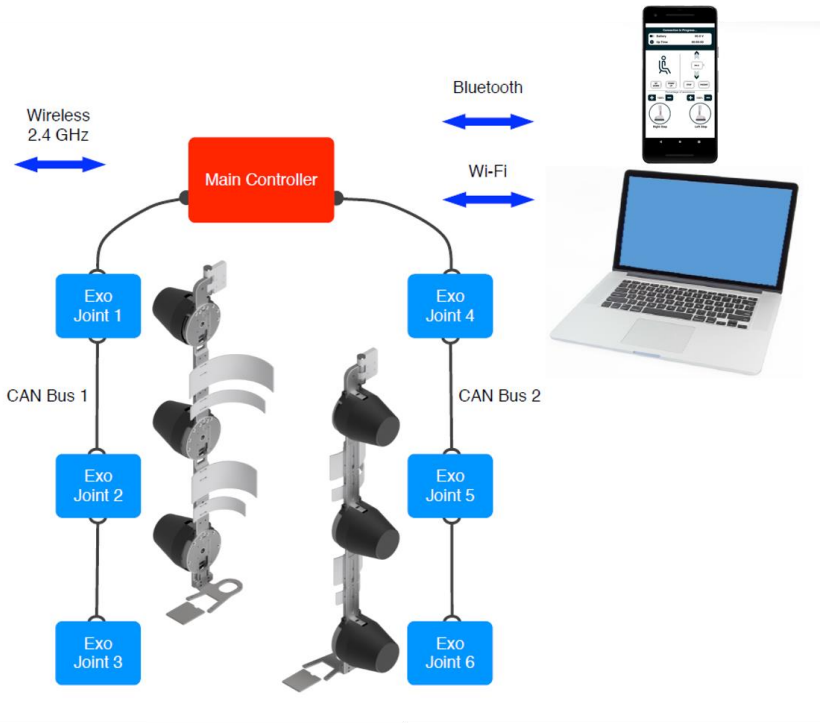


Figure 1. General electronic architecture

4.2.1. Main Controller

The EXO-H3 Main Controller was designed specifically for real- time control of the whole exoskeleton. It runs the control algorithms and interacts with the electronic drives by acquiring sensory information and controlling the actuators.

Main Controller	MC Connections and buttons
	1. Power connector (DC IN) 2. CAN Bus Connector (CAN Bus) 3. Left leg connector (Left) 4. Right leg connector (Right) 5. Led 1 (L1) 6. Led 2 (L2) 7. Power On/Off

Table 4. Main Controller Connections and buttons.

The small size of the MC and its very low power consumption allows it to be placed on the exoskeleton structure, reducing the bulk, complexity and difficulty of wiring, in addition to minimizing connections.

The board has two independent CAN transceiver channels (one for each leg) used to connect with all the six exoskeleton's joints, exchanging information and controlling the joint's actuator. A physical communication network that guarantees strict determinism, data collision avoidance and optimized data transfer for small data packets between the MC and the electronic drivers.

Figure 2 depicts the diagram used in the Exo-H3. It considers the energy source, controller, modules, and the different outputs configured by the system.

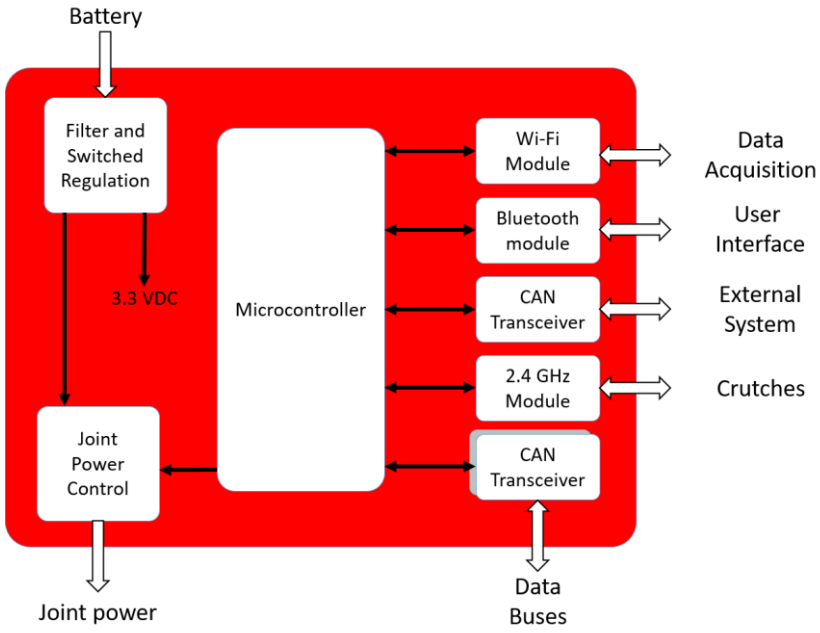


Figure 2. Main control scheme

4.2.2. Joint Controllers

Each one of the six Exo-H3 joints are equipped with an electronic driver board. Each board is in charge of data acquisition of the different joint's sensors: angular position, interaction torque, motor torque, and foot-ground contact. A small data packet of eight bytes aggregates the sensor's information on each joint and these data are sent to the MC every one millisecond.

MC and Joint Controllers communicate via a deterministic real-time network based on CAN technology. Through this digital bus working at 1 Mbps, each joint is connected to the MC. The network is flexible in terms of configuration and automatically avoids data collision and corrects errors regarding to data packets' transmission.

Each communication cycle in the network protocol involves passing a message from the MC node to all joints in the network. As the message travels through the bus, each joint reads its assigned actuator command data (by looking for its own ID number and message byte sequence). Then, each joint returns one message back to MC node with its locally collected sensor's data.

Because the communication cycles occur at a fixed rate (1 kHz) set by the control scheme, this protocol allows for deterministic control. Also, it provides built-in network error detection because at every message received, each joint has to return data information to the MC. In this way, the MC has a strong way to determine the integrity of the network.

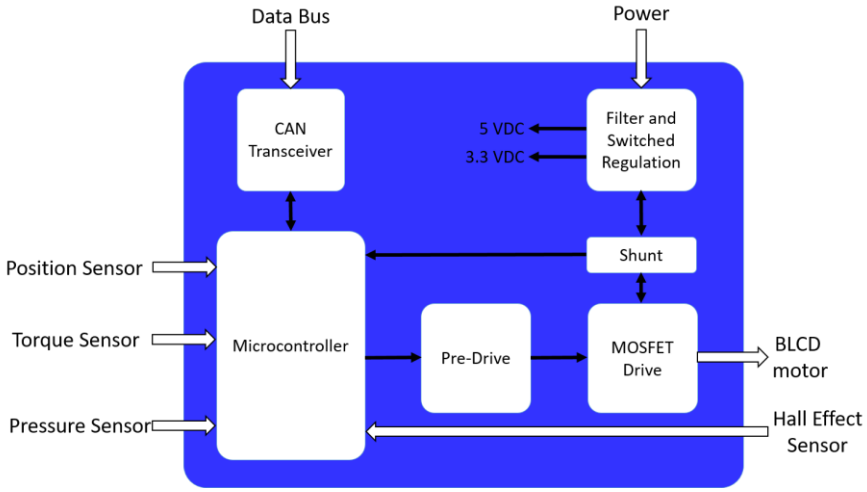


Figure 3. Joint controller scheme

4.2.3. Sensors

Several sensors are disposed in strategic parts of the device, giving robustness to the system through real-time feedback. The sensors are located as it is shown below.

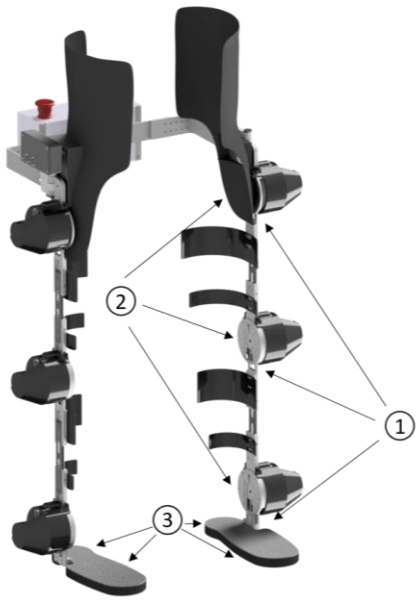
Sensor Location	Sensor description
	1. Torque Sensor 2. Position sensor 3. Pressure Sensors

Table 5. Sensors placement.

a. Torque Sensor

In order to measure strain exerted by each joint, a torque sensor is placed as it is shown in Figure 4.

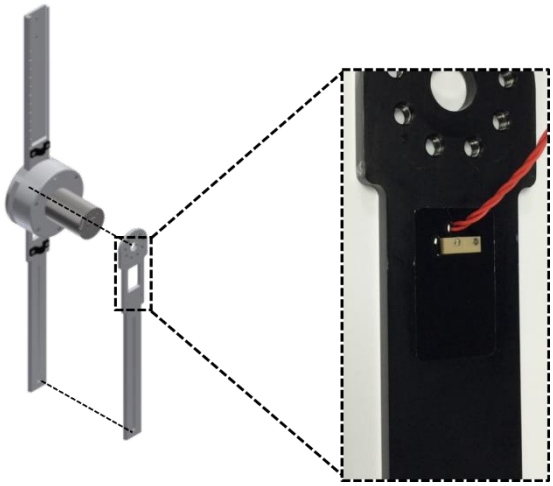


Figure 4. Torque sensor

b. Position sensor

Figure 5 depicts the strategy used in each joint in order to obtain high accuracy in the position of the joint.

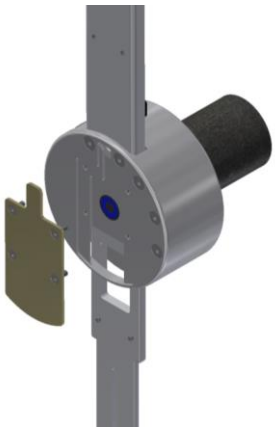


Figure 5. Position sensor

c. Pressure sensor

In each insole in the device are located two pressure sensors, one placed in the heel and the other in the toe. Figure 6 represents the general model of the sensors location.

Figure 6. Insole sensors

4.2.4. Communication Protocols

The communication board, connected on top of the MC, is designed to provide the exoskeleton with wireless communication with external devices. This board has three wireless communications ports: a Bluetooth module to connect to the UI on a smartphone, a Wi-Fi module to collect all data generated by the exoskeleton, and a 2.4 GHz transceiver with proprietary protocol designed to interact with other hardware devices in the environment.

The CAN Communication Protocol is managed directly by the MC and allows the wired communication with external devices in real time.

a. Bluetooth Communication Protocol

Exo-H3 runs an algorithm for walking, based on a pre-recorded gait pattern. It also can perform sit down and stand up movements. Moreover, the maximum assistance level on each leg can be independently adjusted. These tasks can be controlled by means of an UI based on a smartphone, via Bluetooth commands. Exo-H3 sends and receives commands in byte format.

Table 4 summarizes the Bluetooth commands sent from the interface to Exo-H3. Bytes values are in decimal format. Value 0 will stop gait if the exoskeleton is walking, otherwise it will block all joints in the current position. Values 1 to 10 start the exoskeleton gait in different speeds. Value 1 will generate a gait speed of approximately 0.8 m/s, and value 10 approximately 2.2 m/s. Gait speed increase linearly from 0.8 m/s to 2.2 m/s. Value 11 will put all joints in passive mode. Once joints are in passive mode, button "PASSIVE" will turn into a "FREE" button. When pressed, this button will send the value 12, that put all joints in compliant mode.

Values 21 and 22 perform a stand up and sit down movement, respectively. Values from 31 to 40 adjust the maximum assistance level on the right leg, from 10% to 100%. Values from 41 to 50 adjust the maximum assistance level on the left leg, from 10% to 100%.

The interface also received data from Exo-H3 via Bluetooth every 150 milliseconds. Table 7 summarizes the data sent by Exo-H3. Based on this data, the interface shows to the user the current battery voltage, the time since the exoskeleton was turned on and the exoskeleton state.

Byte Value	Command
0	Stop gait if walking. Block all joints otherwise
1-10	Walk at desired speed – 1 to 10
11	Joints in passive mode
12	Joints in compliant mode
21	Stand up
22	Sit down
23	Perform just one right step
24	Perform just one left step
31-40	Right leg max assistance level – 10 to 100%
41-50	Left leg max assistance level – 10 to 100%

Table 6. Bluetooth command format

Byte 1	Exo state. (see Table 4 for more details)
Byte 2	Battery voltage
Byte 3	Exo run time – hours
Byte 4	Exo run time – minutes
Byte 5	Exo run time – seconds
Byte 6	CRC – Exclusive OR from bytes 1 to 5

Table 7. Bluetooth data send by Exo-H3 to the interface

See Table 6 for more details about the exoskeleton states. Battery voltage value is given without decimal separator (e.g. 225 means 22.5 volts).

Byte Value	Command
0	Standing up
1-10	Walk at desired speed – 1 to 10
11	Joints in passive mode
12	Joints in compliant mode
13	Exoskeleton is stopping walk
14	Exoskeleton is performing stand up movement
15	Exoskeleton is performing sit down movement
16	Seated down
17	Performing left step. Only when is step by step mode
18	Performing right step. Only when in step by step mode
19	All joints blocked at the current position
21	Right hip failure
22	Right knee failure
23	Right ankle failure
24	Left hip failure
25	Left knee failure
26	Left ankle failure

Table 8. Exoskeleton states

b. *Wi-Fi data collection*

Wi-Fi port is intended to collect data generated from Exo-H3 internal sensors. When turned on, Exo-H3 creates an open Wi-Fi spot named H3. Simply connect a computer in this network and you will be able to receive data via UDP from Exo-H3. Your device should receive the following IP automatically: **192.168.1.2**. Exo-H3 is the network host and has the following parameters: IP: **192.168.1.1**; Subnet mask: **255.255.255.0**; Port: **2000**. Exo-H3 will send data to the following device: IP: **192.168.1.2**; Subnet mask: **255.255.255.0**; Port: **3000**.

Exo-H3 will send 40 bytes in an UDP packet every 10 milliseconds regarding its internal data. Table 9 summarizes the data sent. Angular positions and references are given in degrees. Torques are given in Nm. Foot switch information goes from 0 to 255. The run time is a 32-bit value (distributed in 4 bytes) that express the time in milliseconds since the exoskeleton was turned on. Battery voltage value is given without decimal separator (for instance, 225 means 22.5 volts), as well as the battery current (for instance, 43 means 4.3 amperes). Step flag value is 0 when Exo-H3 is not walking, 1 when the left step is being performed, and 2 when the right step is being performed.

Byte 1	115 (Start of the frame)
Byte 2	Right hip angular position
Byte 3	Right knee angular position
Byte 4	Right ankle angular position
Byte 5	Left hip angular position
Byte 6	Left knee angular position
Byte 7	Left ankle angular position
Byte 8	Right hip interaction torque
Byte 9	Right knee interaction torque
Byte 10	Right ankle interaction torque
Byte 11	Left hip interaction torque
Byte 12	Left knee interaction torque
Byte 13	Left ankle interaction torque
Byte 14	Right hip motor torque
Byte 15	Right knee motor torque
Byte 16	Right ankle motor torque
Byte 17	Left hip motor torque
Byte 18	Left knee motor torque
Byte 19	Left ankle motor torque
Byte 20	Right heel foot switch
Byte 21	Right toe foot switch
Byte 22	Left heel foot switch
Byte 23	Left toe foot switch
Byte 24	Exoskeleton run time in milliseconds - bits 0 to 7
Byte 25	Exoskeleton run time in milliseconds - bits 8 to 15
Byte 26	Exoskeleton run time in milliseconds - bits 16 to 23
Byte 27	Exoskeleton run time in milliseconds - bits 24 to 31
Byte 28	Battery voltage
Byte 29	Battery current
Byte 30	Exoskeleton state. See Table III for details
Byte 31	Right hip angular reference
Byte 32	Right knee angular reference
Byte 33	Right ankle angular reference
Byte 34	Left hip angular reference

Byte 35	Left knee angular reference
Byte 36	Left ankle angular reference
Byte 37	Step flag
Byte 38	Right leg assistance level
Byte 39	Left leg assistance level
Byte 40	120 (End of the frame)

Table 9. Wi-Fi data frame sent

c. 2,4 GHz Proprietary Communication Protocol

This protocol is envisaged for future accessories.

d. CAN Communication Protocol

Exo-H3 CAN port is intended to communicate with external devices in real time. The bus speed is set to 1 Mbps and it accepts messages in standard format with packets of 6 bytes. Table 10 summarizes commands accepted and its functions. Byte values are in decimal format.

The command Joint Control can be used to control each one of the six joints independently. Motor ID values are given in the following order:

1. Right Hip,
2. Right Knee,
3. Right Ankle,
4. Left Hip,
5. Left Knee and
6. Left Ankle.

For type of control, it has the following values:

1. Position control,
2. Stiffness control,
3. Torque control,
4. Motors disabled and
5. Motors stopped.

The control can be done in the following manners depending on the type of control used:

- Position Control: byte 3 is the set point for that joint and bytes 4, 5 and 6 are not used.
- Torque Control: byte 3 is the set point for that joint and bytes 4, 5 and 6 are not used.

- Stiffness Control: byte 3 is the set point for position and byte 4 is the percentage of stiffness for that joint (where the value 0 means no stiffness and the value 100 means the maximum possible stiffness).

- Start/Stop CAN Data: used to start or stop sending data thought CAN (byte 1 = 1 starts data; byte 1 = 0 stops data).

The commands Min Angles Accepted and Max Angles Accepted can be used to set the minimum and maximum angles accepted as set point for Position Control.

If CAN data has been started, H3 will send 3 messages with 6 bytes every 10 milliseconds, regarding its internal data. Table 10 summarizes the data sent.

Angles are given in degrees. Torque is given in Nm. Foot pressure sensor value information is from 0 to 255. Battery voltage value is given without decimal separator (for example, 245 means 24.5 volts).

Messages commands	
Message ID = 70	**Joint Control**
Byte 1	Motor ID
Byte 2	Type of control
Byte 3	Position/torque set point
Byte 4	Stiffness set point
Byte 5	Reserved for future use
Byte 6	Reserved for future use
Message ID = 71	**Type of control**
Byte 1	Right hip type of control
Byte 2	Right knee type of control
Byte 3	Right ankle type of control
Byte 4	Left hip type of control
Byte 5	Left knee type of control
Byte 6	Left ankle type of control
Message ID = 72	**Position set point**
Byte 1	Right hip position set point
Byte 2	Right knee position set point
Byte 3	Right ankle position set point
Byte 4	Left hip position set point
Byte 5	Left knee position set point
Byte 6	Left ankle position set point
Message ID = 73	**Torque set point**
Byte 1	Right hip torque set point
Byte 2	Right knee torque set point
Byte 3	Right ankle torque set point
Byte 4	Left hip torque set point
Byte 5	Left knee torque set point
Byte 6	Left ankle torque set point
Message ID = 74	**Stiffness set point**
Byte 1	Right hip stiffness set point
Byte 2	Right knee stiffness set point
Byte 3	Right ankle stiffness set point
Byte 4	Left hip stiffness set point

Data frames sent	
Message ID = 110	**Joint Angle**
Byte 1	Right hip angle
Byte 2	Right knee angle
Byte 3	Right ankle angle
Byte 4	Left hip angle
Byte 5	Left knee angle
Byte 6	Left ankle angle
Message ID = 120	**Joint Torque**
Byte 1	Right hip sensor torque
Byte 2	Right knee sensor torque
Byte 3	Right ankle sensor torque
Byte 4	Left hip sensor torque
Byte 5	Left knee sensor torque
Byte 6	Left ankle sensor torque
Message ID = 130	**Foot Switch**
Byte 1	Right heel pressure value
Byte 2	Right toe pressure value
Byte 3	Left heel pressure value
Byte 4	Left toe pressure value
Byte 5	Battery voltage
Byte 6	Reserved for future use
Message ID = 140	**Motor Torque**
Byte 1	Right hip motor torque
Byte 2	Right knee motor torque
Byte 3	Right ankle motor torque
Byte 4	Left hip motor torque
Byte 5	Left knee motor torque
Byte 6	Left ankle motor torque

Byte 5	Left knee stiffness set point
Byte 6	Left ankle stiffness set point
Message ID = 75	**Min Angles Accepted**
Byte 1	Right hip min angle
Byte 2	Right knee min angle
Byte 3	Right ankle min angle
Byte 4	Left hip min angle
Byte 5	Left knee min angle
Byte 6	Left ankle min angle
Message ID = 76	**Percentage of assistance**
Byte 1	Right hip percentage of assistance
Byte 2	Right knee percentage of assistance
Byte 3	Right ankle percentage of assistance
Byte 4	Left hip percentage of assistance
Byte 5	Left knee percentage of assistance
Byte 6	Left ankle percentage of assistance
Message ID = 80	**Max Angles Accepted**
Byte 1	Right hip max angle
Byte 2	Right knee max angle
Byte 3	Right ankle max angle
Byte 4	Left hip max angle
Byte 5	Left knee max angle
Byte 6	Left ankle max angle
Message ID = 85	**Start/Stop CAN Data**
Byte 1	Start/Stop CAN Data
Byte 2	Reserved for future use
Byte 3	Reserved for future use
Byte 4	Reserved for future use
Byte 5	Reserved for future use
Byte 6	Reserved for future use

Table 10. CAN messages and data frames command

4.3. Battery

Exo-H3 is powered by a Lithium Iron Phosphate battery of 22.4 VDC nominal voltage. A switched regulator with high efficiency is designed to generate 3.3 VDC to power the electronic boards. $LiFePO_4$. batteries provide a higher performance than others with a higher security level.

Figure 7. Exo-H3 battery

The battery has a 20A fuse to protect from short circuits the power output. Besides, the battery has an "Emergency Stop" button to cut the power supply as a safety measurement.

Warning: The battery should not be opened or burned. Exposure to the ingredients contained within or their combustion products could be harmful.

4.3.1. Handling and storage

Handling: Do not expose the battery to excessive physical shock or vibration. Short-circuiting should be avoided; however, accidental short-circuiting for a few seconds will not seriously affect the battery. Prolonged short circuits will cause the battery to rapidly lose energy, could generate enough heat to burn skin. In any case, the internal fuse will prevent of this situation.

Sources of short circuits include: jumbled batteries in bulk containers, coins, metal jewelry, metal covered tables, or metal belts used for assembly of batteries in devices. Do not disassemble or deform the battery. Do not allow contact with water.

Storage: The lithium iron phosphate battery should be between 25% and 75% of full charge when stored for a long period of time. Stored in a cool, dry and well ventilated area. Elevated temperatures can result in loss of battery performance, leakage, or rust. Do not expose the battery to open flames.

4.3.2. Charging the battery

1. Properly connect the charging ports of charger and battery completely. (in case of damage of the ports structure because of improperly big force, avoid the connection between port and put in contact with Technaid Support Department.)

2. Insert the power plug of charger into AC socket, when a RED led light up, charger enters into charging status. (if the power plug inserted into AC socket without battery connecting with charger, the green LED will light, which means it is in normal stand-by status)

3. The LED light turns to green when the battery is fully charged, when it comes to end of charging, pull out the power plug of charger, then remove the battery.

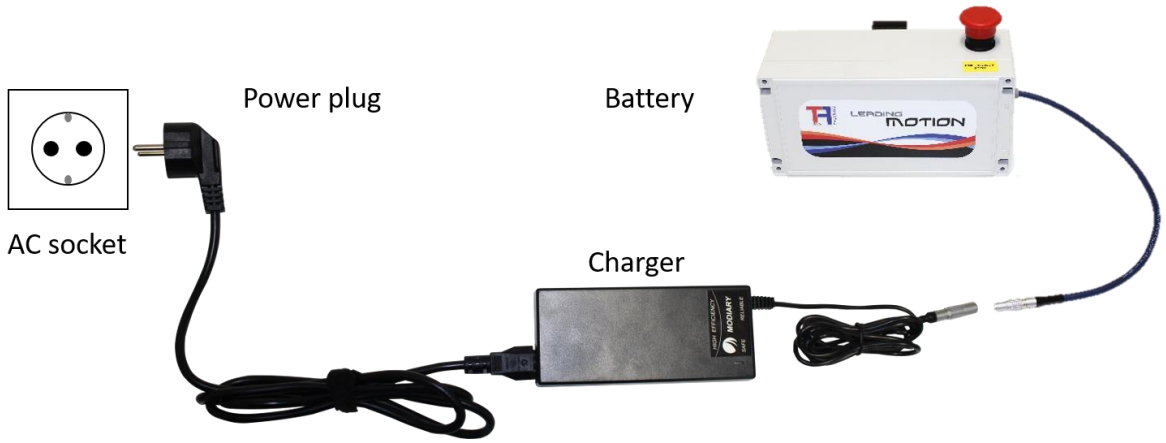


Figure 8. Charging the battery

4.4. Software

Exo-H3 has three different software to control and/or collect the information of the device:

4.4.1. Android App.

This is the main UI to control EXO-H3. It provides a simple control of the system that allows to enter the walk, stop, sit down and stand up orders, among others. Before trying to command EXO-H3 with the interface, the user has to pair EXO-H3 Bluetooth interface with the smartphone. The sequence for this should be: turn EXO-H3 on; turn Bluetooth on in your device and look for near devices; pair with H3. After successfully paired, you are ready to open the App and communicate with EXO-H3. For installing instructions see section 5.2.

4.4.2. Simulink Model

This model is oriented to the collection of data provided by the Exo-H3 through Wi-Fi protocol. It allows the real-time visualization of the different values form the sensors, refreshed each 10ms.

4.4.3. Command table for CAN protocol

The operation of this control mode has been explained in section 4.2.4.d.

4.5. Tool case.

Within the Exo-H3 package a case with different tools and accessories is included. Cables and bars to extend the length of the device are included in this case. Besides, to solve any malfunction easy to repair, some tools for quick reparations are included.

The breakdown of the different tools and elements is as follows:

Image	Name
	Tool Case
	Allen Wrench 5 mm.

	Allen Wrench 3 mm
	Allen Wrench 2.5 mm
	Allen Wrench 2 mm
	Pin Tool
	Tool for connectors

	Extension bars
	External CAN Cable
	Leg cables

* Some of these tools are optional and depend on the package agreed.

Table 11. Tools within the package.

Note: The content of the tool case may vary according to the Exo-H3 model.

5. Setting-up the Exo-3

This section of the manual explains how to adapt and install the device to the end-user and how to install the Android UI.

Before the use of the system with subjects, some steps should be completed. These steps are going to be detailed as following:

- Adapting the Exo-H3 to the end-user.
- Installing the Exo-H3 in the end-user
- Installing the User interface.

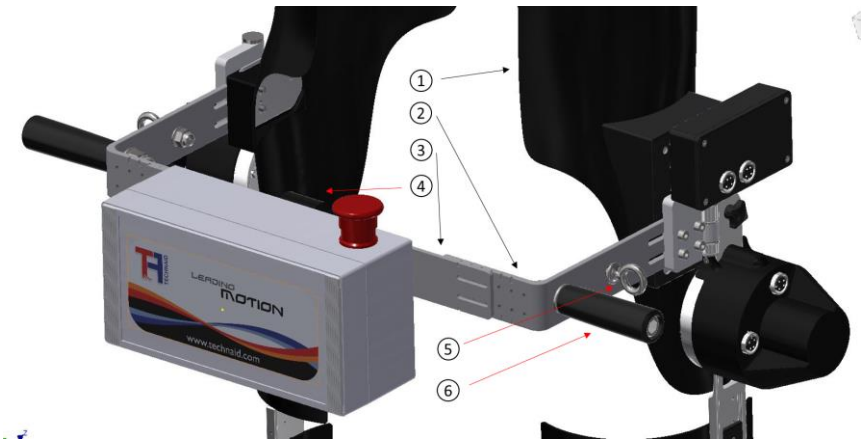
While the "Installing the Exo-H3 in the end-user" will be detailed in section 6, the previous adaptation/assembling of the device, together with the installation of the UI, will be explained within this section.

5.1. Assembling the Exo-H3

5.1.1. Assembling the Hips-Attachment

All the Exo-H3 packages include at least one hips attachment compound with several elements. Different Hips-Attachment sizes are available and must be agreed previously.

In the following table the different parts of the Hips-Attachment are listed:

Element Location	
	
Element description	
1. Hips Orthosis	4. Battery adapter
2. Hips-Attachment Lateral Bars	5. Crane eye bolt

3. Hips-Attachment Rear Bar	6. Handle Grip

Table 12. Hips-Attachment elements.

To assemble the Hips-Attachment, lateral bars (2) must fixed to the rear bar (3) so that the battery adapter (4) is opposed to the Hips Orthosis. Then lateral bars should be attached to Hips Orthosis between Hips Orthosis and leg hinge using M5x25 screws.

Left shell and right shell of Hips Orthosis are not interchangeable. See a description of the two shells in Table 13. (From left to right and from top to bottom) Left-external half shell, right-external half shell, left-internal half shell and right-internal half shell. Table 13. Right shell is identified through the Main Controller attachment piece.

Table 13. (From left to right and from top to bottom) Left-external half shell, right-external half shell, left-internal half shell and right-internal half shell.

Finally, Crane Eye Bolt and Handle Grip must be screwed as Table 12 shows.

5.1.2. Assembling the insoles

Insoles should be screwed to ankle joint to assemble them to the exoskeleton. In the same way, binder connector from Ankle Joint Module should be connected to the connector in the internal part of the upper surface of the insole.

To fix the insole is necessary to introduce the screws pointing to the internal side of the exoskeleton. Previously to tightly tighten the screws, we can adjust vertically the insole to achieve the most suitable distance of the insole to the Ankle Joint Module.

Table 14. Screw orientation on ankle joint.

5.2. Adapting the exoskeleton to the end-user

As explained in section 4.1. the Exo-H3 could come with 4 sets of 4 bars each. Each set has a different measurement. Using this set in both limbs allows the user to adapt the system to end-users from 1,10 m. to 2,10 m. height. All the bars are named with a letter (from A to D) and the maximum and minimum heights allowed for the bar. This name is written in the upper part of each bar and should always be installed in the upward direction (vertically). The bars are described below:

Size options			
Type	Length	Min height	Max Height
A (4x)	150.5 mm	1.10 m	1.35 m
B (4x)	211.0 mm	1.35 m	1.60 m
C (4x)	271.5	1.60 m	1.85 m
D (4x)	332.0 mm	1.85 m	2.10 m

Table 15. Size options.

Once we measure the end-user, we should decide the type of bar we are going to use to assemble the Exo-H3 This bars are fixed to the joint modules by two screws on each end. The way to reach the expected height once we have selected the type of bars is using as reference the white marks on the bars following this scheme:

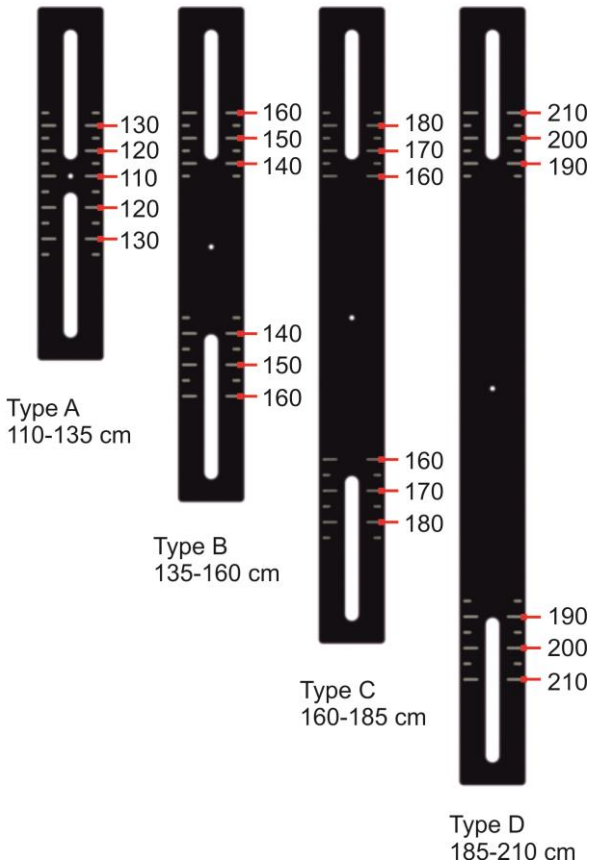


Figure 9. Measurements achieved with each bar type.

As an example, if the end-user is 170 cm. tall we should choose type C bar and screw the screws when the border of the joint modules reaches the white mark named above with the number 170.

Joint modules, together with bars, allow a longitudinal displacement that help to adjust the total height of the device. The longitudinal displacement measures are detailed in the table below:

Extension Bar Type	Available distances between joints (hips-knee / knee-ankle) (mm.)
Type A	270,2 – 330,7
Type B	330,7 – 391,2
Type C	391,2 – 451,7
Type D	451,7 – 512,2

Table 16. Distances between joint modules.

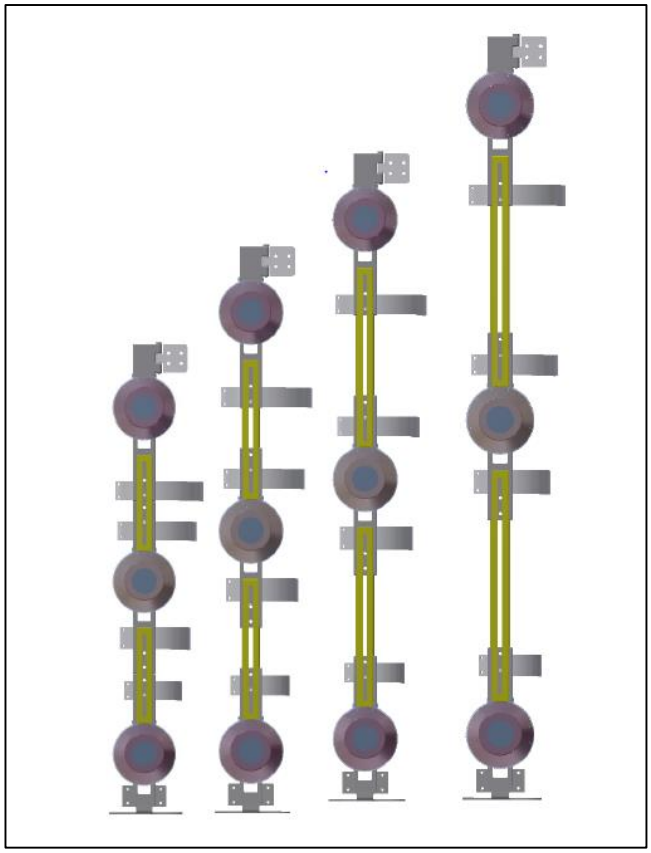


Figure 10. Extension bars and joint modules

In the same way, 8 cables (2 different cable sizes) are provided to ensure an optimal connection between joint modules whatever the combination between bars is. Cables are named combining the longitude and the side of the exoskeleton where they are envisaged to be used.

	Right Side (Blue)	Left Side (Red)	Bar Type
Longitude	Long-R	Long-L	C, D
	Short-R	Short-L	A, B
	Right (shorter)	Left (larger)	All bars

Table 17. Cables denomination.

Figure 11. Leg cables. Right Leg (Blue) and Left Leg (Red)

Then, use the tools provided with device to follow these steps:

1. With the help of a measuring tape (not included) measure the distances in the subject between hips and knees and between knees and ankles, in both limbs (measurements could vary from one side to another)

Figure 12. Measuring the end-user.

2. Place the stretched exoskeleton on a horizontal and flat surface.

3. Using the Allen Wrench No. 5 (included) loose the four screws that fasten each bar to the joint module.

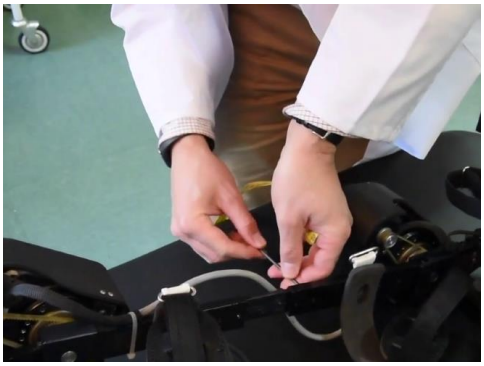


Figure 13. Loose the screws.

4. Select the most suitable bars to get the length needed to fit the end-user. Use the information provided on Table 15.

Figure 14. Adapt the legs of the Exo-H3.

5. Once the bars are inserted on the corresponding joint modules with the needed length, tighten the screws on each joint module with the Allen Wrench No. 5 (included).

Once these steps are completed we have our exoskeleton ready to install on end-user lower limbs.

5.3. Installing the Android App

Note: Since there are multiple versions of the Android operating system, the layout of the controls can vary in the different user interfaces. The process described below is explained in general terms and it is recommended to consult the instructions of the Android device to achieve each of the steps

We are going to describe the different steps to proceed with the installation of the app provided by Technaid. As a previous consideration you should copy the file Exo_H3.apk into the internal storage of your mobile phone, to do this consult the documentation of Android.

Previously to the installation you should allow your mobile phone to install apps from different sources than the Play Store. To do this follow these steps:

1. Go to Settings > Security.
2. Check the options “Unknown Sources”.
3. Tap OK on the prompt message.
4. Select “Trust”.

Then, with the file browser of the mobile phone, find the application and tap on "Exo_H3.apk" to install. Screens shown on Figure 15 will appear successively.

> **Note:** In general, all Android devices have a file explorer installed by default. If this is not the case, you can download a free one from the Play Store or any application repository

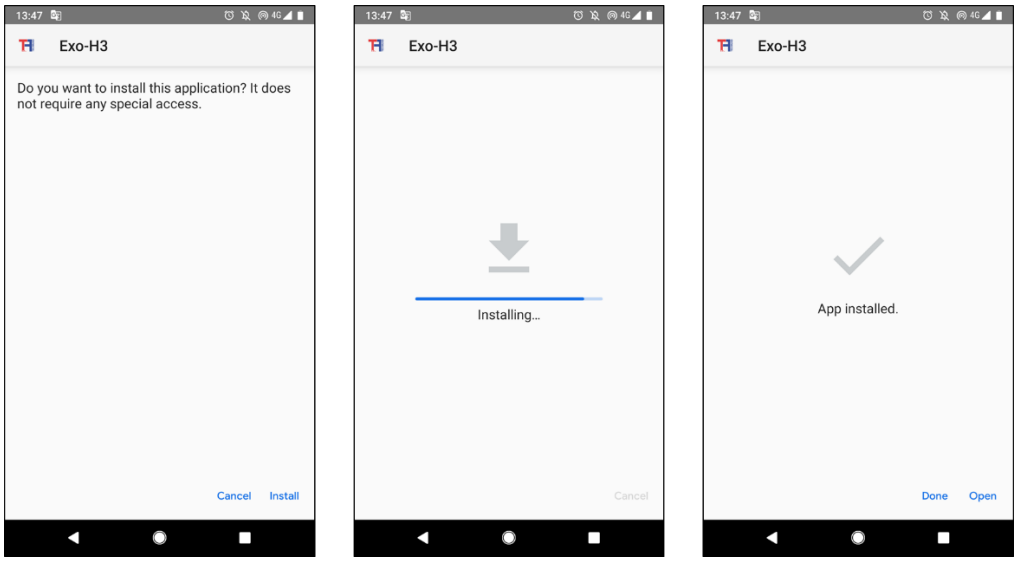


Figure 15. Installing APK file.

5. Once the application is installed, go to the Bluetooth menu of the mobile phone, Within the Settings>Bluetooth area.
6. Turn on the Main Controller.
7. Update the list of visible Bluetooth devices, wait for a device called H3 to appear.
8. Click on it and then synchronize granting it all the permissions that the device consults or requests.

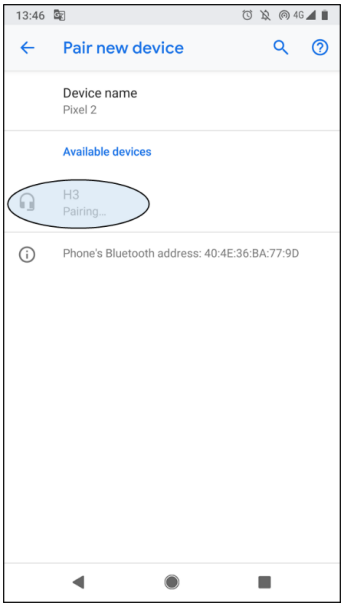


Figure 16. Pairing Exo-H3

9. Open the App. Initially the message "Connecting in progress" will appear in the top of the screen and then it will change to "Exo Passive", as shown in the following image.

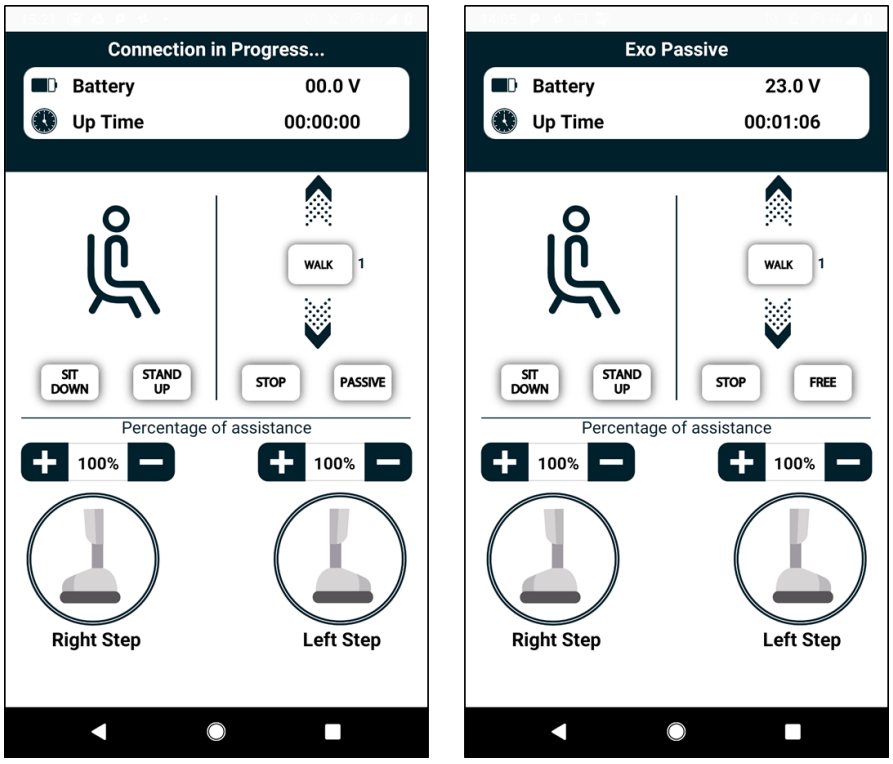


Figure 17. Exo-H3 App Main Window.

If the installation and pairing process is correct, the previous image will be seen and the device will be connected and ready to start operating with it.

5.4. User Interface

Figure 18 depicts a screen of the UI that allows to control Exo-H3. It was developed for a smartphone with Android operational system. Before trying to command Exo-H3 with the UI, the user has to pair Exo-H3 Bluetooth interface with the smartphone. The sequence for this should be: turn Exo-H3 on; turn Bluetooth on in your device and look for near devices; pair with H3. After successfully paired, you are ready to open the App and communicate with Exo-H3.

Figure 18. User Interface.

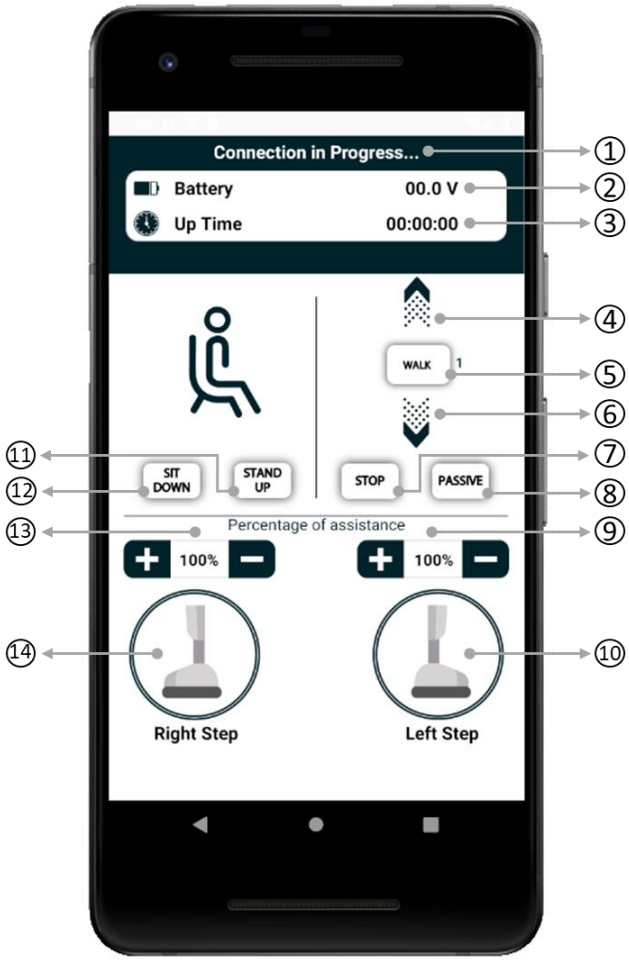
Buttons Layout	Operational Modes
	1. **Process status:** Here is placed the current status of the device. 2. **Battery level:** Real-time value of the battery. 3. **Time Up:** It shows all the time elapsed since the device was turned on. 4. **Up velocity:** It allows to increase the speed of the gait. 5. **Walking:** Once the end-user and the user are ready to use the device, "Walk" bottom allows to start the operation with a preloaded gait pattern. By using the Up and Down arrows it is possible to increase or to decrease the speed of the gait (ten speed levels). 6. **Down velocity:** It allows to decrease the speed of the gait. 7. **Stop:** When the end-user is Walking with the device, the Stop bottom allows to finish the gait carrying out the whole gait pattern, and then the motors will be blocked. 8. **Passive/Complain:** The "Passive" bottom allows free engines movement with resistance; and the "Complain" bottom allows the same but very low resistance. 9. **Left Leg Assistance:** It is possible to set the assistance percentage, in the left leg, from 10% to 100%, increasing (+) or decreasing (-) in steps of 10%. 10. **Left Step:** It is possible to send independent step patterns for the left leg 11. **Stand Up:** When the device is completely placed, it is possible to enable this instruction. The end-user will feel assistance when rising. 12. **Sit Down:** Always the device has been placed on "stand" or "walking" mode, "stand to sit" is able to be used. The end-user will feel the device "brake", which slow down the end-user's movement onto the seat. 13. **Right Leg Assistance:** It is possible to set the assistance percentage, in the right leg, from 10% to 100%, increasing (+) or decreasing (-) in steps of 10%. 14. **Right Step:** It is possible to send independent step patterns for the right leg.

Table 18. UI Buttons Layout.

5.4.1. Exo-H3 speeds

Among the different options of the User Interface listed on Table 18, buttons "Up Velocity" (4) and "Down Velocity" (6) are used to vary the gait speed of the exoskeleton. Each velocity is named with a number, from 1 to 10, that correspond with the velocities of step detailed on Table 19

Speed Number	Seconds per Step
1	4,5 sec.
2	4,2 sec.
3	3,9 sec.
4	3,6 sec.
5	3,3 sec.
6	3,0 sec.
7	2,7 sec.
8	2,4 sec.
9	2,1 sec.
10	1,8 sec.

Table 19. Exo-H3 speed table.

At this point, it is important to explain the relationship between the velocity and the assistance level in the Exo-H3. Due to security reasons, speed and percentage of assistance are related so that at high speed levels assistance is reduced. In the same way, when, at a high speed (>7), we want to increase the level of assistance, the speed will be reduced automatically.

Table 20 details the relationship between speed and assistance within the Exo-H3 User Interface.

Speed	Assistance
1	100%

2	100%
3	100%
4	100%
5	100%
6	100%
7	80%
8	60%
9	50%
10	40%

Table 20. Constraint of speed over assistance on Eo-H3.

6. Using the Exo-H3

6.1. Installing and starting the Exo-H3

We begin this phase starting from section 5.1 above. Then. we hold the exoskeleton from the flat surface and position it in vertical.

1. With the exoskeleton standing, connect the battery.
2. Turn on the Exo-H3 and put it on sitting position by means of the Android App "Exo-H3" (see section 5.3).

> **Note:** In this step we recommend to place the Exo-H3 on a chair to make it easier to operate.

3. Release all fasteners of the exoskeleton.

Figure 19. Release fasteners.

4. Disconnect and remove the battery.
5. Loose the screw, on each hip attachment, that is outlined below:

Figure 20. Screw to release hips attachment from the sagittal plane.

6. Open the legs of the exoskeleton manually so both legs are perpendicular to the sagittal plane

Figure 21. Opening the Exo-H3 in the sagittal plane.

7. The end-user must be sit on a chair. In case of a wheelchairs, the arms of the wheelchair should be dismounted and with the brakes engaged.

8. Place the exoskeleton behind the sitting end-user.

Figure 22. Place the Exo-H3 behind the end-user.

9. Close the legs of the exoskeleton in the sagittal plane so the device's legs embrace the end-user's legs.

10. Place end-user feet one on each insole.

Figure 23. Place feet on the insole.

11. Fasten all the straps. Be careful to prevent a cut off the circulation.

Figure 24. Fasten the straps.

Warning: The end-user should wear trousers and shoes to avoid skin abrasion.

12. Place and connect the battery.

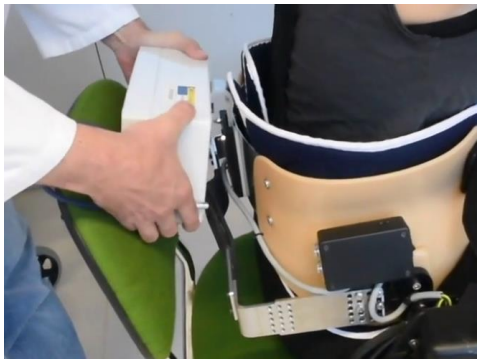


Figure 25. Place the battery.

Figure 26. Connect the battery.

13. Switch on the Main Controller.

Figure 27. Switch on the Main Controller.

Note: Two LEDs are used to report the Exo-H3 state. When you switch on the Main Controller, Led 1 (L1) and Led 2 (L2) on Main Controller will turn on and off in the following order:

a. Led 1 will light red while L2 remains turned off.

b. Then L1 will turn off while L2 lights orange

c. Then L2 will switch to green and L1 will light green.

In case not all the joints are correctly connected, L1 will light green while L2 remains orange. If this occurs, Exo-H3 has to be restarted with a power cycle.

In case the communication among the joints fails while using the Exo-H3, L1 will blink red.

14. Update the list of visible Bluetooth devices in your mobile phone, wait for a device called H3 to appear.

15. Click on it and then synchronize granting it all the permissions that the device consults or requests.

16. Open the App. Initially the message "Connecting in progress" will appear and then it will change to "Exo Passive", as shown in the following image.

17. Change the state of the Exo-H3 to “Exo Stopped” by pressing the button “Stop” (7)

18. Press the button “Stand Up” (11). A beep will sound warning about the standing up movement.

Figure 28. Assist the stand up.

Warning: the standing up movement should be assisted by the companion.

19. Once standing up, we can start the walking by pressing the button "Walk" (1). In case you prefer, you can give isolated steps by pressing buttons "Left Step" (10) and "Right Step" (14) consecutively

Figure 29. Press walk.

Note: We strongly recommend that new end-users execute the first walks using these "Left Step" (10) and "Right Step" (14) buttons

20. On "Walk" (1) mode, it is possible to vary the walking speed of the device by pressing buttons "Up Velocity" (4) and "Down Velocity" (6)

6.1. Disconnecting and removing the Exo-H3.

Once the walking session has finished, the exoskeleton must me properly stopped, shut down and uninstalled from the end-user. To avoid an incorrect use of the system, follow these steps:

1. With the Exo-H3 stopped and with the end-user standing up, place a chair (or the blocked wheelchair) behind the end-user.

2. Press "Sit down" (12) button. A beep will warn about the sitting down movement.

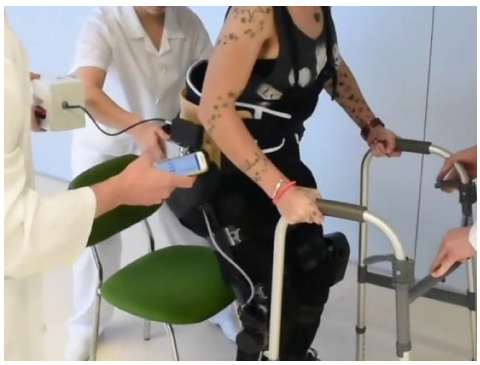


Figure 30. Assist the sit down movement.

Note: The end-user should not leave all its weigh fall down and should use the crutches to accompany the movement. Companion could assist the sitting down movement.

3. Once the end-user, together with the exoskeleton, are sit down on the chair press "Passive" (8) to deactivate motors.

4. Then switch off the Main Controller pressing the "Power" button.

Figure 31. Switch off the main controller.

5. After switching off the device we should disconnect the battery and take it out from the system.

6. Now, we can proceed to release all the straps from the end-user.

Figure 32. Release the straps.

7. To remove the device, open the legs of the device till they are perpendicular to the sagittal plane.

8. Take off the system from the end-user.

Figure 33. Take off the system.

9. Place the Exo-H3 in another chair and prepare it to store it.

7. Environmental and safety conditions.

7.1. Operating conditions

The Exo-H3 can be operated under following conditions:

Condition	Values
Operating temperature	$10°C$ to $40°C$
Humidity	30% to 75% RH, non-condensing

Table 21. Operative conditions

7.2. Storage and transportation

The Exo-H3 must be stored and transported in the following conditions:

Condition	Values
Temperature	$-20°C$ to $55°C$
Humidity	10% to 85% RH, non-condensing

Table 22. Storage/transport conditions

Note: The Exo-H3 should be protected against shock and vibration during transportations.

7.3. Care and maintenance

7.3.1. Cleaning

To clean the Exo-H3 use a moist cloth and follow these instructions:

- Do not use acetone-based products to clean the Exo-H3.
- System surfaces that touch the body may be cleaned periodically using a dampened cloth with an alcohol-based disinfectant.
- If the device is used by more than one end-user, it is essential to clean the device with disinfectant before use.
- Straps that are torn, worn, or contaminated should be discarded and replaced with new ones.

7.3.2. Maintenance

Regularly check the operation of the device:

- Visible damage
- Before using the device, make sure all parts are securely attached
- Functioning of the adjustments and switches

7.3.3. Repair

For customer service and repair, please contact the Technaid Support (support@technaid.com).

7.3.4. Disposal

Please contact Technaid company if you no longer need the product or for any reason to be disposed. The disposal must be properly and in accordance with the country legislation.

8. Mechanical Design and Technical Specifications

8.1. Size adaptability and joint range motion

Range of Motion (RoM)			
Joint	**RoM**	**Flexion**	**Extension**
Hip	135°	105°	30°
Knee	110°	105°	5°
Ankle	60°	30°	30°
Size options			
Type	**Length**	**Min height**	**Max Height**
A	150.5 mm	1.10 m	1.35 m
B	211.0 mm	1.35 m	1.60 m
C	271.5	1.60 m	1.85 m
D	332.0 mm	1.85 m	2.10 m

Table 23. Range of Motion and size options

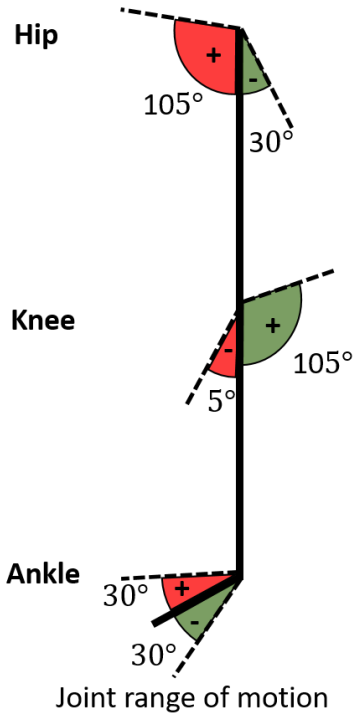


Figure 34. Range of motion in each joint

8.2. Technical Specifications

Number of Degrees of Freedom	6 degrees of freedom in the sagittal plane. One for hip, knee and ankle in both right and left legs.
Type of Control	Position, Torque and Admittance in real time control.

Actuators	Ratio	160	i
	Limit for repeated peak torque	123	T_R [Nm]
	Limit for average torque	75	T_A [Nm]
	Rated torque at rated speed 2000 rpm	47	T_N [Nm]
	Limit for momentary peak torque	152	T_M [Nm]
	Max. input speed (Oil Lub)	7500	rpm
	Max. input speed (Grease Lub)	5600	rpm
	Limit for average input speed (Oil Lub)	5600	rpm
	Limit for average input speed (Grease Lub)	3500	rpm
	Moment of inertia	0.282×10^{-4}	[kgm^2]
	Weight	0.24	[kg]
Motors specifications (Hips, Knees and ankles)	Nominal voltage	18	V
	No load speed	4550	rpm
	No load current	352	mA
	Nominal speed	3930	rpm
	Nominal torque (max. continuous torque)	218	mNm
	Nominal current (max. contin. current)	5.7	A
	Stall torque	3260	mNm
	Starting current	87	A
	Max. efficiency	88	%
	Characteristics:		
	Terminal resistance phase to phase	0.207	Ohm
	Terminal inductance phase to phase	0.169	mH
	Torque constant	37.5	mNm/A
	Speed constant	255	rpm/V
	Speed/torque gradient	1.41	rpm/mNm
	Mechanical time constant	0.648	ms
	Rotor inertia	44	gcm^2
Final Actuator	Net Torque	35	Nm
	Peak Torque	152	Nm
Communication	External CAN-Bus Wi-Fi 2.4 GHz IEEE 802.11 b/g/n		

	Bluetooth v3.0 (Class 2) 2,4 GHz Transceiver		
Power supply (Charger)	100 – 240 V AC / 50-60 Hz (AC power line)		
Battery LiFePO4	Size (H)	14	cm
	Size (W)	10	cm
	Size (L)	16	cm
	Normal capacity Type	12.0	Ah
	Normal voltage	22,4	VDC
	Normal Power	230	Wh
	Standard discharge current	2.4 (const)	A
Principal structure production material	Stainless steel and high resistance aluminum (7075).		
Exoskeleton sensors	6x Joint Position. 6x Joint Interaction Torque 4x Pressure Sensor (heel and toe)		
Joints Range of Movement (Flexion/Extension)	Hip (135°)	105° (flex.)	30° (ext.)
	Knee (110°)	105° (flex.)	5° (ext.)
	Ankle (60°)	30° (flex.)	30° (ext.)
Size Adaptability	Min. subject's height (*)	110	cm
	Max. subject's height (*)	210	cm
	Min. subject's weight	40	Kg
	Max. subject's weight	100	Kg
Dimensions	118 cm tall		
	45 cm long (side view)		
	30 cm wide (front view)		
Weight	17 kg. approx. / 14,2 kg. without battery.		

* Some sizes options are only available through optional accessories.

Table 24. Exo-H3 Specifications.

9. Risk Analysis.

Risk	Description	Probability	Severity	Action plan
Chafing	Some misaligned clamping straps can yield chafing during the operation of the device	Medium	Low	Pay close attention when performing the alignment between the Exo-H3 and the leg. During each experimental session the skin of the end-user should be inspected, in order to evaluate any redness or chafing. To eliminate this effect add foam.
Catastrophic failure in the control software or in the inter-system communications	Joint motor becomes unstable	Low	Medium	The device is designed with mechanical restrictions in order to prevent reaching non-physiological limits by the joints. There is an emergency switch to stop the engines and to cut off power of the entire system.
Wear and breakage of the sensor cables				
Wear and breakage of motor control cables				
Internal mechanical rupture of some joint	The joint is stopped	Very low	Medium	
Rupture of any structural part: webbings and bars	Some structural part is broken, but does not belong to the joint			
Risk of Falling	The subject may fall during use	Low	Medium	The exoskeleton will always be used with external support means (canes or walker) in order to ensure the balance and stability of the end-user. At least one therapist or companion will

				remain close to the person to provide vigilance and support during use.
Electric Risk	Electrical contact with the subject	Very low	Medium	Electronics are contained within insulating and fireproof housings. They completely isolate the interior.
Thermal Risk	There is thermal contact with the end-user.	Very low	Low	Each motorized joint is covered with a plastic housing that avoids direct contact with possible sources of heat.
Risk of entrapment	The end-user deliberately introduces some part of his body into the output of the actuator element.	Low	Medium	Each motorized joint is covered with a plastic housing. At least one therapist will remain close to the person to provide vigilance and support during use. Caution instructions are given before using the system.

Table 25. Risk analysis and action plan

10. Declaration of Conformity and regulations compliance.

10.1. Declaration of Conformity.

Exo-H3 exoskeleton device is compliant with the following directives:

Gears:

UNE EN 10204 2.1(Technical Rule of metallic materials.)

Motors:

Anti-corrosion protection according with rule DIN EN 60068-2-30

Power supply:

Technical Rule for metallic materials UNE EN 10204 2.1

Wi-Fi Module:

FCC ID: VRA-SG9011203

IC ID: 7420A-SG9011203

ETSI EN 300 238 v1.9.1:2015

EN 301 489-1 V1.9.2:2011 + EN 301 489-17 V2.2.1:2009

EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011 + A2:2013

EN 62479:2010

SRRC CMIIT ID: 2015DJ6514

Bluetooth Module:

Bluetooth SIG, Inc. Certification QD ID: B019224

EN 300 328 V1.8.1. (2012 06)[1]

[1] EN 300 328 V 1.8.1 (2012 06): "electromagnetic compatibility and radio spectrum Matters (ERM); Wideband transmission systems; data transmission equipment operating in the 2,4 GHZ ISM band and using wideband modulations techniques; harmonized EN covering essential requirements under article 3.2. of the R&TTE directive"

EN 301 489-17 V 2.2.1 (2012 09)[1]

EN 301 489-1 V 1.9.2 (2011 09)[2]

EN60950-1:2006 +A11:2009+A1:2010[3]

The Bluetooth module has been certified according the certification rule:

- CE Expert opinion: 0448-ARSO00049

10.2. Regulations compliance.

List of exceptions to compliance with Essential Requirements 1, present in Annex 1 of Council Directive 93/42 / EEC of June 14, 1993, concerning medical devices.

This section lists the points that the device does not currently fulfill and describes the actions that are being carried out to comply with them or the reason why it is impossible to comply with said requirement.

Exception 1:

Item 11.3.1 of Annex I. Products should be designed and manufactured in a way that minimizes the exposure of patients, users and others to unintended, parasitic or dispersed radiation emissions.

In the current prototype, no activities have been carried out for the measurement of this type of emissions since it is a device still under evaluation. In any case, the electronic components used to emit / receive wireless information are CE marked and comply with the radio frequency emission regulations.

Exception 2:

Point 11.4.1. of Annex I. The instructions for use of the products that emit radiation must include detailed information on the characteristics of the emitted radiation, the means of protection of the patient and the user and the ways to avoid erroneous manipulations and to eliminate the risks derived from the installation.

[1] EN 301 489-17 V 2.2.2.1 (2012 09): "electromagnetic compatibility and radio spectrum Matters (ERM); electromagnetic compatibility (EMC) standard for radio equipment and services; part 17: specific condition for 2,4 GHz wideband transmission systems and 5 GHz high performance RLAN equipment".
[2] EN 901 489-1 V 1.9.2 (2011 09): "electromagnetic compatibility and radio spectrum Matter (ERM); electromagnetic compatibility (EMC) standard for radio equipment and services; part 1: Common technical requirements"
[3] EN60950-1:2006 + A11:2009+A1:2010: "Information technology equipment – safety"

Currently we are working to include this information in the corresponding place of the documentation and in the device where it is required.

Exception 3:

Point 12.5. of Annex I. Products must be designed and manufactured in a way that minimizes the risks of creating electromagnetic fields that could affect the operation of other products or equipment located in their usual environment.

As part of the development and improvement of the device, it has been used in several scientific investigations in the framework of European projects. There is currently no reference to the existence of interference generated by the device that will affect the proper functioning of the rest of the equipment used during the work carried out in these projects. No tests have been carried out to verify interference with equipment other than those used.

Exception 4:

12.8.2. of Annex I. The product must be provided with means to prevent and / or indicate any inaccuracy of the rate of contribution of the product when a danger may arise from it.

The products must be equipped with adequate means to prevent, as far as possible, the accidental release of dangerous amounts of energy from a source of energy and / or substances.

There are no overload failures in the device from which any danger may arise. However, we are working on a superior control system for supervision, which warns of system failures, even if they are negligible from the user.

The current prototype has a watertight compartment for the LiFePO4 battery housing, which does not make physical contact with the user, in order to prevent accidental release of substances from the battery, if any. In addition, it has an internal security system to prevent the accidental release of dangerous amounts of energy.

11. General Warranty

Technaid S.L. guarantees for one year, starting from the date of the shipping, the functioning of this product against any defect on the materials and labor employed for its manufacturing.

During the warranty period, defective parts will be repaired or replaced, which includes labor and pieces. Shipping costs are not included. To save transportation costs to the Buyer, Technaid offers tele-assistance for reparations

THIS GUARANTEE WILL NOT BE VALID UNDER THE FOLLOWING CONDITIONS:

- Whenever this guarantee shows clear signs of having been altered in the original data therein described.
- Premeditated or irresponsible breakage
- Whenever the use, care and product handling has not been in accordance with the instructions included in the user's manual.
- Whenever the product has been used out of its specifications, mistreated, hit, exposed to humidity, soaked by a liquid or corrosive substance, as well as by any other fault attributable to the consumer.
- Whenever the product has been dismantled, modified or repaired by people not authorized by Technaid S.L. Even the handling of the warranty seals will avoid the warranty conditions agreed.
- Whenever the failure is due to the normal wear of the parts due to their normal use.

Without prejudice to any other article or agreement, the Buyer can manipulate electronically and mechanically the device for research activity. However, The Seller is not liable to support the warranty under some type of manipulation, such as those that may produce damage of the device.

Note: There are some stickers distributed along the Exo-H3 that works as seals. A broken seal will avoid the warranty conditions agreed. These stickers contain a QR Code.

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