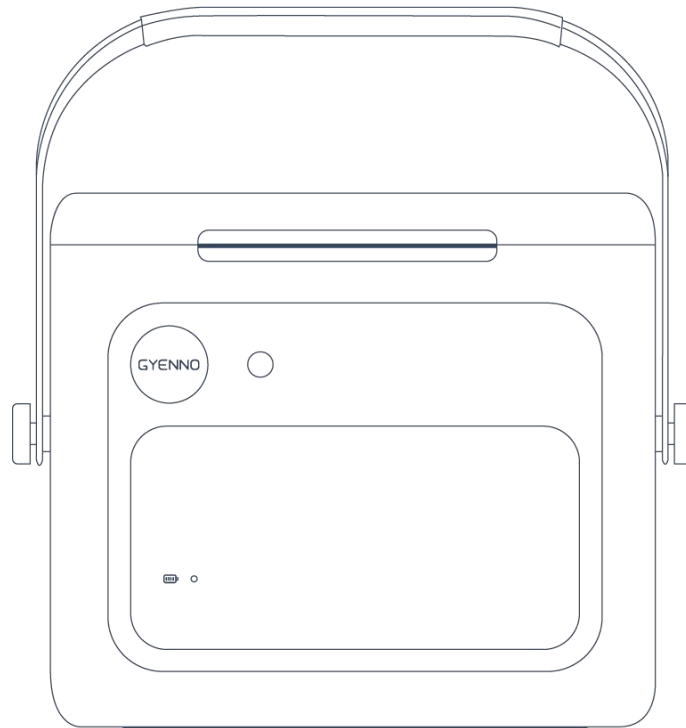


# User Manual

## Wearable Motion and Gait Quantification Assessment System



MA100/MA200-IFU-EN

V1.1

## Revision History

| Version number | Reason for revision and content | Date of revision | Revisionist |
|----------------|---------------------------------|------------------|-------------|
| V1.0           | New Fiction                     | 2022-03-01       | Hongyuan Wu |
| V1.1           | Update as required              | 2022-05-31       | Hongyuan Wu |
|                |                                 |                  |             |
|                |                                 |                  |             |
|                |                                 |                  |             |
|                |                                 |                  |             |



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## Description of terms in this manual

|                                                                                                |                                                                                                                                                         |
|------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| <br>Warning   | Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.                                             |
| <br>Caution   | Indicates a potentially hazardous situation which, if not avoided, may result in invalid data collecting ,damage to the equipment or invalid operation. |
| <br>Attention | Information necessary to be known before using the equipment.                                                                                           |

Table 1 Description of terms

# 1 Intended use

The Wearable Motion and Gait Quantification Assessment System (hereinafter referred to as "the product") is used for the analysis and assessment of movement symptoms in movement disorders. For patients with movement disorders.

## 2 Safety information

---

### **Warning**

1. Do not place or store this product near an open flame or heat source.
  2. Do not use a broken charging cable or socket.
  3. Do not charge this product with a charging base that is not designed for this product.
  4. Do not plug or unplug the charging cable with wet hands.
  5. Do not use this product in areas where there are flammable gases and where it can cause an explosion.
  6. The user must carry out a safety check on the system before each use and should ensure that the system is safe to use and works properly.
  7. When other devices are connected to the patient's body at the same time, the total amount of leakage current may exceed the permissible limit and pose a potential danger to the patient.
  8. Although all patient contact parts have been tested for biocompatibility, a very small number of people may have allergic reactions and should be discontinued in patients with allergic reactions.
  9. The various accessories of this product must not be replaced at will. If replacement is necessary, the accessories provided by the company or those of the same type, manufacturer and standard as those supplied with the product should be used, otherwise there may be adverse consequences in terms of safety and biocompatibility.
  10. If the product is dropped accidentally or if other malfunctions occur, it cannot be used any longer.
  11. Repairs are to be carried out only by professional repairers appointed by the manufacturer.
  12. Contact with wounds and scars should be avoided.
  13. Do not use the instrument in the presence of high voltage equipment, or in an environment with a high level of static electricity, as this may cause sparks due to momentary discharge.
  14. The product must be disposed of in accordance with local regulations or it may cause contamination.
  15. When walking with this product, you must be aware of your surroundings.
  16. Patients with abnormal gait are at high risk of falls, so please take precautions against falls during the use of this product.
-

---

 **CAUTION**

1. Do not use this product while charging.
  2. If the product is accidentally dropped in water or other liquids while charging, please unplug the charging cable immediately, remove the product and wipe it off promptly.
  3. If the product is accidentally dropped into water during use, please remove it promptly and wipe it off and allow it to dry completely before using again.
  4. Do not use this product in an environment with strong magnetic fields.
  5. Do not disassemble or modify this product yourself.
- 

## **3 Overview**

### **3.1 Introduction**

This product is a quantitative assessment system for Parkinson's disease based on wearable motion sensing technology. It captures motion data from 10 positions of the human body in real time through high-precision sensors, and performs relevant spatial motion posture analysis and feature mining by a model constructed from human kinematics and dynamics, and outputs a detailed and complete motion assessment report.

The product also supports the display of the freezing index, providing a quantifiable indicator of freezing gait for clinical studies.

### **3.2 Product composition**

The product is mainly consists of Main Box, Nodes, Camera, Computer, Special Software and Accessories.

Accessories include: Straps, Adapter, Type-C Data Cable and Tape Measure.

#### **3.2.1 Main Box**

The Main Box is used to connect nodes, receive data, charge nodes, strap and store nodes, as shown in the following figure:

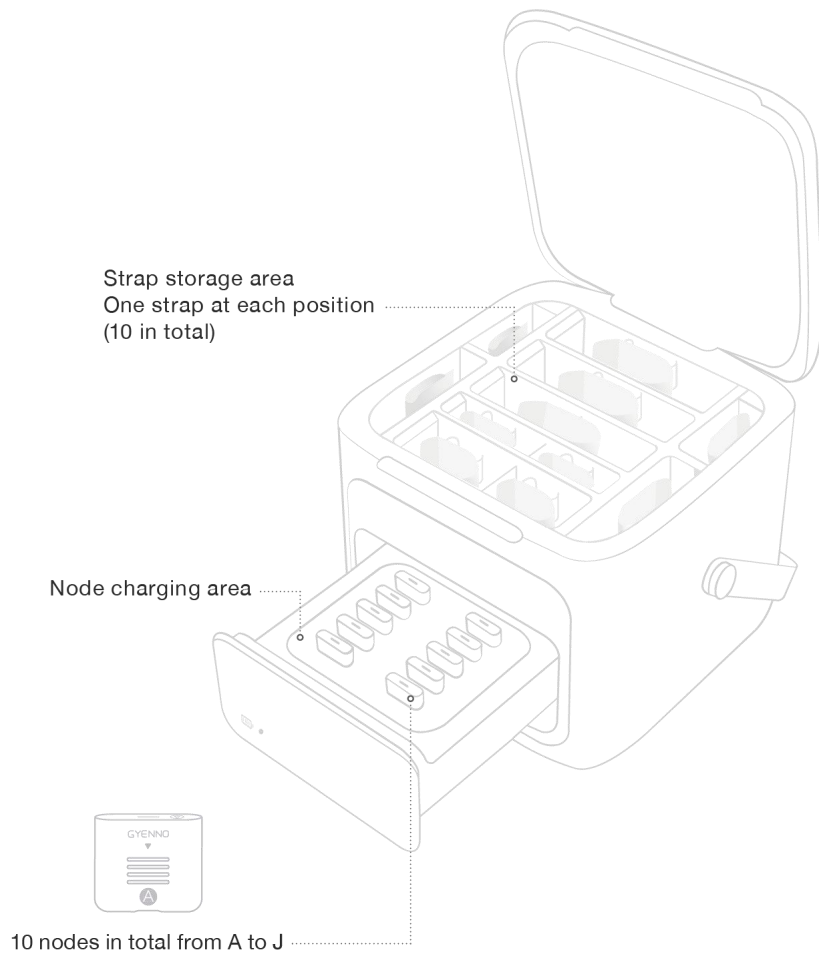


Figure 1 Main Box

The Main Box FCC ID :2ACGF-MA00A.

### 3.2.2 Nodes

The nodes is a sensor used to collect motion data. There are 10 nodes marked with letters a – J. During node configuration, the parts worn by each node will be configured. During the collection process, the collection node needs to be worn according to the configuration.



Figure 2 Node A-J

The Node FCC ID : 2ACGF-MA00B.

### 3.2.3 Straps

This product monitors human activities in real time through the strap wearing collection node. The strap and wearing position are shown in the following figure:

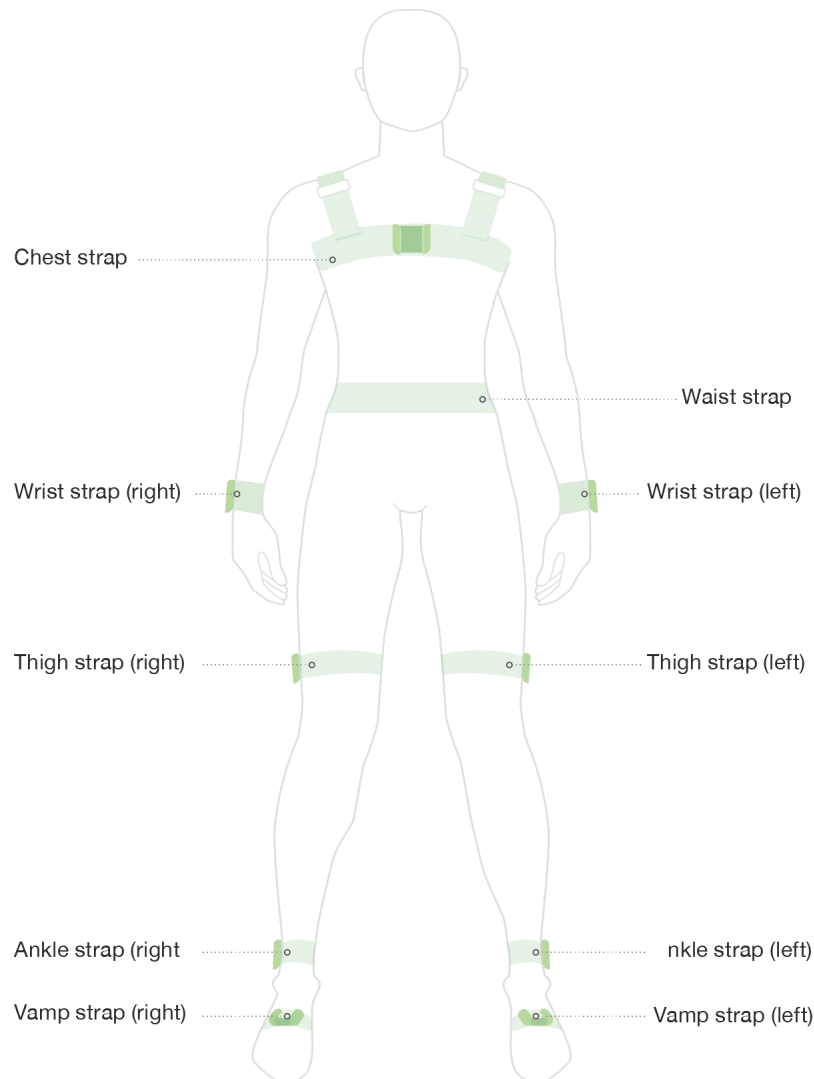


Figure 3 Taping

### 3.2.4 Computer and Camera

In addition to the above components, this system requires a PC with the Wearable Motion and Gait Quantification Assessment System PC application installed and a HD camera with USB port. The requirements are shown in the table below.

| Accessories | Requirements                                     |
|-------------|--------------------------------------------------|
| Computer    | CPU: 7th generation Intel I5 processor and above |
|             | RAM: 8G and above                                |
|             | Hard drive: 256G SSD and above                   |
|             | USB ports: 2 or more                             |
|             | Screen size: 11" and above                       |
|             | Screen resolution: 1280×720 and above            |
|             | OS: Windows 10 and above                         |
| Camera      | USB interface HD camera                          |

Table 2 Computer and Camera configurations

### 3.3 Working conditions

| Conditions           | Parameters                 |
|----------------------|----------------------------|
| Ambient temperature  | 0 °C ~ +45 °C              |
| Relative humidity    | 10% ~ 95% (non-condensing) |
| Atmospheric pressure | 70kPa ~ 106kPa             |

Table 3 Working conditions

### 3.4 Transport and storage conditions

| Conditions           | Parameters                 |
|----------------------|----------------------------|
| Ambient temperature  | -25 °C ~ +70 °C            |
| Relative humidity    | 10% ~ 95% (non-condensing) |
| Atmospheric pressure | 70kPa ~ 106kPa             |

Table 4 Transport and storage conditions

### 3.5 Symbols used in this product

|                                                                                     |                                                     |
|-------------------------------------------------------------------------------------|-----------------------------------------------------|
|    | Warning                                             |
|   | Caution                                             |
|  | Attention                                           |
|  | Refer to user manual                                |
|  | Waste Electrical and Electronic Equipment           |
|  | Type BF applied part                                |
|  | DC                                                  |
|  | Non-ionizing radiation                              |
|  | Authorized representative in the European Community |
|  | Medical device                                      |
|  | Manufacturer                                        |

Table 5 Symbols used in this equipment

## 4 Specifications and parameters

### 4.1 Specification

| Products / Components | Main parameters      |                    | Indicators                              |
|-----------------------|----------------------|--------------------|-----------------------------------------|
| Main chassis          | Size                 |                    | Approx340. (L) * 340 (W) * 300 (H) (mm) |
|                       | Weight               |                    | Approx. 9.5KG                           |
|                       | Bluetooth            | Wireless standards | BLE                                     |
|                       |                      | Frequency range    | 2402MHz to 248MHz                       |
|                       | Type of power supply |                    | 5V $\overline{\text{---}}$ 3A           |
|                       | Data Interface       |                    | Type-C                                  |
| Collection Nodes      | Number               |                    | 10 A-J nodes                            |
|                       | Size                 |                    | ≈ 38.9 (L) * 37 (W) * 12.7 (H) (mm)     |
|                       | Weight               |                    | ≈ 17g                                   |
|                       | Bluetooth            | Wireless standards | BLE                                     |
|                       |                      | Frequency range    | 2402MHz to 248MHz0                      |
|                       | Power supply         |                    | DC 3.7V 210mAh lithium battery          |
|                       | Charging voltage     |                    | DC 5V                                   |
|                       | Charging time        |                    | ≤2 hours                                |
|                       | Duration             |                    | ≥ 8 hours                               |
| Service life          |                      | 5 years            |                                         |

Table 6 Specification parameters Table No.

### 4.2 Indicator light description

#### 4.2.1 Main Box indicator

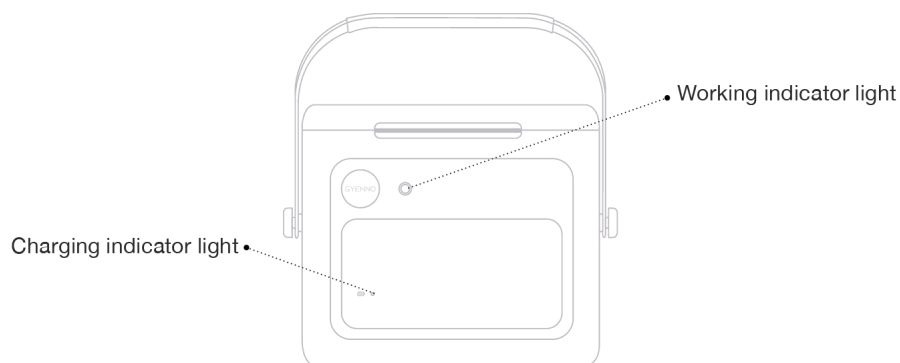


Figure 4 Main Box indicator

| Indicator light type | Indicator colours | Status Description |
|----------------------|-------------------|--------------------|
| Working light        | Green             | Normal operation   |

|                    |               |                                             |
|--------------------|---------------|---------------------------------------------|
|                    | Blue Flashing | Data transfer in progress or being upgraded |
|                    | Red Flashing  | Equipment exceptions                        |
| Charging indicator | Green         | Node is fully charged                       |
|                    | Yellow        | Any node not filled                         |

Table 7 Main Box indicator descriptions

#### 4.2.2 Node indicator

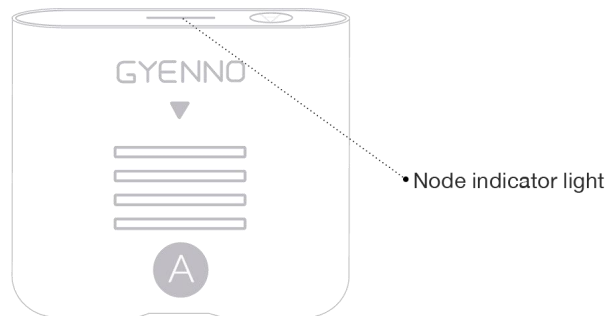


Figure 5 Node indicator

| Status type          | Indicator colours | Status Description   |
|----------------------|-------------------|----------------------|
| At work              | Green             | Working properly     |
|                      | Yellow Flashing   | Not connected        |
|                      | Yellow            | Low battery          |
|                      | Blue Flashing     | In data transmission |
| Charging in progress | Green             | Fully charged        |
|                      | Yellow            | Not fully charged    |
|                      | Blue Flashing     | Upgrades in progress |
| Any state            | Red Flashing      | Node anomalies       |

Table 8 Node indicators descriptions

## 5 Instructions for use

### 5.1 Preparation for use

#### 5.1.1 Charging

- ① Please insert all nodes into the charging cradle and ensure that the nodes are fully charged before use.

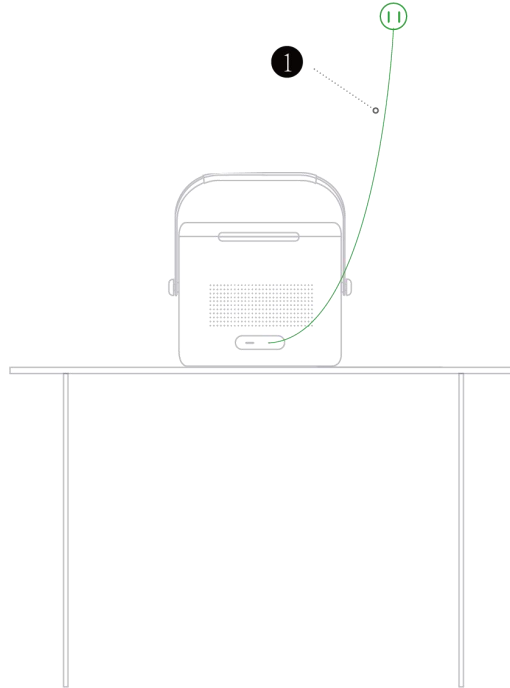


Figure 6 Device Charging

#### 5.1.2 Device connection

- ① Please use the TPYE-C data cable to connect the mainframe and the computer
- ② Camera connected to computer

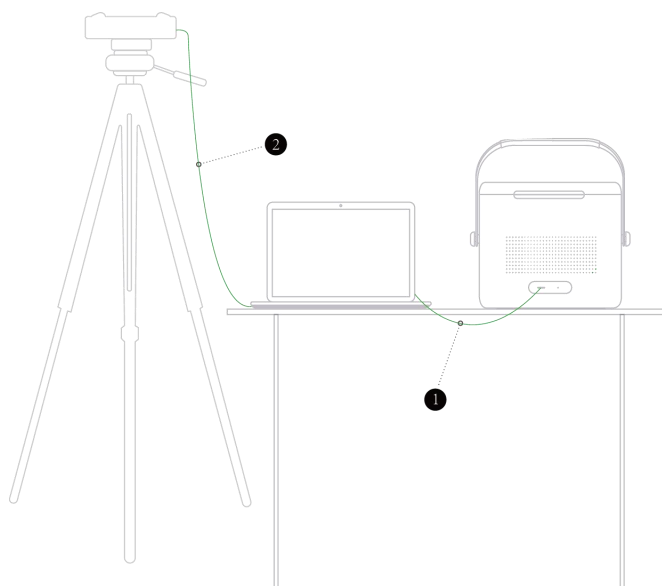


Figure 7 Device connection

### 5.1.3 Venue set-up

- ① Please arrange the venue according to the diagram below
- ② The distance from the starting point to the return point supports 3-10 metres, the recommended distance is 5 metres
- ③ Distance from the turning position to the camera is 4 metres
- ④ The camera should be positioned 2 metres from the return point so that it can capture the whole body of the person being examined



Figure 8 Site layout plan

## 5.2 Strap-on wear

### 5.2.1 Effect after wearing

Each set of equipment is equipped with 10 straps, which are worn at 10 different positions of the human body. The wearing effect is shown in the figure below. After the hands naturally droop, the wrist, thigh and ankle nodes are in the same line (such as the side):

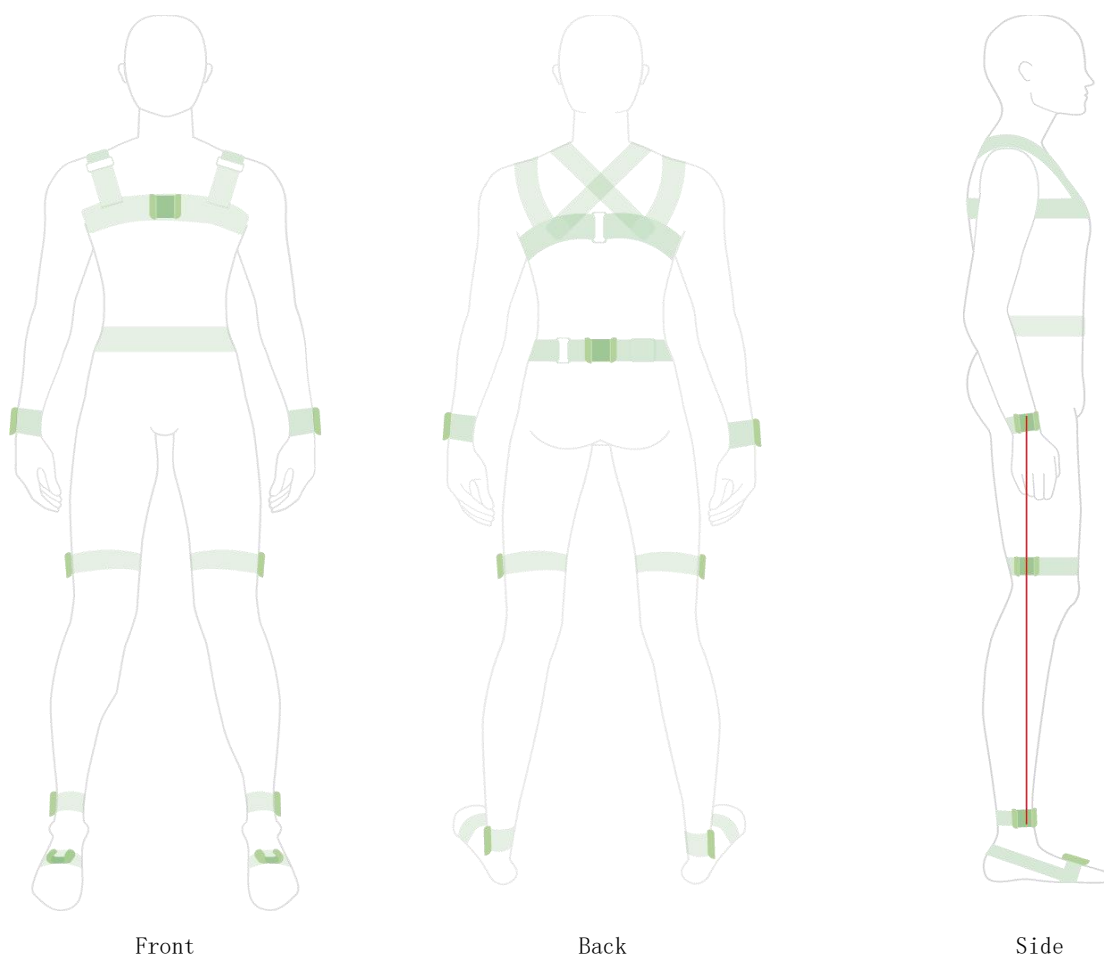
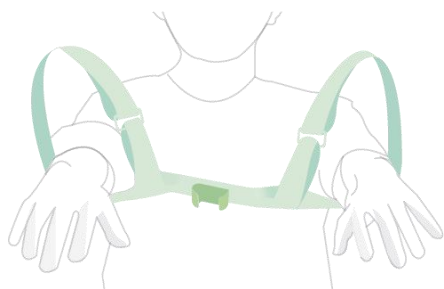
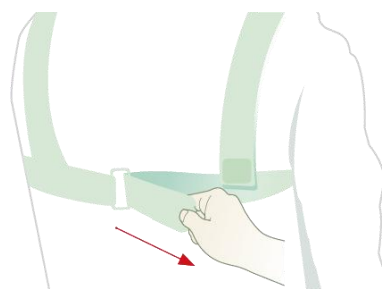


Figure 9 Effect after wearing

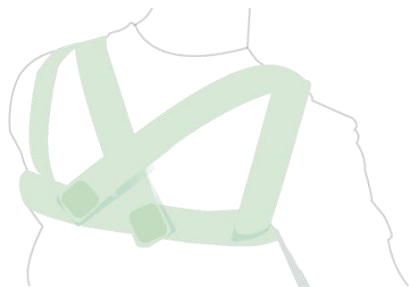
### 5.2.2 Chest strap



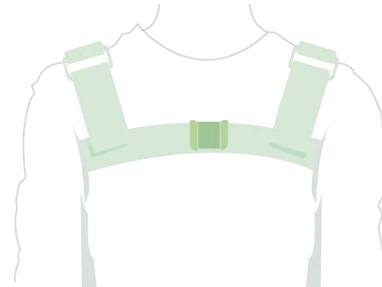
① Put your hands through the shoulder straps



② Adjust the tightness of chest strap



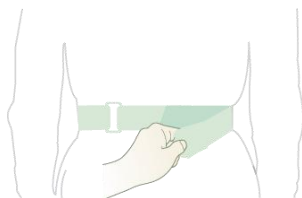
③ Adjust the tightness of the shoulder straps. Thinner users can cross the shoulder straps in an "X" shape on the back



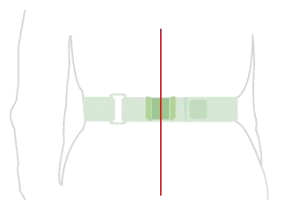
④ Make sure that the buckle is located between the two ribs, the chest strap is parallel to the shoulder, and the buckle opening is facing upward

Figure 10 Chest strap after wearing

### 5.2.3 Waist strap



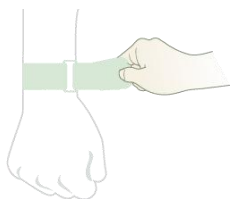
① The strap is tied around the waist



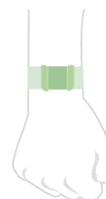
② Adjust the buckle to the end of the spine with the buckle opening facing upward

Figure 11 Waist strap after wearing

### 5.2.4 Wrist strap



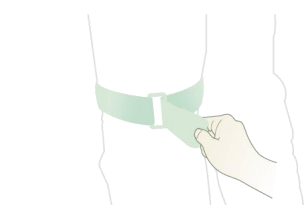
① The strap is tied in the middle of the wrist



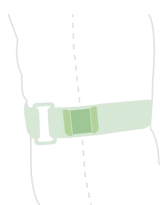
② The buckle position shall be in the center of the wrist, and the buckle opening shall face upward

Figure 12 Wrist strap after wearing

### 5.2.5 Thigh strap



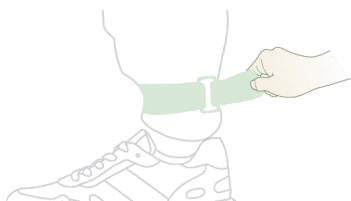
① The strap is tied above the knee



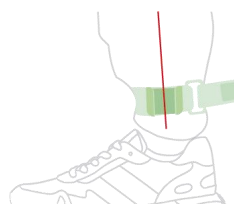
② Adjust the buckle to the outer trouser seam with the buckle opening facing upward

Figure 13 Thigh strap after wearing

### 5.2.6 Ankle strap



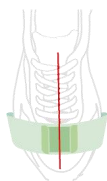
① The strap is tied to the ankle



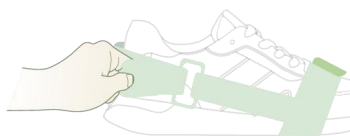
② Adjust the buckle to the outer trouser seam line and align with the position of the thigh buckle, and the buckle opening is facing upward

Figure 14 Ankle strap after wearing

### 5.2.7 Vamp strap



① Put the strap over the toe cap and adjust the buckle to the midline of the foot



② The long strap is passed through the buckle, tightened and glued, and the buckle opening is facing upwards

Figure 15 Vamp strap after wearing

## 5.3 Node Wearing

### 5.3.1 Node snap-in

Please put the nodes on in the corresponding order. When snapping the nodes in, please note that the side with the numbered letters faces outwards and the nodes are snapped in when you hear a "pop". Do not force the nodes in with the non-slip side facing inwards.

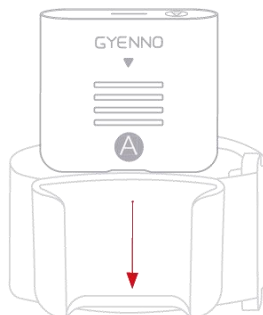


Figure 16 Node snap-in

| 节点 | 位置          | 节点 | 位置               |
|----|-------------|----|------------------|
| A  | Back Waist  | F  | Right Thigh      |
| B  | Chest       | G  | Left Ankle       |
| C  | Left Wrist  | H  | Right Ankle      |
| D  | Right Wrist | I  | Left Vamp Upper  |
| E  | Left Thigh  | J  | Right Vamp Upper |

Table 9 Description of node wear position

### 5.3.2 Node pull-out

To pull out the nodes, place four fingers on the bottom of the node clasp with your thumb on the bottom of the node, palm facing the top of the node, halfway up the node and then push the node out with a little force. Be careful when pulling out the node that it bounces off with too much force.

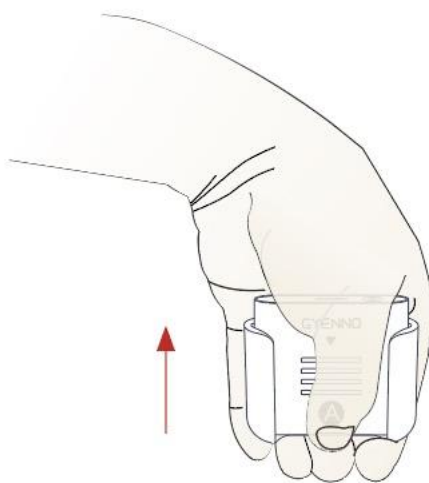


Figure 17 Node pull-out

## 5.4 Getting started with the software

### 5.4.1 Visit the Wearable Motion and Gait Quantification Assessment System PC application

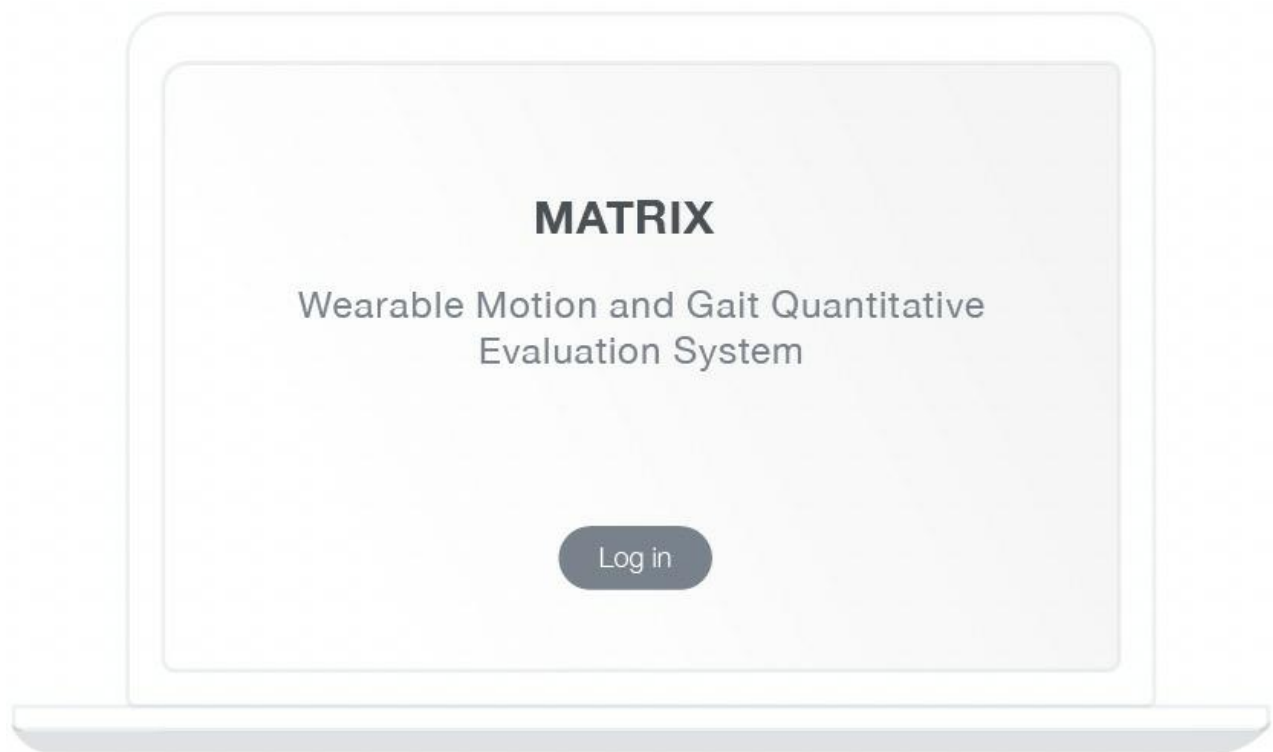


Figure 18 Login software

### 5.4.2 New assessment

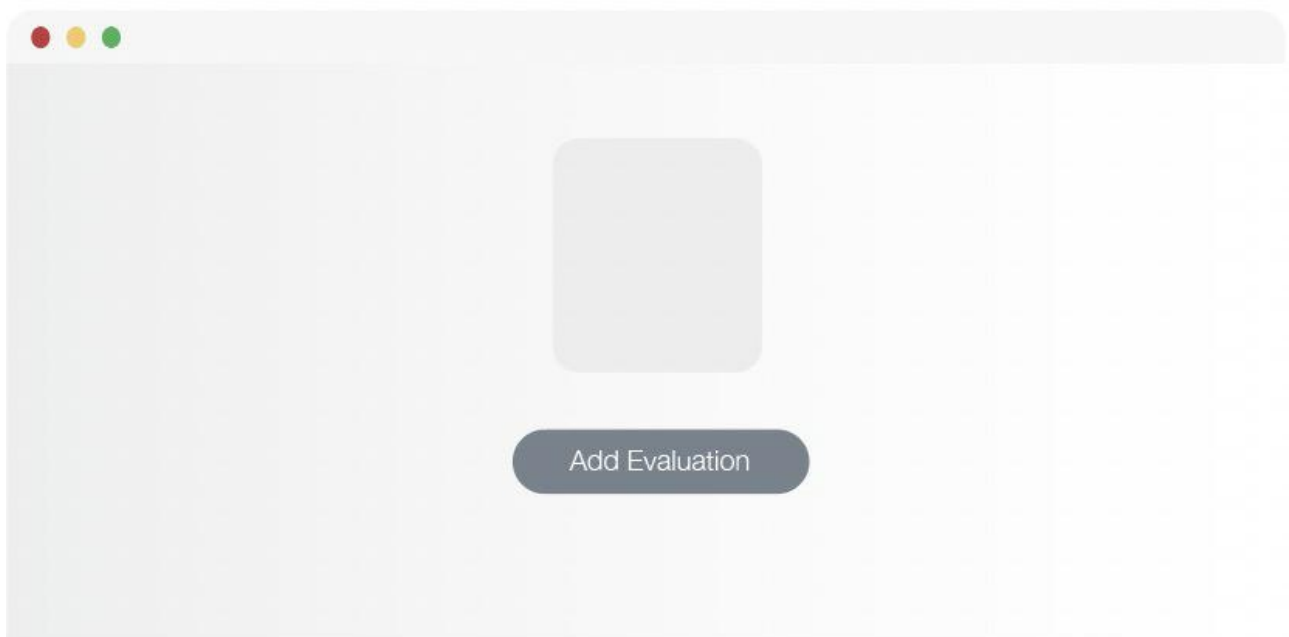


Figure 19 New assessment

### 5.4.3 Enter the assessment name and description of the assessment

Once the assessment name and description have been saved, they cannot be changed. Please confirm that they are correct before clicking [Next].

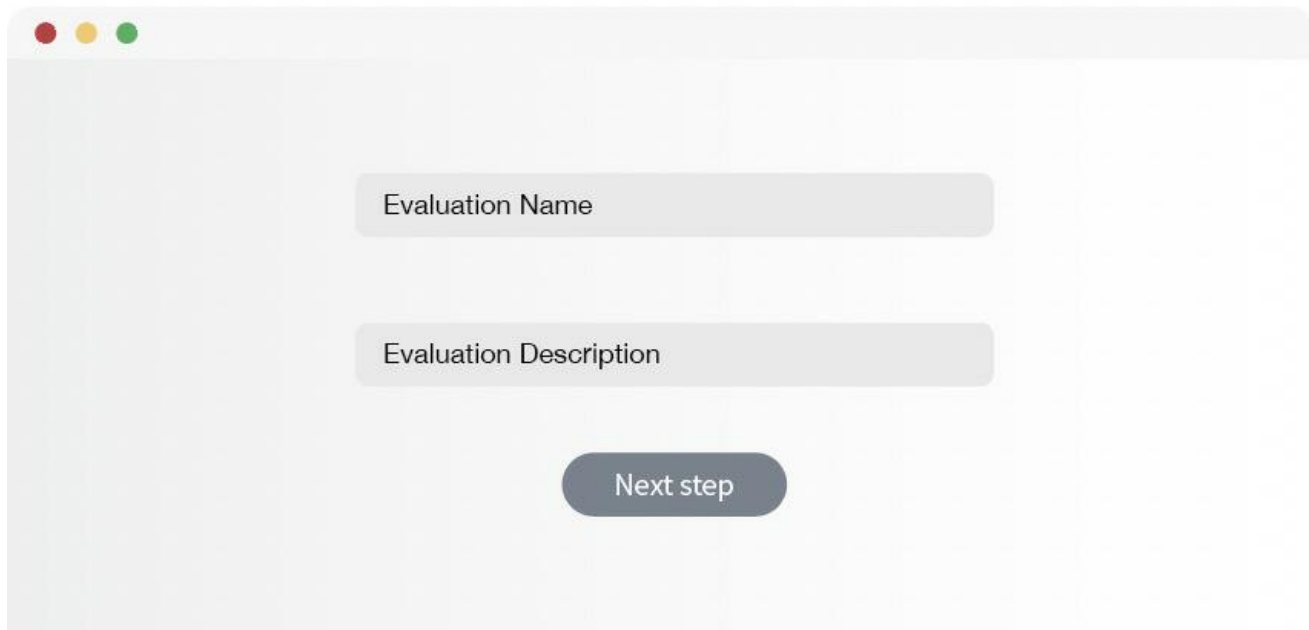
A screenshot of a web application window with a light gray background. At the top, there are three colored window control buttons (red, yellow, green). The main content area contains two text input fields. The first field is labeled "Evaluation Name" and the second field is labeled "Evaluation Description". Below these fields is a dark gray button with the text "Next step" in white.

Figure 20 Enter the name of the assessment

### 5.4.4 Add a check

- a. Click to add a check item      b. Delete a check item

Add up to 10 checks and click [Save] on the assessment template

A screenshot of a web application window with a light gray background. At the top, there are three colored window control buttons (red, yellow, green). The main content area shows a list of check items. On the right side, there is a dark gray button labeled "Save". Below the "Save" button, there are three small buttons labeled "TUG", "Narrow", and "Turning". To the left of these buttons, there is a list of check items: "TUG", "Narrow", and "Turning". To the right of each check item, there is a trash icon for deleting the item.

Figure 21 Adding check items

#### 5.4.5 Select an assessment template to carry out the assessment

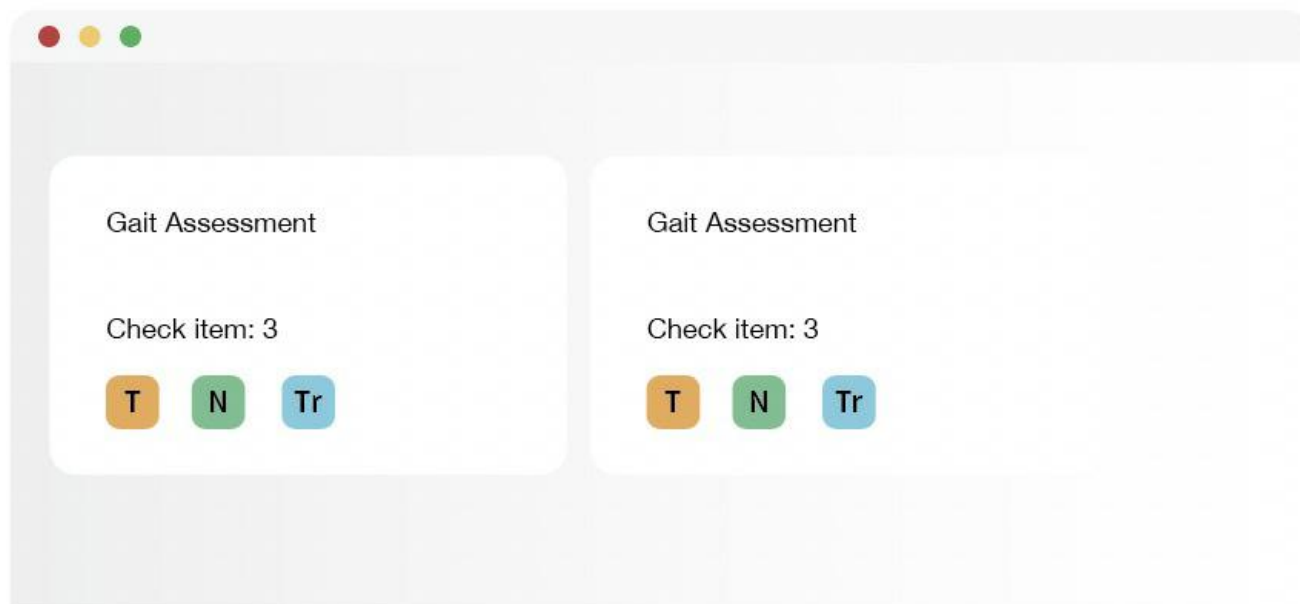


Figure 22 Selecting an assessment template

#### 5.4.6 Enter patient information

Enter the patient information and click on [Go to Assessment] (\* symbols are required)

Please see the diagram on the right for the measurement of thigh length: the thigh length shown above is A, which is the length from the hip bone to the midpoint of the knee

The calf length is B, which is the length from the midpoint of the knee to the ground

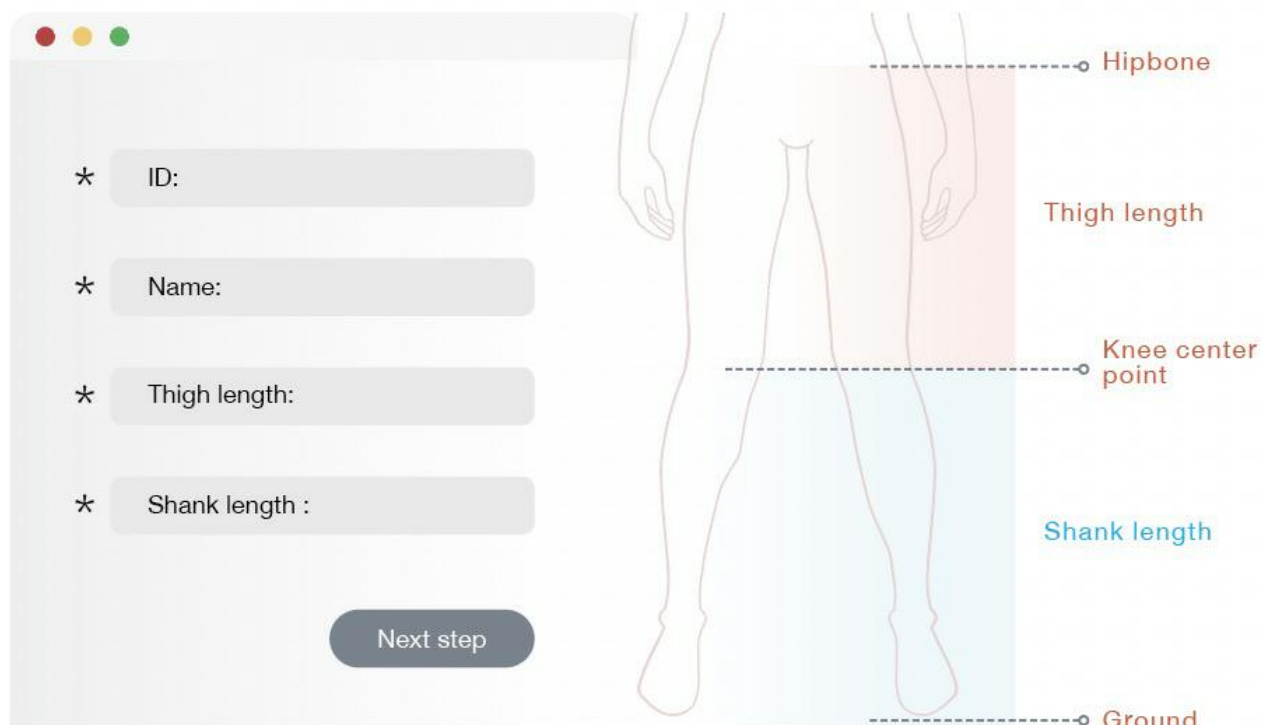


Figure 23 Selecting an assessment template

### 5.4.7 Start assessment

Once you have entered the assessment, click on [Start Assessment] or use the controller to control the assessment process.

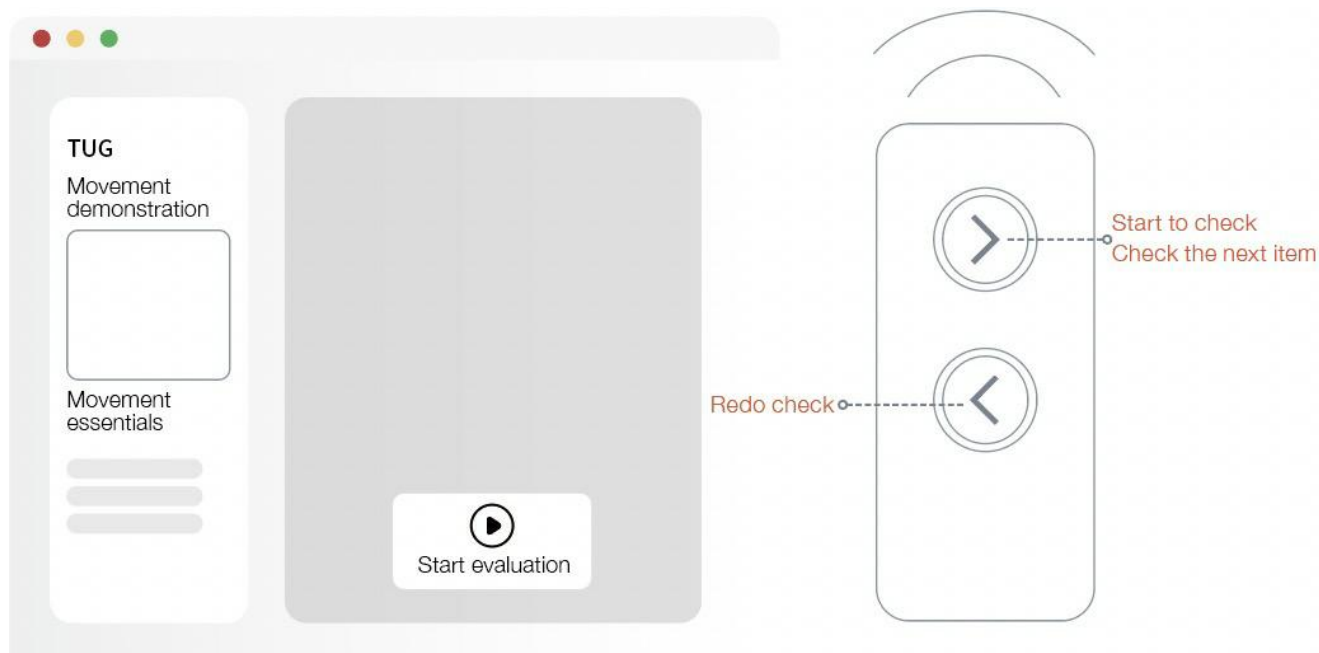


Figure 24 Start of assessment

### 5.4.8 View the assessment report

At the end of the assessment, review the assessment conclusions and the parameters of the assessment report.

| Evaluation Report |                                |        |        |                 |
|-------------------|--------------------------------|--------|--------|-----------------|
| Serial number     | Test item                      | Unit   | Result | Reference value |
| 1                 | Experiment duration            | second | 37.12  | -               |
| 2                 | Experiment effective duration  | second | 0      | -               |
| 3                 | Duration of standing up        | second | 0      | -               |
| 4                 | Effective duration of the test | second | 0      | -               |

Figure 25 View the assessment report

### 5.4.9 Other functions

#### ① Node configuration

The PC application of wearable Motion and gait Quantification Assessment system can perform one click

configuration and status query on nodes in [settings] - [node configuration].

## ② Patient management

The PC application of wearable movement and gait quantitative evaluation system can view, add and modify patient information in [patient].

## 5.5 After use

### 5.5.1 End of use

At the end of use, remove the straps and store them; it is recommended that the straps are cleaned promptly after use.

## 6 Cleaning and disinfection

### 6.1 Cleaning the main chassis and nodes

Please use a clean cotton cloth with neutral detergent or clean water to wipe and clean the nodes and the main box, and dry them with a dry cloth. In case of accidental pollution and disinfection, a cloth stained with medical alcohol can be used for wiping and disinfection.

Wipe down and dry with a dry cloth.

### 6.2 Cleaning straps

After each use, please use neutral detergent or medical alcohol to wipe, clean or disinfect.

Please wash your hands regularly with clean water to keep the bandage clean.

## 7 Maintenance and Care

- This product contains precision devices, please keep away from magnetic field environment, long-term magnetic interference will reduce the performance and affect the service life of the product.
- When you have finished using this product, please switch it off promptly.
- This product should not be flushed or doused with water.
- Do not place any part of this product near an open flame or heat source when in use or storage.
- Clean the stained area promptly after use.
- Avoid dropping any part of this product when in use or storage.
- Do not pull, press or twist the product with force.
- This product should be charged in time. When not in use for a long time, it should be stored fully charged and recharged at intervals of one to two months. Store in a cool, dry environment, avoid

humidity and exposure to the sun.

## 8 Exceptions and their handling

| Type of fault                                                 | Possible causes and treatment                                                                                                                                                                                                                                                                                         |
|---------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The main case charging indicator does not light up            | 1 Verify that the power cable is connected properly<br>2 If the power cable is connected properly<br>Please call our customer service hotline for solutions.                                                                                                                                                          |
| The main chassis operating status indicator does not light up | 1 The data cable is not connected.<br>Connect the data cable correctly.<br>2 Data cable problem.<br>Verify that the data connection cable between the main case and the computer is intact.<br>3 If you confirm that the data cable is connected properly.<br>Please call our customer service hotline for solutions. |
| Node indicator does not light up                              | 1 No power to the node.<br>Please charge the nodes.<br>2 If the node charge indicator also does not light up.<br>Please call our customer service hotline for solutions.                                                                                                                                              |
| Node indicator flashes red                                    | 1 Node hardware exception.<br>Please charge the node, if it still flashes red, please call the customer service hotline for a solution.                                                                                                                                                                               |
| Unable to charge                                              | 1 Not properly charged<br>Check that the charging cable or charging base is correctly connected.<br>2 Battery or charging component failure<br>Please contact the manufacturer for a solution.                                                                                                                        |

Table 10 Exceptions and their handling

## 9 Cautions

- Please ensure that the product is fully charged before use. When the battery is low, stop using the device for a short time and recharge the system as soon as possible.
- Please follow the operating instructions when using the product.
- Do not wash the straps in the washing machine, hand wash only.

## 10 Contraindications

- In the case of patients with abnormal gait, please assess whether they are at risk of execution before using the system, if so, do not carry out an assessment.

# 11 Electromagnetic compatibility information

| Guidelines and manufacturer's statements - Electromagnetic emissions                                                                                                                                                                                     |                |                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Wearable Motion and Gait Quantification Assessment System is intended for use in the following specified electromagnetic environments and the purchaser or user of the Freeze Gait Assist System should ensure that it is used in such environments: |                |                                                                                                                                                                                                                                                                                                                                                                                 |
| Launch test                                                                                                                                                                                                                                              | Conformity     | Electromagnetic Environment - Guide                                                                                                                                                                                                                                                                                                                                             |
| Radio Frequency Emission GB 4824                                                                                                                                                                                                                         | 1 group        | The Freeze Gait Assist uses RF energy only for its internal functions. It therefore has very low RF emissions and the potential for interference with nearby electronic equipment is minimal.<br><br>The Freeze Gait Assist system is suitable for use in all facilities, including domestic and residential public low-voltage supply networks connected directly to the home. |
| Radio Frequency Emission GB 4824                                                                                                                                                                                                                         | Category B     |                                                                                                                                                                                                                                                                                                                                                                                 |
| Harmonic emission GB 17625.1                                                                                                                                                                                                                             | Not applicable |                                                                                                                                                                                                                                                                                                                                                                                 |
| Voltage fluctuations/flicker emission<br>GB17625.2                                                                                                                                                                                                       | Not applicable |                                                                                                                                                                                                                                                                                                                                                                                 |

Table 11 Declaration of conformity for electromagnetic emissions

| Guidelines and manufacturer's statements - Electromagnetic Immunity                                                                                                                                                                                      |                                                                                                                                                                                                                                                                      |                                                |                                                                                                                                                                                                                                                                                                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Wearable Motion and Gait Quantification Assessment System is intended for use in the following specified electromagnetic environments and the purchaser or user of the Freeze Gait Assist System should ensure that it is used in such environments: |                                                                                                                                                                                                                                                                      |                                                |                                                                                                                                                                                                                                                                                                                                   |
| Immunity tests                                                                                                                                                                                                                                           | IEC 60601 Test levels                                                                                                                                                                                                                                                | Conformity level                               | Electromagnetic Environment - Guide                                                                                                                                                                                                                                                                                               |
| Electrostatic discharge<br>GB/T 17626.2                                                                                                                                                                                                                  | ±6 kV contact discharge<br>±8 kV air discharge                                                                                                                                                                                                                       | ±6 kV contact discharge<br>±8 kV air discharge | The floor should be wood, concrete or tile, or at least 30% relative humidity if the floor is covered with a synthetic material                                                                                                                                                                                                   |
| Electric fast transient pulse train<br>GB/T 17626.4                                                                                                                                                                                                      | ±2kV to charging line                                                                                                                                                                                                                                                | Not applicable                                 | The network power supply should be of a quality typical of use in a commercial or hospital environment                                                                                                                                                                                                                            |
| Surge<br>GB/T 17626.5                                                                                                                                                                                                                                    | ±1 kV wire-to-wire<br>±2 kV line to ground                                                                                                                                                                                                                           | Not applicable                                 | Net power should be of a quality typical of use in a commercial or hospital environment                                                                                                                                                                                                                                           |
| Voltage transients on the power input line, short Time interruptions and voltage variations<br>GB/T 17626.11                                                                                                                                             | <5 % $U_T$ for 0.5 cycles<br>(on $U_T$ , >95% temporary drop)<br>40% $U_T$ , duration 5 cycles<br>(on $U_T$ , 60% temporary drop)<br>70% $U_T$ , duration 25 cycles<br>(on $U_T$ , 30% temporary reduction)<br><5 % $U_T$ for 5s<br>(on $U_T$ , >95% temporary drop) | Not applicable                                 | The network power supply should be of a quality typical of that used in a commercial or hospital environment. If the user of a freeze gait assist system requires continuous operation during a power interruption, it is recommended that the freeze gait assist system be powered by an uninterruptible power supply or battery |
| Industrial frequency magnetic field (50/60Hz )                                                                                                                                                                                                           | 3A/m                                                                                                                                                                                                                                                                 | 3A/m                                           | The FT magnetic field should have the characteristics of the FT magnetic field levels                                                                                                                                                                                                                                             |

|                                                                                  |  |                                                                   |
|----------------------------------------------------------------------------------|--|-------------------------------------------------------------------|
| GB/T 17626.8                                                                     |  | typical of a site in a typical commercial or hospital environment |
| Note: $U_T$ refers to the AC network voltage before the test voltage is applied. |  |                                                                   |

Table 12 Electromagnetic Immunity Declaration of Conformity A

| Guidelines and manufacturer's statements - Electromagnetic Immunity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Wearable Motion and Gait Quantification Assessment System is intended for use in the electromagnetic environment specified below and the purchaser or user of the Freeze Gait Assist System shall ensure that it is used in such electromagnetic environment:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Immunity tests                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | IEC 60601 Test levels       | Conformity level | Electromagnetic Environment - Guide                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Radio frequency conduction GB/T 17626.6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 3 V (rms) 150 kHz to 80 MHz | Not applicable   | <p>Portable and mobile RF communications equipment should not be used closer to any part of the freeze gait assist system, including cables, than the recommended isolation distance. This distance is calculated by the formula corresponding to the frequency of the transmitter.</p> <p>Recommended isolation distance <math>d = 1.2\sqrt{P}</math></p> <p><math>d = 1.2\sqrt{P}</math> 80MHz to 800MHz</p> <p><math>d = 2.3\sqrt{P}</math> 800MHz to 2.5GHz</p> <p>Where:</p> <p>P - maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer;</p> <p>d - recommended isolation distance in metres (m) <sup>b</sup>. The field strength of a fixed RF transmitter is determined by <sup>a</sup> survey of the electromagnetic field house <sup>a</sup>, which should be lower than the compliance level in each frequency range <sup>b</sup>. Interference may occur in the vicinity of equipment marked with the following symbols :</p>  |
| Radiofrequency radiation GB/T 17626.3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 3V/m<br>80 MHz to 2.5 GHz   | 3V/m             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Note 1: At 80MHz and 800MHz frequencies, the formula for the higher band is used.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Note 2: These guidelines may not be appropriate in all cases, electromagnetic propagation is influenced by absorption and reflection from buildings, objects and the human body.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p>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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.</p> <p>b. Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3V/m.</p> <p>a. The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to</p> |                             |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Table 13 Electromagnetic Immunity Declaration of Conformity B

| Recommended separation distances between portable and mobile RF communications equipment and freeze gait assist systems                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                |                                        |                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|----------------------------------------|-----------------------------------------|
| The Wearable Motion and Gait Quantification Assessment System is intended for use in electromagnetic environments with controlled RF radiated disturbances. Depending on the maximum rated output power of the communication equipment, the purchaser or user of the Freeze Gait Quantification System may be protected from electromagnetic interference by maintaining the minimum distance between portable and mobile RF communication equipment (transmitters) and the Freeze Gait Quantification System as recommended below. |                                                                                |                                        |                                         |
| The transmitter is rated for a maximum of High output power W                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Isolation distance corresponding to different frequencies of the transmitter m |                                        |                                         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 150 kHz to 80 MHz<br>$d = 1.2\sqrt{P}$                                         | 80 MHz to 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.3\sqrt{P}$ |
| 0.01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 0.12                                                                           | 0.12                                   | 0.23                                    |
| 0.1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 0.38                                                                           | 0.38                                   | 0.73                                    |
| 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 1.2                                                                            | 1.2                                    | 2.3                                     |
| 10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 3.8                                                                            | 3.8                                    | 7.3                                     |
| 100                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 12                                                                             | 12                                     | 23                                      |
| For transmitter maximum output power ratings not listed in the table above, the recommended isolation distance d, in metres (m), can be determined using the formula in the corresponding transmitter frequency column, where P is the transmitter maximum output power rating in watts (W) provided by the transmitter manufacturer.                                                                                                                                                                                               |                                                                                |                                        |                                         |
| Note 1:At the 80MHz and 800MHz frequency points, the formulae for the higher frequency bands are used.                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                |                                        |                                         |
| Note 2:These guidelines may not be appropriate in all cases. Electromagnetic propagation is influenced by absorption and reflection from buildings, objects and the human body.                                                                                                                                                                                                                                                                                                                                                     |                                                                                |                                        |                                         |

Table 14 Recommended separation distances for electromagnetic interference

## 12 Name and content of hazardous substances

| Part name      | Harmful substances |              |              |                              |                                |                                       |
|----------------|--------------------|--------------|--------------|------------------------------|--------------------------------|---------------------------------------|
|                | Lead (Pb)          | Mercury (Hg) | Cadmium (Cd) | Hexavalent chromium (Cr(VI)) | Polybrominated Biphenyls (PBB) | Polybrominated Diphenyl Ethers (PBDE) |
| Housing        | ○                  | ○            | ○            | ○                            | ○                              | ○                                     |
| Silicone parts | ○                  | ○            | ○            | ○                            | ○                              | ○                                     |
| Battery        | ○                  | ○            | ○            | ○                            | ○                              | ○                                     |
| Charging cable | ○                  | ○            | ○            | ○                            | ○                              | ○                                     |
| PCB components | ○                  | ○            | ○            | ○                            | ○                              | ○                                     |
| Packaging      | ○                  | ○            | ○            | ○                            | ○                              | ○                                     |

|           |  |  |  |  |  |  |
|-----------|--|--|--|--|--|--|
| materials |  |  |  |  |  |  |
|-----------|--|--|--|--|--|--|

This table has been prepared in accordance with the provisions of SJ/T 11364.

○ indicates that the content of the hazardous substance in all homogeneous materials of the component is below the limit specified in GB/T 26572.

× Indicates that the content of the hazardous substance in at least one homogeneous material of the component exceeds the limit specified in GB/T 26572.

Table 15 Harmful substances and content

## 13 REGULATORY INFORMATION

### FCC Caution

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.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This device should be installed and operated with minimum distance 20cm between the radiator & your body. This part belongs to the main Box.

\* RF warning for Portable device:

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction. This part belongs to the nodes.

## 14 Quality commitment

This product comes with a two-year warranty on all nodes and main chassis.

Any part of the device, including attachments and accessories, is not allowed to be repaired by unspecified maintenance. One of the following occurs is not eligible for warranty claim:

- Damaged caused by disassembling or modifying on customer's own
- Damage caused by unspecified maintenance by manufacturer.
- Damaged caused by exceeding the specified conditions of use.
- Damage caused by the failure to use in abnormal environment or without following the user manual.
- Damage caused by improper use or transportation.
- Manufacturing label being replaced or removed.

Repairing services out of the warranty will be charged as required.

## 15 Disposal

When the product is disposed of, please dispose of it as electronic waste. GYENNO has always been committed to earth care, we also encourage our users to make contribution by executing proper disposal:

- Packaging materials should be handed to local recycling companies for the possibility of re-use.
- Comply with relevant laws and regulations when disposing wasted parts and components.
- This device should be disposed as electronic waste.

## 16 Copyright and Responsibility

The copyrights and confidentiality of this manual are owned by GYENNO.

This manual is subjected to be a reference for operating and maintaining the equipment.