

User Manuals

Freezing of Gait Aid System



GA100-IFU-EN
V1.1

REVISION HISTORY

Version No.	Contents and reasons for revision	Revision date	Reviser
V1.0	New Fiction	2021-11-03	Qianyu Liu
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Description of terms in this manual

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

1. INTENDED USE

Freezing of Gait Aid System (hereinafter referred to as “the product”) is used to collect Freezing of Gait (FoG) data and alleviate FoG through visual and auditory prompting, help people with Parkinson's Disease improve their gait. For FoG's patients.

2. SAFETY INFORMATION



WARNING

1. Do not place or store this device near an open flame or heat source.
2. Do not use a damaged power cord or outlet.
3. Do not use other charger that is not designed for this product char
4. Patients using cardiac pacemakers or other electro-stimulation devices should not use this device.
5. Do not plug or unplug the power cord with wet hands.
6. Do not give self-judgment of the data and results to give treat
7. Class 1 laser product, Laser has radiation, avoid directing the laser beam towards the eye of any person.
8. Do not use this product in a place where there is a flammable gas which might cause an explosion.
9. The user must perform a safety check on the system before each use, and ensure that the system can be safely used and working properly.
10. When the patient's body is connected to other devices at the same time, the total amount of leakage current may exceed the allowable limit and pose a potential hazard to the patient.
11. Equipment or devices interconnected with this product must comply with the requirements of GB9706.1-2007 of "Medical Electrical Equipment Part 1: Safety General Requirements". Equipment or devices that have not been tested by a national inspection agency may not be interconnected with this product.
12. Although all patient contact parts have undergone bio-compatibility testing, very few people may have allergic reactions and should be discontinued for patients with allergic reactions.
13. The various accessories of this product cannot be replaced at randomly. If you need to replace it, you should use the accessories provided by the company or the same model, and standard accessories attached to the system, otherwise it may bring safety, bio-compatibility, etc. bad consequences of the aspect.
14. If the product falls unexpectedly or causes other malfunctions, it cannot be used.
15. Repairs should only be carried out by qualified service personnel designated by the manufacturer.
16. Avoid contact with wounds and scars.
17. Do not use the instrument in high-voltage equipment or in a high-static environment, as it may cause

sparks due to transient discharge.

18. Do not use this product outdoors in inclement weather.
19. Do not use the Binaural earphones.
20. Disposal of this product must be handled in accordance with local regulations, otherwise it may cause pollution.
21. Use this product with caution when working on wet floors.
22. Please use the laser hint function of this product carefully in bright light environment.
23. Please be cautious in using the audio hint function of this product in noisy environments.
24. When using this product, you must pay attention to the surrounding environment.
25. FOG patients are high-risk groups who fall, it is still necessary to take protective measures for falls while using this product.



CAUTION

1. Please do not use this product while charging.
2. If the product accidentally falls into water or other liquid during charging, please unplug the power cord immediately, pick the product and wipe it in time.
3. If the product accidentally falls into the water during use, please take it out in time and use it after it is completely dry.
4. Do not use this product under strong magnetic field conditions.
5. Do not disassemble or modify this product yourself.
6. If there is any problem before or during use of the device, it is recommended to consult the doctor or manufacturer.
7. Initial use by the user may take some time to adapt to the visual hint or auditory hint of the product.



ATTENTION

Clean the attachments before using the equipment.

3.Review

3.1 BRIEF INTRODUCTION

The product collects and automatically analyzes the user's gait data through motion sensors, intelligently identifies FOG, and gives visual (laser) and/or audible (audio) hint to help the user unfreeze. At the same time, the product records the information of the user's frozen gait, which can assist the doctor to quantitatively evaluate the patient's symptoms.

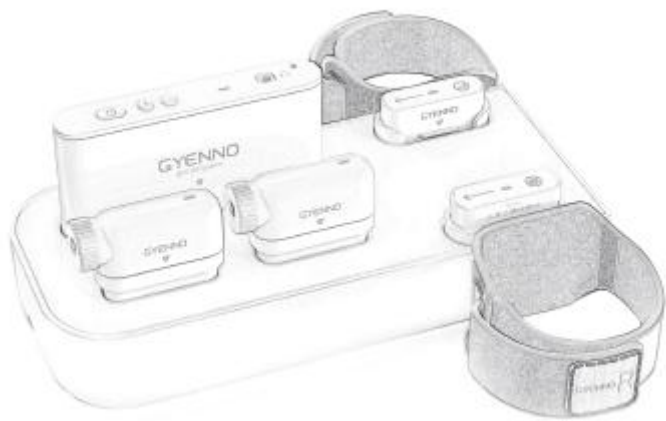


Image 1 Freezing of Gait Aid System

3.2 COMPOSITION

This product is mainly composed of AI center, laser, collector, earphone and application software.

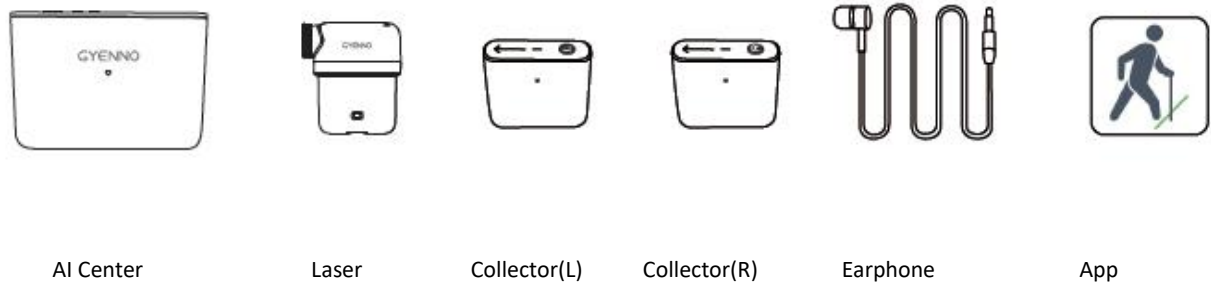


Image 2 Product Composition

The part list of this product shows as follows:

Item No.	Part Name	Part Model	Product Model GA100
			Support three wearing solutions (Waist, Cane, Vamp)
1	AI Center	PU100	1
2	Laser	L100	2
3	Collector (Left)	SM120L	1
4	Collector(Right)	SM120R	1
5	Earphone	E100	1
Accessories			
6	Waist belt	-	1
7	Cane strap	-	1
8	Ankle strap (Left)	-	1
9	Ankle strap (Right)	-	1
10	Vamp strap (Left)	-	1
11	Vamp strap (Right)	-	1
12	USB charging cable	-	1
13	Charging base	CB100	1
14	Hand Strap	-	1
Wireless Parts			
Item No.	Part Name	Part Model	FCC ID
1	AI Center	PU100	2ACGF-GA00A
2	Laser	L100	2ACGF-GA00B
3	Collector(Left,Right)	SM120L, SM120R	2ACGF-GA00C

Chart 1 Model Configuration Chart

3.2.1 AI CENTER

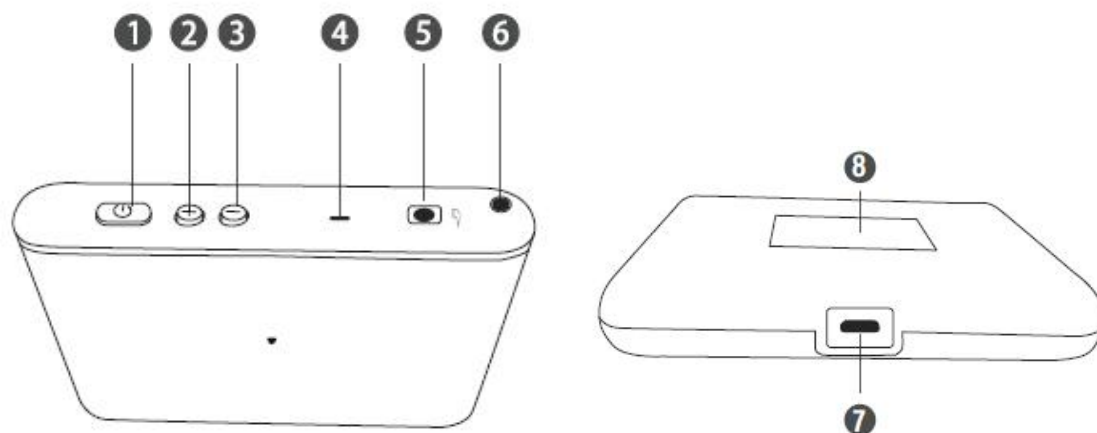


Image 3 AI Center

Name: AI Center Model: PU100

Part	Description
1	On/Off button - Click to open the AI Center when it is shut down. - Click to turn on/turn off the hint when the AI Center is turned on - When the calculation center is turned on, press and hold the AI Center for about 3 seconds to turn it off.
2	Volume button "+" - Increase the volume.
3	Volume button "-" - Decrease the volume .
4	The indicating light shows the working status of the AI center. For details, see "4.3 Indicating Light Description".
5	Earphone phone jack for inserting earphone.
6	Hand strap hole for attaching a hand strap.
7	Charging hole for plugging in the charging base.
8	The tag, which contains a QR code, can be used to perform device binding operations by scanning the QR code to the application software.

Chart 2 AI Center Description

3.2.2 LASER

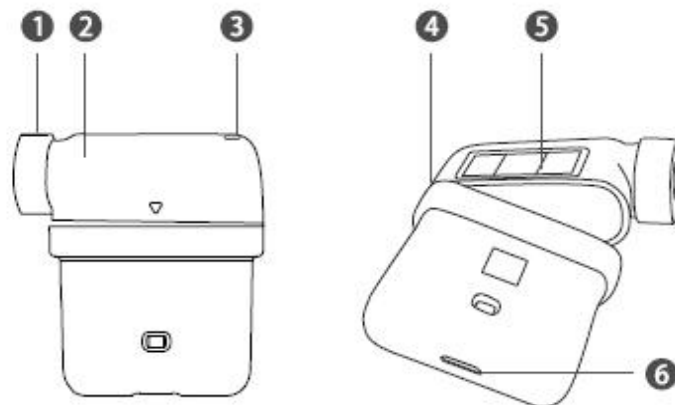


Image 4 Laser

Name: Laser Model: L100

Part	Description
1	Lens knob.
2	Laser head.
3	The indicating light shows the working status of the laser node. For details, see "4.3 Indicating Light Description".
4	The rotating shaft can be rotated to adjust the direction of the laser line.
5	Laser warning label.
6	Charging hole for plugging in the charging base.

Chart 3 Laser Description



WARNING

Class 1 laser product, Laser has radiation, avoid directing the laser beam towards the eye of any person.

3.2.3 COLLECTOR

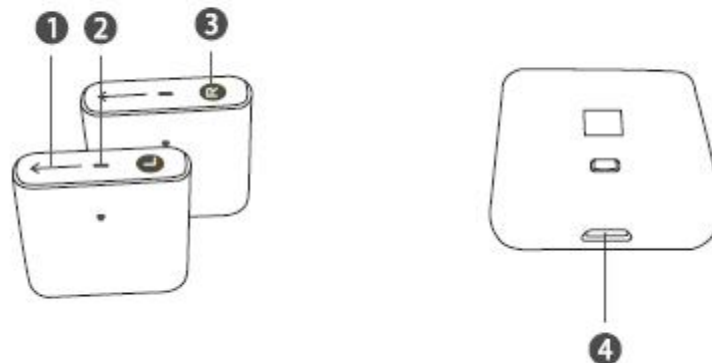


Image 5 Collector

The collector is divided into two models:

1) Name: Collector(Left) Model: SM120L:

2) Name: Collector(Right) Model: SM120R:

Part	Description
1	Indicator arrow for wearing direction
2	The indicating light shows the working status of the collector, for details, see "4.3 Indicating Light Description".
3	Wearing location identifier - "R" stands for the location on the right ankle - "L" stands for the left ankle location
4	Charging hole for plugging in the charging base.

Chart 4 Collector

3.2.4 EARPHONE

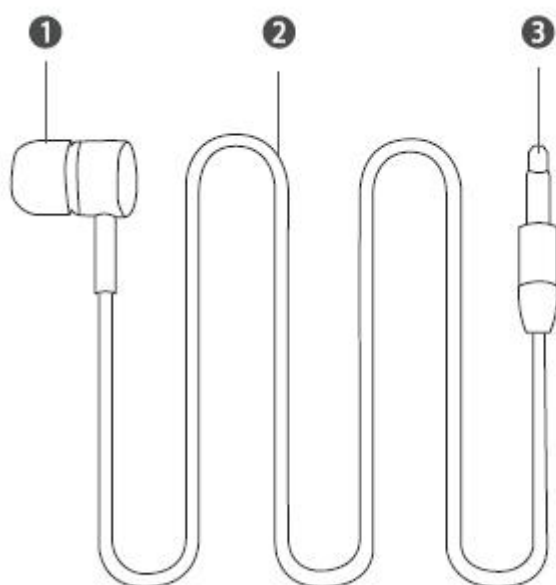
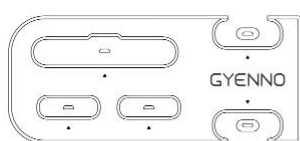


Image 6 Single hole earphone

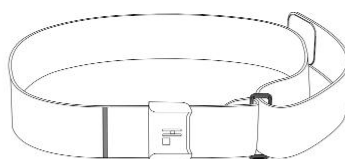
Part	Description
1	Earplug
2	Earphone cable
3	Audio plug

Chart 5 Earphone

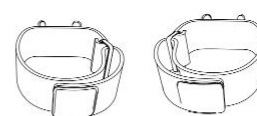
3.2.5 ACCESSORIES



Charging Base



Waist belt (M)



Ankle strap



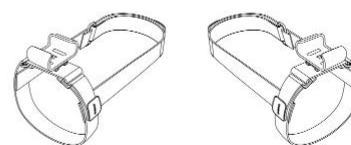
Cable



Sling



Cane strap



Vamp strap

Image 7 Accessories

3.3 WORKING CONDITIONS

Conditions	Parameters
Environment Temperature	+5 °C ~ +45 °C
Relative Humidity	10% ~ 95% (No condensation)
Atmospheric Pressure	70kPa ~ 106kPa

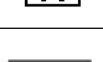
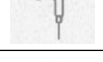
Chart 6 Working Conditions

3.4 TRANSPORTATION AND STORAGE CONDITIONS

Conditions	Parameters
Environment Temperature	-20 °C ~ +60 °C
Relative Humidity	10% ~ 95% (No condensation)
Atmospheric Pressure	70kPa ~ 106kPa

Chart 7 Transportation and Storage Conditions

3.5 SYMBOLS USED IN THIS DEVICE

	Warning
	Caution
	Attention
	Refer to user manual
	Waste Electrical and Electronic Equipment
	Type BF applied part
	DC
	Laser Warning Sign
	Single Earphone
	Increase Volume

	Decrease Volume
	Switch
	Non-ionizing radiation
	Authorized representative in the European Community
	Medical device
	Manufacturer

Chart 8 Symbols Used in This Device

4 SPECIFICATIONS AND PARAMETERS

4.1 SPECIFICATIONS

Product/Part	Main Parameter		Description
Freezing of Gait Aid System GA100	Model GA100		Main configuration: AI Center *1, laser *2, Collector*2, earphone *1; Support two kinds of node configuration A/B, three wearing solutions 1/2/3
	Identification frequency		Range 4-7Hz, Precision±1Hz
	Response time		≤3s
	Audio hint		Support
	Audio rhythm		Fast/Middle/Slow (Users can use application software to configure it)
	Laser hint		Support
	Laser lighting duration		6s/10s/15s/20s (Users can use application software to configure it)
	Running time		Longer than 8 h (100 times/day,)
	Charging time		≤4 h
AI Center PU100	Bluetooth	Wireless standard	802.11 b/g/n
		Frequency Range	2400MHz ~ 2483.5MHz
	Bluetooth h	Wireless standard	BLE/Classic BT
		Frequency	2400MHz ~ 2483.5MHz

		Range	
	Charging voltage	1200mAh	BLE/Classic BT
	Battery capacity	DC 5V	2402MHz ~ 2480MHz
	Charging time	≤4 h	
	Size	Approximately 96 (L) * 68.4 (W) * 16.5 (H) (mm)	
	Weight	88 g	
Charging Base CB100	Input	DC 5V2A	
	Size	Approximately 200.6 (L) * 88 (W) * 40.6(H) (mm)	
	Weight	Approximately 200 g	
Laser L100	Bluetooth	Wireless standard	BLE
		Frequency Range	2402MHz ~ 2480MHz
	Battery Capacity		DC 3.7V 210mAh lithium battery
	Laser	Wavelength	514nm
		Power	0.316mW
	Size		Approximately 56(L)*50.9(W)*17(H) (mm)、
	Weight		Approximately 38g
	Charging Voltage		DC 5V
	Charging Time		≤4 h
Collector SM120	Size		Approximately 38.9(L) * 37 (W) * 12.7 (H) (mm)
	Weight		Appoximately 17 g
	Battery Capacity		DC 3.7V 210mAh lithium battery
	Charging Voltage		DC 5V
	Bluetooth	Wireless Standard	BLE
		Frequency Range	2402MHz ~ 2480MHz
	Charging time		≤4 h
	Model SM120L		Collector(Left)
	Model SM120R		Collector(Right)

Chart 9 Specifications and Parameters Chart

4.2 INDICATING LIGHT DESCRIPTION

Part	Light color	Status description
AI Center	Green breathing	Standby mode
	Green	Charging completed/Normal Operation
	Blue flashes	Uploading data or upgrading device while charging
	Yellow flashes four times	WIFI network configuration failed / node configuration failed
	Yellow	Low battery status/Charging, not fully charged
	Red flashing	Hardware abnormal
Collector/ Laser	Green breathing	Standby mode
	Green	Charging completed/Normal Operation
	Yellow flashing	Node not connected / sensor is invalid
	Yellow	Low battery status/Charging, not fully charged
	Blue flashing	Upgrading
	Red flashing	Hardware abnormal
	Red	The laser temperature exceeds the safe temperature, the system does not light the laser,

Chart 10 Indicating light description

5 OPERATION DESCRIPTIONS

5.1 WEARING SOLUTIONS

This product supports three wearing solutions

- Wearing solution 1 (Laser node is worn at the waist)
- Wearing solution 2 (Laser node is worn on cane)
- Wearing solution 3 (Laser node is worn on the shoes face)



Wearing solution 1
(Laser node is worn at the waist)



Wearing solution 2
(Laser node is worn on cane)



Wearing solution 3
(Laser node is worn on the shoes face)

Image 8 Wearing Solutions

Item No.	Part Name	Part Model	Wearing Solution 1 (Waist)	Wearing Solution 2 (Cane)	Wearing Solution 3 (Vamp)
1	AI Center	PU100	1	1	1
2	Laser	L100	1	1	2
3	Collector(Left)	SM120L	1	1	×
4	Collector(Right)	SM120R	1	1	×
5	Earphone	E100	1	1	1
6	Waist Belt	-	1	×	×
7	Cane Strap	-	×	1	×
8	Ankle Strap (Left)	-	1	1	×
9	Ankle Strap (Right)	-	1	1	×
11	Vamp Strap (Left)	-	×	×	1
12	Vamp Strap	-	×	×	1

Chart 11 Wearable Parts Configuration

5.2 PREPARATION BEFORE INITIAL USE

Before using for the first time, please follow the steps below to prepare:

1. Choose your wearing solution
2. Download and install the application software
3. Registration and Sign in
4. Device binding
5. Device networking
6. Mode configuration
7. Use the product

5.2.1 DOWNLOAD AND INSTALL THE APPLICATION SOFTWARE

The product must be used in conjunction with the mobile application software "SKYWALK". Please obtain

and download from the following channels:

Cybersecurity

“SKYWALK” APP needs to use user name and password for user authentication, and can log in and view data only after passing the authentication; If verification failed, use will be unable to log in and system will give a prompt.

- iOS device: Please search for “SKYWALK” in the App Store and download and install it.
- Android device: Please search for “SKYWALK” in all major Android application markets, download and install it.



- You can also go to <http://www.gyenno.com/> to download the application.
- Operating Environment

Hardware Configuration: RAM≥1 GB

ROM≥8 GB

Screen ≥ 4.7 inches

Software Environment: Android 5.0 or above

iOS 8.0 or above

Network Conditions: Bluetooth, WiFi and Network



ATTENTION

1. The device does not support PC.
 2. The default standard font is recommended to be used on the mobile phone where application software is going to be installed to avoid incomplete screen content
-

5.2.2 USER REGISTRATION AND LOGIN

Before using for the first time, please follow the user guide of the APP to complete user registration and login.

5.2.3 DEVICE BINDING

After the user log in, please follow the user guide of the APP to complete the device binding operation.



ATTENTION

1. When you bind the device, you need to use the mobile phone to scan the QR code on the label at the back of the AI center.
 2. If the bound AI center needs to be replaced, you must unbind it in the APP and then re-bind the device.
-

5.2.4 NETWORK CONNECTION

Please follow the steps below to complete the WiFi network connection.

1. Plug the AI center into the charging base or charge it with the charging cable.
 2. Make sure that your mobile phone's Bluetooth is turned on.
 3. Ensure that the AI center is in a WiFi environment, open "SKYWALK" APP and follow the instruction of "Network connection" to complete the connection.
 4. If the connection is successful, "Connection successful" will pop-up on "SKYWALK" APP.
 5. If the connection fails, "Connection failed" will pop-up on "SKYWALK" APP, please follow the guide on APP to reconnect.
-



ATTENTION

1. The device must be bound with your phone before configuring the WiFi connection.
 2. AI Center should be in normal charging status while configuring the WiFi connection.
 3. The WiFi network connection should be reconfigured if the wireless environment changes.
 4. The device only supports 2.4G WiFi connection.
-

5.2.5 MODE CONFIGURATION

Before using the device, you must configure the nodes and AI center in advance. The product supports three configuration modes:

	AI center	Laser nodes	Collector nodes
Waist/Cane Mode Configuration	1	1	2
Shoe Mode Configuration	1	2	0

* If the wearing mode is switched, the mode configuration must be changed.

Waist/Cane mode network status :



Shoe mode network status:



Please follow the steps below to complete the configuration of the AI center and each node of the device:

1. Specify the corresponding mode configuration according to the way you want to wear the device.
2. Plug the corresponding nodes and AI center into the charging base.
3. Make sure that mobile phone's bluetooth is on.
4. Open "SKYWALK" in your mobile phone and follow the "Mode Configuration" guide to complete the node configuration.
5. If the mode configuration is successful, "Configuration Successful" will pop-up on "SKYWALK" APP.
6. If the mode configuration fails, "Configuration failed" will pop-up on "SKYWALK" APP. Please follow the APP guide to reconfigure.



ATTENTION

1. When configuring the mode, you must ensure that the AI center and nodes are in normal charging state.
2. If you need to replace the configured AI compute center or node, the mode configuration must be reconfigured.
3. If you need to switch other node configuration, the node configuration must be reconfigured.
4. Charge the nodes according to the number of nodes in wearing solution during mode configuration. Do not charge the nodes which are not going to be configured simultaneously .

5.2.6 HINT MODE SETTING

- The device has two hint modes:
 - 1) Laser hint: laser line is projected in front of the user's walking, guiding the user to walk normally by vision.
 - 2) Audio hint: beat rhythm is played in the earphone, and user is encouraged to walk normally by audio.
- Users can set the hint mode in the APP.
 - 1) Only laser hint is turned on.
 - 2) Only audio hint is turned on.
 - 3) Laser hint and audio hint are simultaneously turned on.
- User can set the parameters in the APP:
 - 1) The duration of laser and audio hint after each trigger;
 - 2) Beat rhythm of the audio hint: fast/medium/slow.



Warning

1. Do not use binaural earphones when using audio hint.
-

5.3 HOW TO USE

5.3.1 WEARING THE DEVICE

Users need to select a wearing mode, take out the corresponding parts according to the selected wearing mode and wear the device according to the following steps of the chosen wearing mode:

1. WEARING MODE 1(WAIST)



Wearing mode 1

Wear the laser node on the waist

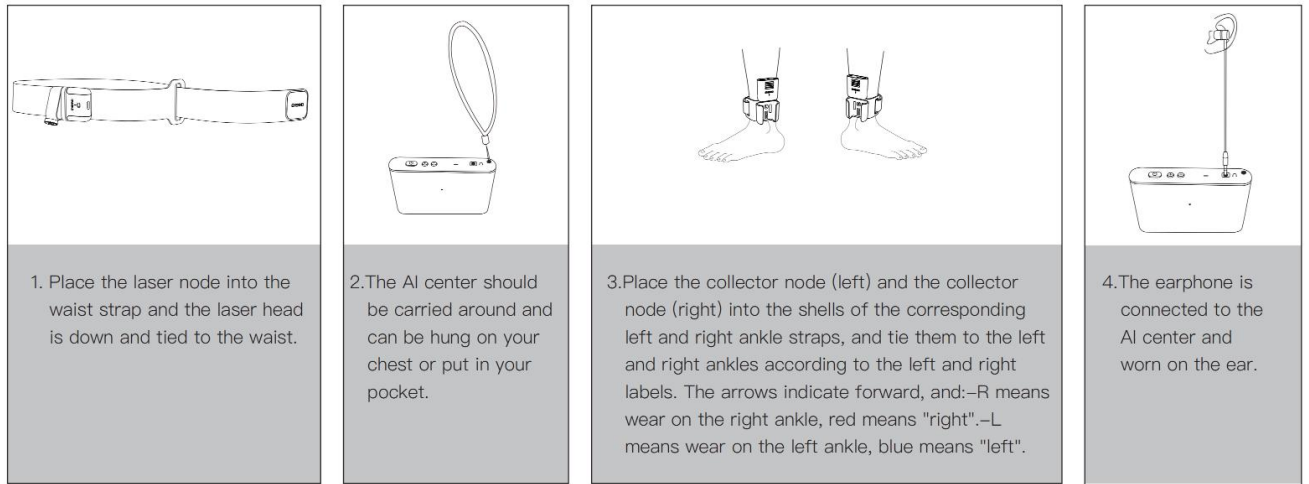


Image 9 Wearing mode 1

2. WEARING MODE 2(CANE)



Wearing mode 2 (cane)

Wear the laser node on the cane

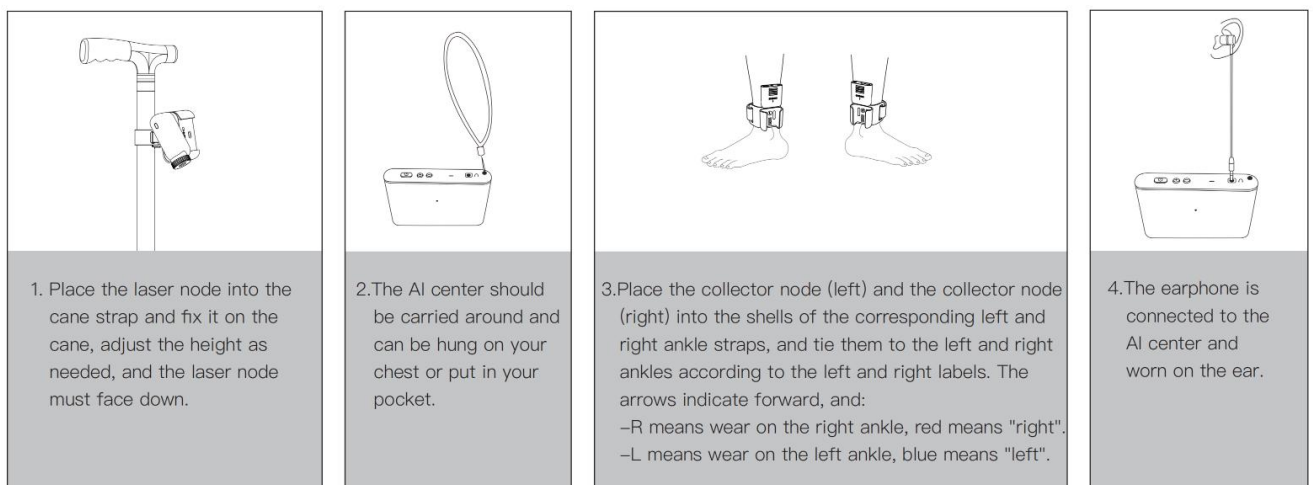


Image 10 Wearing mode 2

3. WEARING MODE 3(SHOE)



Wearing mode 3 (shoes)

Wear the laser node on the shoes

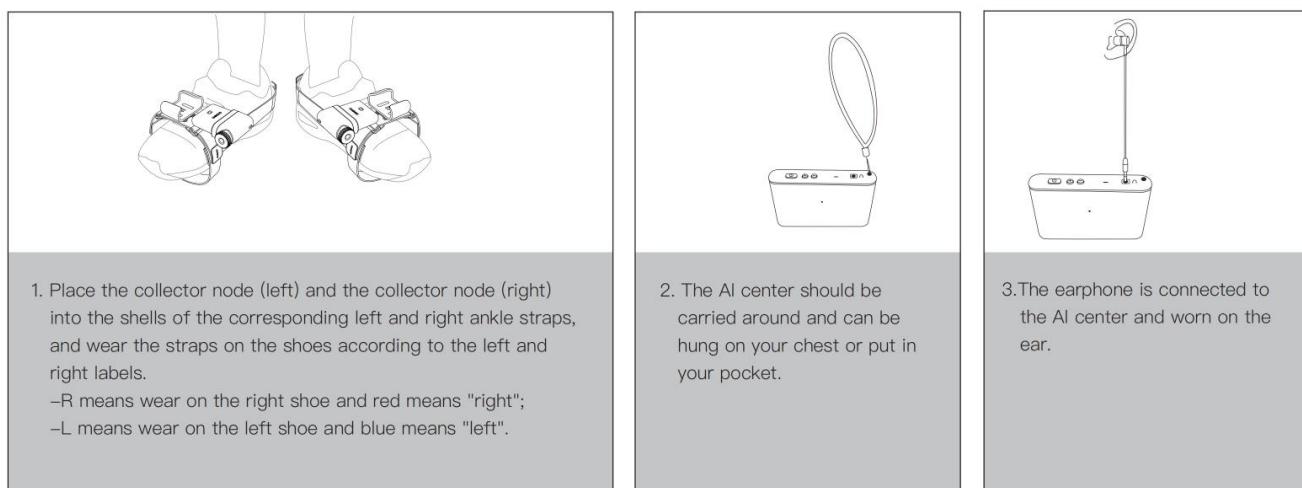


Image 23 Wearing mode 2



ATTENTION

1. The left and right ankle straps is different from each other, please distinguish them before use;
2. The laser head of laser node must face down;
3. Ensure that the AI center is within 3 meters from the collector node and the laser node;
4. The AI center should be carried around and can be hung on your chest or put in your pocket.

5.3.2 POWER ON AND OFF

When the wearing is completed, press the power button of the AI center to turn on the device. If the indicating light of AI center is green, you can start using the product; if the indicating light of AI center is yellow, check if the battery is low. Press and hold the switch button for about 5 seconds to turn off the AI center.



Image 24 turn on/off



ATTENTION

After the AI center is not in use for 5 minutes, the indicating light goes out and the device automatically turns off.

5.3.3 FROZEN GAIT RECOGNITION AND HINT

● AUTOMATIC RECOGNITION AND HINT

After the device is turned on normally, it can be used while walking.

1. Real-time detection and automatic analysis to recognize user's walking gait;
2. When the frozen gait occurs, laser hint, audio hint or both hints will be triggered according to the system setting;
3. The device will not give any hint if user is walking normally and no frozen gait occurs.
4. The duration of each hint is based on the system setting.

● MANUAL HINT

At normal operation status, short press AI center's power button to trigger manual hint. Laser hint, audio hint, or both hints will be triggered according to the system setting, the default hint duration is 30s. Short press AI center's power button to turn off manual hint.

LASER LINE ADJUSTMENT

The most suitable position of laser line to project on the ground is 20 to 50 cm in front of the user's foot;

the correct direction of the laser line is parallel to the toe. If not, adjust the laser node axis and lens knob:

1) Distance adjustment

Rotate the angle of the laser node' axis to control the projection position of the laser line, the distance between the laser line and the user should be controlled at 20~50cm, as shown in Image 25:

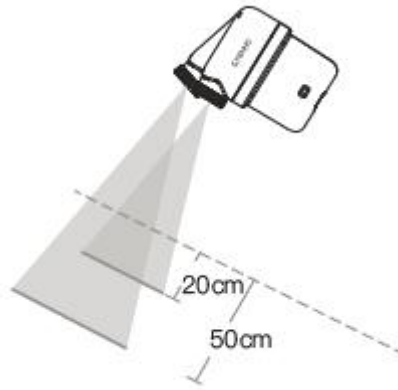


Image 25 Laser node

2) Direction adjustment

Rotate the lens knob to control the direction of the laser line projected on the ground so that the laser line is parallel to your toe, as shown in Image 26:



Image 26 Laser node

● WARNINGS OF LASER HINT



1. The laser cannot be projected directly into eyes, laser projected onto a person should be avoided.
 2. Users should not only attention the laser line, but must also pay attention to the surrounding environment while walking.
-

- WARNINGS OF AUDIO INTERFERENCE

Earphone can be used by directly plugging into the AI center.



Warning

1. Do not use binaural earphone.
 2. Users should not only attention the audio rhythm, but also pay attention to the surrounding environment.
-

5.3.4 DATA COLLECTION

The device automatically records the user's gait data while using, and the gait data is automatically stored in the AI center.

5.3.5 DATA TRANSFERRING

All data stored in the device will be transferred while charging.

1. Please charge the AI center before transferrring data.
2. The AI center will automatically access the network through WiFi and upload data to the cloud while charging.
3. Data transfer will start once a wireless connection is successfully set up. When transferring data, the indicating light of AI center indicator will flash in blue and when the process is completed, the indicating light stays in yellow(charging) or green(charged).

5.3.6 VIEW RESULTS

Open the APP, select “Data”, and view the frozen gait data in the interface, including the statistics of the daily activity duration, the number of frozen gait occurrences, the start and end time of the frozen gait, the average duration of the frozen gait, and the duration distribution of the frozen gait.



Caution

If no measurement results are shown, it may be caused by the following reasons:

1. None or incomplete data transfer due to WiFi connection problems or others.
 2. The measurement is terminated. The measurement time is insufficient or it's not an actual measurement.
-

5.4 AFTER USING

5.4.1 END OF USE

Please power off, take off straps from your body and remove AI center and each node from the straps. It is suggested that the device should be cleaned each time after using.

5.4.2 CHARGING

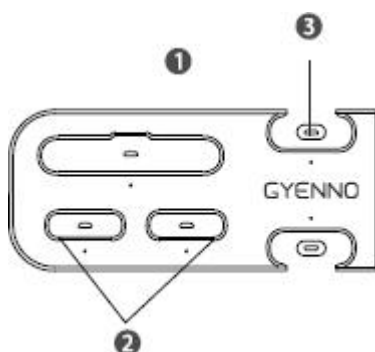


Image 27 Charging base

Name: Charging base, Model: CB100

Serial	Description
1	AI center charging port
2	Laser node charging port
3	Collector node charging port
4	Charging hole for connecting the charging cable.

Chart 3 Charging base description

When the battery of AI center or node is low, the indicating light stays in yellow which means it needs to be charged as soon as possible.

Place the AI center and nodes individually or completely in the corresponding charging port of the

charging base and connect to the external power supply of DC 5V/2A. The indicating light stays in yellow while charging and it turns to green when charged.

6 CLEANING AND DISINFECTION

- The plastic shell parts of AI center, charging base, cane and nodes can be washed with a cotton swab, neutral detergent and clean water. Do not use sharp tools such as toothpicks, tweezers, and knives for cleaning. Dry it with a clean, soft cotton swab. Do not use corrosive solutions to wipe or clean.
- The fabric, PU leather and buckle parts of the strap can be washed with a brush, detergent and clean water. The metal part of the strap should never be submerged in water to avoid corrosion, it can be wiped and cleaned with antibacterial tissue or cotton cloth soaked with alcohol.
- Remove the hand strap and wash it with a mild detergent, then rinse it off.

7 MAINTENANCE

- The device consists of sophisticated mechanical parts. Performance and service life of this device may be significantly reduced if under long-term magnetic interference.
- Power off the device after using.
- Any part of the device is not waterproof, do not splash water on it or submerge it into water washed or drenched.
- Do not place or store the device near fire or heat articles.
- The device should be cleaned in time after use.
- Please avoid dropping or impacting the device at any time.
- Do not forcefully pull, press or twist the unit or components.
- The device should be charged in time. It should be fully charged and stored when it's not in use for a long time. It should be charged every one to two months and stored in a cool or dry environment in order to avoid moisture and exposure.

8 TROUBLESHOOTING

PROBLEMS	Possible Causes and Troubleshooting
Unable to bind with APP	1. The network signal is weak. Please move to a place where the signal is strong and try again.

	2. The device is already bound by another user. Please call the customer service hotline. 3. The QR code is missing or damaged and cannot be scanned. Please call the customer service hotline.
Unable to connect network	1. Enter the wrong wireless network password. Please enter the correct wireless network password and try again. 2. The device exits the connecting state due to timeout. Please try again according to the "Network connection" section. 3. The wireless network signal is weak. Please move to a location where the signal is stronger and try again.
Unable to intervene when a frozen gait occurs	1. The device is not used as required. Please check if the product is properly worn. 2. The connection signal between AI center and nodes is weak. Observe the status of the node indicator and check if it is under normal operation status of green. If not, please re-network according to the "Mode Configuration" section
Unable to transmit data	1. The device is not bound to the APP. Please try again according to the "Device Binding" section. 2. The wireless network signal is weak. Please move to a place where the signal is stronger and try again.
Unable to charge	1. Not charging properly Check if the charging cable or charging base is properly connected. 2. Battery or charging component failure Please contact the manufacturer.
Others	Please stop using the device and contact GYENNO Service.

Chart 10 Troubleshooting

9 PRECAUTIONS

- It is suggested to proactively adjust wearing modes and try visual or auditory hints to find the best way to wear and intervene at the beginning of adopting the equipment.
- Make sure that the device is fully charged before use. When the battery is low, stop using the device and charge it as soon as possible.
- Please follow the instruction to use the device.
- Do not wash the straps by any washing machine, it can only be washed by hand.
- Do not remove the QR code on the product.

10 CONTRAINDICATIONS

- Do not use the device for patients with implanted metal such as pacemakers, nerve stimulators and artificial metal heart valves.
- Users who have other metal implants should follow doctor's advice.

11 EMC INFORMATION

Guidance and manufacture's declaration – electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that they are used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic device. The device is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emission CISPR 11	Class B	
Harmonic emissions IEC/EN 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	N/A	
NOTE The EMISSIONS characteristics of the device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) the device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.		

Guidance and manufacture's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that they are used in such an environment.

Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines	N/A	N/A
Surge IEC/EN 61000-4-5	±1 kV for line to line ±2 kV for line to ground	N/A	N/A
Power frequency (50/60Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5 % U_T (>95% dip in U_T) for 5 s	N/A	N/A

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacture's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that they are used in such an environment.

Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC/EN 61000-4-6	$3 V_{rms}$ 150 kHz to 80 MHz $6 V_{rms}$ in ISM bands between 0,15 MHz and 80 MHz	N/A	Portable and mobile RF communications device should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150KHz to 80MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d=6$ /E at RF wireless communications device bands (Portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer).
Radiated RF IEC/EN 61000-4-3	$3 V/m$ 80 MHz to 2.7 GHz See table 1	$3 V/m$ 80 MHz to 2.7 GHz Comply with table 1	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of device marked with the following symbol: 

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

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

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which **the 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**.
- b. Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3V/m.
- c. 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 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.

Test specifications for enclosure port immunity to RF wireless communications device						
Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	Test frequency (MHz)
385	380-390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM ^{c)} $\pm$ 5 kHz deviation	2	0,3	28
710	704-787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0,3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0,3	28

5240	5100-5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9
5500						
5785						
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.						
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.						
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

Chart 13 EMC Compliance Statement B

Recommended Separation Distances Between Portable and Mobile RF Communications Device and This Device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications device (transmitters) and the device as recommended below, according to the maximum output power of the communications device.			
Rated Maximum Output Power of Transmitter (W)	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
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 transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Chart 14 Recommended Separation Distance of Electromagnetic Interference

12 REGULATORY INFORMATION

FCC Caution:

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

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.

FCC RF Radiation Exposure Statement (Model: SM120L& L100) :

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

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

FCC RF Radiation Exposure Statement (Model: PU100) :

This radio is designed for and classified as "General population/uncontrolled Use", the guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons regardless of age or health.

Body and limbs operation; this device was tested for typical body and limbs operations kept 0mm for body worn. To maintain compliance with RF exposure requirements, use accessories that maintain a 0mm for body worn.

13 LIMITED WARRANTY

All center and all nodes of the device is warranted to be free from defects within 12 months starting from the date of purchase.

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.

14 DISPOSAL

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.

15 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.