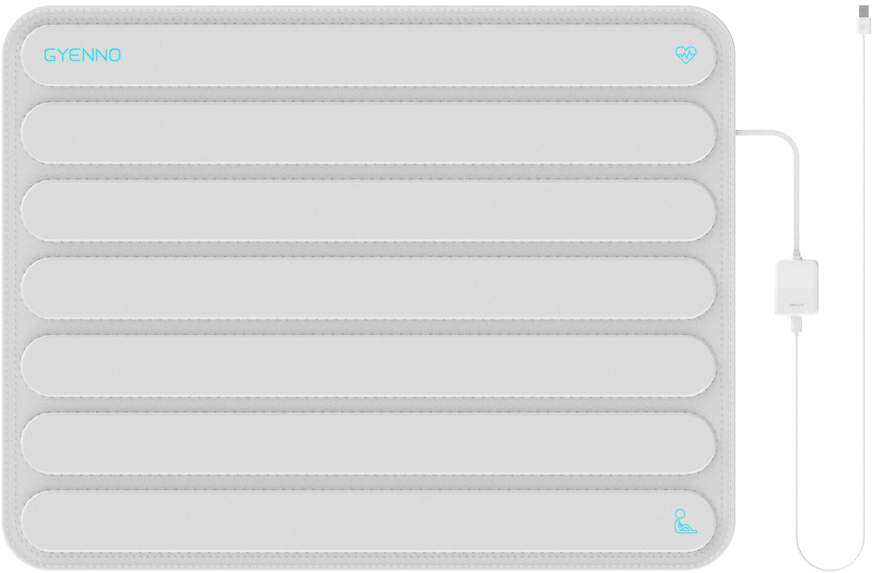
User Manuals

Parkinson's Disease Sleep Assessment System



MS100-IFU-EN
V1.1

Revision History

Version number	Reason for revision and content	Date of revision	Revisionist
V1.0	New Release	2022-03-01	Xiaoyun Liu
V1.1	Added FCC ID content	2022-04-20	Xiaoyun Liu

Manufacturer: GYENNO Technologies CO., LTD.
Address: A805 A806,Shenzhen Institute of Industry-University-Research of HUST,No.9 Yuexing 3rd Road,Science Park,Nanshan District,Shenzhen,518000,P.R.China
Tel.: 0086-755-86724035
Email: service@gyenno.com
Website: www.gyenno.com

CE

MD

EC REP MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany

Catalog

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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

Parkinson's Disease Sleep Assessment System (hereinafter referred to as "the device") is used to quantitatively analyze and assess sleep quality, nocturnal symptoms and early morning motor symptoms, mainly for patients with Parkinson's disease.For Parkinson's disease patients.

2 Security Information

Warning

1 Do not place or store this equipment near an open flame or heat source.
2 Do not use broken power cords or outlets.
3 Patients with pacemakers or other electrical stimulation devices should not use this device.
4 Do not plug or unplug the power cord with wet hands.
5 Do not use the measurement results of this device as a basis for diagnosis.

Caution

1 This equipment must not be immersed in liquid outside the B side.
2 If you accidentally fall into the liquid (such as bedwetting and other situations) when using this equipment, please immediately unplug the power cord and promptly clean up the A-side.
3 The A-side of this equipment can be washed using a washing machine without high-temperature cooking.
4 Do not use this device in a strong magnetic field environment.

5 Do not exceed the maximum load of this equipment.

6 Do not disassemble or modify this equipment by yourself.

3 Overview

3.1 Introduction

The device collects the sleep data of Parkinson's disease patients through the built-in sensor module and uploads the data through the wireless communication module. After further analysis and processing, the measurement results of sleep quality, nocturnal movement symptoms and early morning movement symptoms can be obtained.

Figure 1 HYPNOS

3.2 Composition

This device consists of side A, side B, data box and 5V3A adapter.

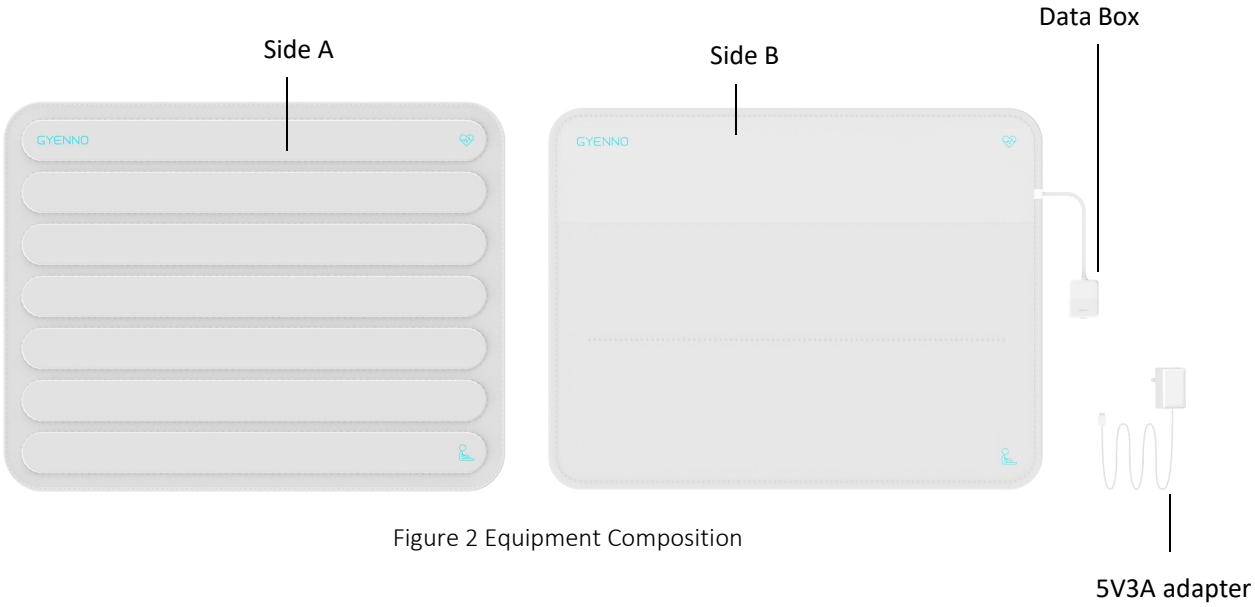

Figure 2 Equipment Composition

3.2.1 Equipment front

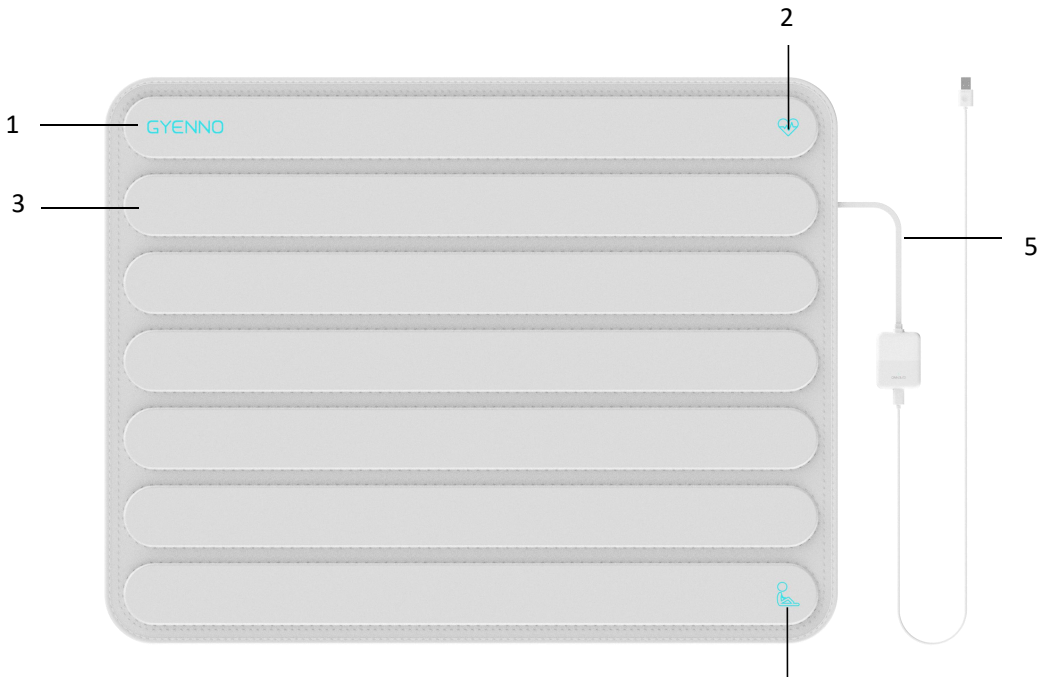

Figure 3 Front of the device

Part	Description
1	A side screen printing "GYENNO"
2	A side screen printing ♡
3	Built-in memory foam on A side
4	A-side silkscreened sit down icon
5	B-side data cable and data box connection

Table 1 Equipment front

3.2.2 Data Box Description

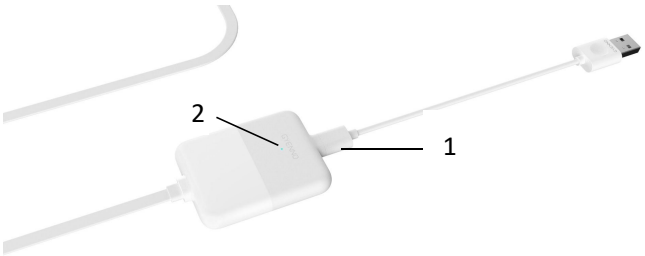

Figure 4 Data Box

Part	Description
1	5V3A adapter
2	Equipment Indicator

Table 2 Data Box Description

3.3 Working conditions

Conditions	Parameters
Ambient temperature	5 ℃ ~ +40 ℃
Relative Humidity	10% ~ 85% RH (no condensation)
Atmospheric pressure	70 kPa ~ 106 kPa
Supply Voltage	Internal power supply 3.7 V⎓ 900 mAh External power supply 5V ⎓3A

Table3 Working conditions

3.4 Storage conditions

Conditions	Parameters
Ambient temperature	-20 ℃ ~ +50 ℃
Relative Humidity	10% ~ 93% RH (no condensation)
Atmospheric pressure	70 kPa ~ 106 kPa

Table 4 Storage conditions

3.5 Symbols used in this equipment

These symbols will be indicated in this operation manual where necessary to warn of potential hazards.

	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

MD	Medical device
	Manufacturer

Table 5 Symbols used in this equipment

4 Specifications and parameters

4.1 Terminology

Sleep efficiency: refers to the efficiency of the patient's sleep detected by this device.

Total sleep time: The total time the patient sleeps as detected by this device.

Sleep latency: refers to the sleep latency of the patient detected by this device.

Number of night-time wake-ups: The number of night-time wake-ups of the patient detected by the device.

Sleep time point: The time point at which the patient falls asleep as detected by the device.

Wake up time point: The time point at which the patient wakes up as detected by this device.

Wake up time: The time consumed by the patient from waking up to waking up as detected by this device.

Number of wake up attempts: The number of wake up attempts detected by this device for the patient.

Concomitant tremor: This refers to whether tremor occurs from the time the patient wakes up to the time they get up as detected by the device.

5.2 Specification

Figure 5 Dimensional schematic

Main parameters		Indicators
Overall size		870 mm(L) * 670 mm(W) * 8 mm(D)
Overall weight		≈500 g
Charging form		DC input
Maximum load capacity		200kg
Wireless	Wireless Standards	802.11 b/g/n
	Frequency range	2400 MHz ~ 2483.5 MHz
	Antenna Type	Built-in antenna

Table 6 Specification parameters

4.2 Indicator light description

Indicator color	Status Description
Yellow is always on	Not connected
Always blue	Networked, no one on the mat
Blue Breath	Networked, someone on the mat
Red flashing	Equipment abnormalities
Indicator light is off	Shutdown

Table 7 Indicator light description

5 Instructions for use

5.1 Prepare for first time use

This device needs to be used with the device mobile application - HYPNOS APP, Please download the "HYPNOS" APP from the following channels and install it, after completing the installation, according to the "HYPNOS" APP user guide to complete the registration.

This device needs to be used with the device mobile application – “HYPNOS”APP. Please search for “HYPNOS” in the appropriate mobile application store, download and install it. after completing the installation, according to the "HYPNOS" APP user guide to complete the registration.

Before using this device for the first time, you need to complete the binding and network configuration with "HYPNOS" APP, please follow the user guide of mobile application "HYPNOS" APP to complete.

Cybersecurity

“HYPNOS” app software needs to use user name and password for user authentication, and can log in and view data only after passing the authentication; Verification failed, unable to log in and give a prompt.

Ruihang app software needs to use user name and password for user authentication, and can log in and view data only after passing the authentication; Verification failed, unable to log in and give a prompt.

5.2 When using

5.2.1 Mounting accessories

Tear the A-side and B-side Velcro, as shown in the figure below.

The direction of the B-side data line out can be selected according to the left and right of the sleeping position.

Gyenno and ♡alignment of side A and side B, fitting side A and side B

Figure 6 Equipment assembly

5.2.2 Placement of cushion bed

As shown in the picture below, please place the assembled device, under the sheet, with the top of the device flush with the shoulder.

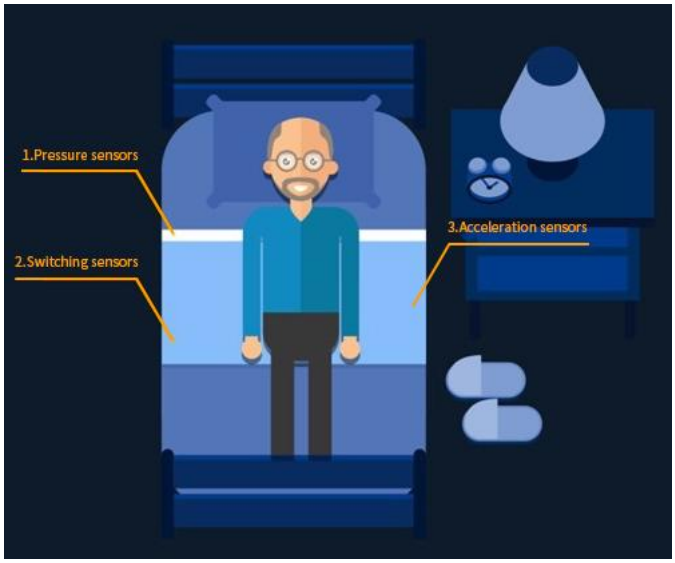

Figure 7 Equipment placement position

5.2.3 Open and Close

Turn on: Insert the adapter into the data box, then connect the power supply and the device indicator lights up.

Turn off: Disconnect the adapter from the power supply and the device indicator goes off.

Attention

1 Adapter requirement: 5V⎓3A.

2 Discarded equipment and power cords must be disposed of in accordance with local regulations or they may cause contamination.

5.2.4 Equipment Monitoring

This device is turned on and the person lies down on the device to automatically start the detection.

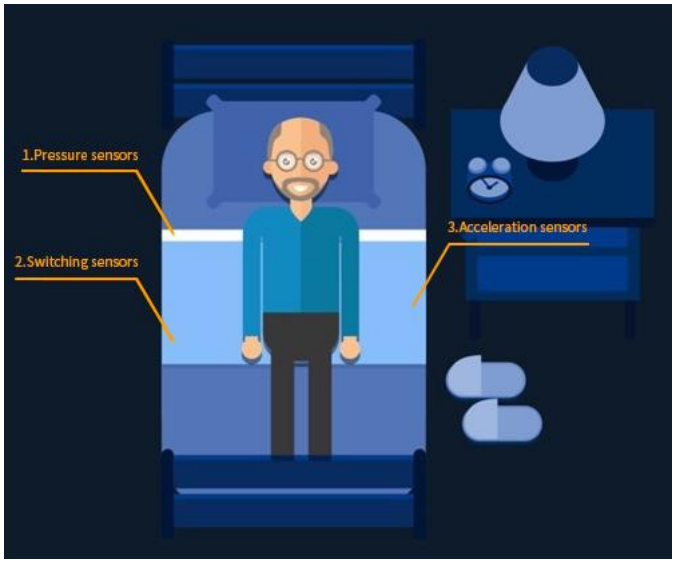

Figure 8 Equipment Inspection

5.2.5 Transferring data

The data recorded by the device is saved in the device and uploaded in bulk with the wireless network configured.

1) Turn the unit on before preparing to transfer data.

2) Wait for the network connection to be ready, the indicator light indicates blue and the waiting time is about 5minutes.

Figure 9 Device connected to wireless network

5.2.6 View Results

The measurement results of this device can be viewed in the mobile application "HYPNOS" APP→ "Data", including the data of sleep quality, nighttime symptoms, early morning movement symptoms, etc. by date.


Caution

If the corresponding measurement results cannot be viewed, it may be due to the following reasons.

1 After the measurement cycle is completed, no data is uploaded or the uploaded data is incomplete due to lack of wireless network connection or other reasons.

2 Leave the equipment while monitoring.

5.2.7 Cleaning equipment

Please take the A side pad to wash separately, you can use the washing machine to wash.

Side B is not washable, but can be wiped with a cloth dampened with water.

6 Maintenance and Care

- The B side of the equipment should not be immersed in water, please wipe it with a cloth with water.
- Turn off the equipment before disassembling it.
- Do not place or store this equipment near an open flame or heat source.
- This equipment contains motors and precision devices, long-term magnetic field interference will reduce product performance and affect service life.
- Avoid dropping or impacting this equipment during use or storage.
- Do not fold the device or use sharp objects to press the device.
- This device is used for sleep detection and early morning motion detection, both in bed.

7 Troubleshooting

Fault Type	Possible causes and treatment methods
Failed to bind the mobile application	1 Insufficient signal strength of cellular or wireless networks for mobile terminals Please move to a location with a stronger signal and try again. 2 The device has been tied by another user Please call customer service for a solution.

Fault Type	Possible causes and treatment methods
	3 The QR code is lost or broken and cannot be scanned Please call customer service for a solution.
Failed to connect to wireless network	1 Enter the wrong wireless network password Please enter the correct wireless network password and try again. 2 Device exits fast connection due to timeout Please try again following the section "Connecting to the wireless network". 3 Insufficient signal strength of wireless network Please move to a location with a stronger signal and try again.
Failure to transfer data	1 The device is not bound to the mobile program Please try again according to the section "Binding the mobile application". 2 Insufficient signal strength of wireless network Please move to a location with a stronger signal and try again.
Device indicator flashes red	Please call customer service for a solution.
Other faults	Please call customer service for a solution.

Table 8 Fault List

8 Precautions

This device has no sleep therapy function.

9 Contraindications

Do not use this device if you are allergic to polyester and spandex.

10 EMC information

Guidelines and Manufacturer's Statement - Electromagnetic Emission		
The device is expected to be used in the following prescribed electromagnetic environment, and the purchaser or user of the device should ensure that it is used in such an environment.		
Launch test	Conformity	Electromagnetic Environment-Guide
Radio Frequency Emission GB 4824	1 group	The device uses RF energy only for its internal functions. Therefore, its RF emissions are low and the potential for interference with nearby electronic devices is minimal.
Radio Frequency Emission GB	Class B	The device suitable for use in all facilities, including domestic and residential

4824		public low-voltage supply networks connected directly to the home.
Harmonic emission GB 17625.1	Class A	
Voltage fluctuation / flicker emission GB17625.2	Conformity	

Table 9 For all equipment and systems

Guidelines and Manufacturer's Statement - Electromagnetic Immunity			
the device is expected to be used in the following specified electromagnetic environment, and the purchaser or user of the device should ensure that it is used in such electromagnetic environment.			
Immunity test	IEC 60601 test level	Conformity level	Electromagnetic Environment-Guide
Electrostatic discharge GB/T 17626.2	±6 kV contact discharge ±8 kV Air discharge	±6 kV contact discharge ±8 kV Air discharge	The floor should be wood, concrete or tile, and if the floor is covered with synthetic material, the relative humidity should be at least 30%
Electric fast transient pulse train GB/T 17626.4	±2kV to power line	±2kV to power line	Net power should be of a quality typical of use in a commercial or hospital environment
Surge GB/T 17626.5	±1 kV wire-to-wire ±2 kV line-to-ground	±1 kV wire-to-wire ±2 kV line-to-ground	Net power should have qualities typical of use in a commercial or hospital environment
Voltage transients, short interruptions and voltage variations on the power input line GB/T 17626.11	<5 % U_T, for 0.5 cycles (on U_T,>95% of the temporary drop) 40 % U_T, duration 5 cycles (on U_T, 60% of temporary drop) 70 % U_T, for 25 cycles (on U_T, 30% temporary drop) <5 % U_T, for 5s (on U_T, >95% of temporary drop)	<5 % U_T, for 0.5 cycles (on U_T, >95% of temporary drop) 40 % U_T, duration 5 cycles (on U_T, 60% temporary drop) 70 % U_T, for 25 cycles (on U_T, 30% temporary drop) <5 % U_T, for 5s (on U_T, >95% of temporary drop)	The network power supply should be of a quality typical of use in a commercial or hospital environment. Uninterruptible power supply or battery power is recommended for (equipment or system) if users of (equipment or system) require continuous operation during power interruptions
Industrial frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m	The FT magnetic field should have the FT magnetic field level characteristics 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 10 For all equipment and systems

Guidelines and Manufacturer's Statement - Electromagnetic Immunity			
The device is expected to be used in the following specified electromagnetic environment, and the purchaser or user of the device shall ensure that it is used in such electromagnetic environment.			
Immunity test	IEC 60601 test level	Conformity level	Electromagnetic Environment-Guide
Radio Frequency Conduction GB/T 17626.6	3 V(rms) 150 kHz ~ 80 MHz	3 V(rms)	Portable and mobile RF communications equipment should not be used closer to any part of the (equipment or system), including cables, than the recommended isolation distance. This distance is calculated by the formula corresponding to the transmitter frequency. Recommended isolation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz ~ 800 MHz $d = 2.3\sqrt{P}$ 800 MHz ~ 2.5 GHz where : P - the maximum rated output power of the transmitter, in watts (W), according to the transmitter manufacturer. d - The recommended isolation distance in meters (m)[b]. The field strength of the fixed RF transmitter is determined by the electromagnetic field house of Survey [a] to determine, in each frequency range[b] should be lower than the compliance level. Interference may occur in the vicinity of equipment marked with the following symbols. 
Radio Frequency Radiation GB/T 17626.3	3V/m 80 MHz ~ 2.5 GHz	3V/m	
Note 1: At 80 MHz and 800 MHz 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.			

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.

Table 11 For non-life support equipment and systems

Recommended isolation distance between portable and mobile RF communication equipment and (equipment or system)			
The device is expected to be used in an electromagnetic environment with controlled RF radiation harassment. Based on the maximum rated output power of the communication equipment, the purchaser or user of the device can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below.			
The transmitter is rated for maximum High output power W	Isolation distance corresponding to different frequencies of the transmitter m		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.38
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
Note 1: At 80 MHz and 800 MHz 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.			
For transmitter maximum output power ratings not listed in the table above, the recommended isolation distance d, in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where P is the maximum transmitter output power rating in watts (W) provided by the transmitter manufacturer. Note 1: At the 80 MHz and 800 MHz frequency points, the formula for the higher frequency 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.			

Table 12 For non-life support equipment and systems

11 Regulatory Information

FCC ID: 2ACGF-MS00A

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.

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 rential 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.

NOTE: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. such modifications could void the user’s authority to operate this equipment.

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 Industry Canada RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

(1) il ne doit pas produire de brouillage et

(2) l’ utilisateur du dispositif doit étre prêt à accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fomctionnement du dispositif.

Specific Absorption Rate (SAR) information

This Hand Tremor Data Collector meets the government's requirements for exposure to radio waves. 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.

FCC RF Radiation Exposure Statement:

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.

3.This equipment should be installed and operated with minimum distance 20cm between the radiator& your body.

12 Quality Commitment

The equipment comes with an 1annual warranty.

(hereinafter referred to as "the Company") is not responsible for direct, indirect or final damage and delays caused by.

- Equipment is disassembled or modified
- Repair or modification of equipment by persons not authorized by the Company
- Damage caused by abnormal use beyond the specified conditions of use
- Manufacturing logo replacement or removal
- Improper use of operation

13 Disposal in case of disposal

GYENNO has always been committed to caring for the global environment and reducing the environmental load, and we hope that local citizens will also do their part in environmental protection activities, especially in the disposal of waste in general.

- In order to recycle the unused packaging materials, please deliver them to the relevant local recycling companies for disposal.
- Disposal of discarded consumables or parts shall comply with the relevant laws and regulations, and please dispose of them appropriately in accordance with the relevant laws and regulations.
- When the product is disposed of, please dispose of it as electronic waste.

14 Copyright and Responsibility

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