

GYENNO

USER MANUAL

HAND TREMOR DATA COLLECTOR

Model TC200

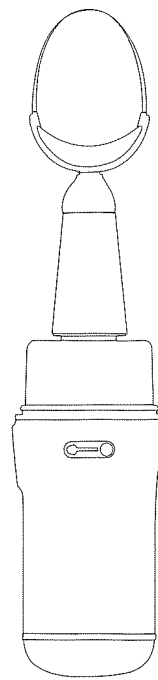


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 **WARNING:** Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

 **CAUTION:** Indicates a potentially hazardous situation which, if not avoided, may result in invalid data collecting, damage to the equipment or invalid operation.

 **NOTICE:** Information necessary to be known before using the equipment.

1 INTENDED USE

The hand tremor data collector is used to collect hand tremor data of people with Parkinson's Disease, Parkinson's Syndrome, Essential Tremor, or other physical disabilities. It can also be used as an assistive equipment to eat.

2 SAFETY INFORMATION



WARNING

1. Do not place or store the equipment near fire or heat articles.
2. Do not use a damaged charging cable or socket.
3. Do not use the equipment if a pacemaker or electrical stimulation equipment is adopted.
4. Users allergic to medical rubber are not commended to use this equipment.
5. Do not plug or unplug the charging cable when hands are wet.
6. Do not make self-diagnose based on data collected by the equipment.
7. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
8. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

2 SAFETY INFORMATION



CAUTION

1. Do not immerse the equipment except for attachments into any kind of liquid.
2. Do not use the equipment while charging.
3. In case the equipment falls into liquid while charging, unplug the cable immediately and wipe the equipment.
4. The attachments should not be disinfected with high temperature or microwaved.
5. The handle should not be washed in dishwasher, disinfected with high temperature or microwaved.
6. Do not use this equipment in a strong magnetic environment.
7. Do not exceed the maximum load of the device.
8. Do not dismount or attempt to repair the unit or components.



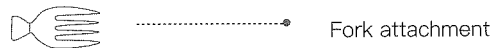
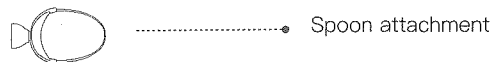
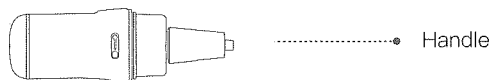
NOTICE

Clean the attachments before using the equipment.

3 KNOW YOUR UNIT

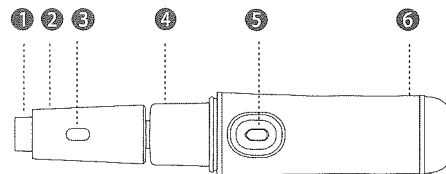
The equipment can collect tremor data of user by built-in sensors and transfer the data via WIFI. It can also detect and offset shaking of hand to help user eat smoothly.

COMPONENTS



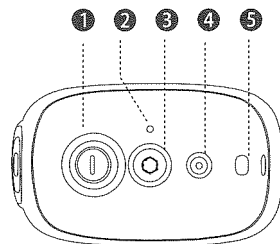
3 KNOW YOUR UNIT

HANDLE



- ① Connecting point to attachments
- ② Front part of handle
- ③ Distance sensor
- ④ Soft sleeve
- ⑤ Twist button
- ⑥ Rear part of handle

3 KNOW YOUR UNIT



① Power button

Short press: Turn on or off the equipment

Long press for 5 seconds: Enter WiFi configuration mode

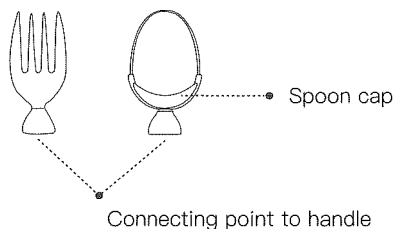
② Indicating light to identify different status

③ Fixing screw

④ Charging cable jack

⑤ Connecting dock for hand strap

ATTACHMENTS



4 SYMBOLS USED

	General warning sign
	General caution sign
	Notice sign
	Refer to user manual
	WEEE—Properly dispose of electronic waste
	Type BF applied part
	Non-ionizing radiation
	CE mark
	Universal recycling sign
IP24	IP24 degree of protection
	Direct current
	Indicates the authorized representative in the European Community
	Indicates the item is a medical device

5 SPECIFICATIONS

Total Weight:

≈ 155 g

Spoon Weight:

≈ 6.7 g

Fork Weight:

≈ 5.4 g

Measurement Range:

Frequency: 3 Hz to 12 Hz

Amplitude: 6 mm to 100 mm

Resolution:

Frequency: 0.1 Hz

Amplitude: 1 mm

Accuracy:

Frequency: ±10% of reading

Amplitude: ±1 mm or 10% of reading

Operational Conditions:

Temperature: 41 °F to 104 °F (+5 °C to +40 °C)

Humidity: 10% to 85% RH (No Condensation)

Air pressure: 700 hPa to 1060 hPa

Transportation and Storage Conditions:

Temperature: -4 °F to 140 °F (-20 °C to +60 °C)

Humidity: 10% to 93% RH (No Condensation)

Air pressure: 700 hPa to 1060 hPa

Power Source:

5 V  1 A

Working Time:

3 days(3 meals per day) or 60 measurements

(3 minutes per time)

Charging Time:

5 SPECIFICATIONS

Maximum Load:

≈ 15 g

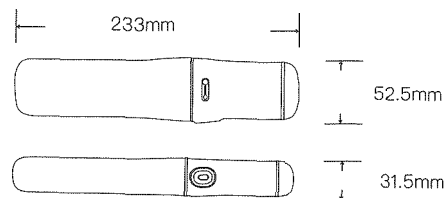
WiFi:

Protocol: 802.11 b/g/n

Frequency Range: 2400 MHz to 2483.5 MHz

Antenna Type: Built-in antenna

Dimensions:



6 INDICATING LIGHT DESCRIPTION

COLOR	STATUS
Breathing in green	Standby
Green	Fully charged
Breathing in blue	Collecting data
Flashing in blue	WiFi connected or data transferring
Breathing in red	Low battery
Red	Charging
Flashing in yellow	Under WiFi configuration
Yellow	WiFi not connected

NOTICE

- 1.If the indicating light alternates in red and yellow, the equipment is charging and not connected to WiFi.
- 2.If the indicating light alternates in green and yellow, the equipment is fully charged and not connected to WiFi.

7 DOWNLOAD MOBILE APP

Please search for “GYENNO SPOON” in the appropriate mobile application store, download and install it.



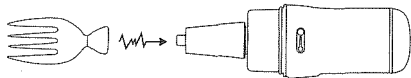
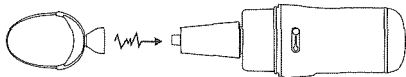
You can also visit www.gyenno.com/spoon2 for downloading the mobile application “GYENNO SPOON”.

Open the app on your smartphone and follow the WiFi configuration instructions.

8 BEFORE USING

ATTACHMENTS INSTALLATION

The attachments will adhere to the handle by magnetic force when the attachments are placed near the handle as shown below.

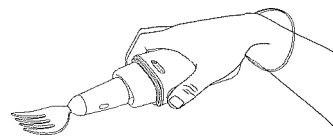


8 BEFORE USING

HOW TO HOLD THE EQUIPMENT

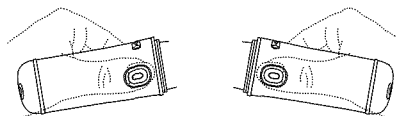
Make sure the attachment is firmly connected to the handle before using. It is recommended to hold the equipment as shown below.

For users with severe tremor or stiff, please put on the hand strap before using to avoid dropping the equipment.



CAUTION

Please always keep the twist button towards human body while using the equipment to ensure validity of data collecting and assisting to eat.



8 BEFORE USING

POWER ON AND OFF

Short press the power button to turn on or off the equipment. When the equipment is standby, the indicating light breaths in green.

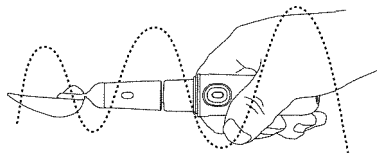


NOTICE

The equipment will automatically turn off if it had not been working for 5 minutes.

9 TAKING A MEASUREMENT

When the equipment is on and once it detects tremor, data collecting will start. The indicating light breaths in blue.



The data collecting process takes a few minutes (measurement period), when it is completed, the indicating light breaths in green. Each measurement period the equipment exports a measurement result including frequency and amplitude.



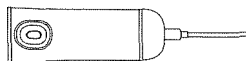
NOTICE

- 1.Reboot the equipment before taking the next measurement.
- 2.Do not power off or put down the equipment before the measurement completes.

9 TAKING A MEASUREMENT

DATA TRANSFERRING

All data stored in the equipment will be transferred while charging. To transfer data, please connect the equipment with power supply by the charging cable.



The equipment will automatically retry the saved latest wireless connection in a scanning window. If successfully connected, the indicating light flashes in blue for a while. If failed, the indicating light flashes in yellow.

If WiFi connects failed, please follow the instructions in "GYENNO SPOON" to retry.

Data transfer will start once a wireless connection is successfully set up. When transferring data, the indicating light flashes in blue and when the process is completed, the indicating light stays in red (charging) or green (charged).

9 TAKING A MEASUREMENT

VIEW THE MEASUREMENT

The measurement results, including the frequency (Hz) and amplitude (mm), can be viewed in "GYENNO SPOON".



NOTICE

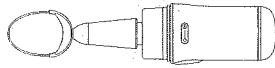
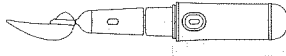
If no measurement results are shown, it may be caused by:

1. None or incomplete data transfer due to WiFi connection problems.
2. The measurement is terminated.

10 ASSIST TO EAT

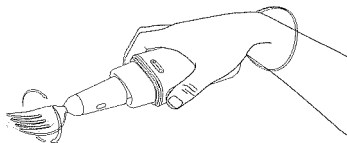
SHAKING OFFSET

Once the equipment detects tremor, the internal motors actively offset the shaking to keep stable.



TWIST FUNCTION

The equipment offers a twist function to help the user eating noodles, spaghetti, pasta, etc. Install the fork before using the twist function, press and hold the button to start twisting, loose the button after twisting the noodles, the fork will then reset to horizontal.



11 AFTER USING

ATTACHMENTS UNINSTALLATION

Please power off and uninstall the attachments after using. The handle should be placed horizontally. It is suggested that both the handle and attachments should be cleaned each time after using.

CHARGING

If the indicating light breaths in red, the equipment can still work for approximately 10 minutes. In order to protect the mechanic parts, please charge the equipment as soon as possible.

To start charging, plug in the charging cable and connect to power. Keep the equipment horizontal while charging. The indicating light stays in red while charging and it turns to green when charged.

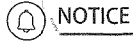


NOTICE

1. Adapter specification: 5V $\equiv$ 1A.
2. To avoid pollution, please properly dispose the equipment and charging cable according to local laws and rules related.

12 CLEANING AND DISINFECTION

ATTACHMENTS



The attachments should be cleaned before the first use.

Please uninstall the attachments from the handle before cleaning. The attachments are suggested to be washed with utensil detergent and water, they can also be cleaned in the dishwasher. Wipe the attachments with dry cloth. Do not submerge the attachments into detergent contains corrosive ingredient.

If low-level disinfection is required, use alcohol solution (ethanol (75%), isopropyl (70%), e.g.), or disinfect it with ozone, ultraviolet rays, high temperature disinfection is not permitted.

SOFT SLEEVE

To clean the soft sleeve, use a cotton swab with warm water and mild detergent, and dry it with a clean cotton swab. Never clean it with toothpicks, tweezers, or anything sharp.

If low-level disinfection is required, use a cotton swab with alcohol solution (ethanol (75%), isopropyl (70%), e.g.), and dry it with a clean cotton swab.

12 CLEANING AND DISINFECTION

HANDLE AND COVER

The handle should never be submerged in water or cleaned in the dishwasher. Wipe the handle or cover clean with antibacterial wipes or a cloth with alcohol solution (ethanol (75%), isopropyl (70%), e.g.) and dry it with a clean, soft cloth.

The cover can be cleaned with a sponge, dishwashing detergent, and clean water, and can also be cleaned in the dishwasher. After cleaning, dry it with a clean, soft cloth. Do not use corrosive solutions to wipe or clean.

HAND STRAP

Please put off the hand strap from the handle and wash it with a mild detergent, then rinse it off.

13 MAINTENANCE

- 1.The attachment should be uninstalled from the handle before cleaning. Use a small portion of utensil detergent and water to wash.
- 2.The attachment should not be submerged into detergent contains corrosive ingredient.
- 3.Any part of the handle is not waterproof, do not splash water on the handle or submerge it into water. Wipe and clean the handle with antibacterial tissue or cotton cloth soaked with alcohol.
- 4.Power off the equipment before installing or uninstalling the attachment or accessories, or after using.
- 5.Do not place or store the equipment near fire or heat articles.
- 6.This equipment consists of motors and sophisticated mechanical parts. Performance and service life of this equipment may be significantly reduced if under longterm magnetic interference.
- 7.Please avoid dropping or impacting the equipment at any time.
- 8.Do not forcefully pull, press, or rotate the unit or components. Do not press other objects with the equipment.
- 9.The equipment is only used for hand tremor data collecting and an assistive tool for eating. Do not use for other purposes.
- 10.The service life of this equipment is 3 years (3 meals per day) or 50000 measurements (3 minutes per time).

14 TROUBLESHOOTING

PROBLEMS	CAUSES AND SOLUTIONS
No data shown	The equipment is not registered in "GYENNO SPOON". Please register the equipment follow the instructions in "GYENNO SPOON". The equipment is not connected to the WiFi. Please configure the WiFi follow the instructions in "GYENNO SPOON". Insufficient time for measurement Please refer to the section "TAKING A MEASUREMENT".
The rubber sleeve breaks	Please stop using the equipment and contact GYENNO Service.
Unable to charge	
Unable to offset shaking	
Unable to twist	
Others	

15 PRECAUTIONS

1. It is suggested to use this equipment independently at the first time to avoid worse tremor caused by the anxiety and nervous since the users may have difficulties on daily eating and being taken care of.
2. It is suggested to proactively adjust holding gestures and ways of sending food to mouth at the beginning of adopting the equipment. The best way of using the equipment will come after some time.
3. A big and shallow bowl helps when using the equipment as an assistive tool to eat.
4. It may take several days for a user to use the equipment well. Please keep using for at least a week to get used to this new way of eating.
5. Do not apply any kind of forces to arm and hand using the equipment. Relax as much as possible, keep the original shaking to make sure high performance of the equipment.

16 CONTRAINDICATIONS

1. Do not use the equipment if a pacemaker or electrical stimulation equipment is adopted.
2. Users allergic to medical rubber are not commended to use this equipment.

17 EMC INFORMATION

Guidance and manufacture's declaration — electromagnetic emission

TC200 is intended for use in the electromagnetic environment specified below. The customer or the user of TC200 should assure that they are used in such an environment.

Emission test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	TC200 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.
RF emissions CISPR 11	Class B	TC200 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.
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 TC200 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) TC200 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.

17 EMC INFORMATION

Guidance and manufacture's declaration — electromagnetic immunity

TC200 is intended for use in the electromagnetic environment specified below. The customer or the user of TC200 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	When the relative humidity is approximately 5% and there are synthetic materials present, static charges approaching 15kV can be generated.
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	This test level assumes a minimum distance between TC200 and sources of power frequency magnetic field of at least 15 cm.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0 % U_n ; 0,5 cycle 0 % U_n ; 1 cycle and 40 % U_n ; 10/12 cycles 70 % U_n ; 25/30 cycles 80 % U_n ; 250/300 cycle	N/A	N/A

NOTE:

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

17 EMC INFORMATION

Guidance and manufacturer's declaration – electromagnetic immunity

TC200 is intended for use in the electromagnetic environment specified below. The customer or the user of TC200 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 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz	N/A	Portable and mobile RF communications devices should be used no closer to any part of TC200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1,2√P 150 kHz to 80 MHz d=2,0√P 150 kHz to 80 MHz d=0,35√P 80 MHz to 800 MHz d=0,70√P 800 MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of device marked with the following symbol:
Radiated RF IEC/EN 61000-4-3	10 V/m 80 MHz to 2,7 GHz See the table below	10 V/m 80 MHz to 2,7 GHz Comply with the table below	

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 TC200 is used exceeds the applicable RF compliance level above, TC200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating TC200.
b. Over the frequency range 150 kHz to 800 MHz, field strengths should be less than 3V/m.

17 EMC INFORMATION

Recommended separation distances between portable and mobile RF communications equipment and TC200

TC200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of TC200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and TC200 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	150 kHz to 80 MHz outside ISM and amateur radio bands d=1,2√P	150 kHz to 80 MHz in ISM and amateur radio bands d=2,0√P	80 MHz to 800 MHz d=0,35√P	800 MHz to 2,5 GHz d=0,70√P
0.01	N/A	N/A	0.035	0.07
0.1	N/A	N/A	0.11	0.22
1	N/A	N/A	0.35	0.70
10	N/A	N/A	1.10	2.21
100	N/A	N/A	3.5	7

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.

Test specifications for enclosure port immunity to RF WIFI communications equipment

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						

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

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

For some services, only the uplink frequencies are included.

The carrier shall be modulated using a 50 % duty cycle square wave signal.

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.

18 REGULATORY INFORMATION

FCC ID: 2ACGF-TC200

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

NOTE: This device 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 device 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 device does cause harmful interference to radio or television reception, which can be determined by turning the device 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 device and receiver.*
- Connect the device 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.*

18 REGULATORY INFORMATION

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.

18 REGULATORY INFORMATION

IC: 24095–TC200

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) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

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.

18 REGULATORY INFORMATION

FCC RF Exposure Information and Statement

The SAR limit of USA (FCC) is 1.6 W/kg averaged over one gram of tissue. Device types: DTS (FCC ID: 2ACGF-TC200) has also been tested against this SAR limit. The highest SAR value reported under this standard during product certification for use at the body is 0.307 W/kg. This device was tested for typical body-worn operations with the back of the product kept 0 cm from the body. To maintain compliance with FCC RF exposure requirements, use accessories that maintain a 0 cm separation distance between the user's body and the back of the handset. The use of belt clips, holsters and similar accessories should not contain metallic components in its assembly. The use of accessories that do not satisfy these requirements may not comply with FCC RF exposure requirements, and should be avoided.

19 LIMITED WARRANTY

The handle of the equipment is warranted to be free from defects within 12 months starting from date of purchase. The attachments and accessories (charging cable) are free from defects within 6 months starting from date of purchase.

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

- 1.Damage caused by dismounting on customer's own.
- 2.Damage caused by unspecified maintenance by manufacturer.
- 3.Damage caused by improper transportation.
- 4.Damage caused by the failure to use in normal environment or according to the user manual.
- 5.Manufacturing label being replaced or removed.

20 DISPOSAL

GYENNO has always been committed to earth care, we also encourage our users to make contribution by executing proper disposal:

- 1.Packaging materials should be handed over recycling companies for possibility of reuse.
- 2.Comply with relevant laws and regulations when disposing wasted parts and components.
- 3.The equipment should be disposed as electronic waste.

21 COPYRIGHT AND RESPONSIBILITY

- 1.The copyrights and confidentiality of this manual are owned by GYENNO.
- 2.This manual is subjected to be a reference for operating and maintaining the equipment.

22 COMPLIED STANDARDS

EN ISO 14971:2019
(ISO 14971:2019 IDT)

EN ISO 15223-1:2016
(ISO 15223-1:2016 IDT)

EN ISO 780:2015
(ISO 780:2015 IDT)

EN 1041:2008+A1:2013

EN 60601-1:2006+A11:2011+A1:2013+A12:2014
(IEC 60601-1:2005+A1:2012 IDT)

EN 60601-1-11:2015
(IEC 60601-1-11:2015 IDT)

EN 60601-1-2:2015
(IEC 60601-1-2:2014 IDT)