User Manual

Hand Tremor Data Collector



Version NO.: TC20-EN-V2.1

DEFINITIONS



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.

INTENDED USE

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

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.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could 7 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.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of 8 this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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 equipment.
- 8 Do not dismount or attempt to repair the unit or components.

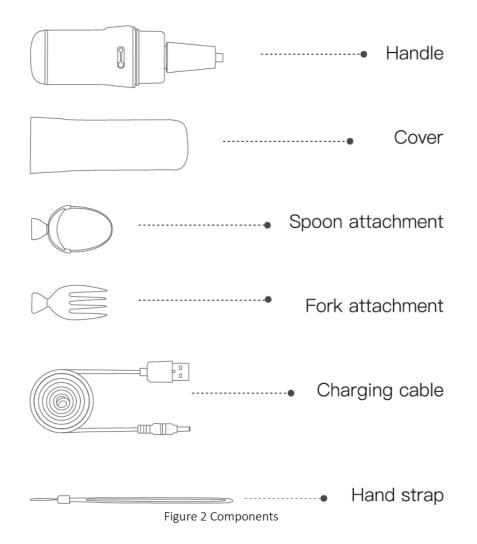
NOTICE

1 Clean the attachments before using the equipment.

KNOW YOUR UNIT

The equipment can collect tremor data of user by built-in sensors and transfer the data via WiFi. A measurement result will be obtained after further process. The equipment can also detect and offset shaking of hand to help user eat smoothly.

Components



Handle

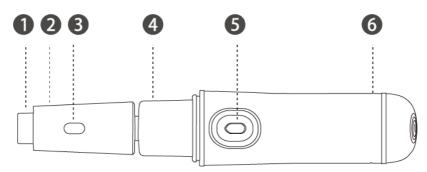


Figure 3 Handle Side View

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

Table 1 Handle Side View Description

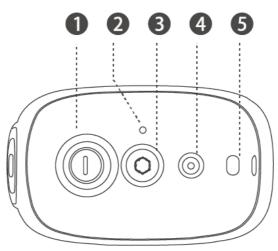
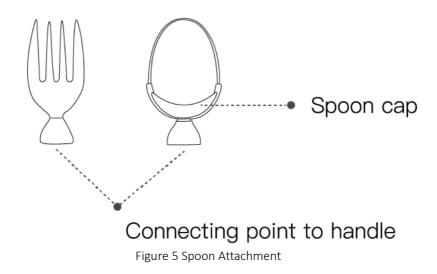


Figure 4 Handle Rear View

Item	Description
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

Table 2 Handle Rear View Description

Attachment



SYMBOLS USED

	General warning sign
	General caution sign
	Notice sign
8	Refer to user manual.
X	WEEE-Properly dispose of electronic waste
Ŕ	Type BF applied part
(((•••)))	Non-ionizing radiation
CE	CE mark
	Universal recycling sign
IP24	IP24 degree of protection
	Direct current
EC REP	Indicates the authorized representative in the European Community

Table 7 Symbols Used by this Equipment

SPECIFICATIONS

Dimensions		Approx. 233 (L) * 52.5 (W) * 31.5 (H) (mm)		
		← 233mm → ↑ 52.5mm		
		(() 31.5mm		
T	Fotal Weight	≈ 155 g		
SI	poon Weight	≈ 6.7 g		
ſ	Fork Weight	≈ 5.4 g		
Meas	surement 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		
Opera	tional Conditions	Temperature: 32 $^\circ$ F to 113 $^\circ$ F (0 $^\circ$ C to +45 $^\circ$ C) Humidity: 10% to 85% RH Air pressure: 700 hPa to 1060 hPa		
	rtation and Storage Conditions	Temperature: -13 $^\circ \!$		
Р	ower Source	5 V 1 A		
W	Vorking Time	3 days (3 meals per day or 30 records per day)		
Cl	harging Time	≤ 3hours		
М	aximum Load	≈ 15 g		
	Protocol	802.11 b/g/n		
WiFi	Frequency Range	2400 MHz to 2483.5 MHz		
	Antenna Type	Built-in antenna		

Table 8 Specifications

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	

<u>NOTICE</u>

- 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.

DOWNLOAD MOBILE APPLICATION

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



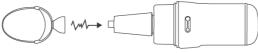
You can also visit <u>www.gyenno.com/spoon2</u> for downloading the mobile application "GYENNO SPOON".

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

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.



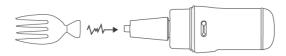


Figure 8 Install Attachment

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.

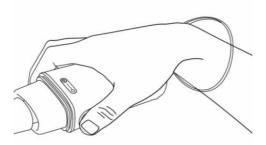
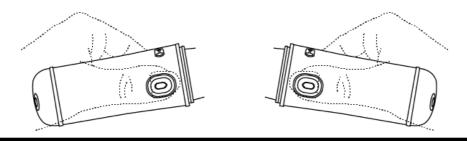


Figure 9 Holding with the Hand Strap

CAUTION

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



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.

TAKING A MEASUREMENT

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

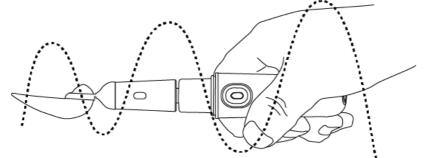


Figure 11 Taking a Measurement

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.

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.



Figure 12 Connecting Power

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 yellow (charging) or green (charged).

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.

ASSIST TO EAT

Shaking Offset

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

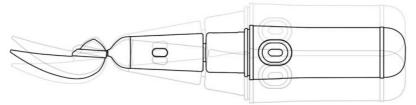


Figure 14 Vertical Shaking Offset

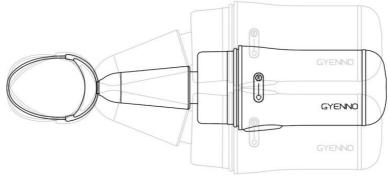


Figure 15 Horizontal Shaking Offset

Twist Function

The equipment offers a twist function to help the user eat 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.

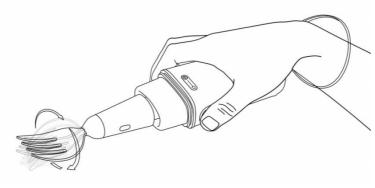


Figure 16 Twist Function

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.

0	
Figure 17 Charging	

NOTICE

- 1 Adapter specification: $5V_{--}1A_{\circ}$
- 2 To avoid pollution, please properly dispose the equipment and charging cable according to local laws and rules related.

CLEANING AND DISINFECTION

Attachments

NOT I CE

The attachments should be cleaned before the first use.

Please uninstall the attachments from the handle before cleaning. The attachments are suggested to wash 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.

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.

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 Long-term 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 30 records per day).

TROUBLESHOOTING

Problems	Causes and solutions		
	The equipment is not registered in "GYENNO SPOON". Please register the equipment follow the instructions in "GYENNO SPOON".		
No data shown	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			
Unable to charge			
Unable to offset shaking	Please stop using the equipment and contact GYENNO Service.		
Unable to twist			
Others			

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.

CONTRAINDICATIONS

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

EMC INFORMATION

Guidance and manufacture's declaration – electromagnetic emission				
TC20 is intended for use in the electromagnetic environment specified below. The customer or the user of TC20 should assure that they are used in such an environment.				
Emission test	Compliance	Electromagnetic environment – guidance		
RF emissions CISPR 11 Group 1 TC20 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 d				
RF emission CISPR 11	Class B			
Harmonic emissions IEC/EN 61000-3-2	N/A	TC20 is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that		
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	N/A	- supplies buildings used for domestic purposes.		
NOTE The EMISSIONS characteristics of TC20 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) TC20 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

TC20 is intended for use in the electromagnetic environment specified below. The customer or the user of TC20 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		N/A	N/A

Guidance and manufacture's declaration – electromagnetic immunity

TC20 is intended for use in the electromagnetic environment specified below. The customer or the user of TC20 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 devic should be used no closer to any part of TC20, 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
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	$d = 1.2\sqrt{P}$ 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 TC20, including cables specified by the manufacturer). 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 eac frequency range. ^b Interference may occur in the vicinity of device marked with the following symbol:
OTE 2 These guid	and 800 MHz, the higher frequence lelines may not apply in all situation objects and people.		ation is affected by absorption and reflection from

relocating TC20. 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.

field strength in the location in which TC20 is used exceeds the applicable RF compliance level above, TC20 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or

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 $^{\rm c)}$ ± 5 kHz deviation	2	0,3	28
710						
745	704-787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9
780						
810		GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5		2	0,3	28
870	800-960		Pulse modulation ^{b)} 18 Hz			
930						
1720						
1845	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
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						
5500	5100-5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9
5785						
IOTE 2 The	0 MHz and 800 se guidelines m ctures, objects a) MHz, the higher frequency range ay not apply in all situations. Elections and people	applies. romagnetic propagation is affec	ted by absorp	tion and refle	ction from

^{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.

Recommended separation distances between portable and mobile RF communications device and TC20

TC20 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of TC20 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications device (transmitters) and TC20 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.

REGULATORY INFORMATION

FCC ID: 2ACGF-TC20

IC: 24095-TC20

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 residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following

measures:

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

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.

RF Radiation Exposure and SAR Statements SAR Statement.

The TC20 has been tested for body-worn Specific Absorption Rate (SAR) compliance. The FCC/IC has established detailed SAR requirements and has established that these requirements. This model meets the applicable government requirements for exposure to radio frequency waves. The highest reported SAR level for usage near the body (0mm) is 0.36 W/kg

LIMITED WARRANTY

The handle of the equipment is warranted to be free from defects within 12 months starting from date of purchase. The attachments (spoon and fork) 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:

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

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 over recycling companies for possibility of re-use.
- Comply with relevant laws and regulations when disposing wasted parts and components.
- The equipment should be disposed as electronic waste.

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.

COMPLIED STANDARDS

EN ISO 14971:2012(ISO 14971:2007 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)

MANUFACTURER INFORMATION

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