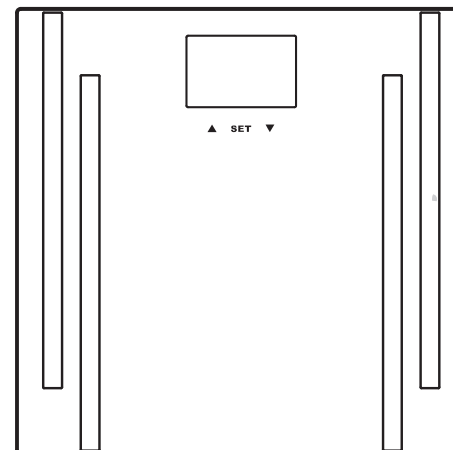


User Manual

Body Fat Analyzer

GBF-1319-B



- Thank you very much for selecting the Transtek Body Fat Analyzer GBF-1319-B.
- Please do read the user manual carefully and thoroughly so as to ensure the safe usage of this product, and keep the manual well for further reference in case you have problems.



Contains FCC ID: OJ9AW2540-LS

GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO., LTD

Zone A, 5/F., Investment Building, No. 12, Huizhan East Rd., Torch Development District, Zhongshan, Guangdong, 528437, China









TEL:86-760-88282982 www.transtek.cn

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♥ Safety and Usage Information

The warning signs and symbols are essential to ensure your correct and safe use of this product and protect you and others from injury. Please kindly find the meanings of the warning signs and symbols, which you may encounter in the label and user manual, as follows:

	Symbol for "THE OPERATION GUIDE MUST BE READ"		Symbol for "MANUFACTURER"
	The Bluetooth Combination Mark		Symbol for "COMPLIES WITH FCC RULES"
	Symbol for "TYPE BF APPLIED PARTS"		Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice"
SN	Symbol for "SERIAL NUMBER"		
	Symbol for "DIRECT CURRENT"		
	Symbol for "INDOOR USE ONLY"		

 CAUTION

Transtek's Body Fat Analyzer GBF-1319-B offers you a seamless way to manage your health. Please be aware that this device is designed for adults' self-measuring and self-monitoring body fat level. Any information provided by this device is in no way meant to treat, cure or prevent any disease or illness from happening. This device should not be used by anyone who is acutely or chronically ill, suffering from a disease or taking medications that affect your water levels. The accuracy of readings for these patients has not been verified. Specific medical advice should be obtained from a physician.

GBF-1319-B is equipped with data transmission function. It may emit electromagnetic energy so as to perform its intended function. Nearby portable and mobile RF communications equipment can affect the performance of GBF-1319-B.

Portable and mobile RF communications equipment can affect the measuring accuracy of GBF-1319-B.

Kindly note that the use of accessories, transducers or cables other than those specified, with the exception of transducers and cables sold by the manufacturer as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of GBF-1319-B.

Be aware that misuse of electrical equipments can cause electric shock, burns, fire and other hazards.

Warning that the GBF-1319-B should not be used adjacent to or stacked with other equipment.

Manufacturer will make available on request circuit diagrams, component parts list, etc.

WARNING: No modifications of this equipment is allowed.

During using the Analyzer, the patient will contact with the surface and the electrode of the Analyzer.

The device doesn't need to be calibrated in two years lifetime.

INDICATIONS FOR USE

The Transtek Body Fat Analyzer measures weight and uses bio-electrical impedance analysis (BIA) technology to estimate body fat, total body water percentage, bone mass, and muscle mass in generally healthy adults 18 years of age or older.

It is intended for use in the home / domestic setting only.

CONTRAINDICATIONS

1. This device is contraindicated for any female subject who may be suspected of, or is pregnant. Besides provided inaccurate readings, the affects of this device on the fetus are unknown.
2. This device is contraindicated for any person who is connected to a wearable or implantable electronic device or instrument such as a pacemaker or defibrillator.

♥ Your Scale and Its Environment

To ensure your safety as well as the service life of your scale, please avoid using the scale under the following circumstances:

- Concurrent use of this device and implantable medical electronic instruments, e.g. Cardiac Pacemaker
- Concurrent use of this device and wearable medical electronic instruments, e.g. electrocardiograph
- Concurrent use of this device and other medical electronic instruments for life support, e.g. mechanical heart
- Slippery floor such as tile floor
- Jumping onto the platform immediately after bath or with wet hands
- Near a cell phone or microwave oven

Avoid storage in the following locations:

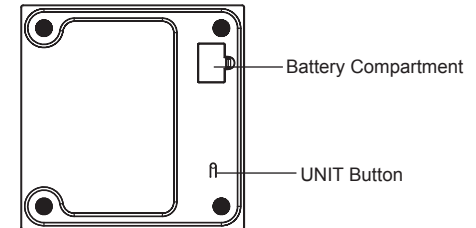
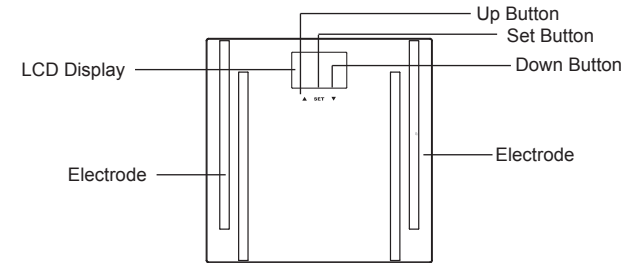
- Where there is water
- Where the device may be exposed to extreme temperatures, humidity, moisture, direct sunlight, dust, or salt air
- Where there is risk of shock or drop
- Where you store chemicals or full of corrosive gases
- Where in reach of the infants or children

♥ Efficient Use of Your Scale

To ensure the accuracy of measurement, please follow below instructions when you start measurement.

- Place the scale on a flat, hard surface. Soft surface such as carpet will affect the performance of the scale.
- Step onto the platform with bare feet. Stand still and keep full contact with the electrodes until the measurement is complete.
- Start measurement at least two hours after Getting up or Dinning.
- Avoid measurement immediately after strenuous exercise, sauna or bath, drinking, and dinning.
- Always start measurement in the same time slot and on the same scale located on the same flat, hard surface.

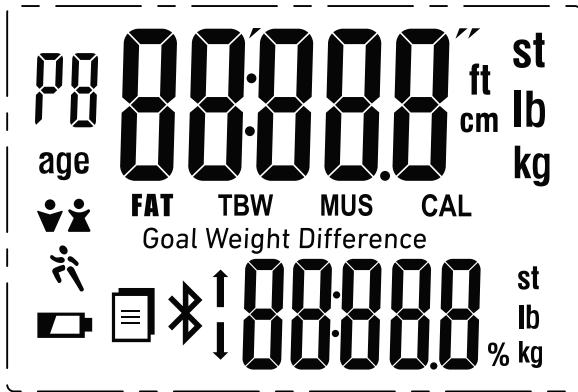
♥ Device Components



♥ List

1. Body Fat Analyzer GBF-1319-B
2. 3xAAA Batteries (1.5V each)
3. User Manual

♥ LCD Display



FAT	Body Fat Analysis Result		Male
TBW	Total Body Water Analysis Result		Male Athlete
MUS	Muscle Mass Analysis Result		Female
CAL	Calorie Analysis Result		Female Athlete
st	Stone		Data hasn't been sent out
lb	Pound		Bluetooth icon
kg	Kilogram		More than target weight
%	Percentage		Less than target weight
ft	Foot	P8	User ID (Range from P1 to P8)
cm	Centimeter	age	Age
Goal Weight	Target Weight		
Goal Weight Difference	Difference compare with target weight		

♥ General Instructions

Transtek Body Fat Analyzer GBF-1319-B applies BIA (Bio-impedance Analysis) technology. A small amount of weak current flows through the human body so as to detect the bio-impedance and estimate body fat, body water, muscle mass and CAL-MAX. The electrical current is small and may not be felt.

This BIA technology is cheap, safe, non-invasive, toxic-free and harmless. It also possesses the characteristics of simple operation and abundant information.

The current mentioned above is less than 1mA. However, please be aware that anyone with an wearable or implantable medical electronic instrument, such as a pacemaker, must avoid using this device.

The intended use of this device is for adult's indoor use only.

♥ Insert the Batteries

- Open the battery door in the back of the scale.
- Insert the batteries (3 x AAA) into the battery compartment according to the polarity indications marked inside the compartment.

* The digits "8888" will be shown on the LCD.



- Close the battery door and wait until the digits "0.0" are shown on the LCD.

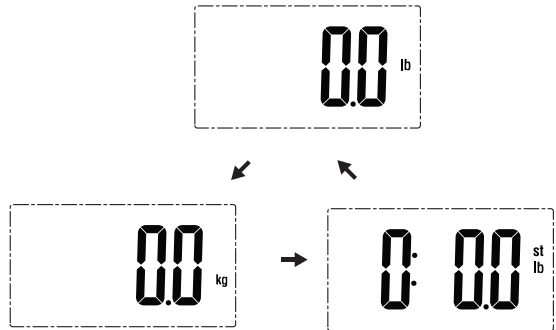


CAUTION

- When the symbol "Lo" appears, the device will power off in four seconds. Then you shall replace with a new set of batteries. Please replace all three batteries at the same time. Do NOT mix the old batteries with the new one.
- Worn batteries are hazardous waste. Do NOT dispose of them together with the household garbage. Please refer to the local ordinances and recycling instructions regarding disposal of the worn batteries.

♥ Select Measurement Unit

With batteries correctly installed, press “UNIT” button in the back of the scale to select measurement unit. The default measurement unit is “pound”. You may press “UNIT” button to choose among pound, kilogram, stone.



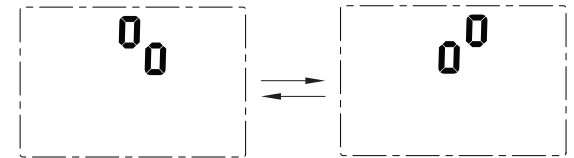
Note: If there is no operation in the weighing mode, the scale will turn off after a few seconds.

♥ Pair-Up

With the advanced Bluetooth 4.0 technology applied, the mobile or portable equipments, which are equipped with Bluetooth function in line with BLE Technical Specifications established by global organization Bluetooth SIG, are capable to receive your personal health data.

- Turn on Bluetooth and the App. Make sure both are ON when pair-up is proceeding.
- Press and hold “UNIT” button in the back of the scale to start pair-up.

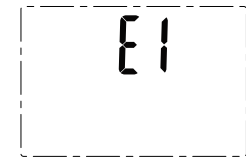
Symbol 0^0 and symbol 0^0 will be shown on the LCD alternatively, indicating pair-up is proceeding.



If SUCCEED, symbol [] will be shown on the LCD.



If FAIL, symbol “E1” will be shown on the LCD.



Bluetooth Module No. :AW2540MV1

Frequency Range	2402MHz - 2480MHz	Supply Voltage	2-3.6 V
Output Power Range	-1 dBm	Transmitting Distance	10 meters

♥ Set Up Your Profile

The body fat analyzer GBF-1319-B supports multiple users (Up to Eight). You may follow below instructions to assign User ID and set up your own profile, including Gender, Goal Weight, Stature, Age and Athletic Level.

1. Assigning User ID

- With batteries correctly installed, press “SET” button to enter setting when the scale is off.

The system will request User ID selection first. As pictured below, “P1” blinks. The operator may press the function key ▲ or ▼ to select User ID among P1 to P8.

Press “SET” button to confirm User ID.



2. Setting Gender

- After confirming User ID, the system will divert to Gender setting.
- As pictured below, the portrait ▼ blinks. The operator may press the function key ▲ or ▼ to select Gender (Male/Female/Male Athlete/ Female Athlete).

Press “SET” button to confirm Gender.

Athlete Mode:

An athlete is defined as an adult who is involved in intense physical activity of approximate 12 hours per week and who has a resting heart rate of approximately 60 beats per minute or less.



3. Setting Goal Weight

- After confirming Gender, the system will divert to Goal Weight setting automatically.
- As pictured below, the digits blink. The operator may press the function key ▲ or ▼ to increase or decrease the numeral. (Range: 20 kg to 180 kg /44.0 lb to 396.8lb)
- You may press and hold the function key ▲ or ▼ for fast changing the numeral.
- Press “SET” button to confirm.



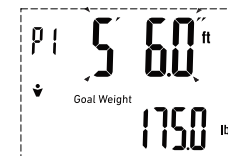
4. Setting Stature

After confirming Goal Weight, the system will divert to Stature setting automatically.

As pictured below, the digits blink. The operator may press the function key ▲ or ▼ to increase or decrease the numeral. (Range: 100 cm to 220 cm / 3'3.5"~7'2.5" ft)

You may press and hold the function key ▲ or ▼ for fast changing the numeral.

Press “SET” button to confirm.



5. Setting Age

- After confirming Stature, the system will divert to Age setting.
- As pictured below, the digits “30” blinks. The operator may press the function key ▲ or ▼ to increase or decrease the numeral.
(Age Setting Range for Normal Mode: 10 to 85 years old, Age Setting Range for Athlete Mode: 15-85years old)
- You may press and hold the function key ▲ or ▼ for fast changing the numeral.
- Press “SET” button to confirm Age.

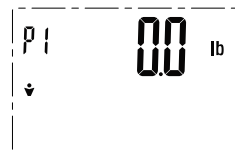


6. Setting Athletic Level

- After confirming Age, the system will divert to Athletic Level setting.
- As pictured below, the digit “1” blinks. The operator may press the function key ▲ or ▼ to increase or decrease the numeral. (Range: AC 1 to AC 5)
- You may press and hold the function key ▲ or ▼ for fast changing the numeral.
- Press “SET” button to confirm Athletic Level.



- The display will show your settings once, then display “0.0”, you can start measuring.



- Repeat procedure for a second user, or to change user details.
Note: To update or overwrite the memorised data, follow the same procedure, making changes as required.

♥ Initialising Your Scale

- Press the platform centre and remove your foot.
- “0.0” will be displayed.

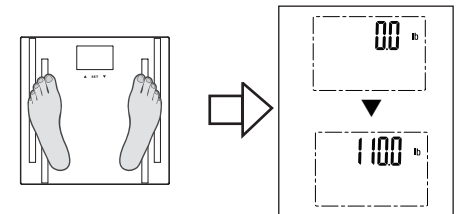


- The scale will switch off and is now ready for use. This initialisation process must be repeated if the scale is moved. At all other times step straight on the scale.

♥ Weight Only Operation

Your TRANSTEK Body Fat Analyzer will operate as a conventional weight - reading scale. No special programming steps are required. Once the scale is initialized, as previously described, you may simply step on the scale to measure your current weight. For only weight reading.

- Position the scale on a flat, hard surface. Carpeted or uneven floors may affect accuracy.
- Step onto the scale platform and remain still while the scale computes your weight.
- The scale will display your weight value.
- The scale will automatically turn off after a few seconds.



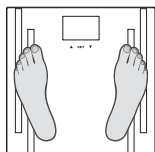
Note: The weight value won't be saved in the scale, and won't be transmitted to the APP.

♥ First Measurement

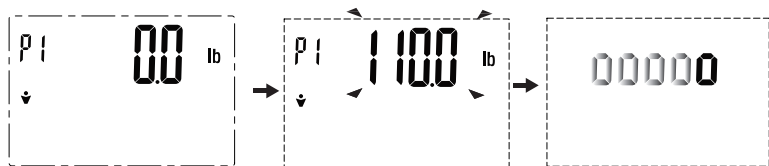
- Position scale on a firm flat surface.
- Press SET button.
- While the user number of the latest measurement is flashing, select your user number by pressing ▲ or ▼ button. After 3s, the selected number is locked, the user's personal data will be shown once, and then the scale shows zero reading.

(Note: When the user number is flashing, if you press SET button again, it will enter the setting mode, after all the settings are finished, the settings will be shown once, and then display zero reading.)

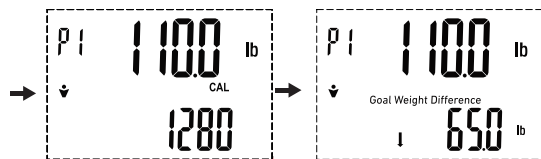
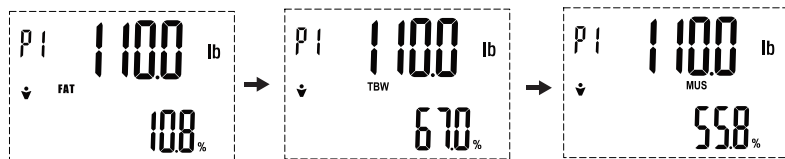
STEP 1: Step on the platform barefooted when the LCD displays "0.0".



STEP 2: Stand still and keep full contact with the electrodes until the LCD stops displaying moving "o".



STEP 3: Your weight will be displayed followed by Body Fat, Total Body Water, Muscle Mass, CAL-MAX and the weight difference value. The data will be displayed three times.



* If it fails to complete the analysis, the LCD will only display the weight data.

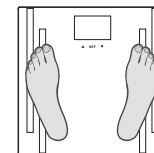
(To find out the solutions, please refer to [Troubleshooting](#) for more details.)

• When your scale is successfully paired with your iPhone and the Bluetooth is ON, GBF-1319-B will process data transmission automatically.

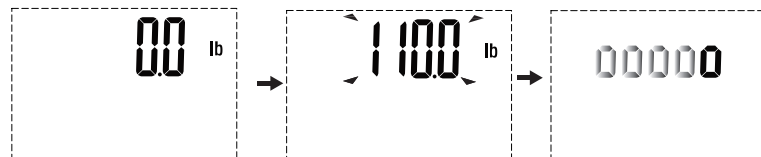
(Please refer to [Data Transmission](#) for more details.)

♥ Daily Measurement

• With original SENSE ON patent technology, GBF-1319-B will automatically switch on as you step on the platform barefooted.

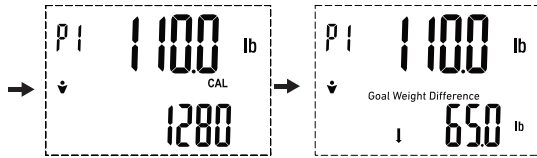
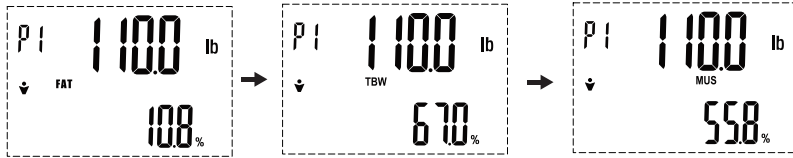


• Stand still and keep full contact with the electrodes until the LCD stops displaying moving "o".





• According to the analysis results, the system will automatically identify the possible User ID with most similar history records. Then the measuring results will be displayed sequentially three times .

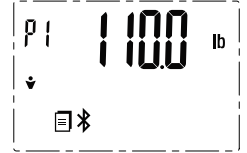
- When the system finds out two or more users with similar history records, it will notify you to choose between, for example, P1 and P2. You may press ▲ key for P1 and or ▼ key for P2. The measuring results will then be sorted into the User ID you selected and displayed sequentially three times.





- If it fails to identify the possible User ID, the LCD will only display the weight data. *(To find out the solutions, please refer to [Troubleshooting](#) for more details.)*
- When your scale is successfully paired with your iPhone and the Bluetooth is ON, GBF-1319-B will process data transmission instead. *(Please refer to [Data Transmission](#) for more details.)*


♥ Data Transmission

- With GBF-1319-B successfully pair-up with your iPhone, the measurement data will be transmitted to your mobile via Bluetooth.
- ONLY when the measuring results are attached to a specific User ID will it be transmitted to your mobile after measurement.
- The symbol  will disappear after successful data transmission, and you may check your personal health data stored in your iPhone.
- If the data transmission fails, the symbol  will remain. The pending measurement data will be temporarily kept in the scale and transmitted to your iPhone when next measurement is complete.



	Successful Bluetooth Connection
	Data transmitting to wireless wellness system: -If SUCCEED, the symbol disappears; -If FAIL, the symbol remains.

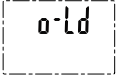

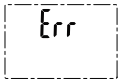
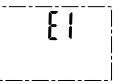
CAUTION

- Interference may occur in the vicinity of equipment marked with the following symbol . And the Analyzer may interfere vicinity electrical equipment.
- To enable the data transmission function, this product should be paired to a Bluetooth end at 2.4 GHz.

How to mitigate possible interference?

- The range between the Analyzer and the Bluetooth end should be reasonably close, from 1 meter to 10 meters. Please ensure no obstacles between the Analyzer and the Bluetooth end so as to obtain quality connection.
- To avoid interference, other electronic devices (particularly those with Bluetooth transmission / Transmitter) should be kept at least 1 meter away from the Analyzer.

♥ Error Prompt

Error	Description	Solution
	Overload. The device will power off in four seconds.	Stop using this scale for measurement.
	Low Battery. The device will power off in four seconds.	Replace all three batteries at the same time. Please purchase the authorized batteries for replacement.
	Measuring error.	Stand still, and measure again.
	Failure of pairing up your scale with your smartphone.	Please check below items: -Bluetooth is ON. -App Collector is ON. -Both devices are within the transmission distance of Bluetooth.

♥ When Measuring ...

Problem	Root Cause	Solution
Abnormal measuring results: - Too high; OR - Too low; OR - Huge difference between two recent measurement.	Incorrect posture	Please step on the platform barefooted and stand still.
	The device is located on the soft ground such as a carpet OR on a rugged surface.	Please place the device on a flat, hard surface.
	Either your hands or your feet are too dry.	Wipe your feet with a damp cloth, keeping them slightly damp when starting measurement.
No display on LCD when the device powers on.	Batteries not yet installed.	Install the batteries. (Please refer to <u>Insert the Batteries</u>)
	Worn batteries.	Replace all three batteries at the same time. Please purchase the authorized batteries for replacement.

Problem	Root Cause	Solution
CANNOT proceed to analyze body fat, total body water, muscle mass and CAL-MAX.	Step onto the platform wearing socks or shoes.	Please keep barefooted during the measurement, and keep full contact with the electrodes as well.
	The system cannot identify the possible User ID with most similar data.	Please assign a User ID following the instruction in Set Up Your Profile .
	The user fails to select the User ID from what the system found.	Please assign a User ID following the instruction in Set Up Your Profile .
The device powers off.	Low battery.	Replace all three batteries at the same time. Please purchase the authorized batteries for replacement.

♥ When Data Transmitting ...

Problem	Root Cause	Solution
Data transmission failed.	Bluetooth is OFF.	Turn ON the Bluetooth via "Setting >> General >> Bluetooth".
	The App is OFF.	Press the icon to turn ON your app.
	Out of range of Bluetooth transmission.	Place your iPhone closer to the scale.
	None of the user ID is assigned.	Please assign a User ID following the instruction in Set Up Your Profile .

♥ Specifications

Product Name	Body Fat Analyzer (GBF-1319-B)	
Dimension	Scale: 300x300x23mm	
	Panel: 300x300x6mm	
Net Weight	Approximately 1.85 kg	
Display	Digital LCD V.A.: 76x51mm	
Measurement Unit	Kilogram / Stone/ Pound	
Measurement Range	5kg to 180kg / 0st: 11lb to 28st: 5lb / 11lb to 397lb	
Division	0.1kg / 0.2lb	
Accuracy	5-50kg: ±0.3kg; 100-150kg: ±0.5kg;	50-100kg: ±0.4kg; 150-180kg: ±0.7kg
Working Environment	Temperature: 10 °C to 40 °C Humidity: 15%RH to 90% RH	
Storage Environment	Temperature: -20 °C to 55 °C Humidity: ≤90% RH	
Power Source	4.5V (3xAAA Batteries)	
Turn on Method	SENSE ON technology	
Auto-OFF	The scale will turn off after about 10s if there is no operation.	
Accessories	1. 3xAAA batteries 2. User Manual	
Mode of Operation	Continuous Operation	
Protection Against Ingress of Water	IPX0	
Software Version	1.0	

About the Accuracy of This Product

- This product passes strict inspection before delivery and therefore its accuracy is guaranteed by the manufacturer. Please refer to the above table for the descriptions on accuracy.

• This product is specially designed for body fat analysis as well as weight measurement. It should NOT be used by anyone during the process of transaction for verification of goods' weight.

♥ Maintenance

When carrying out usual maintenance, please ensure practice of the following Do's and Don'ts:

- DO use a dry soft cloth to wipe the dust.
- DO use a wet soft cloth, dipped into water and wrung out, to wipe the dirt. Then use a dry soft cloth to dry up the device.
- DON'T wash the device with water or immerse it in water.
- DON'T use propellant, abrasive or other chemicals to wipe the dirt in avoidance of discolor or malfunction.
- DON'T disassemble this device. If you have any problems, please contact Transtek. (Please refer to Warranty for contact information)

♥ Warranty

- Transtek warrants its products free of defects in materials and workmanship in normal use for a period of TWO years from the date of retail purchase.
- This warranty does NOT cover damages caused by misuse or abuse, including but not limited to:
 - Failure caused by unauthorized repairs or modifications;
 - Damage caused by shock or drop during transportation;
 - Failure caused by improper operation inconsistent with the instructions stated in this user manual;
 - Malfunction or damage from failure to provide the recommended maintenance;
 - Damage caused by improper use of power supply.
- Should this device require maintenance (or replacement at our option) under warranty, please deliver the original package to GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO., LTD prepaid. Please return the store receipt (with the retail purchase date) and a note with reasons to return on it as well.

GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO., LTD
 Zone A, 5/F., Investment Building, No. 12 Huizhan East Rd., Torch Development District,
 Zhongshan, 528437, Guangdong, China
 Tel: 86-760-88282982
 Website: <http://www.transtek.cn>

♥ FCC Regulations

FCC User Guide Information

Radio Frequency Interface Requirements - FCC

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.

Radio Transmitters (Part 15)

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 equipment.

FCC RF Exposure Guidelines

Safety Information

Reducing RF Exposure - Use Properly

Only operate the device in accordance with the instructions supplied. This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. In order to avoid the possibility of exceeding the FCC radio frequency exposure limits, human proximity to the antenna shall not be less than 20 cm (8 inches) during normal operation.

♥ Table of Body Fat Level (Unit: %)

a) The body fat percentage (%): 5%-60%/0.1%

Standard for Men

Standard for Women

Rating	Age					Rating	Age				
	20-29	30-39	40-49	50-59	60+		20-29	30-39	40-49	50-59	60+
low	<13	<14	<16	<17	<18	low	<19	<20	<21	<22	<23
Normal	14-20	15-21	17-23	18-24	19-25	Normal	20-28	21-29	22-30	23-31	24-32
Moderately High	21-23	22-24	24-26	25-27	26-28	Moderately High	29-31	30-32	31-33	32-33	33-35
High	>23	>24	>26	>27	>28	High	>31	>32	>33	>34	>35

Source: University of Illinois Department of Food Science and Human Nutrition. Body Fat Percentage Calculator.

www.ag.uiuc.edu/~food-lab/ai/bfc.html

♥ Table of Body Water Level (Unit: %)

b) The body water percentage (%): 43%-73%/0.1%

Source: Derived from Wang & Deurenberg: "Hydration of fat-free body mass". American Journal Clin Nutr 1999,69:833-841.

	BF % RANGE	OPTIMAL TBW % RANGE
Men	4 to 14%	70 to 63%
	15 to 21%	63 to 57%
	22 to 24%	57 to 55%
	25 and over	55 to 37%
Women	4 to 20%	70 to 58%
	21 to 29%	58 to 52%
	30 to 32%	52 to 49%
	33 and over	49 to 37%

♥ Muscle Mass Percentage

(Source: International Commission on Radiological Protection, 1975)

Men	Approximately 40% of total body weight
Women	Approximately 30% of total body weight

♥ Bone Mass Percentage

(Source: Rico et al. 1993)

The average bone mass percentage for both men and women is between 4 to 5%.

♥ Health Tips - About Body Fat

Fat is essential for human body. It can not only store energy and protect viscera, but also regulate body temperature and maintain normal physiological function of human body. However, too much body fat is harmful to human body. It is always accompanied by Fatty Liver, diabetes, coronary heart disease, etc.

Therefore self-measuring and self-monitoring body fat level are beneficial to your health. Since we can't judge body fat level simply by our weight, this body fat analyzer GBF-1319-B, with BIA (Bio-impedance Analysis) technology applied, is an accurate device that offers a quick and comfortable way to obtain your body fat level.

♥ EMC Guidance

Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 2	The device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 – Guidance and MANUFACTURER’S declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer'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 it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 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	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 4 – Guidance and MANUFACTURER’S declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING


Guidance and manufacturer'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 it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment 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 $d = \left[\frac{3,5}{f_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,167 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,333 \sqrt{P}$ 800 MHz to 2,5 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 metres (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 equipment 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 re-orienting or relocating the device.			
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[f_1] V/m$.			

Table 6 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the 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 equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter <i>P</i> W	Separation distance according to frequency of transmitter <i>d</i> m		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = 1.167 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.333 \sqrt{P}$
0,01	Not applicable	0.117	0.233
0,1	Not applicable	0.369	0.738
1	Not applicable	1.167	2.333
10	Not applicable	3.690	7.378
100	Not applicable	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where <i>P</i> 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.			