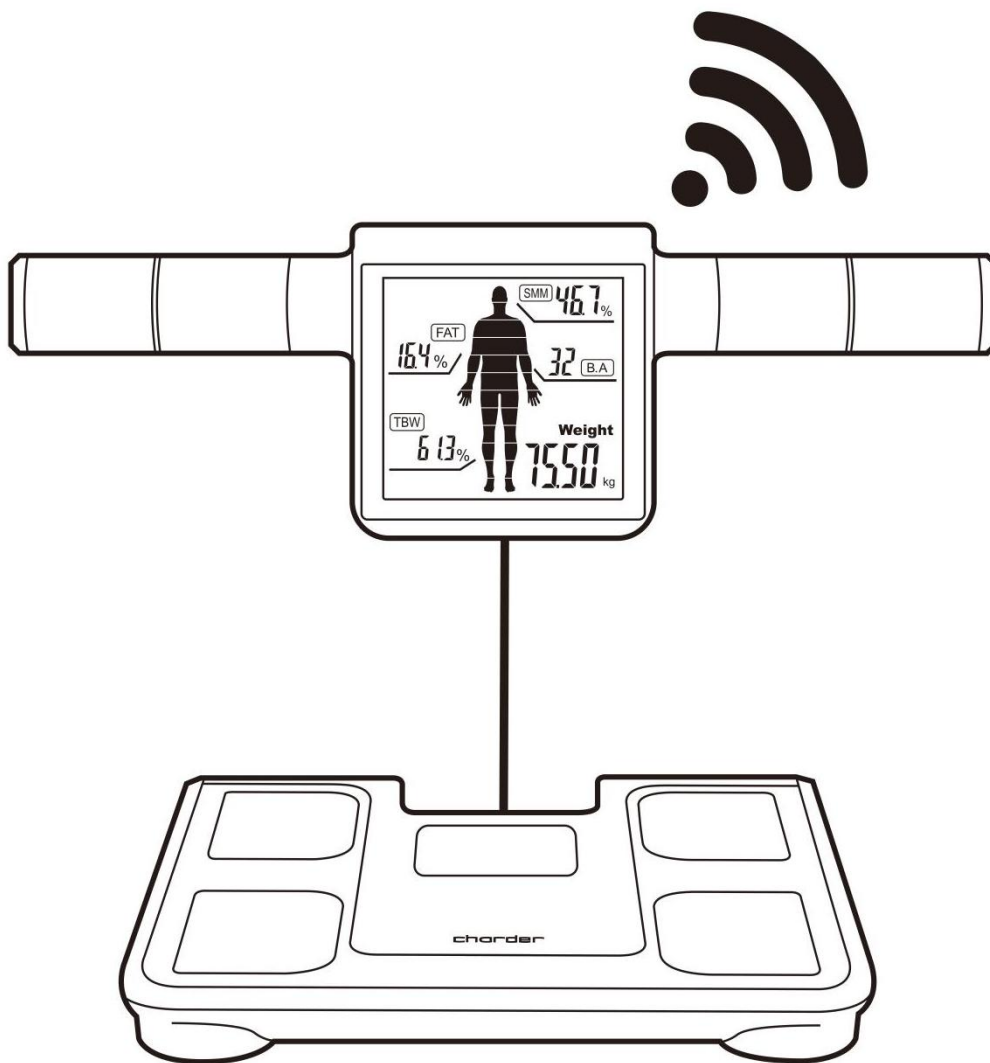




Body Composition Analyzer

USER MANUAL U310/B310








Please keep the instruction manual at hand all the time for future reference.

chorder[®]

Reliable | Precise | Easy-to-use

Explanation of Text/Symbols on Device Label/Packaging

Text/Symbol Meaning

	Caution, consult accompanying documents before use
	Separate collection for waste of electrical and electronic equipment, in accordance with Directive 2002/96/EC. Do not dispose of device with everyday waste
	Name and address of device manufacturer, and year/country of manufacture
	Carefully read user manual before installation and usage, and follow instructions for use.
REF	Device catalogue number / model number
LOT	Manufacturer's batch or lot number for device
SN	Device's serial number
UDI	Device's Unique Device Identifier
CE	Device conforms to Declaration of Conformity
e	Value in mass units (verified models only). This is the difference between two consecutive display values, used to classify and verify a scale
	Device's Taiwan NCC approval number

Copyright Notice

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Charder Electronic Co., Ltd.
No. 103, Guozhong Rd., Dali Dist.,
Taichung City, 41262 Taiwan

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I . Safety Notes

Contraindications

During measurement, this machine will send a low level imperceptible electrical current throughout the body. Individuals with implanted medical devices, such as:

- Pacemakers
- Electronic lungs and other electronic medical life support equipment
- ECG devices

must not use this machine, as the electric current may affect the implanted device, endangering lives.

Contraindications

This product is not a medical device
Results should be used for reference only

General Information

Thank you for choosing this Charder Medical device. It is designed to be easy and straightforward to operate, but if you encounter any problems not addressed in this manual, please contact your local Charder service partner. Before beginning operation of the device, please read this user manual carefully, and keep it in a safe place for reference. It contains important instructions regarding installation, proper usage, and maintenance.

Intended Purpose

This device is designed to be used in accordance with national regulations, to estimate body composition within specifications, for body composition-related usage by professionals.

Clinical Benefit

Measurement results can be used by professionals to monitor body composition-related issues.

Measurement Guidelines

- Subjects with implanted medical devices must not use the device.
- Pregnant women should avoid using this device.
- Shoes and socks must be removed for measurement.

Using Adapter

- Only the original adapter should be used with the device. Using an adapter other than the one provided by Charder may cause malfunction
- Do not touch the power supply with wet hands.
- Use only a correctly wired (100-240VAC) outlet, and do not use a multiple outlet extension cable.
- Do not crimp the power cable, and avoid sharp edges.
- Do not overload extension cables connected to the device.

Using Batteries

- Only the specified batteries should be inserted in the correct polarity.
- If the device will not be used for an extended period of time (>3 months), please remove batteries to avoid device damage.
- Do not mix old and new batteries.
- Batteries should be kept away from children. If swallowed, promptly seek medical assistance.
- Batteries should be recycled/disposed of via designated competent organizations. Batteries should not be incinerated.

General Handling

- Device is a precision measurement instrument, please handle with care.
- Device should be placed on stable, flat, solid, non-slippery surface. Usage on soft surfaces (ex: carpet) may result in inaccurate results.
- Avoid stepping on the edge of the platform or the LCD screen.
- Device is intended to measure one subject at a time.

Cleaning

- Device surface should be cleaned using alcohol-based wipes.

- Do not use large amounts of water when cleaning the device, as it may cause damage to the internal electronics.
- Always disconnect device from mains power before cleaning.

Warranty/Liability

- The period of warranty shall be eighteen (18) months, beginning on the date of purchase. Please retain your receipt as proof of purchase.
- No responsibility shall be accepted for damage caused through any of the following reasons: unsuitable or improper storage or use, incorrect installation or commissioning by the owner or third parties, natural wear and tear, changes or modifications, incorrect or negligent handling, chemical, electrochemical, or electrical interference.
- All maintenance, technical inspections, and repairs should be conducted by an authorized Charder service partner, using original Charder accessories and spare parts. Charder is not liable for any damages arising from improper maintenance or usage.
- The device has an expected service life of 5 years when correctly handled, serviced, and periodically inspected in accordance with manufacturer's instructions.

Maintenance

- Do not place the device in direct sunlight, or in close proximity to an intense heat source. Excessively high temperatures may damage the internal electronics.
- Do not under any circumstances dismantle or alter the device, as this could result in electric shock or injury as well as adversely affect the precision of measurements.
- The device is intended for indoor use only.
- Device does not require routine user maintenance. However, regular checking of accuracy is recommended; frequency to be determined by level of use and state of device, or local metrology/measuring instrument regulations if applicable. If results are inaccurate, please contact local distributor.
- Observe permissible ambient temperatures for use
- The device has an expected service life of 5 years when correctly handled, serviced, and periodically inspected in accordance with manufacturer's instructions.

Disposal

- This product is not to be treated as regular household waste, but should be taken to a designated collection points for electronics. Further information should be provided by local waste disposal authorities.

Caution

Usage of Results


- The U310/B310 is not a diagnostic device.
- BIA results are calculated based on impedance values validated with representative population studies and statistical analysis. As such, the technique is best suited for tracking progress for an individual over a period of time, or for categorizing large groups of people, rather than used as a one-time analysis. Accuracy of results is highly dependent on proper measurement procedure. Please follow instructions carefully for best results.

EMC Guidance and Manufacturer's Declaration

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.			
Emission test	Compliance	Electromagnetic environment-guidance	
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A	The product is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.	
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	<u>± 8 kV contact</u> <u>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air</u>	<u>± 8 kV contact</u> <u>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air</u>	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	<u>30 A/m</u>	<u>30 A/m</u>	The device power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

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 is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,7 GHz	3 V/m <u>80MHz to</u> <u>2,7 GHz</u>	<p>Recommended separation distance: $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,5 GHz</p> <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 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 3 V/m.

Recommended separation distance 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.

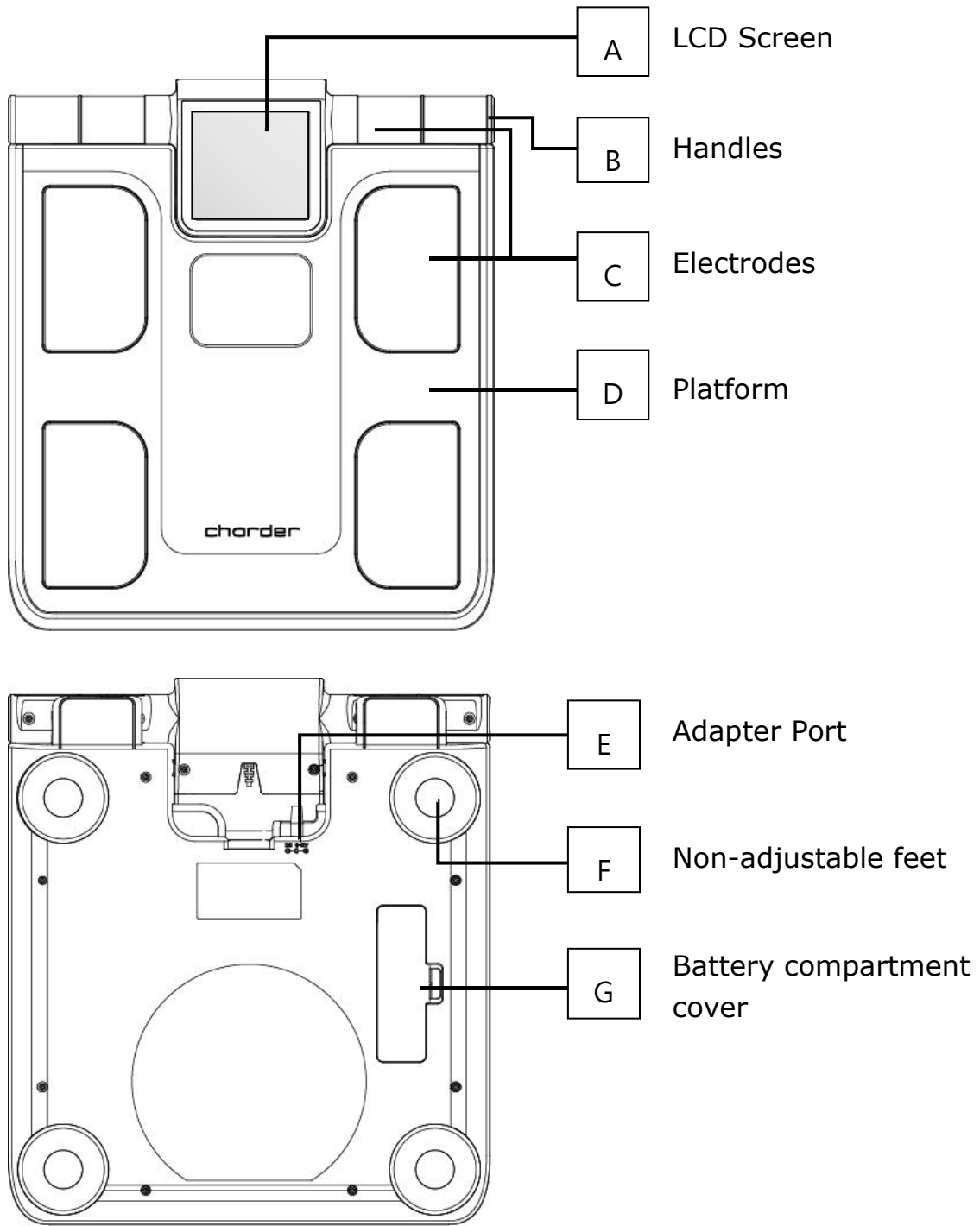
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,7 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

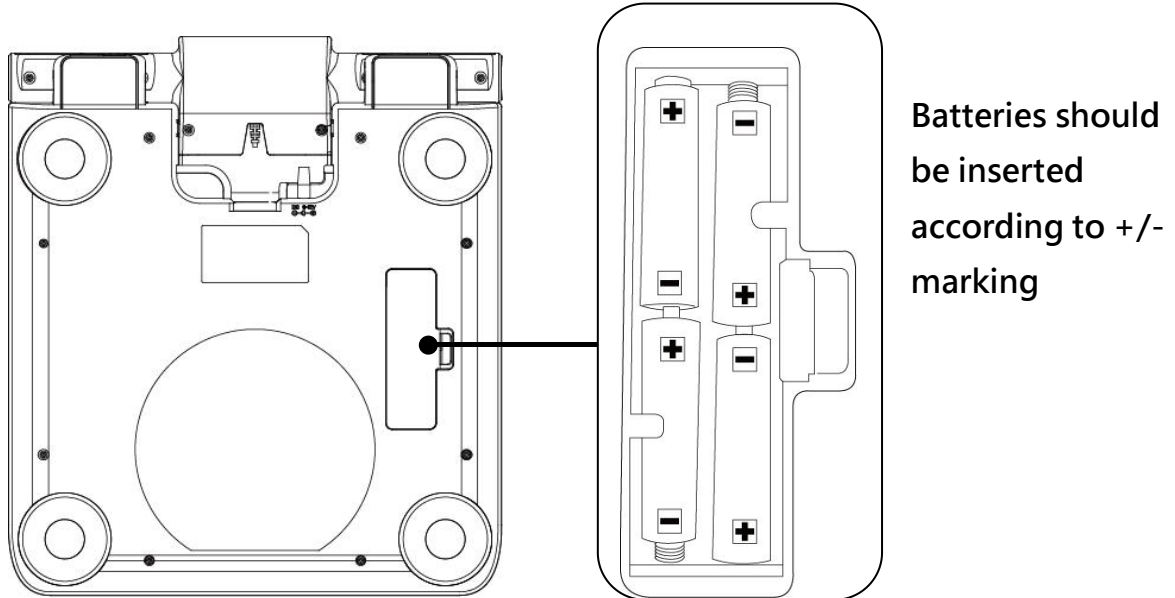
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

II. Device Description



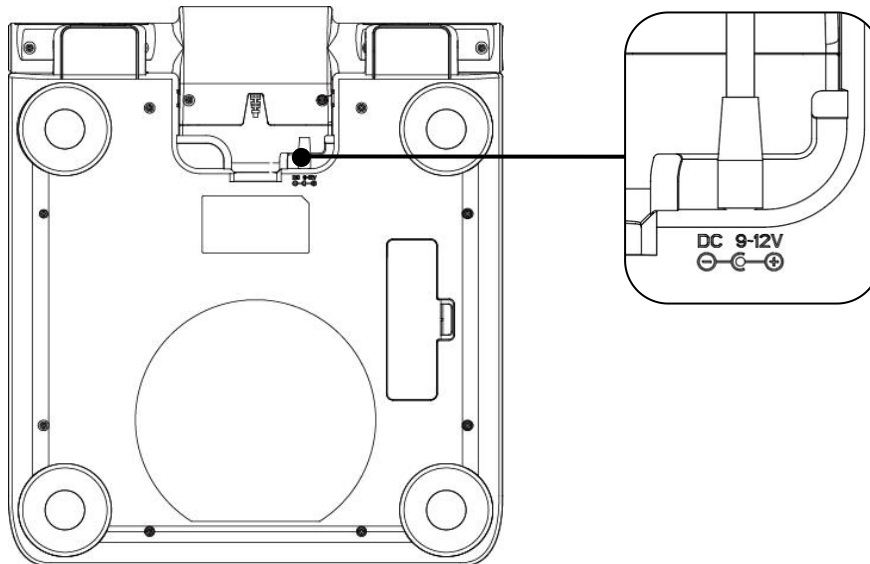
III. Assembly

A. Insert Batteries



Open battery compartment cover, and insert 4 AA 1.5V batteries. Place cover back in place.

B. Using Adapter

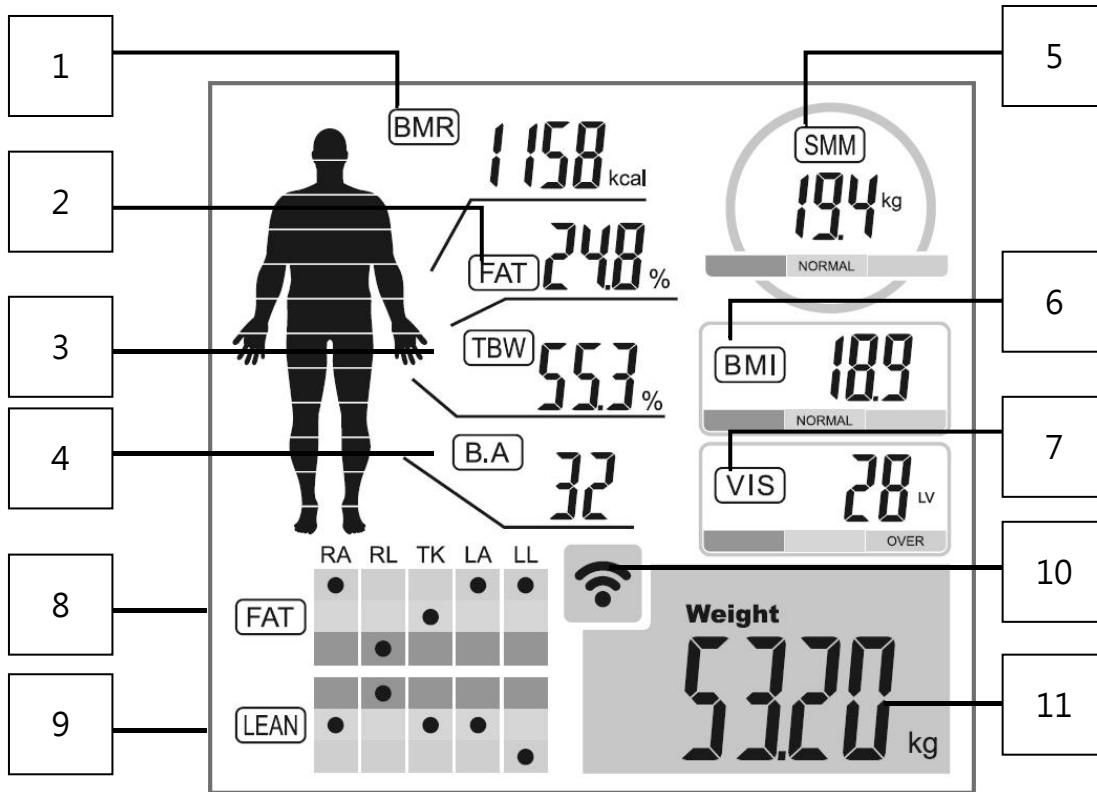


Insert adapter into port on the bottom of device:

If **LO** appears on LCD screen, please replace batteries or plug adapter into power outlet.

IV. Screen

A. LCD Indicator (U310)

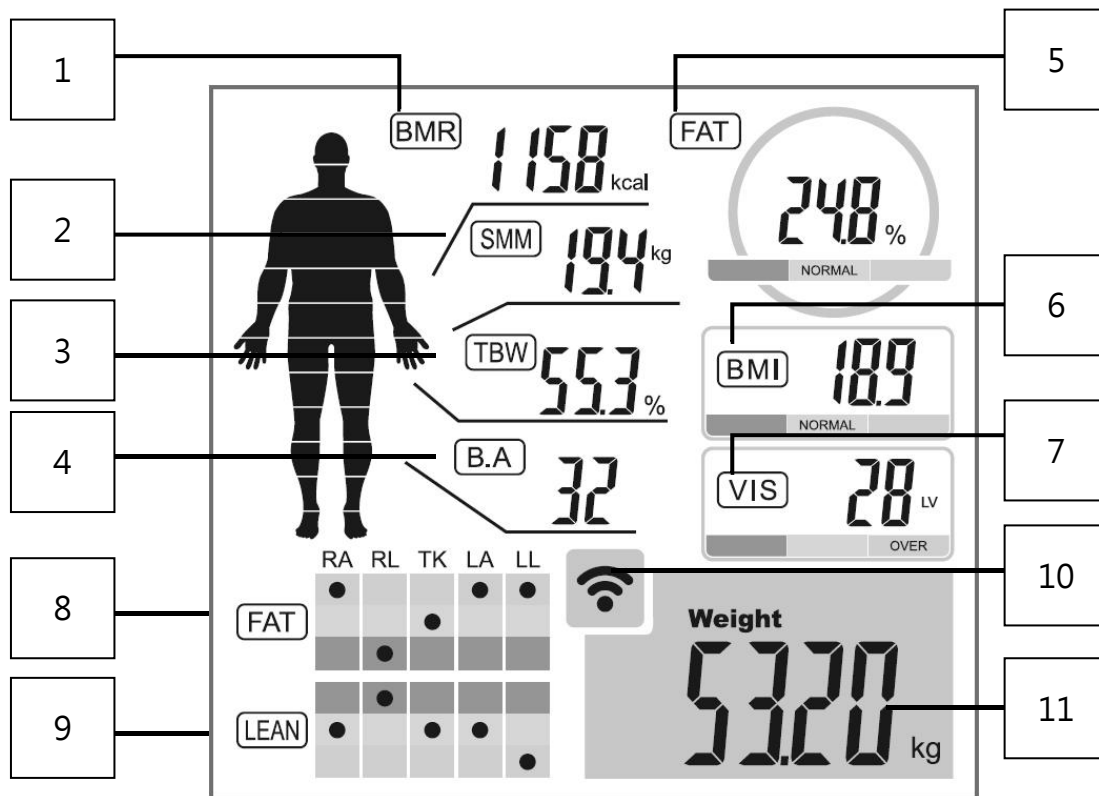


After measurement completion, results will be displayed on LCD screen briefly to indicate that measurement was successful.

1. BMR (Basal Metabolic Rate)
2. FAT
3. TBW (Total Body Water)
4. B.A (Body Age)
5. SMM (Skeletal Muscle Mass)
6. BMI (Body Mass Index)
7. VIS (Visceral Fat Level)
8. FAT (Segmental Fat)
9. LEAN (Segmental Lean Mass)
10. Wireless connection status
11. Weight

(Measurement results are for reference only, and should not be used for medical treatment or diagnosis)

B. LCD Indicator (B310)



After measurement completion, results will be displayed on LCD screen briefly to indicate that measurement was successful.

1. BMR (Basal Metabolic Rate)
2. SMM (Skeletal Muscle Mass)
3. TBW (Total Body Water)
4. B.A (Body Age)
5. FAT
6. BMI (Body Mass Index)
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(Measurement results are for reference only, and should not be used for medical treatment or diagnosis)

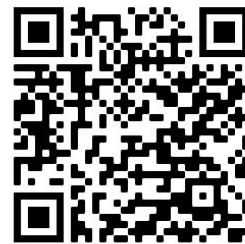
V. Conducting Measurement

The U310/B310 must be used with the Charder ProScan app. An iOS or Android device (with operational Bluetooth and Wi-Fi) is required to download the app and operate the product.



Charder Proscan

Android



iOS



After installation of app, you must create an administrator profile as instructed by the app to begin using the product.

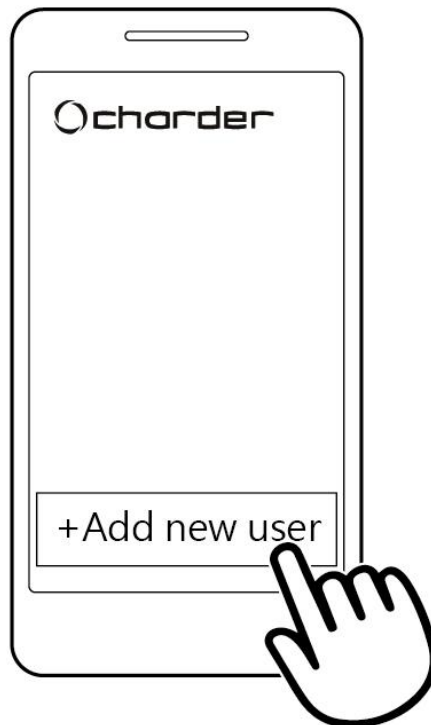
A. Turn on Bluetooth and Location

Bluetooth function must be turned on for device to connect to U310/B310.
On some devices, Location must also be turned on for data transfer.




B. Create user profile

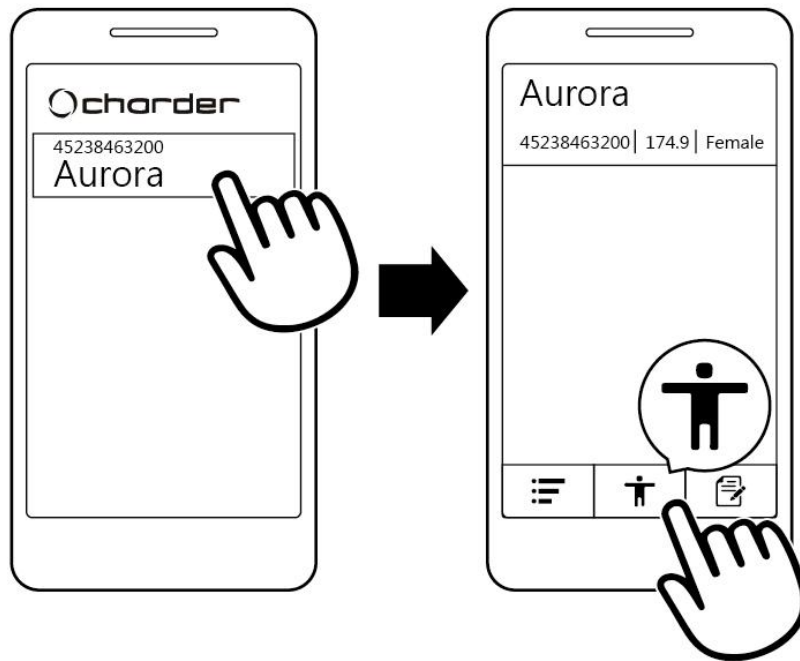
Press **+Add new user** and input the required user information (ID, Name, Birthday, Height, Gender) and press **Save** to create a new user profile, which can now be used to conduct measurement.



C. Conducting measurement

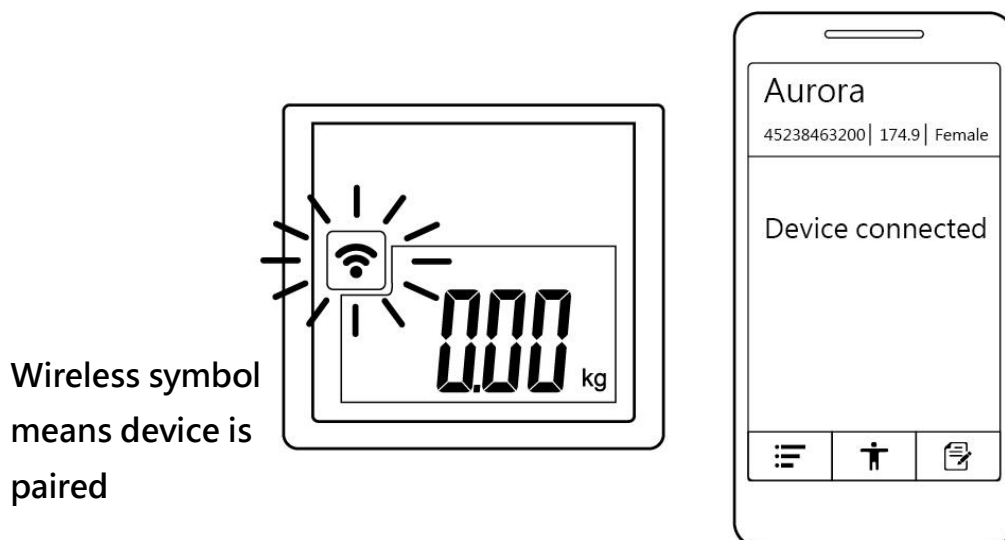
1. Select user account

Select a user, and press  icon below to enter measurement screen.



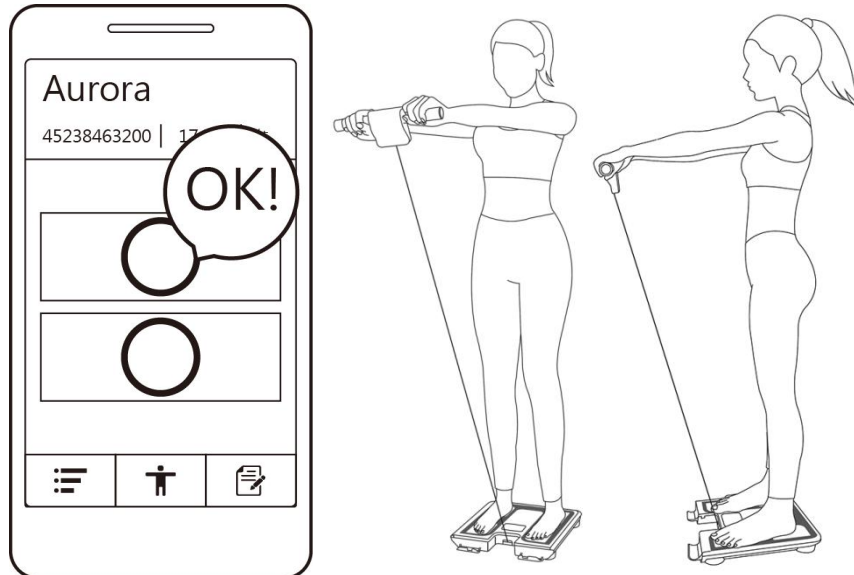
2. Pair with device

Step onto platform to turn on product, and step off as it turns on and conducts auto-calibration. After calibration is complete, "0.00" will appear on LCD screen.



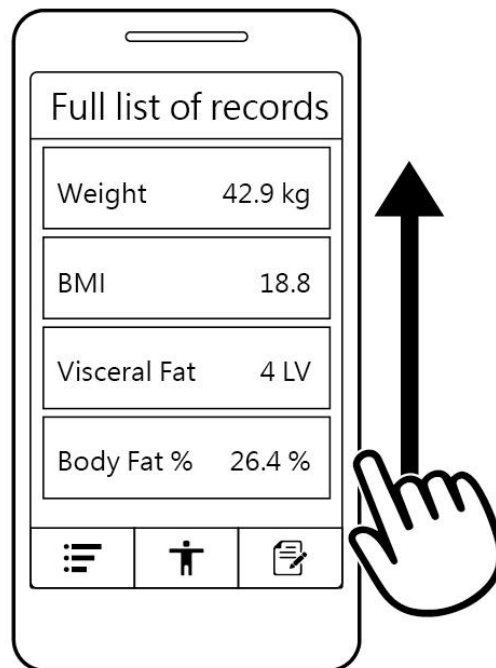
3. Begin Measurement

Step onto measurement platform's foot electrodes with bare feet. Pick up hand electrodes and stand straight. Straighten arms, making sure they are not pressed against the side of the body.



4. Measurement Complete

After measurement, LCD screen will briefly display results before sending data to Charder ProScan app.



VI. Measurement Results Explained

1. BMI (Body Mass Index)

BMI is a commonly used index by the World Health Organization (WHO), utilizing height and weight to classify underweight, normal, over, and obesity in adults.

Category	BMI (kg/m ²)	Risk of obesity-related disease
Under	< 18.5	Low
Normal	18.5-24.9	Average
Over	24.9-29.9	Slightly Increased
Obese I	30.0-34.9	Increased
Obese II	35.0-39.9	High
Obese III	> 40	Very High

(World Health Organization adult BMI standards)

2. Visceral Fat Level

Abdominal fat can be divided into visceral and subcutaneous fat. Visceral obesity can occur even if a subject's weight or BMI is within normal standards. Such subjects are thin on the outside, but fat on the inside¹. Visceral fat level has high correlation with risk of a variety of obesity-related diseases, including cardiovascular diseases and Type-2 diabetes²³.

3. Body Fat % / 4. Body Fat Mass

Body fat percentage is useful in determining the specific cause of weight loss or gain. Average percentages differ according to specified groups and categories, most significantly by gender. Although no universally accepted published ranges or cut-off points for body fat percentage currently exist, it is still an important value in assessing change in body composition and health.

¹Dudeja V, Misra A, Pandey RM, Devina G, Kumar G, Vikram NK. BMI does not accurately predict overweight in Asian Indians in northern India. *Br J Nutr.* 2001;86:105-112

² Sandeep S, Gokulakrishnan K, Velmurugan K, Deepa M, Mohan V. Visceral & subcutaneous abdominal fat in relation to insulin resistance & metabolic syndrome in non-diabetic south Indians. *Indian J Med Res.* 2010;131:629-635.

³ Klein S. The case of visceral fat: argument for the defense. *J Clin Invest.* 2004;113(11):1530-1531

5. SMM (Skeletal Muscle Mass)

Cardiac muscle, smooth muscle, and skeletal muscle are the three major muscle types found in the body. Skeletal muscle mass correlates with athletic performance, as it is under voluntary control and used to power movement. In addition, it can be developed actively through proper nutrition and training, thus making this value an important indicator for evaluation of fitness progression.

6. Muscle Mass (Lean Body Mass)

Increase in muscle mass increases BMR, which in turn allows the body to burn calories more quickly.

7. Body Water

Total Body Water (TBW) refers to the water contained in the tissues, blood, bones, and elsewhere. TBW in a healthy (non-obese) adult can fluctuate by roughly 5% daily, influenced by physiological activity and consumption of food and drink⁴. Due to larger size and muscle mass, healthy adult men have more TBW than women (on average)⁵.

For healthy (non-obese) adults, TBW constitutes ~60% of body weight and ~73% of Fat-Free Mass⁶. However, it is important to note that this percentage is not applicable to children - typically, children have a higher percentage of body water than adults, and TBW levels reportedly decrease further around middle age as part of the aging process⁷. In addition, various diseases can affect body water percentage, including renal deficiency diabetes, cardiac failure, and cancer⁸. Therefore, BIA estimations should be used with particular caution if subject's body water differs significantly from the representative populations used to formulate BIA algorithms.

⁴ Askew EW Present Knowledge in Nutrition (7th ed) 1996, p.98-107

⁵ Lesser GT, Markofsky J. Body water compartments with human aging using fat-free mass as the reference standard. 1979. Am J Physiol, 236, p.R215-R220.

⁶ Wang ZM, Deurenberg P, Wang W, Pietrobelli A, Baumgartner RN, Heymsfield SB. Hydration of fat-free body mass: review and critique of a classic body-composition constant. The American Journal of Clinical Nutrition. 1999. Vol.69 Issue 5, p.833-841.

⁷ Cameron CW, Guo SS, Zeller CM, Reo NV, Siervogel RM. Total body water for white adults 18 to 64 years of age: The Fels Longitudinal Study. 1999. Kidney Internationalk Vol.56 Issue 1, p.244-252

⁸ Moore FD, Haley HB, Bering EA, Brooks L, Edelman I. Further observations on total body water. Changes of body composition in disease. 1952. Surg Gynecol Obstet, 95, p.155-180

8. Body Age

The app will compare your results with database to calculate your body age.

9. BMR (Basal Metabolic Rate)

Basal Metabolic Rate is the minimum required energy to sustain the body's vital functions while at rest. These functions include breathing, blood circulation, regulation of body temperature, cell growth, brain function, and nerve function. BMR tends to decrease with age or reduction in weight, and is positively correlated with increase in muscle.

10. Bone Mass (Bone Mineral Mass)

Higher bone mineral content may be an indicator of higher bone density.

Ⅶ. Measurement Guidelines

About Bioelectrical Impedance Measurement

The U310/B310 uses Bioelectrical Impedance Analysis (BIA) to calculate body composition. At its core, BIA operates by treating the human body as an electrical conductor within an alternating current circuit, from which the alternating current resistance and impedance is measured.

Using a combination of existing population data and in-house research, body composition analysis formulas can calculate results based on the Impedance, Height, Gender, Age, and Weight of the subject. These algorithms are formulated with reference to "gold standard" measurements such as Dual-Energy X-ray Absorptiometry (DXA) to confirm viability and accuracy.

Measurement Rules

For best results, body composition analysis via BIA should be conducted under specific conditions. Inconsistent measuring conditions will affect the accuracy and validity of BIA results, and interpretation of body composition. The information below regarding the effect of various factors on measurement results is largely sourced from related research by Kushner et al⁹. Before measurement, please take note of the following:

1. Do not exercise or perform strenuous physical tasks before measurement

Strenuous physical tasks and exercise can result in a temporary change in body composition measurements. As BIA analyzes electrical impedance in the body, activities that might affect impedance (e.g. increased perspiration, dehydration, blood circulation) may affect measurement accuracy.

2. Affect of food and drink on measurement results

Ingestion of food and drink can affect impedance and weight, and thus analysis results. This change generally lasts 2-5 hours after each meal. For most accurate results, BIA measurements should ideally be conducted in a fasting state (e.g. before breakfast)¹⁰.

⁹ Kushner RF, Clinical characteristics influencing bioelectrical impedance analysis measurements, 1996

¹⁰ R Gallagher, M & Walker, Karen & O'Dea, K. The influence of a breakfast meal on the assessment of body composition using bioelectrical impedance. European journal of clinical nutrition. 52. 94-7.

3. Do not shower or bathe directly before measurement.

Perspiration can result in a temporary change in body composition measurements, as the accuracy of BIA depends largely upon interpretation of measured impedance values, which are affected greatly by hydration levels.

4. Perform the measurement under normal temperature conditions (24-28°C)

Extreme temperatures (both hot and cold) can result in temporary physiological changes. For example, excessive sweating due to heat can cause increased impedance measurements, resulting in a higher fat calculation. For best results, measurements should be conducted in an environment between 24-28°C.

5. Remove shoes and socks before measurement.

Shoes and socks will interfere with the electric current, making measurement inaccurate or in some cases, impossible.

6. Avoid physical contact with other people during measurement.

Because BIA measures the impedance encountered as the electric current travels through the subject's body, if another individual is touching the subject, the electric current may passthrough the other individual, causing inaccuracy in measurement results.

7. Measure height accurately

Inaccurate height input will affect estimation of body composition.

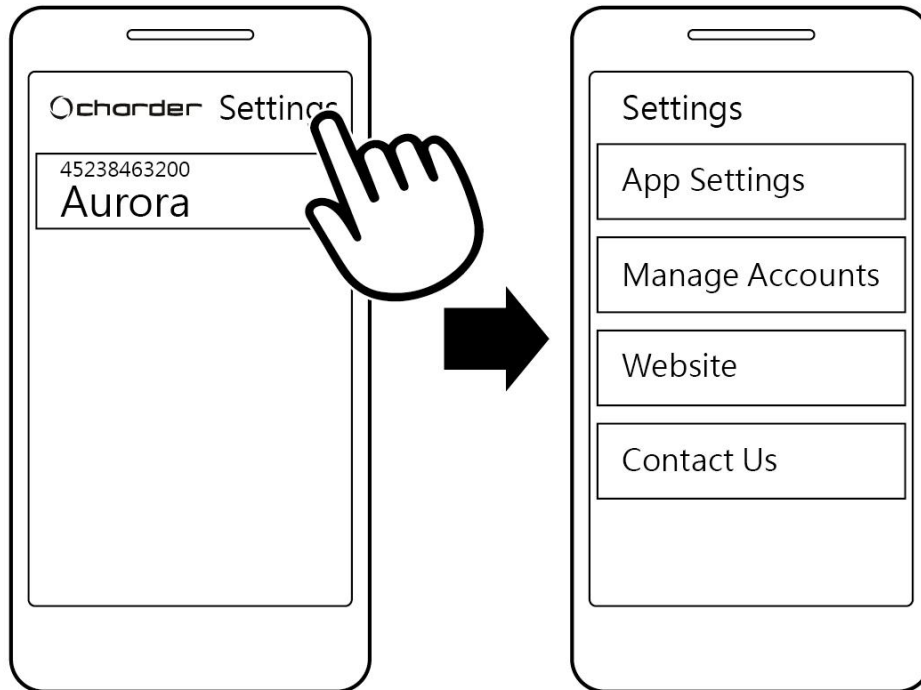
8. Perform the measurement in the morning.

As a general rule, BIA measurements should be performed in the morning to minimize the influence of activity throughout the day on measurements¹¹.

¹¹Oshima Y & Shiga T. Within-day variability of whole-body and segmental bioelectrical impedance in a standing position, European Journal of Clinical Nutrition 2006, 60, 938-941

VIII. Settings

Press **Settings** at top right of home page to access App Settings, Manage Administrator Accounts, Find information, and Sign out.



1. Select App Settings to adjust the following:

- Unit switch (Metric / Imperial)
- Data format
- Language
- Visual theme
- Auto login (if turned on, you must manually select "Sign out")

2. Select Manage Accounts to add/edit administrators.

NOTE: currently selected account cannot be deleted

3. Website

Link to Charder Medical website

4. Contact Us

Contact Charder Medical via E-mail

IX. Troubleshooting

Before contacting your local Charder distributor for repair service, we recommend considering the following troubleshooting procedures:

Self-inspection

1. Device will not power on

- If battery power is depleted, replace with new batteries
- If batteries are not used, check if the power adapter is plugged into the device properly. Check if power adapter is plugged into mains properly

2. Indicator showing "Err"

- Interference due to factors such as RF disturbance or ground vibration. Relocate device to location without interference and try again
- External objects interfering with measurement platform. Clear platform of objects and try again
- Device may not function properly on soft surfaces such as carpets or lawns. Relocate device to location with solid, stable floor
- If the steps above cannot resolve the problem, re-calibration may be required to correct weighing accuracy

Distributor support required

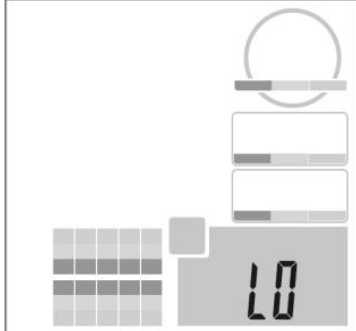
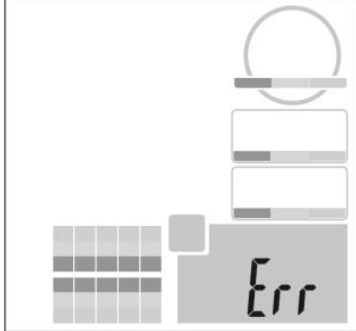



If the following errors occur, we recommend contacting your local Charder distributor for repair or replacement services:

1. Device will not power on

- Broken or damaged wires causing short circuit or faulty connection
- Safety fuse burnout
- Faulty adapter

2. Indicator damage

- Possible hardware defects include: uneven brightness in LCD screen, blurred text, smeared rainbow screen, incorrect decimal display
- Unable to save or read data

Error Message	Reason	Action
	<p>Low battery warning Voltage of battery is too low to operate device</p>	<p>Replace batteries, or plug in adapter</p>
	<p>Overload Total load exceeds device's maximum capacity</p>	<p>Reduce weight on measurement platform and try again</p>
	<p>Program Error</p>	<p>Please restart device (unplug adapter and remove batteries). If problem persists, please contact distributor</p>
	<p>Result exceeds allowed range</p>	<p>Remove all objects from platform, wipe electrodes clean with cloth, and try again after restarting. If problem persists, please contact distributor</p>
	<p>Result exceeds allowed range</p>	<p>Remove all objects from platform, wipe electrodes clean with cloth, and try again after restarting. If problem persists, please contact distributor</p>

X. Product Specifications

A. Device Information

Model Number	U310/B310
Measurement Method	Segmental Multi-frequency Bioelectrical Impedance Analysis
Method	8 touch electrodes
Frequency Type	Dual
Frequencies	5 kHz , 50 kHz
Indicator	87.5*90mm LCD screen
Capacity	200kg
Graduation	0-100 kg / 0.05 kg ; 100-200 kg / 0.1 kg
Applicable age	6~ 85 years old
Input device	App
Data transfer	Wireless
Dimensions	About 385 (L) x 350 (W) x 51 (H) mm
Device weight	About 2.2kg
Electrode current	< 500 μ A
Power supply	Batteries: AA (1.5V)*4 or Power Adapter UE24WCP1-120100SPA Input: 100-240V~50/60Hz , 800mA Output : DC12V , 1A adapter <small>*Manufacturer's adapter must be used with device</small>
Operation environment	5 ~ 35 $^{\circ}$ C , 35 ~ 85% RH
Storage environment	-20 $^{\circ}$ C~60 $^{\circ}$ C , 25% ~ 95 % RH

B. Measurement Results

Displayed on app	<p>Body Composition Analysis Weight, BMI (Body Mass Index), Visceral Fat Level (VIS/VFA), Percent Body Fat (PBF), Body Fat Mass (BFM), Skeletal Muscle Mass (SMM), Soft Lean Mass/Muscle Mass (SLM), Body Water (TBW), Body Age (BA), Basal Metabolic Rate (BMR), Bone Mineral Mass</p> <p>Segmental Muscle/Fat and Body Type Analysis Soft Lean Mass/Muscle Mass (Right Arm, Left Arm, Trunk, Right Leg, Left Leg) Fat Mass (Right Arm, Left Arm, Trunk, Right Leg, Left Leg) Body Type Analysis History: Weight, Percent Body Fat, Skeletal Muscle Mass, Body Water</p> <p>Analysis Modules Weight, Fat, Muscle, Water, Body Type</p> <p>This product is not a medical device Results should be used for reference only</p>
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Manufacturer's Declaration of Conformity

This product has been manufactured in accordance with the harmonized EU standards, following the provisions of the below stated directives:

Electromagnetic Compatibility Directive 2014/30/EU
Electromagnetic Compatibility Regulations 2016

RoHS Directive 2011/65/EU and Delegated Directive (EU) 2015/863



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