

Body Composition Analyzer

USER MANUAL MBF6000 / MBF6010

Body Composition Analyzer



Please keep the instruction manual at hand and follow instruction for use.

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I. Explanation of Graphic Symbols on Label/Packaging

| Text/Symbol | Meaning | | |
|-----------------|---|--|--|
| \triangle | Caution, consult accompanying documents before use | | |
| X | 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. | | |
| <u> </u> | Medical electrical device, Type B applied part | | |
| † | Medical electrical device, Type BF applied part | | |
| REF | Device catalogue number / model number | | |
| EC REP | Name and address of authorized representative in the European Union | | |
| MD | Device is a medical device. Text indicates device category type | | |
| LOT | Manufacturer's batch or lot number for device | | |
| SN | Device's serial number | | |
| UDI | Device's Unique Device Identifier | | |
| е | Verification Scale Interval. Value expressed in units of mass. Used to classification and verification of an instrument. | | |
| C € 2460 | Device conforms to (EU) 2017/745 Regulation on Medical Devices. Fourdigit number is identifier for medical device Notified Body | | |

| C€ M200122 | Device complies with EC directives (verified models only) M: Conformity label in compliance with Directive 2014/31/EU for non-automatic weighing instruments 20: Year in which conformity verification was performed and the CE label was applied. (ex: 16=2016) 0122: Identifier for metrology Notified Body |
|-------------------------------|--|
| | Device is a Class III scale in compliance with Directive 2014/31/EU (verified models only) |
| | Name and address of entity importing device (if applicable) |
| °≯Ž | Name and address of entity responsible for translating Information For Use (if applicable) |
| CON. | Event counter confirming how many times device has been calibrated (if applicable) |
| | Device conforms to Taiwan National Communications Commission(NCC) approval |
| Æ | Device conforms to U.S. Federal Communications Commission regulations |
| 변 <u>M 20</u> 8506 | Device complies with UK non-automatic weighing instruments regulations 2016 (verified models only) M: Conformity label in compliance with Non-automatic Weighing instruments Regulations 2016 20: Year in which conformity verification was performed and the UKCA label was applied. (ex: 20=2020) 8506:Identifier for metrology approved body |
| UK | Device complies with all UK applicable product legislation |
| $\bigcirc - \bullet - \oplus$ | Device's polarity of power. |

"In case of differences, icon on device itself takes precedence"

II. Copyright Notice

Copyright Notice Charder Electronic Co., Ltd.

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

III. Safety Notes

A.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 medical device is designed to estimate body composition in professional settings in accordance with national regulations. The device measures the patient's weight and bioelectrical impedance measurements using foot touch electrodes, combining them with input data (ex: age, gender, height) to estimate:

Body Fat Percentage (BF %), Fat-Free Mass (FFM), Fat Mass (FM), Bone Mineral (BM), Muscle Mass (MM), Basal Metabolic Rate (BMR), Total Body Water (TBW), Protein Mass (PM), Intracellular Water (ICW), Extracellular Water (ECW), Skeletal Muscle (SM), Health Score, Visceral Fat Area Level (VFALEVEL), Metabolic Age (AGEM)

The device is not a diagnostic device. Results should be used as part of a broader comprehensive assessment.

Clinical Benefit

The device is used for body measurement/estimation. The measurement results can be used in such a wide variety of applications that it may not be practical or beneficial to narrowly define the associated clinical benefits of receiving such results. Therefore, the benefit of the device is that it is able to perform its intended (measurement/estimation) function. A list of potential applications for key measurement outputs includes but is not limited to:

| Result Category | Example Application |
|--------------------|--|
| Fat | Obesity: evaluating risk of obesity-related diseases |
| Water | Peritoneal Dialysis: assessment of change in water balance before and after treatment |
| Muscle | Sarcopenia: evaluating muscle mass and effectiveness to identify malnutrition or training/rehabilitation needs |
| Metabolism | Nutrition: determining suitable level of daily caloric consumption based on goals and projected expenditure |

Intended medical indications/contraindications

Measurement: patient's body composition and body weight.

Contraindications

Measurement should not be conducted on patients with electronic medical implants (ex: cardiac pacemakers)

Intended patient profile

(a) Age: 10-80

(b) Weight: within 300 kg

(c) Patient Conditions: require measurement of body weight and body composition. Able to stand independently without support.

Intended user profile

- (a) At least 20 years old
- (b) Minimum knowledge:
 - To be able to read at a high-school level and understand Arabic numerals (e.g. 1, 2, 3, 4...)
 - Basic hygiene knowledge
 - Trained in device's operation
 - Read the instruction manual
- (c) Language
 - Able to read the language of instruction manual and onscreen instructions
- (d) Qualifications
 - No special certifications or qualifications required

Residual Risk Evaluation

- (a) All foreseeable risks have been evaluated and considered acceptable. Generally speaking, the most likely risk caused by incorrect usage of the device is less accurate measurement (or inability to use device to acquire measurement), which does not pose imminent physical risk to patient or user.
- (b) Benefit-risk ratio is considered acceptable. Body composition analyzers are an important option for measuring patients. Usage of device is unlikely to result in harm to user or patient.

General Handling

- Ensure all parts are properly locked and tightened before operating the device.
- Measurement accuracy requires the subject's feet, back, and head to be straightly aligned. Please note that height can vary throughout the day
- **CAUTION**: Do not use next to equipment that may cause electromagnetic or other types of interference.

Safety Instructions

Before putting device into use, please read this user manual carefully. It contains important instructions for installation, usage, and maintenance of device.

The manufacturer shall not be liable for damages caused by failure to heed the following instructions:

- The device has an expected service life of 5 years when correctly handled, serviced, and periodically inspected in accordance with manufacturer's instructions.
- Improper installation will render the warranty null and void.
- Observe permissible ambient temperatures for use

Cleaning

Device surface should be cleaned using alcohol-based wipes.

Maintenance

Please contact your local Charder distributor for regular maintenance and calibration, regular checking of accuracy is recommended; frequency to be determined by level of use and state of device.

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, unless damage is attributable to negligence on the part of Charder.
- This device does not contain any user-maintained parts. All maintenance, technicalinspections, 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. Dismantlement of the device will void the warranty.

Incident Reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer, EU representative (if device is used in EU member state), and competent authority of user/subject's member state.

B. EMC Guidance and Manufacturer's Declaration

Guidance and manufacturer's declaration-electromagnetic emissions

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

| Emission test | Compliance | Electromagnetic environment-guidance |
|--|------------|---|
| RF emissions CISPR 11 | Group 1 | The product uses RFenergy 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 |
| Harmonic emissions IEC 61000-3-2 | Class A | than domesticand those directly connected to a low voltage power supply network which supplies buildings used |
| Voltage fluctuations /flicker emissions IEC 61000-3-3 | Compliance | for domestic purposes. |

Guidance and manufacturer's declaration-electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product 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 | | ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 | ± 2kV for power supply lines | ± 2kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1kV line(s) to line(s) ± 2kV line(s) to earth | ± 1kV line(s) to line(s) ± 2kV line(s) to earth | 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 | 0% UT for 0,5 cycle 0% UT for 1 cycle 70% UT(30% dip in UT) for 25cycles 0% UT for 5 s | 0% UT for 0,5 cycle 0% UT for 1 cycle 70% UT(30% dip in UT) for 25cycles 0% UT for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from anuninterruptible power supply or a battery. |
| Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | The product power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospitalenvironment. |

Guidance and manufacturer's declaration-electromagnetic immunity

Theproduct is intended for use in the electromagnetic environment specified below.

The customer or the user of the product should assure that is used in such and 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 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz | 3 Vrms 150 KHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of the product including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| Radiated RF IEC 61000-4-3 | 3 V/m 80MHz to 2,7 GHz | 3 V/m 80MHz to 2,7 GHz | Recommended separation distance: $d = 1,2 \sqrt{p}$ $d = 1,2 \sqrt{p}$ 80MHz to 800 MHz $d = 2,3 \sqrt{p}$ 800MHz to 2,7GHz 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: |

NOTE1 At 80 MHz and 800 MHz, the higher frequency rangeapplies.

NOTE2

Theseguidelinesmaynotapplyinallsituations. 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, amateurradio, AMandFMradiobroadcastandTVbroadcastcannotbepredictedtheoretically withaccuracy. 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 product is used exceeds the applicable RF compliance level above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distance between portable and mobile RF communications equipment and the product

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

| Rated maximum output power of | Separation distance according to frequency of transmitter m | | |
|-------------------------------|---|-------------------------------------|--------------------------------------|
| transmitter W | 150 kHz to 80 MHz d =1,2√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.

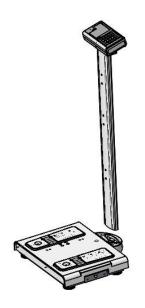
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

IV. Installation

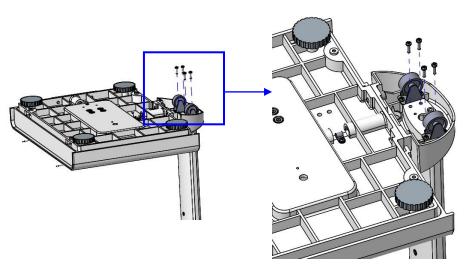
A. Assembly (MBF6010 only)

1. Remove base and column from box

NOTE: remove entire device (column + platform) from box at the same time. Do not lift column by itself, as this may damage wire connecting measurement platform to indicator.

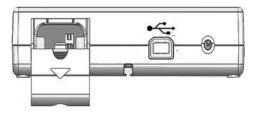


2. Fasten and tighten four screws at the bottom of the base



B. Inserting Batteries

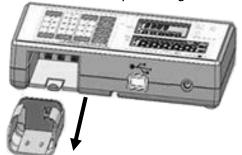
1. Open battery housing cover



2. Push down tab securing battery housing



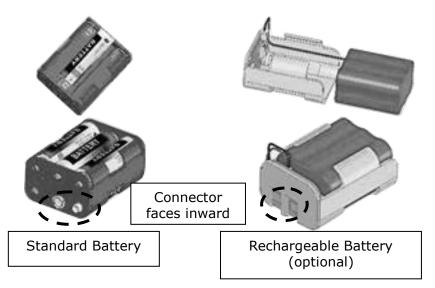
3. Remove battery housing



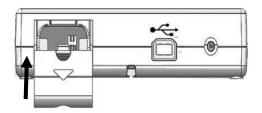
4. Insert battery pack



NOTE: Ensure that batteries are installed into housing correctly

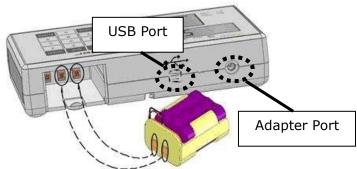


5. Slide battery housing cover back in place. Turn on power to confirm that battery is correctly installed.



C. Using Adapter

- 1. Connect adapter to indicator before connecting to mains power supply
- 2. Disconnect adapter from mains power supply before unplugging adapter pin from indicator.



C. Using Rechargeable Battery (optional)

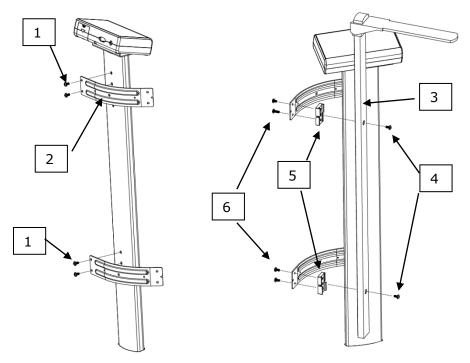
To charge the rechargeable battery, plug in the device's power adapter.

The rechargeable battery should be recharged at least once every 3 months, regardless of if the device has been used.

After a long period in storage (e.g. >3 months), the battery should run a full cycle (charge/discharge) to allow it to restore full capacity.

If prompt displays on the LCD, please charge battery promptly to avoid battery damage.

D. Attaching Height Stadiometer to MBF6010 Column

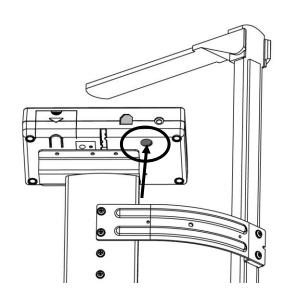


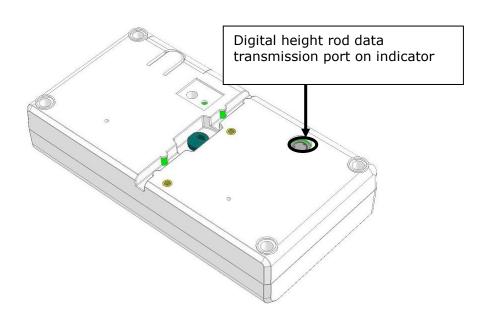
1. Attach brackets to column with round-head screws

2. Attach height rod to brackets using flat-head screws

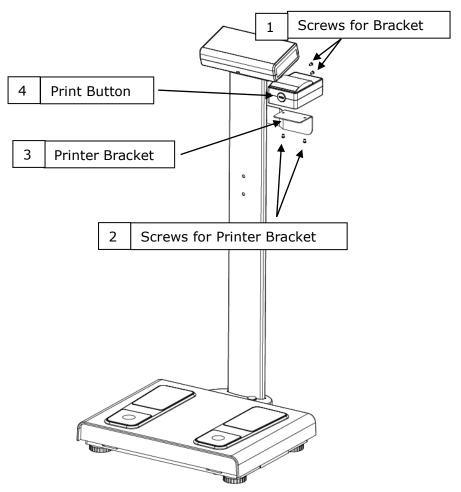
| Item | Name | Quantity |
|------|--|----------|
| 1 | M5x0.8x11 round head screw | 4 |
| 2 | Bracket for HM200D/HM201D/HM201M | 2 |
| 3 | Height Rod (Compatible with: HM200D/HM201D/HM201M) | 1 |
| 4 | M5x10L flat head screw | 2 |
| 5 | Fixing block | 2 |
| 6 | M5x0.8x11 | 4 |

Connecting Digital Height Stadiometer to Indicator (HM200D/HM201D)



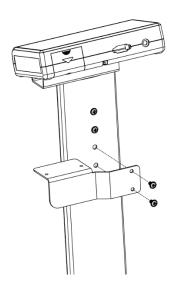


E. Attaching Thermal Printer to MBF6010 Column

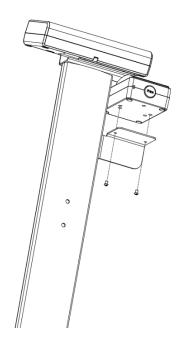


| Item | Parts | Qty |
|------|---------------------------------|--------------------------|
| 1 | M5*15L head screw | 2 |
| 2 | M4*6 Screws for printer bracket | 2 |
| 3 | Printer bracket | 1 |
| 4 | TP2100/TP2110 Thermal Printer | 1 (purchased separately) |

1. Install the side bracket

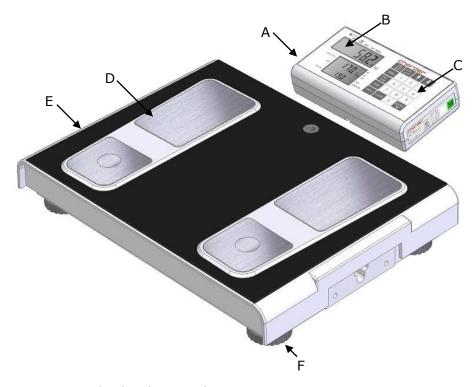


2. Install the thermal printer on the bracket



V. Exterior and Panel

A. Quick Guide to components



A: Remote display (DP3710)

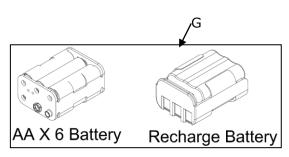
B: Digital LCD

C: Keypad

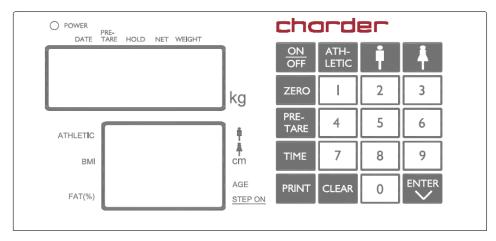
D: Foot Electrodes

E: Measurement Platform

F: Adjustable feet G: Battery Type



B. Indicator and Key Functions



Key Function

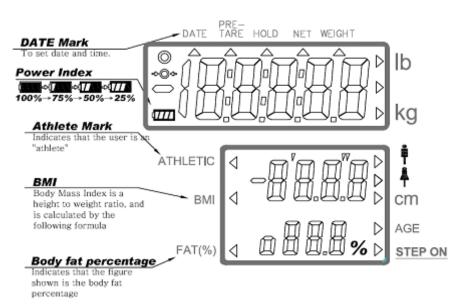
- 1. ON/OFF: Power on or power off.
- 2. ZERO: Reset display to 0.0 kg display. Press and hold for 3 seconds to enter device settings.
- 3. PRE-TARE: Pre-tare the known weight of an object (ex: clothing) before beginning measurement.
- 4. TIME: Set time and date.
- 5. CLEAR: Clear incorrect data input.
- 6. PRINT: When printer or PC is connected to the scale, press this key to print results
- 7. ENTER: Confirm input
- 8. 0-9: For entering digits.
- 9. BODY TYPE:
 - : Male : Female ATH-LETIC : Athletic

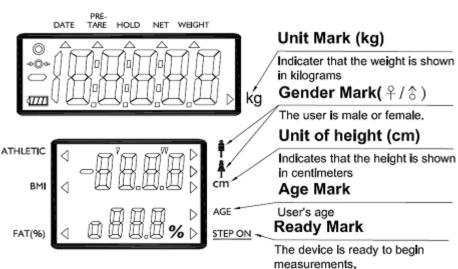
NOTE: selecting appropriate body type

The "Athletic" setting is recommended for subjects that regularly perform

intense physical activity for at least 10 hours per week (or have previously maintained such a habit for an extended period of time), with a resting heart rate of approximately 60 beats per minute or less.

C. Display layout

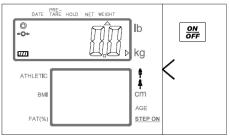




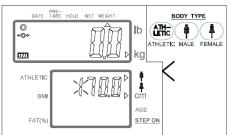
VI. Using Device

A. Setup Device for Measurement

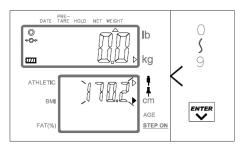
To conduct a Body Composition Analysis using the MBF6000/MBF6010, the subject's height, age, and gender needs to be input prior to measurement.



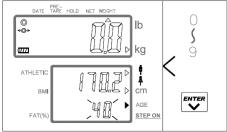
1. Press the key. "0.0" will appear on the upper portion of the display.



2. Select the body type from standard male, standard female, and athletic.Press to enter setting mode.

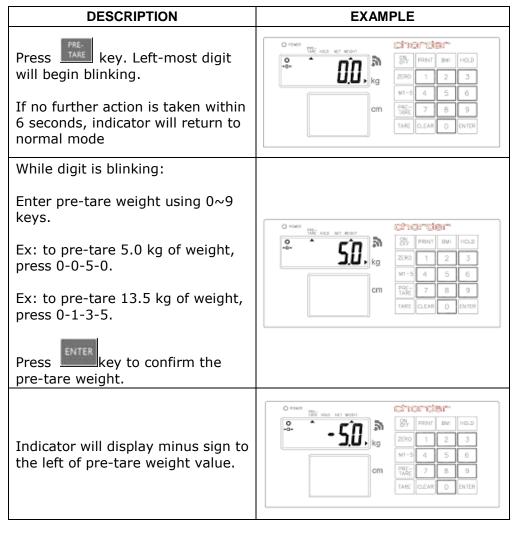


3. Use keypad to enter the subject's height and age when prompted.



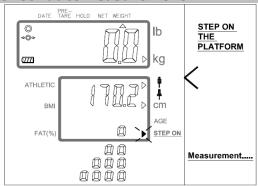
B. Pre-Tare

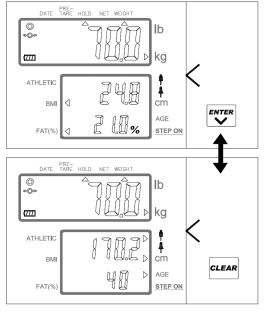
The Pre-Tare function is used to subtract the known weight of a substance prior to weighing.



NOTE: Pre-tare weight must be under max capacity, otherwise screen will show 0.00 after key is pressed, and the operator will have to re-input pre-tare settings.

C. Conduct Measurement

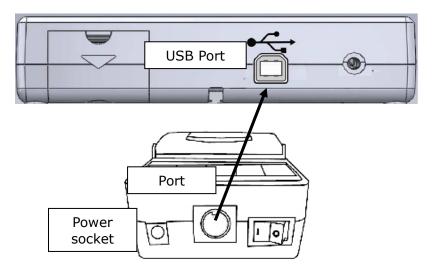




- When subject's data (gender, height, age) has been input, indicator will display a flashing arrow next to STEP ON when ready.
- Instruct subject to step on the four electrodes of platform with bare feet. Subject should stand in a stable position without bending your knees.
- 3. After subject has stepped onto weighing platform, weight will be displayed on the LCD. will appear at the bottom of the display, and the impedance measurement will begin. The marks will disappear one by one during the measurement; after three full cycles, the measurement will be complete.
 - to delete the data, and return to Step 1.

D. Print

If thermal printer is connected to indicator, results can be printed by pressing key.



NOTE: Thermal printer needs to be powered by adapter

E. Measurement Results Explained

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/m²) | 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)

FAT% (Body Fat Percentage)

Body fat percentage is useful in determining the specific cause of weight loss or gain. Averagepercentages 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.

FM (Body Fat Mass)

An essential level of fat is required for the body to function, though excessive fat can result in obesity-related diseases.

FFM (Fat-Free Mass)

Fat-Free Mass is the weight of the body after deducting total fat mass. In other words, FFM is the weight of everything except body fat.

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

| Charder | | |
|------------|-----------|--|
| MBF-6000 | | |
| 31/03/2009 | 14:55 | |
| | | |
| BODY TYPE | STANDARD | |
| GENDER | MALE | |
| AGE | 40 | |
| HEIGHT | 170.2 cm | |
| PRE-TARE | 0.0 kg | |
| NET WEIGHT | 70.0 kg | |
| ВМІ | 24.7 | |
| FAT% | 21.0 % | |
| FM | 14.7 kg | |
| FFM | 55.3 kg | |
| BMR | 1660 kcal | |
| TBW | 40.6 kg | |
| IMPEDANCE | 402.2ohm | |
| | | |

(Simplified sample print-out for reference only)

growth, brain function, and nerve function. BMR tends to decrease with age or reduction in weight, and is positively correlated with increase in muscle.

TBW (Total 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 drink¹. Due to larger size and muscle mass, healthy adult men have more TBW than women (on average)².

For healthy (non-obese) adults, TBW constitutes ~60% of body weight and ~73% of Fat-Free Mass³. 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 process⁴. In addition, various diseases can affect body water percentage, including renal deficiency diabetes, cardiac failure, and cancer⁵. 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.

TBW can be divided into Intracellular Water (ICW) and Extracellular Water (ECW). ICW:ECW proportion for healthy populations is roughly 3:2 $(ECW/TBW = \sim 0.38)^6$.

BM (Bone Mineral content)

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

MM (Muscle Mass)

1

¹ Askew EW Present Knowledge in Nutrition (7th ed) 1996, p.98-107

² 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.

³ 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.

⁴ 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

⁵ Moore FD, Haley HB, Bering EA, Brooks L, Edelman I. Further observations on total body water. Changes of body composition in disease. 1952. Surg GynecolObstet, 95, p.155-180
⁶ Tai R, Ohashi Y, Mizuiuri S, Aikawa A, Saki K. Association between ratio of measured extracellular volume to expected body fluid volume and renal outcomes in patients with chronic kidney disease: a retrospective single-center cohort study. BMC Nephrology, 2014;15:189

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

PM (Protein Mass)

The total amount of protein in the body.

SM (Skeletal Muscle)

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

HS (Health Score)

The overall health score is calculated using the body composition readings. It works on a percentage basis, with 100 being the highest possible score attainable.

VFA (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 inside⁷. Visceral fat level has high correlation with risk of a variety of obesity-related diseases, including cardiovascular diseases and Type-2 diabetes⁸⁹.

AGEM (Metabolic Age)

The subject's Basal Metabolic Rate is compared to average BMR for his/her age and gender group.

⁷Dudeja V, Misra A, Pandey RM, Devina G, Kumar G, Vikram NK. BMI does not accurately preduct overweight in Asian Indians in northern India. Br J Nutr. 2001;86:105-112

⁸ 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.

⁹ Klein S. The case of visceral fat: argument for the defense. J Clin Invest. 2004:113(11):1530-1531

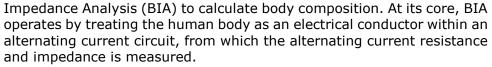
IMPEDANCE

In the conventional 4-electrode foot-to-foot BIA method, current is supplied from the electrodes at the tips of the toes on both feet, with the voltage measured on the heel. This current flows from one lower limb through the lower abdomen and then into the other lower limb, and the bioelectrical impedance is measured. For reference, the impedance measurement methods for the legs are shown in the diagram.

The MBF-6000/6010 measures impedance at 50kHz to calculate body composition results.



The MBF6000/MBF6010 uses Bioelectrical



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 al¹⁰. 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

¹⁰ Kushner RF, Clinical characteristics influencing bioelectrical impedance analysis measurements, 1996

in body compositionmeasurements. As BIA analyzes electrical impedance in the body, activities that might affectimpedance (e.g. increased perspiration, dehydration, blood circulation) may affectmeasurement 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)¹¹.

3. Do not shower or bathe directly before measurement.

Perspiration can result in a temporary change in body composition measurements, as theaccuracy of BIA depends largely upon interpretation of measured impedance values, whichare 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. Forexample, 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 insome cases, impossible.

6. Avoid physical contact with other people during measurement.

Because BIA measures the impedance encountered as the electric current travels throughthe 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.

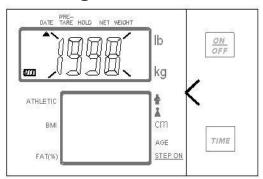
As a general rule, BIA measurements should be performed in the morning

¹¹ R Gallagher, M & Walker, Karen & O'Dea, K. The influence of a breakfast meal on the assessment of body compositionusing bioelectrical impedance. European journal of clinical nutrition. 52. 94-7.

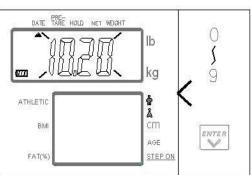
to minimize theinfluence of activity throughout the day on measurements¹².

VII. Device Setup

A. Setting Time & Date



- 1. Press key to power on the device.
- 2. Press key once.
- The date input screen will appear. The upper row of numbers represents years (YYYY).

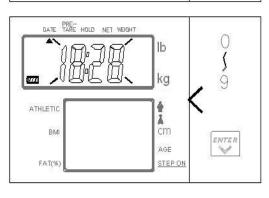


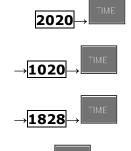
4. Input year in the flashing space.

Press

to enter the date.

Example: To input 2020, Oct 20, 6:28pm, press the following keys in order:





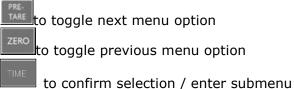
5. Press key. The date and time are set, and the clock function is running. The display will now return to the step prior to entering this mode.

¹²Oshima 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

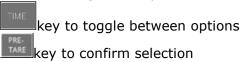
B. Device Setup

key for about 3 When the device is switched on, press and hold the seconds, until the display shows the "SETUP", followed by "A.OFF" (first option in setting menu).

In device setup menu:



After selecting menu option:



Auto Power-Off: Instruct device to shut off automatically after a certain period of time.

Auto off options: 120 sec / 180 sec / 240 sec / 300 sec / off

Ito toggle, and lacksquarekey to confirm selection.



Buzzer/Beep:

When function is turned on, beeping noise will be made when: indicator is turned on, keys are pressed, and weight is stable.

to toggle on/off, and 🍱 kev to confirm selection.



Language: Set thermal printer language

Press to toggle between English and Polish. Press key to confirm selection.



BT / Wifi (optional): If device has BT or Wifi module installed,the function can be turned OFF/BT/Wifi.

Press [HOLD] to toggle between OFF/BT/Wifi, and [TARE] to confirm selection.

BPSEŁ

Wi-Fi Setting (optional): If device has Wi-Fi module installed, this option will appear.

Press to toggle between "Auto" and "PKEY". Press to confirm selection.

If "Auto" is selected, weight measurement will be automatically sent to connected printer or device. If "PKEY" is selected, transfer will occur

manually only after key is pressed.

Save Changes

After completing changes, press until "END" is displayed on screen.

Press to save.

VIII. Connecting scale to receiving device

The device can transfer results to receiving device. Please consult instruction manual for receiving device.

Connection directly to Electronic Medical System should be conducted by qualified distributors/administrators only.

NOTE: Wireless transfer is only available on wireless model.

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 "0000" ZERO SPAN out of range

- Interference due to factors such as RF disturbance or ground vibration. Relocate device to location without interference and try again
- Unstable platform feet adjust platform feet according to bubble level indication (clockwise to retract, counter-clockwise to extend) 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

3. Connection failure for data transmission to PC or printer

 Ensure wires are connected correctly between indicator and PC or printer ■ Ensure printer is supplied with power. Ensure PC software is set up properly as indicated in this manual

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

- Faulty on/off key
- 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
- Indicator shows "ERRL" after device is switched on
- Keys not responding
- Buzzer malfunction

Error Messages

| Error Message | Reason | Action |
|---------------|---|---|
| Lo | Low battery warning Voltage of battery is too low to operate device | Replace batteries, or plug in adapter |
| Err | Overload Total load exceeds device's maximum capacity | Reduce weight on measurement platform and try again |
| Err.H | Counting Error (too high) Signal from loadcells too high | Error normally caused by faulty loadcell or wiring. Please contact distributor |
| Err.L | Counting Error (too low) Signal from loadcells too low | Error normally caused by faulty loadcell or wiring. Please contact distributor |
| 00000 | Zero count over calibration zero range +10% while power on | Re-calibration required. Please contact distributor |

| 00000 | Zero count under calibration zero range -10% while power on | Re-calibration required. Please contact distributor |
|--------|---|--|
| Err.P | Program Error Fault with device software | Please contact distributor |
| Err.Ad | Program Error Fault with device software | Please contact distributor |
| Err-1 | Impedance Error Impedance exceeds measurement limits | Try measurement again. Contact distributor if problem persists |
| Err-2 | Impedance Error Impedance cannot be measured | Try measurement again. Contact distributor if problem persists |
| Err-3 | Result Error Calculated results are invalid | Try measurement again. Contact distributor if problem persists |
| Err-4 | Impedance Error Impedance exceeds measurement limits | Try measurement again. Contact distributor if problem persists |

X. Product Specifications

A. Device Information

| Model | | MBF6000 / MBF6010 | |
|--------------------------|------------------|---|--|
| | Capacity | 300kg x 0.1kg | |
| | Accuracy | Weight Measurement Accuracy ±1.5e | |
| Weight | Weight Unit | kg (OIML), kg / lb (CE model) | |
| Measurement | LCD Screen | 0.8-inch LCD screen (Three row LCD) | |
| | Key Functions | On/Off, Zero, Pre-Tare, Body Type, 0~9, Clear, Enter, Time, Print | |
| | System | 4-electrode Bioelectrical Impedance Analysis | |
| | Accuracy | Impedance Measurement accuracy± 3% | |
| Impedance Measurement | Current | 50kHz 500uA | |
| riedsul ellielle | Style | Left leg-Right leg Foot-to-foot | |
| | MeasurementRange | 200 ~ 1000Ω / 0.1Ω | |
| | Gender | Male / Female | |
| | Body Type | Standard / Athletic | |
| Input Items | Age | 10 ~80 years old | |
| | Height | 60 ~ 210cm / 3ft ~ 7ft11.0in | |
| | Overall | 450(W) x 450(D) x 970(H) mm | |
| Dimensions | Platform | 450(W) X 340(D) X 90(H) mm | |
| | Column | (MBF6010 only) 850 mm | |
| Device Weight | | (MBF6000) 8.6 kg (MBF6010) 10.2 kg | |
| Data Transmission | | USB, Wireless Module (optional) NOTE: Device should be connected to network by qualified distributors only | |
| Power Supply | | 7.2V 2000mA rechargeable battery or 6 AA batteries / adapter | |

| Operation Environment | 0°C~+40°C 30% / 80% RH, | |
|-----------------------|-------------------------|--|
| | 700 hPa ~1060 hPa | |
| Standard Accessories | User manual*1,Power | |
| | Adapter*1, USB cable*1 | |
| Optional Accessories | Thermal Printer, | |
| Optional Accessories | HeightStadiometer | |

B. Output Items (Display and Print-out)

| MODEL | | MBF6000 / MBF6010 | |
|-----------------|----------------------|--|--|
| Serial Number | | C12345678 (example) | |
| Date/Time | | DD/MM/YYYY hh:mm EX: 30/10/2020 10:55 | |
| | Body Type | Standard / Athletic | |
| | Gender | Male / Female | |
| Age | | 10 ~ 80 years old / 1 year increments | |
| | Height | 60 ~ 210cm / 3ft ~ 7ft11.0in | |
| F | Preset Tare | 0 ~ 299 kg | |
| ľ | Net Weight | 0 ~ 300 kg | |
| ВМІ | Body Mass Index | 0.1 increments | |
| BF % | Body Fat Percentage | 5 ~ 50% / 0.1% increments | |
| FFM | Fat-Free Mass | 0.1kg increments | |
| FM | Fat Mass | 0.1kg increments | |
| ВМ | Bone Mineral | 0.1kg increments | |
| ММ | Muscle Mass | 0.1kg increments | |
| BMR | Basal Metabolic Rate | 1 kcal increments | |
| TBW | Total Body Water | 0.1L increments | |
| PM | Protein Mass | 0.1kg increments | |
| ICW | Intracellular Water | 0.1L increments | |
| ECW | Extracellular Water | 0.1L increments | |
| SM | Skeletal Muscle | 0.1kg increments | |
| HEALTH SCORE | | XX.X score | |
| VFALEVEL | Visceral Fat Level | Visceral Fat Level | |
| AGEM | Metabolic Age | XX.X | |
| IMPEDANCE | | XXX.X ohm | |

C. Power Adapter Standards



The device is only compatible with the power adapters specified in the dashed block below.

| Amp Voltage | Drawing No. | CE Approved Type No./Model No. | Туре | |
|----------------|-------------|-----------------------------------|------|-------------|
| | CD-AD-00041 | UES24LCP-120200SPA | US | |
| 40) (0.4 | CD-AD-00041 | UES24LCP-120200SPA | EU | |
| 12V 2A | CD-AD-00041 | UES24LCP-120200SPA | UK | 90 - degree |
| | CD-AD-00041 | UES24LCP-120200SPA | AU | |

| N | Notes | |
|---|-------|--|
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XI. Declaration of Conformity

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

| C € 2460 | (EU) 2017/745 Regulation on Medical Devices |
|-------------------|--|
| C € M year | 2014/31/EU Non-automatic Weighing Instruments Directive (OIML models only) |

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

Radio Equipment Directive 2014/53/EU

(applicable if wireless module is used)

Part 15 of the Federal Communications Statement Rules

This device may not cause harmful interference.

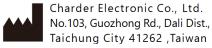
This device must accept any interference received, including interference that may cause undesired operation.

Please see separate document showing on sticker of device for above markings.

Authorized EU Representative:



Manufactured by:



CD-IN-1256 14202R 08/2024