charder®

# Height measurement

## USER MANUAL
## HM200U
Ultrasonic Stadiometer



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

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## Explanation of Text/Symbols on Device Label/Packaging

| Text/Symbol | Meaning |
|---|---|
|  | Caution. Failure to follow instructions may result in adverse events |
|  | 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 |
|  | Carefully read user manual before installation and usage, and follow instructions for use. |
|  | Medical electrical device, Type B applied part |
|  | Medical electrical device, Type BF applied part |
| REF | Device catalogue number |
| EU REP | Name and address of authorized representative in the European Union (applicable for medical devices only) |
| 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 |
| # | Device’s model number |
| UDI | Device's Unique Device Identifier<br>(01) GTIN (11) Production date (21) Serial number |
| e | Value in mass units (verified models only). This is the difference between two consecutive display values, used to classify and verify a scale |
| CE 2460 | Device conforms to (EU) 2017/745 Regulation on Medical Devices. Fourdigit number is identifier for medical device Notified Body |

| | |
|---|---|
| CE | Device conforms to (EU) 2017/745 Regulation on Medical Devices. Four digit number is identifier for medical device Notified Body. |
| CE M 20 0122 | Device complies with EU directives (verified models only)<br><br>**M**: Conformity label in compliance with Directive 2014/31/EU for non-automatic weighing instruments<br>**20**: Year in which conformity verification was performed and the CE label was applied. (ex: 20=2020)<br>**0122**: Identifier for metrology Notified Body |
| III | Device is a Class III scale in compliance with Directive 2014/31/EU |
| | Name and address of entity importing device |
| | Name and address of entity responsible for translating Information For Use |
| CON. | Event counter recording how many times protected-mode parameter adjustments relating to metrology-related characteristics (ex: gravity value) have been conducted for device |
| | Device has received Taiwan NCC approval |
| FC | Device conforms to U.S. Federal Communications Commission regulations |
| UK CA | Device complies with all UK applicable product legislation |
| ⊖—◉—⊕ | Device's polarity of power. |

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

# Copyright Notice

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

# 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 be used in accordance with national regulations, to measure height within specifications, for height-related usage by professionals.

**Clinical Benefit**
Measurement results can be used by professionals to diagnose (and monitor) height-related issues.

**Intended medical indications/contraindications**
Measurement: subject's body height.

**Intended patient profile**
(a) Age: no restrictions
(b) Weight: no restrictions
(c) Patient Conditions: require measurement of body height. Can physically fit within device capacity limits and be able to stand straight (non-infant versions only).

**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 on-screen 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. Height measurement meters 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.
- **CAUTION**: Do not use next to equipment that may cause electromagnetic or other types of interference.

**Safety Instructions**

- The device has an expected service life of 5 years when correctly handled, serviced, and periodically inspected in accordance with manufacturer's instructions.

**Cleaning**

- Device surface should be cleaned using alcohol-based wipes. Corrosive cleansing liquids should not be used.

**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.

**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.

**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.

# 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<br>CISPR 11 | Group 1 | The product 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<br>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. |
| Harmonic emissions<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations /flicker emissions IEC 61000-3-3 | Compliance | |

| 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<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air | ±8 kV contact<br>±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)<br>± 2kV line(s) to earth | ± 1kV line(s) to line(s)<br>± 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<br>0% UT for 1 cycle<br><br>70% UT(30% dip in UT) for 25cycles<br><br>0% UT for 5 s | 0% UT for 0,5 cycle<br>0% UT for 1 cycle<br><br>70% UT(30% dip in UT) for 25cycles<br><br>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 an uninterruptible 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 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 product is intended for use in the electromagnetic environment specified below.<br><br>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<br>RF IEC<br>61000-4-6 | 3 Vrms<br>150 KHz to 80 MHz<br><br>6 V in ISM bands between 0,15 MHz and<br>80 MHz<br>80 % AM at 1 kHz | 3 Vrms<br>150 KHz to 80 MHz<br><br>6 V in ISM bands between 0,15 MHz and<br>80 MHz<br>80 % AM at 1 kHz | 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<br>RF IEC<br>61000-4-3 | 3 V/m<br>80MHz to 2,7 GHz | 3 V/m<br>80MHz to 2,7 GHz | **Recommended separation distance:**<br>$d = 1,2\sqrt{P}$<br>$d = 1,2\sqrt{P}$ 80MHz to 800 MHz $d = 2,3\sqrt{P}$ 800MHz to 2,7GHz<br>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 range applies.<br>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 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 prevent electromagnetic 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 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.

## Assembly

### ■ Parts



Ultrasonic Height Stadiometer Rod A

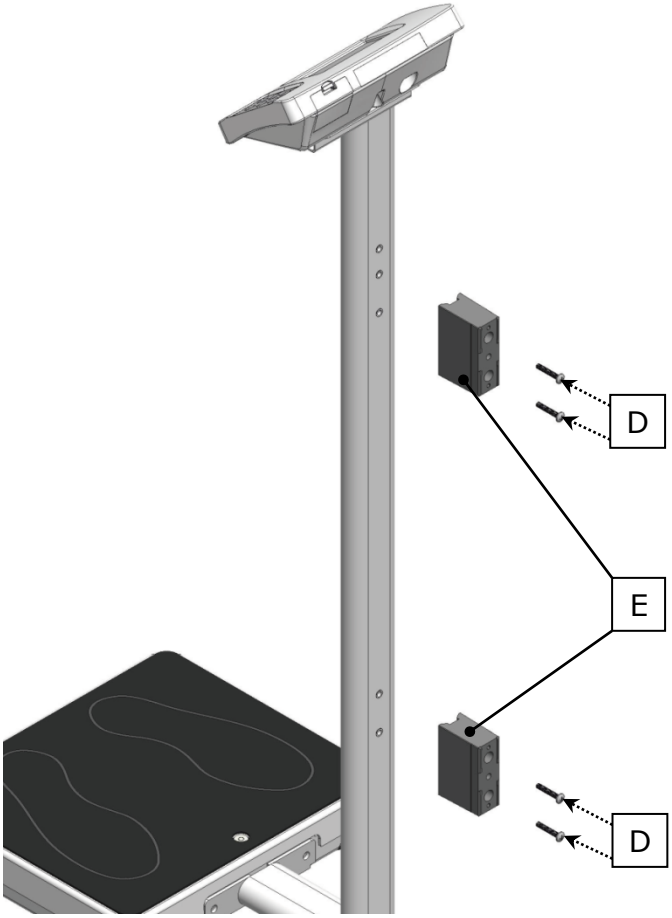


Ultrasonic Height Stadiometer Rod B

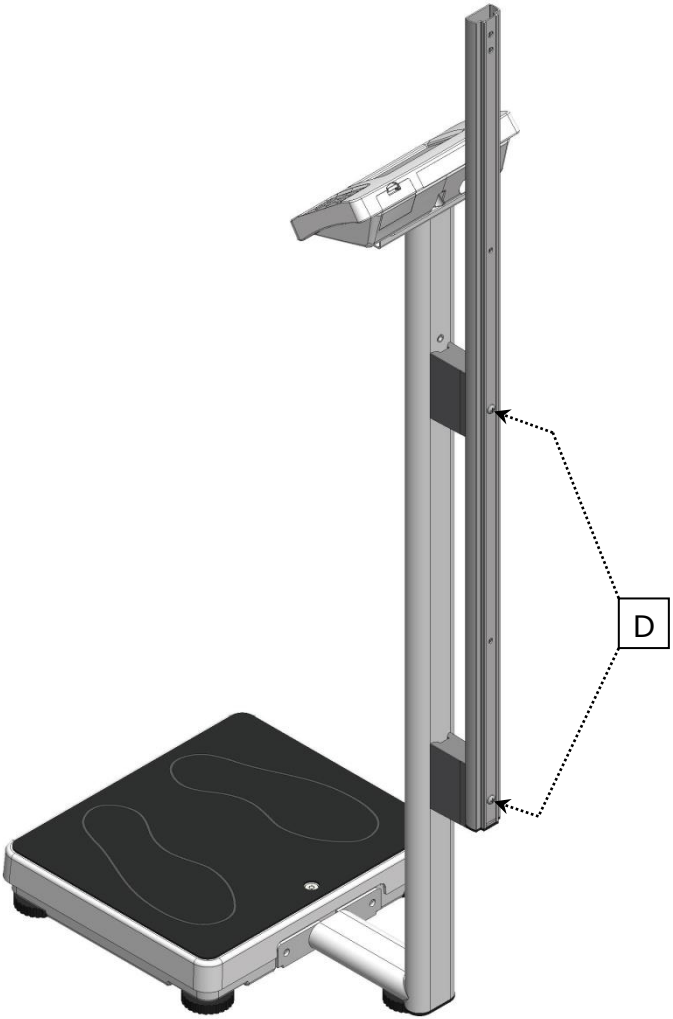
| Parts No. | Included Parts Name | Diagram | Qty. |
|---|---|---|---|
| C | Phillips round combo screw (for attaching headpiece to metal rod) |  | 1 |
| D | Round-head screw (longer) (for attaching fixing block to column) |  | 6 |
| E | Fixing block (for attaching stadiometer to column) |  | 2 |
| F | Round-head screw (shorter) |  | 2 |
| G | Rubber Gasket (for assembling stadiometer together) |  | 1 |
| H | clip |  | 1 |
| I | Round-head screw M3 X 8 |  | 1 |

## ■ Installation

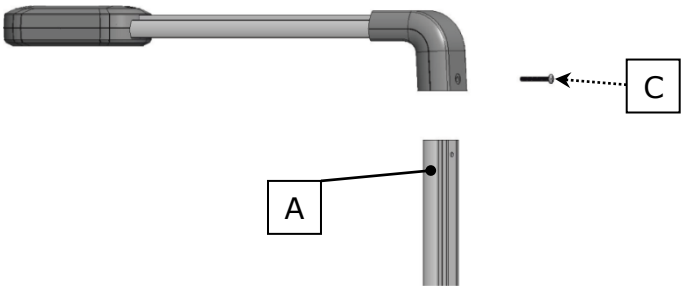
a. Use 4 longer round-head screws **[D]** to attach fixing blocks **[E]** to column.



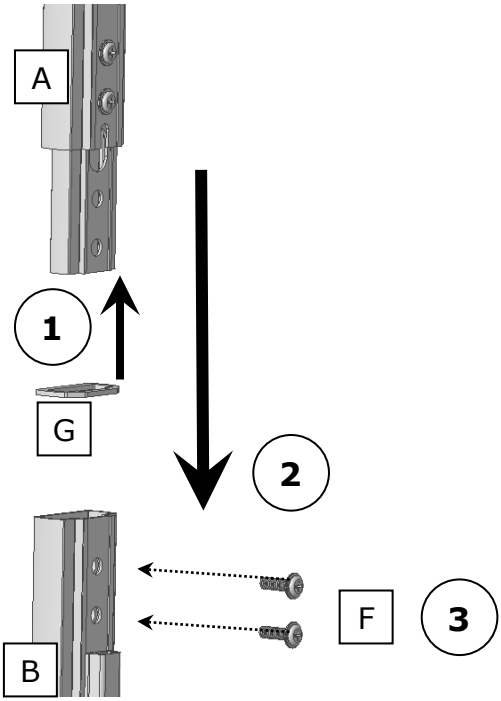
b. Use longer round-head screws **[D]** to attach rod **[B]** to fixing blocks.



c. Use Phillips round combo screw **[C]** to attach headpiece to rod **[A]**.

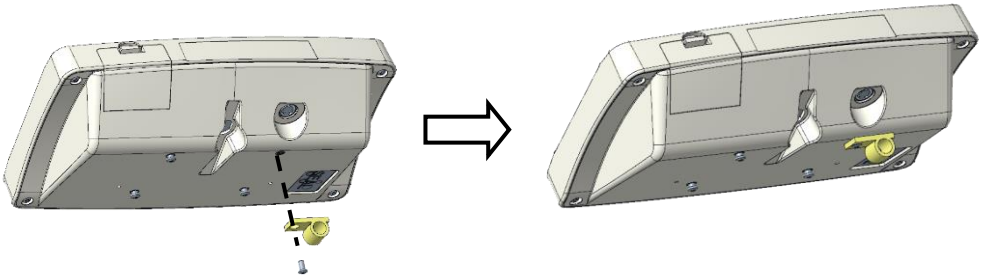



d. Slide rubber gasket **[G]** into rod **[A]**. Insert rod **[A]** into rod **[B]** and use round-head screws **[F]** to secure rods together.

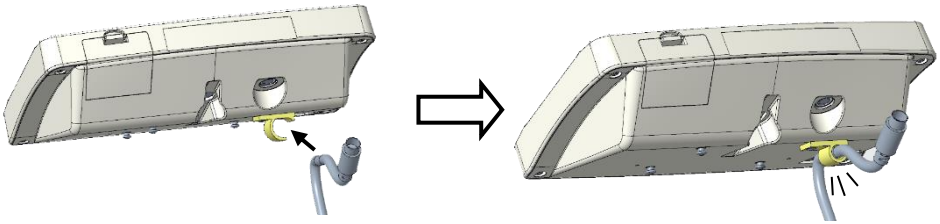


## ■ Connecting Height Stadiometer Cable

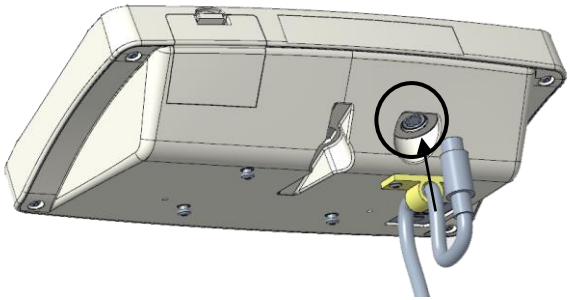
a. Attach cable clip **[H]** to bottom of indicator using screw**[I]**



b. Open clip, insert stadiometer cable into cable clip, and close clip.



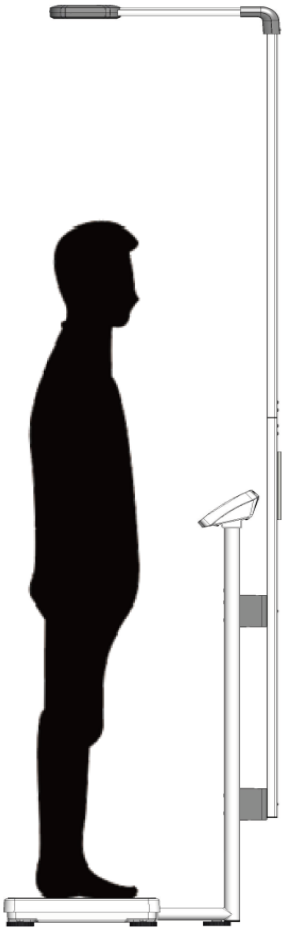
c. Plug stadiometer cable into 6 pin DIN port on bottom of indicator.



## Using Device

Stand still and look forward to ensure height measurement accuracy.

The device will automatically measure height and transfer result to weighing scale. Indicator will display weight, height and BMI.



## Product Specifications

| Model | | HM200U |
|---|---|---|
| Height Measurement | Range | 60-210 cm |
| | Graduation | 0.1 cm |
| | Accuracy | 60~200 cm : ±1.2 cm<br>200~210 cm : ±1.5 cm |
| Dimensions (approximate) | Overall | 500(L) x 61(W) x 2083(H) mm |
| | Device weight | 1.4kg |
| Data Transmission | | Transfer cable to indicator |
| Operation Environment | | +5℃~+35℃<br>15%~85% RH<br>700 hPa ~1060 hPa |

## Notes

# Notes

## Notes

## Notes

# Declaration of Conformity

Manufacturer hereby declares that this product is in conformity with the regulations and standards outlined in the following directives:

| | |
|---|---|
| CE 2460 | **(EU) 2017/745 Regulation on Medical Devices** |

**RoHS Directive 2011/65/EU and Delegated Directive (EU) 2015/863**
(applicable if device is electronic device)

**Radio equipment and telecommunications terminal equipment Directive 2014/53/EU**
(applicable if device has wireless function)

**Part 15 of the Federal Communications Statement Rules**
This device may not cause harmful interference
This device must accept interference received without causing undesired operation

(Full Declaration of Conformity is available on manufacturer's website)

**Authorized EU Representative:**

EU REP

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