

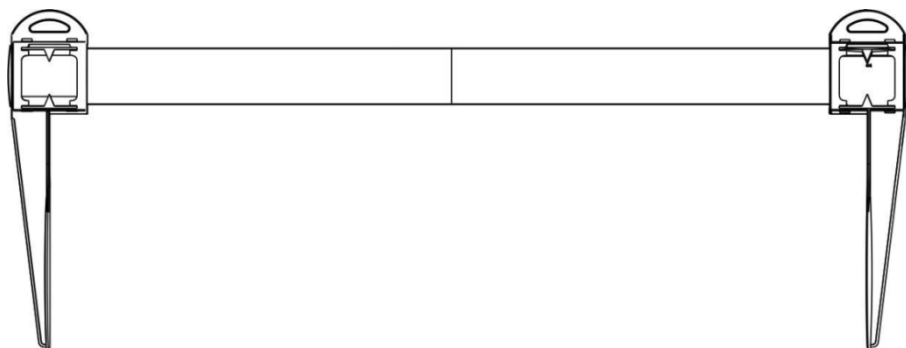


Height Measurement

USER MANUAL

HM80P

Infant Height Stadiometer

















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

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Explanation of Graphic Symbols on 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.
	Medical electrical device, Type B applied part
	Medical electrical device, Type BF applied part
	Device catalogue number / model number
	Name and address of authorized representative in the European Union
	Device is a medical device. Text indicates device category type
	Manufacturer's batch or lot number for device
	Device's serial number
	Device's Unique Device Identifier
	Verification Scale Interval. Value expressed in units of mass. Used to classification and verification of an instrument.
	Device conforms to (EU) 2017/745 Regulation on Medical Devices. Fourdigit number is identifier for medical device Notified Body

Device complies with EC directives (verified models only)

CE **M 20** 0122 **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)



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



Device conforms to U.S. Federal Communications Commission regulations

UK **CA** **M 20** 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



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.
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Taichung City, 41262 Taiwan

I. Safety Notes

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.
- 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

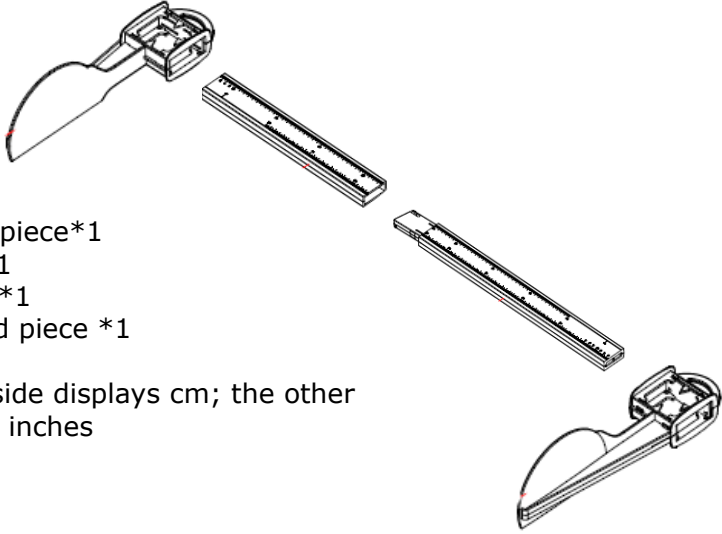
- The period of warranty shall be eighteen(18) months, beginning on the date of purchase. Please retain your receipt as proof of purchase.
- No responsibility shall be accepted for damage caused through any of the following reasons: unsuitable or improper storage or use, incorrect installation or commissioning 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, 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. 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.

II. Installation

A. Parts

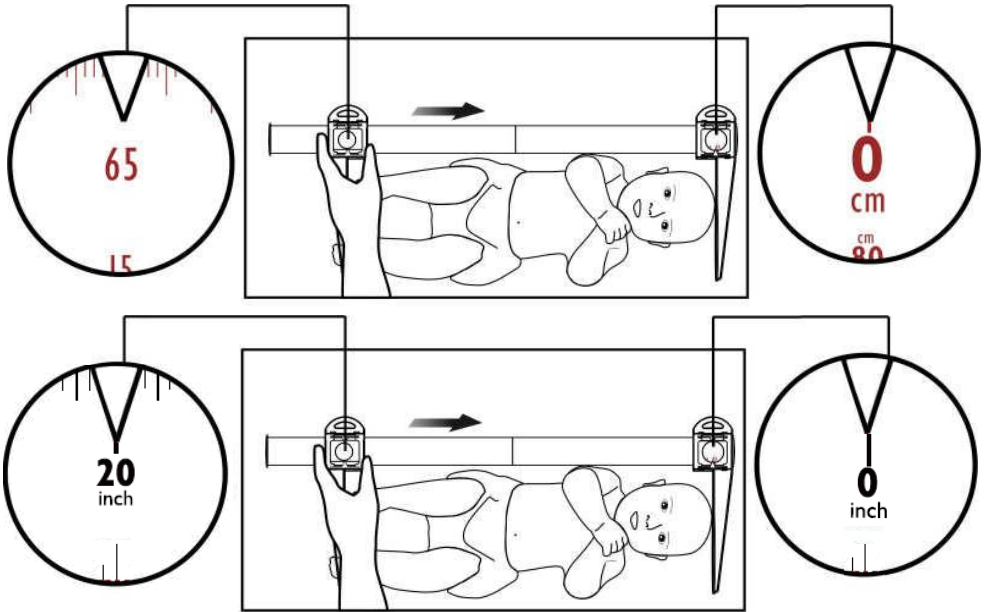


1. Left head piece*1
2. Left rod *1
3. Right rod *1
4. Right head piece *1

NOTE: one side displays cm; the other side displays inches

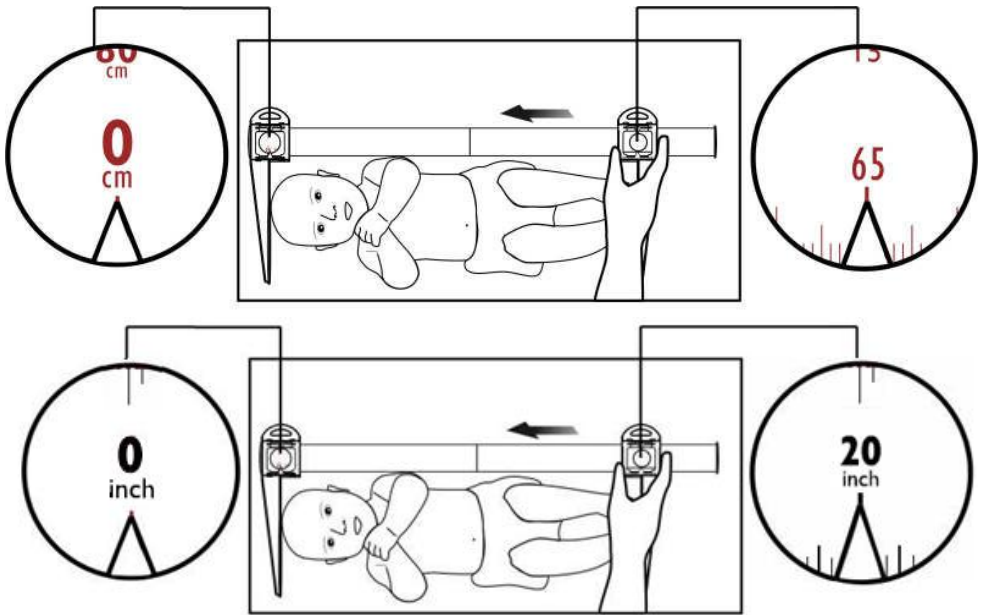
III. Using Device

A. Left-handed usage



1. Fix right head piece at 0 cm.
2. Straighten infant's feet.
3. Slide left head piece until it touches the soles of the infant's feet.
4. The reading on the left head piece is the length of the infant.

B. Right-handed usage



1. Fix left headpiece at 0cm.
2. Straighten infant's feet.
3. Slide right headpiece until it touches the soles of the infant's feet.
4. The reading on the right headpiece is the length of the infant.

IV. Product Specifications

A. Device Information



Model		HMS0P
Height Measurement	Range	10-80 cm 3 15/16-31 1/2 in
	Graduation	1 mm 1/16 in
	Accuracy	±10 mm
Dimensions	Overall	890(W) x 330(D) x 100(H) mm
	Device Weight	0.7 kg
Operation Environment		+5°C~+35°C 700 hPa ~1060 hPa
Optional Accessories		None
Standard Accessories		User manual x1

Notes

Notes

V. Declaration of Conformity

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

	(EU) 2017/745 Regulation on Medical Devices
	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:



Obelis s.a.

Bd Général Wahis, 53
B-1030 Brussels
Belgium

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