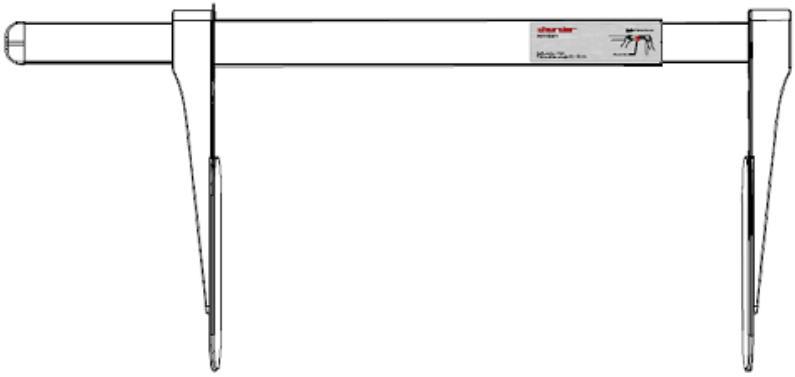
charder®

Height Measurement

USER MANUAL
HM80M
Infant Stadiometer



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

CONTENTS

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 (01) GTIN (11) Production date (21) Serial number
	Value in mass units. 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 claims conformity with essential regulations set by the relevant European Union legislation
CE M 20 0122	Device complies with EU directives **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: 20=2020) **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 conforms to Taiwan National Communications Commission(NCC) approval
	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

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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

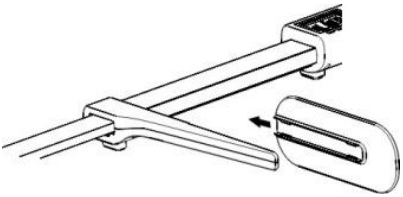
- The period of warranty shall be eighteen(18) months, beginning on the date of purchase. Please retain your receipt as proof of purchase.
- No responsibility shall be accepted for damage caused through any of the following reasons: unsuitable or improper storage or use, incorrect installation or commissioning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

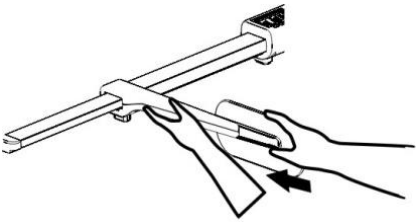
Any serious incident that has occurred in relation to the device should be reported to the manufacturer, EU representative (if device is used in EU member state), and competent authority of user/subject's member state.

II. Installation

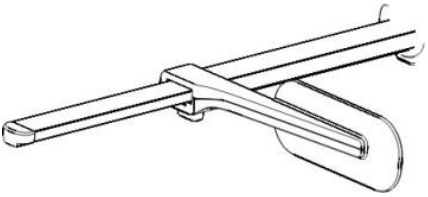
A. Attaching head stopper
If head stopper is loose, please assemble as seen below:
1.



2.

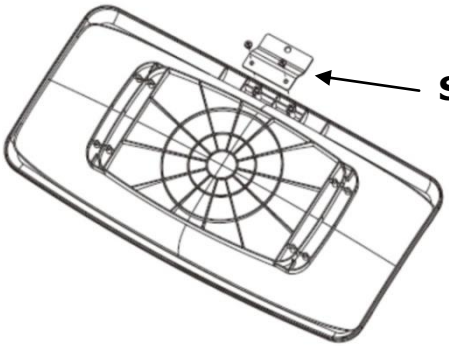


3.

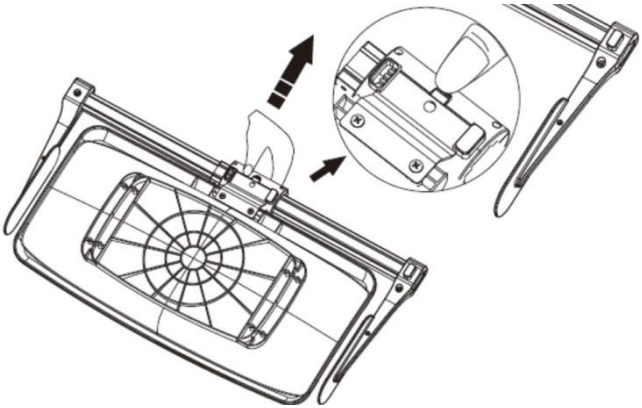


B. Assembly with Infant Scale (removable measurement tray)

1. Attach bracket to tray using bracket screws*2

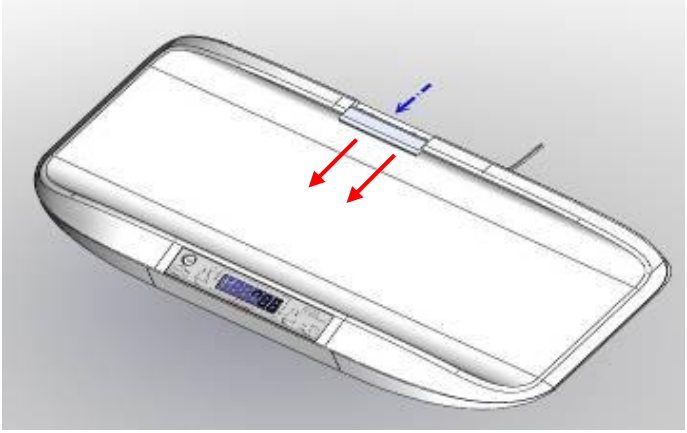


2. Slide HM80M onto bracket, and press buckle to secure

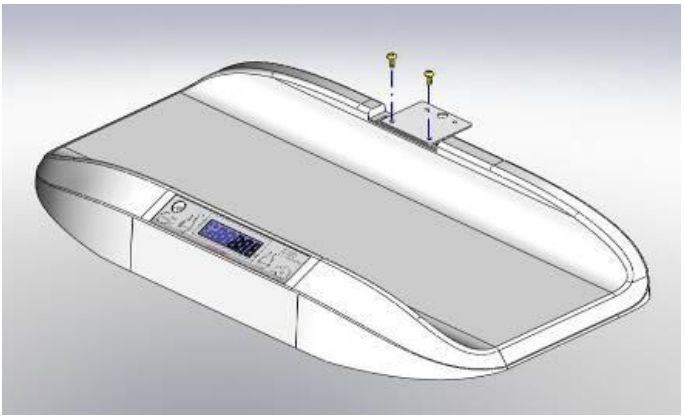


C. Assembly with MS5900 Infant Scale

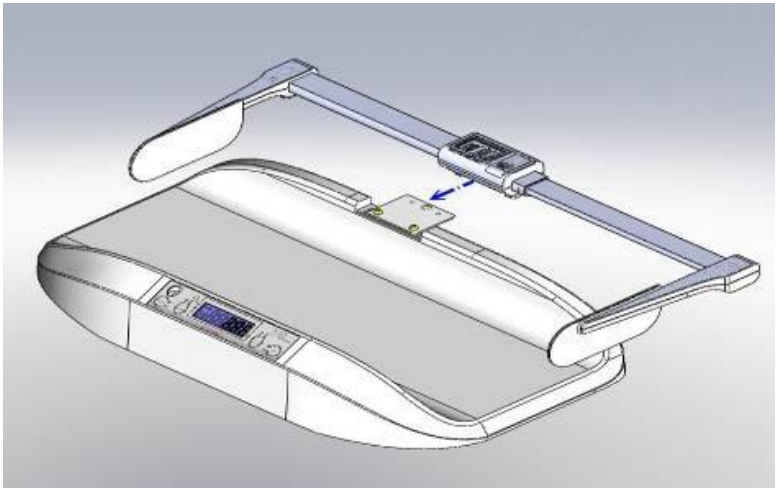
1. Remove bracket holder cover.



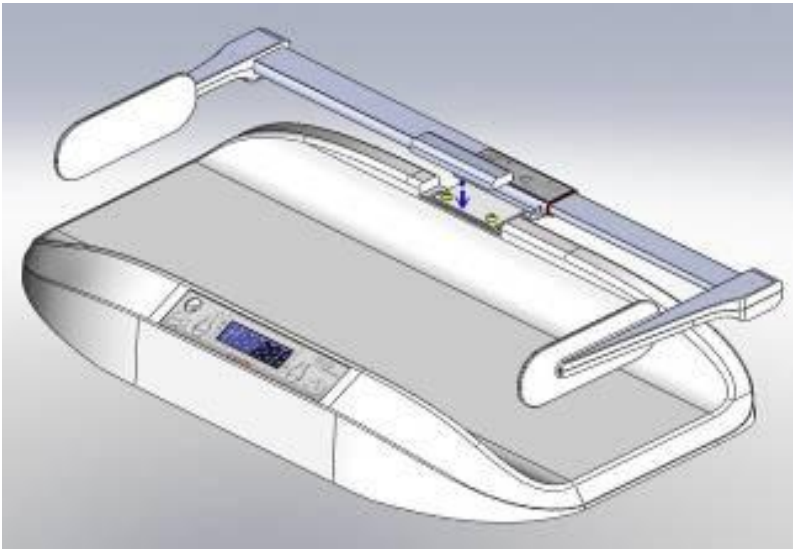
2. Attach bracket to device with two screws.



3. Attach height rod to bracket carefully until a click noise is heard.
(HM80D used as example, same procedure for HM80M)

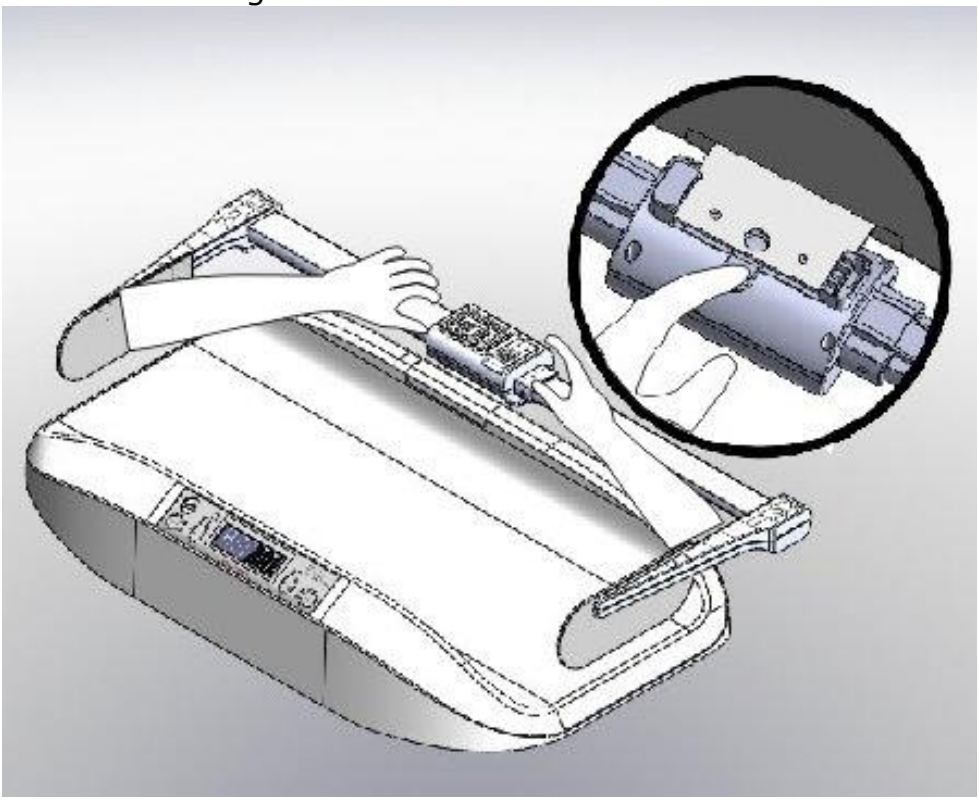


4. Install bracket holder cover.



5. Disassembling height rod

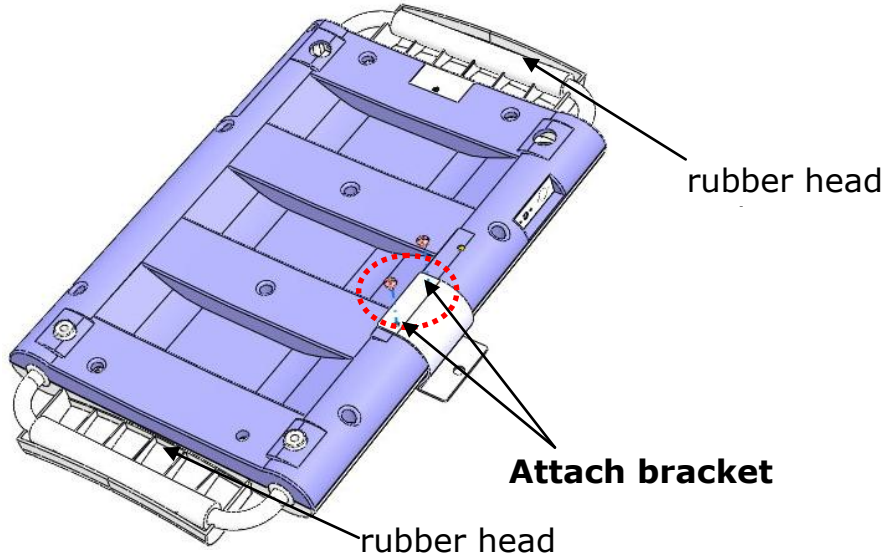
Locate buckle at bottom of height rod. Press down on buckle and slid out height rod.



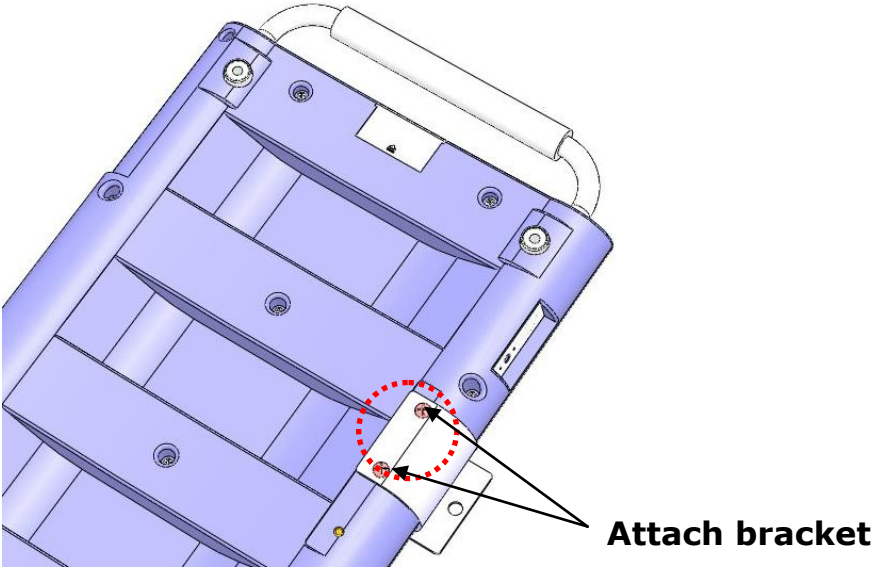
D. Assembly with MS2400 Infant Scale

1. Attach bracket to device, and fasten screws using screwdriver.

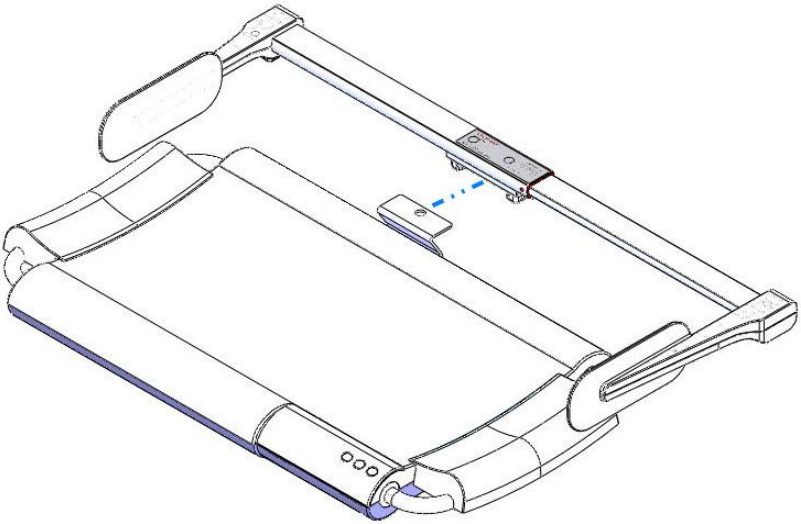
Version with rubber head pad



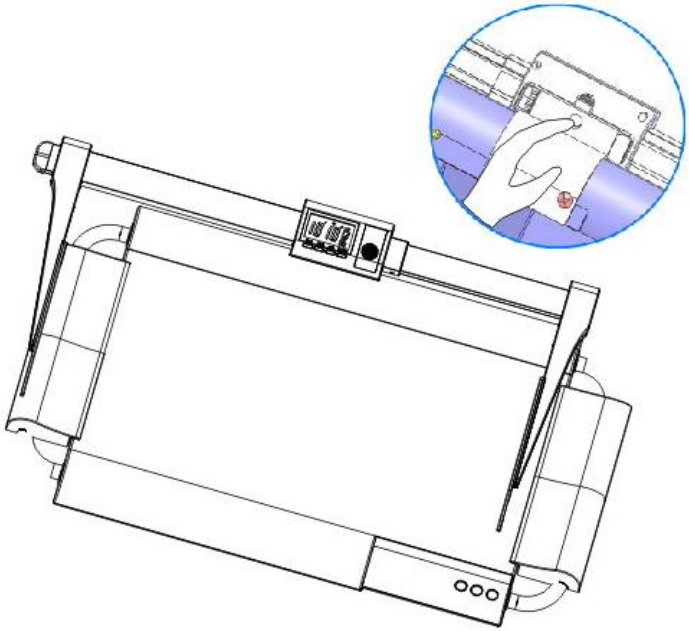
Version without rubber head pad



2. Connect height measure attachment (HM80D or HM80M) to bracket. A clicking noise will be heard.



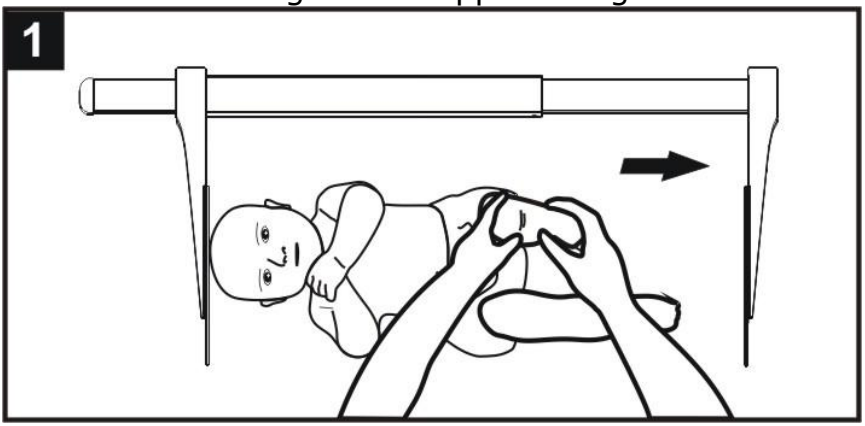
3. To detach height measure, find the latch located at the rear of the attachment. Press down on the buckle, and gently remove the attachment from bracket.



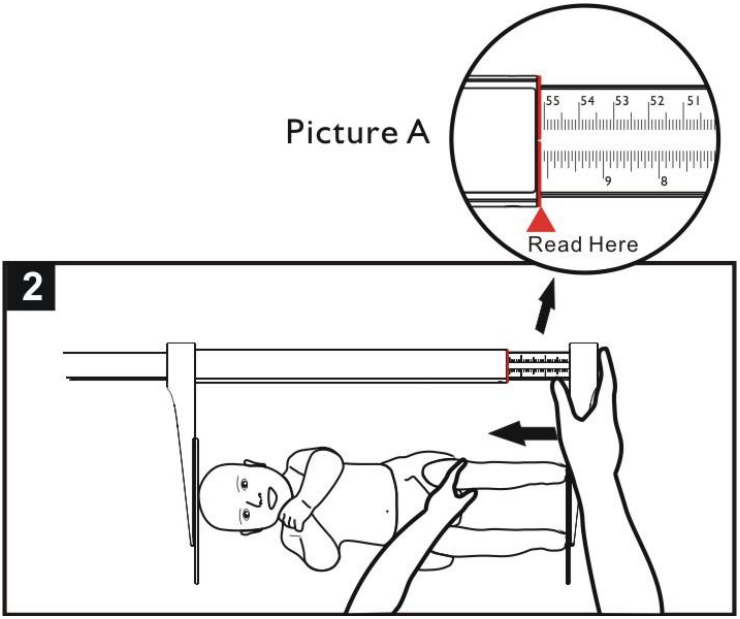
III. Using Device

A. Performing measurement

1. Lay infant on flat platform,
with head touching head stopper.Straighteninfant’sfeet.



2. Use right hand to push foot stopper until it touches soles of infant's feet. Read measurement result.



IV.Product Specifications

Model		HM80M
Height Measurement	Range	35-80 cm 133/4-31 1/2 in
	Graduation	1 mm 1/16 in
	Accuracy	±5 mm
Dimensions	Overall	870(W) x 290(D) x 70(H) mm
	Device Weight	0.5 kg
Operation Environment		+5℃~+35℃ 700 hPa ~1060 hPa
Optional Accessories		Bracket set for installation on compatible Charder Infant Scale
Standard Accessories		User manual x1

Notes

V.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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