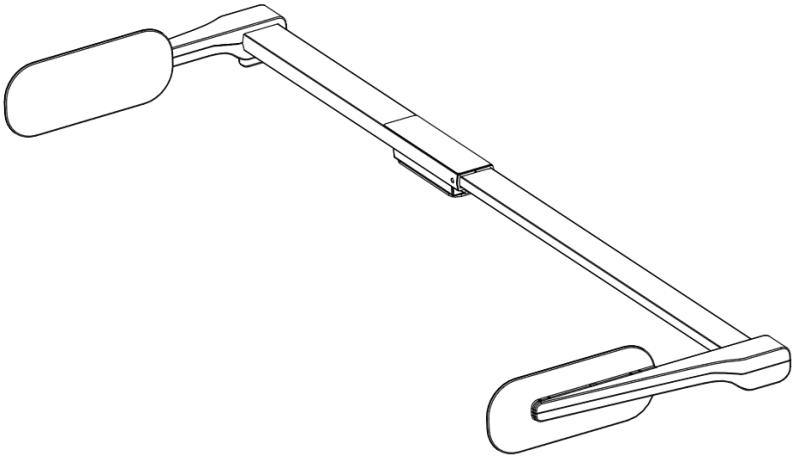
charder®

Height Measurement

USER MANUAL
HM80DT
Digital Infant Stadiometer



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

CONTENTS

I. 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.
	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
e	Verification Scale Interval. Value expressed in units of mass. Used to classification and verification of an instrument.
CE 2460	Device conforms to (EU) 2017/745 Regulation on Medical Devices. Fourdigit number is identifier for medical device Notified Body

CE M 20 0122	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
III	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
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"

II. Copyright Notice

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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 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

- Device should be placed on stable, flat, solid, non-slippery surface.
- 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

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.

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 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.
Harmonic emissions 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 ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±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 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. 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 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 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 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 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.

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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.

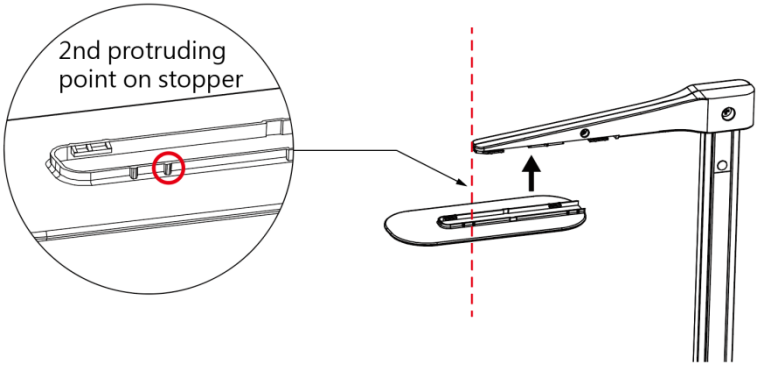
NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

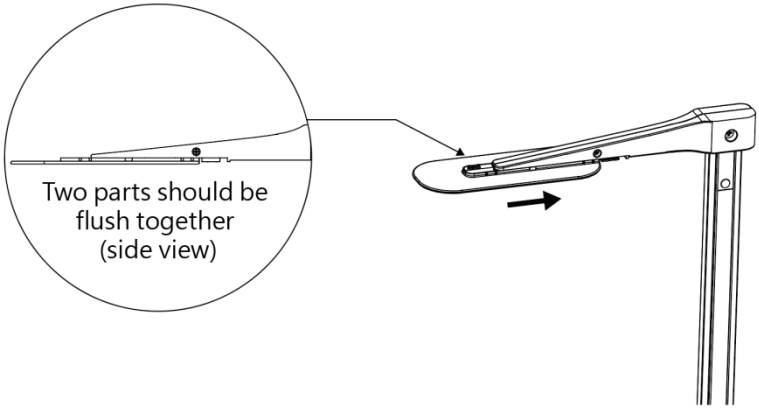
IV. Installation

A.Assembly with MS5980 Infant Scale

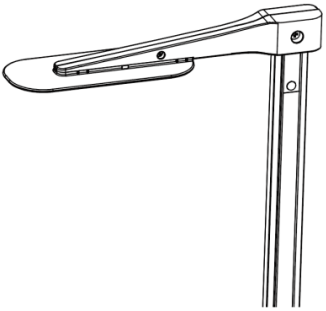
1、Align end of stadiometer with 2nd protruding point on stopper.



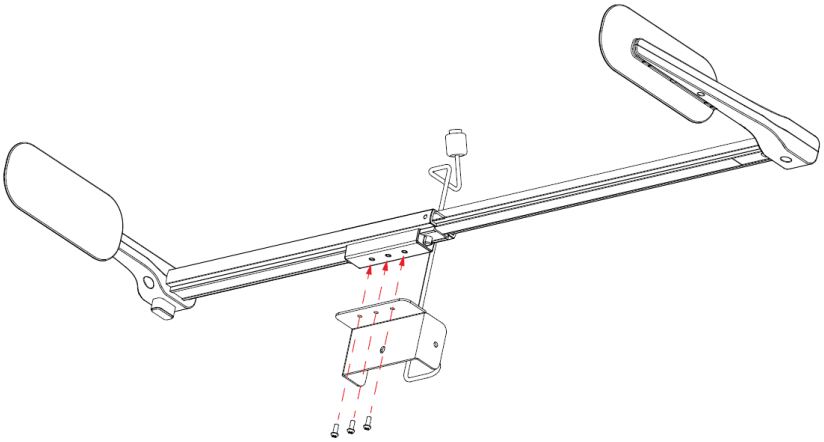
2、Press two parts together, and then push stopper inwards



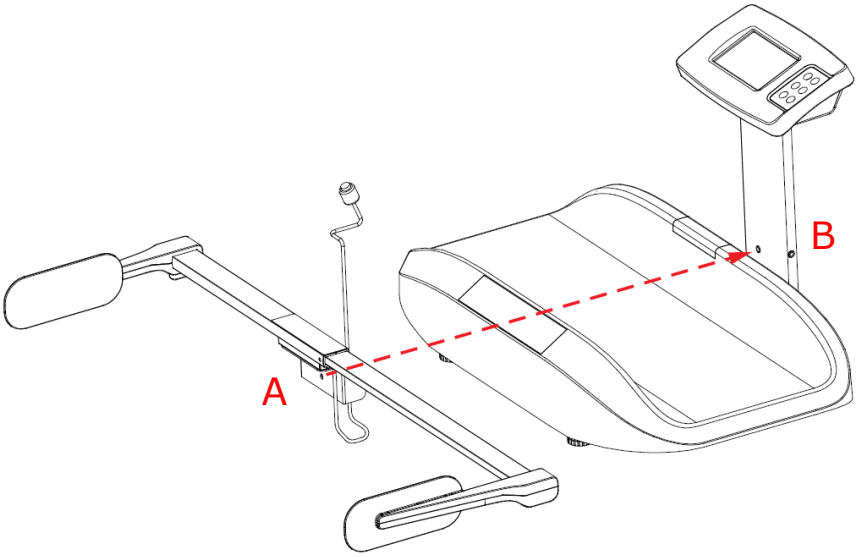
3、Stopper assembly complete (repeat steps 1-3 for other side)



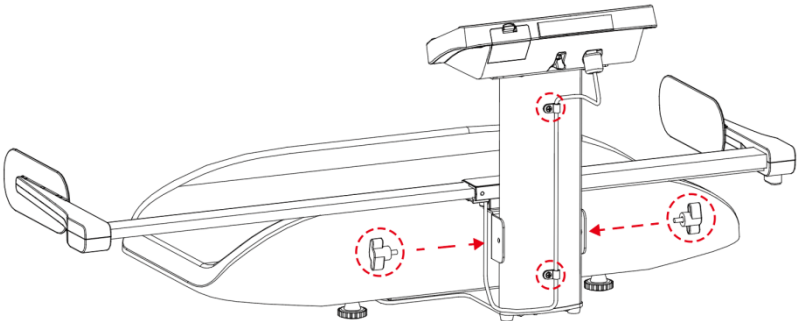
4. Install height rod + headstopper onto bracket using Philips screws



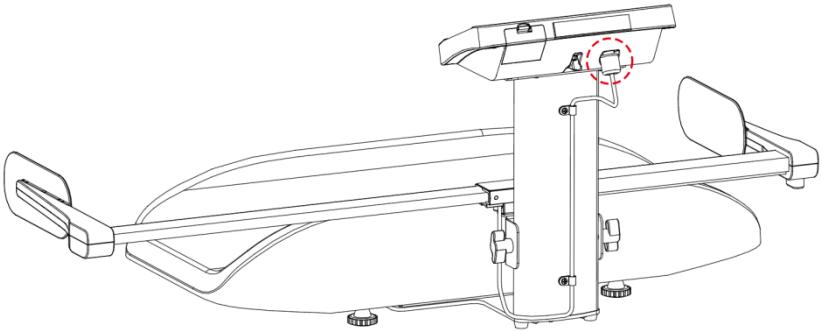
5. Line up "A" on Stadiometer with "B" on Column



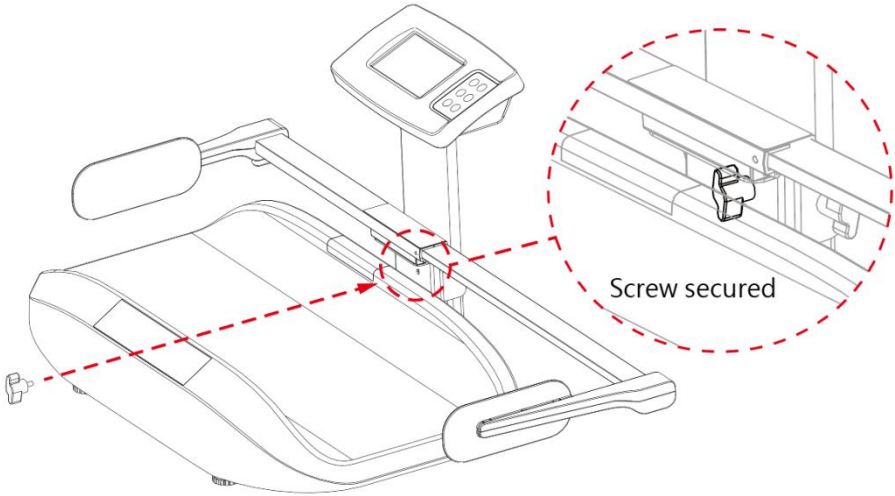
6. Install height rod + headstopper + bracket onto infant scale.
(Twist knobs clockwise to secure bracket)



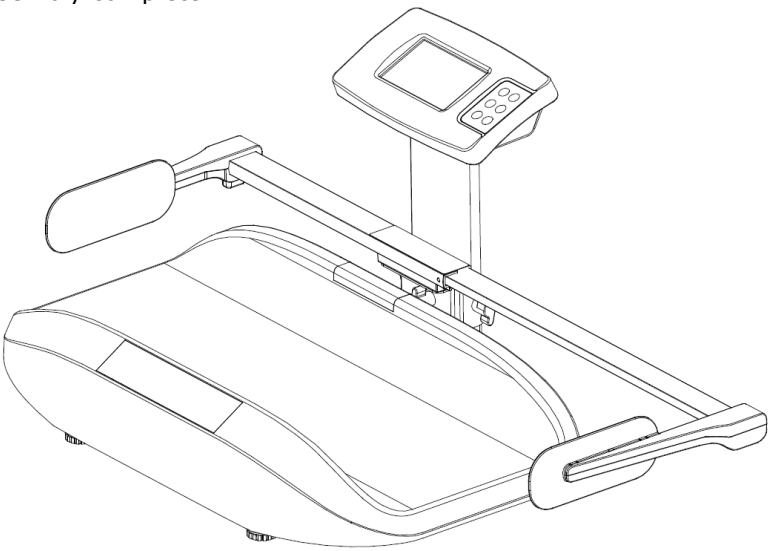
7. Plug data transmission port into indicator.



8. Fasten screw on front of column

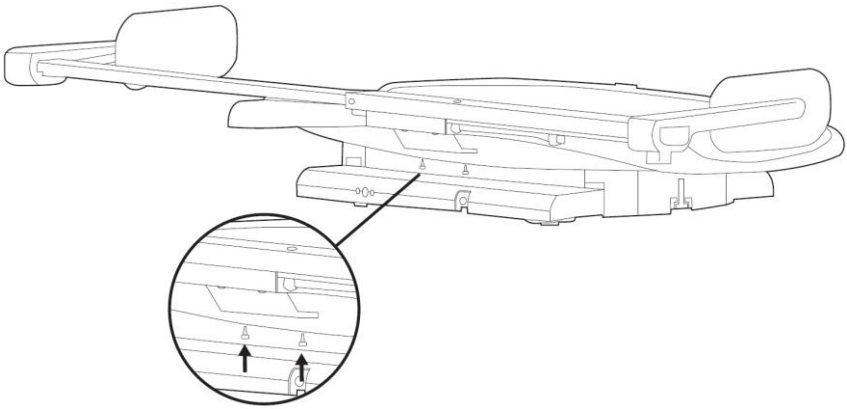


9. Assembly complete

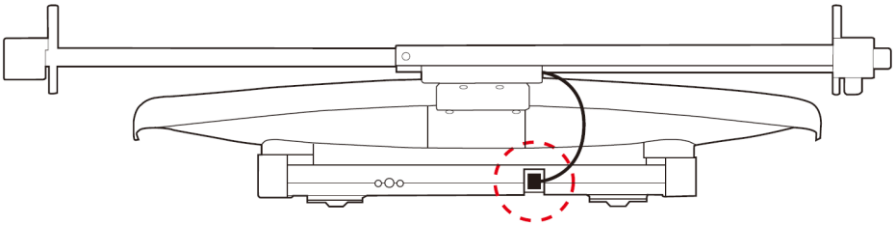


B. Assembly with MS3500 and MS21NEOV Infant Scale

1. Attach bracket to tray using bracket screws*2



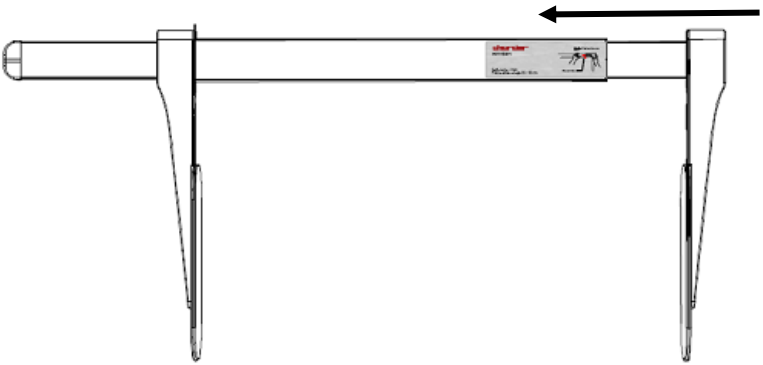
2. Connect HM80DT cable to scale.



V. Using Device

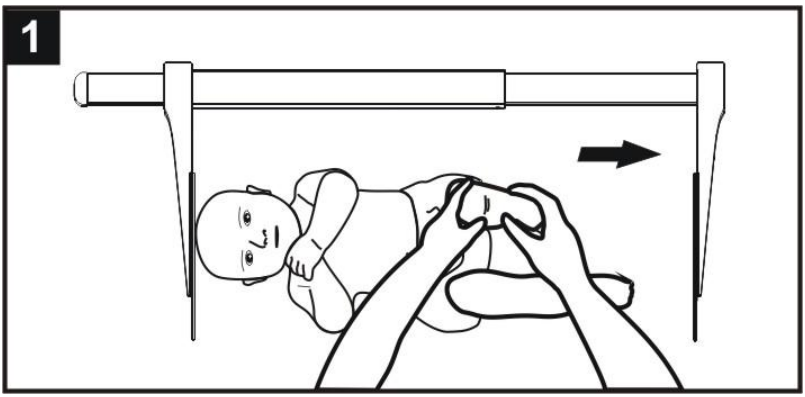
A. Calibrating Height Stadiometer

Before using height stadiometer, slide measurement rod to left completely then turn on scale to finish calibration.

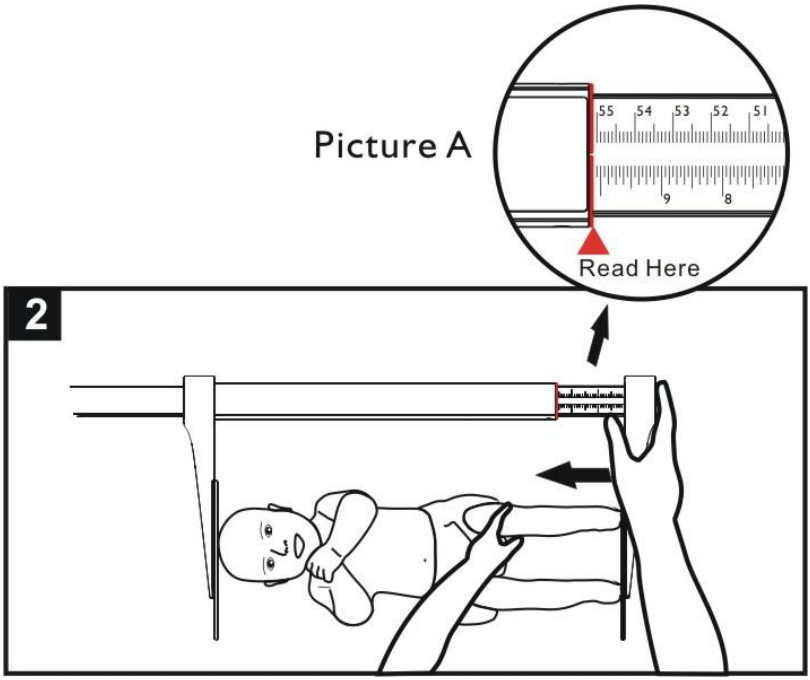


B. Performing measurement and operating

1. Lay infant on flat platform, with head touching head stopper. Straighten infant's feet.



2. Use right hand to push foot stopper until it touches soles of infant's feet. You can also read measurement result from stadiometer. The height measurement result will automatically be sent to device indicator and display at the same time.



VI. Product Specifications

Model		HM80DT
Height Measurement	**Range**	35-80 cm 13 3/4-31 1/2 in
	Graduation	0.1 cm 1/16 in
	Accuracy	±2 mm
Dimensions	**Overall**	870(W) x 290(D) x 72(H) mm
	Device Weight	0.6 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

Notes

VII. Declaration of Conformity

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

CE 2460	(EU) 2017/745 Regulation on Medical Devices
CE 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:

EC REP **Obelis s.a.**
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Belgium

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CD-IN-00471 REV005 11/2025