

Infant Scale

USER MANUAL **MS4400I**



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
Z	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
ॐ	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
е	Verification Scale Interval. Value expressed in units of mass. Used to classification and verification of an instrument.
€ 2460	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)
C€ M200122	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)
A)÷Ż	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
FC	Device conforms to U.S. Federal Communications Commission regulations
Ľ န <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
$\bigcirc - \bigcirc - \bigcirc +$	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 be used in accordance with national regulations, to measure weight within specifications, for weight-related usage by professionals.

For the sake of consistency, "patient" will be used to refer to infants or toddlers for the rest of this document.

Patient is placed on a tray or sling which is attached to a weighing platform for the device to measure patient weight.

Clinical Benefit

Measurement results can be used by professionals to diagnose (and monitor) weight-related issues.

Intended medical indications/contraindications

Measurement: patient's body weight. No known contraindications to measurement of body weight.

Intended patient profile

- (a) Age: no restrictions (subject to size limitations of device and maximum capacity)
- (b) Weight: no restrictions within device weight capacity
- (c) Patient Conditions: require measurement of body weight. Can fit upon device.

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. Infant scales 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

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.

Cleaning

Device surface should be cleaned using alcohol-based wipes.

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				
Guidance and mandiacturer's declaration-electromagnetic emissions				
The product is inten	The product is intended for use in the electromagnetic			
environment specific	ed below. The cus	tomer or the user of the		
		n such an environment.		
Emission test	Compliance	Electromagnetic		
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.		

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
discharge(ESD)	± 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%
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

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Immunity test	IEC 60601 test	Compliance	Electromagnetic	
	level	level	environment-guidance	
			Recommended separation	
Radiated	3 V/m	3 V/m	distance:	
RF IEC	80MHz to 2,7	80MHz to 2,7	$d = 1.2 \sqrt{P}$	
61000-4-3	<u>GHz</u>	<u>GHz</u>	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 theoretic call. 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 $√P$
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. Adjusting footrests

Device does not require assembly, and can be used once batteries have been inserted, and S-hook and sling are attached.

B. Inserting Batteries

1. Locate battery cover on bottom of device. Open cover, and remove battery case from device.

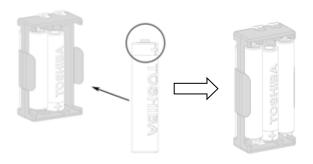


Tig. 1. battom, cover legation) (Fig. 2)

(Fig. 1: battery cover location)

(Fig 2. Empty battery case)

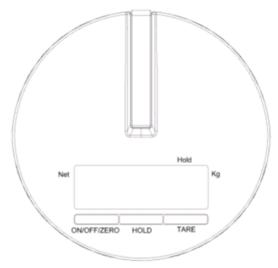
2. Insert 6 AAA batteries. Ensure polarity is correct.



3. Insert battery case into device and close battery cover. Turn on device to test if batteries are installed correctly.



V. Key Functions and Indicator



Key Functions

1. $\boxed{\text{ON/OFF/ZERO}}$: Turn device on and off. Zero scale ($\pm 2\%$ of full capacity). Press and hold to turn off device.

2. HOLD: Determine stable weighing value - should be used when weight is unstable.

3. TARE: Deduct weight from reading after measurement



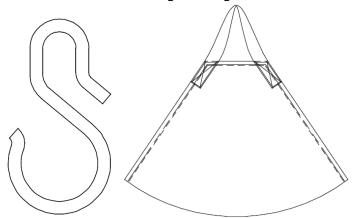
Indicator

- 1. Stable indicator: indicates that reading is stable
- 2. Net weight: indicates current reading is net weight
- 3. Zero indicator: indicates that device is at zero weight
- 4. Low battery: displays remaining battery life
- 5. Hold: indicates if Hold function is activated
- 6. Unit (kg / g / lb): unit of current reading. (lb unavailable on OIML approved model

VI. Getting Started

Inspection before use

1. Confirm hook and sling are in good condition and undamaged



2. Clear and remove any sharp objects in area to ensure safety of infant



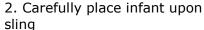
3. We recommend placing a cushion under the sling before weighing for comfort and safety

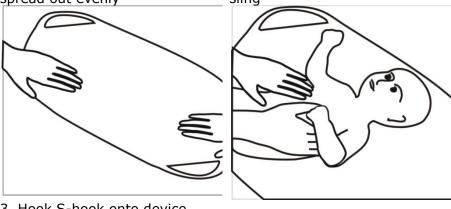


VII. Using Device

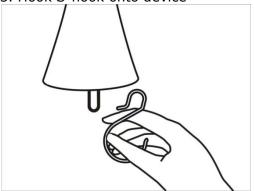
A. Correct usage

1. Lay sling upon table and spread out evenly





3. Hook S-hook onto device

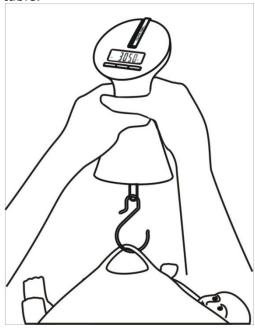


- 4. Hook s-hook onto sling. S-hook should now be hooked to both device and sling.
- 5. Switch on the device using [ON/OFF/ZERO] key. The device will automatically perform self-calibration, displaying software version.

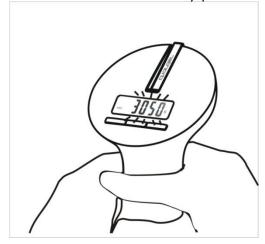
Once "0.00 kg" appears on indicator, device is ready for measurement.

Note: If "0.00 kg" does not display on indicator, press [ON/OFF/ZERO] key to zero the device. This function can be used for weight within ±2% of full capacity.

6. Carefully lift device with both hands until baby no longer touches table.



After weight has stabilized, the reading on the indicator will flash. This means the result has been locked. Device should be carefully lowered until infant is safely placed back upon table.



Note: If infant's weight exceeds scale capacity (including tare), indicator will display "Err" prompt due to overload.

B. Tare

The tare function allows the user to deduct the weight of objects from the device's measurement result. Tare can be used when weight of object is ≧at/above 2% of max capacity.

- 1. Place object that needs to be tared onto sling. Lift sling from ground until weight is displayed on indicator.
- 2. Press [TARE] key. Display will indicate "0.00 kg".
- 3. Carefully place infant upon sling (along with tared object). Conduct measurement.
- 4. To clear tare value, remove all objects from sling, and press **[TARE]** key.

C. Hold

The hold function determines average weight, designed to be used if subject's weight will not stabilize (ex: an active infant).

Note: if fluctuation is too severe, average weight determination will be difficult and hold may not function correctly

- 1. Switch on the device normally.
- 2. Press the **[HOLD]** key. "HOLD" will be displayed on the indicator.
- 3. Carefully place infant on sling. Lift sling from ground.
- 4. After a few seconds, the average weight will be displayed on the indicator. This weight will be locked at this point, infant can be removed from sling.
- 5. To release the locked weight, press the **[HOLD]** key again to return to the device to normal mode.

Note: Hold function can be activated before or after infant is placed on sling and lifted. However, if infant finds it difficult to hold still, we recommend activating Hold after infant is placed on sling and lifted.

D. Incorrect usage examples



Thumbs not properly supporting device weight. Thumbs should be wrapped around "neck" of device.

VIII. Wireless Connection

If the device has the wireless or bluetooth module installed, the indicator can transmit measurement results wirelessly. Please see Charder wireless or bluetooth software instructions for details.

IX. Troubleshooting

Product Defects

Charder's warranty is effective for the original purchaser of this device, subject to the terms and conditions listed in the Warranty Program & Return Policy.

- 1. If Charder is responsible for a fault or defect present upon receipt of the unit, Charder shall either repair the fault, or supply a replacement unit. Should the repairs or replacement delivery fail, statutory provisions shall be valid. The period of warranty shall be two years, beginning on the date of purchase. Please retain your receipt as proof of purchase.
- 2. 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.

If device is not covered under warranty, a service maintenance charge will apply, plus cost of replacement parts.

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

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

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

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

Error Messages

Error Message	Reason	Action
Lo	Voltage of battery is too low to operate device	Replace batteries
[rr	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
ErrL	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
ErrE	Program Error Fault with device software	Please contact distributor

X. Product Specifications Device Information

Model		MS4400I	
	Capacity	10 kg x 10g	15 kg x 20g
Weight	Accuracy	±1.5e	
Measurement	LCD Screen	1.0-inch LCD screen (5 digits)	
	OIML	Class III	
. .	Device	105(W) x 79(D) x 193(H) mm	
Dimensions	Device Weight	0.4 kg	
Key Functions		On/Zero/Off, Hold, Tare	
Data Transmission			
Power Supply		6 AAA batteries	
		+5°C~	+35℃
Operation Environment		15% / 85% RH 700 hPa ~1060 hPa	
		User ma	nual x 1
Standard Accessories		Sling x 1	
		S Hoo	
Optional Accessories		Carrying bag, different sling and s-hook configurations	

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
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.

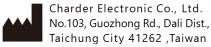
This device must accept any interference received, including interference that may cause undesired operation.

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

Authorized EU Representative:



Manufactured by:



CD-IN-1034 [8001T] 08/2024