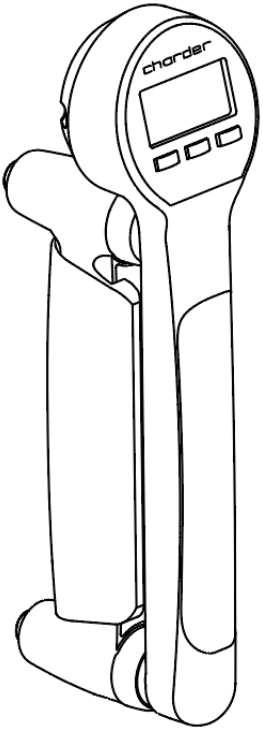
Hand Dynamometer

USER MANUAL

MG4800 AA



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

CONTENTS

I. Explanation of Graphic Symbols on 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
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
e	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. Four digit number is identifier for medical device Notified Body
CE	Device claims conformity with essential regulations set by the relevant European Union legislation
CE M 17 0122	Device complies with EU directives **M**: Conformity label in compliance with Directive 2014/31/EU for non-automatic weighing instruments **17**: Year in which conformity verification was performed and the CE label was applied. (ex: 17=2017) **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
	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.

II. Copyright Notice

Copyright Notice
Charder Electronic Co., Ltd.
No.103, Guozhong Rd., Dali Dist., Taichung City 41262 Taiwan
Tel: +886-4-2406 3766
Fax: +886-4-2406 5612
Website: www.chardermedical.com
E-mail: info_cec@charder.com.tw

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

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 grip strength within specifications, for grip strength-related usage by professionals.

Clinical Benefit
Measurement results are for doctor’s reference of user’s grip strength.

Intended medical indications/contraindications
Measurement: patient's handgrip. No known contraindications to measurement of handgrip.

Intended patient profile
(a) Age: no restrictions
(b) Weight: no restrictions
(c) Patient Conditions: require measurement of grip strength
(d) Other: hand needs to be large enough to grip device in one hand
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

(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. Handgrip dynamometers 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

Environmental

All batteries contain toxic compounds; batteries should be disposed of via designated competent organizations. Batteries should not be incinerated.

Cleaning

- Device surface should be cleaned using alcohol-based wipes. Corrosive cleansing liquids should not be used. Pressure-washers should not be used.
- Do not use large amounts of water when cleaning the device, as it may cause damage to the internal electronics.
- Always disconnect device from mains power before cleaning.

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.

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

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.

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%
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
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 meters (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.

.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 meters(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.

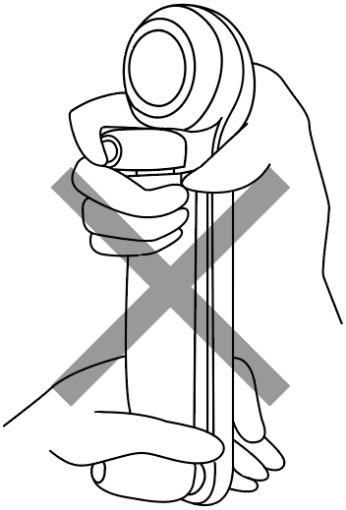
NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

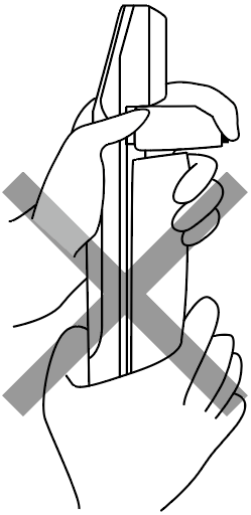
IV. Gripping Posture

A. Incorrect Gripping Posture

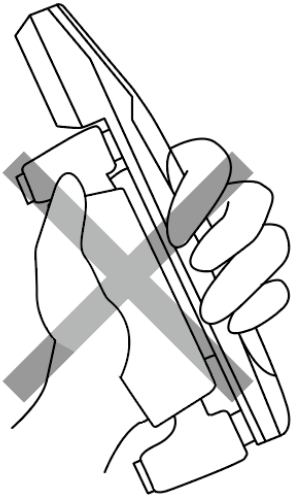
a.



b.

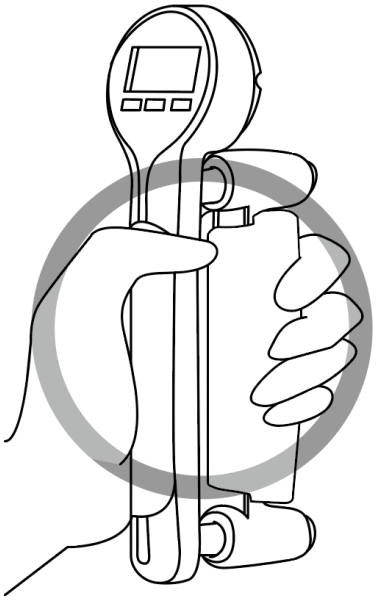


c.

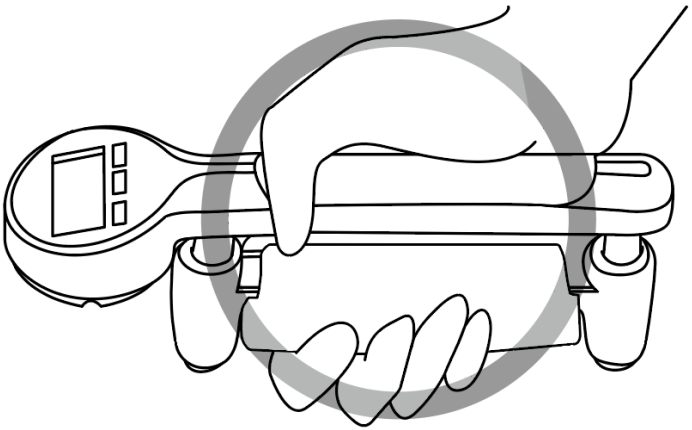


B. Correct Gripping Posture

a.

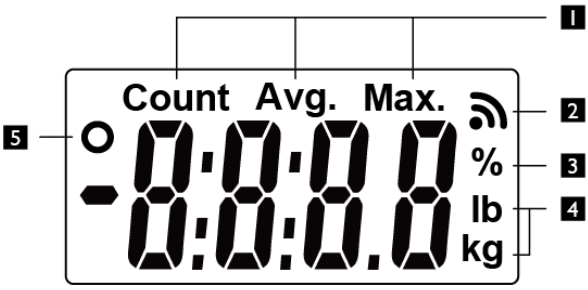


b.



V. Display and Key Functions

LCD Screen



1 Mode Indicator

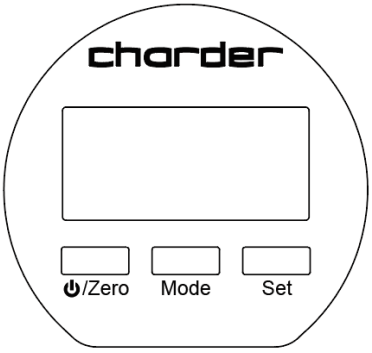
2 Wireless Indicator

3 Percentage Indicator

4 Unit (lb / kg)

5 Stable symbol

Key Function



⏻/Zero

Power on / Power Off / Zero

Press to Power On, hold for 3 seconds to ⏻Power Off.

Press to ZERO the value.

Note：Please release the device before zeroing the value.

Mode

Mode selection

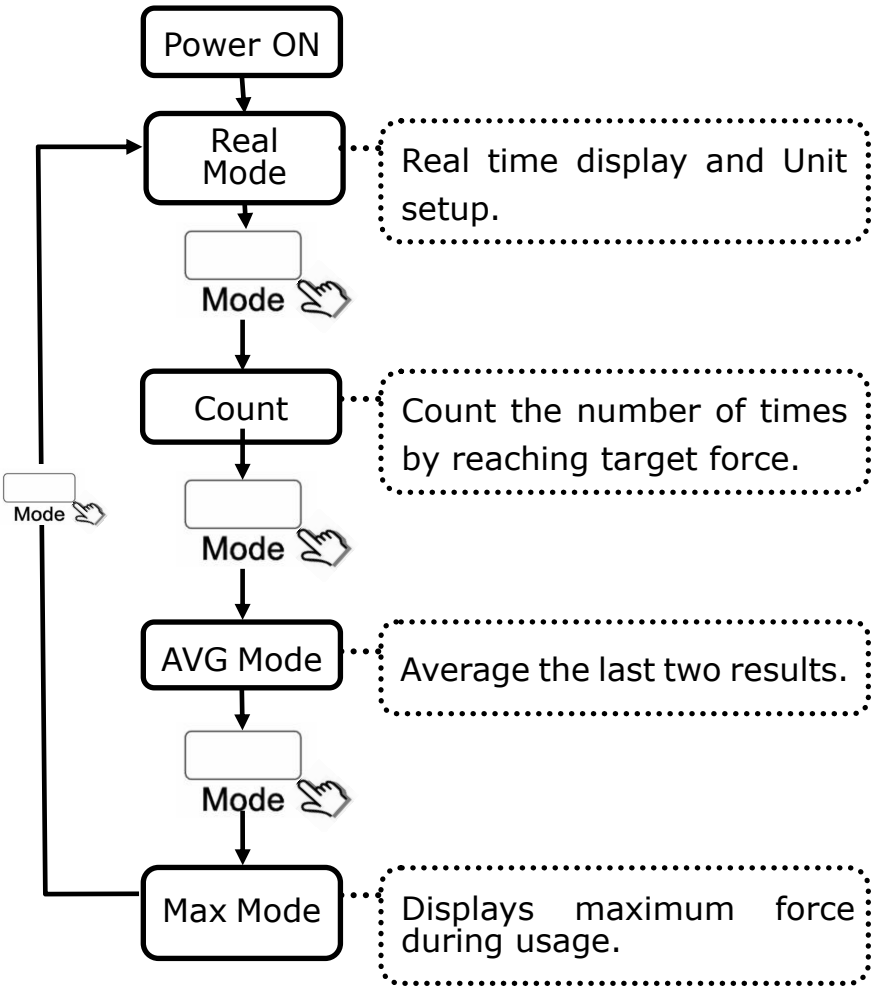
Set

Real Mode: Unit switches

Other modes: digit adjusts

VI. Mode Switching

- The following procedure gives you a specific idea of using Medical Hand dynamometer.
- Please note that Real Mode is the default mode. If the device is powered off in any other modes. Next time it will start with the powered off mode.



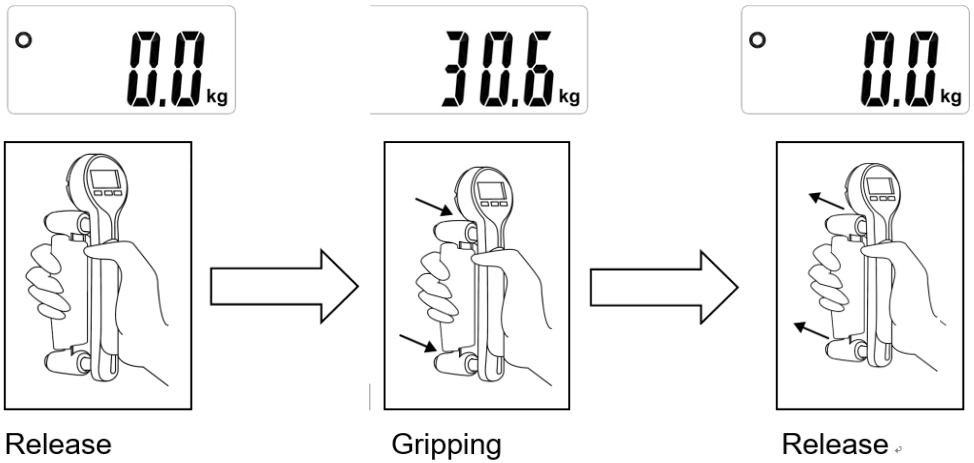
VII. Mode Description

REAL MODE

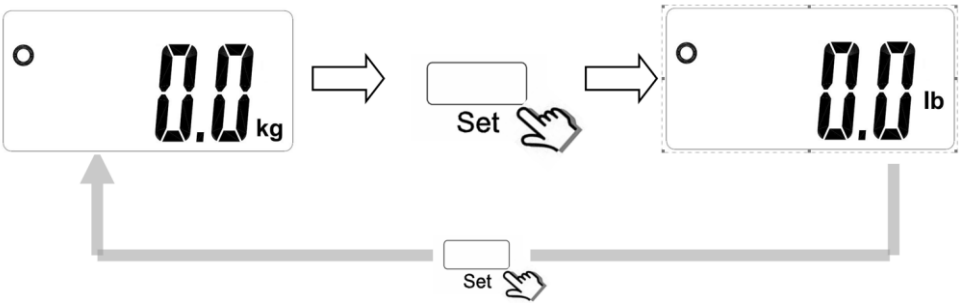
The **Real Mode** is a dynamic mode. The force value fluctuates according to the gripping force during usage.

Real Time Display：

Following is an operation process.



kg & lb SETUP：



COUNT MODE

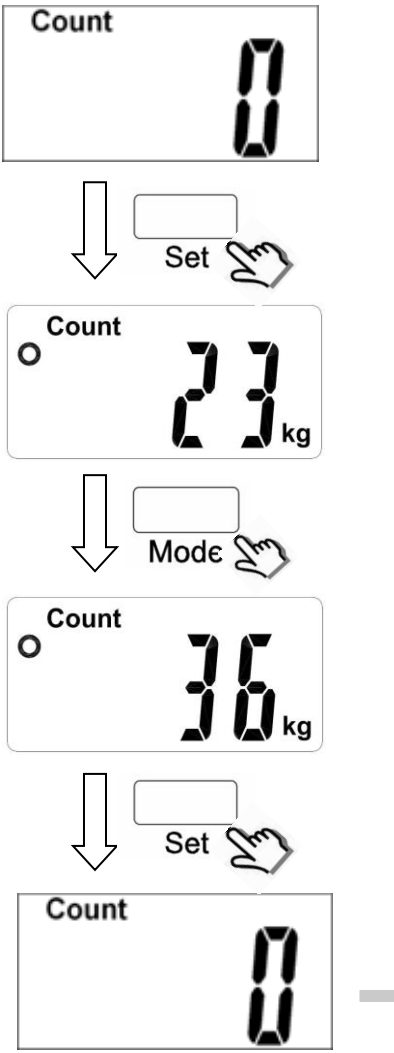
The **Count Mode** is for physician to set up a rehabilitation program for patient to do rehabilitation exercise with exact force measurement.

For Example :

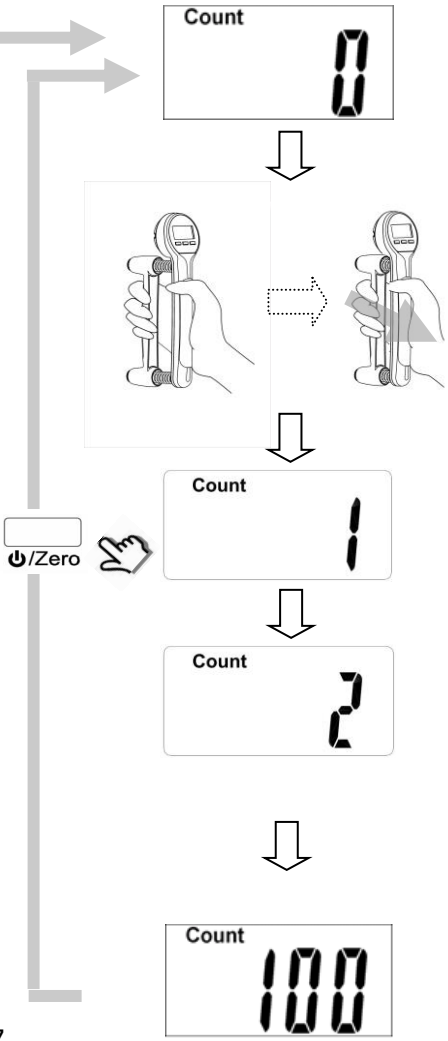
Set up target grip force before use.

NOTE: Only if the force reaches the target is counted one times.

SETUP TARGET GRIP FORCE



COUNTING OPERATION



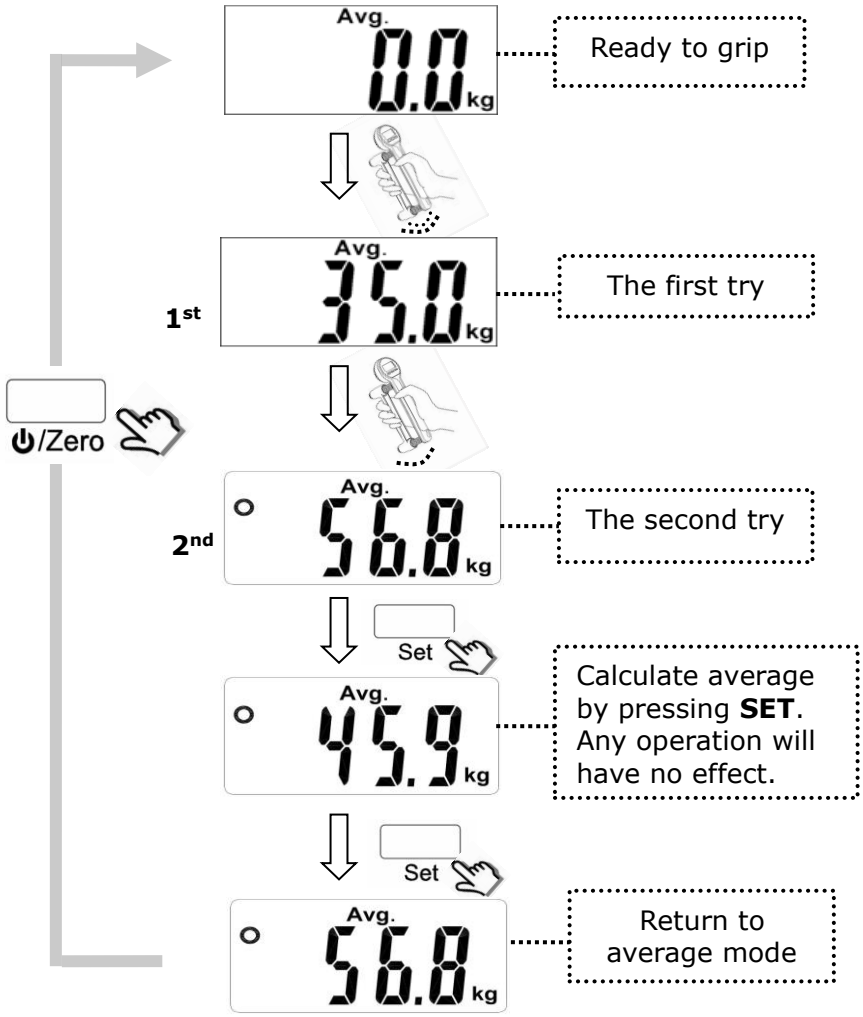
AVG MODE

The **AVG Mode** is for physician to evaluate the average of both hand's force.

For example：

Grip once individually with right and left hand, then press **SET** to calculate average value of last two grips.

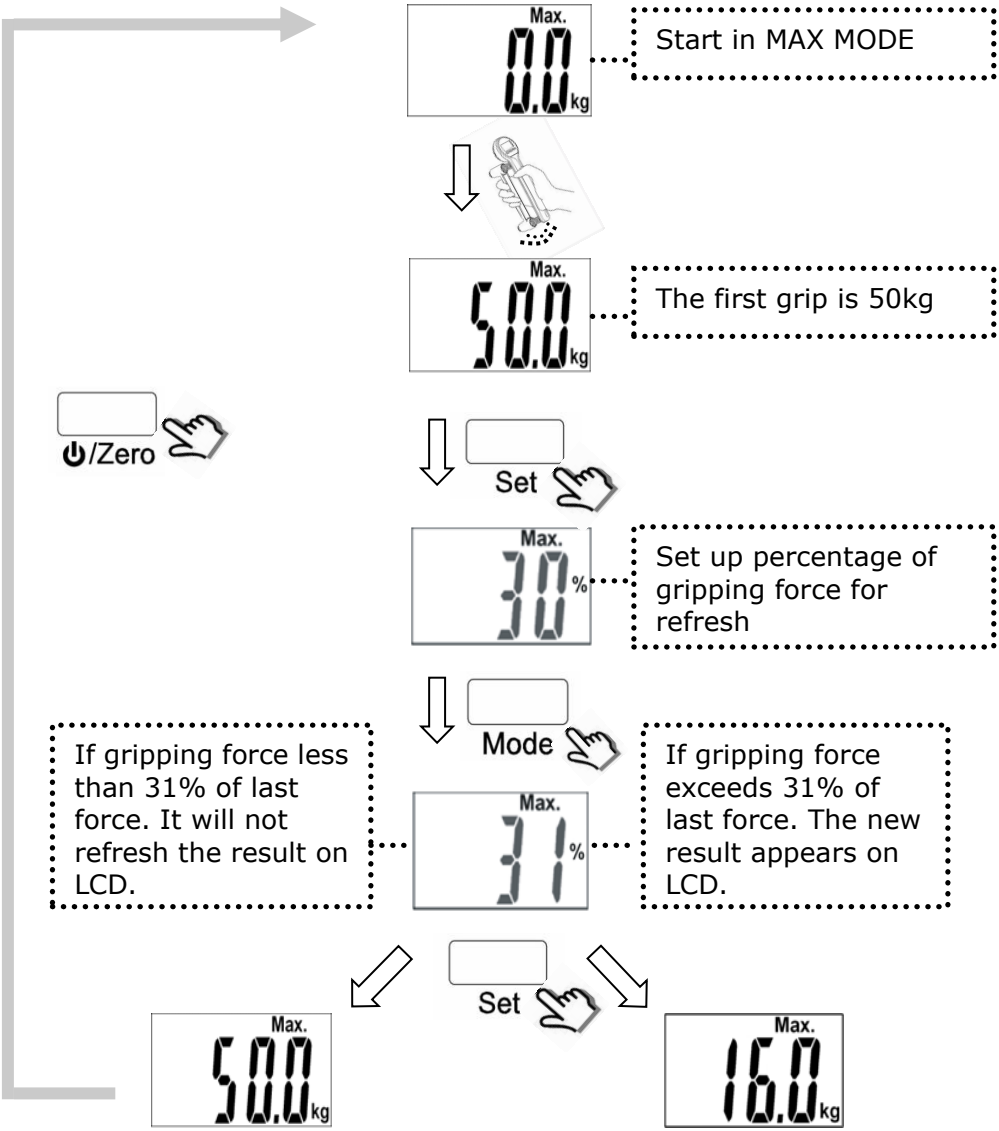
NOTE: The force must be greater than 2kg



MAX MODE

The **MAX Mode** presents the maximum force of impaired hand. Medical professions can evaluate the condition of patient's impaired hand through the results.

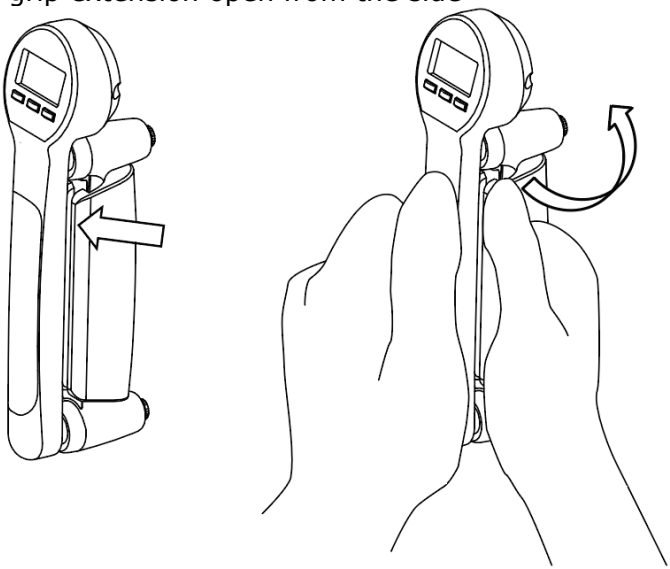
For example：



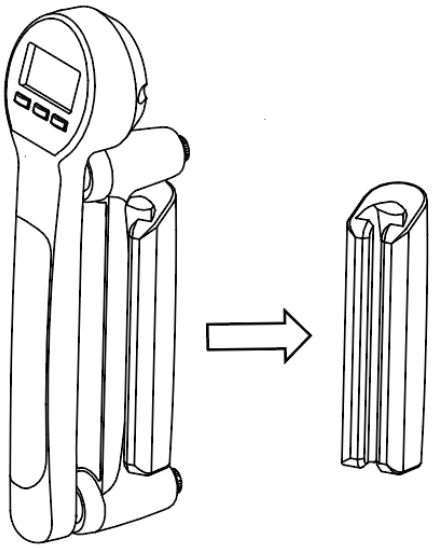
VIII. Removing the grip extension

The grip extension can be removed to fit different hand sizes and can be replaced according to the following instructions.

1. Push grip extension open from the side

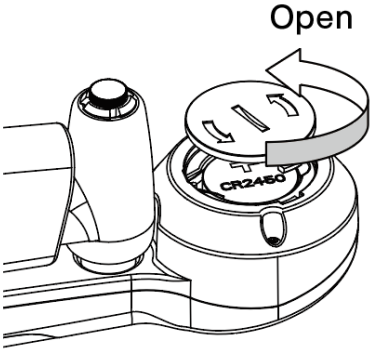


2. Remove grip extension

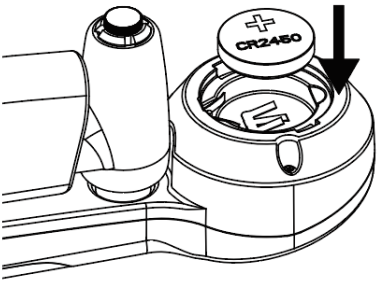


IX. Instruction for Battery Installation

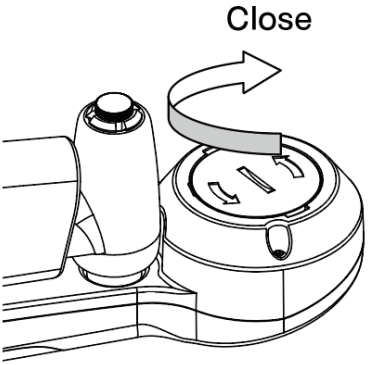
MG4800 uses CR-2450 lithium battery. Please read the following instruction before replacing battery.



1. Removing the battery cover by turning anticlockwise.

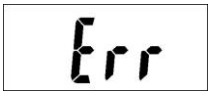
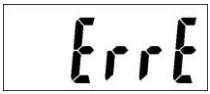


2. Installing a new CR-2450 lithium battery.



3. Locking the battery cover by turning clockwise.

Error Messages

Error Message	Reason
	**Low Battery Indication** This warning show that the voltage of battery is too low for operation, please replace battery.
	**Force Under Zero** The force is under zero when power on; press ZERO key and try again.
	**Force Over Zero or Counting Error** The force is over limit when power on, please reduce the force and power on again. If the problem still exists, please contact your local CHARDER MEDICAL service partner.
	**Counting Error (too low)** The force is lower than limit when power on, please increase the force and power on again. If the problem still exists, please contact your local CHARDER MEDICAL service partner.
	**EEPROM Error** The program has encountered internal error; please contact your local CHARDER MEDICAL service partner.

X. Product Specifications

Model	MG4800 AA
Capacity	80 kg / 130 kg
Division	0.1kg / 0.2lb
Accuracy	±2%
Unit	kg/lb
LCD Display	0.5 inch 4 digital LCD
Dimensions	212(W) x 55(D) x 73(H)mm
Grip Span	48mm / 64 mm
Device Weight	0.33kg
Key Functions	On/Zero, Mode, Set
Auto Off Time	60 sec
Power Supply	CR-2450 Battery
Standard Accessories	Carry case x 1 CR-2450 x 1 Grip extension x1
Operation Environment	+5℃ ~ +35℃ 15% RH ~ 85% RH 700 hPa ~ 1060 hPa

Notes

Notes

Notes

XI. Declaration of Conformity

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

CE

RoHS Directive 2011/65/EU and Delegated Directive (EU) 2015/863

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)

Manufactured by:
Charder Electronic Co., Ltd.
No.103, Guozhong Rd., Dali Dist.,
Taichung City 41262 ,Taiwan

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