

Motion detection sensor device indicator light P.7



	Bluetooth indicator light	The meanings of LED color	
Power On	Broadcast	Blue Flash (1 times/s)	
	Connected	Blue On	
	Data transmission	Green Flash (1 times/s)	
	Low battery	Green Flash (5 times/s)	
	OTA	Not connected	Blue Flash (1 times/s)
		Connected (Firmware update has not yet started)	Blue On
Connected (Firmware update in progress)		Blue Flash (2 times/s)	
Power off	Shut down (Long press 3 seconds)	Blue Flash	
	Charging	Flashing blue/green	
	Full Battery	Green On	

Motion detection processing cradle indicator light P.8

Bluetooth LED indicator



Wi-Fi LED indicator

	Wi-Fi LED	LED Status	Bluetooth LED	LED Status
Power On	Search	Blue Flash	Broadcast	Blue Flash (1 times/s)
	Connected	Blue On	Connected	Blue On
	Data transmission	Green Flash	Data transmission	Green Flash (1 times/s)
			Low battery	Green Flash (5 times/s)
			Firmware update (OTA) Connected	Blue Flash (2 times/s)
Power Off			Shut down (Long press 3 seconds)	Blue Flash
			Charging	Flashing blue/green
			Full Battery	Green On

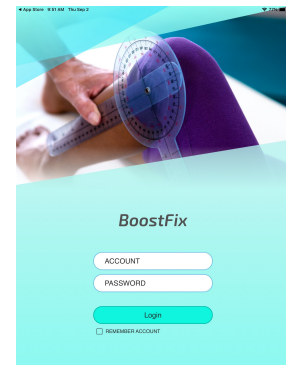
Preparation before use - Create user account, download and login

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Create user account: The professional creates an account and password for the user based on the name, date of birth, and user code provided by the user.

Download: Download the BoostFix® application from the Apple Store or Google Play, and download the manual from the official website, read it carefully and follow the instructions.

Login: Run the BoostFix® application on your tablet, and the screen on the right will appear. After entering the account and password, you can log in to the system.



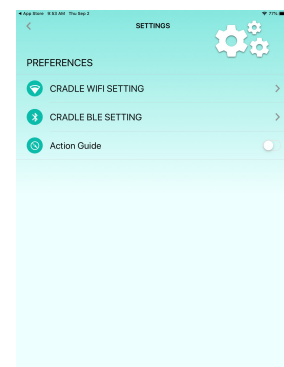
Preparation before use - Bluetooth connection

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Setting: The Bluetooth setting of the tablet and the motion detection processor, the pairing management of the motion detection device and the Wi-Fi setting of the motion detection processor are required for the first use.

1.Run the BoostFix® application on your tablet, log in to the system and enter the main page. Tap the personal page at the bottom right of the tap bar, and then tap Settings to enter the setting screen (see the picture on the right).

2.Click the Bluetooth settings of the motion detection processor to connect the tablet and the motion detection processor with Bluetooth.

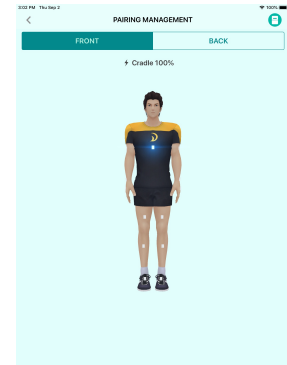


Preparation before use - confirm the wearing position of each motion detection sensor device (1/2)

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3. Press Pairing Management to enter the pairing management screen.

3-1. The 5 motion detection devices have been paired with the charging cradle at the factory, so you will see the lights of the 5 position motion detection devices on the screen, click each of its corresponding motion detection devices. The measuring device will vibrate, so you can confirm which part of the body each motion detection device should be fixed to.

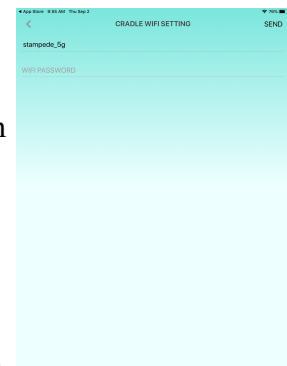


Preparation before use - confirm the wearing position of each motion detection sensor device (2/2)

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3-2. To change the placement of the motion detection device (for example, from the upper right arm to the upper left arm), first click on the upper left arm. At this time, a QR Code scanner will appear to scan the motion detection you want to place on the upper left arm. The QR Code of the device, the light of the motion detection device on the upper left arm will light up after the pairing is completed.

4. Press the Wi-Fi setting of the motion detection processor, the system will automatically bring in the SSID of the Wi-Fi AP connected to the tablet, enter your Wi-Fi AP password, and press Send in the upper right corner to complete the connection.



How to use the straps (1/2)

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Warning: This product is used by many people, taking into account the maintenance of hygiene and safety, the strap must be fixed on the clothing and do not touch the skin.

1. Fix to the arm: connect the two sides of the strap to the two sides of the base of the motion detection device (Figure 1 and Figure 2), and then put your hand through the strap ring (Figure 3).
2. Fix to the chest: first connect the strap to one side of the base (Figure 1), wrap the strap around the chest, and then connect to the other side (Figure 4).
3. Adjust the position and tightness of the strap to confirm that the base is in the correct position and will not move.

How to use the straps (2/2)

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4. Put the motion detection sensor devices into the processing cradle.



Figure 1



Figure 2



Figure 3



Figure 4

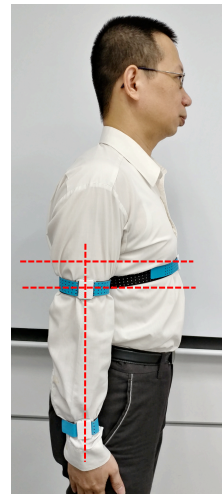
Example of using motion detection sensor device

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Warning: Please be sure to wear the motion detection device in accordance with the method of each rehabilitation mode specified by the doctor.

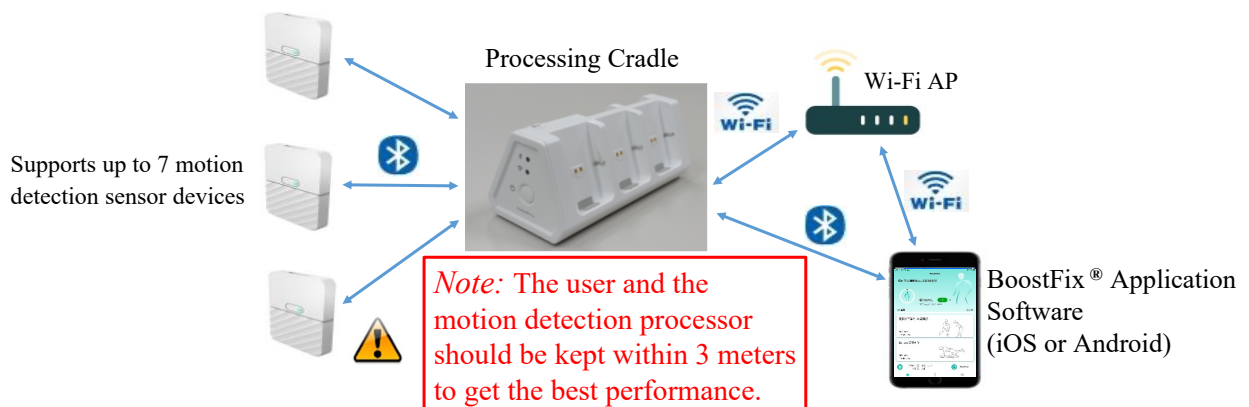
The number of motion detection devices used and their fixed position on the body must be in accordance with the rehabilitation mode specified by the physician, and they must be worn correctly. The picture on the right is an example of use: fix the motion detection device on the upper arm, wrist, and chest. The upper arm and wrist must be kept on the same vertical line. The chest part must be in the center and level with the upper arm detector.



Product application architecture

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After you download the BoostFix[®] application and complete the Bluetooth settings, pairing management and Wi-Fi settings of the motion detection processor, you are ready to start using the applications of this product. Please follow the instructions in the user manual to use this product and software operations correctly.



Cautions (1/2)

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- 1. The waterproof level of this product: the motion detection device is IP22, the motion detection processor is IP21, only a small amount of water splashing is prevented, and a large amount of water splashing or immersing the product in water will damage the product.*
- 2. Please use the power supply attached to this product to charge. When using it for the first time, fully charge the motion detection device.*
- 3. The charging contacts have positive and negative polarity. When charging, please make the end of the motion detection device with the diagonal pattern face down.*
- 4. When charging, please put the motion detection device in the power-on mode, and the indicator light will flash to show the charging status.*
- 5. If the voltage is unstable during charging, the charging indicator will go out. This is not a product problem, it will not affect the performance and there is no safety concern. When the voltage returns to a stable condition, the charging indicator will automatically resume flashing.*

Cautions (2/2)

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- 6. This product is used by many people, taking into account the maintenance of hygiene and safety, the strap must be fixed on the clothing and do not touch the skin. After use, please wipe the product with a cotton cloth dampened with 75% alcohol.*
- 7. Too much muscle expansion may cause the straps to loosen. If necessary, adjust the straps or replace the straps with a suitable length.*
- 8. In order to reduce 2.4GHz interference, it is recommended to use 5GHz to connect this product to the IP sharer.*
- 9. There is a high-sensitivity G-sensor in the motion detection device. If it falls heavily, it will damage the product.*
- 10. If the angle measurement result exceeds the specification range, please consult a physician or confirm that the appropriate measurement steps have been followed. If it is a machine problem, please contact the product distributor.*

Product Safety Information

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Storage/transportation conditions: -25°C ~ 70°C, humidity < 90%.

Use environment: home and medical institutions. Use this product in an environment with 5°C ~ 40°C, humidity: 15% ~ 90%, and a smooth network connection.

Caution for use in radio environment

This product is equipped with Bluetooth (BLE) and wireless network (Wi-Fi). In some situations or areas, users may need to turn off the radio. E.g:

When releasing the "signal" area, the user needs to shut down the system to avoid interference with operation.

Caution for use in radio frequency environment

This product complies with government requirements for radio wave exposure and does not exceed radio frequency (RF) energy radiation limits set by the Federal Communications Commission.

Product Safety Information

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Battery safety information

Do not open, disassemble, puncture or squeeze the battery.

Do not place the device near heat sources, such as vehicle dashboards, clothes dryers or other heat sources.

Please follow the local waste battery recycling regulations for battery recycling.

If you have any product warranty issues, please contact the product distributor

Pharmaceutical company /Address
COMPAL ELECTRONICS, INC.

No. 581 & 581-1, Ruiguang Rd., Neihu District Taipei City
11492, Taiwan (R.O.C.)

Product manufacturer/Address

COMPAL ELECTRONICS, INC. (Pingzhen)


1~2F., No.8, Nandong Rd., Pingzhen Dist., Taoyuan City 324015,
Taiwan (R.O.C.)

1~5F., No.8-1, Nandong Rd., Pingzhen Dist., Taoyuan City
324015, Taiwan (R.O.C.)

Manufacturer’s declaration-electromagnetic immunity

The CEX01-MD1801 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.



The customer or the user of the CEX01-MD1801 should assure that is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home and professional healthcare environment)
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <u>CEX01-MD1801</u> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p>
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	<p>Recommended separation distance:</p> $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P} \quad 80\text{MHz to } 800 \text{ MHz}$ $d = 2,3 \sqrt{P} \quad 800\text{MHz to } 2,7 \text{ GHz}$ <p>Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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.

Other matters needing attention

1. Known contraindications: None
2. The patient is one of the intended users
3. Product classification: class I, symbol: , the motion detection processor (Cradle) is IP21, the motion detection device (Sensor) is IP22. IPN₁N₂ The first mark digit N₁ indicates the level of contact protection and foreign object protection, the second mark The digit N₂ represents the waterproof protection level, and the Type BF Applied Part symbol:  , This type of contact part can be connected to the patient's body, and it is allowed to be connected to the patient with other contact parts.
4. Warning: Use the attached parts, otherwise it may be dangerous.
5. Warning: The plug is a way of disconnecting the power supply and should not be placed in a difficult-to-unplug position
6. Warning: May cause suffocation hazard due to small parts or wires
7. Warning: Do not touch the wound
8. Avoid letting young children or pets chew on small parts or straps
9. Expected useful life: 4 years
10. If the connection is wrong, there is a risk that the measurement will be stopped and the data will not be uploaded
11. Android/iOS operation update please update according to the method specified by the original factory. If it is not updated, there is no risk of use. After the update, some functions of the application may be unavailable due to the compatibility of the operating system. At this time, please do not use it. This software, and continue to do rehabilitation exercises in accordance with the recommendations of the original professionals.

Additional information

Manufacturer's declaration-electromagnetic immunity

The CEX01-MD1801 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the CEX01-MD1801 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home and professional healthcare environment)
Electrostatic discharge(ESD) IEC 61000-4-2	Contact: ± 8 kV Air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Contact: ± 8 kV Air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5 kV, ± 1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T ; 0,5 cycle 0 % U_T ; 1 cycle 70 % U_T ; 25/30 cycles Voltage interruptions: 0 % U_T ; 250/300 cycle	Voltage dips: 0 % U_T ; 0,5 cycle 0 % U_T ; 1 cycle 70 % U_T ; 25/30 cycles Voltage interruptions: 0 % U_T ; 250/300 cycle	Mains power quality should be that of a typical home healthcare environment. If the user of the <u>CEX01-MD1801</u> requires continued operation during power mains interruptions, it is recommended that the <u>CEX01-MD1801</u> be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	The <u>CEX01-MD1801</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

**Recommended separation distance between
portable and mobile RF communications equipment and the CEX01-MD1801**

The CEX01-MD1801 is intended for use in an electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the CEX01-MD1801 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CEX01-MD1801 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.

Manufacturer's declaration-electromagnetic immunity**Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment**

The CEX01-MD1801 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the CEX01-MD1801 should assure that it is used in such an environment.

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home and professional healthcare)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Subclause 5.2.2.1 c)

Providing the RESPONSIBLE ORGANIZATION with maintenance instructions with regard to EM DISTURBANCES is a good and practical way for the MANUFACTURER to assure that the ME EQUIPMENT OF ME SYSTEM remains safe with regard to EM DISTURBANCES throughout the EXPECTED SERVICE LIFE.

For example, the technical description could include the following recommendations for actions that are known to affect the EMISSIONS and IMMUNITY of equipment throughout the EXPECTED SERVICE LIFE:

- recommendations for maintenance or service intervals;
- service procedures to maintain effectiveness of shields and grounds;
- precautions to take if the use location is near (e.g. less than 1,5 km from) AM, FM or TV broadcast antennas.

NOTE AAMI TIR 18 [28] provides guidance in management of the EM ENVIRONMENT and management of medical devices for EMC, including assessment of the EM ENVIRONMENT, investigation and reporting of EMI problems and site selection, design, and construction of new healthcare facilities. Table A.3 of AAMI TIR 18:2010 shows field strengths at 1 km from FIXED transmitters such as AM, FM and TV broadcast antennas.

Product appendix description

1. BoostFix electronic protractor system (CEX01-MD1801) is used to measure and record the degrees of freedom of joints. This product contains five motion detector devices (or simply called sensor/perceptor/detector), one motion detection processor (or called Cradle or charger); it has charging/data processing/communication functions) And the BoostFix APP (application: iOS or Android) implemented on the tablet. Connect the processor and the tablet via Wi-Fi or Bluetooth, and then connect 3 to 5 detectors to the appropriate parts of the body as needed. Then we can measure the relevant joint degrees of freedom in the BoostFix APP.
2. Working principle: Through 6 axis IMU (Inertial measurement unit), MEMS (Microelectromechanical Systems) device, output Accelerator X, Y, Z and Gyroscope X, Y, Z raw data (raw data) and use mathematical fusion algorithm (fusion algorithm) Convert the quaternion to indicate the space vector of each sensor, and use this space vector to evaluate the relative angle of the sensor at the corresponding position on the limb of the wearer.
3. Operation method: The user can operate it by himself or with the help of a rehabilitation practitioner.
4. The user or patient himself does not need to maintain or repair. All maintenance and repairs should be performed by appropriately trained personnel. These personnel must be re-certified and approved by the manufacturer within a predetermined time. Unauthorized disassembly may cause damage to the product.