

# **PelPal Biofeedback Therapy Device**

(Biofeedback Probe Model: BIO-06A

Wireless Charging Cradle Model: MWCC-01A)

## **Instructions for use**

2020-07-01 revised

Version:V1.4 Document No:MD-E1-04

**Ningbo MedKinetic Medical Device Co., Ltd**

# Table of Contents

Company information .....	1
Indications for Use .....	1
Safety warnings and precautions .....	1
Chapter 1 PelPal device and accessories.....	3
1.1 List of included parts .....	3
1.2 Key components.....	3
1.3 Biofeedback probe .....	4
1.4 Wireless charging cradle .....	4
1.5 Android App .....	5
Chapter 2 Directions For Use .....	7
2.1 Preparing the device for the first use.....	7
2.2 Charging the device.....	8
2.3 Turning the device on and off .....	10
2.4 Initiating the biofeedback training.....	11
2.5 Performing the biofeedback training .....	13
Chapter 3 Product Maintenance.....	15
3.1 Cleaning.....	15
3.2 Device storage.....	15
3.3 Waste Disposal .....	16
Chapter 4 Fault analysis and troubleshooting.....	17
Chapter 5 Therapy scope, indications, and contraindications .....	18
5.1 Therapy scope .....	18
5.2 Indications .....	19
5.3 Contraindications .....	19
Chapter 6 Product warranty.....	19
Chapter 7 Electromagnetic compatibility.....	22
Chapter 8 Technical Specifications.....	25
Chapter 9 FCC Statement .....	27

**Dear Customers:**

Thank you for choosing our product.

For your convenience, please read the instructions carefully and follow all instructions. If you experience any problems during the device use, please contact us by phone or mail, using the information below.

**Contact Us:**

Name of Registrant: Ningbo MedKinetic Medical Device Co., Ltd.

Address: Lushan West Road, 167-8, Ningbo Free Trade Zone (South), 315806 Ningbo, China

Phone: +86 574 86808886

Email: PELservice@medkinetic.com

Website: [www.medkinetic.com/products/PEL](http://www.medkinetic.com/products/PEL)

USA Authorized Representative

MedKinetic LLC

Address: 420 S Madison Ave, Suite 206, Pasadena, CA 91101, USA

Phone: +1 626-497-9441

Email: PELservice@medkinetic.com

# Company information

The customer service center at Ningbo MedKinetic Medical Device Co., Ltd can provide help to customers who encountered problems while using the product. Please go to <http://www.medkinetic.com> for support. In addition, customers can keep up-to-date with the latest product developments through the website of Ningbo MedKinetic Medical Device Co., Ltd. and download the required technical documents from the download center.

The conventions about the icons in the manual are as follows:

Tip: This icon mainly gives some information related to the text, and also gives users some guidelines to help users better understand the content of the manual.



## Scope of application

This manual provides the instructions for use of the biofeedback therapeutic device produced by Ningbo MedKinetic Medical Device Co., Ltd.

# Indications for Use

The PelPal biofeedback therapy device is an Over-The-Counter Class II medical device intended to treat constipation and fecal incontinence. It is to be used by adults only. This manual will introduce the performance, operation methods and other safety information of the PelPal device in detail. This is the best starting point for new users to start using and master the use of BIO series biofeedback therapy devices.

The following symbols will be used throughout the manual:

<b>Symbol</b>	<b>Meaning</b>
	Warning about a situation when if the device is used incorrectly it can result in death or injury to the patient or user or damage to the equipment or other property
	Attention indicates an important information

# Safety warnings and precautions

## Precautions for use

Please read this manual carefully first and always follow the operating instructions.



- Please stay away from children and pets;
- Don't use in lint, dust, bright light (including sunlight), etc;
- Children or people with disabilities need special supervision to use this instrument;
- Do not use for contraindication patients of this product;
- If you are pregnant or have menstrual cramps, please do not use this instrument;
- Please use the USB data cable provided by the manufacturer for charging;
- It is recommended to use an adapter that meets the G9706.1-2007 standard;
- If the instrument or charging cable is damaged, do not use it;
- Before charging, please ensure that the charger and product charging are dry;
- When the product or charger may be submerged in water, it can not be used for charging;
- Do not use other therapeutic instruments while using this machine;
- Do not use this product when you are drunk or unwell;
- Patients with malignant tumors, heart disease, severe hypertension, etc., please use with caution (requires normal person supervision);
- Do not disassemble the internal components of the product without permission to avoid the possibility of machine failure;
- Except for the repair technicians appointed by our company, the products must not be decomposed, modified or modified. If you have any questions, please contact the dealer in time;
- Do not use a power supply other than the rated voltage to avoid fire or damage to the product;
- When unplugging the power cord, grasp the plug of the power cord instead of the wire;
- Do not damage, excessively bend, pull, twist, or knot the power cord;

- When the power cord is damaged, please do not dismantle and replace it privately, please contact the dealer or qualified professional to replace and repair
- Do not use in strong electromagnetic radiation environments, such as portable communication equipment other than mobile phones used in conjunction with this product;
- Do not use in an oxygen-rich environment;
- Do not use it at an altitude of more than 3000 meters;
- Do not forcefully pinch or break the biofeedback probe;
- The product cannot be used in the presence of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide;
- The probe is scrapped. The probe contains lithium batteries. Please recycle according to the scrapped battery. Please do not discard it in the environment.
- Please do not use when the equipment performance changes.



It is prohibited to disassemble or modify the device or accessories

Turn off the device before removing the lead cable or pads

Unplug the USB power adapter from the power socket before using the device

Use only the provided USB power adapter for device charging, as using unapproved power adapter can be dangerous

It is prohibited to use this device with accessories not supplied by manufacturer

# Chapter 1 PelPal device and accessories

## 1.1 List of included parts

Part name	Quantity
Biofeedback probe	1
Wireless charging cradle	1
USB charging cable	1
USB power adapter	Purchased separately
Instructions for Use	1
Android application software	Downloaded by user

## 1.2 Key components

The PelPal device consists of a biofeedback probe, a wireless charging cradle with a protective cover and a USB data cable, an APP. as shown in Figure 1.1.



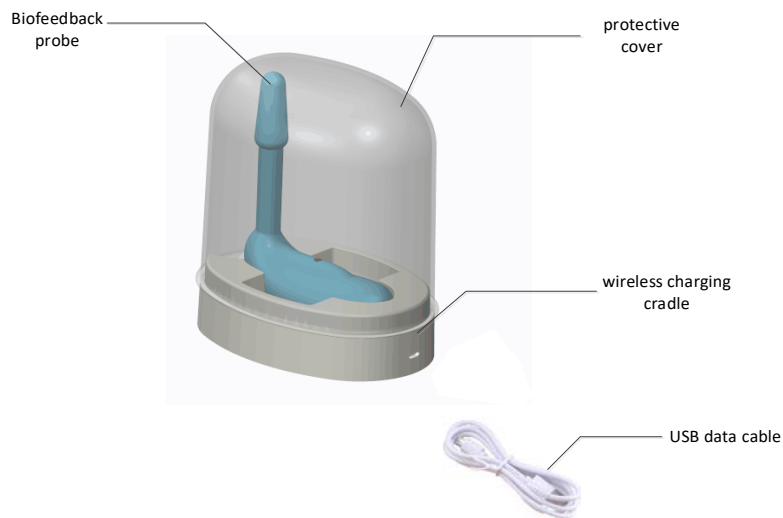


Figure 1.1 Composition of PelPal device

### 1.3 Biofeedback probe

The biofeedback probe consists of a handle with sensors. The probe sensors are inserted in the subject's anorectal area to detect the pressure of the rectum and anal sphincter when the subject is performing a simulated defecation or clamping the anus, as shown in Figure 1.2.

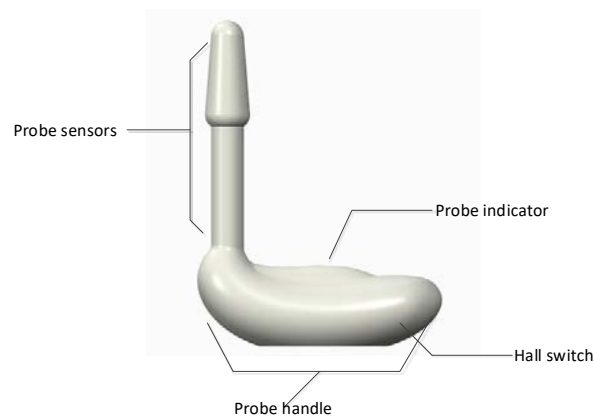


Figure 1.2 Biofeedback Probe

### 1.4 Wireless charging cradle

The wireless charging cradle is used for storing and managing the probe charging before and after

use, as shown in Figure 1.3.

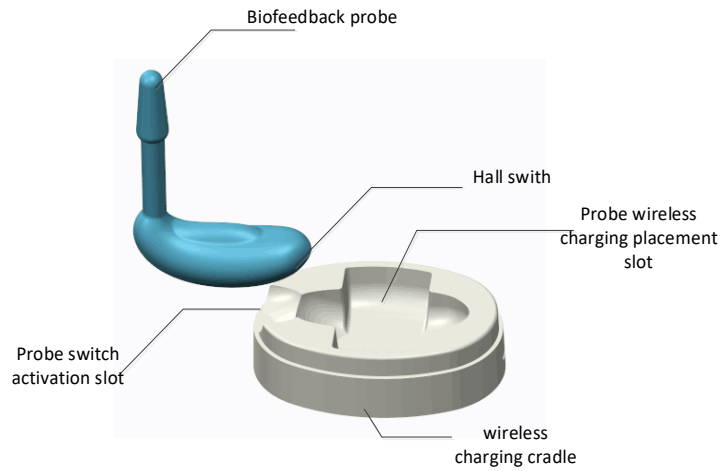


Figure 1.3 Wireless charging cradle

## 1.5 Android App

The app needs to be installed by the user on a smartphone with Android operating system. The app is used to provide data interactive interface for subjects during biofeedback training. The app provides two training modes, which are suitable for the rehabilitation of patients with constipation and fecal incontinence. The training process uses a game playing interface, making you feel relaxed and comfortable. The training interface is shown in Figure 1.4:

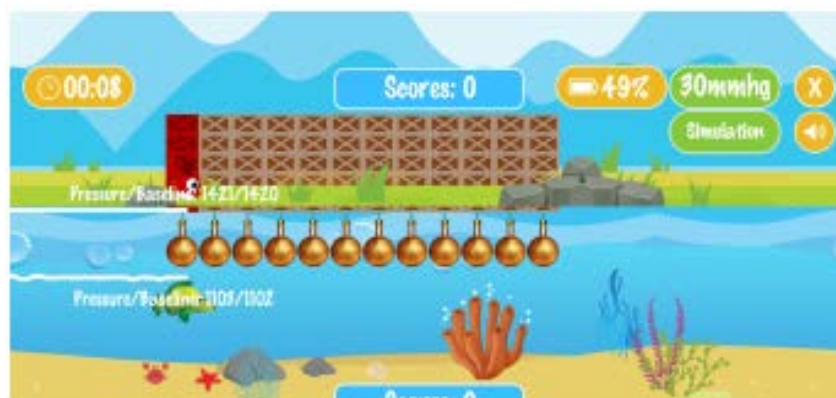


Figure 1.4 Biofeedback app training page

If you need to know the past training achievements, you can browse the historical data on the app software and watch the entire training process, which can provide you with rich information for the next training.

# Chapter 2 Directions For Use

## 2.1 Preparing the device for the first use

- Open the product package, remove the product and accessories;
- open Biofeedback Protective cover on the wireless charging cradle, clean and stick the fixed probe and the auxiliary sticker on the charging box;
- take out the charger and connect the USB data cable, connect the USB data cable mini port to the USB data cable connection port on the wireless charging cradle, and the charger Connect the other end to a 110V power socket;
- place the biofeedback probe into the charging slot (note that it is neatly placed). At this time, the charging function is performed between the biofeedback probe and the wireless charging cradle, and the charging status indicator flashes on the handle of the biofeedback probe. , Steady green indicates full charge, and yellow flashing indicates charging. The first full charge lasts about 2 hours. The description of the probe indicator is shown in Table 2.1 below:

Table 2.1 Description of the probe indicator status

	Turn on, Bluetooth is not connected	Bluetooth is connected	Data transmission is on	Data transmission is off	Charging	charging is completed	Low battery
<b>blue</b>	off	off	off	off	slowflashing	steady	fast flashing
<b>green</b>	flashes slowly	steady	flash	off	off	off	-

- cleaning before use, washing and disinfecting see specific probe portion;

- power the probe, by placing it in the slot on wireless charging cradle for about 5 seconds; after activation, the probe indicator lights green;
- subject prepares before training;
- launch the Biofeedback application on the smartphone;
- register a username (first use), and logs in;
- in the selected training mode, connect the probe Bluetooth, And began to record the data and set the data to zero;
- biofeedback probe is inserted into the anorectum, with the subject adjusting the posture;
- training was started and the training mode was entered. The subject adjusted the anorectal simulation training action according to the mobile app content prompts , Training lasts about 30 minutes;
- after training, unplug the probe, disinfect, clean, dry, put back into the wireless charging cradle for storage.

## **2.2 Charging the device**

- Connect the USB data cable plug to the socket under the charger, and then insert the DC connector into the USB data cable connection port of the probe wireless charging cradle.
- The biofeedback probe is placed in the charging slot on the probe wireless charging cradle, as shown on Figure 2.1.

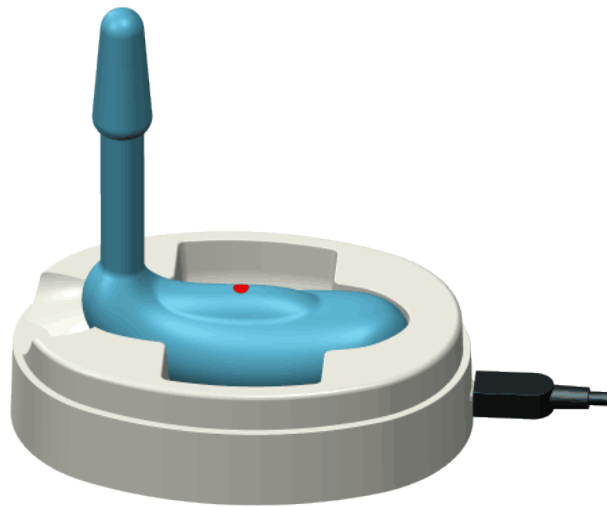


Figure 2.1 Placing the probe into the charging slot on the wireless charging cradle.

- Insert the charger plug into the AC100 ~ 240V, 50 / 60Hz power socket, as shown on Figure 2.2.

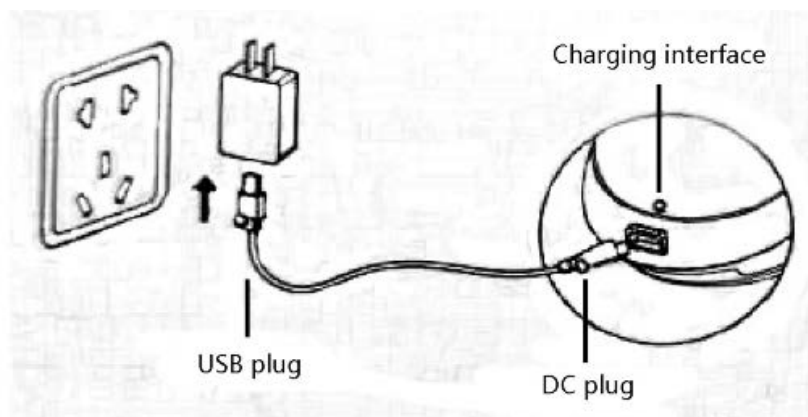


Figure 2.2 Charger and USB data cable connection

- Once the charger is powered on, the charge indicator on the probe will light up.
- It takes about 2 hours to fully charge the battery. After the battery is fully charged, the charging indicator on the probe is steady green.



#### Caution

- ◆ The device does not work during charging
- ◆ Use only the provide medical-grade power adapter
- ◆ Do not bend or twist the power cord
- ◆ Keep the probe in the charging box to maintain its battery capacity

## 2.3 Turning the device on and off

- The physical switch of the probe is a magnetic switch, which is located at the end of the probe handle, as shown in the "magnetic switch" position.
- The other end of the USB data cable interface of the probe wireless charging cradle is the probe switch activation slot, as shown on Figure 2.3.

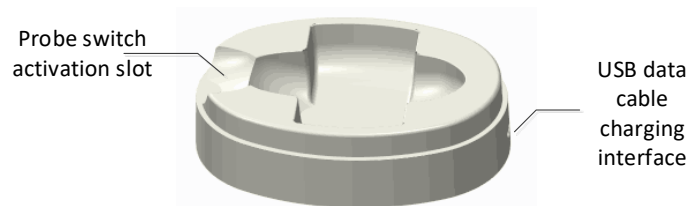


Figure 2.3 Base of the wireless charging cradle

- Turning on the probe of the: Close the magnetic switch at the end of the probe handle to the probe switch activation slot on the base of the wireless charging cradle. It takes about 5 seconds to activate the probe switch. When activated, the probe indicator is blue. Blinks, as shown on Figure 2.4.

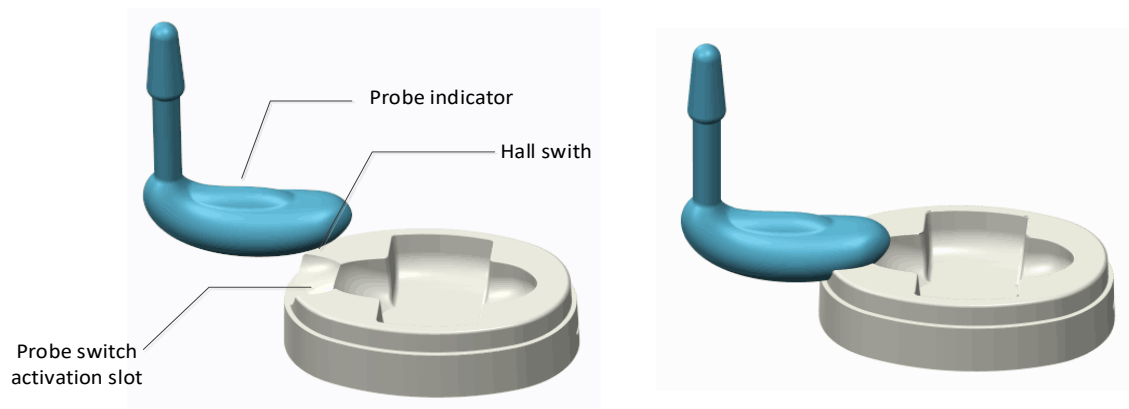


Figure 2.4 The position of the activated magnetic switch is shown on the left. The right is placed


- sensor is turned off when the. The operation mode is the same as when the probe is turned on. When the probe is turned off, the indicator on the probe is off.



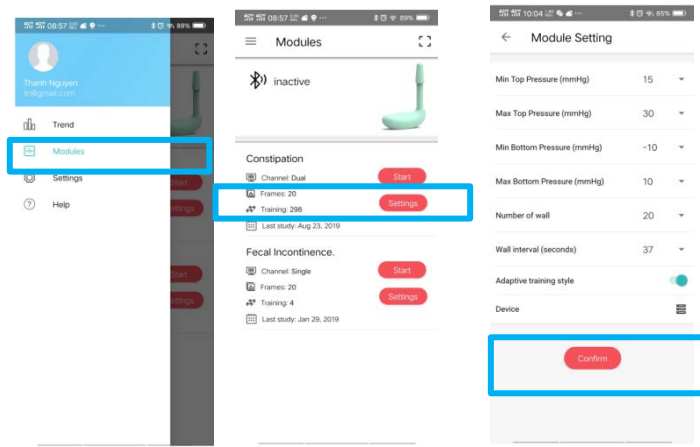
**Caution**

- ◆ Do not pinch the probe to avoid damaging the sensors
- ◆ After use, turn off the device to prevent depleting the battery

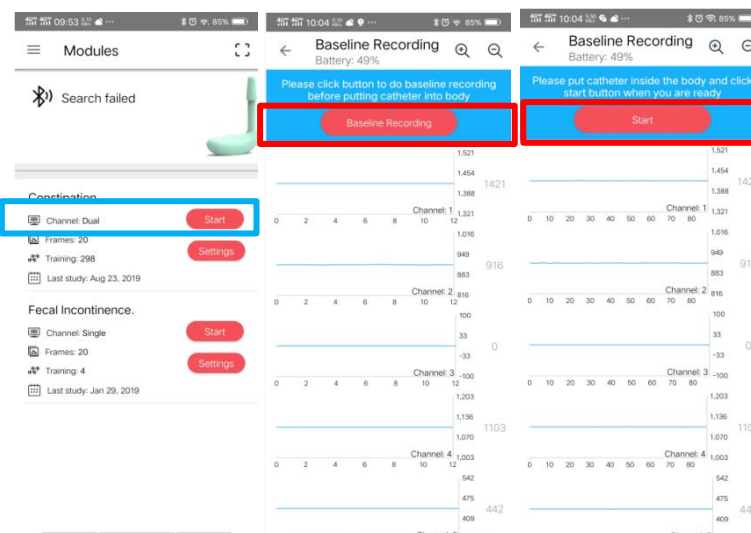
## 2.4 Initiating the biofeedback training

- When the probe is turned on, press the “BioFeedback” icon  to proceed to the biofeedback training login interface.
- For first time use, you need to register.
- After logging in, on the My Data page, click the menu in the upper left corner and select "Training" from the pop-up menu, as shown in the operations on Figures 2.5 and 2.6 below:





Click training to select dual channels (constipation) and click to start (parameters are default)



Click the recording baseline and click "Start"

Figure 2.5 Sequence of operations



Figure 2.6 Training screen

- You could complete one training by default, which requires 30 obstacles, which takes about 30 minutes.

- Hold the probe handle, slowly insert the sensor part of the probe sensor into your anus, and leave the probe handle outside the body. Please insert the sensor part of the probe completely (if you feel discomfort when inserting, please use water-soluble lubricating fluid), fix it, adjust the proper posture of the lying or sitting position, and then click the "start game" button.
- Choose the right exercise position: Most people prefer sitting exercises, holding your phone at your knees. If you feel uncomfortable with this position, try lying down and lying on your side. For better results, set goals and keep exercising in the same position.
- During the simulated defecation, observe the movements of the two game characters, the bird and the fish, to adjust the movement of each simulated defecation.

## 2.5 Performing the biofeedback training

- anorectal coordination training (functional constipation rehabilitation training)

You can inhale deeply and feel that the lower part of the thorax slowly expands to both sides. Relax the abdominal muscles completely, then slowly expand the abdomen outward. At the same time completely relax the anus and pelvic floor muscles. Facial expressions are relaxed and natural. Then exhale slowly.

If you choose the functional constipation rehabilitation training mode, you need to do defecation simulation during training. The character of the game bird on the mobile phone represents the abdominal pressure, and the fish represents the anal pressure. The direction of movement of the two characters indicates that you are simulating defecation Movement coordination. The goal of each training control defecation is to let the birds fly over the obstacle wall and let the fish sink to the bottom of the lake without touching the hook. Whenever the bird hits the obstacle or the fish hits the hook, the corresponding obstacle will turn red. . Whenever

the birds and fish pass the obstacle, please relax and rest until the next time the birds and fish are reminded 3, 2, 1 again, and then do a simulated defecation action.

- Anus contraction training (fecal incontinence rehabilitation training)

If you choose the fecal incontinence rehabilitation training module, you need to do anal clamping (anal lift) during training. The game bird on the mobile phone represents anal pressure, and the height of the bird flying represents training. Anal clamping pressure. The goal of enzyme washing training to control the clamping of the anus (anus) is to let the birds fly over obstacles. Whenever a bird hits an obstacle, the corresponding obstacle will turn red. Whenever the bird passes the obstacle, please fully relax and rest until the next time the bird is reminded 3, 2, 1 again, then do anal clamping (anal lift).



**Caution**

- ◆ Please do not use this product for two or more people.



# Chapter 3 Product Maintenance

## 3.1 Cleaning

Clean the probe before and after each use. Wipe the surface of the probe thoroughly with soft cloth that is dampened with a warm cleaning solution, such as household soap or mild detergent, which are recommended for cleaning hands and or lightly soiled kitchen items. Do not immerse the probe in a cleaning solution. Finally, rinse the cloth in water, squeeze out the water, and wipe the probe. Let the probe dry completely before placing it in the charging case.



### Caution

- ◆ Don't wash the probe with very hot water or harsh cleansing agents or detergents (such as those containing bleach, benzene or alcohol)
- ◆ Don't clean using strong pressure or abrasives
- ◆ Don't place the probe in a microwave oven
- ◆ Don't place the probe in a dishwasher

## 3.2 Device storage

- Put the device in the cradle and put it in a safe place.
- Please do not place heavy objects on the product to make the product moisture-proof, mouse-proof and stain-proof.
- Under storage conditions, it can be used immediately after being taken out.

**Caution**

- ◆ Do not expose this device to high or extremely low temperature
- ◆ Do not use this device on children



### **3.3 Waste Disposal**

This equipment mainly includes a biofeedback probe and a charging box. The probe contains a polymer lithium battery and electronic components. The charging box has a charging coil. It is recommended to dispose of it as a general medical device waste.

### **3.4 Expected service life**

3 years.

### **3.5 Application Environment**

Home or Hospital.

## Chapter 4 Fault analysis and troubleshooting

Possible	causes	approach
does not turn	magnetic on / off is not open	switch to activate the probe slot on the on / off
	the battery runs out	charge
	of the magnetic switch location misalignment	on the probe switch activation slots, the aligned position
can not be charged	is not plugged	is plugged
	probe not properly seated in	the probe is placed flat probe wireless the charging tank
phone can not connect	is not on the probe	the probe opening magnetic switch
	is not turned Bluetooth phone	to open the handset Bluetooth
	phone and a probe distance can not exceed 3 meters	reducing handset and probe The distance
no data	probe is not connected biofeedback software.	to the Bluetooth connection of the probe

If there is any other abnormality in the, please contact the dealer to request maintenance and do not disassemble it by yourself.

## **Chapter 5 Therapy scope, indications, and contraindications**

### **5.1 Therapy scope**

The device is suitable for the treatment of functional constipation or fecal incontinence.

## 5.2 Indications

4.2.1 Functional defecation disorders;

4.2.2 Fecal incontinence caused by:

- weakened external anal sphincter tone;
- rectal sensory disorders;
- loss of coordination of internal and external anal sphincter responses after stretch rectal stimulation.

## 5.3 Contraindications

- Patients have recently undergone colon, rectal and anal surgery;
- patients are allergic to silicone (because the biofeedback probe outsourcing material is silicone);
- patients with malignant tumors, heart disease, severe hypertension, etc .;

# Chapter 6 Product warranty

### BIO-06 Biofeedback Therapy Device Warranty Card (Saved by the User)

Product Name	Biofeedback Therapy Device	Product Number	
User Name		Phone	
Address		Fax	



Purchase Date		Zip	
<p>User Notice:</p> <ol style="list-style-type: none"> <li>This product is guaranteed for one year.</li> <li>During the warranty period, if the product has a quality failure, you can directly contact the manufacturer. (User can hold invoice or complete warranty card)</li> <li>Any one of the following conditions is not covered by the warranty, but can be repaired for a fee: the <ul style="list-style-type: none"> <li>warranty period is exceeded; the</li> <li>user disassembles the machine by himself, and the structure of the machine is artificially damaged;</li> <li>failure and damage caused by non-product quality reasons such as falling and moving after purchase ;</li> <li>of damage caused by force majeure</li> </ul> </li> </ol>			

Repair record (filled by maintenance technician)

<b>Date</b>	<b>failure phenomenon and</b>	<b>signature of maintenance personnel</b>	<b>User signature</b>


Company name: Ningbo MedKinetic Medical Device Co., Ltd.

Company address: Lushan West Road 167-8, Ningbo South Free Trade Zone, 315806, Ningbo

Telephone: +86(574)-86808886      Fax: +86(574)-86808885

website: <http://www.medkinetic.com>

## Chapter 7 Electromagnetic compatibility

Below cables information are provided for EMC reference.

Cable	Max. cable length, Shielded/unshielded		Number	Cable classification
USB data cable	1m	shielded	1 Set	DC Power

### Important information regarding Electro Magnetic Compatibility (EMC)

This electrical medical equipment needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; The equipment conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

➤ The equipment with Following ESSENTIAL PERFORMANCE: When exposed to interferences, the error between the output pressure value of the pressure sensor of each channel and the pressure of the standard pressure chamber is  $\leq \pm 4.0\text{mmhg}$ .

The equipment is intended used in Home healthcare environment and Professional healthcare facility environment except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

- WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally”.
- The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.”
- WARNING: If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected service life.
- STATEMENT: For the purpose of its operation, the equipment has Bluetooth communication function, it includes RF transmitter and receiver, 2402-2480MHz, GFSK modulation.

### EMI Compliance Table (Table 1)

**Table 1 - Emission**

<b>Phenomenon</b>	<b>Compliance</b>	<b>Electromagnetic environment</b>
RF emissions	CISPR 11 Group 1, Class B	Home healthcare environment
Harmonic distortion	IEC 61000-3-2 Class A	Home healthcare environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Home healthcare environment

**EMS Compliance Table (Table 2-4)**

**Table 2 - Enclosure Port**

<b>Phenomenon</b>	<b>Basic EMC standard</b>	<b>Immunity test levels</b>
		Home healthcare environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3

**Table 3 – Proximity fields from RF wireless communications equipment**

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Home healthcare environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, $\pm 5$ kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

**Table 4 – Input a.c. power Port**

Phenomenon	Basic EMC standard	Immunity test levels
		Home healthcare environment
Electrical fast transients/burst	IEC 61000-4-4	$\pm 2$ kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	$\pm 0.5$ kV, $\pm 1$ kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands and amateur radio bands between 0.15MHz and 80MHz 80%AM at 1kHz

Voltage dips	IEC 61000-4-11	0% U <sub>T</sub> ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U <sub>T</sub> ; 1 cycle and 70% U <sub>T</sub> ; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U <sub>T</sub> ; 250/300 cycles

## Chapter 8 Technical Specifications

Name	PeiPal Biofeedback Therapy Device
Model	BIO-06A
Power supply	
Power	Internal battery
Battery type	3.7V Lithium-Polymer Battery 200mAh
Wireless charging with cradle	DC5V 500mA (custom USB charging cable is included)
Battery life	300 Charge Cycles (≥80% Nominal capacity)
Probe physical specifications	
Dimensions	80 × 31.5 × 119 mm
Weight	45 g
Housing	ABS plastic
Cradle physical specifications	
Dimensions	125 × 85 × 125 mm
Weight	168 g
Housing	ABS plastic
Environment	

Operating/storage/transport temperature	5 to 40°C
Operating/storage/transport humidity	25% to 90% RH
Storage/transport atmospheric pressure	70 to 106 kPa
Electric shock	Internally Powered Equipment, type BF Applied Parts
IP Rating	IP27
Classification of safety levels	Not suitable for is in the presence of flammable mixtures: No Ap/apg
Running mode	Continuous Operation
EMC	Group 1, Class B
Smartphone compatibility	
Google Android	Version 6.0 (or later) with Bluetooth 4.0 (or later)
Apple iOS	Not supported

## Chapter 9 FCC Statement

This device complies with Part 18 of the FCC Rules.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

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

Attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This product has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This product generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/TV technician for help.



This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.