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SYREBO®

SYREBO® Soft Rehabilitation Glove SY-HRC10 User Manual

Shanghai Siyi Intelligent Technology Co., Ltd.

Address: East Area of Floor 5, No. 26, Lane 3399, Kangxin Road, Pudong New Area, Shanghai, China, 201321

Office: 400-6886-275

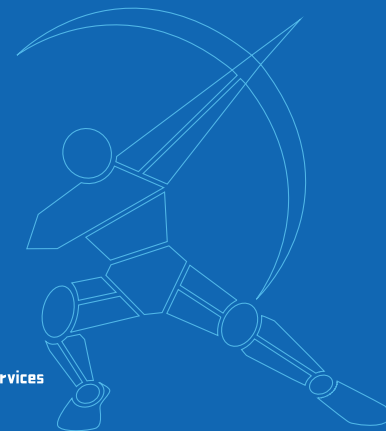
E-mail: wmsales@siyizn.com

Mobile & whatsapp: (+86)17317983724

Website: www.syrebo.com



**Innovative Rehabilitation Products & Services
For Clinicians & Patients**



Contact Information

Manufacturer:



Shanghai Siyi Intelligent Technology Co.,Ltd.

Address: East Area Of Floor 5, No.26, Lane 3399, Kangxin Road, Pudong New Area, Shanghai, China, 201321

Tel: 008617317983724

Country of Origin: China

Website: www.syrebo.com

E-mail: wmsales@siyizn.com

EC REP

Name: MedPath GmbH

Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Tel: +49(0)89 189174474

Fax: +49(0)89 5485 8884

E-mail: info@medpath.pro

Important

Descriptions on Environment of Use

This product is a common device that can run continuously (enclosed device without the ability to prevent liquid from entering), and it cannot be used in the presence of a mixture of flammable anesthetic gas and air or a mixture of flammable anesthetic gas and oxygen or nitrous oxide. This product may break down due to the interference of electromagnetic waves from portable TV, radio transceiver, and electric toys, etc. Please keep it away from these products.

Electromagnetic compatibility. This product should be kept away from the objects that can generate strong electromagnetic waves or noise, such as nuclear magnetic resonance equipment, microwave generator, and radiation equipment (e.g. X-ray machine, CT machine, etc.); This product should be kept away from high-frequency surgical instruments, such as high-frequency electrotome, and mobile phone, etc.

Intellectual Property

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Disclaimer








All contents in this manual are written in strict accordance with relevant national laws and regulations and the technical specifications of Shanghai SiYi Intelligent Technology Co., Ltd., and have been strictly checked and ensured to be correct. Shanghai SiYi Intelligent Technology Co., Ltd. is not liable for any consequences caused by improper use. Shanghai SiYi Intelligent Technology Co., Ltd. has the right to change the contents and version number of this User Manual according to the changes of product specification and the software upgrades without prior notice. The product picture is only for reference, please make the object as the standard.









Notification

Before using the Soft Rehabilitation Glove, please read this manual carefully to have a clear understanding of its functions and operations. Keep this manual handy so that it can be referred to whenever needed. Follow the operating procedures and usage described in this guide. Do not modify the device, replace any parts, use non-specified parts, or remove protection devices, as these actions could result in a hazardous situation.

PLEASE READ THIS USER MANUAL BEFORE OPERATING THE SYSTEM

General Warnings	
	Training is mandatory. Use this document as a guide during training and as a reference after training. This manual is not a substitute for training.
	Plug and unplug the power supply with the normal procedure! Otherwise, it will lead to serious injury or death!
	Do not plug and unplug the power supply with wet hands! Otherwise, it will lead to serious injury or death!
	Use the power supply as specified, otherwise it will damage to equipment or failure to charge!
	The device must not be disassembled or repaired by non-professionals without permission, otherwise it will cause fire or electric shock!
	The power must be disconnected before opening the casing of the host. When the casing is opened, the device cannot be used.
	The power supply of the device is 100~240V, Before using the device, it is necessary to verify that the power supply voltage matches with the voltage value of the adapter.
General Cautions	
	Do not use the device if users are distracted or not paying attention to the operation of the glove.
	This product is contraindicated in the following people: 1) Patients with severe disturbance of blood circulation; 2) Patients with comminuted fracture or bone cancer; 3) Patients with burn injury, bleeding condition, suppuration or uncontrollable infectious diseases; 4) Patients with severe deformation or spasm of hands; 5) Patients with obvious hand trauma or allergy to N Cloth and Lycra.

	Attention should be paid to avoid static electricity during use, which may cause damage to the device.
	Please remove the adapter and disconnect the power supply in time if the device is not used for a long time.
	Do not use unofficial accessories for the sake of safety.
	Shut down the device and unplug the power supply immediately in any one of following conditions during operation: 1) Lightning strike; 2) Occurrence of abnormal sound, smoke or peculiar smell; 3) Excessive surface temperature of the host; 4) Entry of water into the host; 5) The user feels pain, swelling or other discomfort.
	It is suggested that the duration of single training should be about 20 minutes. After 40 minutes of continuous training, the equipment enters the rest mode, and the training can be resumed after 40 minutes of rest.
	As gloves are often worn by patients, the following measures can be taken to ensure the safety and hygiene of gloves: 1) Patients need to wear disposable gloves for isolation during training; 2) Gloves shall be regularly wiped with 75% medical alcohol for five times or disinfected with ultraviolet radiation for one hour; 3) PG02E-1 Power-assisted glove and DG11E Data Glove are consumables, with a service life of 3 months and 6 months respectively under continuous use. Failure to replace the gloves after their expiration may reduce rehabilitation effect and clinical experience.
	The following requirements on storage shall be observed: 1) Do not place weights on the device and its accessories; 2) Do not expose it to direct sunlight or high temperature; 3) Do not expose it to high humidity; 4) Do not store it in a place with intense vibration; 5) Do not store it in a place where children or pets can reach.

	Working environment: Temperature, +5°C~+40°C; relative humidity, ≤ 80%; atmospheric pressure: 860 hPa ~ 1060 hPa; Transportation and storage environment: Temperature: -35°C~+60°C; relative humidity, ≤93%; atmospheric pressure: 860 hPa ~ 1060 hPa.
	It could be transported by general means or transported in the manner specified in the contract. During transportation, it shall be protected from sunlight, rain, severe vibration and impact, and shall not be transported together with toxic, corrosive or explosive substances.
	The device should be maintained regularly, and the routine maintenance should be carried out once a week to clean the dirt and dust outside the host and check whether all interfaces on the host function properly.
	When using the training system in a wheelchair, it is necessary to ensure that there is enough barrier-free space under the desktop to accommodate the wheelchair.
	The hand length of patients using this product must be in the range of 8 ~ 22 cm.
	The wearing parts need to be cleaned and disinfected regularly, and the power-assisted rehabilitation gloves are consumable and need to be replaced regularly to ensure hygiene and effectiveness.
	Please inform the manufacturer and competent authority in case of any adverse events related to the device occur.
	The therapist should evaluate the patients' hand function before training; The user should evaluate whether the product is suitable for patients by letting the device running for a trial cycle; If any questions, consult your therapist on time.

Content

Contact Information	2
Important	1
Disclaimer	1
Notification	2
1. Introduction	7
1.1 About this User Manual	7
1.2 Glossary and Abbreviations	7
2. System Description	8
2.1 Intended Use	8
2.2 Applicable Locations	8
2.3 Indications	8
2.4 Contraindications	8
3. Symbols used in this User Manual	9
4. System Components	10
4.1 Host	10
4.2 PG02E-1/PG14E-1 Power-assisted glove	10
4.3 DG11E Data Glove	11
4.4 Adapter	11
5. System Features	12
5.1 Working Mechanism	12
5.2 Product Model and Software Version	12
5.2.1 Product Model	12
5.2.2 Software Version	12
6. Instructions on Use and Installation	12
6.1 Preparation before Use	12
6.2 Wearing Glove	12
6.3 Glove Size	13
7. Descriptions on Product Training Functions	14
7.1 Product introduction	14
7.1.1 Buttons and Icons introduction	14
7.2 Passive training	15
7.3 Mirror training	16
8. Trouble-Shooting	17
9. Cleaning and Maintenance	18
9.1 Cleaning and Maintenance	18
9.2 Maintenance of Training Equipment	18
10. Repair Policy	19
11. Disposal	19
12. Warranty	19
12.1 Service Support	19
13. Technical Specifications	20
14. Packing List	20
Appendix A	21

1. Introduction

1.1 About this User Manual

This User Manual provides the information necessary to operate the Hand Rehabilitation System. PLEASE READ THIS USER MANUAL BEFORE OPERATING THE SYSTEM. If any part of this User Manual is not clear, contact Customer Support for assistance.

1.2 Glossary and Abbreviations

Table 1.1 Glossary and Abbreviations

Mode	The current method to operate the Soft Rehabilitation Glove system, such as Passive Mode, Mirror Mode, Active Mode etc.
Therapist	A specially-trained medical professional who is qualified to adjust the Soft Rehabilitation Glove to the user, and provides the user with proper usage instructions.
User	The person who uses the Soft Rehabilitation Glove.

2. System Description

2.1 Intended Use

The Soft Rehabilitation Glove is suitable for rehabilitation training of patients with finger joint dysfunction.

2.2 Applicable Locations

The device can be used in institutions engaged in rehabilitation, including hospitals, rehabilitation centers or clinics, community-based rehabilitation centers and elderly-care institutions. Patients can also use it at home.

2.3 Indications

The Soft Rehabilitation Glove is mainly used for finger joint rehabilitation training of patients with finger movement dysfunction caused by cerebral stroke and brain trauma.

2.4 Contraindications

Absolute Contraindications: The device must not be used!

- Patients with severe disturbance of blood circulation;
- Patients with comminuted fracture or bone cancer;
- Patients with burn injury, bleeding condition, suppuration or uncontrollable infectious diseases;
- Patients with severe deformation or spasm of hands;
- Patients with obvious hand trauma or allergy to N Cloth and Lycra.



















Relative Contraindications: Each patient must be conscientiously assessed by the doctor/therapist in charge individually to determine if Soft Rehabilitation Glove therapy is suitable for the patient in case of:

- A patient after surgery;
- A patient with twisted finger joints;
- A patient with abnormal skin function;
- A patient with various acute diseases;
- A patient with disturbance of blood circulation;
- A patient with fever above 38°C;
- A patient undergoing treatment;
- A patient during menstruation or pregnancy;
- A patient with heart diseases and implanted with pacemaker and other medical electronic devices.

Note: In case of abnormal hand muscle tension or severe hand swelling, pain and other discomfort during training, please contact the attending doctor or rehabilitation physician in time, and stop using the Soft Rehabilitation Glove immediately if necessary. Before using the Soft Rehabilitation Glove, it is necessary to consider the opinions of the attending doctor or rehabilitation physician to carry out the corresponding hand function rehabilitation treatment.

3. Symbols used in this User Manual

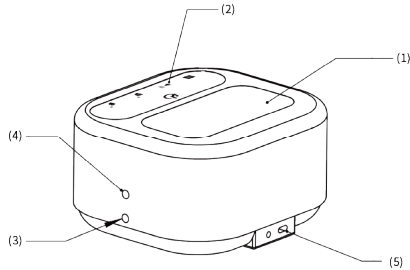
Table 3.1 Symbols

Symbol	Description	Symbol	Description
	Warning! Please refer to the document attached!		General warning symbol
	Do not discard with household waste		Information about the manufacturer of the device
	Follow the user manual		Frangible
	Upward		Protected from rain
	Protected from direct sunlight		Protected from radiation
	Serial number		Authorized representative in the E.U.
	Use by		Type B applied part
	Date of manufacture		Medical device
	CE Marking		Electrical safety class II

4. System Components

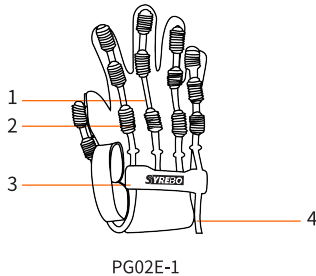
This section describes various components of the Soft Rehabilitation Glove system.

4.1 Host



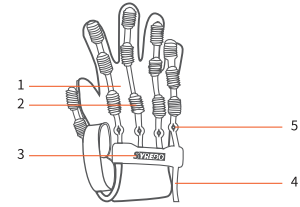
Components of host: (1) display space; (2) buttons area; (3) data interface; (4) Power interface; (5) Charge interface

4.2 PG02E-1/ PG14E-1 Power-assisted glove



PG02E-1

Components of PG02E-1 Power-assisted glove: (1) Non-indentation fabric; (2) Corrugated pipe; (3) Air manifold box; (4) Air outlet pipe

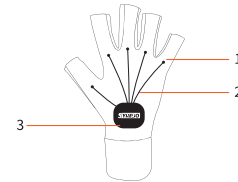


PG14E-1

Components of PG14E-1 Power-assisted glove: (1) Non-indentation fabric; (2) Corrugated pipe; (3) Air manifold box; (4) Air outlet pipe; (5) air shut-off knob

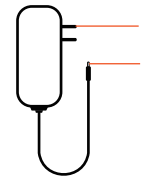
Notes: Two types of rehabilitation glove, PG02E-1 and PG14E-1, are common. When the following instructions refer to rehabilitation glove again, the default is PG02E-1.

4.3 DG11E Data Glove



Components of DG11E Data Glove: (1) Sensor; (2) Hyper-elastic lycra fabric; (3) Collection plate

4.4 Adapter



Components of adapter: (1) DC plug; (2) Power plug

5. System Components

This section explains the features of the Soft Rehabilitation Glove system.

5.1 Working Mechanism

The working mechanism of the Soft Rehabilitation Glove is described as below. The control module of the glove issues a control instruction according to the parameters set by the operator in advance, to realize the bending and stretching movements of the PG02E-1 Power-assisted glove through the positive and negative pressure switching of the pneumatic driving technology, thus to drive the joints for rehabilitation training. Through repeated rehabilitation training, the glove could stimulate joints, generate a virtuous circle of the physiological synovial fluid, reduce joint swelling, and prevent or treat joint motion amplitude reduction and joint stiffness caused by trauma or insufficient exercise.

5.2 Product Model and Software Version

5.2.1 Product Model

SY-HRC10


5.2.2 Software Version

The software is used in this product in its full version of V1.4.0.0

The software is used in this product in its release version of V1.

6. Instructions on Use and Installation

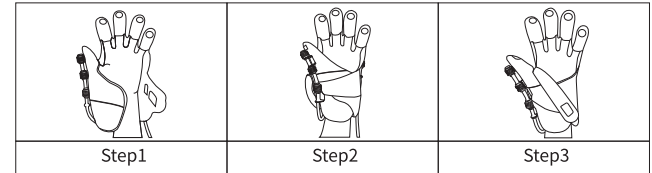
6.1 Preparation before Use

- (1) Take out all parts from the box, confirm the absence of any abnormal conditions such as breakage or missing, and place them on a horizontal and vibration-free desktop;
- (2) Connect the air supply plug of PG02E-1 Power-assisted glove with Rehabilitation interface on the side of the host;
- (3) Connect the power supply;
- (4) Press the switch button “” to turn on the host;
- (5) Wear PG02E-1 Power-assisted glove in your affected hand and prepare for training;

6.2 Wearing Glove

PG02E-1 Power-assisted glove have halves for left hand and halves for right hand with various sizes. Patients should select suitable glove to wear according to their own conditions. If the stiffness of joint or the muscle tension of hand is high, please massage the affected hand for 3-5 minutes first.

When wearing the glove, put fingers into the glove first, and properly pull the whole glove towards the wrist, so that the fingertips go as far as possible into the glove, then tighten the glove with the hook & loop waist fastener on the inner side of the glove. Finally, wrap the tying tape around between the thumb and forefinger and stick it tightly.



Step 1 : Wear the PG02E-1 Power-assisted glove on the affected hand.

Tip :All fingers should reach the top.

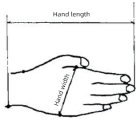
Step 2 : Pull the velcro over your wrist and stick it on.

Tip : Try to keep your fingers touching the top of the glove.

Step 3 : Pull the velcro strap from the end of the thumb on the back along the middle of the thumb and index finger to the velcro on the palm to complete wearing.

Tip: Please wear gloves correctly, there is no gap between the wrist and the glove when making a fist.

6.3 Glove Size

Size	Height (cm)	Hand length (mm)	Hand width (mm)	
L	>178	190-210	85-89	
M	156-178	162-190	78-85	
S	140-156	135-162	60-78	
XS	<140	90-135	50-60	

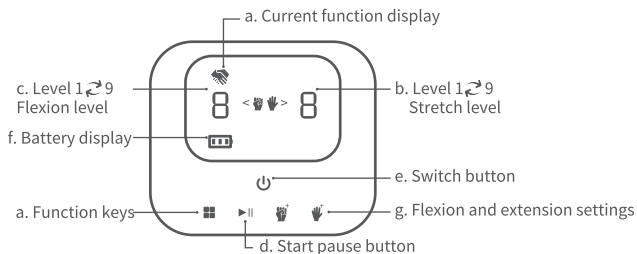
Other sizes are available through customization

7. Descriptions on Product Training Functions

The functions and operation steps in this Manual are described according to full functions, some of which are not universally applicable to all types of products. For detailed information on model configurations and functions, please refer to the descriptions specific to the product model or seek advice from Shanghai SiYi Intelligent Technology Co., Ltd. or its authorized agent.

7.1 Product introduction

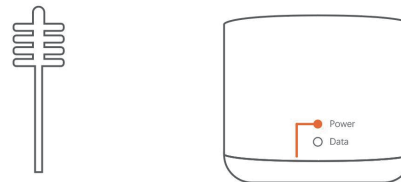
7.1.1 Buttons and Icons introduction



- Function display, "☞" passive training mode and "☜" mirror training mode. Click the function button "☞☜" to select training mode.
- Flexion level of passive training (1-9), the higher the number, the longer the hand stays in the flexion state. Click "☞" button to adjust the flexion level, click once to increase one level.
- Extension level of passive training (1-9), the higher the number, the longer the hand stays in the extended state. Click "☜" button to adjust the extension level, click once to increase one level.
- After the parameter setting is completed, click the "▶||" button to start the training. During training, click the "▶||" button to pause the training;
- Long press the "☞" switch button, it will display when the machine is turned on, no display when it is turned off;
- Battery indicator, when the icon flashes, it means the battery is too low. When it is fully charged, it will be displayed as three-grid (please make sure that the battery-display ≥ 1 grid before use, or plug in to use).
- Adjust the bend or stretch strength/level

7.2 Passive training

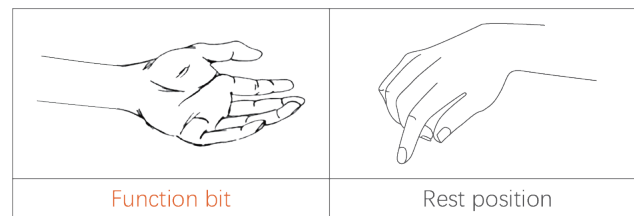
- Connect the PG02E-1 Power-assisted glove to the "power" interface of the host, and wear the PG02E-1 Power-assisted glove on the affected hand.



- Click "☞" power button, then click the function button to select "☞☜" passive training, set the training parameters of flexion level and extension level (only need to be set for the first time, the parameters are automatically saved, and the last training data will be displayed by default when the next training.)



- During training, the affected hand need to be in the "function position", not in the "rest position".



(4) Click “▶||” button, with the help of Soft Rehabilitation Glove, the affected hand begins to do passive training.

(5) When the PG14E-1 rehabilitation glove is selected, adjust the knob on the glove to horizontal, then the valve will be closed, and the corresponding finger will stop passive training and maintain the extension/flexion action; when the knob on the glove is adjusted to the vertical, the valve will open. The corresponding finger will start passive training.

7.3 Mirror training

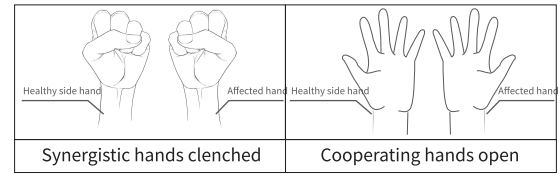
(1) Connect the PG02E-1 Power-assisted glove to the "power" interface, the DG11E Data Glove to the "data" interface of the host, and wear the PG02E-1 Power-assisted glove on the affected hand and DG11E Data Glove on the healthy hand.



(2) Click “⏻” power button, click the function button to select “👤👤” mirror training.

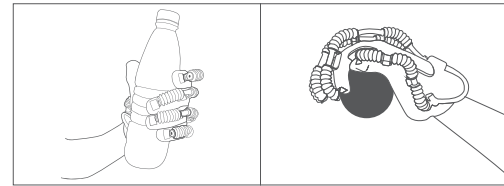


(3) Click “▶||” button, hold the healthy hand tightly (touch the sensor in the DG11E Data Glove), the affected hand could be simultaneously clenched under the drive of PG02E-1 Power-assisted glove. Open the healthy hand (loosen the sensor in the DG11E Data Glove), and the affected hand can be opened synchronously under the drive of the PG02E-1 Power-assisted glove. The healthy hand drives the affected hand, two hands move in coordination.



(4) In the mirror training mode, the patient's active consciousness focuses on the mirror movement of the two hands to enhance the training effect.

(5) When doing mirror training, after the patient is proficient in grasping, he can try to use the PG02E-1 Power-assisted glove to grasp small objects driven by the healthy hand to increase the sense of autonomy and the real tactile stimulation of the hands.



(6) After the training, please turn off the machine first, and then take off the PG02E-1 Power-assisted glove and DG11E Data Glove to avoid damage your hands or glove parts. (Reminder: please take the initiative to participate in rehabilitation.)

8. Trouble-Shooting

This section includes a guide to troubleshooting various operational incidents, describes the symptoms and gives an explanation of how to fix them if these occur.

8.1 The movement range of PG02E-1 Power-assisted is obviously reduced or there is no movement at all:

- Check whether the joint between glove and host is damaged;
- Check whether the glove hose is twisted and knotted or pressed by heavy objects;
- Check whether the corrugated pipes on the glove is damaged or missing;

8.2 The device cannot be turned on:

- Check whether the power of the device is sufficient, if the power is insufficient, please connect the adapter, restart after charging for 1 hour.

8.3 The device cannot start training:

- If the interface displays a countdown and the device cannot be started, please wait for the countdown to end and try again.

9. Cleaning and Maintenance

9.1 Cleaning and Maintenance

(1) Host: After the host is powered off, wipe its external surface with a fine fiber cloth moistened with water and wrung out, pay attention to avoid water entering the host, and prohibit the use of corrosive liquid to clean the product;

(2) Glove: Wipe it with 75% medical alcohol for five times or disinfect it with ultraviolet radiation for 1 hour before use.

9.2 Maintenance of Training Equipment

(1) The routine maintenance is carried out regularly by the user, mainly including the cleaning of the external surface of the host and the regular cleaning and disinfection of the wearing parts. For specific descriptions on the operation, refer to the section “Cleaning and Maintenance” above.

(2) Overhauling of the host:

a. Power supply-related components (e.g. charger ,data line and power interface) get loose, invalid or damaged;

b. Connection, operation and display components (e.g. buttons or interfaces on the host) fail or get damaged;

The above maintenance operations need to be performed by the professional technicians appointed by Shanghai SiYi Intelligent Technology Co., Ltd.

(3) Update of software: Shanghai SiYi Intelligent Technology Co., Ltd. will update the glove software according to the stability and actual use of the device;

(4) It is recommended to refer to the Section 8. “Troubleshooting” of this Manual for troubleshooting

10. Repair Policy

Shanghai SiYi Intelligent Technology Co., Ltd. is the only organization that can determine and confirm whether the products are within the warranty scope. The host is guaranteed or could be replaced free of charge within one year from the date of purchase if it has been found with any manufacturing or assembly defect; and the glove is guaranteed or could be replaced free of charge within three months from the date of purchase if it has been found with any manufacturing and assembly defect.

Shanghai SiYi Intelligent Technology Co., Ltd. will be responsible for the safety, reliability and performance of the product only when the assembly, adjustment, maintenance and upgrade of the product are all carried out by Shanghai SiYi Intelligent Technology Co., Ltd. or its authorized party; the electrical equipment used together with the product meets the special requirements of national standards and this Manual; and the operation of the product is carried out according to the methods and steps described in this Manual.

Faults caused by improper use of the product or by use of the product beyond the conditions indicated in the Manual are all not covered by the warranty. Faults caused by wearing or negligence accidents, improper supervision or unauthorized disassembly and use change of the product are all not covered by warranty.

11. Disposal

Mechanical parts of this product cannot be discarded at will, otherwise they will pollute the environment.

Please consult or contact a professional waste disposal company or the distributor to dispose the scrapped or waste products or accessories in accordance with the requirements of relevant local laws and regulations.

12.Warranty

12.1 Service Support

If the device needs repair, contact Shanghai SiYi Intelligent Technology Co.,Ltd. or the local distributor for Warranty details.

If the device needs to be shipped, pack the device and its accessories carefully to prevent shipping damage. Always transport the device in the original shipping container.

13. Technical Specifications

No.	Items	Technical Parameters
1	Training level	1-9 level, adjustable continuously by 1 level, with an error of $\pm 10\%$
2	Training mode	Passive training, Mirror training, Active training
3	Safety type	Class I, Type B
4	Size of host	105mm*95mm*60mm (L*W*H)
5	Weight	0.45kg \pm 0.1kg
6	Nominal voltage	DC 5V 2A
7	Rated power	10W
8	Date of manufacture	See the certificate of product
9	Service life	3 years

14. Packing List

Detail	SY-HRC10
Host	1pcs
PG02E-1 Power-assisted glove/PG14E-1 Power-assisted glove (Choose one of the two)	1pcs
DG11E Data Glove	1pcs
Adapter	1pcs
User Manual	1pcs
Certification	1pcs

Appendix A

Product Cable Information

Cable	Max. cable length, Shielded/unshielded		Number	Cable classification
AC Power Line	1.8m	Shielded	1 Set	AC 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 no ESSENTIAL PERFORMANCE/Following ESSENTIAL PERFORMANCE is intended used in 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. /Home healthcare environment

ESSENTIAL PERFORMANCE: None

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 Model Name, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.*

STATEMENT: For the purpose of its operation, the equipment has wireless communication function, it includes RF transmitter and receiver, 2.4GHz, Pulse modulation.

STATEMENT: The equipment is a large, permanently-installed system. According to chapter 8.6 of IEC 60601-1-2:2014, the test was only performed at some discrete frequencies.

- An exemption has been used and that the equipment has not been tested for radiated RF immunity over the entire frequency range 80 MHz to 6 000 MHz;
- WARNING: This equipment has been tested for radiated RF immunity only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation* ; and
- Following frequencies and modulations are used to test the immunity of the equipment.

Selected Frequency (MHz)	Emitter	Frequency Range	Modulation
103.7	Radio	Business radio band	FM
433.92	Remote controller	ISM frequency	FM
446	Walkie-talkie	walkie-talkie	FM
915	Mobile phone	GSM900	Pulase
2400	Wireless router	WIFI	Pulase
5000	Wireless router	WIFI	Pulase

STATEMENT: The equipment is designed compatible with high frequency surgical equipment; the condition includes working or standby in close proximity to high frequency surgical equipment.

When the AC input voltage is interrupted, the equipment will shut down and if the power supply restored, it should be recovered by operator manually, this degradation could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance.

Following degradation caused by Electrostatic Discharge or Electrical fast transients/burst could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance:

Vertical bars appear on the screen, it can recover to previous condition by operator manually by restart the power switch.

Data transmission stopped, the transmission could be restarted by operator manually by restart the power switch or re-insert the data cable.

EMI Compliance Table (Table 1)

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Professional healthcare facility environment and Home healthcare environment
Harmonic distortion	IEC 61000-3-2 Class B	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class B). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

EMS Compliance Table (Table 2-5)

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810		
870	800-960	Pulse modulation 18Hz, 28V/m
930		
1720		
1845	1700-1990	Pulse modulation 217Hz, 28V/m
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
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	± 2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 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_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U_T ; 1 cycle and 70% U_T ; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T ; 250/300 cycles

Table 5 – Signal input/output parts Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
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