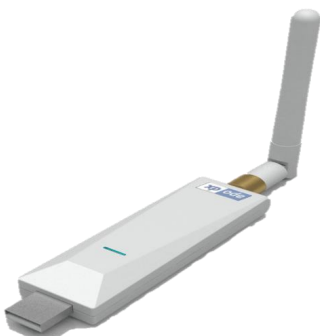




“DxPatch” Receiver User Guide



ApoDx Technology, Inc.

Version 1.0

Read and follow instructions in the manual before using the product

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Declaration of title

The manual provides some information of the device for users. Without the written consent of ApoDx Technology, Inc., the ownership of the content cannot be used for purpose, duplication, or disclosure.



DxPatch Warnings and Cautions

The signs and their implications are as follows ◦

| | |
|--|--|
|  Warning | Read and follow instructions in the manual before using the product. |
|  Cautions | Malfunction or error data might be caused by mistake. |
|  Prohibition | Must be observed. |
|  Notice | Must follow instructions in the manual. |
|  Recycling | Be recycled and not dispose to trash. |










Warnings

-  **This product is only an accessory for signal receiving; does not have a record, data access or analysis.**
-  **This product should be used with “DxPatch Electrocardiograph/Phono Recorder” by ApoDx Technology Inc..**



Cautions

-  **Do not misuse, abuse, or drop the product.**
-  **Do not use or store the product in a harsh environment, such as direct sunlight, high temperature, near flammable materials, high vibration intensity, and strong magnetic fields.**

-  **Do not use this product under the following hazardous conditions:**
 - 1. During defibrillation**
 - 2. During MRI examination**
 - 3. Exposed to high electromagnetic sites**
 - 4. In high pressure environment, such as hyperbaric oxygen chamber, near ultraviolet germicidal lamp, and oxygen tent.**
-  **The product comply with the IEC/EN 60601-1 standards.**
-  **Do not disassemble or modify the product.**
-  **Do not directly immersed in water for cleaning.**
-  **Product warranty period of 3 years.**

FCC Statement:

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.

NOTE: This equipment 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 equipment 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 equipment 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.

FCC Warnings

Changes or modifications not expressly approved by the

party responsible for compliance could void the user's authority to operate the equipment.

IC Statement

This device complies with Industry Canada license-exempt RSS standard(s).

Operation is subject to the following two conditions:

- (1) This device may not cause interference, and
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

Taiwan regulatory information (NCC)

Article 12. Without permission granted by the NCC, any company, enterprise, or user is not allowed to change frequency, enhance transmitting power or alter original characteristic as well as performance to approved low power radio-frequency devices.

Article 14. The low power radio-frequency devices shall not influence aircraft security and interfere legal communications; If found, the user shall cease operating immediately until no interference is achieved. The said legal communications means radio communications is operated in compliance with the Telecommunications Act. The low power radio-frequency devices must be susceptible with the interference from legal communications or ISM radio wave radiated devices.

1. Product Introduction

“DxPatch” Receiver, a wireless to signal receive and work direct with “DxPatch Electrocardiograph/Phono Recorder” (Model:8ZP7).

2. Suitable age

DxPatch Electrocardiograph/Phonocardiograph recorder is a portable electrocardiogram for adults over the age of 18.

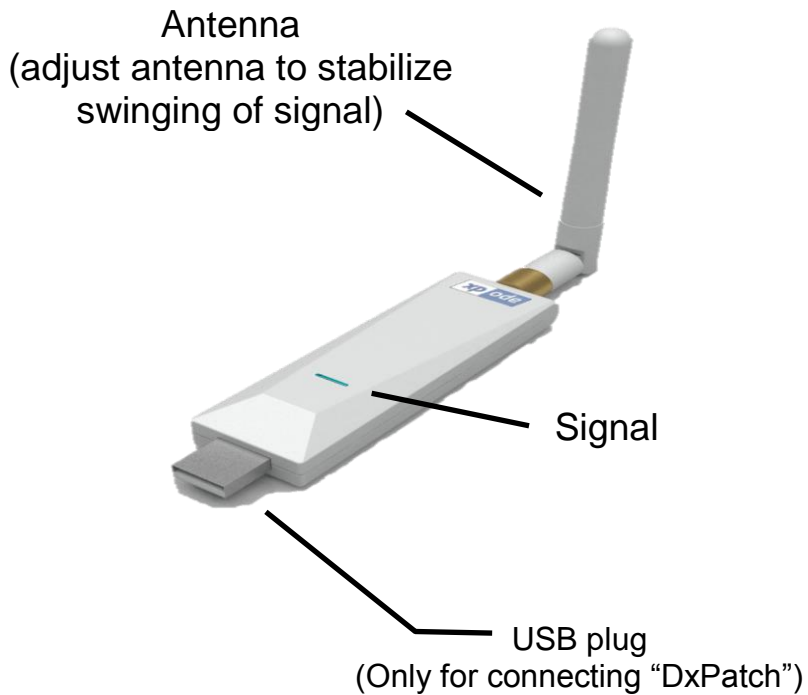
3. Item List

- “DxPatch” Receiver
- User Guide
- Warranty card


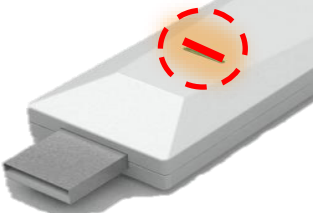
Note: “DxPatch Electrocardiograph/Phono Recorder” (Model:8ZP7), a non-invasive ECG recorder can record continuously for up to 24 hours of ECG and heart sound signals; , if necessary please contact the medical equipment store or retailers.


4. Product Appearance

Front







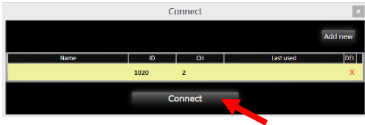
5. Manual Instruction

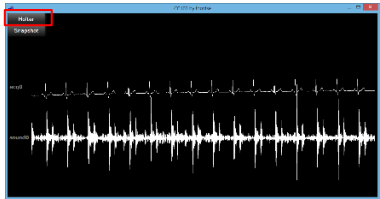
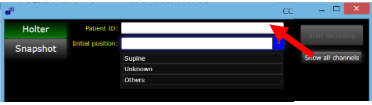
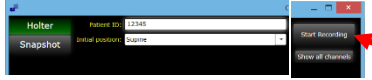
| | |
|---|--|
|  | <ol style="list-style-type: none">1. DxPatch Receiver is connected to USB plug of the computer contained Holter Setup software. |
|  | <ol style="list-style-type: none">2. Once the signal starts to blink red light, it indicates that it has connected with "DxPatch". |

 **This product should be used with “DxPatch Electrocardiograph/Phono Recorder” by ApoDx Technology Inc..**





7.2 Wireless Starting

| | |
|---|---|
|  | <p>DxPatch Receiver is connected to USB plug of the computer contained Holter Setup software.</p> |
|  | <p>Open the Holter Setup.</p> |
|  | <p>Chose COMMUNICATE.</p> |
|  | <p>Key in the ID number, CH number and name.</p> |
|  | <p>Confirm the information and then click the Connect.</p> |

| | |
|---|---|
|  | <p>Confirm the ECG and heart sound signals are no abnormal and then chose the Holter.</p> |
|  | <p>Input the patient ID and chose the patient's posture on the drop-down menu of Initial position.</p> <p>Notes: The usual setting is Supine of the Initial position. If users chose Unknown or Others, please take a note about the situation.</p> |
|  | <p>Click Start Recording to begin recording ECG and then the product will start to blink the orange light.</p> |
| | <p>The Holter Setup will close after the product is started. If users need to start the other Dxpatch, please click the Holter Setup and repeat these steps.</p> |

6. Data Transfer

| | |
|---|---|
|  | Use Micro-USB cable to connect from DxPatch (shown in image) to the PC to begin data transferring. |
|  | Make the location of PoGo Pin insert in the mistake-proofing slots. Use the USB plug of the base to connect with the computer. |

7. Troubleshooting

| Issue | Causes | Suggest method |
|--------------------------------|-----------------------------|--|
| Unable to turn on the product | Low battery | Follow the “battery installment” instruction |
| | Install battery incorrectly | Follow the “battery installment” instruction |
| | Damage to the product | Contact your local dealer |
| Problem occur not listed above | | Contact your local dealer |

8. Maintenance and Storage

➤ Maintenance

- (1) Before use, clean the skin with either 75% alcohol or water to the affix location. Wait till its dry then attach to patient.
- (2) Do not use alcohol or detergent to clean the product.
- (3) Do not disassemble or modify the product. If there are any maintenance problems, please contact authorized personnel.
- (4) Do not bath, swim, or engage in any other activities that involves immersing the product.
- (5) Do not let product come in contact with any sort of detergent liquid.
- (6) Do not undergo autoclave.
- (7) Product does not need recalibration after each use.
- (8) Do not place the product directly under the sunlight.

➤ Storage

- (1) This product is waterproof rating of IP55, it can be used in the shower condition but do not immersed the product directly in water.
- (2) Keep this product out of reach of children.
- (3) Keep the product in the environment of the proposed specification.

Warranty

Dear user,

Thank you for purchasing the Holter recorder product. By using this product you are able to record and monitor for a long duration of physiological signals. If you have any concern, please contact your local dealer. This product provides the following warranty:

1. The product warranty period is under the normal use of the product, for three years from the date of the purchase; if you cannot provide invoices or other supporting documents to verify the date of the purchase, it is one year from the date of the factory.
- (1) According to Article 19 of the Consumer Protection Law, mail order takes seven business days to arrive. If returning the merchandise, it must be in new, undamaged condition, and complete packaging the product. After returning merchandise, consumers need to get in touch with the local dealer.
- (2) If repair is required, please return the original package. The company does not provide warranty for damage to the product during transit.
- (3) If not cause by human factors to deform the product, hardening, or cannot turn on the device. The product can be exchange for a new one or return the product.
- (4) Non-warranty coverage disclaimers:
 - i. Product was damaged due to earthquake or flood.
 - ii. Product was damaged due to human error.
 - iii. Product was damaged due to improper dismantling the product

- iv. Product was damaged due to improper usage.
Non-defective product due to the factors of warranty coverage will depend on the company's maintenance standards fee.
- (5) Return policies
 - i. When returning the product, please contact the customer service in advance and the reason for returning the product.
 - ii. Returning the merchandise, they shall be in non-damaged and in good shape along with all of the items included with the product such as box, brochures, invoices, and shipping time of the original. Once the company personnel receives the product and check in is complete, then will begin the returning process.
- (6) New Replacement:
 - i. Defective product is returned (not due to human error), a new replacement will be provided within seven business days. It will only provide the replacement of the same product.
 - ii. If the product was caused by human error or incomplete in return of the product, the product will be disposed.
- (7) Return Note:

The product shall be packaged with all of other items that comes with it. The invoice shall be returned with the product. Return will be invalid if invoice is not included during return. Company ID shall be used during returning process.

Appendix

Warranty

Card DxPatch Electrocardiograph/

Phonocardiograph Recorder

8ZP7

Model No: _____

Name: _____

Company (Business only): _____

Company Stamp

Sex: Age: Phone: - _____ Cell Phone: - _____

Address: _____

E-mail: _____ Purchase Date: _____

1. The warranty card is subject to the sales agents or the company stamp and fill in the dates is not effective.
2. The warranty coverage only the device; consumable parts, such as electrode, battery, SD card, transmission lines and other accessories and supplies neither within the scope of warranty.
3. We grant 3 years service since the date of delivery.
4. Malfunctioned/damaged caused by accident, abuse, misuse, liquid contact, fire, earthquake or other external cause, will be charged the costs even within warranty period.
5. Under following conditions, you will be charged for the costs.
 - * Damages caused by service performed by anyone who is not representative of ApoDx.
 - * Out of the warranty period.
 - *Warranty card obliterated or copied.
6. Warranty card is not be replaced if lost, please keep it in a safe place.
7. Health Department Medical device system No. XXXXX.

Manufacture and Medical company information

Manufacture: ApoDx Technology, Inc. entrust the
manufacture to Leadtek Research, Inc.

Manufacture location: 5F, No.2, and 5F, No.4, Aly. 11,
Ln. 327, Sec. 2, Zhongshan Rd.,
Zhonghe Dist., New Taipei City
235, Taiwan (R.O.C.)

Medical Company: ApoDx Technology, Inc.

Location: Suite ER16, 17F., No.3 Yuanqu St., Nangang
Dist., Taipei City 115, Taiwan(R.O.C.)