



DxPatch Electrocardiograph/Phono Recorder  
User Guide



Model No: 8ZP7

ApoDx Technology, Inc.

Health Department Medical device system No. XXXXX  
Version A

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 .

	The instructions indicate that some of the conditions or operation might make users and patients be hurt.
	The instructions indicate that some of the conditions or operation might destroy the equipment or property.
	Prohibition of matters.
	The consumable parts cannot be reused.
	Be recycled and not dispose to trash.
	Using indirectly for cardiac.
	The information about manufacturing
	Please read the instructions in the manual before using the product.

### **Warnings**

- This product is only an accessory for patient that still requires professional technicians' and physicians' evaluation.**
- This product can be used as the recording and analysis purpose; it detects pacemaker function; does not contain warning device.**
- Providing self-treatment based on analysis result may worsen the conditions. Please consult with a physician for interpretation and**

analysis of the report.

- ⚠ This product only provides parameter results. If there are any discomfort during the recording, please contact your physicians.
- ⚠ This product cannot render the heart and help the symptom. If there are any discomfort during the recording, please contact your physician.
- ⚠ Immediately consult a physician if there are any discomfort; if user have sensitive skin or allergic reaction to ECG electrodes.
- ⚠ Do not use this product for emergency rescue.

## Cautions

- ⚠ Do not misuse, abuse, or drop DxPatch.
- ⚠ 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.
- ⚠ If user have implemented pacemaker, ICD, or other device, please do not use this product.
- ⚠ Before use, clean the skin with either 75% alcohol or water to the affix location. Wait till its dry then attach to patient.
- ⚠ Ensure the skin is dry before affix the electrodes to skin.
- ⚠ 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
- ⚠ Please use the specified battery for this product. Make sure to install the battery correctly.
- ⚠ The product comply with the IEC/EN 60601-1

standards.

- ⚠ Do not disassemble or modify the product.
- ⚠ This product is used for the purpose of ECG and no other measurement.
- ⚠ Do not take measurements through clothing.
- ⚠ Do not directly immersed in water for cleaning.
- ⚠ ECG electrodes are to dispose after each use.
- ⚠ Please discard and recycle such items in accordance with local regulation medical devices.
- ⚠ Please note the shelf life of the ECG electrodes.
- ⚠ Memory card is factory built, do not substitute with a different memory card.
- ⚠ 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.

## **Waste Electrical and Electronic Equipment (WEEE)**

Below the information is for The European Union (EU)

Member States :

The product is classified as a medical device in compliance with directives 2002/96/EC. Holding producers responsible for end of life cost for recycling and disposal of nearly all Electrical and Electronic Equipment (EEE).

The symbol adopted by the European Council to represent waste electrical and electronic equipment comprised a crossed out wheelie bin with or without a single black line underneath the symbol. The black line indicates that goods have been placed on the market after 2005, when the Directive came into force.



## 1. Product Introduction

DxPatch(Model:8ZP7), a non-invasive ECG recorder can record continuously for up to 24 hours of ECG and heart sound signals; user can transfer the data for further analysis by using the Micro-USB to upload onto the PC.

## 2. Suitable age

- DxPatch  
Electrocardiograph/Phonocardiograph recorder is a portable electrocardiogram for adults over the age of 18.
- The technicians using Dxpatch(Model:8ZP7) need to have the medical license and get specialized training. The technicians have to read and follow the instructions in the manual before using the product for patients.

## 3. Item List

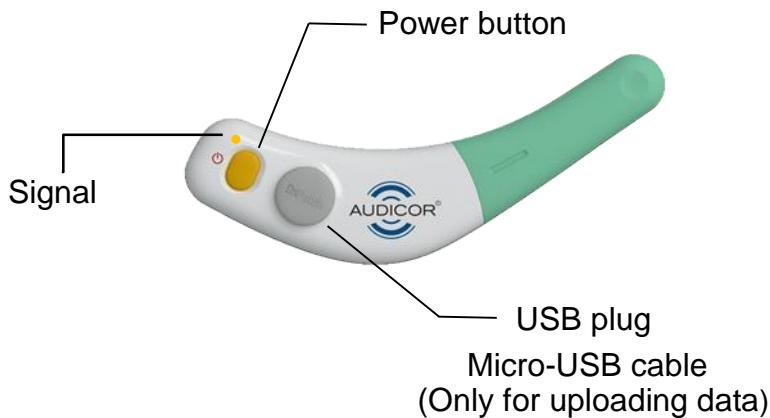
- DxPatch  
Electrocardiograph/Phonocardiograph Recorder x 1
- The covers of PoGo Pin x 3
- User Guide x 1
- Warranty card x 1 (attached the user guide)

**Note:**

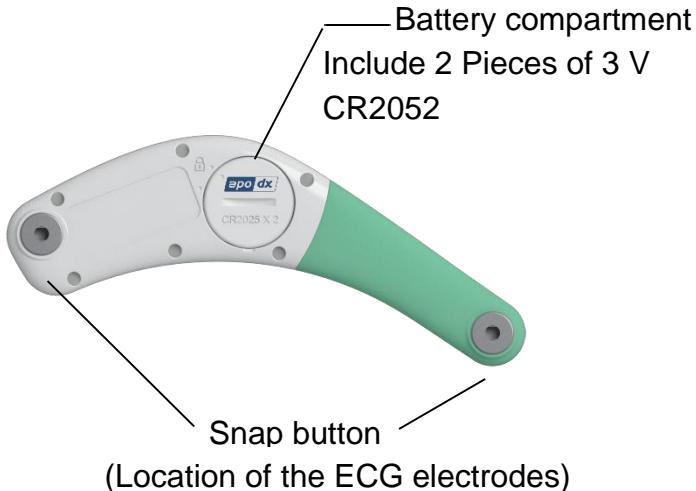
- \* ECG electrodes are disposable product, if necessary please contact the medical equipment store or retailers.**
- \* DxPatch Docking Station and DxPatch Receiver are optional-product, if necessary please contact the medical equipment store or retailers.**

## 4. Product Appearance

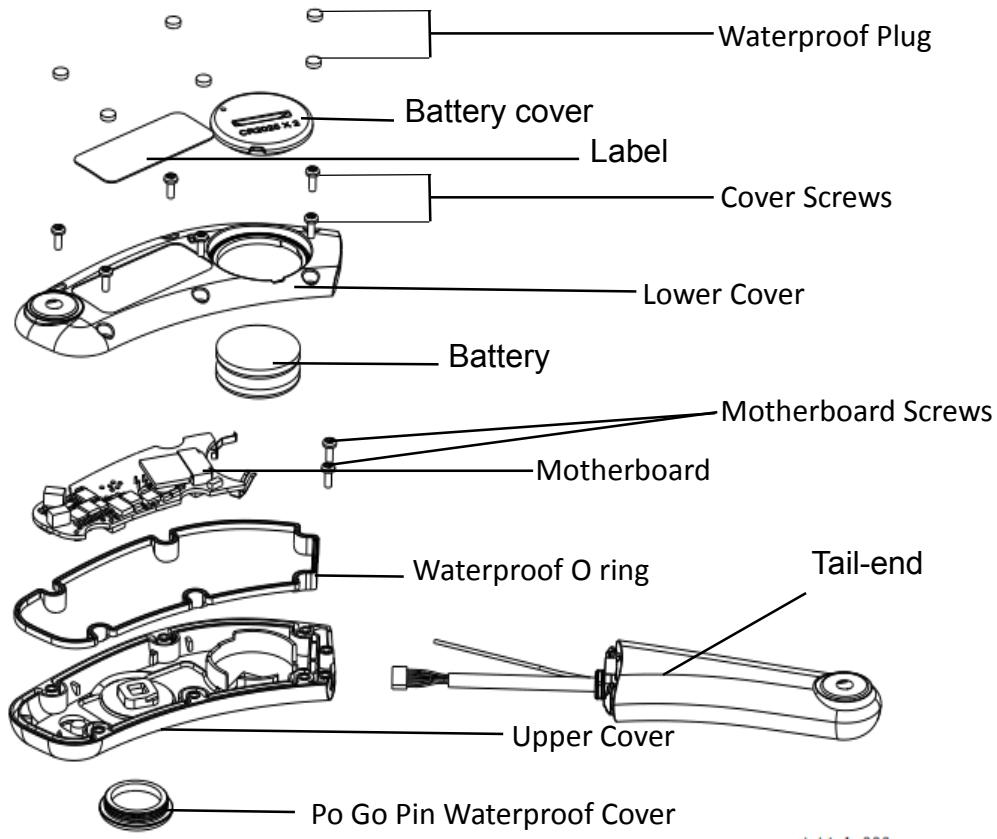
Front



Back



## 5. DxPatch Assembly Drawing



比例 1,000

## 6. Battery Installment

	1. Remove the battery if there are any.
	2. Insert 2 3-volt CR2025 button lithium battery with "+" facing upward in the battery holder
	3. Re-attach the battery cover and check that the battery compartment is locked.

### Note:

- ⚠ Please confirm the product is dry before twisting the battery cover.
- ⚠ Please follow the above instruction to install the battery to the product.
- ⚠ Always replace both batteries.
- ⚠ If the product won't be used for a long duration, please remove the batteries to avoid damage to the product
- ⚠ Do not remove the battery while it is recording; otherwise, the data file may be corrupted.
- 🚫 Do not mix old and new batteries or mix different brand of batteries to avoid risk of damage product.
- 🚫 All old batteries shall be recycled and not dispose to trash.

## 7. ECG Electrodes Placement

<p>Step 1</p> <p>Remove paper</p> 	<p>Before use, confirm whether the ECG electrodes are firmly attach to the snap button on the product.</p>
<p>Step 2</p> 	<p>Then remove the paper on the ECG electrodes and affix to the chest location in the image shown.</p>

### Note:

- ☒ ECG Electrodes and batteries are disposable items.
- ☒ ECG Electrodes and batteries shall be recycled and not dispose to trash.
- ⚠ Skin should be cleaned before affix to the body.

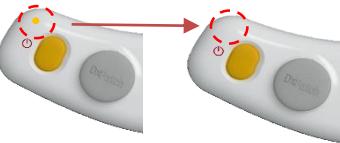
## 8. Operating Instruction

### 8.1 Manual Starting

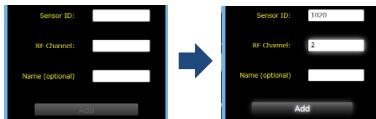
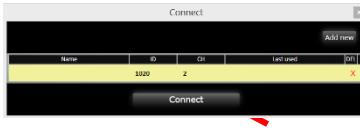
Change batteries before each long term recording.  
User can relax and perform their daily routine normally as the recorder is capturing ECG and heart sound signals.

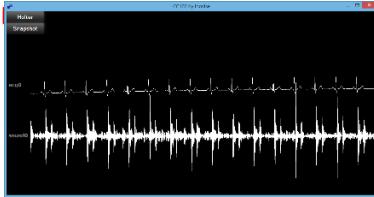
	Press and hold the power button for 5 seconds to turn on the product.
	Once the signal starts to blink orange light, it indicates that it has begun recording.

### Turning off the product

	To turn off the DxPatch recorder, press and hold the power button until the power signal light disappears.
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## 8.2 Wireless Starting

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

	<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. 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>



In order to avert electromagnetic interference, please confirm the distance of between DxPatch and DxPatch Receiver is in 10 centimeters when wireless starting.

## 9. 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.

- 1) Make sure Dxpatch is connected with the computer and click on the right button of your mouse on the removable storage device to choose “properties” → choose “tool” page → choose “check” on the error checking frame → choose “Scan drive”.
- 2) After scanning drive open the removable storage device to copy the file to your computer.
- 3) Delete the file inside the removable storage device and format it.



Before formatting the removal store device, please double check the file is copied to your computer.

## 10. 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

## 11. 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.

## 12. Guidance and manufacturer's declaration electromagnetic emissions

### Guidance and manufacturer's declaration-electromagnetic emissions

The 8ZP7 is intended for use in the electromagnetic environment specified below.

The customer or the user of the 8ZP7 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The 8ZP7 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The 8ZP7 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

### 13. Specification

ITEMS	SPECIFICATION
HEART RATE RANGE	30-230 bpm
ECG CHANNEL	SINGLE LEAD
SOUND SIGNAL	11Hz 至 155Hz
BATTERY	3V CR2025 BUTTON LITHIUM BATTERY
ANALOG/DIGITAL CONVERTER	12 bit
FREQUENCY	500Hz
RECORDING DURATION	24 hours
MEASUREMENT (cm) (L) x (W) x (H)	15 x 2x 0.5
WEIGHT	43g (Battery included)
HEIGHT ABOVE SEA LEVEL	3000m/700hPa
STORAGE TEMPERATURE	-10°C ~55°C
TRANSPORT TEMPERATURE	20°C ~50°C
OPERATING TEMPERATURE	0°C ~40°C
HUMIDITY	10%~95%
RECORDING TRANSMISSION	4G Micro SD/DxPatch Docking Station
RECORDING TRANSMISSION	2.4GHz Wireless Transmission / Micro-USB
WATERPROOF RATING	IP55

## **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.)