



DxPatch Electrocardiograph/ Phonocardiograph 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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The signs and their implications are as follows °




 <b>Warning</b>	Read and follow instructions in the manual before using the product.
 <b>Cautions</b>	Malfunction or error data might caused by mistake.
 <b>Prohibition</b>	Must be observed.
 <b>Notice</b>	Must follow instructions in the manual.
 <b>Disposable</b>	The consumable parts can not be reused.
 <b>Recycling</b>	Be recycled and not dispose to trash.

## DxPatch Warnings and Cautions









### **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.**
- ⚠ 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.

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 a 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(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.

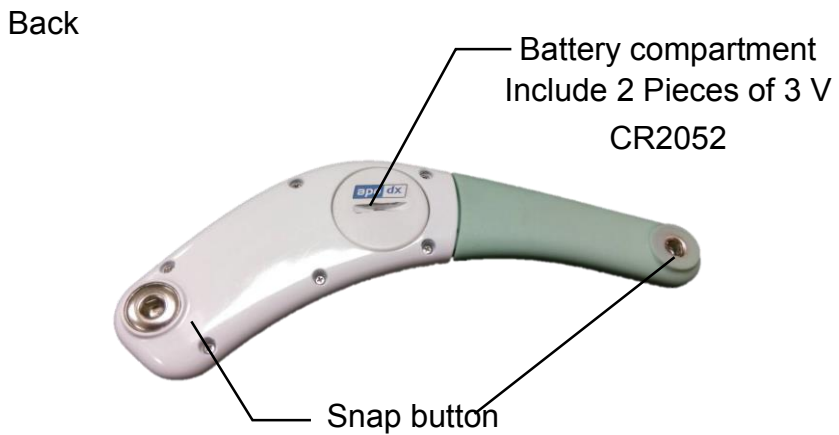
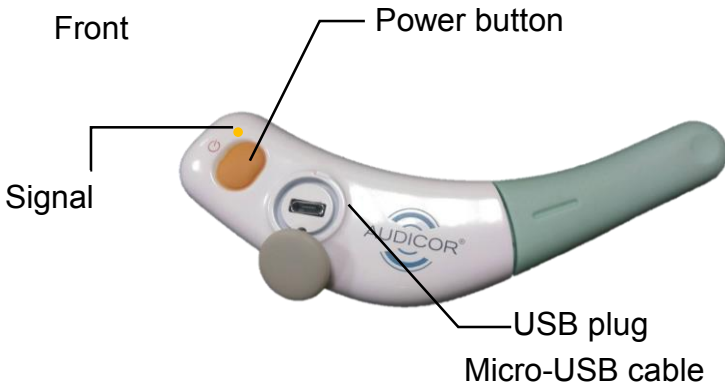
## 3. Item List

- DxPatch Electrocardiograph/Phonocardiograph Recorder x 1
- User Guide x 1
- 2 Pieces of button lithium battery (CR 2025) x 2  

- User warning band x 5
- Micro-USB data cable x 1
- Warranty card




**Note: ECG electrodes are disposable product, if necessary please contact the medical equipment store or retailers.**



## 4. Product Appearance



## 5. 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 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.

## 6. User warning band

-  The DxPatch package includes a user warning band which is designed to prevent the user from using the micro USB slot whilst the DxPatch is attached to the body. In accordance with the instructions the user must tie the warning band around the DxPatch before each use, otherwise the company can not provide compensation for repair of the micro USB slot or associated damage.

<p>User warning band</p>  <p>Warning 使用中請勿離開</p>	<p>To determine the user's security is not damaged and the end of sticky strap.</p>
 <p>Warning 使用中請勿離開 AUDICOR</p>	<p>Take Write Warning of User warning band, Cover the micro USB slot with back clung, Check not fall to complete.</p>

## 7. ECG Electrodes Placement



<p>Step 1</p> <p>Remove paper</p>  An image showing two circular ECG electrodes with a green handle. Two arrows point to the top of each electrode, labeled 'Remove paper', indicating the removal of the protective paper from the adhesive surface.	<p>Before use, confirm whether the ECG electrodes are firmly attach to the snap button on the product.</p>
<p>Step 2</p>  An image showing a human torso from the chest up. A single ECG electrode is affixed to the chest, positioned between the two breasts.	<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 Instructions


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.

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

### Turning off the product

	<p>To turn off the DxPatch recorder, press and hold the power button until the power signal light disappears.</p>
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## 9. Data Transfer

	Use Micro-USB cable to connect from DxPatch (shown in image) to the PC to begin data transferring.
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## 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. Specification

<b>ITEMS</b>	<b>SPECIFICATION</b>
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)
STORAGE TEMPERATURE	-10°C~55°C
TRANSPORT TEMPERATURE	20°C~50°C
OPERATING TEMPERATURE	0°C~45°C
HUMIDITY	10%~95
RECORDING TRANSMISSION	2.4GHz Wireless Transmission / Micro-USB
WATERPROOF RATING	IP55



## 13. 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.)