

“LARGAN”ECG Holter

※Please read the Instructions for Use and follow the instructions before use

Product model number: AT-202C

TABLE OF CONTENTS

1.	Introduction.....	2
1.1.	Federal communications commission interference statement.....	2
1.3.	Contraindications.....	2
1.3	Side effects.....	2
1.4	Patient group.....	2
2.	Safety information.....	2
2.1	Warranty information.....	3
2.2	Warnings.....	3
2.3	Precautions.....	4
2.4	Other	4
3.	Device information.....	4
3.1	Device specifications.....	4
3.2	Applicable ECG electrode patch	5
	This device does not contain the electrode patches, applicable electrode patches are listed below...	5
3.3	Device light notifications	6
3.4	Label description	6
3.5	Operation steps	7
3.6	Contents.....	7
3.7	Cleaning , Maintenance and Disposal	7
3.8	Error elimination	7
4	Patent information.....	8

1. Introduction

This is the manual of “LARGAN” ECG Holter. The ECG Holter is designed for continuously recording ECG data for up to 50 hours. The device does not supply with accessory of third-party ECG electrodes which attach directly on patient chest. The manual contains all information for safely using.

Class B: (Section 15.105)

1.1. Federal communications commission interference statement

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.

(Section 15.21)

1.2. Indication

This product is used to record patient's ECG signal for later analysis.

1.3. Contraindications

- Patients with pacemaker should not use this product.
- Patients with implantable cardioverter defibrillator should not use this product.
- This product should not be used by infants and children.
- This product should not be used on pregnant women.
- This device should not be used on patients with life-threatening condition.
- This device should not be used on breached skin.

1.3 Side effects

None

1.4 Patient group

All adult but exclude the patient with pacemaker, implantable cardioverter defibrillator, pregnant woman and patient with life-threatening condition.

2. Safety information

Users should carefully read bellow information before using the ECG Holter.

2.1 Warranty information

- 2.1.1 Largan Medical recognizes the serial number on the back of the ECG Holter recorder as warranty certificate. Therefore, please be careful not to damage the logo containing the serial number, otherwise you will not be able to enjoy the free warranty repair service.
- 2.1.2 The warranty period is 12 months from the date of purchase. If there is no purchase receipt, the warranty period is 12 months from the date of manufacture.
- 2.1.3 A malfunction of the ECG Holter (other than fair wear and tear expected) that cannot be attributed to the user under normal usage, will be repaired by Largan Medical with no charge.
- 2.1.4 Normal use, repair and maintenance should be carried out in accordance with instructions or instructions, and manufacturer warranty obligations do not apply when:
 - Users willfully destroy the ECG holter.
 - Negligent behavior (immersed ECG holter in water, fall etc).
 - Irresistible force (lightning, fire), etc., is not caused by the control factors of the company.
 - Fair wear and tear of the battery or any other consumables
 - Report the defects after the warranty period.

2.2 Warnings

■ **Important safety instructions:** Please observe the following points, otherwise it may cause harm to the safety or health of users.

- 2.2.1 *The recorded ECG signal can be evaluated by a trained medical professional, but does not have direct diagnostic capabilities.*
- 2.2.2 *Users are not allowed to disassemble or repair this product by themselves. It must be disassembled or repaired by a person authorized by Largan Medical.*
- 2.2.3 *Do not perform heart rate measurement while charging.*
- 2.2.4 *Connection of other electrical devices must comply with the safety regulations IEC60601-1.*
- 2.2.5 *Instant ECG information obtained using Bluetooth cannot be used as a diagnostic.*
- 2.2.6 *Do not use in a flammable or explosive environment.*
- 2.2.7 *Electromagnetic radiation may affect the monitoring results of this product, and should be used away from the places with strong electromagnetic radiation.*
- 2.2.8 *Please keep the device away from the strong sources of static electricity.*
- 2.2.9 *Do not use defibrillator or receive MRI scan when using ECG holter.*
- 2.2.10 *Please confirm that this product is operated, transported and stored in the environment listed in the product specifications.*
- 2.2.11 *This product is not waterproof and needs to be protected from water ingress.*
- 2.2.12 *Do not use this product while taking flight.*
- 2.2.13 *For compatibility and safety, only use the cable and analysis software accompany with the device.*
- 2.2.14 *Always clean and maintenance the device by following the instruction in this manual.*

2.2.15 Do not put ECG holter in mouth.

2.2.16 RF exposure warning: The device has been evaluated to meet general RF exposure requirement.
The device can be used in portable exposure condition without restriction

2.3 Precautions

2.3.1 If the ECG electrode patches are insufficient adhesion, use a medical tape to strengthen the adhesion.

2.3.2 Do not perform strenuous exercise when recording ECG signals.

2.3.3 Do not use corrosive or abrasive substances to clean the device.

2.3.4 Dispose of this product and consumables should be disposed of in accordance with the relevant waste management regulations of each country to avoid environmental pollution.

2.3.5 Charge the battery for at least 2 hours before using it for the first time.

2.3.6 Do not force or drop the product to avoid strong vibration or shaking.

2.3.7 Store the device in the storage bag which comes with the product when it is not in use.

2.3.8 Do not reuse the disposable ECG electrode patch.

2.3.9 The light on the ECG holter only reflects the status of device. It is not diagnostic of cardiac condition.

2.3.10 Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

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.

2.4 Other

2.4.1 Users should realize while using the ECG Holter with accessorized electrodes might have skin reaction. Users should follow accessory's instruction for using.

2.4.2 If user does not follow instruction for using the ECG Holter, he/she might have electric safety issue.

2.4.3 If user does not follow instruction for using the ECG Holter, the ECG holter might have error recording issue.

3. Device information

3.1 Device specifications

Induction device	Electrocardiograph ● Sampling frequency : 250 Hz ● Measurement range : ± 350 mV ● Sensitivity : 4.81×10^{-8} V ● Input impedance : ≥ 10 M Ω ● Number of leads : 1 ● Common mode rejection ratio : ≥ 80 dB ● Bandwidth : Covering 0.67~40 Hz ● System noise: <50 μ V ● Gain error: <10% Acceleration sensor
Power supply	DC 5V 100mA
Continuous recording time	50 hours
Maximum standby time	60 days
Transfer method	USB 2.0 BLE 4.2
Battery	Lithium battery

Size	52 (diameter) × 9 (height) mm
Weight	18 g
Material	PC
Use environment	Ambient temperature: 20°C ~ 35°C Relative humidity: 45% to 75% (excluding condensation) Atmospheric pressure : 86kPa ~ 106kPa
Transportation and preservation environment	Ambient temperature: -10°C ~ 45°C Relative humidity: 45% ~ 75% (excluding condensation) Atmospheric pressure : 86kPa ~ 106kPa
Warranty	1 year

3.2 Applicable ECG electrode patch

This device does not contain the electrode patches, applicable electrode patches are listed below.

3.2.1 *“Ambu” Blue Sensor ELECTRODE*





3.2.2 *“Hurev” HeartRode ECG Electrode*

3.2.3 *3M RED DOT MONITORING ELECTRODE*





3.3 Device light notifications




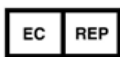





- Green light : Recording, less than 1 min
- Green flash : Blue tooth connected, less than 1 min
- Blue light : Recording, more than 1 min
- Blue flash : Blue tooth connected, more than 1 min
- Yellow light : Low battery, disable recording
- Yellow Gradual : Charging
- White light : Uninitialized

Light	Meaning	Actual picture
Green	Ready for recording/ Recording less than 1 minute	
Blue	Ready for recording/ Recording more than 1 minute	
Yellow	Low battery Level(< 35 %)	
Green Flash	Blue tooth connected/ Connected less than 1 minute	-
Blue Flash	Blue tooth connected/ Connected more than 1 minute	-
Yellow Flash	While charging	-
White	Uninitialized	

3.4 Label description

Symbol	Description of symbol	Symbol	Description of symbol
	BF-Type		Warning
	Read this manual before use.		Bluetooth-enabled

	Wireless communication complies with NCC specifications		Serial number
	Manufacturer		Authorized representative in the European community
	CE approved device with notifying body identification number		Keep dry
	Compliance with FCC rules		

3.5 Operation steps

- 3.5.1 Remove grease and excess hair from the ECG electrode patch.
- 3.5.2 Attach the three grommets to the ECG electrode patch.
- 3.5.3 Attach the product to the left chest or right chest for dextrocardia patients. The button should be on the up side. Please note that “LARGAN” on the ECG holter should not be upside down.
- 3.5.4 Press the button to start recording.
- 3.5.5 The record will be automatically saved when the product is removed.

3.6 Contents

There will have a dynamic electrocardiograph, a user's Guide and a Storage bag inside a complete package. Do not provide any ECG electrode patch in the package.

Dynamic electrocardiograph	1
User's Guide	1
Storage bag	1

3.7 Cleaning , Maintenance and Disposal

- 3.7.1 Wipe the surface with a dry cloth after use
- 3.7.2 Wipe the surface of the product with 75% alcohol every month.
- 3.7.3 Electrocardiogram electrode patches and other product parts must be well preserved. If the surface is oxidatively discolored, the ECG electrode patch should be replaced.
- 3.7.4 The ECG Holter should be disposed according to EU WEEE directive for electronic waste.

3.8 Error elimination

Error condition	Exclusion method
The device has no response while pressing the start button.	Ensure the electrode is attached to the ECG holter and chest properly.

While recording, the product shuts down by itself.	The device is in low battery level, please charge.
While recording, beep sound appears.	The patch is detached from the ECG holter, please check and adjust the patch.

4 Patent information

- 4.1 Manual in this product is copyright Largan Medical Co. Ltd (hereinafter referred to as Largan Medical). No company or individual or other entity may copy or extract any content in this manual in any way or form without the written permission of Largan Medical. , back up, modify, disseminate, translate into other languages, and use them in whole or in part for commercial purposes.
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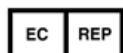
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