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SE-2003&SE-2012 Series

Holter System

Recorder

Version 2.2

User Manual

CE 0123

EDAN

About this Manual

P/N: 01.54.456520

MPN: 01.54.456520022

Release Date: July 2023

Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which Edan Instruments, Inc. (hereinafter called EDAN) can not be held liable.

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Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

Table of Contents

Chapter 1 Safety Guidance

This chapter provides important safety information related to the use of SE-2003/SE-2012 series Holter System Recorder.

1.1 Indications for Use/Intended Use

The SE-2003&SE-2012 Series Holter System (including recorder and analysis software) is intended to record, analyze, display, edit and generate report of ambulatory ECG. The Holter System is intended to be used by trained personnel under the direction of doctors. The analysis results are offered to doctors on an advisory basis only. The Holter System is intended for adult, pediatric patients including infants weighing less than 10 kg.

It can be used for the following indications:

1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
2. Evaluation of patients for ST segment changes.
3. Evaluation of drug response in patients taking anti-arrhythmic medications.
4. Evaluation of patients with pacemakers.

WARNING

1. This recorder is not designed for internal use or direct cardiac application.
2. This recorder is not intended for treatment.
3. The results given by the recorder should be examined based on the overall clinical condition of the patient, and they can not substitute for regular checking.

1.2 Warnings and Cautions

Consideration of Safety and Efficiency

- The dependability of the recorder depends on the proper operation in accordance with operation and maintenance guidance given in the manual.
- The lifetime of the recorder mainly depends on the components validity, which is 5 years under normal conditions. If components validity exceeds the time limit, the possibility of aging failure will increase and it may lead to operational failure.
- The measure result provided by the recorder is just a reference for physician. The final diagnosis is made by physician.
- The Holter recorder belongs to type CF equipment  , and defibrillation shouldn't be performed on a patient wearing the recorder.

In order to use the recorder safely and effectively, and avoid possible dangers caused by improper operation, please read through the user manual and be sure to be familiar with all functions of the equipment and proper operation procedures before use.

Please pay more attention to the following warning and caution information.

1.2.1 Safety Warnings

WARNING

1. The recorder is intended to be used by qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.
2. Only qualified service engineers can install this recorder, and only service engineers authorized by the manufacturer can open the shell. Otherwise, safety hazards may happen.
3. **EXPLOSION HAZARD** - Do not use the recorder in the presence of flammable anesthetic mixtures with oxygen or other flammable agents.
4. Do not use this recorder in the presence of high static electricity or high voltage equipment which may generate sparks.
5. Prevent any liquid from seeping into the recorder; otherwise the safety and the performance of the recorder can not be guaranteed.
6. Only the patient cable and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection can not be guaranteed.
7. Make sure that all electrodes are connected to the patient correctly before operation.
8. Wrap and secure excess cabling to reduce the risk of entanglement or strangulation.
9. Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.
10. The disposable electrodes can only be used for one time.
11. The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.
12. The use of equipment that applies high frequency voltages to the patient (including electrosurgical equipment and some respiration transducers) is not supported and may produce undesired results. Disconnect the patient data cable from the recorder, or detach the leads from the patient prior to performing any procedure that uses high frequency surgical equipment.
13. If multiple instruments are connected to a patient, the sum of the leakage currents may exceed the limits given in the IEC/EN 60601-1 and may pose a safety hazard. Consult your service personnel.

WARNING

14. The belt, Lanyard, and protective case cannot contact the skin directly.
15. The recorder shall not be serviced or maintained while in use with a patient.
16. The medical electrical equipment needs to be installed and put into service according to Appendix 2 EMC information.
17. The equipment should not be used adjacent to or stacked with other equipment, refer to the recommended separation distances provided in Appendix 2 EMC Information.
18. Portable and mobile RF communications equipment can affect medical electrical equipment, refer to the recommended separation distances provided in Appendix 2 EMC Information.

1.2.2 Alkaline Battery Care Warnings

WARNING

1. Do not heat or splash the battery or throw it into fire or water.
2. Do not destroy the battery; Do not pierce battery with a sharp object such as a needle. Do not hit with a hammer, step on or throw or drop to cause strong shock. Do not disassemble or modify the battery.
3. When leakage or foul smell is found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.
4. Properly dispose of or recycle the depleted battery according to local regulations.
5. Remove the battery from the recorder when the recorder isn't used for a long time.

1.2.3 General Cautions

CAUTION

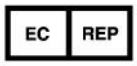
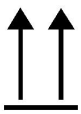
1. Federal (U.S.) law restricts this device to sale by or on the order of a physician.
2. Avoid liquid splash and excessive temperature. The temperature must be kept between 5 ºC and 45 ºC during operation, and it should be kept between -20 ºC and 55 ºC during transportation and storage.
3. The time required for the Holter recorder between uses to warm from the minimum storage temperature till it is ready for intended use is at least 2 hours and that

required to cool from the maximum storage temperature till it is ready for intended use is at least 2 hours.

4. Do not use the recorder in a dusty environment with bad ventilation or in the presence of corrosive.
5. Make sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitters or mobile phones etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. is likely to bring electromagnetic interference.
6. The recorder and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose of them together with house-hold garbage. At the end of their lives hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.
7. Prevent babies or children from swallowing small components, e.g. the battery.

1.3 List of Symbols

NO.	Symbol	Description
1		TYPE CF APPLIED PART
2		Caution
3		Consult operating instructions
4		SERIAL NUMBER
5		Date of manufacture

6		MANUFACTURER
7		CE marking
8		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
9		Disposal method
10		Insert SD card in the direction the arrow indicates.
11	Rx Only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
12		Refer to instruction manual/booklet (Background: Blue; Symbol: White)
13	IP 27	Protected against solid foreign objects of 12.5 mm Ø and greater Protected against the effects of temporary immersion in water
14	IP 22	Protected against solid foreign objects of 12.5 mm Ø and greater Protected against dripping water when tilted up to 15°
15		General symbol for recovery/recyclable
16		This way up
17		Fragile, handle with care
18		Keep away from rain

19		Stacking limit by number
20		Handle with care
21		Do not step on
22		Front
23		Medical Device
24		Unique Device Identifier

NOTE: The user manual is printed in black and white.

Chapter 2 Introduction

The manual mainly describes how to operate and maintain SE-2003/SE-2012 series Holter System Recorder (thereafter referred as SE-2003/SE-2012 series). The SE-2003/SE-2012 series Holter Analysis System consists of the recorder and analysis software. For the operation of analysis software, refer to software manual.

The SE-2003/SE-2012 series have four recorder models: SE-2003, SE-2012, SE-2003A, and SE-2012A. The difference lies in the SD card. SE-2003 and SE-2012 recorders can be inserted with micro-SD card while SE-2003A and SE-2012A inserted with SD card.

Ambulatory Electrocardiogram (Holter) detection technology is an effective tool to detect cardiovascular without the inference of distance, time, environment, the restriction of body position and activity. It can detect large amount of ECG information and is unique in capture of transient myocardial ischemia and diagnosis of transient arrhythmia.

SE-2003/SE-2012 series is powered by an AAA battery. SD card is used as storage media and LCD screen is used to set parameters and check wave quality. With a normal AAA alkaline battery, SE-2012/SE-2012A can continuously record non-compressed and full-disclosure 12-lead ECG data for 24～48 hours or 3-channel ECG data for 24~96 hours . With a normal AAA alkaline battery, SE-2003/SE-2003A can continuously record non-compressed and full-disclosure 3-channel ECG data for 24~96 hours. With a Li-Fe battery, SE-2003/SE-2003A can continuously record non-compressed and full-disclosure 3-channel ECG data for 7 days. SE-2003/SE-2012 series can detect and record pacemaker pulse information.

The Holter System is intended to be used in hospitals and clinics by trained personnel under the direction of doctors. The patient wears the Holter Recorder with the help of the doctor and the recorder records ECG data for at least 24 hours continuously. The patient may return home during the recording process. Finally, the doctor analyzes the ECG data recorded and makes diagnosis.

NOTE:

1. Long-time recording analysis should be supported by software with corresponding functions.
2. The manufacturer recommends the type of LiFe battery that can be used.

   Recommended LiFe battery: ENERGIZER L92
3. The manufacturer does not provide Ni-MH rechargeable battery and its charger.

2.1 Appearance

Please find appearance of SE-2003/SE-2012 Holter System Recorder below:

When powered on, the main screen displays the time, battery capacity, and basic device information.

The confirmation key serves as patient events key in monitoring process. If patients feel uncomfortable or want to record time of symbolic meaning (start to do exercise, begin to sleep, etc.), press the key and the recorder will record the time.

NOTE:

1. Pay attention to the plug direction. Please insert the side with marker toward recorder with appropriate force.
2. Press Confirmation key to restart SE-2003/SE-2012 series if it shuts off automatically. There is no need to load battery again.

CAUTION

Do not sway plug during use. Plug may fall off and that will cause record failure and even damages to socket.

2.2 Data Storage

SE-2003/SE-2012 series stores ECG data in Secure Digital card (SD card) which will be analyzed by Holter analysis software after finishing recording.

Only the SD card specified by manufacturer can be used in SE-2003/SE-2012 series. If you need to add or replace SD card, please contact manufacturer or dealer. Do not insert incompatible or unknown SD card into SE-2003/SE-2012 series recorder. That is to avoid unnecessary damages.

Capacity of SD card accompanied with recorder is 1G. If the SD card is not provided together with recorder, please contact the manufacturer or distributor.

CAUTION

SD card is a light and precise device. Do not knock or bend it or insert articles into the jacks. Keep the SD card in the recorder and it helps to prevent foreign matters from falling into SD card slot.

2.3 SD Card Loading and Unloading

SD card holder is push-push structure.

Load:
Face front of SD card with a cut angle toward back cover of recorder, slightly push it into SD card slot until the end of SD card and card slot are at the same level. Release the finger and let SD card automatically draw back 1 mm or so. It means SD card is in the right place.

Unload:
Use finger to push SD card inside until its end and card slot are at the same level. Release the finger and SD card will automatically eject 5 mm or so. Use fingernail to catch the end of SD card and slightly pull it out.

CAUTION

1. Do not load SD card with too much force. If you feel resistance, please check load direction or check if any articles block in the slot.
2. The first step to unload SD card is to push card inside and then let it pop up automatically. Never pull out the card by force before it pops up. It may cause damage to recorder and SD card.

2.4 Battery Loading

SE-2003/SE-2012 series is powered by one AAA battery. Large capacity AAA alkaline battery is recommended. Press  mark on battery compartment on the back of recorder by thumb and push outwards with force. The cover of battery compartment will open. Load one AAA battery according to polarity indication inside battery compartment.

NOTE: There is battery type setting in the setting menu of SE-2003/SE-2012 series: alkaline battery and Ni-MH battery. The purpose is to give more exact warning message on battery under-voltage according to discharge performance of different battery types. Please set the menu according to used battery type.

WARNING

1. Start a new patient with a new battery, to delete all old data and to reset the device's settings to fit the new patient.
2. Take out battery if the recorder is not to be used for more than an hour. Or else damage from corrosion could result.
3. Do not throw off used or scrapped batteries. Observe operation instructions and local laws for battery disposal.

2.5 Features

- SE-2012 Holter System Recorder is able to create standard 12 leads or 3 channels full ECG data;
- EDAN's unique multi-channel pacemaker detect circuit effectively prevents wrong detection of pacemaker signal caused by all kinds of artifacts (such as movement, polarized voltage and skin impedance) and missing detection caused by software detecting only. The detection sensitivity can reach 10^{-4} second.
- 1.92" full color screen plus a 3-key keyboard make it easy to set recording parameters of the Holter System Recorder. Real time ECG waves display helps to check electrode placement quality. During recording, you can switch to ECG display window at any time to master ECG recording situation;
- Multi-languages menu, easy and friendly to operate;
- Real-time clock, real-time display of year, month and date; the recording time is actual time, which prevents trouble and poor accuracy caused by recording manually.
- E-label: Support either registration in analysis software or entry of patient ID by recorder keyboard. Basic information (patient ID, name, gender, age) of patients is written into data package before making records. In this way recorders used by different patients will not be mixed up when reviewing data package. Numerous data are included in the package like hospital, signal channel, sampling rate, event information, recording date and time, so as to facilitate data management and exchange.
- Leads-off warning: Poor electrode connection will be warned.
- Power supply management, prompt of detection of battery under voltage; the power supply will shut off automatically after long time idling (15 minutes after last keyboard response) or 30 minutes after end of recording so as to save battery capacity and avoid battery leakage.
- Flexible communication mode, support plug-and-play SD card as well as USB 2.0 high-speed direct communication. SD card helps to speed up patient turnaround and is convenient to maintain so as to alleviate users' burden; on the other hand, USB 2.0 high-speed communication mode is simple and easy.
- Events button precisely records event time.

Chapter 3 Operation Preparations

WARNING

Before use, the recorder, patient cable and electrodes should be checked. Replace them if there is any evident defectiveness or aging which may impair the safety or the performance, and make sure that the equipment is in proper working condition.

3.1 Requested Materials

1. Recorder, patient cables, leads, SD card;
2. An analysis system able to make electronic labeling registration or other specialized software;
3. 10 (or 5, 7) disposable electrodes;
4. 1 AAA Alkaline battery or 1 fully charged Ni-MH rechargeable battery;
5. Patient log, pen;
6. Other supplementary materials like alcohol, medical adhesive plaster.

3.2 Preparing the Patient

3.2.1 Instructing the Patient

Give necessary guidance to patients before they leave:

1. Show them how to use events button and explain when to press the button;
2. Explain to the patients or nursing staff the importance of registering patient log timely and completely. Introduce writing format, contents, recording time, location, activities and self-feeling in detail;
3. Warn patients:
   - ♦ Do not immerse the recorder in water for more than 30 minutes or to depth more than 1 m.
   - ♦ Do not touch electrodes or unplug leads.
   - ♦ Do not open recorder. Do not take out battery or SD card;
   - ♦ Do not place mobile phones, TV or other electrical appliances one meter around the recorder.
   - ♦ Do not place heat source like heater close to the recorder.
4. Tell them how to record an event when they feel extremely uncomfortable;
5. Let them revisit 24 hours (48 hours or longer) later.

3.2.2 Cleaning the Skin

Thorough skin preparation is very important. The skin is a poor conductor of electricity and frequently creates artifacts that distort the ECG signals. By performing methodical skin preparation, you can greatly reduce the possibility of noise caused by muscle tremor and baseline drift, ensuring high-quality ECG waves. There is natural resistance on the skin surface due to dry, dead epidermal cells, oils and dirt.

To Clean the Skin

1. Shave hair from electrode sites, if necessary. Excessive hair prevents a good connection.
2. Wash the area thoroughly with soap and water.
3. Dry the skin with a gauze pad to increase capillary blood flow to the tissues and to remove the dead, dry skin cells and oils.

NOTE: If you don't have enough time for the steps above, you can use gauze to scrub the electrode sites to remove the dead, dry skin cells and oils and increase capillary blood flow to the tissues.

3.3 Connecting the Patient Cable to the Recorder and Electrodes

WARNING

The performance and electric shock protection can be guaranteed only if the original patient cable and electrodes of the manufacturer are used.

Follow the arrow on the patient cable to connect it to the cable socket on the top of recorder. Make sure that the connection is tight.

3.4 Attaching the Electrodes to the Patient

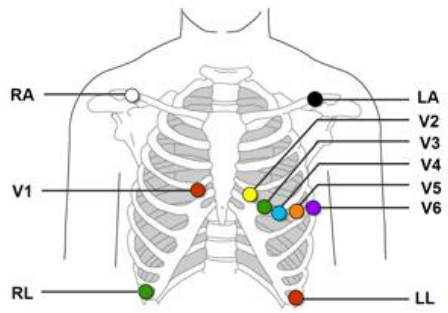
3.4.1 Electrode Placement

WARNING

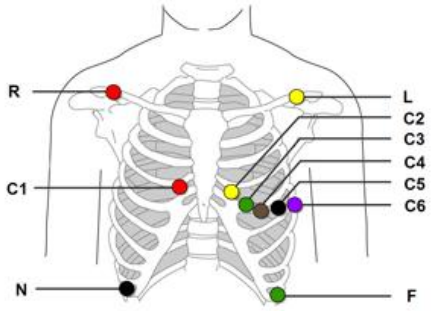
1. Make sure that all electrodes are connected to the patient correctly before operation.
2. Make sure that the conductive parts of electrodes and associated connectors, including neutral electrode, do not come in contact with earth or any other conducting objects.

3.4.1.1 10 Electrodes 12 Leads

10-electrode standard lead wires are utilized by the recorder (12-channel) to create a 12-lead ECG signal.



AHA

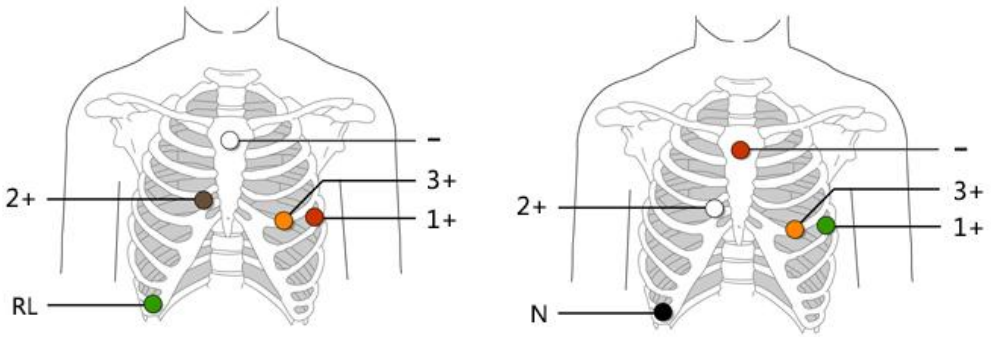


IEC

IEC	AHA	Electrode Placement
Red R	White RA	Below clavicle, close to right shoulder.
Yellow L	Black LA	Below clavicle, close to left shoulder.
Black N	Green RL	Lower right rib margin over bone.
Green F	Red LL	Lower left rib margin over bone.
Red C1	Red V1	Right of Mid-Clavicular line 4th rib
Yellow C2	Yellow V2	Left of Mid-Clavicular line 4th rib
Green C3	Green V3	In the middle of V2 and V4.
Brown C4	Blue V4	Brown V4: Fifth intercostal space on the left mid-clavicular line
Black C5	Orange V5	Left Anterior Axillary line, the same level of V4
Purple C6	Purple V6	Left Middle Axillary line, the same level of V4

3.4.1.2 5 Electrodes 3 Channels

Five-electrode-three-channel lead wires are utilized by the recorder to create a 3-channel ECG signal.

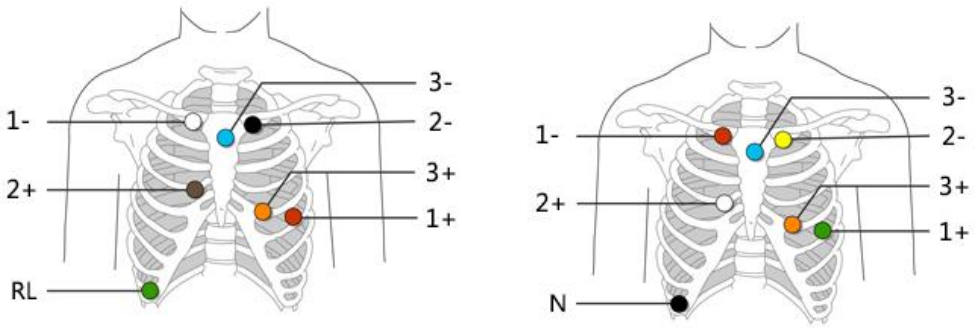


AHA IEC

IEC	AHA	Electrode Placement
Red (COM-)	White (COM-)	Right Manubrial border of the Sternum.
Green (CH1+)	Red (CH1+)	Fifth intercostal space on the left anterior axillary line, equivalent to V5 breast lead.
White (CH2+)	Brown (CH2+)	Right of Xiphoid Process on the rib, equivalent to V1.
Orange (CH3+)	Orange (CH3+)	Left fifth rib, equivalent to V3.
Black(N)	Green (RL)	Lower right rib margin over bone.

3.4.1.3 7 Electrodes 3 Channels

Seven-electrode-three-channel lead wires are utilized by the recorder to create a 3-channel ECG signal.



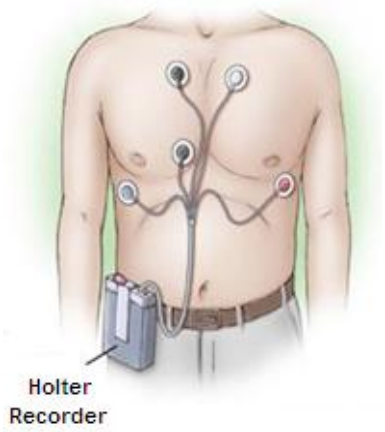
AHA IEC

IEC	AHA	Electrode Placement
Green (CH1+)	Red (CH1+)	Fifth intercostal space on the left anterior axillary line, equivalent to V5 breast lead.
Red (CH1-)	White (CH1-)	Right Manubrial border of the Sternum.
White (CH2+)	Brown (CH2+)	Approximately 1 inch right of Xiphoid Process on the rib.
Yellow (CH2-)	Black (CH2-)	Left Manubrial border of the Sternum.
Black (N)	Green (RL)	Lower right rib margin over bone.
Orange (CH3+)	Orange (CH3+)	Left fifth rib, equivalent to V3...
Blue (CH3-)	Blue (CH3-)	Center of the Manubrium.

3.4.2 Attaching the Electrodes

CAUTION

The disposable electrodes can only be used for one time.



Disposable Electrode Connection

1. Clean the electrode areas on the body surface with 75% alcohol.
2. Attach the disposable electrodes to the electrode positions on the body surface.
3. Clip the disposable electrodes with the lead wires.

Proper skin preparation (abrasion if necessary), proper electrodes, and patient cables in fixed position are very important for a good signal quality.

Chapter 4 ECG Sampling

4.1 Overview

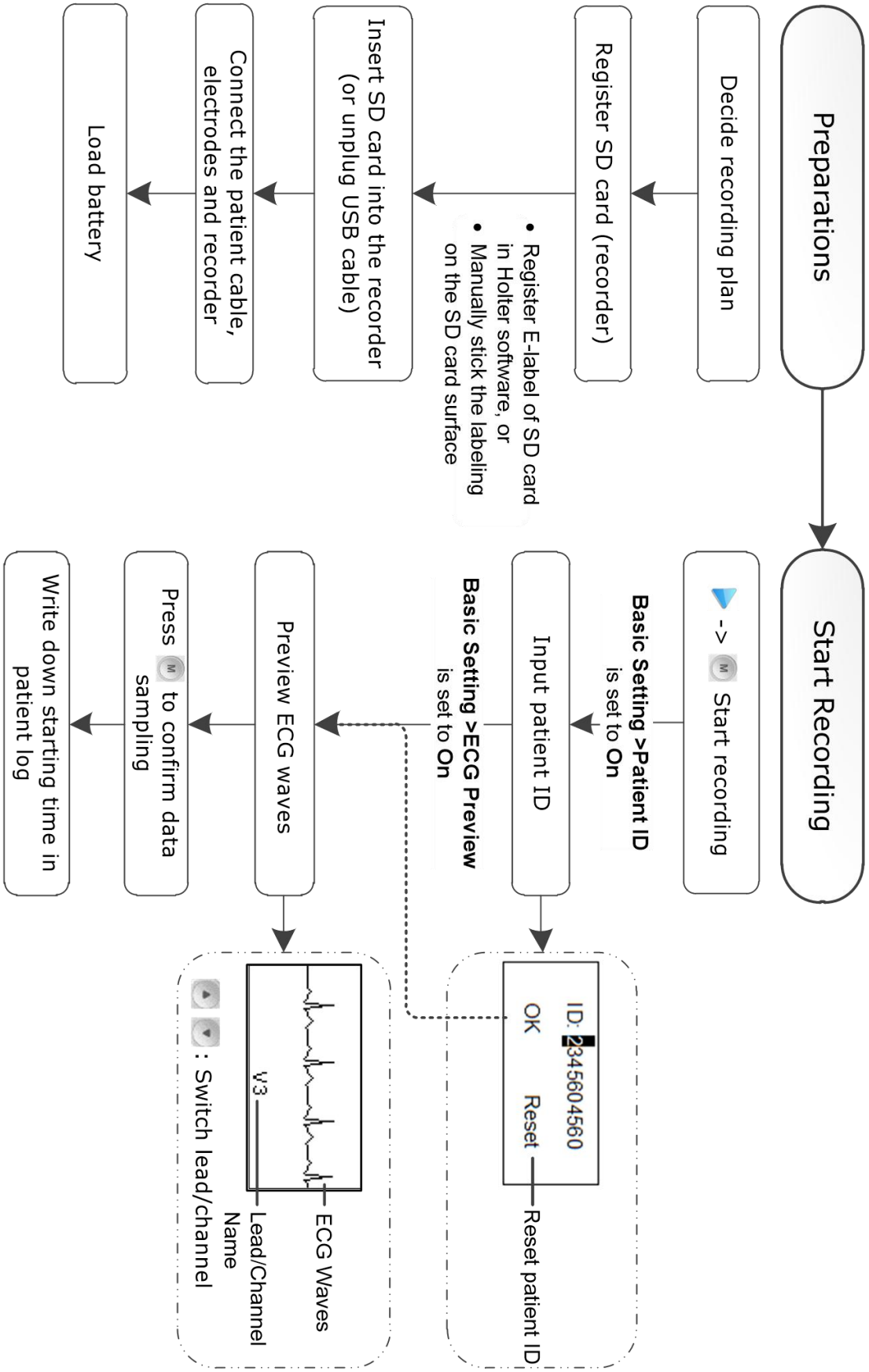
The operation steps of SE-2003/SE-2012 series recorder are as follows:

1. Decide recording plan, such as lead mode, pacemaker pulse data needed or not;
2. Insert SD card into card-reader of analysis system or directly connect it with analysis system via USB cable to register E-label. The registered SD cards prevent possible confusion caused by recording of different patients at the same time;
3. Place electrodes;
4. Load a full and fresh AAA battery;
5. Set recording parameters through recorder keyboard and LCD;
6. Preview ECG wave through LCD and check whether electrodes are properly placed and make adjustment if necessary;
7. Start to record through menu when all steps above are ok;
8. Begin to record formally after recorder initialization;
9. Check wave quality of ECG signal during recording process through LCD and check placement quality of electrodes;
10. End of recording.

NOTE:

1. SE-2012/SE-2012A supports three kinds of lead mode: 10-electrode standard 12-lead mode, 7- electrode-3-channel mode and 5-electrode-3-channel mode. Recorder will automatically identify and record data generated from different leads accordingly.
2. SE-2003/SE-2003A supports 7-electrode or 5-electrode 3-channel mode.

4.2 Start ECG Sampling

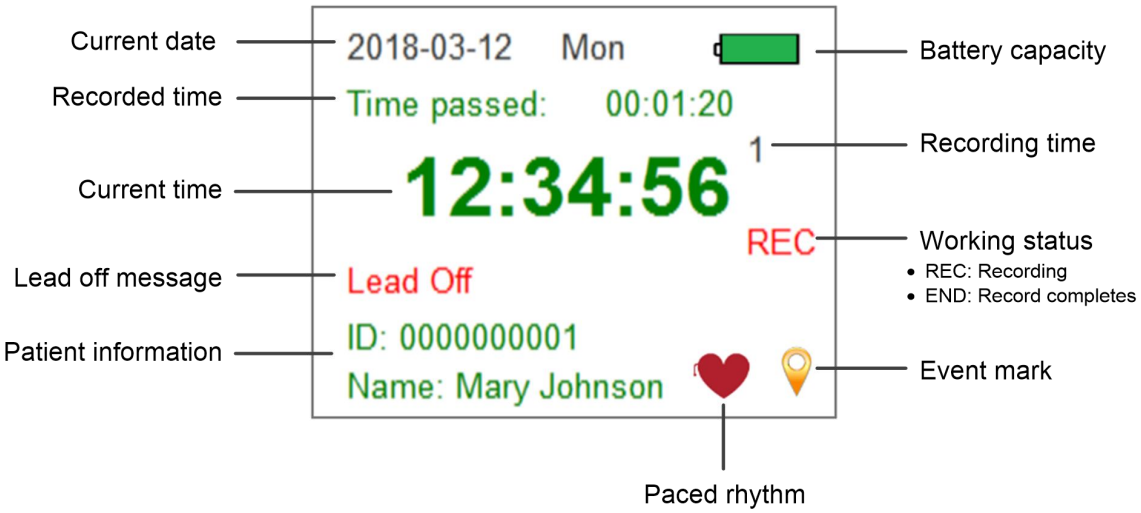


NOTE:

1. If the patient has been registered in the analysis software beforehand, the recorder enters the recording screen directly.
2. The inner-placed clock in SE-2003/SE-2012 series exactly records starting and ending time which can be obtained from creating time of event files or data files afterwards. Some analysis software possibly does not support the function. Manual recording time depends on the analysis software used.
3. New battery is recommended for each ECG sampling process.
4. The time axis (paper speed) in waveform display mode is around 1.5cm/s or 3cm/s, which is slightly different from regular ECG with paper speed of 2.5cm/s or 5cm/s. Actually the main purpose is to visually assess signal quality and basic form, but not to be basis of quantitative measurement.

4.3 Sampling…

The recorder will erase the existing data first to stabilize the circuit and ECG electrodes.



4.4 Stop Sampling

Recommended regular ways to terminate recording:

1. Recording will automatically stop if recording has lasted for 1 day (or 2 days, 3 days set beforehand);
2. Recording will automatically stop if battery is used up;
3. Directly connect with USB cable after removing patient cable;

4. Press  and  together, a dialog box will be displayed. Press  or  to move the cursor to **Yes**, and then press  to stop recording.

Directly taking out battery will also terminate recording, while it may cause damages to data. SD card may have to be scanned and repaired through disk scanning program of operating system, which shall be avoided.

After sampling finishes:

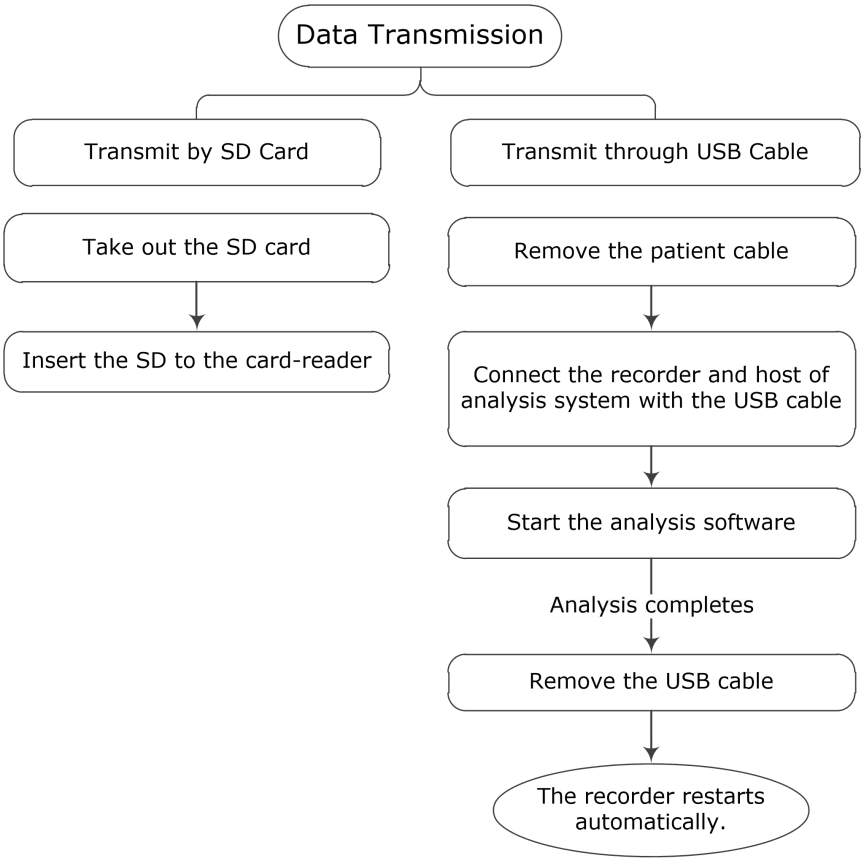
1. Take out SD card and insert it into analysis system card reader or connect USB cable with recorder to prepare for analysis;
2. Remove leads and electrodes from patients and do necessary cleaning for them.
3. After necessary cleaning and disinfection to recorder and leads, it is well prepared for the next patient.

WARNING

1. Electrodes are for one-off use only as they may cause cross infection between different patients. Repeated use is forbidden!
2. For disposal of abandoned electrodes, please follow hospital requirements or local laws and regulations. Do not discard them carelessly.

4.5 Data Transmission

After the end of recording, the collected data shall be transmitted to analysis software to make analysis and diagnosis.



NOTE: It is recommended to equip one recorder with two SD cards so as to facilitate patient turnover. Move to next patient quickly by change of SD card only.

Chapter 5 System Setting

After setting the parameters, press **Exit** to return to upper level menu.

NOTE: The underlined options are the default value.

5.1 Basic Setting

Item	Description
Channels	For SE-2003 or SE-2012 connected with 5- or 7-electrode patient cable, the number of recording channels can be set to **3**, **2** or **1**.
Gain	Choose from: **0.5**, **1**, or **2**. The default startup setting is the value adjusted last time.
Record time	Set the duration for the data sampling process. For SE-2003/SE-2003A, choose from: 1 day, 2 days, 3 days, 4 days or 0. For SE-2012/SE-2012A, choose from: 1 day, 2 days or 0. 0 means no recording time limit. The recording won't stop until the battery runs out.
ECG Preview	ECG preview can be set to **On** or **Off**. If set to **Off**, ECG preview will be skipped.
Patient ID	**Patient ID** can be set to **On** or **Off**. When set to **On**, you need to input the patient ID before recording. **NOTE**: If the patient has been registered in the analysis software beforehand, the recorder enters the recording screen directly.
ECG Display	ECG display during recording process can be set to **On** or **Off**. ● Set the value as **On** and enter ECG display mode by pressing Left-up key and confirmation key during recording process and observe waveform. ● It is unable to enter ECG display mode by pressing Left-up key and confirmation key during recording process if the value is set to **Off**. This helps to prevent unnecessary influence to patients. Whether entering ECG display mode or not, recording signals will not be influenced.
Data Protected	Data protection is used to detect if the recorded data has been analyzed. The default value is **On**. If it is set to **On**, the recorded data has to be analyzed by analysis software at least once before starting the next recording.

Item	Description
	NOTE: Please confirm that your analysis system supports this function. It's suggested to turn on this setting to effectively prevent the unanalyzed data from being deleted unexpectedly.
Language	Set the system language.
Battery Type	Battery type used for the recorder can be set to **alkaline** or **Ni-MH**. Default value is the value set last time.
System Time	Adjust year-month-date and hour-minute-second of real-time clock. Week will adjust itself automatically. SE-2003/SE-2012 series has a clock backup battery inside. Even if the battery of recorder is taken out for a long time, the clock circuit still works normally. Only if the recorder is unused for a long time or time zone is changed, the clock has to be adjusted. **NOTE**：Pay attention to the time shown on the recorder prior to use. If the time is abnormal, adjust the clock.
Date Format	Set the format for system time display.

5.2 Advanced Setting

Item	Description
Sample Rate	For EDAN file format, **Sample Rate** can be set to 128, 256, 512, or 1024. For file format of other companies, **Sample Rate** is set to 256Hz by default and cannot be modified.

Chapter 6 Hint Information

Hints	Description
Low Battery! Continue?	The warning message will show up if battery is detected to be under voltage and cannot support long-time recording. If you choose **No** to stop recording, the recorder will automatically shut off in 5 seconds; if you choose **Yes**, the recorder will keep working. **WARNING** If you operate the recorder for less than 24 hours, you can choose **Yes** to continue. Otherwise you need to replace it with new battery.
Low Battery. Power off in 30 seconds.	The warning information will show up if battery voltage is detected to be too low and cannot operate normally. The recorder will automatically shut off in 30 seconds.
Power off in 30 seconds!	The recorder will automatically shut off in non-recording state and when no action on keyboard is performed for 15 minutes. The prompt message will show up and last 30 seconds before recorder shuts off.
SD card not found. Please insert.	The prompt message will show up if no SD card is detected when the recorder starts up. Recorder will wait until user inserts SD card.
SD card error!	The prompt message will show up if errors take place during read-write process even though SD card is detected before recording. The recorder will wait until SD card is inserted. The recorder will shut off in 60 seconds. **CAUTION** It is possible that users use incompatible SD card or something is wrong with SD card if such prompt pops up. The SD card has to be repaired or changed.
ECG file is unanalyzed. Continue?	If the **Data Protection** is set to **On** and there is unanalyzed data in the SD card, the recorder will show the message. **NOTE:** To proceed running, data in the SD card has to be analyzed at least once or be canceled on PC.
Lead Off	If any electrode falls off, the recorder will show this message.
No patient cable. Please insert.	The prompt message will show up if no patient cable is detected before recording. The recorder will wait until patient cable is inserted.

Chapter 7 Cleaning, Care and Maintenance

Use only the EDAN-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

Edan Instruments has validated the cleaning and disinfection instructions provided in this User Manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection.

7.1 General Points

Keep your device and accessories free of dust and dirt. To prevent the device from damage, please follow the instructions:

- Use only the recommended cleaning agents and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
- Always dilute according to the manufacturer's instructions.
- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the equipment.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- Inspect the device and reusable accessories after they are cleaned and disinfected.

CAUTION

1. If you spill liquid on the device or accessories, or they are accidentally immersed in liquid, contact your service personnel or EDAN service engineer.
2. The device is chemically resistant to most cleaning agents, disinfectants and non-caustic detergents used in hospital, but cleaning agents or disinfectants that are not listed in this manual are not recommended. For example, didecyl dimethyl ammonium bromide, which contains quaternary ammonium salt, may corrode the device and accessories.

7.2 Cleaning

If the equipment or accessory has been in contact with the patient, then cleaning and disinfection is required after each use.

The validated cleaning agents for cleaning the device and reusable accessories are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied or removed using a clean, soft, non-abrasive cloth or paper towel.

7.2.1 Cleaning the Recorder

WARNING

Turn off the power and take out the battery before cleaning.

1. Switch off the recorder and take out the battery.
2. Wipe the exterior surface of the equipment using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
3. Wipe off the cleaning solution with a fresh cloth or towel dampened with tap water after cleaning until no visible cleaning agent remains.
4. Dry the recorder in a ventilated and cool place.

7.2.2 Cleaning the Patient Cable

1. Wipe the patient cable with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe off the cleaning solution with a fresh cloth or towel dampened with tap water after cleaning until no visible cleaning agent remains.
3. Wipe off with a dry cloth to remove residual moisture.
4. Leave the patient cable to air dry.

CAUTION

Any remainder of cleaning solution should be removed from the recorder and the patient cable after cleaning.

7.3 Disinfection

To avoid permanent damage to the equipment, it is recommended that disinfection is performed only when it is considered as necessary according to your hospital' regulations.

Clean the equipment and reusable accessories before they are disinfected. The validated

disinfectants for disinfecting the device and reusable accessories are:

- Ethanol (75%)
- Isopropanol (70%)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

CAUTION

1. Do not use high-temperature, high-pressure vapour or ionizing radiation as disinfection methods.
2. Do not use chloric disinfectant such as chloride, sodium hypochlorite etc.
3. Clean and disinfect reusable electrodes after each use.

7.3.1 Disinfecting the Recorder

WARNING

Turn off the power and take out the battery before disinfection.

1. Switch off the recorder and take out the battery.
2. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.
3. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
4. Dry the recorder for at least 30 minutes in a ventilated and cool place.

7.3.2 Disinfecting the Patient Cable

1. Wipe the patient cable with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the patient cable to air dry for at least 30 minutes.

7.4 Care and Maintenance

7.4.1 Visual Inspection

Perform a visual inspection of all equipment and peripheral devices daily. If you notice any items that need repair, contact a qualified service engineer to make the repairs.

- Check the case and display screen for cracks or other damage.
- Regularly inspect all plugs, cords, cables, and connectors for fraying or other damage.
- Verify that all cords and connectors are securely seated.
- Inspect keys and controls for proper operation.

7.4.2 Maintenance of the Recorder and the Patient Cable

CAUTION

Besides the maintenance requirements recommended in this manual, comply with local regulations on maintenance and measurement.

The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

a) Inspect the recorder and accessories for mechanical and functional damage.

b) Inspect the safety related labels for legibility.

c) Verify that the recorder functions properly as described in the instructions for use.

d) Test the patient leakage current according to IEC/EN 60601-1: Limit: NC a.c. 10μA, d.c. 10μA; SFC a.c. 50μA, d.c. 50μA.

e) Test the patient auxiliary current according to IEC/EN 60601-1: Limit: NC a.c. 10μA, d.c. 10μA; SFC a.c. 50μA, d.c. 50μA.

f) Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC/EN 60601-1: Limit: 50μA (CF).

g) Test the essential performance according to IEC 60601-2-47, or methods recommended by the hospital or local distributor.

The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the recorder is not functioning properly or fails any of the above tests, the recorder has to be repaired.

WARNING

Failure on the part of the responsible individual hospital or institution employing this equipment to implement a satisfactory maintenance schedule may cause undue equipment failures and possible health hazards.

1) Recorder

- Avoid excessive temperature, sunshine, humidity and dirt.
- Put the dustproof coat on the recorder after use and prevent shaking it violently when moving it to another place.
- Prevent any liquid from seeping into the recorder; otherwise the safety and the performance of the recorder can not be guaranteed.

2) Patient Cable

- Integrity of the patient cable, including the main cable and lead wires, should be checked

regularly. Make sure that it is conductible.

- Align the patient cable to avoid twisting, knotting or crooking in a closed angle while using it.
- Do not drag or twist the patient cable with excessive stress while using it. Hold the connector plug instead of the cable when connecting or disconnecting the patient cable.
- Store the lead wires in a big wheel to prevent any people from stumbling.
- Once damage or aging of the patient cable is found, replace it with a new one immediately.

CAUTION

The recorder and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.

Chapter 8 Accessories

WARNING

Only the patient cable and other accessories supplied by the manufacturer can be used. Or else, the performance and electric shock protection can not be guaranteed.

Table 7-1 Accessory List

Accessory	Part Number
10 Electrodes Patient Cable(AHA)	01.57.471451
7 Electrodes Patient Cable(AHA)	01.57.471453
5 Electrodes Patient Cable(AHA)	01.57.471455
10 Electrodes Patient Cable(IEC)	01.57.471450
7 Electrodes Patient Cable(IEC)	01.57.471452
5 Electrodes Patient Cable(IEC)	01.57.471454
Adult Disposable Adhesive Electrode	01.57.471858
Pediatric Disposable Adhesive Electrodes	01.57.471859
Micro-SD Card	01.18.052345
SD Card	01.18.052548
SD Card Reader	01.18.052549
Recorder protection cover	01.56.465779
Lanyard	01.56.465780
Waistband	01.56.465781
AAA alkaline battery	01.21.064111
USB dongle	02.01.211263
Li-Fe battery	21.21.064248
USB Cable	01.57.471456

The Holter System recorder and accessories are available by contacting the manufacturer or your local distributor.

NOTE: The part name may vary depending on context, but the part number is constant.

Chapter 9 Warranty and Service

9.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in the case of:

a) Damage caused by handling during shipping.

b) Subsequent damage caused by improper use or maintenance.

c) Damage caused by alteration or repair by anyone not authorized by EDAN.

d) Damage caused by accidents.

e) Replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

9.2 Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.

Appendix 1 Technical Specifications

A1.1 Safety Specifications

Comply with:		IEC 60601-1:2015+A1:2012+A2:2020 EN 60601-1:2006/A1:2013 IEC 60601-1-2:2014+A1:2020 EN 60601-1-2:2015 IEC/EN 60601-2-47 IEC 60601-1-11
Anti-electric-shock type:		Internal power supply
Anti-electric-shock degree:		Type CF
Degree of protection against solid foreign objects and harmful ingress of water:		SE-2003 & SE-2012: IP27 SE-2003A & SE-2012A: IP22
Disinfection/sterilization method:		Refer to the user manual for details
Degree of safety of application in the presence of flammable gas:		Equipment not suitable for use in the presence of flammable gas
Working mode:		Continuous operation
EMC:		CISPR 11, Group 1, Class B
Patient Leakage Current:	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)
Patient Auxiliary Current:	NC	<10μA (AC) / <10μA (DC)
	SFC	<50μA (AC) / <50μA (DC)

A1.2 Environment Specifications

	Transport & Storage	Working
Temperature:	-20 ºC (-4 ºF) to +55 ºC (+131 ºF)	+5 ºC (+41 ºF) to +45 ºC (+113 ºF)
Relative Humidity:	10%RH - 95%RH Non-Condensing	10%RH - 95%RH Non-Condensing
Atmospheric Pressure:	70 kPa – 106 kPa	70 kPa – 106 kPa

A1.3 Physical Specifications

Dimensions	SE-2003/SE-2012: 76 mm × 49 mm × 16 mm, ±2 mm SE-2003A/SE-2012A: 92 mm × 56 mm × 20 mm, ±2 mm
Weight	SE-2003/SE-2012: 50 g (excluding battery), ±5 g SE-2003A/SE-2012A: 75 g (excluding battery), ±5 g
Display	1.92" full color screen

A1.4 Battery Specifications

Battery type	1 AAA alkaline battery, LiFe or Ni-MH battery
Battery life	SE-2012/SE-2012A: 24h (Sampling frequency: 1,024 Hz) 144h (Sampling frequency: 128 Hz) SE-2003/SE-2003A: 48h (Sampling frequency: 1,024 Hz) 192h (Sampling frequency: 128 Hz)

A1.5 Performance Specifications

Channels	3 or 12 channels
Recording	Full disclosure, no data compression
Frequency Response	0.05 Hz to 100 Hz (-3 dB)
Input impedance	≥50 MΩ

Gain	5 mm/mV, 10 mm/mV, 20 mm/mV, ±5%
CMRR	≥ 100 dB
A/D Sampling Frequency	25.6 kHz
A/D	24 bits
Minimum Amplitude	50 μVp-p
Resolution	19.53 uV/LSB
Pacemaker Detection	±1 mV ~ ±200 mV, 0.1 ms ~ 2.0 ms
ECG Signal Acquisition Verification	Through screen of the recorder
Data Transmission	Through USB cable or SD card reader
Input Circuit Current	≤0.1 uA
Time Constant	≥3.2s (0, +20%)
Noise	≤20 uVpp
DC Offset Voltage	±300 mV
Pacemaker Detection	
Amplitude	±1 mV to ±200 mV; When the recorder is in continuous operation at the sampling frequency of 128 Hz, the amplitude is in the range of ±2 mV to ±200 mV.
Width	0.1 ms to 2.0 ms

NOTE:

1. Sampling rate and A/D are adapted to default settings before sales.
2. Operation of the equipment below the minimum amplitude may cause inaccurate results.

Appendix 2 EMC Information

Electromagnetic Emissions

<table>
<tr><th colspan="3">Guidance and manufacture's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">Holter System Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of Holter System Recorder should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>Holter System Recorder 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.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class B</td><td rowspan="3">Holter System Recorder 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.</td></tr>
<tr><td>Harmonic emissions
IEC/EN 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC/EN 61000-3-3</td><td>Not applicable</td></tr>
</table>

Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
Holter System Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of Holter System Recorder should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Not applicable
Surge IEC/EN 61000-4-5	±1 kV line to line ±2 kV line to ground	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IMMUNITY to proximity magnetic fields	8A/m, Modulation: CW Test frequency:30KHz; 65A/m, Modulation: Pulse	8A/m, Modulation: CW Test frequency:30KHz; 65A/m, Modulation: Pulse	/

	modulation, 2.1KHz Test frequency:134.2KHz; 7.5A/m, Modulation: Pulse modulation, 50KHz Test frequency:13.56MHz;	modulation, 2.1KHz Test frequency:134.2KHz; 7.5A/m, Modulation: Pulse modulation, 50KHz Test frequency:13.56MHz;	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 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° 0 % U_T; 250/300 cycle	Not applicable	Not applicable
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
Holter System Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of Holter System Recorder should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**

Conducted RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3 Vrms 150 kHz ~ 80 MHz 6Vrms [c] in ISM bands between 0.15 MHz and 80 MHz 10 V/m 80 MHz to 2.7GHz	3 Vrms 150 kHz to 80 MHz 6Vrms [c] in ISM bands between 0.15 MHz and 80 MHz 10 V/m 80 MHz to 2.7GHz	Portable and mobile RF communications equipment should be used no closer to any part of the model recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d = 6\sqrt{P}/\mathrm{E}$ at RF wireless communications equipment bands (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 Holter System Recorder, including cables specified by the manufacturer). Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitter, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model recorder is used exceeds the applicable RF compliance level above, the model recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model recorder.

b Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3V/m.

c The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz . The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Brand [a] (MHz)	Service [a]	Modulation [b]	Maximum Power(W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [C] ±5 kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Brand 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450, LTE Brand 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						
Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM maybe reduce to 1m. The 1 m test distance is permitted by IEC 61000-4-3.						
a) For some services, only the uplink frequencies are included.						

b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM

Recommended separation distances between portable and mobile RF communications equipment and Holter System Recorder

Holter System Recorder is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Holter System Recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Holter System Recorder as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter(m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

P/N: 01.54.456520

MPN: 01.54.456520022

EDAN

EC REP

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