EDAN

SE-2003&SE-2012

Holter System Recorder

Version 1.3

CE 0123

About this Manual

P/N: 01.54.455144-13

Release Date: April 2014

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.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

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

1 Safety Guidance

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

1.1 Intended Use

The SE-2003/SE-2012 Holter System (including analysis software and recorder) is intended to record, analyze, display, edit and generate report of ambulatory ECG. It is mainly used for (but not limited to) 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.

The Holter system is intended to be used in hospitals and clinics 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, paediatric patients and infants weighing less than 10 kg.

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.

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.

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. 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.

9. The disposable electrodes can only be used for one time.

10. 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.

11. 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.

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. Avoid liquid splash and excessive temperature. The temperature must be kept between 5 ℃ and 40 ℃ during operation, and it should be kept between -20 ℃ and 55 ℃ during transportation and storage.

2. Do not use the recorder in a dusty environment with bad ventilation or in the presence of corrosive.

3. 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.

4. 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.

1.3 List of Symbols

Symbol	Description
♥	Type CF equipment
⚠	Caution
📖	Consult Instructions for Use
♻	Waste Electrical and Electronic Equipment (WEEE) It is the responsibility of the end user to dispose of this equipment at a designated collection point for recycling.
�	Year of Manufacture
🏭	Manufacturer
SN	Serial Number
SD CARD ↑	Insert SD card in the direction the arrow indicates.
CE 0123	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.
EC REP	Authorized Representative in the European Community
Rx only (U.S.)	Federal (U.S.) law restricts this device to sale by or on the order of a physician

2 Introduction

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

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 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 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 can continuously record non-compressed and full-disclosure 3-channel ECG data for 24~96 hours. With a Li-Fe battery, SE-2003(7d) can continuously record non-compressed and full-disclosure 3-channel ECG data for 7 days. SE-2003/SE-2012 can detect and record pacemaker pulse information.

NOTE: Long-time recording analysis should be supported by software with corresponding functions.

2.1 Appearance

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

Multifunctional
Socket

LCD Screen

Left-up Key

Confirmation Key

Right-down Key

SD Card Port

Battery
Cathode

Battery Cover
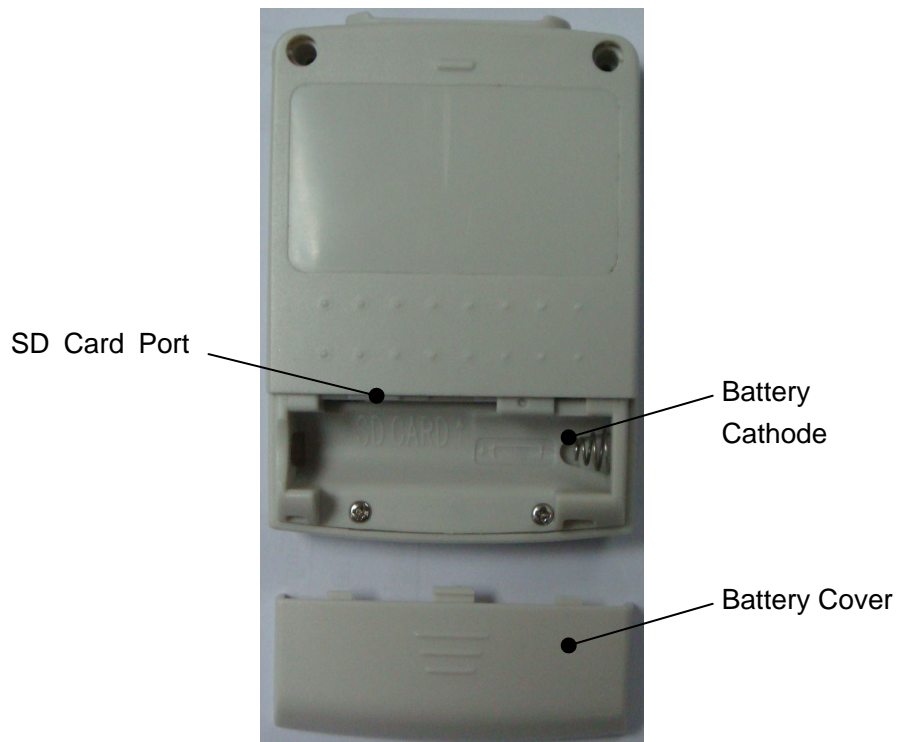
2.2 Lead Input/USB Socket

SE-2003/SE-2012 is featured by a 26-pin lead input/USB multi-functional connector socket. It serves as lead input socket when collecting records. After recording finishes, insert USB cable into the socket and data could be read into analysis system through USB 2.0 high speed transfer.
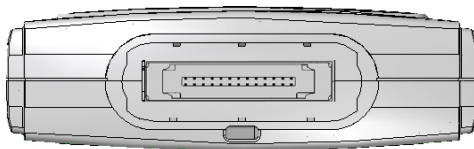
By using the same socket, possibility of connection of lead and USB with recorder at the same time is prevented and potential safety hazards are effectively avoided.

NOTE: Pay attention to the plug direction. Please insert the side with marker toward recorder with appropriate force.

CAUTION

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

2.3 Control Key

SE-2003/SE-2012 keyboard is composed of confirmation key, left-up key and right-down key.

Confirmation key is used to confirm choice operations and change cursor status in menu operation mode.

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.

Left-up key is used to move the cursor to left or move up in menu operation mode.

Right-down key is used to move the cursor to right or move down in menu operation mode.

For detailed functions of different buttons, please refer to parameter setting section.

2.4 Data Storage

SE-2003/SE-2012 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. 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 recorder. That is to avoid unnecessary damages.

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.

2.4.1 Capacity Requirements

Capacity of SD card accompanied with recorder is 2G. If the SD card is not provided together with recorder, please contact the manufacturer or distributor.

2.4.2 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.

2.5 Battery Loading

SE-2003/SE-2012 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: 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.

<u>**WARNING**</u>

1. Take out battery if the recorder is not to be used for a long time. Or else damage from corrosion could result.

2. Do not throw off used or scrapped batteries. Observe operation instructions and local laws for battery disposal.

2.6 Features

- Refined appearance: 68 x 53 x16 mm, 42g

- SE-2012 Holter System Recorder is able to create standard 12 leads or 3 channels complete 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.

- 128 X 64 graphic LCD 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 by voice or icon.

● 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.

NOTE: Press Confirmation key to restart SE-2003/SE-2012 if it shuts off automatically. There is no need to load battery again.

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 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.

SE-2003/SE-2012 adopts optimized and incorporated lead structure, which can reduce potential difference disturbance during monitoring process.

3.2.1 Connecting the Patient Cable to the Recorder

Connect the patient cable to the patient cable socket on the top side of the recorder.

3.2.2 Connecting the Patient Cable to Electrodes

Standard lead name and color code are marked on each electrode head of every lead.

Snap the electrodes to the lead wires according to the color identifiers.

3.2.2.1 10 Electrodes 12 Leads

(AHA)

○ White RA ● Black LA ● Green RL ● Red LL
● Red V1 ● Yellow V2 ● Green V3 ● Blue V4 ● Orange V5 ● Purple V6

(IEC)

○ Red R ● Yellow L ● Black N ● Green F
● Red C1 ● Yellow C2 ● Green C3 ● Brown C4 ● Black C5 ● Purple C6

Table 3-1 Electrode Connectors and Their Identifiers and Color Codes

	IEC		AHA	
Right arm/Right deltoid	R	Red	RA	White
Left arm/Left deltoid	L	Yellow	LA	Black
Right leg/Upper leg as close to torso as possible	N or RF	Black	RL	Green
Left leg/Upper leg as close to torso as possible	F	Green	LL	Red
Chest 1	C1	Red	V1	Red
Chest 2	C2	Yellow	V2	Yellow
Chest 3	C3	Green	V3	Green
Chest 4	C4	Brown	V4	Blue
Chest 5	C5	Black	V5	Orange
Chest 6	C6	Purple	V6	Purple

3.2.2.2 5 Electrodes 3 Channels

(AHA)

○ 1 Red (CH1+)　● 2 Brown (CH2+)　● 3 Orange (CH3+)　● 4 White (COM-)　● 5 Green (RL)
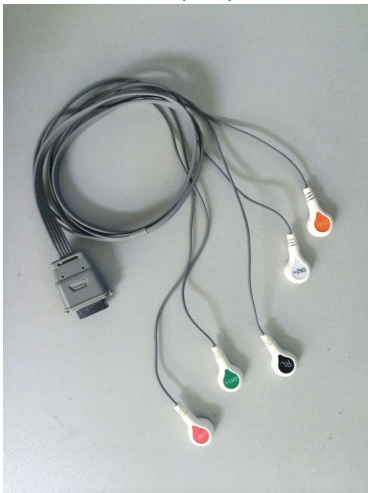
(IEC)

○ 1 Green (CH1+)　● 2 White (CH2+)　● 3 Orange (CH3+)　● 4 Red (COM-)　● 5 Black (RL)

Table 3-2 Electrode Connectors and Their Identifiers and Color Codes

	Electrode	Code (IEC)	Code (AHA)
Channel 1	Positive Electrode	Green	Red
	Negative Electrode	Red	White
Channel 2	Positive Electrode	White	Brown
	Negative Electrode	Red	White
Channel 3	Positive Electrode	Orange	Orange
	Negative Electrode	Red	White
Neutral Electrode		Black	Green

3.2.2.3 7 Electrodes 3 Channels

(AHA)

● 1 Red (CH1+)　　　● 2 White (CH1-)　　● 3 Brown (CH2+)
● 4 Black (CH2-)　　　● 5 Orange (CH3+)　　○ 6 Blue (CH3-) ● 7 Green (RL)
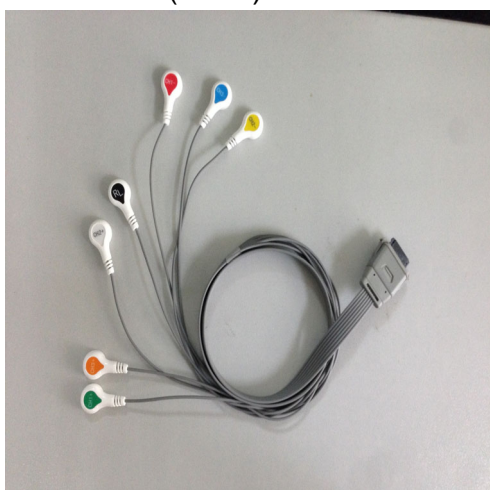
(IEC)

○ 1 Green (CH1+) ● 2 Red (CH1-)　● 3 White (CH2+)　● 4 Yellow (CH2-)
● 5 Orange (CH3+)　● 6 Blue (CH3-)　● 7 Black (RL)

Table 3-3 Electrode Connectors and Their Identifiers and Color Codes

	Electrode	Code (IEC)	Code (AHA)
Channel 1	Positive Electrode	Green	Red
	Negative Electrode	Red	White
Channel 2	Positive Electrode	White	Brown
	Negative Electrode	Yellow	Black
Channel 3	Positive Electrode	Orange	Orange
	Negative Electrode	Blue	Blue
Neutral Electrode		Black	Green

3.3 Preparing the Patient

3.3.1 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, what to record, recording time, location, activities and self-feeling in detail;
3. Warn patients:
   ♦ Do not get the recorder wet. No bathing, shower or shampooing;
   ♦ Do not touch electrodes or unplug leads.
   ♦ Do not open recorder. Do not take out battery or SD card;
   ♦ Do not place mobile, TV or other electrical appliances one meter around the recorder.
   ♦ Do not place heat source like heater close to the recorder.
4. Tell them to stop recording when they feel extremely uncomfortable and tell them how to stop;
5. Let them revisit 24 hours (48 hours or longer) later.

3.3.2 Preparing 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 Prepare 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 pledget to scrub the electrode sites to remove the dead, dry skin cells and oils and increase capillary blood flow to the tissues.

3.4 Attaching the Electrodes to the Patient

Use qualified and valid silver-silver chloride disposable monitoring electrodes specially used for the recorder. It is recommended to choose disposable electrodes complying with YY/T 0196-94 or ANIS/AAMI EC12-1991 requirements.

3.4.1 Electrode Placement

The application of electrodes should be performed by trained medical personnel.
It's better to place electrodes on skin over ribs or cartilage to avoid interference resulting from movement of soft tissues.

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. Different placement positions of 10 electrodes will form different lead modes, and it is recommended to place electrodes as below:
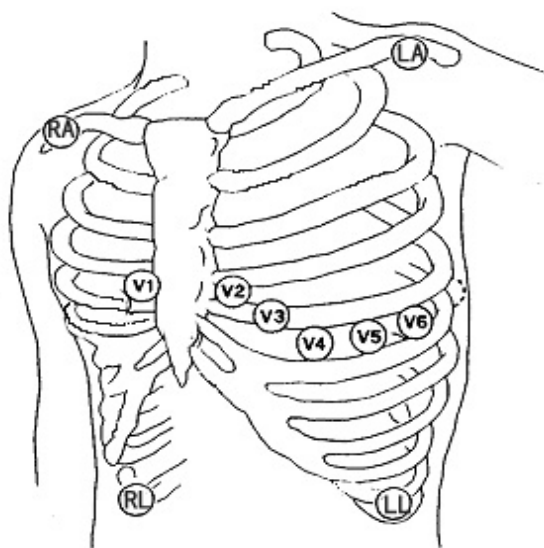
IEC	AHA	Electrode Placement
Red R	White RA	Below clavicle, close to right shoulder.
Yellow L	Black LA	Below clavicle, close to left shoulder.
Black N	Green RL	Lower right rib margin over bone.
Green F	Red LL	Lower left rib margin over bone.
Red C1	Red V1	Right of Mid-Clavicular line 4th rib
Yellow C2	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: Left Mid-Clavicular line 5th rib
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. Different placement positions of 5 electrodes will form different lead modes, and it is recommended to place electrodes as below:
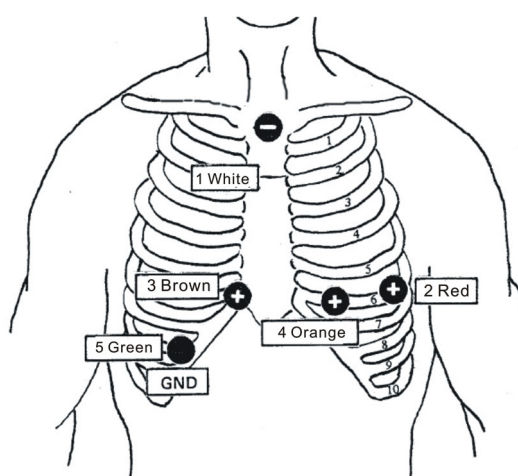
IEC	AHA	Electrode Placement
Red (COM-)	White (COM-)	Right Manubrial border of the Sternum.
Green (CH1+)	Red (CH1+)	Left Anterior Axillary line 6th rib, equivalent to V5 breast lead.
White (CH2+)	Brown (CH2+)	Right of Xiphoid Process on the rib, equivalent to V1.
Orange (CH3+)	Orange (CH3+)	Left Mid-Clavicular line 6th rib, equivalent to V3.
Black(RL)	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. Different placement positions of 7 electrodes will form different lead modes, and it is recommended to place electrodes as below:
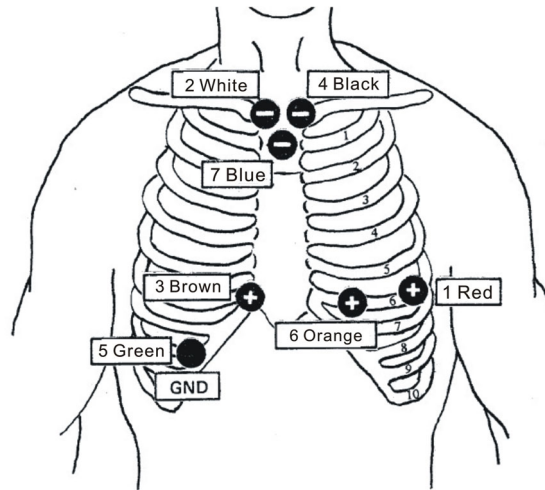
IEC	AHA	Electrode Placement
Green (CH1+)	Red (CH1+)	Left Anterior Axillary line 6th rib.
Red (CH1-)	White (CH1-)	Right Manubrial border of the Sternum.
White (CH2+)	Brown (CH2+)	Approximately 1 inch right of Xiphoid Process on the rib.
Yellow (CH2-)	Black (CH2-)	Left Manubrial border of the Sternum.
Black (RL)	Green (RL)	Lower right rib margin over bone.
Orange (CH3+)	Orange (CH3+)	Left Mid-Clavicular line 6th rib.
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.

The quality of ECG waveform will be affected by the contact resistance between the patient and the electrode. In order to get a high-quality ECG, the skin-electrode resistance must be minimized while connecting electrodes.

4 Recorder Preparation

The menu displays recorder model, serial number, firmware version and manufacturer information. All information is set before final sale and cannot be modified by users.

```
SE-2003 Holter Recorder

Recorder SN: 456789

Firmware Version: 3.1

Manufactured by

Edan Instruments, Inc
```

4.1 Menu Setting

SE-2003/SE-2012 employs two-level menu structure. The first level has four menu items. Use left-up key and right-down key to move cursor to select menu items. Press confirmation key to enter the second level menu of the selected menu item. Still select menu items by left-up key and right-down key in the second-level menu and then enter change status by pressing the confirmation key. Change parameters of selected item by left-up key and right-down key. Press confirmation key to exit change status. Each second level menu has **backspacing** selection item, press confirmation key to return to upper level menu when cursor is on the **backspacing** item.

4.2 System Setting

Set parameters of current recording in the parameters setting menu. Press **Exit** to return to upper level menu. Different parameters have to be set in different versions of recording formats.

```
Gain:          0.5

Channels:    1ch

Record time: 1 day
```

```
              Exit
```

4.2.1 Channels

The number of recording channels of SE-2003 can be set to **3**, **2** or **1**.

4.2.2 Gain

Gain can be adjusted to **0.5**, **1**, or **2**. The default startup setting is the value adjusted last time.

4.2.3 Recording time

Record time can be set to 1 day, 2 days, 3 days, 4 days or Cont. Default value is 1 day. Cont means no recording time limit. The recording won't stop until the battery runs out.

NOTE: Long-time recording needs software support. Not all formats support long-time recording.

4.3 Advanced Setting

Operation interface, procedure and time are set in this menu.

4.3.1 ECG Preview

```
ECG Preview: on

Set Patient ID: off

ECG Display: on

LCD Contrast: 100%

Data Protected: off
```

ECG preview can be set to **on** or **off**. The default value is **off**.
If set to **off**, ECG preview will be skipped.

4.3.2 Patient ID Writing

E-label registration detection can be set to **on** or **off**. Default value is the value set last time. When set to **on**, SD card will be checked whether E-label is registered during start-up process. If not, the recorder will enter **Patient ID writing** process and you need to input Patient ID through keyboard.

When set to **off**, the recorder will skip **Patient ID writing** process, which will not affect normal E-label registration process.

If more than one patient is tested at the same time, it is recommended to set the item as **on**.

If only one patient is tested and registration process is found to be troublesome, the item can be set to **off** so as to simplify the process.

4.3.3 ECG Display

ECG display during recording process can be set to **on** or **off**. Default value is the value set last time.

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.

4.3.4 LCD Contrast

LCD contrast can be adjusted in the range of $10\%\sim100\%$, with 10% of grade difference. Default value is the value set last time.

The item is adjusted according to light environment and user habits. There is no need to modify it under normal situations.

4.3.5 Data Protection

Data protection is used to detect if the recorded data has been analyzed. If it is set to **on**, the recorded data has to be analyzed by analysis software at least once before starting the next recording. It can also be set to **off**. The last configuration will be the default.

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.

4.3.6 Languages

Language of menu and prompting message can be set to **Chinese** or **English** or other languages. Default value is the value set last time.

```
Language: English

Font: Large

Check WP Switch: On

Pole-off sound: On

Battery type: Alkaline
```

4.3.7 Font

Font of menu and prompting message can be set to **Large** or **Small**. Default value is the value set last time.

4.3.8 Check WP Switch

Detection of write-protect switch of SD card, optional value can be set to **on** or **off**. Default value is the value set last time.

If set to **off**, the recorder will not detect write-protect switch of SD card. Recording will not be affected even if write-protect is on **Lock** position.

If set to **on** and recorder detect that write-protect switch is on **Lock** position, the recorder will display a warning message and refuse to record.

NOTE: It is recommended to set the parameter as **on** so as to avoid deleting protected data accidentally.

4.3.9 Pole-fall Sound

The detection and warning for electrodes falling during recording can be set to **on** or **off**. Default value is the value set last time.

4.3.10 Battery Type

Battery type used for the recorder can be set to **alkaline** or **Ni-MH**. Default value is the value set last time.

There are great differences on initial discharge voltage and final discharge voltage between alkaline battery and NI-MH battery. Please set it to be real battery type in use so as to ensure more accurate warning for battery under voltage.

4.3.11 Date and Time

Adjust year-month-date and hour-minute-second of real-time clock. Week will adjust itself automatically.

```
              25-12-2006

              14:45:30

              Wednesday

              Set second

                Exit
```

SE-2003/SE-2012 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.

4.3.12 Exit

```
              Exit
```

Press confirmation key to return to upper level menu.

4.4 Screen Description

4.4.1 Start-up Picture

The start-up picture below will show up for a couple of seconds when SE-2003/SE-2012 is powered on.

```
SE-2003
HOLTER RECORDER
```

4.4.2 Low Battery Message 1

The warning information below 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.

```
WARNING!!!

Low Battery.

Power off in 30 seconds.
```
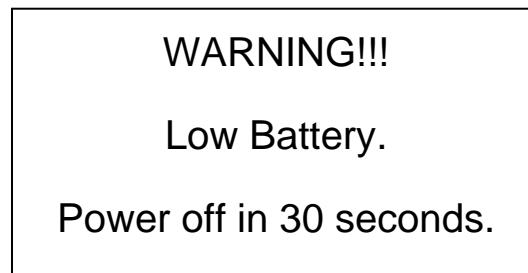
4.4.3 Low Battery Message 2

The warning message below 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.

```
Low Battery!

Continue?

Yes        No
```
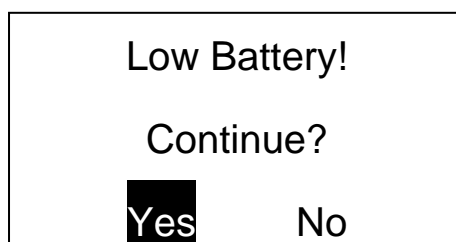
If you operate the recorder for less than 24 hours, you can choose **Yes** to continue. Otherwise you need to replace it with new battery.

4.4.4 Inserting SD Card Message

The prompt message below will show up if no SD card is detected when the recorder starts up. Recorder will wait until user inserts SD card.

```
SD card not found.

Please insert.
```

4.4.5 Read-write Errors of SD Card Message

The prompt message below 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.

```
WARNING!!!

SD card error!

Error code: 40h
```

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.

4.4.6 Write-protect of SD Card Message

The prompt message below will show up if write-protect switch is detected to be at **Lock** position and item of **data protect** under **Advanced setting** is set to **on**. The recorder will shut off in 60 seconds.

```
WARNING!!!

SD card is locked.

ECG can't be recorded.
```

4.4.7 Data Protection Message

If the **Data Protection** is set to ON in the advanced settings and there is unanalyzed data in the SD card, the recorder will show the message:

```
WARNING!!!

ECG file isn't analyzed

Power off in 5 minutes.
```

NOTE: To proceed running, data in the SD card has to be analyzed at least once or be canceled on PC.

4.4.8 No Patient Cable Message

The prompt message below will show up if no patient cable is detected before recording. The recorder will wait until patient cable is inserted.

```
No patient cable.

Please insert.
```

4.4.9 Automatic Shutdown Message

The recorder will automatically shut off in non-recording state and when no action on keyboard is performed for 15 minutes. The prompt message below will show up and last 5 seconds before recorder shuts off.

```
WARNING!!!

No key activity in 15 minutes.

Power off in 5 seconds!
```

4.4.10 Shutdown Message

The recorder will shut down if battery voltage is detected to be too low to keep recording or recording terminates for 30 seconds. The information below will show up before closing.

```
WARNING!!!

Low battery.

Power off in 30 seconds.
```

5 Recording

5.1 Overview

The operation steps of SE-2003/SE-2012 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 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 supports 7-electrode or 5-electrode 3-channel mode.

5.2 Start Recording

The start menu of initiating recording is process-based. According to different parameters set in **Advance Setting**, all processes, from simplified to complete, are listed as below:

| Start recording | → | Input Patient ID | → | ECG preview | → | Startup confirmation |
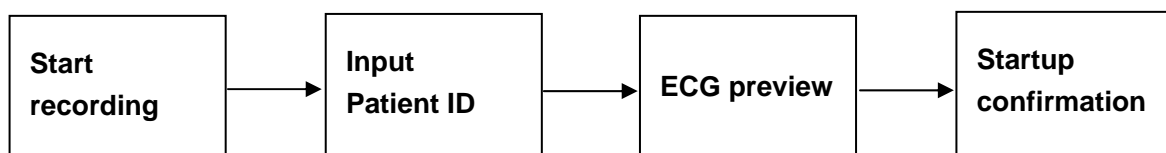
1. Make electronic labeling registration of SD card (recorder) in analysis system or other specialized software, or stick the labeling on the SD card surface manually;

2. Insert the SD card into SE-2003/SE-2012 Holter System Recorder (or unplug USB cable);

3. Attach electrodes on patient as per guidance mentioned in previous section and then insert patient cable into recorder;

4. Load one AAA battery in correct polarity;

5. Set parameters through recorder LCD and keyboard, and then preview ECG wave;

6. If the wave quality is not good, adjust electrodes to receive good ECG graph. Reduce electrode impedance by adding weight of electrodes if baseline shifts when patient breathes.

7. Start to record and write down starting time in patient log;

8. If necessary, switch recording screen to ECG display so as to observe ECG while recording data.

NOTE: The inner-placed clock in SE-2003/SE-2012 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.

5.2.1 Start Recording

Move cursor to **Start Recording** in the first level menu, press confirmation key to initiate Start recording process.

5.2.2 Input Patient ID

The process will be skipped if the setting of **Input Patient ID** is **off** under **Advance Setting** menu.

```
┌─────────────────────────────┐
│  ID: 2345604560             │
│                             │
│  OK        Reset            │
└─────────────────────────────┘
```
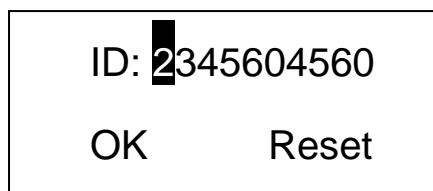
The value of position selected by cursor changes from 0 to 9 by pressing left-up key or right-down key. The cursor will move one digit backward after pressing confirmation key and move to **OK** until all of ten patient ID numbers are entered. Shift the cursor between **OK** and **Reset** by pressing left-up key or right-down key. Confirm the selection by pressing confirmation key to move to the next process. Press **Reset** to delete entered patient ID and re-input.

If the patient has been registered in the analysis software beforehand, it will show

```
ID: 2345604560

Name: Mary

OK      Reset
```

Press **OK** to enter next step. Press **Reset** to reset the patient information.

5.2.3 ECG Preview

The process will be skipped if the setting of **ECG preview** is **off** under **Advance Setting** menu.

V3
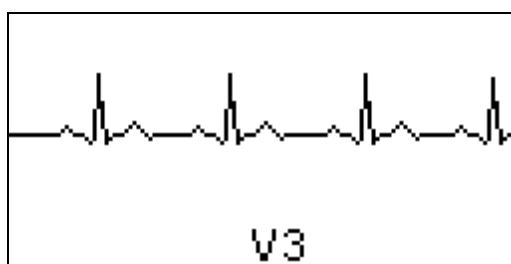
The upper part displays one-channel ECG wave, while the bottom displays name of the lead (channel) (I, II, III, aVR, aVF, aVL, V1, V2, V3, V4, V5, V6 or CH1, CH2, CH3 in 3-channel mode). Press left-up key or right-down key to change ECG lead (channel), and press confirmation key to enter next process.

NOTE: 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.

5.2.4 Confirmation

```
Start Recording ECG?

OK      Exit
```

Shift cursor between **OK** and **Exit** by pressing left-up key or right-down key. Press **Exit** to return to main menu or press **OK** to start recording.

5.3 Recording Status

The SE-2003/SE-2012 will shift from recording process to information display mode to display current date, time, recording time, patient information and recording parameters. Only one second is needed to shift to real-time waveform display mode by pressing left-up key and confirmation key together.

5.3.1 Information Display

Current date, time, recording time, patient information and recording parameters are displayed in a top-down order.

If recording time is not 24 hours, reverse signal of **2**, **3**, **4**, **0** (continuous recording) will show up;

If recording channel of SE-2003 is set to **3**, reverse signal of **3** will show up;

If recording channel of 3-channel recording is set to **2** or **1**, reverse number of **2** or **1** will show up;

If electrodes fall during recording process, reverse signal of the name of fallen electrode will show up;

Indications of **ERA**, **WAIT** and **REC** reflect working status. Reverse signal of **END** will show up at the end of recording.

|	
Date	2007-04-04 Wednesday
Time passed	Time passed: 12:34:56 — END — End of record
Pacing record	P 00:00:00 3 — 3 days
Patient information	ID: 070209 — RL V1 V2 — Electrodes fall Remind
	Name: Rose White — EVENT — Patient event

Meanings of various states will be specified in other sections.

The recorder will erase the existing data first and wait for two minutes to stabilize the circuit and ECG electrodes.

NOTE: Erasing time varies with SD card models and working time. SD card needs to be changed in case erasing time is over 2 minutes.

5.3.2 ECG Display

If **ECG display** is set to **on** in advanced setting menu, only one second is needed to shift to real-time waveform display mode by pressing left-up key and confirmation key together. Users can observe the validity of recorded waveform.
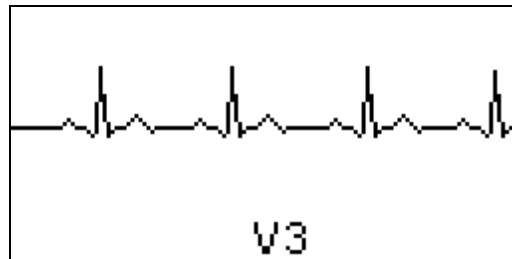
Display one lead (channel) ECG waveform, bottom center displays the name of lead (channel) (I, II, III, aVR, aVF, aVL, V1, V2, V3, V4, V5, V6 or CH1, CH2, CH3 under 3-channle mode). Press left-up key or right-down key to change ECG lead (channel), press left-up key and confirmation key together to shift to information display mode.

5.4 Stopping 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. Recording will automatically stop due to limited SD card capacity;

4. Directly connect with USB cable after removing patient cable;

5. Press confirmation key, left-up key and right-down key together to stop recording.

The above are recommended regular ways to terminate 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.

Take out SD card and insert it into analysis system card reader or connect USB cable with recorder to prepare for analysis;

Remove leads and electrodes from patients and do necessary cleaning for them.

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.

After necessary cleaning and disinfection to recorder and leads, it is well prepared for the next patient.

5.5 Data Transmission

After the end of recording, the collected data shall be transmitted to analysis software to make analysis and diagnosis. SE-2003/SE-2012 supports transmission by SD card or connection by USB cable. And these two methods are equally effective:

5.5.1 Transmit by SD Card

Take out SD card from recorder and insert it into card-reader of analysis system. Recording data is then transmitted.

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.

5.5.2 USB Connection

1. Connect USB cable distributed together with recorder directly with host of analysis system. Remove patient cable plug and insert USB cable into the socket. Recording data will be transmitted into analysis system through high-speed USB 2.0.
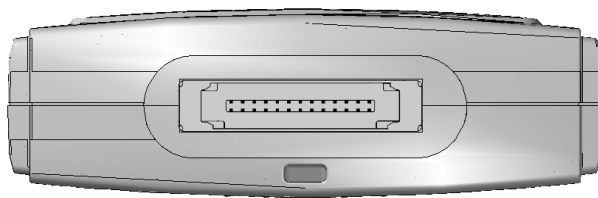
2. Check whether battery is loaded or not when recorder connects with computer through USB cable;

3. When USB cable is connected with recorder, LCD will display as follows:

```
                    Linking PC …
```

It means correct connection of the recorder with computer. A new disk signal and files under this disk can be found under resource manager of operating system. The next step is to run analysis system program.

4. After the end of analysis and unplugging of USB cable, the recorder will restart and prompt as follows:

```
            USB is unlinked,

            System will restart …
```

6 Cleaning, Care and Maintenance

<div align="center">CAUTION</div>

1. Remove the battery and the patient cable from the recorder before cleaning.

2. Prevent any liquid from seeping into the recorder; otherwise the safety and the performance of the recorder can not be guaranteed.

6.1 Cleaning the Patient Cable

<div align="center">CAUTION</div>

Any remainder of detergent should be removed from the patient cable after cleaning.

To clean the patient cable:

1. Dampen a soft cloth with one of the disinfectants or cleaning agents listed below.

2. Wring excess moisture from the cloth before cleaning.

Recommended Cleaning Solutions

♦ Mild soap and water

♦ 75% alcohol

6.2 Care and Maintenance

6.2.1 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.

6.2.2 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) Inspect the fuse to verify compliance with the rated current and circuit-breaking characteristics.

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

e) Test the enclosure leakage current according to IEC/EN 60601-1: Limit: NC 100μA, SFC 500μA.

f) 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.

g) 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.

h) 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).

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.

♦ 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.

7 Accessories

Table 7-1 Accessory List

Accessory	Quantity
Patient Cable	1
SD Card	1
Belt Clip	1
Waistband	1
AAA alkaline battery	2

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

8 Warranty and Service Policy

8.1 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.

8.2 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.cn.

Appendix 1 Technical Specifications

A1.1 Safety Specifications

Comply with:		IEC 60601-1:1988+A1:1991+A2:1995 EN 60601-1:1990+A1:1993+A2:1995 IEC60601-1-2:2001+A1:2004 EN 60601-1-2:2001+A1:2006 IEC/EN 60601-2-47
Anti-electric-shock type:		Internal power supply
Anti-electric-shock degree:		Type CF
Degree of protection against harmful ingress of water:		Ordinary equipment (Sealed equipment without liquid proof)
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:		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 ℃ (-4 ºF) ~ +55 ℃ (+131 ºF)	+5 ºC (+41 ºF) ~ +40 ºC (+104 ºF)
Relative Humidity:	25%~93% Non-Condensing	25%~80% Non-Condensing

Atmospheric Pressure:	700hPa ~1060hPa	860hPa ~1060hPa

A1.3 Physical Specifications

Dimensions	68mm × 53mm × 16 mm (2.68 in × 2.08 in × 0.63in)
Weight	Approx. 42 g (0.1 lbs) (excluding battery)
Enclosure	Molded plastic / water resistant
Operating position	Belt Clip, Lanyard

A1.4 Battery Specifications

Battery type	1 AAA alkaline battery or Ni-MH battery
Battery life	Alkaline battery ≥ 48 hours

A1.5 Performance Specifications

Channels	3 or 12 channels
Recording	Full disclosure, no data compression
Frequency Response	$0.05\text{-}60\text{Hz}\,_{-3.0dB}^{+0.4dB}$
Input impedance	10MΩ
Gain	1/2X, 1X and 2X
CMRR	≥ 60dB
Sample Rate	128 to 1024 samples/second
A/D Resolution	8/10/12/16 Bit Sampling
ECG Signal Verification	LCD at hook-up or on demand
Data Transmission	Through USB cable or SD card reader

NOTE: Sampling rate and A/D Resolution are adapted to software and set before sales.

Appendix 2 EMC Information

**Guidance and manufacture's declaration - electromagnetic emissions-
for all EQUIPMENT and SYSTEMS**

Guidance and manufacture's declaration – electromagnetic emission		
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.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	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.
RF emission CISPR 11	Class B	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.
Harmonic emissions IEC/EN 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Not applicable	

Guidance and manufacture's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS

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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV line to line ±2 kV line to ground	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Holter System Recorder requires continued operation during power mains interruptions, it is recommended that the Holter System Recorder be powered from an uninterruptible power supply or a battery.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

**Guidance and manufacture's declaration - electromagnetic immunity -
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

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 to 80MHz 3 V/m 80 MHz to 2.5GHz	3 Vrms 3 V/m	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** $d = \left[\dfrac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\dfrac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\dfrac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz 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.

**Recommended separation distances between portable and mobile
RF communications equipment and the EQUIPMENT or SYSTEM -
for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING**

<table>
<tr><td colspan="4">Recommended separation distances between
portable and mobile RF communications equipment and Holter System Recorder</td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td rowspan="2">Rated maximum output power of transmitter (W)</td><td colspan="3">Separation distance according to frequency of transmitter(m)</td></tr>
<tr><td>150 kHz to 80 MHz
$d = 1.2\sqrt{P}$</td><td>80 MHz to 800 MHz
$d = 1.2\sqrt{P}$</td><td>800 MHz to 2.5 GHz
$d = 2.3\sqrt{P}$</td></tr>
<tr><td>0.01</td><td>0.12</td><td>0.12</td><td>0.23</td></tr>
<tr><td>0.1</td><td>0.38</td><td>0.38</td><td>0.73</td></tr>
<tr><td>1</td><td>1.2</td><td>1.2</td><td>2.3</td></tr>
<tr><td>10</td><td>3.8</td><td>3.8</td><td>7.3</td></tr>
<tr><td>100</td><td>12</td><td>12</td><td>23</td></tr>
<tr><td colspan="4">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.</td></tr>
</table>

P/N: 01.54.455144-13

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