

Operator Manual

HOLTER RECORDER

MC6800 SERIES

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Notes on reading

To operate this device safely and make full use of the functions, please read this instruction manual carefully before use.

It is recommended to keep this manual near the device or have it kept by an operator, so as to make references when required during operation.

This instruction manual is subject to change without prior notice.

This instruction manual is the general manual of MC6800-12/MC6800-3/MC6800-7D Holter ECG recorder. Some components and functions mentioned in this manual may not be of standard configuration. Certain functions may need software support. Please refer to the accompanying document list and contact distributor if necessary.

Limited Warranty

MC products are warranted to be free from manufacturing and material defects for a period of one (1) year or as specified in associated documentation.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, lead wires, patient cables, and batteries. This warranty does not apply to any product, which MC determines has been modified or damaged by the customer, or damage arising from negligence, accident, fire, flood, lighting, misuse or even intentional act, or loss of the original identification label will not be covered in this warranty. And our company will not bear any warranty liability.

Except for the express warranties stated above, MC disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations of liabilities on the part of MC for damages, including but not limited to, special indirect or consequential, arising out of or in connection with the use or performance of MC products.

Any repairs made to the product, which are not covered by the warranty, shall be billed to the customer.

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Safety Information

Thank you very much for using MC6800 Series Holter recorder.

To use the device correctly and safely, please read and understand the following contents before operation.

In addition, besides the safe operation of the device, the general safety precautions in connection with the patient and the operator are summarized herein.

The following texts are descriptions for the special precautions for the instrument, and before use, please read this operation manual carefully.

Please keep the manual together with MC6800 Series Holter Recorder in order to be aware of important instructions and trouble shooting.

Consideration of Safety and Efficiency

The following safety and effectiveness should be considered before using this product.

Safety protection type: Internally powered equipment, Type CF equipment.

The recorder should be used with a physician's consultation and instructions.


The lifetime of the recorder depends primarily on component reliability, which is 5 years under normal conditions. If components reliability exceeds the time limit, the possibility of failure may increase.


This recorder shall be used by qualified medical personnel with a full knowledge of its operation.

The recordings provided by the Recorder are just for physician reference. The final medical diagnosis is made by physician.


Label identification instructions


Instructions for figures, symbols, and abbreviations


 **1.5V** : Use 1.5VDC power supply

 : Date of manufacturing (YYMMDD)

SN : Serial number (9-digit English letters and numbers)

 : CF type device

 : Required to consult the instruction manual

 : Do not litter

 : Manufacturer

1 AAA : Use one AAA alkali battery

Warnings, Caution and Notes

Warnings, cautions and notes are used in this manual to alert or signal the reader to specific information:

WARNING: A warning alerts the user to possible injury or death associated with the use or misuse of the instrument.

CAUTION: A caution alerts the user to possible injury or problems associated with its use or misuse such as instrument malfunction, instrument failure, damage to the instrument, or damage to other property.

NOTE: A note provides specific information, in the form of recommendations, pre-requirements, alternative methods or supplemental information.

For the other individual precautions, refer to the contents in each chapter and please make references.

Special Precautions

- ⚠ Warning:** This recorder can only be powered by battery. Please do not use any external DC power supply to connect to the battery polarity. Otherwise risk of electrical shock to the patient may happen.
- ⚠ Warning:** Never use the electrocardiograph in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.
- ⚠ Warning:** Never use the electrocardiograph in a hyperbaric oxygen chamber. Failure to follow this warning may cause explosion or fire.
- ⚠ Warning:** This recorder is not waterproof. Please do not have such activities as taking a bath when using it. Note not to splash any liquid onto the recorder. Otherwise severe damage to the recorder may occur.
- ⚠ Warning:** Unauthorized replacing with any non-genuine accessory would not only lead to recording data error, but also may result in severe safety problems.
- ⚠ Warning:** The liability for the repair of this recorder shall be borne by the manufacturer or the dealer, and any unauthorized person shall not attempt to repair this recorder.
- ⚠ Warning:** The electrode used with this recorder should be disposable, which shall not be reused. Otherwise cross infection may occur; and for the disposal of the used disposable electrode, please follow the relevant standard of the local government or institution for infectious waste for disposal. In case that it is not correctly disposed, human infection or environment contamination may happen.
- ⚠ Warning:** Before defibrillation, remove everything including electrodes

and patches from the patient's chest.

⚠ Warning: When performing defibrillation for the heart, for any device and cable connected to the patient or the body of the patient, please do not touch any metal part of such device. Otherwise the electrical discharge may lead to electrical shock.

⚠ Warning: When performing MRI test, remove all electrodes and transducers from the patient which are connected to this instrument. Failure to follow this warning may cause skin burn on the patient. For details, refer to the MRI manual.

⚠ Caution: Avoid using this device near any heavy-duty device or any source of strong electromagnetic interference. Otherwise the recording data may have severe interference, influencing the accuracy of analysis and diagnosis.

⚠ Caution: After connecting the electrode to the patient and at the same time connecting the lead and the recorder, in case some electrode on the patient drops off, and the recorder sends out a buzzing sound indicating that the electrode drops off, the user shall confirm whether the electrode drops off and the user shall reinstall the electrode. When any electrode drops off, avoid any metal part of the bed or any conductive object contacting the metal part of the electrode; in addition, the operator shall not have direct contact with hand. Otherwise, the patient may have electrical shock.

⚠ Caution: When using a pacemaker to test, the doctor shall know that false positive and false negative may happen.
False positive – Resulted from incorrect electrode installation and high noise environment.

False negative – Resulted from weak pacemaker pulse on the skin surface of the patient.

When browsing the ECG, the pacemaking signal in the ECG trend does not represent the real amplitude value stimulated by the pacemaker.

- ⚠ Caution:** When the device is not used, please take out the battery. Otherwise leakage may occur and damage the instrument.

- ⚠ Caution:** Comply with the local laws or regulations on alkali battery for proper disposal of the used battery.

- ⚠ Caution:** When the recorder, SD card, lead, or USB cable fails, please follow the local regulations on recycling of the electronic products for disposal.

General Handling Precautions

This device is intended for use only by qualified medical personnel.

The information processed by the device is private and shall be properly managed and used.

This device can only be used with the approved parts. The parts include but not limited to the SD card and the leads.

Please read these precautions thoroughly before attempting to operate the instruments.

1 To safely and effectively use the instrument, its operation must be fully understood.

2 When installing or storing the instrument, take the following precautions:

(1) Avoid water splashing.

(2) Avoid high temperature, moisture and direct sunlight; and select a place with less dirt; and never directly place in an environment with such substance as salt and sulfur.

(3) Avoid unstable places where tilting, vibration and impact (including handling) frequently occur.

(4) Avoid placing in an area where chemicals are stored or where there is danger of gas leakage.

3 Before Operation

(1) Check that the instrument is in perfect operating order.

(2) Any lead connected to the patient shall be double checked.

(3) Please confirm the remaining power of the battery. When replacing the battery, please ensure the correct polarity.

(4) Pay extra attention when the instrument is combined with other instruments to avoid misdiagnosis or other problems.

4 During Operation

(1) Never exceed the time required by the diagnosis.

(2) Always constantly monitor the instrument and the patient for any abnormality.

(3) Turn power off or remove electrodes and/or transducers when necessary to assure the patient's safety.

5 After Use

(1) Remove the leads gently; do not use too much force to remove them.

(2) After cleaning such parts as the accessory and lead, sort and keep them well

(3) Always clean the instrument to ensure normal use for the next time.

6 This device is intended for use only by qualified medical personnel.

If you think that the device is abnormal, follow the following procedures:

(1) Remove such parts as the electrode and sensor connected to the patient to ensure safety.

(2) Remove the battery.

(3) Mark marks as [Out of Order] and [No Use] on the device, and contact our sales department in time.

7 Do not tear down or modify this device.

8 Maintenance and Inspection:

(1) The instrument and parts must undergo regular maintenance inspection, and it is recommended to carry out calibration once a year, and as for the calibration, *JJG 1042-2008 Calibration regulations for Holter (movable) ECG device* may be followed.

(2) If stored for extended periods without being used, make sure prior to operation that the instrument is in perfect operating condition. When the validity period is over one year, it is recommended to use after re-calibration.

9 When this instrument is used with any electronic operation device, only CF type is used, and at the same time, try to keep the electrode far away from the service part of the device, so as to prevent the lead from being burnt due to high frequency spark.

10 This instrument shall not be used with defibrillation, and when performing defibrillation, this instrument shall be separated from the body, so as to avoid burning or damaging the device.

11 Contraindications: None.

EMC Related Caution

This equipment and/or system complies with international Standard IEC60601-1-2 electromagnetic compatibility for medical electrical equipment and/or system. However, an electromagnetic environment that exceeds the limits or levels stipulated in IEC60601-1-2, can cause harmful interference to the equipment and/or system or cause the equipment and/or system to fail to perform its intended function or degrade its intended performance. Therefore, during the operation of the equipment and/or system, if there is any undesired deviation from its intended operational performance, you must avoid, identify and resolve the adverse electromagnetic effect before continuing to use the equipment and/or system.

The following describes some common interference sources and remedial actions:

1. Strong electromagnetic Interference from a nearby emitter source such as an authorized radio station or cellular phone:
Such signal may lead to unexpected error.
Install the equipment and/or system at another location. Keep the emitter source such as cellular phone away from the equipment and/or system, or turn off the cellular phone.
2. Effect of direct or indirect electrostatic discharge:
3. Make sure all users and patients in contact with the equipment through the AC power supply of the equipment and/or system are free from direct or indirect electrostatic energy before using it. A humid room can help lessen this problem and the room can be humidified.
4. Electromagnetic Interference with any radio wave receiver such as radio or television;
If the equipment and/or system interferences with any radio wave receiver, locate the equipment and/or system as far as possible from the radio wave receiver.
5. Interference of lightning:
When lightning occurs near the location where the equipment and/or system is installed, it may induce an excessive voltage in the equipment and/or system.

6. Use with other equipment:

When the equipment and/or system is adjacent to or stacked with other equipment, the equipment and/or system may affect the other equipment. Before using, check that the equipment and/or system operates normally with the other equipment.

7. Use of unspecified accessory, transducer and/or cable:

When an unspecified accessory, transducer and/or cable is connected to this equipment and/or system, it may cause increased electromagnetic emission or decreased electromagnetic immunity. The specified configuration of this equipment and/or system complies with the electromagnetic requirements with the specified configuration. Only use this equipment and/or system with the specified configuration

8. Use unspecified system configuration:

In case that the device and/or system is used with any system configuration not specified and not tested for EMC, enhanced electromagnetic emission or reduced electromagnetic interference resistance may happen. Please use the specified configurations.

In case that the above recommendations are ineffective in solving the problem, please consult the device dealer or MC Digital Solutions, Inc.

As for EMC compliance, please refer to “Specifications – EMC” in the operation manual.

CE mark is a uniform identification protected by European Union. This product complies with the requirements in Directive 93/42/EEC for medical devices.

1 Introduction

1.1 Overview

The manual primarily describes how to operate and maintain the MC6800 Series Holter Recorder (hereafter referred as MC6800 Series). MC6800 Series plus MC6800 Series Holter Analysis System composed of MC6800 Series Holter System. Please confirm with the distributor recorder's name and version of analysis software when individually purchasing MC6800 Series as it is compatible with various software formats. For the operation of the analysis software, refer to software manual.

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

The MC6800 Series is powered by an AAA battery. The SD card is used as a storage medium and the LCD screen is used to set up parameters and check ECG data quality. A regular AAA alkaline battery can continuously record non-compressed and full-disclosure 12-lead ECG data for 24~48 hours and 3-channel ECG data for 24 ~ 96 hours and up to 7 days if using Li-Fe battery. Moreover, it can detect and record pacemaker pulse information.

Remarks: Long-time recording analysis should be supported by software with appropriate functions. 7-day recording is an optional configuration for the 3-channel recorder.

**1.2
Indications
for Use**

The MC6800 Series Holter recorder is intended for patients requiring ambulatory (Holter) monitoring from 1 to 48 hours. Such monitoring is most frequently used for (but not limited to) the indications below:

- Evaluation of symptoms suggesting arrhythmia or myocardial ischemia;
- Evaluation of patients for ST segment changes;
- Evaluation of medication response of patients to anti-arrhythmic drugs;
- Pacemaker patient evaluation.

1.3 Features

- Compact and lightweight: 68 x 53 x16 mm, 49g.
- MC6800-12 Holter recorder, able to create standard 12 lead or 3 channel non-compressed ECG data;
- Recording mode selection function: The user can select high quality or long-time recording mode in accordance with the requirements.
- MC's unique multi-channel pacemaker detection effectively prevents incorrect detection of pacemaker signal caused by artifacts such as movement, electrical polarization and skin impedance and missed detection as a result of software limitations. The detection sensitivity is 0.1 milliseconds.
- 128 X 64 graphic LCD with a 3-key keyboard allows easy setting of the Holter recorder parameters. Real time ECG waveform display checks electrode placement quality. During recording, the ECG display window may be used to check ECG data quality;
- Multi-language 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 errors that may be caused by manual time selection.

- E-label: Supports either registration in analysis software or entry of the patient ID by the recorder keyboard. Basic information (patient ID, name, gender, age) of patients is written into the data package before making records.
- Poor electrode warned by voice or icon.
- Power supply management, prompt detection of battery power; The power supply will shut down automatically with long idle times (15 minutes after last keyboard response) or 30 minutes after end of recording to save battery power and to prevent battery leakage;
- Flexible communication mode, support plug-and-play SD card and USB 2.0 high-speed direct communication. The SD card helps to facilitate patient turnaround and to maintain effective operations; the USB 2.0 high-speed communication mode is simple and convenient.
- Multiple recording formats are available, compatible with various third party company's holter analysis programs.
- The patient event button precisely records event time.

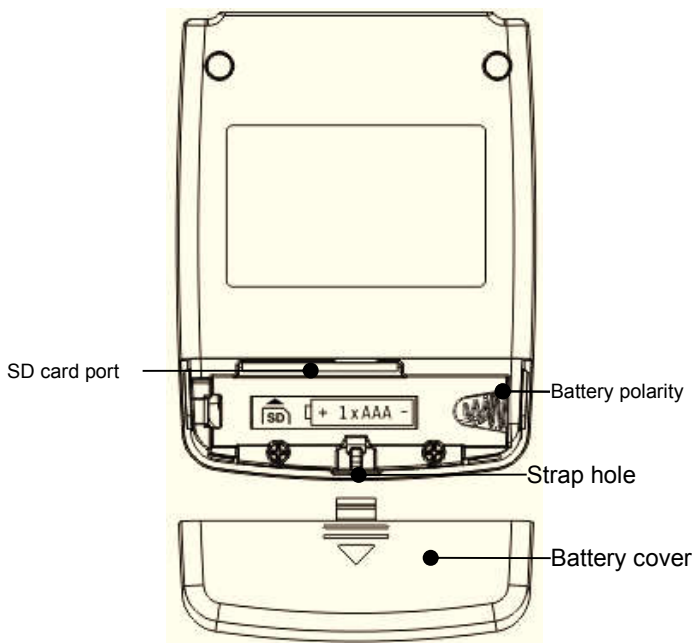
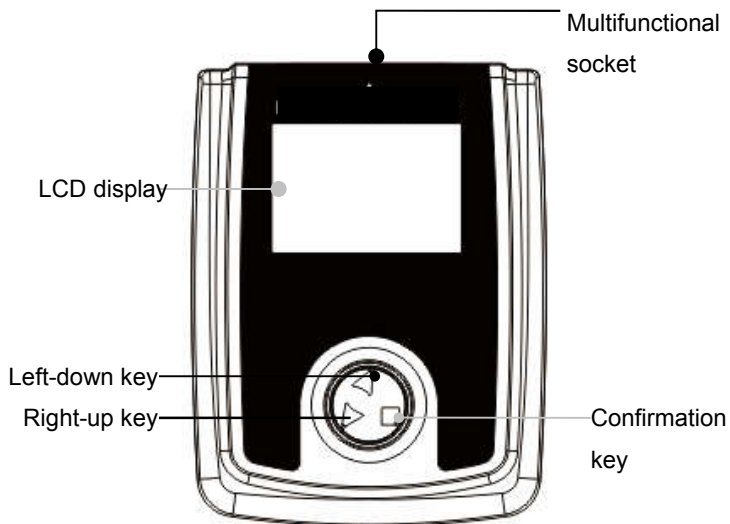
Note:

Press Confirmation key (□) to restart MC6800 Series if it shuts down automatically, it is not necessary to re-load battery again.

2 Recorder Layout

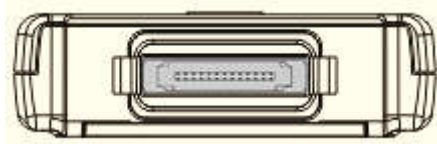
2.1 Overview

The MC6800 Series Holter Recorder layout is shown below:



2.2 Lead input/USB socket

MC6800 Series uses a 26-pin patient input/USB multi-functional connector. It serves as patient input socket when recording. After recording, insert USB cable into the socket and data may be read into the analysis system through USB 2.0 high speed transfer.



By using the same socket, the possibility of connection of lead and USB with recorder at the same time is prevented and potential safety hazards are effectively avoided.

Note: Observe the plug direction. Insert the side with marker toward recorder with appropriate force. Do not pull on plug during use. Plug may detach and cause recorder failure and damage to socket.

2.3 Control key

TheMC6800 Series holter recorder keyboard is composed of confirmation key (□)、right-up key (↶)、and left-down key (↷)

The confirmation key (□) serves as a patient event key in the recording mode. If patients feel uncomfortable or want to record the time of an event (starting exercise, sleeping etc), the key can be pressed and the recorder will record the time of the event.

The Right-up key and the Left-down key are the arrow keys. Right-up key (↶) is used to control the cursor to turn left or move up in the menu operation mode. Left-down key (↷) is used to control the cursor to turn right or move down in the menu operation mode.

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

2.4 Data storage

MC6800 Series will store ECG data in Secure Digital card (SD card) which may be analyzed by Holter analysis software after recording is completed.

To add or replace an SD card, contact the manufacturer or dealer. Do not use incompatible or unknown SD card into MC6800 Series recorder, so as to avoid unnecessary damage and loss.

⚠ Caution: The SD card is a lightweight and precise device. it should not be bent articles inserted into the jacks. Keep the SD card in the recorder to help to prevent foreign materials from entering into the SD card slot.

Capacity requirements

Depending on recording format, sampling rate and recording time, the SD card capacity range is from 128MB to 1024MB. The capacity of SD card accompanying the recorder varies from different sales packages. To use an SD card not provided with recorder, contact the manufacturer or distributor.

SD card load and unload

The SD card holder is a push-push operation.

Loading:

A front facing SD card with a cut angle toward back cover of recorder is inserted into SD card slot until the end of SD card is flush with the slot. On release the SD card is automatically set in the correct position.

Unloading:

Push SD card until its end and card slot are at the same level. On releasing the finger the SD card will automatically eject approximately 5 mm. Using a fingernail, catch the end of SD card and carefully pull it out.



Groove

⚠ Warning: Do not load SD card with too much force. If there is resistance check loading direction or if any articles are in the slot. 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 pop up. It may cause damage to recorder and SD card.

⚠ Caution: Never disassemble or modify the SD card.

Note : Avoid dropping off or folding the SD card, so as to avoid violent vibration.

Note: Avoid operating and using the SD card when smoking and/or drinking. In addition, note not to let water splash onto the card.

⚠ Caution: Avoid touching the metal part of the card.

⚠ Caution: Never remove the label or sticker on the card or stick any other label and/or sticker.

⚠ Caution: The SD card shall only be used for the specified instrument.

⚠ Caution : Never use any pointed object to damage the SD card slot on the recorder. When any foreign object enters into the slot, the operation may be interrupted.

⚠ Caution: After removing the SD card from the recorder, note to put it into a special card box to avoid loss. In addition, please note to select a storage place, so as to avoid cases as eating accidentally by the patient.

⚠ Caution: During storage, avoid direct sunlight or high temperature and high humidity. Never store it in any place where corrosive gas may be released.

2.5 Battery load

⚠ Caution: Keep the write protection switch on the SD card in the “LOCK” status, and when recording data, release the “LOCK”.

MC6800 Series is powered by one AAA battery. Large capacity alkaline battery is recommended. Press “=” mark on battery compartment on the back of recorder by thumb and push outside 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 selection in the setting menu of MC6800 Series alkaline battery and Ni-MH battery. The purpose is to show an exact warning message on battery under-voltage according to the discharge performance of different battery types. Please set the menu according to the battery type in use

⚠ Caution: Remove battery if recorder is unused for a long period of time. Corrosion damage will be prevented.

⚠ Caution: Never put the battery near the patient, and at the same time keep it out of the reach of children.

⚠ Caution: Avoid short-circuiting the “+” and “-” polarity, otherwise high temperature may lead to fire.

⚠ Caution: Never put it into the fire, otherwise explosion may happen.

⚠ Caution: Never use any dismantled battery or any battery damaged due to fall and/or impact.

⚠ Caution: In case that any skin or clothes is contaminated with electrolyte leaked out from any damaged battery, please flush with plenty of clean water.

⚠ Caution: Carefully discard used or depleted batteries. Observe operator instructions and local laws for battery disposal.

2.6 Patient cable

MC6800 Series adopts an optimized and incorporated lead structure that can reduce potential lead and motion artifact during the monitoring process. Standard lead configuration and color coding is marked on each electrode snap.

10 Electrode 12 Lead



- | | |
|---------------|----------------|
| ● 1 Red LL | ● 2 Black LA |
| ○ 3 White RA | ● 4 Green RL |
| ● 5 Red V1 | ● 6 Yellow V2 |
| ● 7 Green V3 | ● 8 Blue V4 |
| ● 9 Orange V5 | ● 10 Violet V6 |

5 Electrode 3 Channel



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

**7 Electrode 3
Channel**



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

3 Recorder preparation

3.1 Overview

The MC6800 Series Recorder operates as follows:

- 1 Confirm recording plan, such as lead mode and pacemaker pulse data requirement;
- 2 Patient register: Write the electrical label in the recorder, so as to avoid any confusion between the recorder and the patient. Connect the recorder with the USB cable to the analysis system for registration, and then remove the USB cable (or insert the SD card into the card reader of the analysis system for registration, and then insert the SD card into the recorder).
- 3 Place electrodes;
- 4 Load a new AAA battery;
- 5 Set recording parameters using recorder keys and LCD;
- 6 Preview ECG wave through LCD and check whether electrodes are properly placed and adjust if necessary;
- 7 Start to record using menu when all prior steps are ok;
- 8 Begin to record formally after recorder initialization;
- 9 Check the waveform quality of ECG signal during recording process using the LCD which also checks for correct placement of electrodes;
- 10 End of recording.

Note: MC6800-12 supports two kinds of lead modes: 10 electrode standard 12 lead mode and 5 electrode 3 channel mode. The recorder will identify and record data generated from different patient cables automatically.

MC6800-3 recorder can use 7-electrode bipolar 3-channel lead or 5-electrode 3-channel lead.

3.2 Menu settings

MC6800 Series uses a two-level menu. The first level has four menu items. Use right-up key (↖) and left-down key (↗) to move cursor to select menu items. Use confirmation key (□) to enter

level menu of selected menu item., Still select menu items by right-up key (◀) and left-down key (▶) in the second-level menu and then enter change status by confirmation key (□) . Change parameters of selected item by right-up key (◀) key and left-down key (▶) . Press confirmation key (□) to exit. Each second level menu has item “backspacing” selection, press confirmation key (□) to return to upper level menu when cursor is on the “backspacing” item.

Start recording

The start menu of recording set-up is process-based. According to different parameters set up in “advanced setting”, all processes, from simplified to complete, are listed as below:

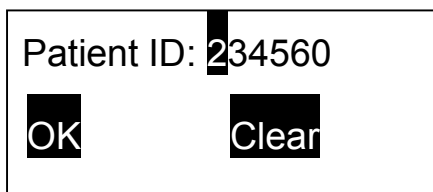


Start recording

Move cursor to “Start recording” in the first level menu, press confirmation key (□) to initiate “Start recording” process;

Input Patient ID

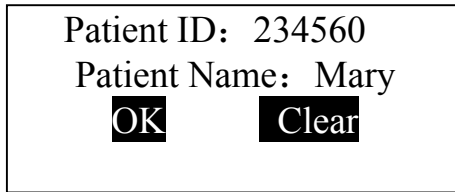
The process will be skipped if the setting of “Input Patient ID” is “off” under “Advanced parameters” menu.



the second

Use the arrow key to change the value of the cursor position, and after pressing the Confirmation key, the cursor will move one digit to the right, until the 10 digits of the patient identification number are input, and move the cursor to the “OK”, and at this time, the arrow key can be used to switch the cursor between “OK” and “Clear”, press “OK” to enter the next process. Press “Clear” to reset the patient information.

If the recorder has registered the patient in analysis software, it will show the following message:

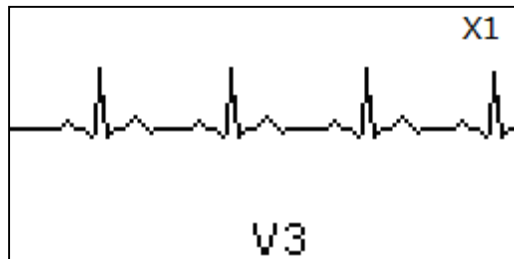


ECG preview

The process will be skipped if the setting of “ECG preview” is “off” under “advanced parameters” menu.

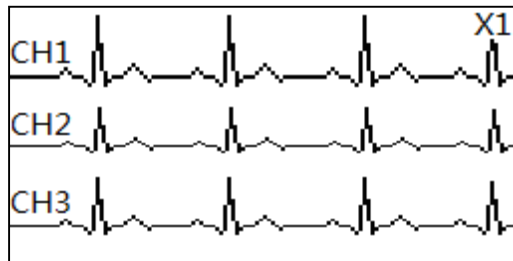
The ECG preview has two modes as 1-channel display and 3-channel display, and the mode selection is set in advanced settings.

1-channel display mode



one-channel ECG wave , the right upper corner displays the current gain setting , 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 under 3-channel mode), Press right-up key (\triangleleft) or left-down key (\triangleright) to change the ECG lead (channel), and press confirmation key (\square) to enter the next process.

3-channel display mode



The LCD simultaneously displays the ECG waveform of three channels, and the right upper corner displays the current gain setting, and the left side displays the name of the corresponding lead (channel). (I, II, III, aVR, aVF, aVL, V1, V2, V3, V4, V5, V6, or CH1, CH2, CH3 under 3-channel mode). Press right-up key (\triangleleft) or left-down key (\triangleright) to change the ECG lead (channel), and press confirmation key (\square) to enter the next process.

During preview, when the lead plug is removed, the ECG waveform will be displayed as straight line, and the message of “LEADS OFF” will be shown.

Note: The time axis (paper speed) under 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. The main purpose is to visually assess signal and basic waveform quality and is not to be used as a basis for quantitative measurement.

LCD displays

Confirmation



Shift cursor between “OK” and “Exit” by pressing right-up key (↖) or left-down key (↘). Press “Exit” to return to main menu or press “OK” to start recording.

Recording status

Display current date, time, recorded time, patient information and recording parameters. Only one second is needed to shift to real-time waveform display mode by pressing right-up key (↖) and confirmation key (□) together.

Information display

After the recorder is started, it will enter into the information display status, current date, time, recorded time, patient information and recording parameters are displayed in a top-down order.

If recording time is not 24 hours, enter “48”, “72”, “O” (continuous recording) which will be displayed.

If the recording channels of the MC6800 Series are set as 3, a reverse signal of “3” will be displayed;

If the “Pacemaker” setting in the parameters setting menu is “on”, a reverse signal of “P” will be displayed;

If electrodes detach during the recording process, reverse signal of name of the electrode snap will be displayed;

During recording, if the lead is removed, the message of “LEADS OFF” will be shown;

The current operation statuses are “ERA” (erase), “WAIT” (wait), and “REC” (record), and after completion of recording,

“END” in white will appear.

Date	2007-04-04 Wednesday		
Time passed	Time passed: 12:34:56	END	End of record
3channels	3	00:00:00	48 48 hours
Pacing record	P		Low battery
Patient information	ID: 070209 Name: Rose White	R1 W1 V2 EVENT	Electrodesf all Remind Patient event

Meaning of various states will be specified in other s

The recorder will firstly erase the existing data and wait for two minutes, so that the recorder circuit and the ECG electrode will enter into the completely stable status.

Note: The erase time of the SD card can be fast and slow, which is related to the type and the service time of the SD card, and if the erase time exceeds 2 minutes, it indicates that the SD card should be replaced.

ECG Display

If “ECG display” is set as “on” in advanced setting menu, only one second is needed to shift to real-time waveform display mode by pressing right-up key (↖) and confirmation key (□) together.

Users can observe the validity of recorded waveform.

The waveform display interface is the same as the waveform preview.

In the waveform display status, simultaneously press and hold the Right-up key and the Confirmation key for one second to switch to the information display status.

Parameters setting

Setting of current recording in the menu: Press “Exit” to return to upper level menu. Different parameters have to be set up in

versions of recording formats.

Mode: high quality Gain: 0.5 Recording time: 48h
--

Recording mode

Modify the recording mode of the recorder: The user can make selections in accordance with the actual requirements, and the ECG data recorded with the “long-time” recording mode can meet the requirements of most analysis functions, and it is suitable for recording for a longer time and reading the analysis data at a faster speed. The data recorded with the “High quality” recording mode will have higher sampling rate and sampling accuracy to acquire more accurate waveform, and can meet advanced functional requirements as for P wave analysis and later potential, but the time for continuous recording is short, and it takes more time to read the analysis data. The “Normal” recording balances the quality and speed.

The recording mode of MC6800 Series can be set to high quality/long time, and the default value when powered on is the value set last time.

The recording mode of MC6800-7D/MC6800-3 can be set to high quality/normal/long time, and the default value when powered on is the value set last time.

Gain

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

Recording time

Record time (day) can be set to be 1、2、3、4、Cont. Default value is 1。Cont is for recording with no specified time, and the recorder

different

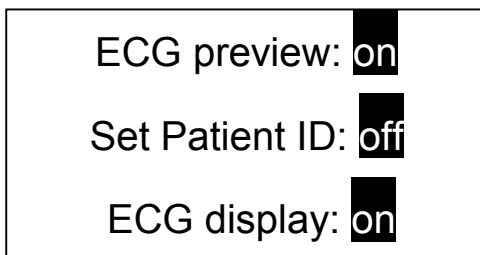
will work continuously until the battery is used up.

The continuous recording time will be connected to the recording mode and the recording channel, for example, for 12 leads, when “High quality” mode is selected, the recording time will be limited to 1 day.

Advanced settings

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

ECG preview



ECG preview can be set to be ON or OFF. The default is the last selected setting.

If set as “OFF”, ECG preview will be skipped.

Patient ID entry

In the E-label registration detection setting, “ON” or “OFF” may be selected. Default value is previously set value.

When set as “on”, SD card will be checked whether E-label is registered during start-up process. If not, recorder will enter “Patient ID writing” process and input Patient ID through keyboard.

When set as “off, recorder will skip “Patient ID writing” process, which will not affect normal E-label registration process.

patient tested at the same time, it is recommended to set the item as “on”.

If only one patient tested and registration process is found to be troublesome, the item can be set as “OFF” to simplify the process.

ECG display

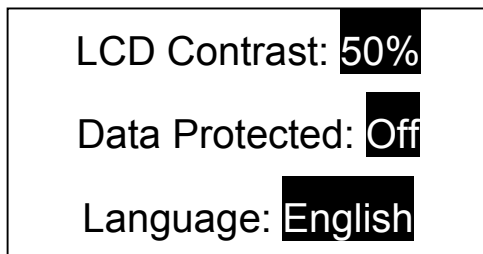
ECG display during recording process can be set as “on” or “off”. Default value is value set at last time.

Set the value as “on” and enter ECG display mode by pressing right-up key and confirmation key () for 1 second during recording process and observe waveform.

It is unable to enter ECG display mode by pressing confirmation key () during recording process if the value is set as “OFF”. This helps to prevent undue effect on the patients.

Entering or otherwise the ECG display mode will not have any effect on the recorded signals.

LCD Contrast



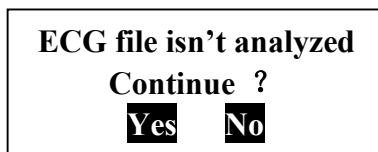
LCD contrast can be adjusted in the range of 10% ~ 100% , with 10% of gradations. Default value is previous selection.

If more than one

The item is adjusted according to light environment and users habits. No need to modify it under normal situation.

Data Protection

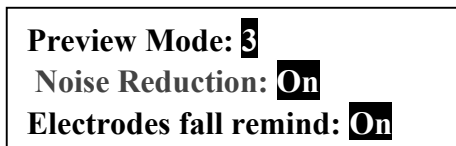
Data protection is used to detect if the recorded data has been analyzed. If it is set to “ON”, the recorded data has to be analyzed by analysis software at least once before starting the next recording, otherwise, the remind confirmation interface will be show. It can also be set “OFF”. The last time configuration setting will be the default.



Reminder: Please confirm that your analysis system will support this function. It is suggested that this setting is turned on to effectively prevent the unanalyzed data from being deleted inadvertently.

Languages

Language in the menu prompting message can be set as “Chinese” or “English” or other language. Default value is the previous setting.



Preview mode

Set the channel display mode of the recorder during preview or during recording, and the value that can be set is 1/3, and the default value when powered on is the value set last time.

When it is set to 1, the waveform display is for 1-channel mode, and the waveform of only one channel is displayed, and by switching the channels, the other channels can be shown. As only one channel is shown, there is no interference between the waveform of channels, for clear observation.

When it is set to 3, the waveform display is for 3-channel mode, and the waveform of three channels is simultaneously displayed, and by switching the channels, the other channels can be shown. The simultaneous display of three channels can be for fast observation.

Noise suppression

Set whether the data is filtered during recording, and whether the noise interference is suppressed. The value which can be set is On/Off; and the default value is the value set last time.

Electrode Off warning

The detection and warning for electrode detachment during recording can be set as “ON” or “OFF”. Default value is previously set value

Battery type

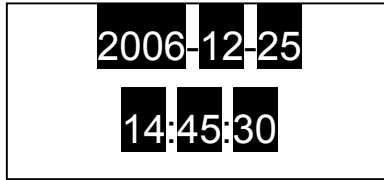
Battery type used for the recorder can be set as “alkaline” or “Ni-MH”. Default value is value set at last time.

Note: There is a great difference between initial and final voltage of alkaline and NI-MH batteries. Set real battery type in use so as to ensure more accurate warning for battery depletion.

Battery type: **Ni-MH**

Date and time

Adjust year-month-day and hour-minute-second of the real time clock. Weeks will adjust automatically.



Reminder: The MC6800 Series has a clock backup battery inside. Even if the battery of recorder is taken out for an extended time, the clock circuit will still function normally. If the recorder is unused for an extended time or the time zone is changed, the clock needs to be adjusted. Suggest monthly time calibration if daily use.

The life of the backup battery for the clock is 6 years, and when exceeding the life, the time to maintain the normal operation of the clock will be reduced, and it shall be replaced.

Backspacing



Press confirmation key to return to upper level menu.

**Version
information**

The menu displays recorder model, serial number, hardware version, copyright information and hospital information. This information is set before final shipment date and cannot be modified by users.

**Manufacturer: MC Digital
Solutions, Inc.**

Model: MC6800-12

Serial Number: 456789

Version: 1.0

3.3 Other interfaces

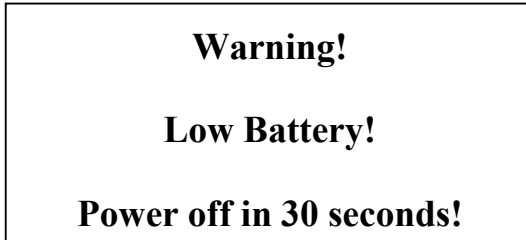
Start-up picture

The start-up image will show for a couple of seconds when MC6800 Series is powered on. It will display the recorder type.



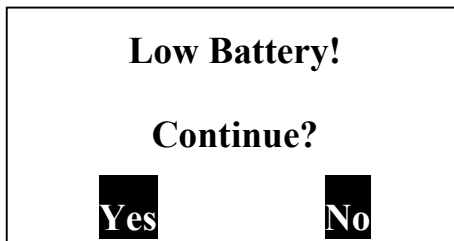
Low Battery Message 1

The warning information below will show if battery voltage is detected to be too low for normal operation. The recorder will then automatically shut off in 30 seconds.



Low Battery Message 2

The warning message below will show if the battery voltage is detected to be too low support long-time recording. If choosing "NO" to stop recording, the recorder will automatically shut off in



5 seconds; if choosing “YES”, the recorder will continue operating.

Note: If choosing “YES” to continue be sure that the recorder will operate for 24 hours. Otherwise replace battery with a new one.

SD card insertion message.

The message below will show if no SD card is detected when the recorder is in start-up mode. The recorder will wait until user inserts an SD card.

Please insert SD card!

Read-Write error messages for the SD card.

The message below will show if errors taking 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!

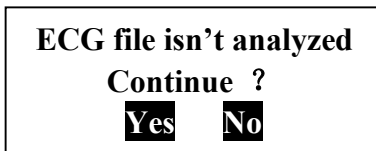
SD card access error!

Error code: 40h

Note: It is possible that incompatible SD card may be used or the SD card is defective if this message is shown. The SD card should then be repaired or changed.

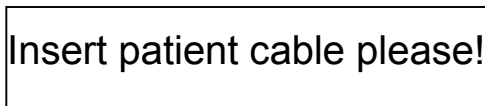
Data Protection Message

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 this message:



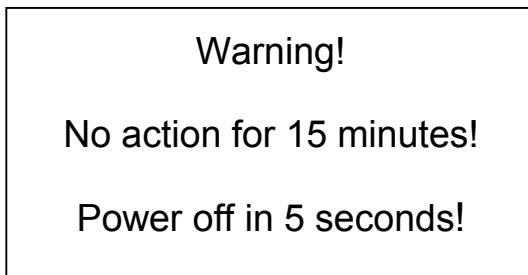
No Patient Cable Message

Message will show if the patient cable is not detected before recording. The recorder will wait for patient cable insertion.



Automatic Shutdown Message

The recorder will automatically shut down under non-recording conditions and keyboard will be inactive for 15 minutes. The message below will show and last 5 seconds before recorder shut off.



Shutdown Message

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

Power off in 5 seconds!

3.4 Stop recording

- 1 Recording automatically stops if recording for 24 hours (or 48, hours is set beforehand);
- 2 Recording automatically stops if battery is depleted;
- 3 Recording automatically stops due to limited SD card capacity;
- 4 Directly connect with USB cable after removing patient cable;
5. Remove the patient cable and press confirmation key for 10s to stop recording.

Stop recording?

Yes

No

The above procedure is recommended or using the regular way to terminate recording.

Removing the battery will also terminate recording, but it may interrupt data flow. The SD card may have to be scanned and repaired through a disk scanning program of the operating system, which should be avoided.

3.5 Data transfer

After the end of recording, the collected data can be transferred to analysis software to analyze and permit diagnosis. The MC6800 Series supports transfer by SD card or connection by USB cable. Both of these methods are equally effective:

Transfer by SD card

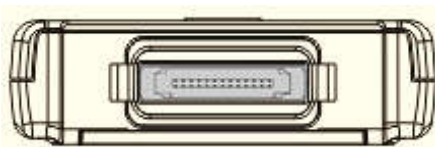
Remove the SD card from recorder and insert it into card-reader of analysis system. Recording data an then be transferred.

Note: It is recommended to equip one recorder with two SD cards so as to facilitate patient turnover. The next patient can be quickly connected by

changing the SD card only.

USB connection

Connect USB cable supplied with the recorder directly to the analysis system platform. Remove patient cable plug and insert USB cable into the socket. Recorded data will be transferred to analysis system through the high-speed USB 2.0 transmission.



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

Connecting USB port ...
Transferring data ...

Message confirms correct connection of the recorder with computer. A new disk file can be found under the resource manager of the operating system. The next step is to run the analysis system program.

After the end of analysis and removal of the USB cable, the recorder will restart and confirm as follows:

USB disconnected,
System will restart ...

4. Electrode Placement

4.1 Overview

Correct electrode placement directly relates to signal quality and therefore affects the analysis results and diagnosis conclusions. Carefully clean skin and place electrodes before each recording.

It is recommended that only trained medical personnel handle the application of electrodes.

4.2 Electrodes

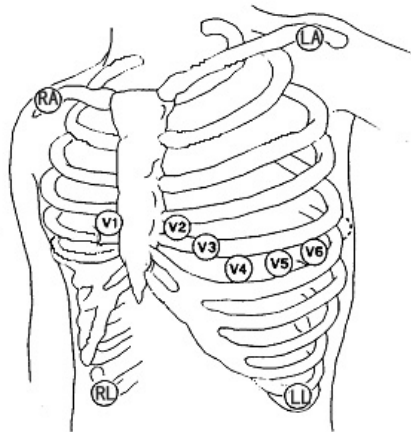
Use high quality silver-silver chloride disposable monitoring electrodes specially used for holter recordings. It is recommended to choose disposable electrodes complying with YY/T 0196-94 or ANIS/AAMI EC12-1991 requirements.

4.3 Position

It is preferable to place electrodes over ribs or cartilage to avoid interference resulting from movement of soft tissues.

10 Electrode 12 Lead

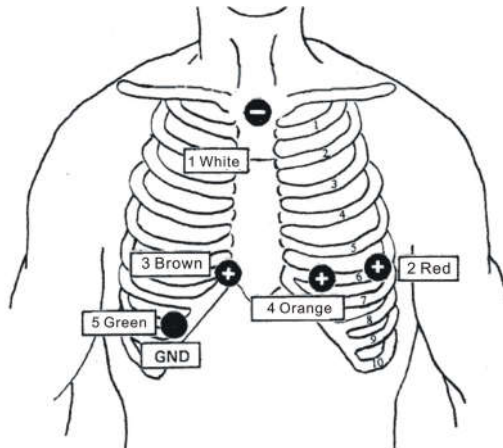
10-pin standard color-coded lead wires are utilized by the MC6800 Series to create a 12-lead ECG signal format. Various placement positions of the 10 electrodes will form different lead modes, and it is recommended to place electrodes as below:



- White RA (right arm) : Below clavicle, close to right shoulder;
- Black LA (left arm) : Below clavicle, close to left shoulder;
- Green RL (Reference) : Lower right rib margin over bone;
- Red LL (left leg) : Lower left rib margin over bone;
- Red V1: Right of Mid-Clavicular line 4th rib;
- Yellow V2: Left of Mid-Clavicular line 4th rib;
- Green V3: In the middle of V2 and V4;
- Blue V4: Left Mid-Clavicular line 5th rib;
- Orange V5: Left Anterior Axillary line, the same level of V4;
- Violet V6: Left Middle Axillary line, the same level of V4;

5 Electrode 3 Channel

Five-electrode-three-channel lead wires are utilized by the MC6800 Series to create a 3-channel ECG signal. Different placement position of 5 electrodes will form different lead modes, and it is recommended to place electrodes as below:



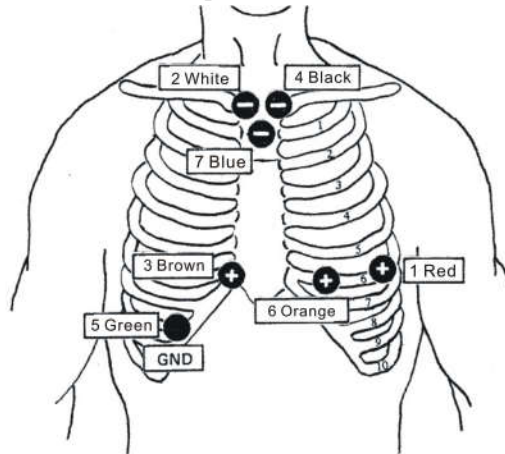
- 1 White (COM-) : Right Manubrial border of the Sternum;
- 2 Red (CH1+) : Left Anterior Axillary line 6th rib, equivalent to V5 chest lead;
- 3 Brown (CH2+) : Right of Xiphoid Process on the rib,

equivalent to V1;

- 4 Orange (CH3+) : Left Mid-Clavicular line 6th rib, equivalent to V3;
- 5 Green (RL) : Lower right rib area over bone

7 Electrode 3 Channel

Seven-electrode-three-channel lead wires are utilized by the MC6800 Series to create a 3-channel ECG signal. Various placements of 7 electrodes will form different lead modes, and it is recommended to place electrodes as below:



- 1 Red (CH1+) : Left Anterior Axillary line 6th rib.
- 2 White (CH1-) : Right Manubrial border of the Sternum.
- 3 Brown (CH2+) : Approximately 1 inch right of Xiphoid process on the rib.
- 4 Black (CH2-) : Left Manubrial border of the Sternum.
- 5 Green (RL) : Lower right rib margin over bone.
- 6 Orange (CH3+) : Left Mid-Clavicular line 6th rib.
- 7 Blue (CH3-) : Center of the Manubrium.

4.4 Cleaning Skin

- 1 Wipe the skin of the electrodes area with Isopropyl alcohol;
 - 2 Shave body hair from the electrode areas;
 - 3 Thoroughly clean grease and corneal layer at the electrodes area;
- Refer to electrode operations manual.

⚠ Caution : For patient with allergic skin, or area with inflammation, never make preparations on the skin.

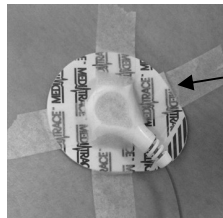
⚠ Caution : When wiping the skin, never use too much force, otherwise inflammation may occur.

Note: Clean skin is very important for the quality of the ECG signal recorded, and the subsequent analysis speed and quality can be improved, so cleaning shall be carefully performed.

4.5 Applying Electrodes

- 1 Connect the color coded lead wire snaps;
- 2 Remove protective pad on the surface of disposable electrodes and firmly apply electrodes on prepared skin;
- 3 In order to prevent the leads from pulling directly on the electrodes, create a strain relief by looping each wire and placing a strip of adhesive tape over the loop and also on the electrode.

[Please find below picture:](#)



Adhesive

⚠ Caution: It is forbidden to use adhesive tape to stick lead wire snaps during electrode placement, to avoid pull off the color coded label of the lead wire snaps. Please find below picture:

5 Starting recording

5.1 Requested Materials

- 1 MC6800 Series Holter Recorder, patient cables, and SD card;
- 2 An analysis system suitable for 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 such as alcohol, medical adhesive tape.

5.2 Start Recording

- 1 Set electronic labeling registration of SD card (recorder) in analysis system or other specialized software.
- 2 Attach electrodes on patient as per instruction shown in previous section and then insert patient cable into recorder
- 3 Load one AAA battery using the correct polarity;
- 4 Set parameters through recorder LCD and keyboard, and then preview ECG waveform;
- 5 If the waveform quality is poor, adjust electrodes to provide a good ECG signal. Reduce electrode impedance if baseline shifts when patient breathes.
- 6 Start recording and note the starting time in patient log;.
- 7 If necessary, switch recording screen to ECG display to observe ECG as well as recorded data..

⚠ Caution: Before applying the device to the examinee, please confirm that the correct time for the recorder has been set. In case that the time is incorrect, the event time of the dynamic recording will not match the time of the event recorded in the SD card, which may lead to misdiagnosis.

5.3 Instruct patients

Give appropriate guidance to patients before they leave:

- 1 Show them how to use event button;
- 2 Explain to the patients or nursing staff the importance of registering patient logs timely and completely. Introduce writing format, contents, what to record, recording time, location, activities and details;
- 3 Warn patients as follows:
 - Do not get the recorder wet. No bathing, shower or shampooing;
 - Do not touch electrodes and unplug leads.
 - Do not open recorder. Do not take out battery and 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 Inform them to stop recording when there is severe discomfort and how they can stop the recording;
- 5 Let them revisit 24 (48 or longer) hours later.

⚠ Caution: When it is suspected that water or other liquid enters into the inside of the recorder due to any damage, please stop use, and contact the dealer or the manufacturer.

⚠ Caution: Noise may be mixed into the ECG completed by the device due to interference. When using this device, never use any mobile phone or small radio device, etc.

5.4 Stop Recording

Normally the recorder will automatically terminate recording when patients revisit the second day or 48 hours later. If the recorder terminates more after 30 minutes, its power supply will automatically shut down. If the recording time is less than preset time, press confirmation key (□), right-up key (↖) and left-down key (↙) simultaneously for one second. Then move the cursor on the LCD with right-up key (↖) or and left-down key (↙) . to

“YES”. Press confirmation key (□) to terminate recording.
Remove 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 patient and clean electrode site for them.

⚠ Caution: Electrodes are for single use only as they may cause cross infection between different patients. Repeated use is forbidden!

Warning: Disposal of abandoned electrodes, follow hospital requirements or local laws and regulations. Do not discard carelessly.

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

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In case that the recorder is not used temporarily, please put it into the packaging box and store it in a dry and well ventilated place with no direct sunlight.

6 Troubleshooting

In case of any problem during use, references can be made to the following table to try to find solutions. In case of any damage or problem, stop using immediately, and contact the dealer or the manufacturer, but never make any repair without authorization.

Problems	Possible causes and corrective actions	Solutions
After powering on, the screen has no response or the display is abnormal	<ol style="list-style-type: none"> 1. The battery voltage is too low. 2. The recorder is powered on continuously too fast. 	<p>Replace with a new battery.</p> <p>Wait for over 5 seconds to power on again.</p>
After powering on, the following message is shown: Warning! The battery voltage is too low! The power supply will be shut off after 30 seconds!	The battery voltage is too low.	Replace the battery with a new one.
After powering on, the following message is shown: Battery low! Continue? Yes No	The battery has been used.	Please replace the battery with a new one.
After powering on, the following message is shown: Please insert the SD card!	<ol style="list-style-type: none"> 1. The SD card is not inserted into the recorder. 2. Poor contact of the SD card or SD card error. 	<p>Insert the SD card into the recorder.</p> <p>Replace the SD card.</p>

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After powering on, the following message is shown: Warning! The SD card is write-protected! No recording can be carried out.	1. The write protection switch on the SD card is moved to the “Lock” side.	After confirming that the content in the SD card can be deleted, move the write protection switch on the SD card to the other side.
After powering on, the following message is shown: Warning! Error when accessing the SD card! Error code XX	1. Error in reading and writing the SD card due to occasional factors as unstable voltage when powering on. 2. SD card error.	Power on again. Replace the SD card.
After powering on, the following message is shown: Please insert the patient cable!	1. The patient cable (lead) is not inserted into the recorder. 2. Patient cable (lead) which is not supported has been inserted. 3. Patient cable (lead) error.	Insert the patient cable (lead) 3-channel recorder does not support 10-lead patient cable (lead) Replace the patient cable (lead).
After powering on, the following message is shown: Recording data is unanalyzed!	.The data recorded last time has not been analyzed.	Please play back the data for analysis and then start the next recording.
During recording, a “beep” sound was heard.	1. The patient had violent movement. 2. The contact of the electrode is poor. 3. Lead error.	Reduce movement suitably. Re-check and install the electrode. Replace the lead.

<p>Recording for 24 hours (or the set time) cannot be performed.</p>	<ol style="list-style-type: none"> 1. The battery is poor. 2. Disoperation, incorrect termination in the midway or the battery is removed in the midway. 	<p>Check the EVT file to confirm the cause of termination, and replace the battery with a good one.</p> <p>Tell the patient not to operate without authorization.</p>
<p>The recording is normal, and when playing back for analysis, the device shows message that ECG data cannot be found, and the SD card disk cannot be seen in the operating system.</p>	<ol style="list-style-type: none"> 1. The SD card is not inserted into the card reader or the card reader is wrong (if a card reader is used). 2. The USB cable of the recorder is not connected to the PC (if the cable is used). 3. SD card error. 	<p>Insert the SD card into the card reader slot or replace the card reader of the SD card.</p> <p>Use the USB cable to connect the recorder and the PC.</p> <p>Replace the SD card.</p>
<p>The device shows message that data cannot be found, and the SD card disk can be seen, but no file in the SD card can be seen or file error occurs.</p>	<ol style="list-style-type: none"> 1. Card reader error. 2. Poor contact of the SD card or other errors. 	<p>Replace the card reader.</p> <p>Replace the SD card.</p>

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<p>The quality of the ECG waveform is low, and no QRS waveform can be seen.</p>	<ol style="list-style-type: none">1. The electrode position is not good.2. The electrode is poor.3. The skin is not clean.4. There is too much hair in the position for applying the electrode.5. Lead error.	<p>Keep far away from such objects as transformer, electrical blanket and electrical blower.</p>
<p>The ECG waveform has interference from working frequency of stable amplitude and frequency.</p>	<p>During monitoring, there is strong working frequency interference source around the patient.</p>	<p>Keep far away from such objects as transformer, electrical blanket and electrical blower. During analysis, the filter switch is enabled.</p>
<p>The ECG waveform has interference from muscle discharge of stable amplitude and frequency.</p>	<p>The electrode position is subject to muscle discharge interference.</p>	<p>Adjust the electrode position. During analysis, the filter switch is enabled.</p>
<p>The baseline of the ECG waveform moves up and down and is not stable.</p>	<ol style="list-style-type: none">1. Apply the electrode firmly.2. The electrode cord is too tense, and the electrode is pulled during movement.3. Electrode failure or quality problem.	<p>Apply the electrode firmly and apply pressure suitably. Arrange the electrode cord, and use a “tension relief loop” near every electrode. Replace the electrode.</p>

7 Service, Cleaning and Maintenance

7.1 Service

Check the following items after use

After use, please check the following items for the next use.

Appearance:

The recorder is not dirty, damaged or in contact with liquid.

The operation panel is not damaged or drops off.

The key is good.

Accessory:

The data in the SD card have been analyzed, and the SD card has no damage in appearance.

The lead is clean and not damaged, and the electrode fastener is normal.

The other accessories are good and have no damage.

The disposable electrode is in good condition.

The battery is in good condition.

Storage:

The lead is cleaned.

The battery is removed.

No chemical or liquid is stored in the surround area.

The storage temperature and humidity are suitable.

There is no direct sunlight in the storage area.

7.2 Cleaning and Sterilization

Clean Holter Recorder

Keep recorder surfaces clean. Use clean, dry and soft cotton cloth to clean the surface. If necessary, use a soft wash cloth soaking in mild disinfectant to clean and disinfect the surface, including display.

⚠ Warning: Do not immerse the recorder into any kind of liquid. Do not allow any part of recorder to be oil stained.

⚠ Caution: Never use volatile liquid, such as thinner or petroleum, as these substances may melt or crack the material of the device.

Before service, cleaning or sterilization, remove the battery in the recorder. Otherwise recorder error may occur.

After cleaning, ensure that the recorder is dried up.

Never sterilize the recorder. Otherwise the material of the device may be deformed, cracked or faded.

Clean Patient Cables and Leads:

Normally use clean, dry and soft cotton cloth to clean the surfaces. Regularly clean and disinfect the patient cables and leads using mild disinfectant. ◦

During cleaning and wiping, note to protect the lead plug, and prevent liquid from entering into the inside.

⚠ Caution: Try to avoid use of alcohol or disinfectant containing alcohol to clean patient cables and leads. Try to avoid alcohol contacting patient cables and leads when cleaning patient skin for electrodes placement as alcohol will harden the leads and cause breakage.

⚠ Caution::After cleaning and sterilizing, ensure that the lead is dried up.

**7.3
Maintenance**

Regular check

Regularly check the following items to ensure that the device is in the best condition.

Appearance:

The recorder is not dirty and damaged, and the metal part is not

The lead is not dirty and damaged, and the electrode fastener is not rusted.

The back clip is not dirty and damaged.

LCD:

The waveform display and the other pictures display are normal.

Operation:

The keys on the recorder work smoothly, and the date and time of the recorded file are correct.

The recorder menu and waveform display are normal.

When changing the gain setting, the waveform amplitude is changed correctly.

The system setting and saving are correct.

The date and time are correct.

SD card:

The SD card works normally

rusted.

**7.4
Measurement
Calibration**

Follow the relevant laws and regulations of the State.

It is recommended that the calibration is carried out once per year, and for the calibration, *JJG 1042-2008 Calibration procedures for Holter (movable) ECG device* may be followed.

The recorder had no external adjustable part. In case that it is suspected that the recorder is damaged or aged, having any influence on the accuracy of measurement, please contact the dealer for repair.

8 Specification

Safe category

Electrical shock resistance category by type: Internal electrical device

Electrical shock resistance category by level: Recorder with CF type application

Protection level category by liquid ingress: General device (IPX0 for device with housing not resistant against liquid ingress)

Safety category when used in flammable anesthetic gas mixed with air or when used in flammable anesthetic gas mixed with oxygen or nitrogen oxide: Cannot be used in flammable anesthetic gas mixed with air or used in flammable anesthetic gas mixed with oxygen or nitrogen oxide.

Operating mode category: Continuous operation

8.2 Physical

Dimensions	72mm X 55mm X 16mm
Weight	49 grams
Enclosure	Molded plastic / water resistant
Operating position	Belt Clip, Lanyard

8.3 Environmental

Operating temperature	+ 5°C ~ +40°C
Operating humidity	≤80%
Non-operating temperature	- 20°C ~ +60°C
Non-Operating humidity	5 ~ 95% (non-condensing)
Atmospheric pressure	86 ~ 106kPa

8.4 Battery

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

8.5 Functional

Channels	12/3
Recording	Disclosure no data compression

Frequency Response	0.05-60Hz $\begin{matrix} +0.4dB \\ -3.0dB \end{matrix}$
Gain	0.5 / 1 / 2
Input impedance	$\geq 5M\Omega$
CMRR	$\geq 60dB$
Sample rate	128~1024 samples/second
A/D Resolution	8/10/12/16 bit
	Remark: Sampling rate and A/D Resolution are adapted to software and set before sales
	LED indicator
Storage media	SDcard ($\geq 512MB$)
Data interface	SD card ($\geq 512MB$)
	Plug-and-play SD card/ USB2.

8.6 Standard parts

MC6800-12

No.	Items		Quantity
1	Patient	10 Electrode 12 Lead	1
	Cable	5 Electrode 3 Channel *	1
2	SD Card		1
3	USB Cable*		1

MC6800-3/MC6800-7D

No.	Items		Quantity
1	Patient	7 Electrode 3 Channel *	1
	Cable	5 Electrode 3 Channel	1
2	SD Card		1
3	USB Cable		1

* Parts with an asterisk mark shall be additionally purchased by the user.



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