

ELECTROCARDIOGRAPH

MN 1028-2A



USER MANUAL

Preface

Please read the User Manual carefully before using this product. The operating procedures specified in this User Manual should be followed strictly. This manual describes in detail the operation steps which must be noted, the procedures which may result in abnormality, and possible damage to the product or users. Refer to following chapters for details. Failed to follow the User Manual may cause measuring abnormality, device damage or personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues of such results due to user's negligence of this user manual for using, maintenance or storage. The free service s and repairs do not cover such faults either.

The content in this user manual complies with real product. For software upgrade and some modifications, the content in this user manual is subject to change without prior notice, and we sincerely apologize for that.

Attentions Before using this product, the safety and effectiveness described in the following shall be considered:

Type of protection against electric shock: class I (AC power supply), internal powered equipment (power supplied by battery)

Degree of protection against electric shock: type CF, defibrillation-proof function applied part


Working mode: continuous running equipment

Enclosure protection class: IPX0

Measurement results shall be described by professional doctor combined with clinical symptoms.

The using reliability depends on whether the operation guide and maintenance instructions in this user manual is followed.

- Service life: 5 years
- Date of manufacture: see the label
- Serial No. : See the label
- Contraindications: none

 **Warning: To ensure the device safety and effectiveness, please use the company recommended accessories. The maintenance and repair of the device should be done by professional personal specified by the company. It is forbidden to refit the device.**

Responsibility of the operator

- The device must be operated by a professionally trained medical staff, and kept by a special person.
- The operator should read the User Manual carefully before use, and strictly follow the operating procedure described in the User Manual.
- The safety requirements have been fully considered in product designing, but the operator can not ignore the observation of the patient and device.
- The operator is responsible for providing the information of product use to the company.

Responsibility of the company

- The company supplies qualified products to user in accordance with enterprise standard.
- The company installs and debugs the equipment and trains the physicians by contract.

- The company performs device repair in warranty period (a year) and maintenance service after warranty period.
- The company responds timely to the user's request.

The user manual is written by Mann Electronics India Pvt. Ltd. All rights reserved.

Manufacturer : Mann Electronics India Pvt. Ltd.

E-55, Road No. 3, Inderprastha Industrial Area
Kota 324005, Rajasthan, India

Service Center : Mann Electronics India Pvt. Ltd.

E-55, Road No. 3, Inderprastha Industrial Area
Kota 324005, Rajasthan, India

Contact No. +91 744 2425779, 2980779

Fax No. +91 7442429680

Mobile no. +91 9887555889

Email Id : mannelectronics @gmail.com
mkt@Manninida.com

Website : www.mannindia.com

CONTENTS

1 General Precaution	2
2 Features	4
3 Operating Precautions	4
4 Theory of Operation	6
4.1 Power Supply Subsystem	6
4.2 Pre-amplification Subsystem	7
4.3 Keyboard Control Subsystem	8
5 Function Description	9
5.1 Top View	9
5.2 Lateral View	11
5.3 Back View	11
5.4 Bottom View	12
6 Installation	13
6.1 Power Connection	13
6.2 Installation of Recording Paper	13
6.3 Patient Cable Connection	14
6.4 Electrode Attachment	15
7 Operating Instructions	17
7.1 Preparatory Checks	17
7.2 Power On/Down	18
7.3 Operating Procedures	18
7.4 Menu Setting & Description	21
8 Maintenance	22
8.1 Battery	22
8.2 Recording Paper	23
8.3 Maintenance Following Operation -----	23
8.4 Patient Cable Maintenance	24
8.5 Electrode Maintenance	24
8.6 Thermal Printer Maintenance	24
8.7 Fuse Replacement	24
9 Troubleshooting	25
9.1 Lead Fault	25
9.2 Printer Failure	25
9.3 Control Panel Failure	25
9.4 AC Interference	26
9.5 EMG Interference	27
9.6 Baseline Drift	28
10 Accessory List	29
11 Appendix A	30
12 Appendix B	31
13 Appendix C	33
14 Appendix D	34

1 General Precaution

ECG machine is designed to be operated by medical professional. Before operating the unit, you are required to read through this manual particularly for information about following general precaution concerning storing, installing, operating and maintaining as well modifying the unit.

1.1 Installing and Storing the Unit

- ⌚ Keep the unit from contact with water.
- ⌚ Do not install/store the unit in a place characterized by excessive atmosphere, humidity, and temperature; bad humidity and ventilation; as well as air containing excessive dust, salt, sulphur and alkali.
- ⌚ The unit shall be placed on a stable platform and be protected from excessive vibration and/or shock in the process of transportation.
- ⌚ Do not store the unit in a place where presents chemicals and hazard of gas leakage.
- ⌚ ECG machine is to work in an environment free from interference caused by high voltage cable, X-ray machine, ultrasound scanner, and electro-therapeutic equipment.
- ⌚ Conditions of local AC power supply shall comply with technical specifications as mentioned in this manual.
- ⌚ Exam room with complete infrastructure is recommended for installing the unit.

1.2 Before Operating the Unit

- ⌚ Make sure that the unit is in good conditions.
- ⌚ Check for proper placement of the unit.
- ⌚ Check for good connection of all cables and wires.
- ⌚ Used together with other equipment, special attention shall be paid to avoid misdiagnosis.
- ⌚ All circuitry directly connected to the patient shall be checked in particular.
- ⌚ Battery capacity shall be checked before operating the unit with DC power.

1.3 Operating the Unit

- ⌚ The operator shall not leave the exam room, and shall keep observation on the patient as well, if necessary, turn off the power or disconnect the electrodes to assure patient safety.
- ⌚ Direct contact between the unit and the patient shall be avoided.

1.4 Following Operating the Unit


- ⌚ Restore the initial setting before turning off the unit.
- ⌚ Gently disconnect the electrodes instead of forcibly pulling the lead wire.
- ⌚ Clean the unit and accessories for next operation.

1.5 Maintenance and Repairing

- ⌚ Maintenance and repairing the unit shall be in the charge of experienced professional. Whenever there is any problem with the instrument, it shall be labeled with visible marks to avoid its following operation with presence of problem.
- ⌚ The unit and accessories shall be periodically maintained at least every half year.
- ⌚ Optional input/output port of the unit shall be connected to class I equipment and be used only when leakage current in total after connection is tested and compliant with requirements.
- ⌚ ECG machine is a meter and shall be annually calibrated in the charge of competent organ.

- Schematics and parts list of the unit is only provided for qualified service engineer under supervision of the MANN.

1.6 Maintenance after use

- Press  button to shut down the device.
- Unplug the power cord and lead cables. Hold the header of plug to disconnect, and do not pull the cable with force directly.
- Clean the device and accessories, cover them up to against dust.
- Store the device in a cool and dry place, avoid strong vibration when moving.
- When cleaning the device, do not immerse it in the cleaner. Power supply must be cut off before . Use cotton cloth for wipe, do not use any detergent or disinfectant containing alcohol.

1.7 Modification

It is not allowed to do any modification and innovation on the unit without authorization from the MANN.

1.8 Warranty

We MANN do claim that all parts and materials as well technology of our products, except accompanying standard accessories & consumable materials, are fully guaranteed 18 months dating from shipment. This warranty does not apply to the products modified, disassembled, innovated, and repaired without our authorization or instructions as well as the ones damaged due to accident, fire, thunder & lightning, flood, intentional destruction, improper installation & operation.

1.9 Symbol Illustration

Following is an illustration of the symbols usually used in MN 1028-1A.



AC power supply



Type CF equipment equipped with protector against defibrillation



Remarks for special attention (see operating instructions for details)



Iso-potential point



The unit is powered on



The unit is powered off



External signal



Signal for output



USB interface

NOTE: See “7.4.1 Setting Menu” for detailed message concerning LCD display and comment.

- **This manual is subject to change without immediate notice to customers.**

2 Features

2.1 MN 1028-1A is characterized by following features.

- ⌚ Designed with a high-resolution thermal printer to print out ECG waveform, annotation as well related parameters for diagnosis reference.
- ⌚ Recording paper for MN 1028-1A is 210mm in width.
- ⌚ Simultaneous 12 lead acquisition.
- ⌚ Visual display of operation menu, ECG waveform and parameters.
- ⌚ Digital isolation technology is adopted to minimize time/temperature drift of components so as to promote adaptability of the unit to circumstance.
- ⌚ Digital filter for effective inhibition of baseline drift, interference, as well automatic position of baseline.
- ⌚ Self-test upon powering on.
- ⌚ Function of rhythm lead for observing abnormal ECG waveform & heart rate.
- ⌚ Automatic measurement and interpretation of ECG waveform to relieve doctors from strain.
- ⌚ Multiple print formats include 6-channel and 12-channel.
- ⌚ AC/Rechargeable battery for continuous examination when AC power supply is unavailable. For battery operation, MN 1028-1A is equipped with a charger & system for battery capacity management and protection itself from excessive discharge.
- ⌚ Safety level for MN 1028-1A corresponds to Class I, type CF.
- ⌚ Compact structure and pleasant appearance.

2.2 MN 1028-1A is applicable to clinical examination.

3 Operating Precautions

In order to assure good operation of the unit, firstly, you are required to read through this manual particularly for information about following operating precautions.

- ⌚ The unit shall be placed on a stable platform and be protected from tilting, excessive vibration, and/or shock in the process of transportation.
- ⌚ Install the unit in a quiet and pleasant environment to guarantee smooth examination.
- ⌚ Do not install/store the unit in a place where chemicals are stored and/or the one characterized by excessive atmosphere, humidity, and temperature; bad humidity and ventilation; as well as air containing excessive dust, salt, sulphur and alkali.
- ⌚ ECG machine is to work in an environment free from interference caused by high voltage cable, X-ray machine, ultrasound scanner, and electro-therapeutic equipment.
- ⌚ Exam room where MN 1028-1A is to be installed shall be equipped with a good system for distribution and grounding connection, lest hazard may occur to the patient.
- ⌚ Whenever continuity between the unit and the earth is in problem, you shall operate the unit of MN 1028-1A by its built in battery.
- ⌚ Conditions of local AC power supply shall comply with technical specifications as mentioned in this manual.
- ⌚ MN 1028-1A shall work with a three-plugged AC power cable to avoid possible hazard of shock to the patient and the operator. Whenever its accompanying three-plugged AC power

cable is unable to work, you shall operate the unit by its built in battery.

- ⌚ Whenever several different equipment are connected to the patient, you shall remember that only the equipment of Class I, Type CF can be connected to MN 1028-1A, and if possible consult a professional for such connection, because leakage current in total may harm the patient. You'd better not operate ECG machine together with any electric stimulator or do it under
- ⌚ the unit instructions from a professional when it is required. MN 1028-1A shall not be in touch with the patient or the exam table. It is not necessary to ground the patient and all electrodes whatever they are connected to the patient or not. The accompanying Argentum-Argentum Chloride electrodes shall be used in priority for actual examination.
- ⌚ Used with a high frequency electric knife, you shall use the accompanying patient cable of the unit MN 1028-1A to avoid burning. Special attentions shall also be paid to keep contact point of the high frequency electric knife away from the electrodes and minimize resistance between the high frequency electric knife and the patient body. If necessary, plate electrodes shall be used to limit the density of high frequency electric current within an acceptable range with the
- ⌚ Whenever an accident occurred in the process of examination, you are required to power down the unit for necessary check.
- ⌚ The instrument can be directly applied to heart.
- ⌚ ECG machine is a meter and shall be at least annually calibrated in the charge of competent organization.
- ⌚ Following descriptions concern special attentions in ECG measurement and interpretation.
 - a. Recognition of P wave and Q wave are not always reliable in the case of intensive muscle artifact or AC interference. So are ST segment and T wave in the case of baseline drift.
 - b. Winding and unclear beginning of S wave and ending of T wave may lead to error in measurement.
 - c. In case R wave is not identified due to QRS repolarization abnormality, the measured heart rate may deviate greatly from the correct one.
 - d. Axis calculation and recognition of QRS borderline are not always reliable in the case of QRS repolarization abnormality.
 - e. Occasionally, frequent ventricular premature complexes might be identified as dominant beat.
 - f. Merging of versatile arrhythmia may result in untrustworthy measurement because of the difficulty in recognizing P wave in such circumstance.
 - g. MN 1028-1A is designed to make ECG interpretation immediately after the measurement. It is this interpretation that does not give report on all possible heart problems of patient and sometimes may not comply with the doctor's diagnosis, because it is done by the computer system based upon acquired ECG waveform. Therefore, final conclusion for each patient shall be made by the doctor on the basis of integrating unit interpretation as well symptom and other examination concerning each patient.

oxygen, WARNING	Do not use MN 1028-1A in a place where presents anesthetic gas, hydrogen, and other flammable chemicals. Otherwise there will be a hazard of explosion or fire.
---------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------

WARNING will be	Do not use MN 1028-1A in a high-pressure oxide barn. Otherwise there a hazard of explosion or fire.
---------------------------	-----------------------------------------------------------------------------------------------------

4 Theory of Operation

4.1 Power Supply Subsystem

4.1.1 Theory of Operation

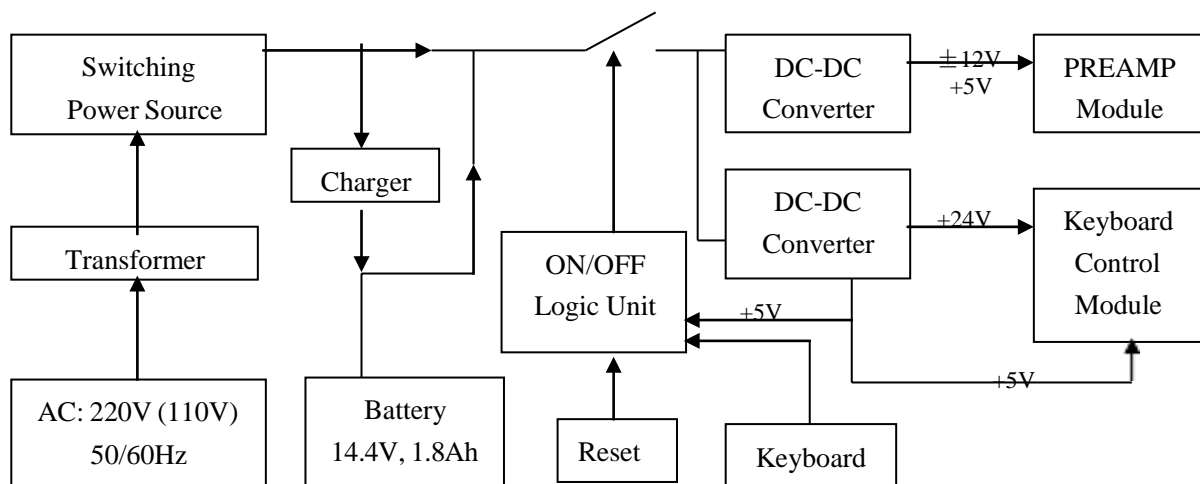
By ways of transformation at the switching power source featuring broad range and high resolution, the 220V, 50Hz (110V, 60Hz) AC power supply becomes a 20V DC voltage. This voltage works to charge the built in rechargeable battery at stable voltage and limited current, and generate a +5V and +24V voltage following procession at the AC/DC switchover circuitry and the switching voltage stabilizer.

The +5V voltage supports the digital part of the circuitry with the earth as reference. By means of width modulation and wave chopping, it provides a +3.5V voltage to support the LCD backlit generator. Through a negative power supply generator, it provides a -20V voltage for negative voltage bias of the LCD. In contrast with its 2A capacity and 2.5A upper limit, normal loading of this +5V voltage is about 750mA.

The +24V voltage supports the paper driving motor and the thermal printer. It is applied to the paper driving motor by means of width modulation & wave chopping in order to enhance its efficiency. In contrast with its 850mA capacity and 1.2A upper limit, normal loading for this +5V voltage is about 500mA.

The self-excitation switching power source and isolating pulse transformer transform output from the AC/DC switchover circuitry to generate voltages for supporting isolated circuitry. A -5V voltage is used to support analogous part of the circuitry with the earth as reference. The +5V voltage needed by isolated digital circuit is the direct output from the switching power supply. Its normal loading is about 150mA in contrast with the 300mA capacity. The $\pm 12V$ voltage for the isolated analogous circuit is the non stabilized output from the switching power source. Its normal loading is about 60mA in contrast with the 100mA capacity.

4.1.2 Block Diagram (Schematics and parts list of this unit is only provided for qualified service engineer under supervision of the MANN.)



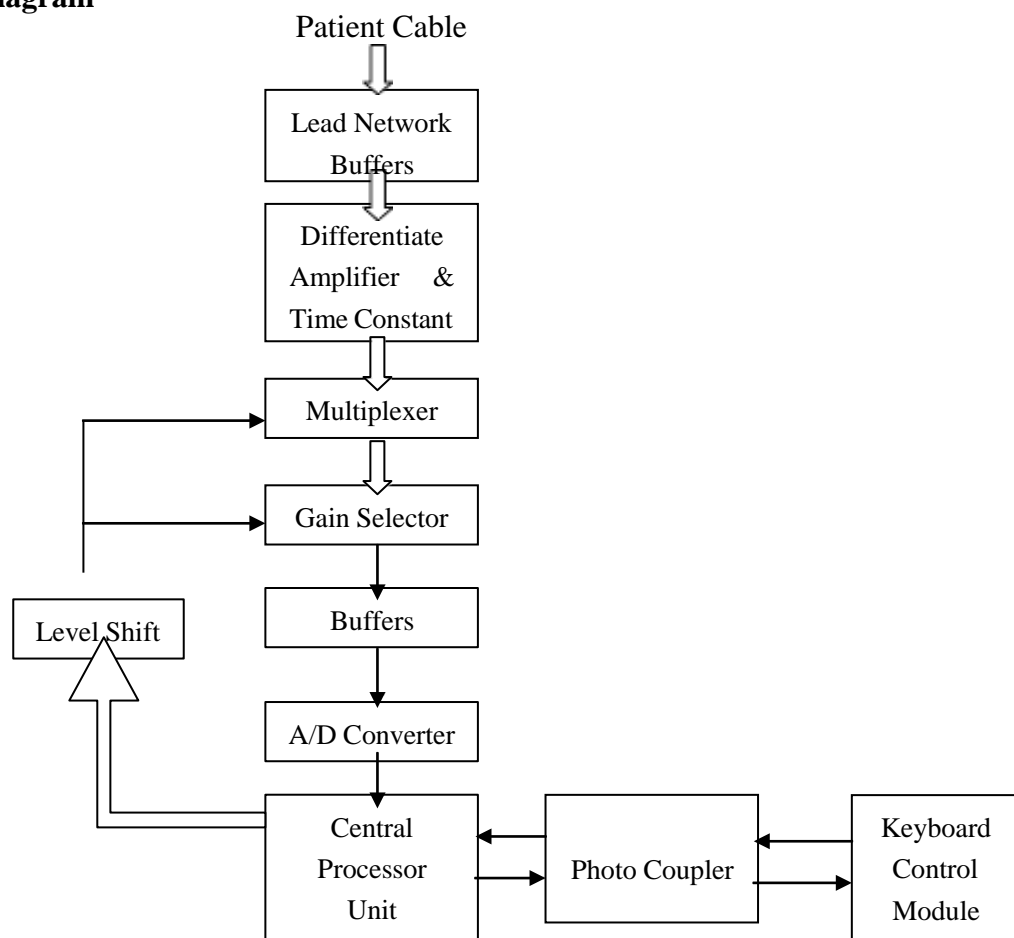
4.2 Pre-amplification Subsystem

4.2.1 Theory of Operation

Isolated circuitry of the machine consists of analogous circuitry, A/D converter and Central Processor Unit. The analogous circuitry includes lead signal amplifier, low pass filter for preventing of superimposing, multiplexer, gain controller and detector for lead disconnection. CPU works to control signal acquisition and detection of lead disconnection by coordinating the A/D converter, multiplexer, gain controller and detector for lead disconnection. It also carries out digital filtration on the acquired lead data before applying them to the Keyboard Control Subsystem through a USB high-speed interface that controls communication of control message between the isolated circuitry and the one with earth as reference.

Sampling rate is 800/960Hz for lead acquisition and 100/120Hz for detection of lead disconnection. Frequency at the -3dB turning point of the low pass filter for prevention of superimposing is. 200Hz. Such a rate complies with the requirement of AHA and CSE standards for interpretive electrocardiograph, which is not less than 500Hz. By ensuring bandwidth of effective signal and limiting input bandwidth of A/D converter, the low pass filter for prevention of superimposing is able to prevent signal superimposing due to defective sampling on high frequency signal.

4.2.2 Block Diagram

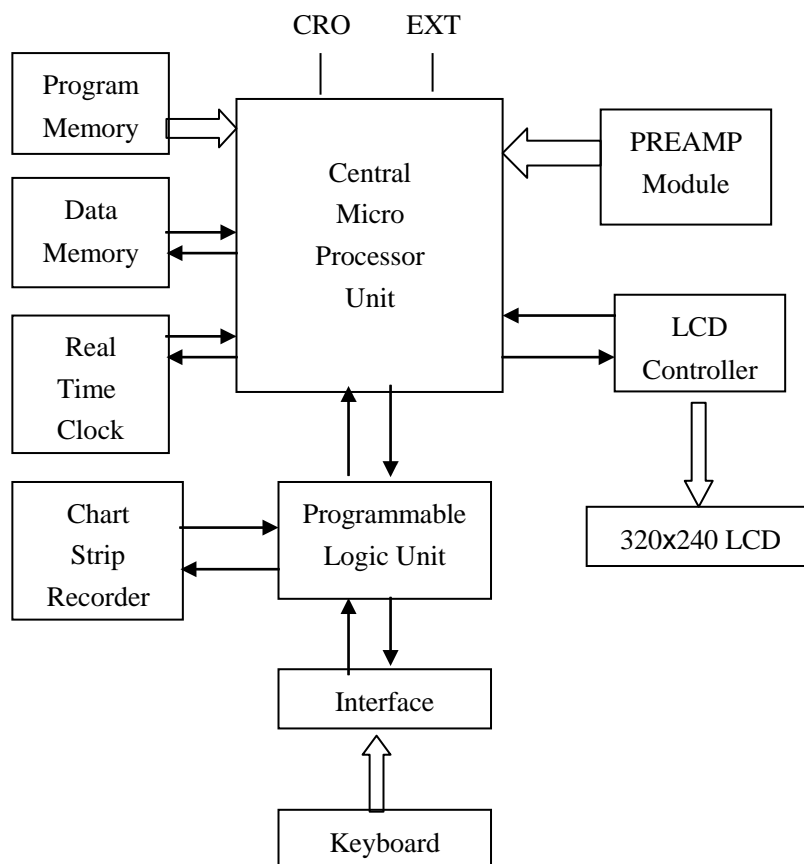


4.3 Keyboard Control Subsystem

4.3.1 Theory of Operation

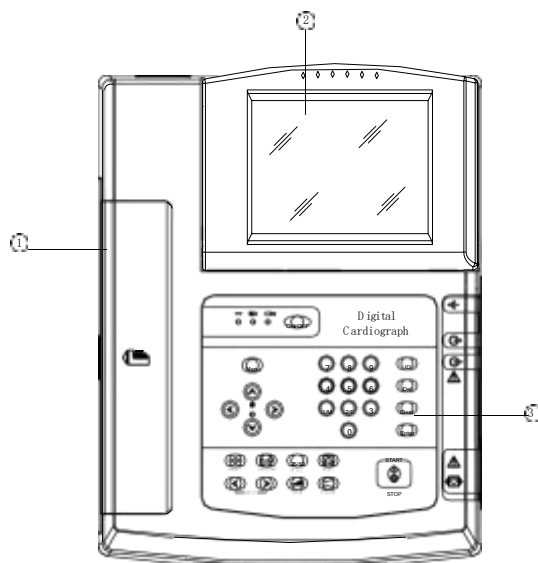
The control subsystem consists of controllers for printer, keyboard controller and LCD as well as Central Processor Unit. The CPU receives lead signal through a high-speed USB interface from the Data Acquisition and Procession Subsystem and applies it, through printer driving circuit and display control circuit, to controllers for printer and LCD, which control printing and display of ECG waveform. In addition to measurement and interpretation on the recorded ECG waveform, the CPU also receives interruption signal and key code from the keyboard controller to carry out interrupt procession. Acquisition and procession on signals for detection of lead disconnection, paper detection, battery capacity management, automatic power off, CRO output and EXT input are all in the charge of the CPU. Controllers for printer and keyboard are controlled by PLD. By receiving instructions and data from the CPU, the printer controller works to manage the buffering area and generate control signal for stepping motor and printer to print out ECG waveforms and related messages. Keyboard controller generates keyboard scan signal to complete anti-distortion on key stroke and output key code and keyboard interruption signal, which is applied to the CPU for further procession. By receiving instructions and data from the CPU, LCD controller works to display ECG waveform of related lead and the unit's operation status.

4.3.2 Block Diagram



5 Functions Description

5.1 Top View



① **Recorder:** For installing recording paper and printing out ECG waveform and parameters

② **LCD:** The graph LCD (320×240), located above the control panel, is designed to display operation mode/status and ECG waveform. Powered on for the first time, MN 1028-1A is to display follows default settings predetermined at MANN factory.

as **Top line:** Patient sex/age (ID); Paper running (▶)/Stopping(||);

Battery capacity (■); Lead mark/Heart rate

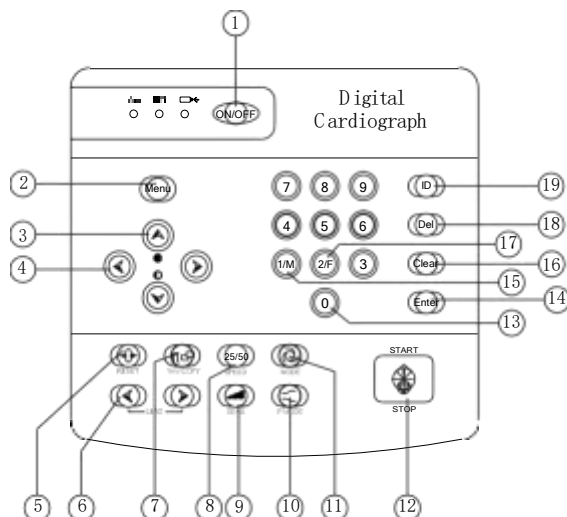
Bottom Line: Operation mode; Paper speed; Sensitivity; Filter condition


Space between the top line and the bottom one is reserved for displaying ECG waveform in the format of 12 channel as predetermined at the factory.

The above mentioned apply to what is displayed when the unit is powered on, and can be changed by way of key “Menu” and the related keys, see related instructions for details.

③ **Control Panel and Description:** The control panel (hereinafter refers to panel) of MN 1028-1A

consists of a group of function keys and another one of numeric keys. See below for description of the function keys.

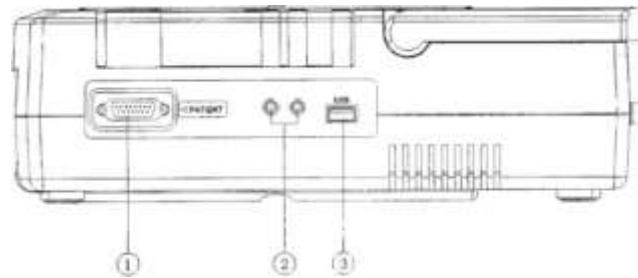


- (1) **Key “ON/OFF”**: Provided its power switch is set to “”, key “ON/OFF” can be used to power on / off the unit of MN 1028-1A.
- (2) **Key “Menu”**: For starting the setting menu to set operation status while the unit is not printing out ECG waveform
- (3) **Menu Selector “^” and “v”**: The two keys are used to select item at setting menu, and change of LCD contrast when the unit is not set to setting menu.
- (4) **Menu Setter “<” and “>”**: The two keys are designed to change setting of the selected item when the unit is set to setting menu as well changeover between limb lead and chest lead when the unit is not set to setting menu.
- (5) **Key “RESET”**: For lead/baseline confinement while the unit is printing out ECG waveform. Baseline confinement leads ECG waveform to be a straight line at the middle of the recording paper. In actual examination, in case of baseline drift, this key can also be used to stabilize baseline at the middle of the recording paper. To cancel lead confinement, just press key “RESET” again.
- (6) **Key “LEAD”**: When the unit is set to 6-channel print format, key “LEAD” can be used to interchange ECG waveform to be printed out between chest leads and limb leads.
- (7) **Key “1mV/COPY”**: For printing out 1mV calibrating waveform while the unit is printing out ECG waveform, or calling and duplicating the already stored ECG records.
- (8) **Key “SPEED”**: For change of paper speed, in turn as 25mm/s→12.5mm/s→6.25mm/s→50mm/s, while the unit is not printing out ECG waveform
- (9) **Key “SENS”**: For changeover of sensitivity, in turn as 10mm/mV→20mm/mV→40mm/mV→5mm/mV, only in operation mode “MAN” while the unit is not printing out ECG waveform.
- (10) **Key “P. MODE”**: For interchange of print format between 6 channel + rhythm and 12 channel
- (11) **Key “MODE”**: For switchover of operation mode between AUTO and MAN while the unit is not printing out ECG waveform
- (12) **Key “START/STOP”**: For starting or stopping of printing out ECG waveform
- (13) **Numeric Keys “0”~“9”**: For inputting patient information and setting concerning date and time
- (14) **Key “ENT”**: For confirming the entered patient information and exit the entering
- (15) **Numeric Key “1/M”**: For entering patient sex at setting menu with “M” stands for male and application of entering the number 1. First pressing enters “M”, the following ones “1”.
- (16) **Key “Clear”**: For deleting all the existing patient information and enter new one
- (17) **Numeric Key “2/F”**: For entering patient sex at setting menu with “F” stands for female and application of entering the number 1. First pressing enters “F”, the following ones “2”
- (18) **Key “Del”**: For deleting one by one the existing patient information and enter new one
- (19) **Key “ID”**: For entering patient information

CAUTION	Do not use any sharp object for key operation, lest permanent damage could be resulted.
----------------	-----------------------------------------------------------------------------------------

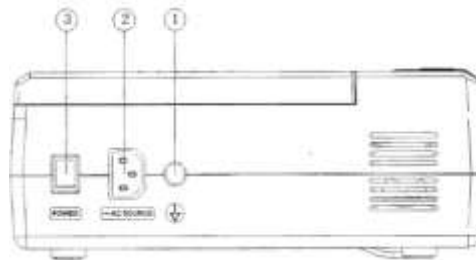
CAUTION	One sound of beep confirms acceptance of keyboard input, while two sounds implies rejection because of wrong keystroke.
----------------	-------------------------------------------------------------------------------------------------------------------------

5.2 Lateral View



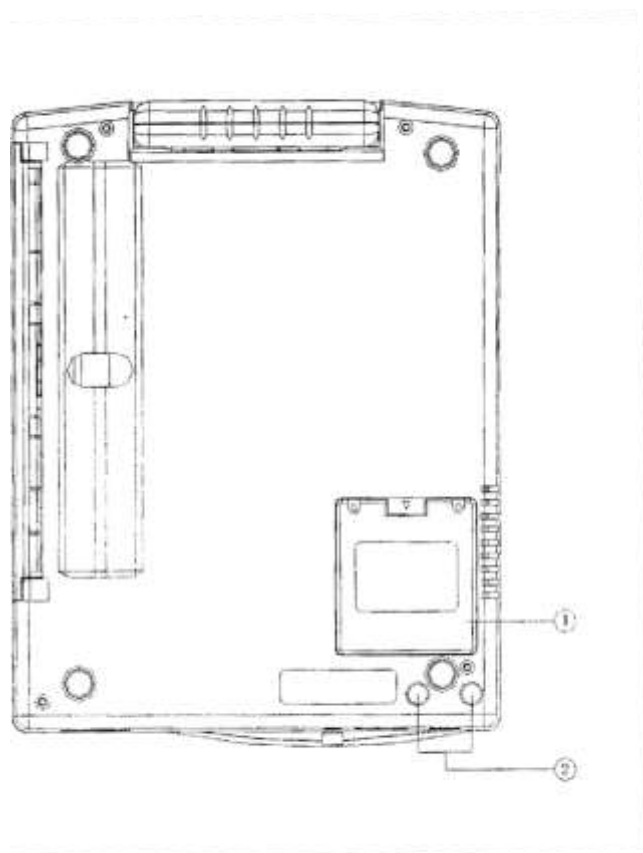
- ① **Patient Cable Connector:** For connection of patient cable
- ② **EXT/CRO Jack (Customized)**
 - ⌚ For inputting and printing out external signal including heart beat, heart sound, and etc.
 - ⌚ For outputting ECG waveform to oscilloscope and the like devices.
- ③ **USB Interface:** For transmitting ECG data and interpretation to a computer so as to make further management and research as well teaching and training.

5.3 Back View



- ① **Grounding Post:** For connection altogether of the grounding cables while the unit is operated together with other equipments.
- ② **AC Socket:** For connection of power cable
NOTE: Disconnection between this socket and power cable can cut completely the unit from the mains.
- ③ **AC Switch:** For turning on/off AC or DC power.
NOTE: When the power cable is connected, turning off this switch does not cut completely the unit from the mains.

5.4 Bottom View



①Battery Compartment Cover

②Fuse Holder

6 Installation

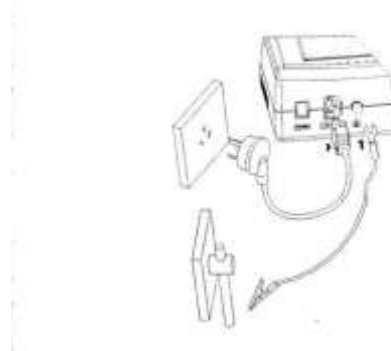
6.1 Power Connection

While connecting the unit of MN 1028-1A, you shall make sure that conditions of local power supply comply with the requirements as mentioned on the nameplate of the unit.

6.1.1 Grounding & Power Connection

- a. Connect the three plugged power cable of MN 1028-1A between the unit and the mains.

- b. Connect the grounding cable for MN 1028-1A between the machine and the earth.



equipments, CAUTION	When MN 1028-1A is operated together with other medical you are required to connect its grounding post altogether with that of the other equipments so as to protect the patient from possible electric shock due to leakage current from those equipment.
grounding CAUTION	Grounding cable must be connected between MN 1028-1A's post and the earth. It is not permitted to connect the grounding cable between a pipe and the grounding post, otherwise there may occur the hazard electric shock to the patient.

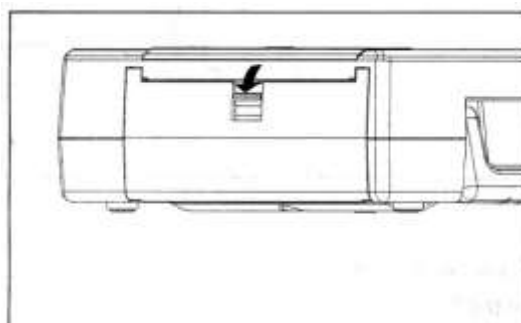
6.1.2 Battery Installation

MN 1028-1A is equipped with a built in rechargeable battery, which requires no extra installation.

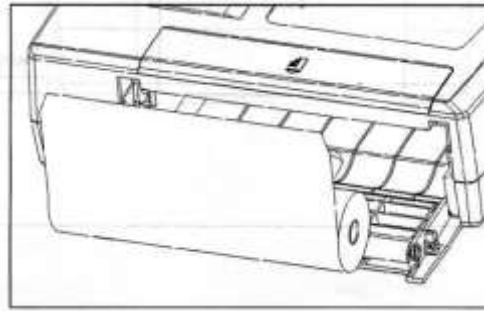
6.2 Installation of Recording Paper

MN 1028-1A is designed to use roll recording paper of 210mm in width or zip fold one of 210×140mm. Generally, the unit is included with one roll recording paper as standard accessory. Alternatively, it could be accompanied with zip fold recording paper at customer request. Follows are description of installing the roll recording paper into the unit of MN 1028-1A.

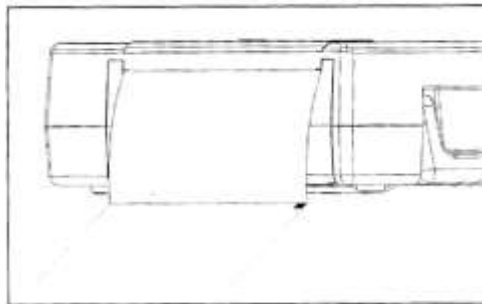
- a. Press the button as shown in the following to open the paper magazine.



- b. Insert the paper shaft into a roll of recording paper and pull out the paper about 10 cm before putting them back to magazine as shown below.



- c. Close the paper magazine as shown in the following figure.

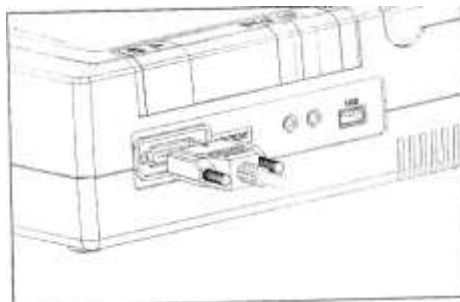


NOTE:

- ① Installation of zip fold recording paper is the same as these procedures except that the zip fold recording paper must be correctly placed in the bottom of the paper magazine.
- ② Whenever the indicator concerning paper detection is blinking in the process of operation, you are required to install another paper roll according to the above mentioned. After the paper roll is properly installed, the unit will return to previous operation status.

6.3 Patient Cable Connection

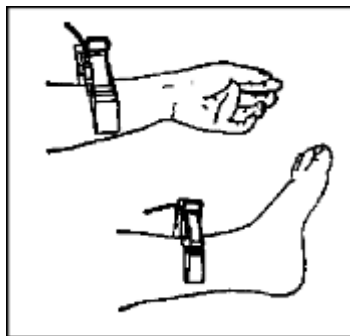
Connect the patient cable to patient cable connector of MN 1028-1A as shown below.



6.4 Electrode Attachment

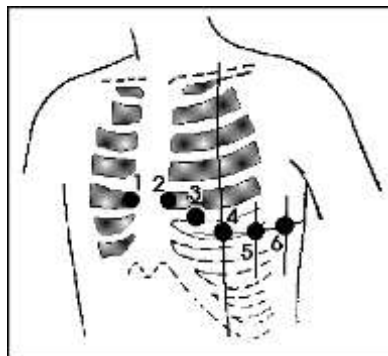
Proper electrode attachment is vital for obtaining accurate ECG waveform. It is generally required to guarantee good contact while attaching the electrodes by attaching them according to the following description while power switch of the unit is turned off. Re-useable electrodes shall not be used together with disposable ones. It is also not allowed to use new electrodes together with used ones. Use of electrodes from different MANN in one exam may result in incorrect ECG waveform. Electrodes or leads of patient cable shall not be in contact with any other metal part or conductor. Change all electrodes when any one is supposed to be changed.

6.3.1 Limb Electrode



- a. Clean all the positions of the patient extremity, to which limb electrodes are to be attached, with alcohol before applying ECG cream to them.
- b. Firmly attach the electrodes to the aforementioned positions.
- c. Limb electrodes shall be attached as: R (RA) for right arm, L (LA) for left arm, RF (RL) for right leg, and F (LL) for left leg.

6.3.2 Chest Electrode



Attach the chest electrodes to the locations as follows after cleaning them with alcohol and applying ECG cream in the similar way as mentioned in part 5.4.1.

- V₁: Fourth inter-costal space at right border of sternum.
- V₂: Fourth inter-costal space at left border of sternum.
- V₃: Midway between V₂ and V₄.
- V₄: Fifth inter-costal space at left mid-clavicular line.
- V₅: Left anterior axillary line at the horizontal level of V₄.
- V₆: Left mid-axillary line at the horizontal level of V₄.

NOTE: Keep in mind that the electrodes' coming into contact with each other or cream's overlap with each other is not permitted. If cream is unavailable, and examination is expected to be short in time, cleaning of the body surface can be done with 75% alcohol as substitute before immediate attaching all the electrodes so as to guarantee good contact between body surface and electrodes. It is not allowed to use saline water as substitute when cream is not available, otherwise, the saline water will cause corrosion on the electrodes.

6.3.3 Connection Formula

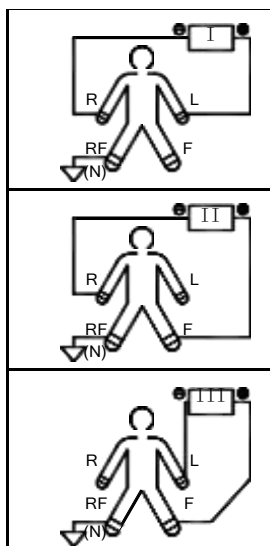
Following table is the description of electrode connection definition and color code.

Electrode Location	Electrode Code	Lead Color	Electrode Color
Right arm	R	Black	Red
Left arm	L	Black	Yellow
Right leg	RF	Black	Black
Left leg	F	Black	Green
Chest	V ₁ (C ₁)	White	Red
	V ₂ (C ₂)	White	Yellow
	V ₃ (C ₃)	White	Green
	V ₄ (C ₄)	White	Brown
	V ₅ (C ₅)	White	Black
	V ₆ (C ₆)	White	Purple

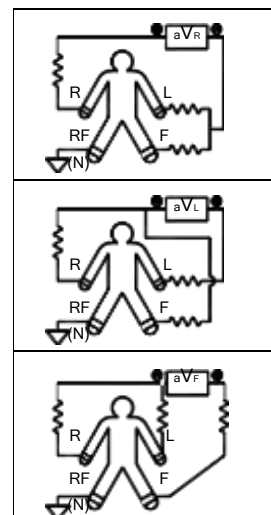
6.3.4 Standard Lead Illustration

Following is the illustration of standard lead and structure.

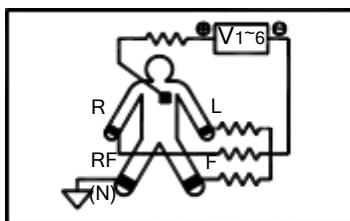
① Bipolar Limb Leads



② Augmented Unipolar Limb Leads



③ Unipolar Chest Leads



7 Operating Instructions

7.1 Preparatory Checks

In order to assure safe examination and stable printing out of ECG waveform, you are required to make below checks before operating the unit.

7.1.1 Checks on Grounding Connection

- ⦿ Good performance (such as continuity, etc) of the grounding cable.
- ⦿ Correct Connection of the grounding cable with the unit.
- ⦿ Correct connection of grounding bolt.
- ⦿ Correct connection of MN 1028-1A's grounding cable with the earth.

7.1.2 Checks on Operation Environment

- ⦿ Operation environment for ECG machine shall be away from X-ray equipment, Ultrasound scanner, and the like. Otherwise, they may impose interference on the unit.
- ⦿ Occasionally, you can power off the aforementioned equipments or move the ECG unit to another environment after turning off its power so as to guarantee its good performance.
- ⦿ Temperature of operation environment shall comply with the requirements.
- ⦿ Dry environment is recommended.

7.1.3 Checks on Power Cable

- ⦿ Loose plug shall be avoided.
- ⦿ Entangling with other cables is not permitted.

7.1.4 Checks on Patient Cable

- ⦿ Loose plug shall be avoided.
- ⦿ The patient cable itself shall be placed away from any power cable.
- ⦿ Correct connection of the plugs between the patient cable and the electrodes.

7.1.5 Checks on Electrode Attachment

- ⦿ Electrodes shall be attached to the body surface only after the latter are applied with cream.

- ⌚ Electrodes shall be kept clean by ways of alcohol and the like.
- ⌚ Loose attachment of the electrodes to the body surface shall be avoided.
- ⌚ Do not use new electrodes together with old ones.
- ⌚ Electrodes shall not be overlapped with each other.

7.1.6 Checks on Patient Situation



- ⌚ The patient shall be relieved from irritation.
- ⌚ The patient shall not be active.
- ⌚ Table for examination shall be comfortable.
- ⌚ The patient shall be kept not in touch with metal parts of examination table, lest interference is inevitable.
- ⌚ Exam room shall be comfortable.

7.1.7 Checks on Recording Paper


Considering patient safety and stable printing out of ECG waveform, operator of the unit shall complete all the aforementioned checks and make sure that recording paper is sufficient in the paper magazine before powering on the machine.

7.2 Power On/Down

7.2.1 AC Power

- ⌚ Power on: Connect the power cable and turn the power switch to “”. Then, keep pressing key “ON/OFF” until operation status is displayed on the LCD.
- ⌚ Power down: Keep pressing key “ON/STANDBY” until operation status disappears from the LCD. Then, turn the power switch to “” and disconnect the power cable.

7.2.2 Rechargeable Battery

- ⌚ Disconnect the power cable.
- ⌚ Operate in the same procedures as that for AC power.
- ⌚ Supported by the built in battery, the unit will display prompt  on the top line of the LCD.

NOTE: The built in rechargeable battery shall be charged for at least 10 hours prior to its first operation. See “8.1 Battery” for details.

7.3 Operating Procedures

7.3.1 Entering Patient Information



Generally, patient information including age, sex, and etc has nothing to do with the unit’s printing out and measurement of ECG waveform. However, they will be useful to ECG interpretation. If patient information is not entered in the process of examination, the unit will utilize default settings as substitute for interpretation. If necessary, patient information shall be entered according to following procedures before staring the unit to print out ECG waveform.

- a. Press key “ID”.



- b. Enter patient sex, age and patient ID number by ways of numeric keys “0”~“9”.
- c. If necessary, press key “Clear” to delete all the existing patient information and enter new one.
- d. If necessary, press key “Del” to delete one by one the existing patient information and enter new one.
- e. Press keys “1/M” and “2/F” to enter patient sex as male and female in respective.
- f. Press key “Enter” to confirm the entered patient information and exit entering.

NOTE: It is not allowed to enter patient information in operation mode “MAN”.

7.3.2 Automatic Operation

- a. Power on: Connect the power cable and turn the power switch to “”. Then, keep pressing key “ON/OFF” until operation status is displayed on the LCD.
- b. Press key “MODE” to select operation mode “AUTO”, and such prompt will be displayed on the LCD. Then, check the leads one by one for stability of the displayed ECG waveform by ways of keys “<” and “>”. If necessary, you can press key “RESET” to guarantee stable ECG waveform.
- c. Press key "START/STOP" to start printing out ECG waveform. Upon the end of each recording, the unit will carry out automatic measurement and interpretation on the ECG waveform as well as print out them before stopping operation.
- d. Immediately after the complete 12 lead ECG trace is printed out, the unit will display prompt for operator to store the examination by entering valid number 00-15 and pressing key “enter” for confirmation.
- e. Power down: Keep pressing key “ON/STANDBY” until operation status disappears from the LCD. Then, turn the power switch to ‘’ and disconnect the power cable.

7.3.3 Manual Operation

- a. Power on: Connect the power cable and turn the power switch to “”. Then, keep pressing key “ON/OFF” until operation status is displayed on the LCD.
- b. Press key “MODE” to select operation mode “MAN”, and such prompt will be displayed on the LCD.
- c. Press key “LEAD” to change lead and select the one with which the printing out begins
- d. Press key “START/STOP” to start printing out ECG waveform.
- e. If necessary, press key “LEAD” to change the lead with which the printing out begins
- f. Press key “START/STOP” to stop/interrupt recording.
- g. Immediately after the complete 12 lead ECG trace is printed out, the unit will display prompt for operator to store the examination by entering valid number 00-15 and pressing key “enter” for confirmation.
- h. Power down: Keep pressing key “ON/STANDBY” until operation status disappears from the LCD. Then, turn the power switch to “” and disconnect the power cable.

7.3.4 Storing and duplicating ECG Waveform & Data

a. Storing

In operation mode “AUTO”, when the unit completes printing, measurement and interpretation of ECG waveform, it will wait the operator to enter a number ranging between 00~15 to mark the

location for storing current ECG waveform and data. The unit will also evaluate each number entered and ask for reentrance whenever the entered one is beyond acceptable range. If you do not want to store current ECG waveform and data, press key “START/STOP”, and the unit will ignore storing ECG waveform and data by stopping operation immediately after completes printing out the measurement and interpretation.

b. Duplicating

When key “1mV/COPY” is pressed, the unit will be ready for duplicating by waiting the operator to enter a number ranging between 00~15 that marks the location where ECG waveform and data are stored. It will also evaluate each number entered and ask for reentrance whenever the entered one is beyond acceptable range. Upon receiving an effective number, the unit will check for validity of ECG waveform and data stored in the localized memory, and, if they are valid, display them on the LCD as well print out them on the recording paper. When the ECG waveform and data are completely printed out, the unit will stop operation. If they are invalid, the unit will exit the current status and stop operation.

7.3.5 Interchange of Print Format

In operation mode “AUTO”/ “MAN”, print format of MN 1028-1A can be interchanged between 6 channel and 12 changed by key “P. MODE” while the unit is not printing out ECG waveform. In operation mode “AUTO”, lead duration is 5 seconds for 6-channel print format and 10 seconds for 12-channel. In operation mode “MAN”, lead duration is manually controlled.

7.3.6 Lead Change

In operation mode “MAN”, when the unit is set to 6-channel print format, key “LEAD” can be used to interchange ECG waveform of the leads to be printed out between chest leads and limb leads. While in other operation mode and when the unit is printing out ECG waveform, lead change is automatically controlled and key “LEAD” is ineffective.

NOTE:

- ⌚ In operation mode “MAN”/“long time recording”, the unit does not print out measurement and interpretation of ECG waveform.
- ⌚ When the unit is set to 12-channel print format, .key “LEAD” is ineffective.
- ⌚ In operation mode “long time recording”, and while duplicating ECG waveform and data, the unit prints out in 12 channel format.
- ⌚ All stored ECG waveform and data will not lose because of the adopted scintillation memory.
- ⌚ Operator of the unit can make individual management by setting relationship between the number that marks location for storing and the actually stored ECG waveform & data.

7.3.7 Computer Communication

MN 1028-1A can transmit to a computer its stored ECG waveform and data as well the interpretation

for further management in the charge of ECG management system installed in the computer. Data is transmitted, at 115200bps baud rate, in the format of 10 bit per frame including 8 bit effective data as well 2 bit as start and end without odd-even ch2e0ck. To start transmission, you shall do as follows.

- Predetermine parameters for high-speed serial-interface in the ECG management system, and connect the communication flat.
- Press key “Menu” to enter setting menu while the unit is not printing out ECG waveform.
- Select item “DATA TRANSMISSION” at setting menu.
- Enter a number in the range between 00~15 and press key “Enter”.
- With the above done, communication between MN 1028-1A and computer is automatically setup, and you shall wait just about 10 seconds for data transmission.
- Enter basic patient information at the ECG management system and press the key “Enter”.

NOTE:

- ☞ ECG management system is an option for MN 1028-1A that requires additional purchase from MANN by customer who needs it.
- ☞ If the computer displays prompt “communication error” after a long time while you are doing as above mentioned, something is probably wrong with setting of the serial interface or the serial communication flat . You 'd better ask for help from a professional or contact our service technician.
- ☞ It seldom fails to complete transmission provided there is good communication between MN 1028-1A and computer. In case the failure does come into existence, you shall just try once again as above mentioned and everything will be OK.

7.4 Menu Setting & Description

7.4.1 Setting Menu

Setting menu of MN 1028-1A is designed to store up to 14 items of operation status that can be selected by scrolling down/up as shown in following table. Default settings are predetermined at manufacturing factory.

Item	Default Value	Description
ANALYSIS OUTPUT	ON	Print out ECG interpretation/analysis
AC FREQUENCY	50(60)Hz	Set AC frequency
QRS BEEP	ON	Set beep sound for alert of QRS complex
DRIF/AC FILTER	ON	Set drift/AC filter
EMG FILTER	ON	Set EMG filter
RECORD FORMAT	AUTO	Set lead duration
DATDA TRANSMIT	START	Transmit ECG data to a computer
DATE SETTING	****_**_**	Set date in the format of yyyy-mm-dd
TIME SETTING	**_**	Set time in the format of hh-mm
RHYTHM LEAD	II	Set rhythm lead
PRINT HEAD TEST	START	Test the thermal printer head
EXTERNAL RECORD	OFF	Input external signal

7.4.2 Setting and Description

Powered on for the first time, MN 1028-1A is to display default settings predetermined at MANN factory. Changed settings will be stored in the memory system, powered by a backup battery, even after the unit is powered off, and be regarded as initial operation status at next powering on. Item settings can be changed by ways of key “Menu” and the related keys according to

following description.

- a. Press key “Menu” to enter setting menu while the unit is not printing out ECG waveform.
- b. Press keys “^” and “v” to select the item to be changed.
- c. Press keys “<” and “>” to change setting of the selected item. For items “DATE” and “TIME”, you can change the existing setting just by ways of the numeric keys


8 Maintenance

8.1 Battery

MN 1028-1A is equipped with a built in rechargeable battery to guarantee continuous operation when


AC power is unavailable. Instructions for charging, capacity indication and replacement of the battery are as follows.

8.1.1 Charging

MN 1028-1A is designed with a charger and protector for the rechargeable battery. While supp  Status indicator “CHRG” on the control panel will blink in the process of charging, and keep in light when charging is nearly completed, then it requires additional 2~3 hours to guarantee complete AC power, the unit is able to charge the battery provided that power switch is turned to “charging”.

NOTE: It is required to charge the battery for at least 10 hours prior to its first operation as well to charge & discharge it at least one time every 3 months.

8.1.2 Capacity Indicator

Whenever the machine is powered by DC battery, there will be a prompt  displayed on the top line of the LCD to indicate battery capacity as follows.



Sufficient battery capacity



Insufficient battery capacity, charging is required.

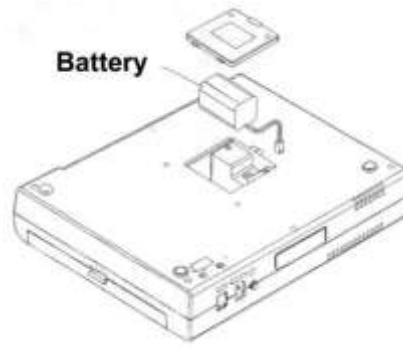


Battery capacity is running out, immediate charging is demanded.

8.1.3 Battery Replacement

Replace battery according to the following procedures.

- a. Power off the unit and disconnect the power cable.
- b. Discover the battery compartment at the bottom plane of the unit.
- c. Replace the existing battery with a new one with attention to the polarity.
- d. Cover the battery compartment.



NOTE:

- ⦿ Do not directly contact together positive and negative poles of the battery. Otherwise, there will be the hazard of fire.
- ⦿ Do not place the battery near a fire. Otherwise, there will be the hazard of explosion.
- ⦿ Do not disassembly the battery without professional instructions.
- ⦿ The battery shall be handled with care and not be dropped to the earth.

8.2 Recording Paper

To attain satisfactory printing out, you are required to use the most suitable thermal recording paper for MN 1028-1A . Otherwise, there will be harm to the printer and a problem including blurring trace and bad paper running. Following comments on recording paper shall be particularly noted.

- a. The suitable paper for MN 1028-1A excludes black/gray one and the one coated with facial wax, otherwise there will occur problem to the printer.
become deteriorate. It is therefore required to store the thermal recording paper in a dry and
- b. Long time exposed to high temperature, damp and direct sunlight, the recording paper will shading environment.
- c. Long time exposed to fluorescent light, the recording paper will become deteriorate.
- d. Stored with polyvinyl chloride (PVC), the recording paper will become deteriorate.
- e. Paper size shall be especially noted.
- f. If the thermal recording paper is stored for a long time with overlapping of the pages with each other, they will press on each other with irregular impression that will mislead reading of the printed ECG waveform.

8.3 Maintenance Following Operation

After each operation, you are required to do the following maintenance.

- a. Turn key “ON/OFF” to power off the unit before turning off the AC switch.
- b. Gently disconnect the patient cable and power cable without forcibly pulling the wires.
- c. Power off the unit before cleaning it as well as accessories and cover the unit with a shade.
While cleaning the unit, neutral cleanse is recommended, and it is not allowed to immerse the unit in the liquid.
- d. Store the unit in a dry and shading environment. There shall be no excessive vibration in the process of transportation..

8.4 Patient Cable Maintenance

After operation, you shall clean the patient cable with water & soap, and disinfected with alcohol (It is not allowed to immerse the patient cable in any liquid). You are also required to periodically check the patient cable for lead continuity by measuring the resistance with a multi-meter. Correct resistance for each lead shall be less than 10 ohms as shown in the below table. Damage of any lead may lead to void of ECG waveform at some lead or the complete leads.

Electrode Lead	R	L	F	RF	C ₁	C ₂	C ₃	C ₄	C ₅	C ₆
Cable Plug	9	10	11	14	12	1	2	3	4	5

Generally, it is not required to bend or entangle the patient cable. You'd better put the patient cable in good order before connecting it to the electrodes.


8.5 Electrode Maintenance

Electrodes shall be properly stored. Due to long time use, they may become corroded, staled, and oxidized at the surface. Whenever these happen, you are required to change the electrodes.

8.6 Thermal Printer Maintenance

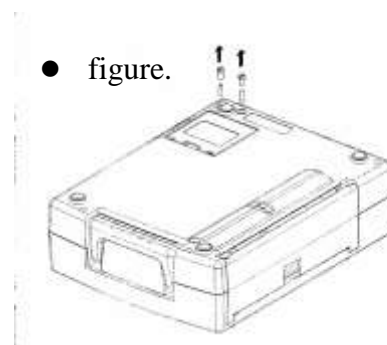
Residue and dirt on the thermal printer could affect the clarity of printing out ECG waveform. To clean the thermal printer, you are required to open the paper magazine and clean the printer with soft cotton dipped with alcohol. It is not permitted to operate on the printer with a sharp object. Otherwise, permanent damage could be resulted. Thermal printer maintenance should be done at least once a month.

8.7 Fuse Replacement

Supported by AC power, if indicator “AC” on the control panel does not light, and prompt  is displayed when key “ON/OFF” is pressed, it implies that AC fuse of the unit is probably damaged and shall be replaced as described below.

Fuse replacement should be done as shown in the right.

- ⌚ Disconnect the power cable.
- ⌚ Discover the fuse holder with a screw-driver and take out the damaged or burned fuse.
- ⌚ Install a new fuse before recovering the fuse holder as shown in the right



NOTE: If a newly replaced fuse with same specification as the existing one is also burned, the unit may be in operating problem. You'd better power off it and contact our service technicians.

9 Troubleshooting

9.1 Lead Fault

Lead fault means that some lead does not give ECG waveform in the process of recording, and is probably caused by the following.

- ⌚ If you start recording immediately after the patient cable is connected to the patient, the unit will probably face problem of lead fault as a result of saturation or overflow at the baseline adjustment software due to receiving and working on unstable ECG waveform & data. In such case, provided good lead connection is guaranteed, you'd better press key "RESET" to rapidly stabilize the waveform of each channel or to try another recording, and everything will be OK.
- ⌚ Damaged patient cable may also cause problem of lead fault. Please refer to "8.4 Patient Cable Maintenance" on page 22 for instructions to do checks on the patient cable, and contact our service technicians if it is damaged.
- ⌚ The last reason for lead fault is the unit problem due to failure in signal communication. If you are sure to exclude other cause for this problem, please do not hesitate to contact our service technicians.

9.2 Printer Failure

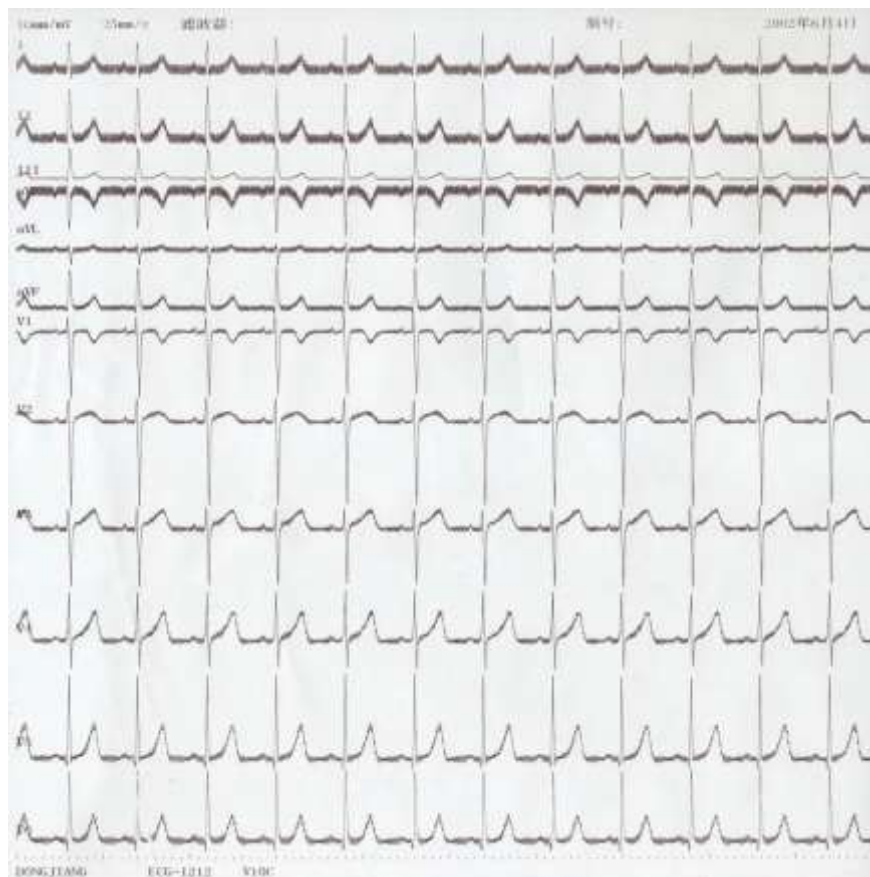
Whenever a printer fault occurs, which manifests itself as not continuous ECG waveform on the recording paper, you are required to clean the thermal printer with soft cotton dipped with alcohol. If this action does not work, certain thermal emitting component is probably damaged, and you are required to contact the MANN or the local agent for help.

9.3 Control Panel Failure

Control panel failure is probably caused by bad continuity between the panel and the Keyboard Control Module due to transportation or vibration. If a reconnection of the control panel to the Keyboard Control Module does not work, you are required to contact a service engineer.

9.4 AC Interference

Obvious trembling of ECG waveform in the process of recording due to AC interference is as shown in the below figure.

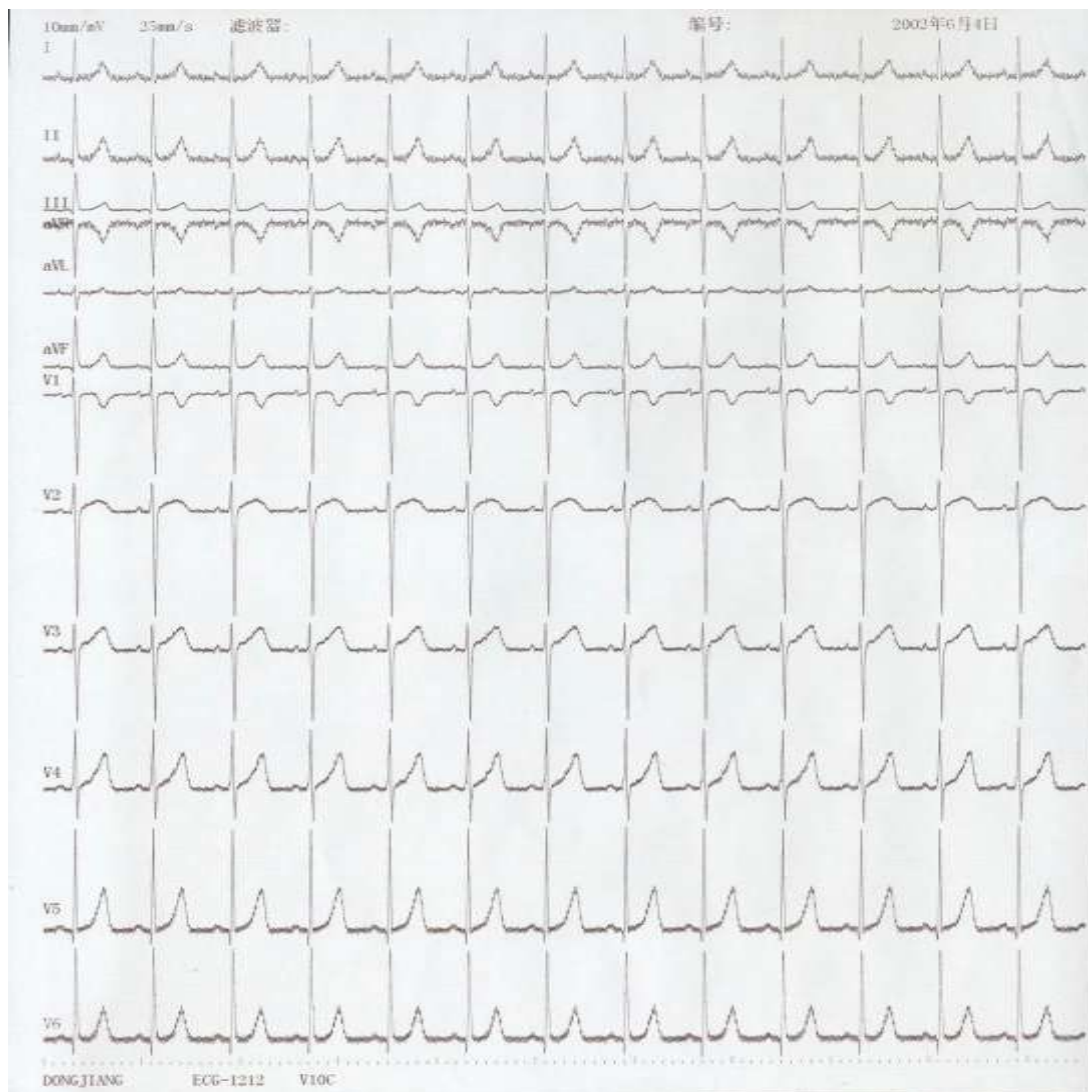


In case of such situation, you are required to do following checks.

- ⌚ Make sure that the unit is properly grounded according to instructions.
- ⌚ Check for good electrode attachment and patient cable connection.
- ⌚ Check the cleaning of electrode and patient body surface.
- ⌚ Make sure that the metal exam bed is properly grounded.
- ⌚ The patient shall not be in touch with the metal parts of the exam bed.
- ⌚ The patient shall not be in touch with anybody else.
- ⌚ There shall be no large power electric equipment (such as X ray machine, Ultrasound scanner and the like) working nearby.
- ⌚ The patient shall put off such things as jewelry and the like
- ⌚ Please use filter if still having above-mentioned interference.

9.5 EMG Interference

Irregular trembling of ECG waveform due to EMG interference is as shown in the below figure.

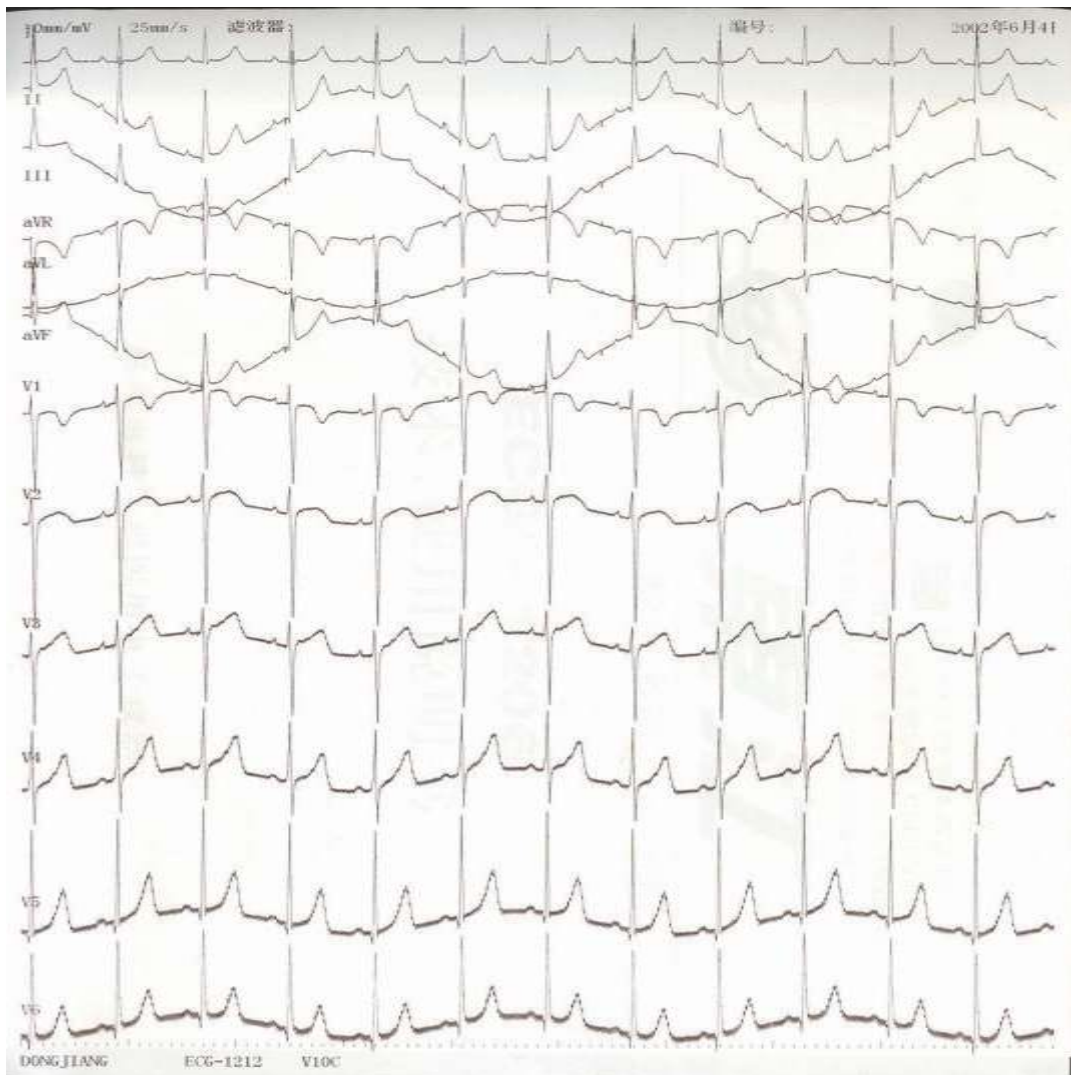


In case of such situation, you are required to do following checks.

- ⦿ Make sure that the exam room is comfortable for examination.
- ⦿ Soothe the patient from irritation or excitement.
- ⦿ Make sure the exam bed shall be in suitable size.
- ⦿ Never have talks with the patient during ECG waveform is recorded.
- ⦿ Please use filter if still having above-mentioned interference.

9.6 Baseline Drift

Irregular movement of ECG waveform due to baseline drift is as shown in the below figure.

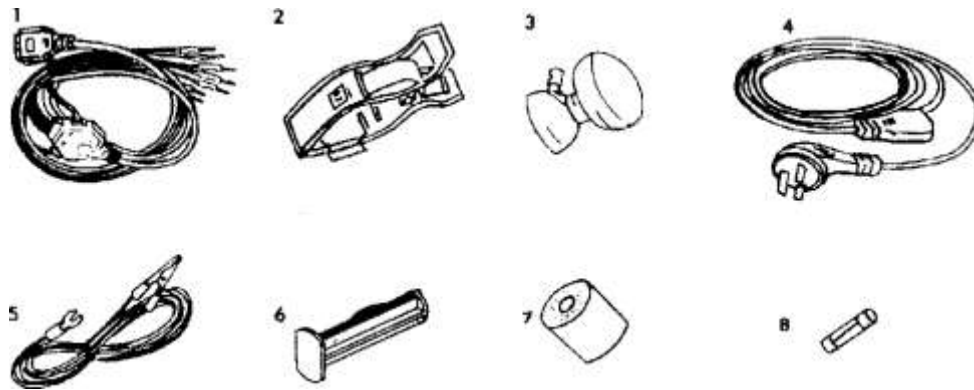


In case of such situation, you are required to do following checks.

- ⦿ Verify the electrode attachment and lead wire performance.
- ⦿ Check the connection between patient cable and electrodes.
- ⦿ Check the cleaning of electrode and patient body surface.
- ⦿ Keep the patient from motion or hyperventilation.
- ⦿ Used electrodes shall not be utilized with news ones in patient examination.
- ⦿ Please use filter if still having above-mentioned interference.

10 Accessory List

In order to obtain a good ECG waveform, you are required to use the accompanying accessories of this unit. Following is the demonstration of the standard accessories for the unit.



Item	Code Number	Description	Quantity
1	F0100	Patient Cable	1
2	F0306	Limb Electrode	4pcs/set
3	F0200	Chest Electrode	6pcs/set
4	W20	Three plugged power cable	1
5	F0800	Grounding Cable	1
6	A0103	Paper Shaft	1
7	P4020	Thermal Recording Paper	1
8	FU	Fuse	2

11 Appendix A: Package and Accompanying Materials

11.1 Accessories

Complete configuration for MN 1028-1A at the MANN factory is as follows

12 channel electrocardiograph (MN 1028-1A)	1unit
Testing protocol	1copy
Packing list	1copy
Warranty	1copy
210mmx20m roll recording paper	1roll
Patient cable	1piece
Three plugged power cable	1piece
Limb electrode	4pieces/set
Chest electrode	6pieces/set
Backup AC fuse	2pieces
Operating instructions	1copy
User's guide for interpretation	1copy

11.2 Note

- ⌚ Please open the package according to comments on the packing box
- ⌚ Accompanying accessories and documents shall be checked according to packing list before starting checks on the unit.
- ⌚ Whenever there will be mismatch of the accompanying materials with the packing list, or unit problem, you'd better immediately contact our service technician.
- ⌚ In order to guarantee good performance and safety of MN 1028-1A, you are required to use the accessories supplied by the manufacturer.

12 Appendix B: Specifications

12.1 Technical Specifications

12.1.1 The Unit

Lead	Standard 12 leads
Input Circuit	Isolated input circuit Protection against defibrillation and pace making
Data Acquisition	Simultaneously 12 lead acquisition
Calibration Voltage	1mV \pm 5%
Sampling Rate	1ms
A/D Converter	12 bit
Print Format	Automatic/Manual: 6 channel +rhythm , 12 channel Neutral value + Rhythm lead
Operation Mode	AUTO: Automatic lead change; Automatic measurement and interpretation MAN: Manual lead change
Parameter Measurement	Ventricle heart rate; P-R interval; QRS duration; QT/QTc interval; P/QRS/T axis; RV ₅ /SV ₁ amplitude
Filter	AC filter, EMG filter, DFT filter
CMRR	> 60dB > 100dB (AC filter in use)
Input Circuit Current	$\leq 0.1\mu\text{A}$
Input Impedance	>50M Ω
Patient Leakage Current	<10 μA
Time Constant	$\geq 3.2\text{s}$
Frequency Response	0.05 ~ 100Hz
Noise Level	<15 $\mu\text{V}_{\text{p-p}}$
Threshold	$\leq 20\mu\text{V}$
Skin Voltage Tolerance	$\pm 400\text{mV}$
Sensitivity	5, 10, 20, 40mm/mV
Baseline Control	Automatic baseline control Automatic inhibition of baseline drift

12.1.2 Recorder

Recording Mode	Thermal printer: 8 dot/mm(Vertical); 32 dot/mm(Horizontal, 25mm/s)
Paper Speed	6.25, 12.5, 25, 50mm/s
Paper Size	210mm \times 30m/210mm \times 20m, roll type 210mm \times 140m/210mm \times 20m, Zip fold

12.1.3 Miscellaneous

Patient Cable	DJ ECG-A.F01.001A
LCD Display	Backlit; Operation status; Time; Heart-rate; ECG waveform
Safety Level	Class I, Type CF
Power Requirements	AC: 220V (110V), 50Hz/60Hz; 60VA Battery : Sealed rechargeable battery, 14.4V, 1.6Ah AC time lag: 2- Φ 5 \times 20mm
Fuse Specifications	T800mA/250V (220V) T2A/250V (110V) DC time lag: T2A/250V
Serial No.
Dimension	333mm \times 260mm \times 95mm
Weight	5Kg

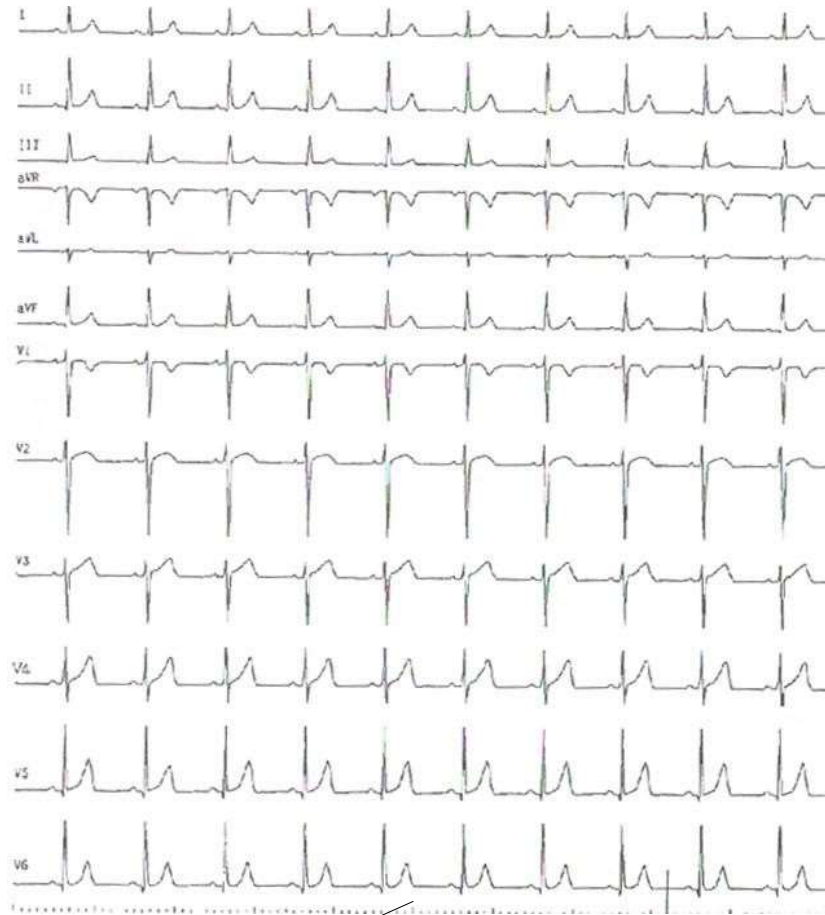
12.2 Environmental Conditions

Transportation	Temperature: -40°C ~ +55°C Relative Humidity: 25% ~ 95% Atmospheric Pressure: 700hPa ~ 1060hPa
Storage	Temperature: -10°C ~ +40°C Relative Humidity: 25% ~ 80% Atmospheric Pressure: 700hPa ~ 1060hPa
Operation	Temperature: +5°C ~ +40°C Relative Humidity: 25% ~ 80% Atmospheric Pressure: 700hPa ~ 1060hPa

12.3 CRO & EXT (Customized)

EXT	Single ended Output Impedance: $\geq 100k\Omega$ Sensitivity: 10mm/mV $\pm 5\%$;
CRO	Single ended Output Impedance: $\leq 100\Omega$ Sensitivity: 0.5V/mV $\pm 5\%$ (10mm/mV)

13 Appendix C Example for Interpretation



Standard 12 lead ECG waveform

Interpretation

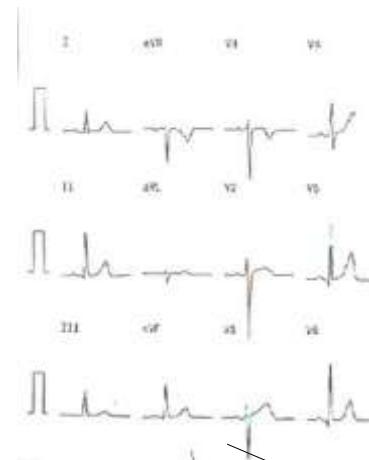
Patient information

Analysis result

Name: Sex: Age:

HR	50bpm
PR	153ms
QRS	101ms
QT/QTc	422/422ms
P/QRS/T	21/67/45°
RV ₅ /SV ₁	1.53/1.26mV
RV ₅ +SV ₁	2.79mV

8110: Sinus rhythm
Normal ECG



Dominant beat for analysis.

14 Appendix D Description of Software for ECG interpretation

With the development of computer, recent years witnessed the coming into existence and wide application of more and more medical diagnostic equipments with practical value including ECG machine of which research on interpretation of ECG waveform has been in working for 30 years. Following description covers computerized diagnosis in MN 1028-1A.

14.1 Advantage of Computerized Analysis

14.1.1 Objectivity

Objective diagnosis made by ECG machine guarantees, together with subjective one by doctor, double exam.

14.1.2 Reliability

In contrast to difference between physician diagnoses due to individuality and time, quantitative analysis of computerized ECG machine is able to present more reliable report/interpretation.

14.1.3 Efficiency

Rapid procession of computerized ECG machine greatly promotes efficiency in evaluation and diagnosis. Sometimes, it is feasible to make particular re-examination on abnormal ECG waveform as made by computerized ECG machine so as to relieve doctors from strain and enable them to do more clinical operation.

14.1.4 Rapid Data Acquisition

With computerized analysis, ECG data, including axis, QTC, and etc, that are generally obtained only by ways of complex computation can be easily released.

14.2 Disadvantage of Computerized Analysis

14.2.1 Consistency

Interpretation and analysis on normal ECG waveform can be one hundred percent compliant with correct one. However, accuracy of the work on abnormal ECG waveform is just 70~80% depending on actual variety.

14.2.2 Reliability

One of the advantages of computerized interpretation and analysis is good reliability. On the other hand, in case of bordering ECG waveform, such interpretation & analysis might be inconsistent because it is done on the basis of acquire data and values.

14.2.3 Waveform Recognition

People are good at recognizing matters by their outline but suffer from complex computation and memorization. On the contrary, it is difficult for a computer to recognize graphs, and easy to do complex computation and memorization. Furthermore, wrong interpretation and analysis may be caused by mistake in measurement due to baseline drift and/or error as a result of EMG interference, as well by the unit's inability to detect a tiny waveform. Finally, and particularly, measurement of P wave is not always satisfying in case there is intensive EMG interference. Therefore, operator of ECG machine shall pay attention to assure proper connection of patient cable and correct operation

of the unit so as to minimize graph interference and baseline drift.

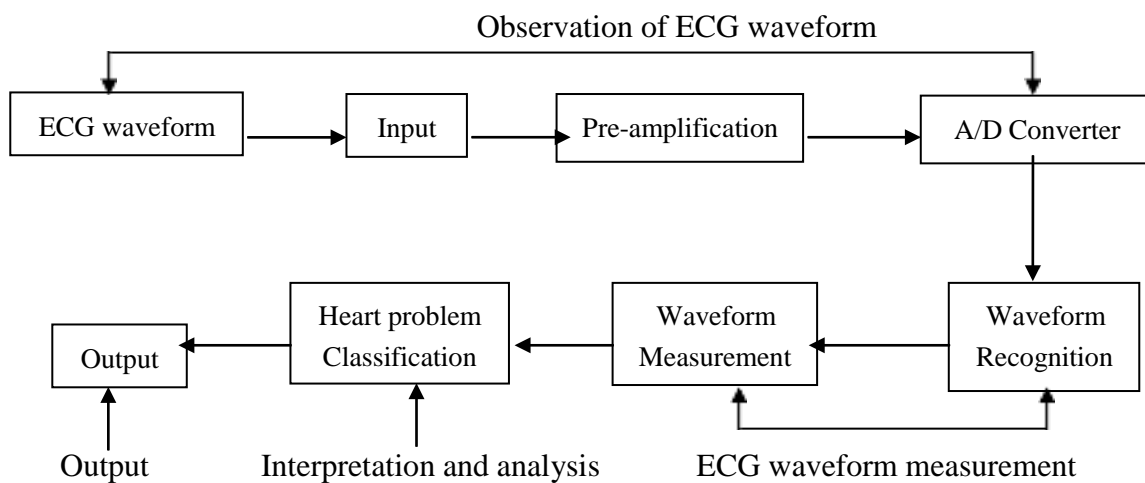
14.2.4 Interpretation Criterion

Different criteria adopted by clinical physicians may affect on analysis. Taking into consideration of this, diagnosis criterion used in MN 1028-1A is the worldly applied “Minnesota Code” and shall be regarded only as reference if there it is different from the one adopted by clinical physician.

14.3 Measurement & Computation Method

Heart Rate	$HR=60/(R-R)$ per minute
PQ Duration	Stands for PQ length in second and is computed by adopting the 4 th PQ as dominant value from any 5 leads.
QRS Duration	Stands for QRS length in second and is computed by adopting the 2 nd smallest value as dominant value from any 5 leads.
R-R Interval	Measured in second and is computed by averaging R-R interval of lead II or V ₆ whichever is larger in amplitude.
QTC interval	$QTC=QT/\sqrt{R-R}$, QT is the middle value of all 12 leads.
AXIS	Measured in second. $AXIS=\text{Arctan}\{3(II+III)/(2\times I+II+III)\}$. Leads I, II, and III are adopted as algebraic add of QRS amplitude.

14.4 Process of Automatic Interpretation and Analysis



14.5 List of Abnormal ECG v/s Code

Here listed below are details about variety of abnormal electrocardiogram.

8 Arrhythmia

Code No.	Description
8002	Marked rhythm irregularity
8110	Sinus rhythm
8102	Sinus arrhythmia
8108	Marked sinus arrhythmia
8120	Sinus tachycardia
8130	Sinus bradycardia
8200	Atrial rhythm
8210	Atrial fibrillation
82101	Atrial fibrillation with rapid ventricular response
82102	Atrial fibrillation with slow ventricular response
82103	Atrial fibrillation with aberrant conduction, or ventricular premature complexes
82108	Atrial fibrillation with rapid ventricular response with aberrant conduction
82109	Atrial fibrillation with slow ventricular response with ventricular premature complexes
8220	Atrial tachycardia
8250	Atrial flutter
82503	Atrial flutter with aberrant conduction or ventricular premature complexes
82505	Cannot rule out atrial flutter
8300	Junctional rhythm
8320	Junctional tachycardia
8400	Supraventricular rhythm
8420	Supraventricular tachycardia
8430	Supraventricular bradycardia
8470	with occasional supraventricular premature complexes
8474	with frequent supraventricular premature complexes
8475	with frequent supraventricular premature complexes in a pattern of bigeminy
8500	Ventricular rhythm
8520	Ventricular tachycardia
8570	with occasional ventricular premature complexes
8574	with frequent ventricular premature complexes
8575	with frequent ventricular premature complexes in a pattern of bigeminy
86006	Electronic atrial pacemaker
86007	Electronic ventricular pacemaker
8901	Undetermined regular rhythm
8902	Undetermined rhythm
8970	with occasional ectopic premature complexes
8974	with frequent ectopic premature complexes
8975	with frequent ectopic premature complexes in a pattern of bigeminy

6 AV Conductive Defect

Code No.	Description
611	Possible third degree AV block
621	Second degree AV block, Wenckebach type
622	Second degree AV block, Mobitz type II
623	First degree AV block
631	Short PR interval
641	Type-A WPW syndrome
642	Type-B WPW syndrome
643	Atypical WPW syndrome
644	Intermittent WPW syndrome

7 Intraventricular Conductive Defect

Code No.	Description
711	Left bundle branch block
712	Incomplete left bundle branch block
721	Right bundle branch block, plus possible RVH
722	Right bundle branch block
723	Incomplete right bundle branch block
724	RSR in lead V1/V2, consistent with right ventricular conduction delay
731	Left anterior fascicular block
741	Nonspecific intraventricular conduction block

1 Myocardial Infarction

Code No.	Description
1113	Cannot rule out anterior myocardial infarction, probably old
1114	Cannot rule out anterior myocardial infarction, age undetermined
1121	Possible anterior myocardial infarction, possible acute
1122	Possible anterior myocardial infarction, probably recent
1123	Possible anterior myocardial infarction, probably old
1124	Possible anterior myocardial infarction, age undetermined
1131	Anterior myocardial infarction, possible acute
1132	Anterior myocardial infarction, probably recent
1133	Anterior myocardial infarction, probably old
1134	Anterior myocardial infarction, age undetermined
1213	Cannot rule out anteroseptal myocardial infarction, probably old
1214	Cannot rule out anteroseptal myocardial infarction, age undetermined
1221	Possible anteroseptal myocardial infarction, possible acute
1222	Possible anteroseptal myocardial infarction, probably recent
1223	Possible anteroseptal myocardial infarction, probably old
1224	Possible anteroseptal myocardial infarction, age undetermined

1231	Anteroseptal myocardial infarction, possible acute
1232	Anteroseptal myocardial infarction, probably recent
1233	Anteroseptal myocardial infarction, probably old
1234	Anteroseptal myocardial infarction, age undetermined
1313	Cannot rule out anterolateral myocardial infarction, probably old
1314	Cannot rule out anterolateral myocardial infarction, age undetermined
1321	Possible anterolateral myocardial infarction, possible acute
1322	Possible anterolateral myocardial infarction, probably recent
1323	Possible anterolateral myocardial infarction, probably old
1324	Possible anterolateral myocardial infarction, age undetermined
1331	Anterolateral myocardial infarction, possible acute
1332	Anterolateral myocardial infarction, probably recent
1333	Anterolateral myocardial infarction, probably old
1334	Anterolateral myocardial infarction, age undetermined
1413	Cannot rule out septal myocardial infarction, probably old
1414	Cannot rule out septal myocardial infarction, age undetermined
1421	Possible septal myocardial infarction, possible acute
1422	Possible septal myocardial infarction, probably recent
1423	Possible septal myocardial infarction, probably old
1424	Possible septal myocardial infarction, age undetermined
1431	Septal myocardial infarction, possible acute
1432	Septal myocardial infarction, probably recent
1433	Septal myocardial infarction, probably old
1434	Septal myocardial infarction, age undetermined
1513	Cannot rule out lateral myocardial infarction, probably old
1514	Cannot rule out lateral myocardial infarction, age undetermined
1521	Possible lateral myocardial infarction, possible acute
1522	Possible lateral myocardial infarction, probably recent
1523	Possible lateral myocardial infarction, probably old
1524	Possible lateral myocardial infarction, age undetermined
1531	Lateral myocardial infarction, possible acute
1532	Lateral myocardial infarction, probably recent
1533	Lateral myocardial infarction, probably old
1534	Lateral myocardial infarction, age undetermined
1613	Cannot rule out inferior myocardial infarction, probably old
1614	Cannot rule out inferior myocardial infarction, age undetermined
1621	Possible inferior myocardial infarction, possible acute
1622	Possible inferior myocardial infarction, probably recent
1623	Possible inferior myocardial infarction, probably old
1624	Possible inferior myocardial infarction, age undetermined
1631	Inferior myocardial infarction, possible acute
1632	Inferior myocardial infarction, probably recent
1633	Inferior myocardial infarction, probably old
1634	Inferior myocardial infarction, age undetermined
16132	Cannot rule out inferior myocardial infarction with posterior extension, probably old
16142	Cannot rule out inferior myocardial infarction with posterior extension, age undetermined
16212	Possible inferior myocardial infarction with posterior extension, possible acute
16222	Possible inferior myocardial infarction with posterior extension, probably recent

16232	Possible inferior myocardial infarction with posterior extension, probably old
16242	Possible inferior myocardial infarction with posterior extension, age undetermined
16312	Inferior myocardial infarction with posterior extension, possible acute
16322	Inferior myocardial infarction with posterior extension, probably recent
16332	Inferior myocardial infarction with posterior extension, probably old
16342	Inferior myocardial infarction with posterior extension, age undetermined
171	Abnormal Q wave ? [Lat.]
172	Abnormal Q wave ? [Inf.]
173	Abnormal Q wave ? [Lat., Inf.]
174	Abnormal Q wave ? [Ant.]
175	Abnormal Q wave ? [Ant., Lat.]
176	Abnormal Q wave ? [Ant., Inf.]
177	Abnormal Q wave ?

3 Ventricular Hypertrophy and Atrial Enlargement

Code No.	Description
311	Possible right ventricular hypertrophy
312	Right ventricular hypertrophy
313	Right ventricular hypertrophy, probably repolarization abnormality
321	Minimal voltage criteria for LVH
322	Possible left ventricular hypertrophy
323	Moderate voltage criteria for LVH
324	Voltage criteria for LVH
325	Left ventricular hypertrophy, probably repolarization abnormality
331	Possible left atrial enlargement
332	Left atrial enlargement
341	Possible right atrial enlargement
342	Right atrial enlargement

5 ST-T Abnormality

Code No.	Description
51	ST abnormality, possible sub endocardial ischemia
52	T wave abnormality, possible sub endocardial ischemia
53	Nonspecific T wave abnormality
54	ST depression
55	Nonspecific ST elevation
561	Possible acute pericarditis
562	Acute pericarditis
571	ST elevation, possible acute myocardial infarction
572	Tall T wave, possible hyperkalemia

2 Axis Deviation

Code No.	Description
21	Moderate left axis deviation
22	Abnormal left axis deviation
23	S1-S2-S3 pattern
24	Abnormal right axis deviation
25	Right axis deviation
26	Indeterminate axis

9 Others

Code No.	Description
911	Low voltage
912	Low voltage in limb leads
913	Low voltage in chest leads
941	Long QT interval
942	Short QT interval
971	Dextrocardia
972	LIMB LEADS REVERSED
973	Abnormal QRS-T angle
974	Consistent with pulmonary disease
981	Artifacts present
982	Cannot be analyzed, re-record recommended

10 Overall Judgment

Code No.	Description
1001	Abnormal ECG
1002	Abnormal rhythm ECG
1003	Borderline ECG
1004	Atypical ECG
1010	Normal ECG

ENVIRONMENT PROTECTION

1. Treatment of waste and residue: Do not throw away, any component of ECG machine. You are advised to send them to professional medical center nearby.
2. When the machine is scrapped, please contact your local supplier or manufacturer.
3. The disposal of wastes and residues should be in accordance with the relevant state laws and regulations.