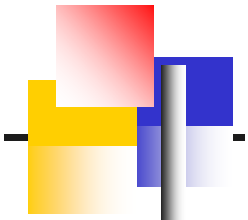
EDAN INSTRUMENTS, INC.

CE 0123



SE-1 Single Channel Electrocardiograph

User Manual

Version No.: V1.1
Release Date: Sep.2007
Part No.: MS1R-19929-V1.1

EC Declaration of Conformity

Manufacturer: EDAN Instruments, Inc.

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European Representative: Shanghai International Holding Corp. GmbH (Europe)

Addr: Eiffestrasse 80 D-20537 Hamburg Germany

Product: Electrocardiograph

Model: SE-1

Classification (MDD, Annex IX): Class II a, Rule 10 According To Annex IX of the MDD

We herewith declare that the above mentioned product(s) meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices - as amended by Directive 98/79/EC on in vitro diagnostic medical devices.

All supporting documentation is retained at the premises of the manufacturer.

DIRECTIVES

General Applicable Directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standards applied: EN ISO14971: 2000, EN 60601-1: 1988, EN 60601-2-25: 1995, EN 60601-1-4: 1997, EN 60601-1-2: 2001, EN 60601-2-51: 2003, EN 1041: 1998, IEC/TR 60878-2003, EN 980: 1997, EN 60417-2-2000, ISO1000: 1998, EN ISO780: 1999.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr 65, D-80339 MÜnchen, Germany.

Identification number CE 0123

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Statements

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Responsibility of the Manufacturer

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

- Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by personnel authorized by EDAN;
- The electrical installation of the relevant room complies with safety standards;
- The instrument is used in accordance with the instructions for use.

Note: This device is not intended for home use.

⚠**WARNING**⚠: This device is not intended for treatment.

Using This Label Guide

⚠**WARNING**⚠

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

CAUTION

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

Note: A NOTE provides useful information about a function or procedure.

Table of Contents

1 Safety Guidance

1.1 Safety Information

The design of the single channel electrocardiograph complies with the international standard IEC 60601-1 Medical Electrical Equipment: General Requirements for Safety and IEC 60601-2-25 Particular Requirements for the Safety of Electrocardiographs etc. The classification of this equipment is Class I, type CF, which means a higher degree of protection against electric shock, and the patient connection is fully isolated. Furthermore it is defibrillation-proof.

This equipment is not explosion-proof. Do not use it in the presence of flammable anesthetics.

This equipment is designed for continuous operation and is 'ordinary' (i.e. not drip or splash-proof).

Classification:

1)	Anti-electric-shock type:	Class I with internal power supply
2)	Anti-electric-shock degree:	CF (with defibrillation-proof applied part)
3)	Degree of protection against harmful ingress of water:	Ordinary equipment (Sealed equipment without liquid proof)
4)	Disinfection/sterilization method:	Refer to this user manual for details
5)	Safety degree of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas
6)	Working Mode:	Continuous operation
7)	EMC:	Group I, Class A

1.2 Warnings and Cautions

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

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

1.2.1 Safety Warnings

⚠WARNING⚠:

- The electrocardiograph is provided for the use of qualified physicians or personnel professionally trained. And they should be familiar with the contents of this user manual before operation.
- Only qualified service engineers can install this equipment. And only service engineers authorized by EDAN can open the shell.
- Only qualified installation or service engineers can shift the mains shift switch (100V~115V/220V~240V) according to local mains supply.
- The results given by the equipment should be examined with respect to the overall clinical condition of the patient. And it can not substitute for regular checking.

⚠WARNING⚠:

- **EXPLOSION HAZARD**-Do not use the electrocardiograph in the presence of flammable anesthetic mixture with oxygen or other flammable agents.
- **SHOCK HAZARD**-The power receptacle must be a hospital grade grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet.
- If the integrity of external protective conductor in installation or arrangement is in doubt, the equipment should be operated from the built-in rechargeable battery.
- Do not use this equipment in the presence of high static electricity or high voltage equipment which may generate sparks.
- This equipment is not designed for internal use and direct cardiac application.

⚠WARNING⚠:

- Only patient cable and other accessories supplied by EDAN can be used. Or else, the performance and electric shock protection can not be guaranteed.
- Be sure that all electrodes have been connected to the patient correctly before operation.
- Be sure that the conductive parts of electrodes and associated connectors, including neutral electrode, should not contact with earth or any other

conducting objects.

- Electrodes with defibrillation protection should be used while defibrillating.
- There is no danger for patients with pacemaker.
- Do not touch the patient, bed, table and the equipment while using defibrillator or pacemaker simultaneously.
- In order to avoid burning, please keep the electrode far away from the radio knife while using electrosurgical equipment simultaneously.

⚠WARNING⚠:

- Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC 60601-1-1. Therefore anybody, who connects additional equipment to the signal input connector or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult our technical service department or your local distributor.
- The summation of leakage current should never exceed leakage current limits while several other units are used at the same time.
- The potential equalization conductor can be connected to that of other equipment when necessary, to make sure that all these equipment are connected with the potential equalization bus bar of the electrical installation.

1.2.2 Battery Care Warnings

⚠WARNING⚠:

- Improper operation may cause the battery to be hot, ignited or exploded, and it may lead to the declination of battery's capacity. It is necessary to read the user manual carefully and pay more attention to warning messages.
- Only qualified service engineer authorized by EDAN can open the battery compartment and replace the battery. And the battery of same model and specification provided by manufacturer should be used.
- Danger of explosion -- Do not reverse the anode and cathode when connecting

the battery.

- Do not heat or splash the battery or throw it into fire or water.
- When leakage or foul smell found, stop using the battery immediately. If your skin or cloth comes into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.
- When the battery's useful life is over, contact with the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

1.2.3 General Cautions

CAUTION:

- A void liquid splash and excessive temperature. The temperature must be kept between 5℃ and 40℃ while working. And it should be kept between -20℃ and 50℃ during transportation, and between -10℃ and 40℃ during storage.
- Do not use the equipment in dusty environment with bad ventilation or in the presence of corrosive.
- Be sure that there is no intense electromagnetic interference source around the equipment, such as radio transmitter or mobile phone etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. are likely to bring electromagnetic interference.

CAUTION:

- Before use, the equipment, patient cable and electrodes etc. should be checked. Replacement should be taken if there is any evident defectiveness or aging symptom which may impair the safety or performance.
- The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.
  a) Inspect the equipment and accessories for mechanical and functional damage.
  b) Inspect the safety relevant labels for legibility.
  c) Inspect the fuse to verify compliance with rated current and breaking

characteristics.

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

e) Test the protection earth resistance according IEC 601-1/1988: Limit 0.2 ohm.

f) Test the earth leakage current according IEC 601-1/1988: Limit: NC 500 uA, SFC 1000uA.

g) Test the patient leakage current according IEC 601-1/1988: Limit: 10 uA (CF).

h) Test the patient leakage current under single fault condition with mains voltage on the applied part according IEC 601-1/1988: Limit: 50uA (CF).

The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

- Ruptured fused must only be replaced with the same type and rating as the original.
- The equipment and reusable accessories can be sent back to the manufacturer for recycling or proper disposal after their useful lives.

1.2.4 Cleaning & Disinfection Cautions

CAUTION:

- Turn off the power before cleaning and disinfection. If mains supply used, the power cord should be drugged out of the outlet also. And prevent the detergent from seeping into the equipment.
- Do not immerse the unit or patient cable into liquid under any circumstances.
- Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.
- Any remainder of detergent should be removed from the unit and patient cable after cleaning.
- Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.

2 Introduction

SE-1 single channel electrocardiograph is a single channel digital ECG (electrocardiograph) recorder with high performance.

One channel cardiogram can be previewed on the LCD (liquid crystal display) screen, and it can be recorded by high-quality thermal printer. Moreover, real-time heart rate can be displayed on the screen which can also be printed out on the record. Manual recording mode and four automatic recording modes can be chosen conveniently. Either mains supply or built-in rechargeable Lithium battery can be used as power supply.

Configurations: Main unit and accessories, including patient cable, chest electrodes, limb electrodes, thermal print paper and power cord etc.

Intended use: The cardiogram and heart rate recorded by the electrocardiograph can help doctors to analysis and diagnose heart disease or arrhythmia in hospitals. And its compact size makes it suitable for use while visiting patients at home.

Note: It is not designed for internal use and direct cardiac application.

2.1 Function Features

- Low weight and compact size
- Touch key for easy operation
- LCD for single channel ECG preview before recording
- Four automatic recording modes and manual mode optional
- General menu for recording parameters setting
- Built-in rechargeable Lithium battery with high capacity
- Alarm information for lead off, lack of paper and weak battery etc.
- Thermal dot-matrix printer for high-resolution printout
- Automatic adjustment of baseline for optimal recording
- Selectable printing formats, standard single channel or single channel & rhythm lead
- Standard external input/output interface and RS232 communication interface for linking to special network and setting up ECG database

2.2 List of Symbols

	External output
	External input
	Equipment or part of CF type with defibrillation proof
	Attention – general warning (see accompanying document)
	Potential equalization
	Mains supply (or indicator)
	On (mains supply)
	Off (mains supply)
	Battery indicator
	Battery recharging indicator

3 General Information

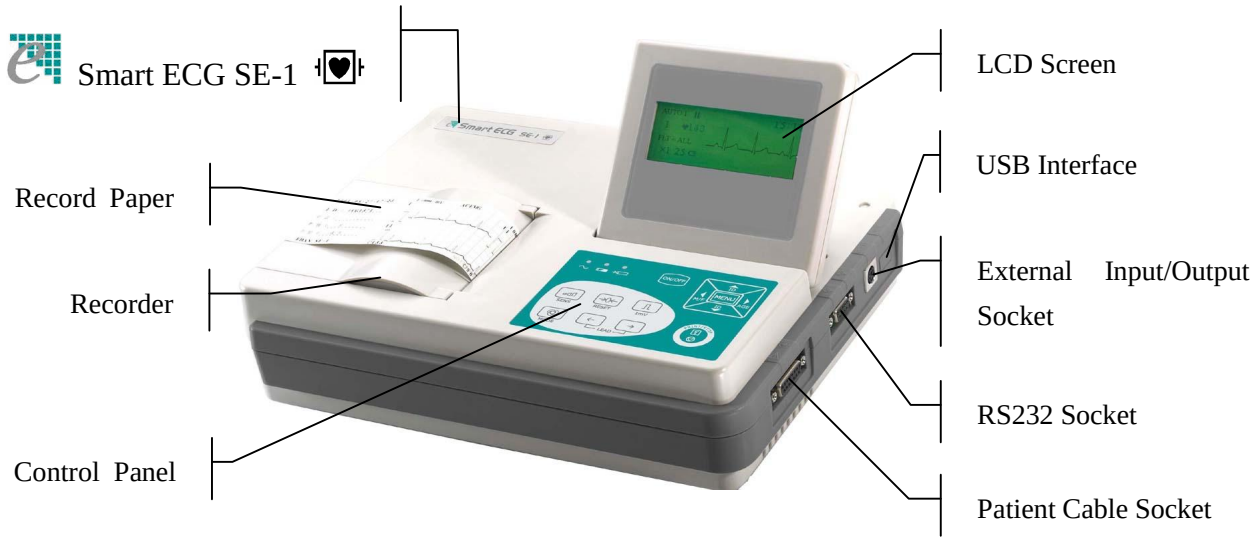


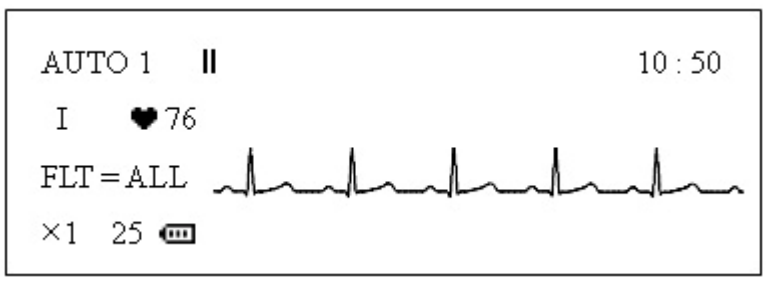
Figure 3-1 Main Unit

(trademark) **Smart ECG** (trade name) **SE-1** (model)

(classification symbol, equipment of CF type with defibrillation proof)

3.1 Top Panel

3.1.1 LCD Screen



The LCD screen can be revolved and settled firmly in different angle. Normally, the contents displayed on the LCD screen include: (described from left to right in row order)

First Row:

- Operation mode (AUTO1, AUTO2, AUTO3, AUTO4 and MANU)
- **II** stop symbol, which will turn to ▶ while recording
- Warning message (LD OFF, or PAPER? etc.)
- Current time

Second Row:

- Current lead (I, II, III, AVR, AVL, AVF, V1, V2, V3, V4, V5, V6)
- Heart rate ♥ (--, actual heart rate, or OVR message)

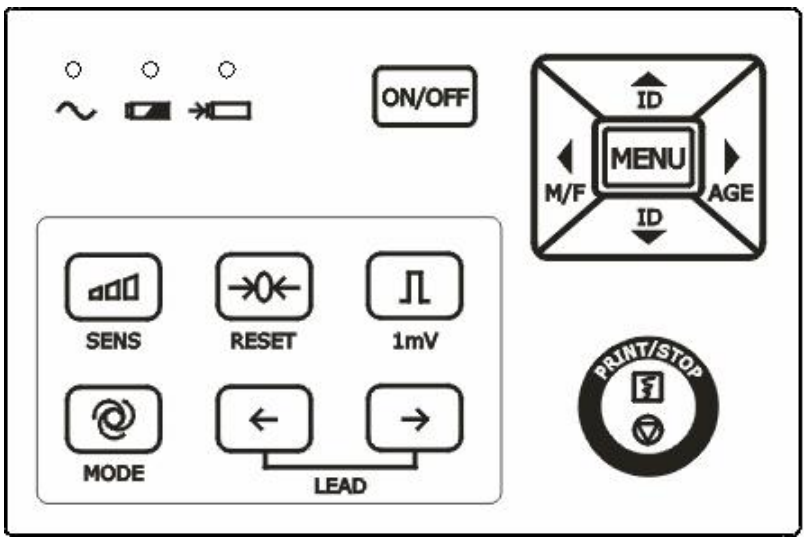
Third Row:

- Filter setting (FLT = AC, EMG, ALL, OFF)
- ECG

Fourth Row:

- Sensitivity (×1, ×2, AGC, · 25, · 5)
- Paper speed (25, 50)
- Battery capacity symbol (, , ,)
- Display the ID, sex (M/F) and age group (CHD/ADL/OLD) while setting; and "BATTERY WEAK" will be showed here when the battery capacity is weak.

3.1.2 Control Panel and Keys



1) Indicator

Mains supply indicator: when mains supply is used, the indicator will be lit.

Battery indicator: when the built-in rechargeable lithium battery is used, the indicator will be lit.

Battery recharging indicator: both the battery recharging indicator and mains supply indicator will be lit after the mains power switch has been turned on.

After **ON/OFF** key being pressed, the battery recharging indicator will be black if the battery capacity is full. However, if the battery capacity is not full, the battery recharging indicator will be lit until the battery is full recharged, and after that the battery recharging indicator will be black.

2) SENS (Sensitivity Switch Key)

The sensitivity switching order: ×1 → ×2 → AGC → · 25 → · 5

The ECG signal range which can be measured and recorded is different according to different sensitivity, as the following list shows.

Options	Sensitivity	Signal range measured
×1	10mm/mV	-2.5mV ~ +2.5mV
×2	20mm/mV	-1.25mV ~ +1.25mV
AGC	Auto Gain Control	Adjust sensitivity automatically
· 25	2.5mm/mV	-10mV ~ +10mV
· 5	5mm/mV	-5mV ~ +5mV

If the fluctuating range of the ECG signal is great, ‘AGC’ would be better to be chosen for the sensitivity can be adjusted automatically under this mode.

3) RESET (Lead Locking Key)

Press this key to lock the lead while ECG recording. After that, the corresponding ECG will be a line. It is always used to draw the baseline to zero quickly in the case of baseline excursion in actual ECG recording. The lead will be unlocked automatically after 0.4

seconds.

4) 1mV Calibration Key

Under manual mode, this key can be pressed to record a 1mV calibration pulse at any time while recording and the ECG trace will re-center.

5) MODE (Mode Switch Key)

There are four automatic modes and a manual mode. This key can be pressed to select recording mode. The switching order of leads in each mode is listed in Table 3-1.

Table 3-1 Lead Switching order of Different Mode

Mode	Switching Order (from left to right)											
MANU	I	II	III	AVR	AVL	AVF	V1	V2	V3	V4	V5	V6
AUTO1	I	II	III	AVR	AVL	AVF	V1	V2	V3	V4	V5	V6
AUTO2	AVL	I	AVR	II	AVF	III	V1	V2	V3	V4	V5	V6
AUTO3	I	AVR	V1	V4	II	AVL	V2	V5	III	AVF	V3	V6
AUTO4	2 channel automatic mode (AUTO1 + Rhythm Lead)											

6) LEAD (Lead Switch Key)

Under manual mode, press the key to switch the lead in order.

7) PRINT/STOP Key

Used to begin recording and stop recording.

8) ON/OFF Key

When the unit has been powered on, press this key to turn on or turn off the electrocardiograph.

9) MENU Key

Press **MENU** key to enter menu settings interface.

10) ID Setting Key

These two **ID** keys can be pressed to set the patient's ID number. Press the upward arrow key to increase ID number while press the downward arrow to decrease ID number on the basis of current ID number.

11) M/F

Press **M/F** key to choose sex, male (M) or female (F).

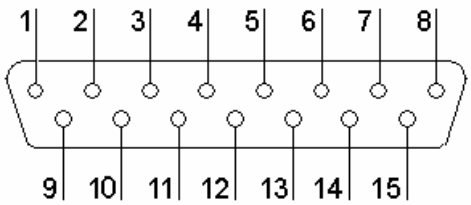
12) AGE

Press **AGE** key to set age: child (CHD), adult (ADL) or elder (OLD).

3.2 Patient Cable Socket and Signal Interface

There are sockets including the patient cable socket, RS232 socket, external input/output socket and USB interface (reserved) at the right side of the main unit as **Figure 3-1** shows.

1) Patient Cable Socket



: Defibrillation-proof applied part of type CF

: Attention – see accompanying document

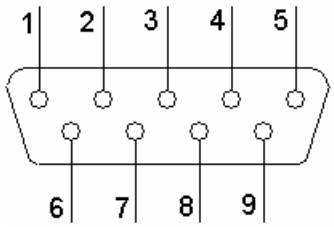
Definition of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	C2 (input)	**6**	N or RF (input)	**11**	F (input)
2	C3 (input)	**7**	NC	**12**	NC
3	C4 (input)	**8**	NC	**13**	NC
4	C5 (input)	**9**	R (input)	**14**	N or RF (input)
5	C6 (input)	**10**	L (input)	**15**	NC

2) RS232 Socket

WARNING:

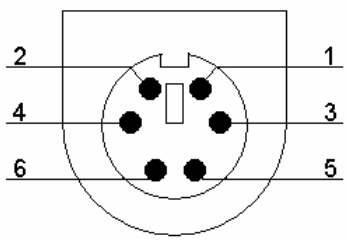
RS232 interface is 1500V AC isolated intensity and the maximum voltage applied should not exceed +15V DC.



Definition of corresponding pins:

Pin	Signal	Pin	Signal	Pin	Signal
1	NC	**4**	NC	**7**	NC
2	RxD (input)	**5**	GND	**8**	NC
3	TxD (output)	**6**	NC	**9**	NC

3) External Input/Output Socket



Definition of corresponding pins:

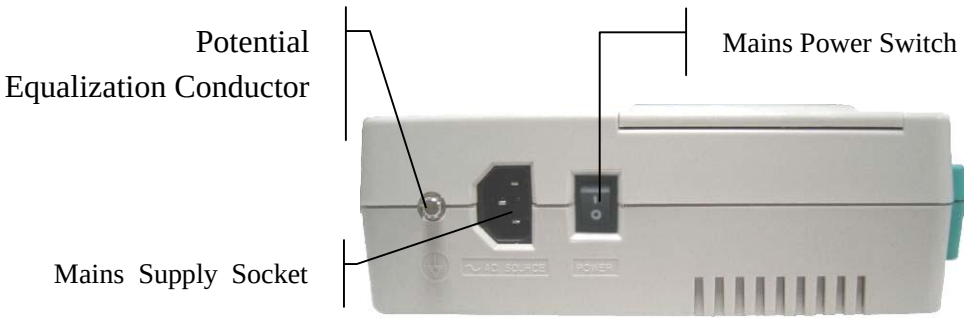
Pin	Signal	Pin	Signal
1	GND	**4**	GND
2	GND	**5**	ECG Signal (input)
3	GND	**6**	ECG Signal (output)

4) USB Interface (Reserved)

⚠**WARNING**⚠:

- Accessory equipment connected to the interfaces must be certified according to the respective IEC standards (e.g. IEC60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC 60601-1-1. Therefore anybody, who connects additional equipment to the input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult our technical service department or your local distributor.
- The summation of leakage current should never exceed leakage current limits while several other units are used at the same time.

3.3 Mains Connection and Switch



At the left side of the main unit, there is the mains supply socket, power switch and potential equalization conductor as the above figure shows.

1) Potential Equalization Conductor

⏚ Potential equalization conductor provides a connection between the unit and the potential equalization bus bar of the electrical installation when necessary.

2) Mains Supply Socket

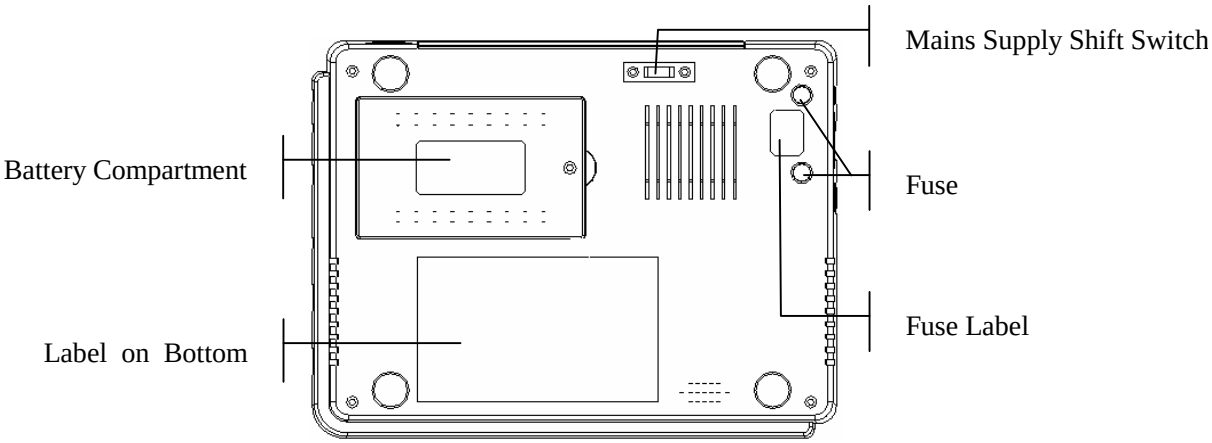
~ AC SOURCE: alternating current supply socket

3) Power Switch

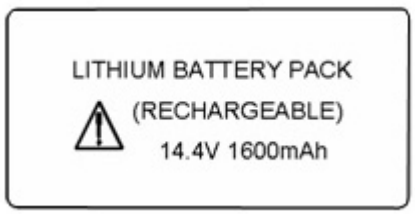
| : Switch on the mains power supply

○ : Switch off the mains power supply

3.4 Bottom Panel



1) Battery Compartment

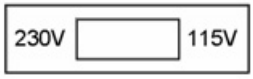


The battery label indicates the rated voltage and rated capacity of rechargeable Lithium battery pack. Rated voltage: 14.4V, Rated capacity: 1600mAh.

⚠ Attention – general warning (see accompanying document)

⚠**WARNING**⚠: Only qualified service engineer authorized by EDAN can open the battery compartment and replace the battery. And the battery of same model and specification provided by manufacturer must be used.

2) Mains Supply Shift Switch



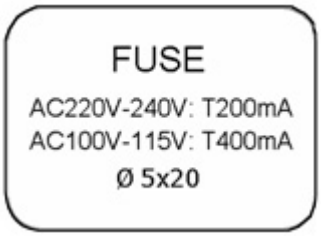
Mains supply with rated input voltage 230V (220V~240V) or 115V (100V~115V) can be

chosen by the shift switch according to local mains supply specification.

⚠**WARNING**⚠: Only qualified installation or service engineer can shift the mains shift switch according to local mains supply.

3) Fuse

There are two same fuses installed on the bottom of the main unit. The specification is showed on the fuse label: AC220V-240V: T200mA; AC100V-115V: T400mA; Φ5×20.



⚠**WARNING**⚠: Ruptured fused must only be replaced with the same type and rating as the original.

4 Operation Preparations

CAUTION: Before use, the equipment, patient cable，electrodes and other accessories should be checked. Replace it if there is any evident defectiveness or aging which may impair the safety or performance. And be sure that the equipment is in proper working condition.

4.1 Power Supply

WARNING: If the integrity of external protective conductor in installation or arrangement is in doubt, the equipment should be operated from the built-in rechargeable battery.

The electrocardiograph can be powered either by mains supply or the built-in rechargeable lithium battery pack.

1) Mains supply

The mains connection socket is on the left of the unit. If mains supply used, connect the power cord to the socket first, and then connect the plug of the cord to the hospital grade outlet.

Rated input voltage: 100V~115V or 220V~240V

Rated frequency: 50Hz/60Hz

Rated input power: 35VA

Make sure the mains supply meets the above requirements before power on. And then press the mains power switch to power on the unit. Then the mains supply indicator (∿) will be lit as well as the battery recharging indicator (→▭).

If the built-in rechargeable battery is weak when mains supply used, the battery recharging indicator will be still lit after **ON/OFF** key pressed, which means the battery is recharged. If the battery capacity if full, the recharging indicator will be black after **ON/OFF** key pressed.

2) Built-in rechargeable battery

While the built-in rechargeable lithium battery pack used, turn on the unit by pressing **ON/OFF** key on control panel directly and the battery indicator (▭) will be lit.

The battery symbol ▭ will be displayed on the LCD screen. Because of the consumption during storage and transport, the capacity of battery may not be full. If the symbol ▭ and the alarm information “BATTERY WEAK” are displayed, which means the battery

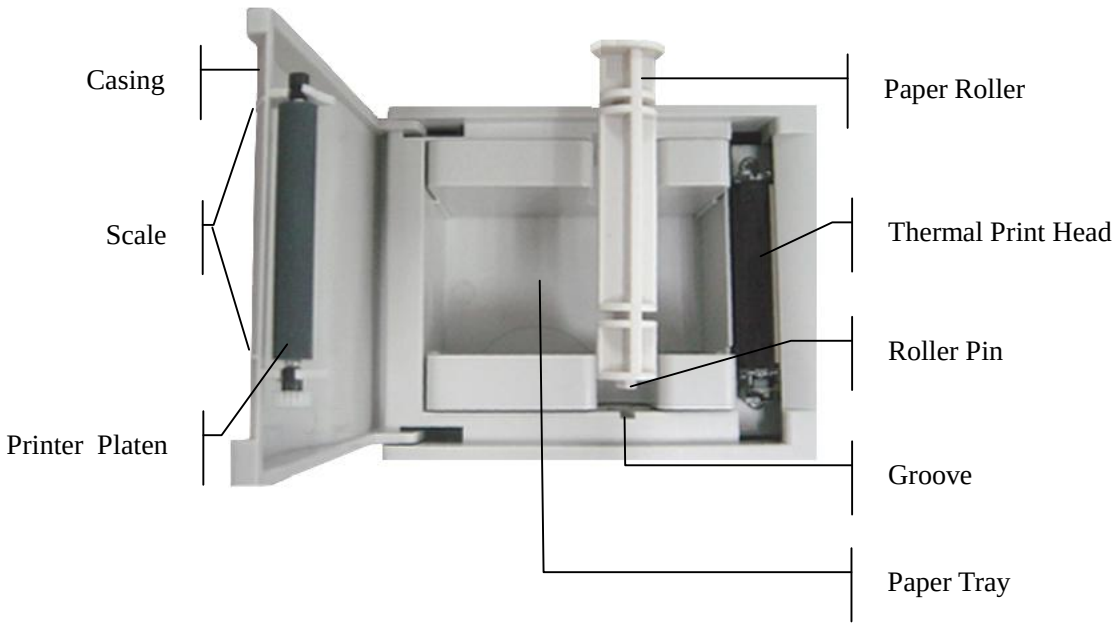
capacity is weak. And in this circumstance please recharge the battery first.

Note: Please refer to the maintenance section for how to recharge the battery. During recharging the battery, the electrocardiograph can be powered by mains supply at the same time.

⚠**WARNING**⚠: Potential equalization conductor of the unit should be connected to the potential equalization bus bar of the electrical installation when necessary.

4.2 Loading/Replacing Record Paper

Rolled thermal paper with 50mm width is used as ECG record paper. When there is no record paper loaded or it reaches the end of record paper, warning message "PAPER?" will be given on the LCD screen. Under this circumstance, record paper should be loaded or replaced immediately.



Loading/Replacing Procedures:

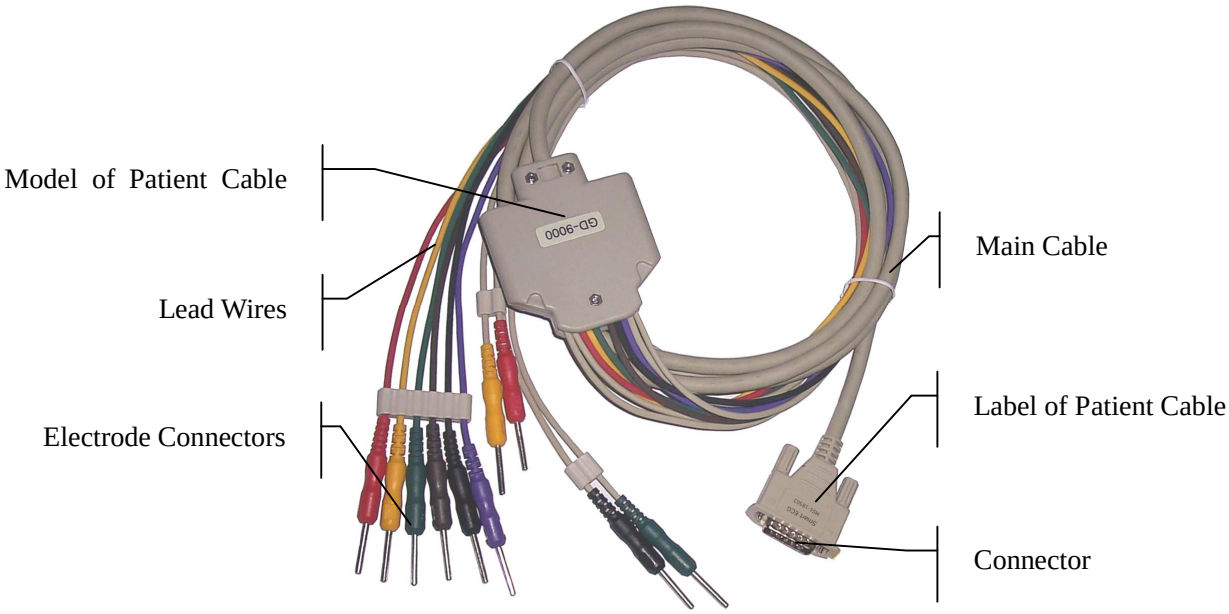
1) Place fingers under the flange of the recorder casing, pull upwards directly to release the casing;
2) Take out the paper roller, and remove remain paper from the left of roller if necessary;
3) Take off the wrapper of the new thermal paper roll, and then put through the roller from the left with the paper's grid side facing downward.
4) Then place the paper and roller gently in the paper tray with the roller pin on the roller's left side facing to the groove;

5) Pull about 2cm of the paper out, and put down the recorder casing with the paper's side edges in parallel with the scale on the surface of casing;

6) Secure the casing by pressing it firmly.

4.3 Patient Cable Connection

Patient cable includes two parts, main cable and lead wires with associated electrode connectors. The electrode connectors can be distinguished from the color and identifier on them.



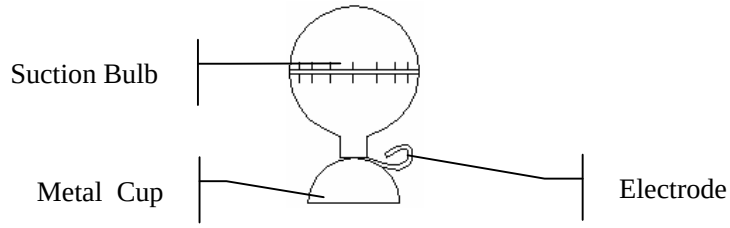
Connect Main Cable: Plug the connector of main cable into the patient cable socket on the right side of the unit, and secure the screw.

⚠**WARNING**⚠:

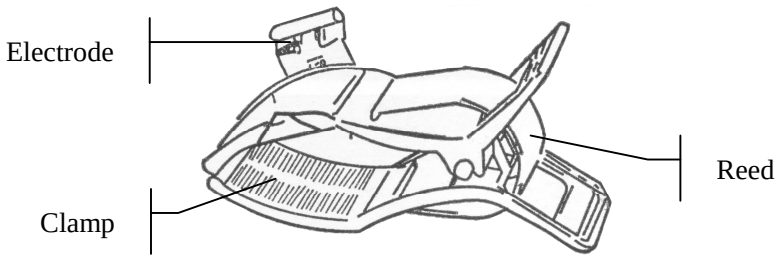
- This product is CF classified and defibrillation protected only when the original patient cable is used. However, as a safety precaution when possible, remove electrodes before defibrillation.
- Precautions must be observed when using high frequency devices. Use the special high frequency EDAN patient cable to avoid possible signal interference during ECG acquisition.

4.4 Electrodes Connections

Chest Electrode:



Limb Electrode:

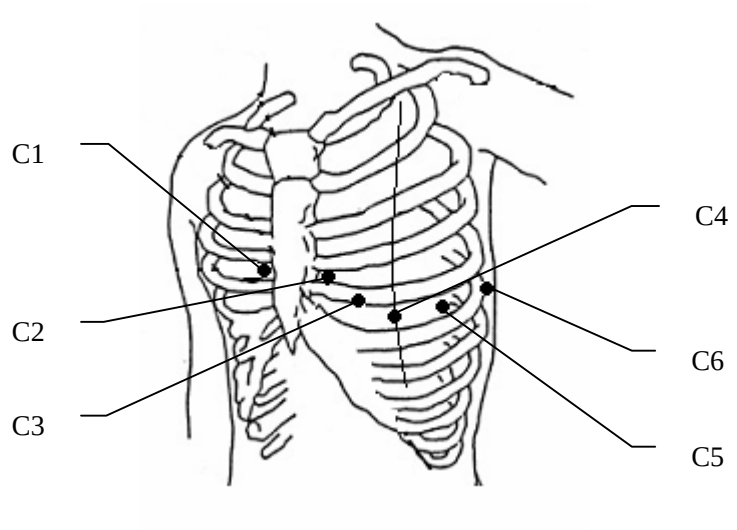


The identifier and color code of electrodes used complies with IEC requirements. In order to avoid incorrect connections, the electrode identifier and color code is specified in Table 4-1. Moreover the equivalent code according to American requirements is given too.

Table 4-1 Electrodes, Identifier and Color Code

	European		American	
Electrodes	**Identifier**	**Color code**	**Identifier**	**Color code**
Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Right leg	N or RF	Black	RL	Green
Left leg	F	Green	LL	Red
Chest 1	C1	White/red	V1	Brown/red
Chest 2	C2	White/yellow	V2	Brown/yellow
Chest 3	C3	White/green	V3	Brown/green
Chest 4	C4	White/brown	V4	Brown/ blue
Chest 5	C5	White/black	V5	Brown/orange
Chest 6	C6	White/violet	V6	Brown/violet

As the following figure shows, the chest electrodes' position on body surface is



C1: Fourth intercostals space at right border of sternum

C2: Fourth intercostals space at left border of sternum

C3: Fifth rib between C2 and C4

C4: Fifth intercostals space on left midclavicular line

C5: Left anterior axillary line at the horizontal level of C4

C6: Left midaxillary line at the horizontal level of C4

The contacting resistance between the patient and the electrode will affect the quality of ECG greatly. In order to get a high-quality ECG, the skin/electrode resistance must be minimized while connecting electrodes.

Chest electrodes connection:

1) Ensure the electrodes to be clean firstly;
2) Align all lead wires of patient cable to avoid twisting, and connect the associated electrode connectors with corresponding electrodes according to the color and identifier;
3) Clean electrode area on chest surface with alcohol;
4) Daub the round area of 25mm diameter on each electrode site with gel evenly;
5) Place a small mount of gel on the brim of chest electrode's metal cup;
6) Place the electrode on chest electrode site and squeeze the suction bulb. Unclench it and then the electrode is adsorbed on chest. Attach all chest electrodes in the same way.

Limb electrodes connection:

1) Ensure the electrodes to be clean firstly;
2) Align lead wires of patient cable to avoid twisting, and connect the electrode connectors

to corresponding electrodes according to the color and identifier;

3) Clean electrode area on a short distance above the ankle or wrist with alcohol;
4) Daub the electrode area on limb with gel evenly;
5) Place a small amount of gel on the metal part of limb electrode clamp;
6) Connect the electrode to limb, and be sure that the metal part be placed on the electrode area above the ankle or wrist. Attach all limb electrodes in the same way.

⚠**WARNING**⚠:

- Be sure that all electrodes have been connected to the patient correctly before operation.
- Be sure that the conductive parts of electrodes and associated connectors, including neutral electrode, should not contact with earth or any other conducting objects.
- There is no danger when using the electrocardiograph with electrical stimulation equipment. However, the stimulation units should only be used at a sufficient distance from the electrodes .If in doubt, the patient should be disconnected from the device.
- Electrodes with defibrillation protection should be used while defibrillating.
- Do not touch the unit casing during defibrillation.

4.5 Inspection before Switching on

In order to avoid safety hazards and get good ECG record, the following inspection procedures are recommended before turning on the unit and beginning operation.

1) **Environment**:
   - Check and make sure that there is no electromagnetic interference source around the equipment, especially large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment etc. Switch off these devices when necessary.
   - Keep the examination room warm to avoid muscle action voltages in ECG signal caused by cold.

2) **Power Supply**:
   - If mains power used, please check whether the power cord has been connected to the unit well. And the grounded three-phase outlet should be used.

- Recharge the battery first before use when the battery capacity is weak.

3) **Patient Cable**:

- Check whether the patient cable has been connected to the unit firmly, and keep it far away from the power cord.

4) **Electrodes**:

- Check whether all electrodes have been connected to lead wires of patient cable correctly according to the identifier and color.
- Be sure that all electrodes have been connected to the patient correctly.
- Ensure that the chest electrodes haven't contacted with each other.

5) **Recorder Paper**:

- Ensure that there is enough recorder paper loaded correctly.
- Make sure the case of the recorder has been secured.

6) **Patient**:

- The patient should not contact with conducting object such as earth, and metal part of bed etc.
- Ensure the patient is warm and relaxed, and breathe calmly.

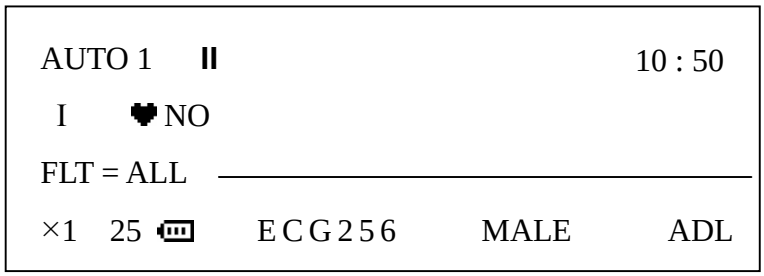
⚠**WARNING**⚠: The electrocardiograph is provided for the use of qualified physicians or personnel professionally trained. And they should be familiar with the contents of this user manual before using.

5 Operation Instructions

5.1 Switching On

- While mains supply used, press the power switch on the left side of the unit first, and the mains supply indicator (∿) is lit. Then press **ON/OFF** key on the control panel to turn on the unit. Equipment information such as name, manufacturer and version etc., will be displayed on LCD screen after self-test. Then the electrocardiograph is ready for examination and recording.
- While built-in rechargeable lithium battery used, press **ON/OFF** key on the control panel directly to turn on the unit, and then the battery indicator (▭) is lit. After self-test, the electrocardiograph is ready for examination and recording.

5.2 Patient Information Input



1) ID Number

Press **ID** (upward arrow) key to increase ID number or **ID** (downward arrow) to decrease it on the basis of current number. The number will be displayed for one or two seconds in the last row on LCD screen such as 'ECG 256' in the above figure.

Under the following circumstances, the ID number may increase automatically:

- Under automatic recording mode, **PRINT/STOP** key can be pressed to record the ECG automatically. When one full lead ECG record finished, or **PRINT/STOP** key is pressed during the recording course, the ID number will automatically increase one when begin recording again.
- Under manual recording mode, press **PRINT/STOP** key to record ECG. If **PRINT/STOP** key is pressed during the course of recording, the ID number will automatically increase one when begin recording again.

2) SEX

Press **M/F** key to set the sex: female or male, which will be displayed for one or two seconds in the last row on LCD screen.

3) AGE

Patients are divided into three groups based on age: CHD (child), ADL (adult), OLD (elder). Press **AGE** key to set the age group, which will be displayed for one or two seconds in the right down corner of LCD screen.

Note: The patient information mentioned above can not be set or changed during the course of recording.

5.3 Menu Settings

19 items in the menu are listed in Table 5-1. In the **Options** column, the value double underlined is the default settings.

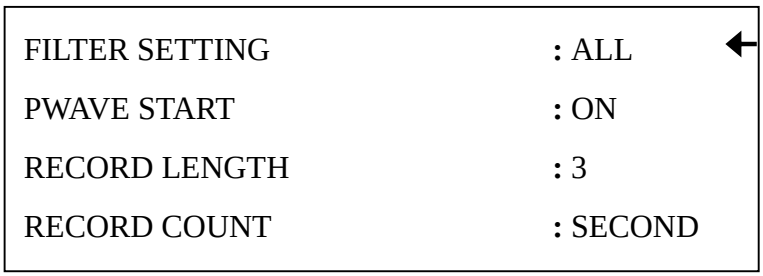
Table 5-1 Menu Items

No.	Menu Items	Options
1	FILTER SETTING	AC, ALL, OFF, EMG
2	PWAVE START	ON, OFF
3	RECORD LENGTH	2, 3, 4, …, 11, 12
4	RECORD COUNT	SECOND, QRS
5	RECORD SPEED	25, 50 (unit: mm/s)
6	HEARTRATE PRINT	ON, OFF
7	YEAR	0~99
8	MONTH	1~12
9	DAY	1~31
10	HOUR	0~23
11	MINUTE	0~59
12	PRINT HEAD TEST	ON, OFF
13	DEFAULT SETTING	NO, RESTORE
14	EXTINPUT RECORD	ON, OFF
15	KEY BEEP	ON, OFF

16	QRS BEEP	ON, OFF
17	RHYTHM LEAD	I, II, III, AVR, AVL, AVF V1, V2, V3, V4, V5, V6
18	LOWPASS FILTER	NO, 75HZ, 100HZ, 150HZ
19	LANGUAGE	ENG, CHN

Setting Method:

1) Press **MEMU** key to enter menu settings displayed as the following figure;



2) Press **ID** key (upward or downward) to move the arrow at the right of LCD screen to the item to be changed. Take 'FILTER SETTING' as for example. The arrow ← stop at the item of FILTER SETTING.
3) Then press **M/F** key or **AGE** key to choose the setting options (EMG, AC, ALL, OFF);
4) Repeat 2) and 3) to set other items in the same way;
5) After modifying the items which need to be changed, press **MENU** key again to quit the menu interface with new settings.

Note: Set the DEFAULT SETTING as RESTORE, and then the defaults of all items will be reloaded except date, time and language.

Descriptions of some items and their settings are given in the following sections.

5.3.1 Filter Settings

The filter can be chosen among EMG, AC, ALL (both of EMG and AC) or OFF (no filter). When choose OFF, the filter will not work. Generally, ALL is recommended to be set in order to get better ECG record.

5.3.2 Recording Settings

Recording settings includes start, length, count unit, speed and contents. Such as:

PWAVE START : ON

RECORD LENGTH : 3

RECORD COUNT : SECOND

RECORD SPEED : 25

HEARTRATE PRINT : ON

Take the above settings as example, the ECG will be recorded from P wave, and the printing speed is 25mm/s. The record length of each lead is 3 seconds. And the heart rate will be printed out at the bottom of each lead recording beginning.

When QRS is taken as recording count unit, the record length will be 3 periods of QRS wave.

Note: The record duration of each lead must be longer than 2 seconds. So when QRS is chosen to be the count unit, no matter how long the record length is, if the period of QRS wave is too short, the electrocardiograph will keep recording for 2 seconds.

5.3.3 Date and Time Settings

The date and time on LCD screen and ECG record can be set in the following items:

YEAR : 4

MONTH : 8

DAY : 6

HOUR : 14

MINUTE : 25

As the above settings, the date & time is Aug. 6th, 2004, 14:25 PM. And it will be printed out as 2004-8-6-14:25 on the record.

5.3.4 Print Head Test

PRINT HEAD TEST : OFF

Print head test is used to check whether the print head can work normally or not. The default status of print head test is OFF. Turn on this item when the print paper has been loaded. Then the triangle wave in effective paper width will be printed out. The status of print head can be estimated from this triangle wave.

5.3.5 External Input/Output Settings

External input/output signal interface is equipped in the electrocardiograph, through which

ECG signal from external equipment can be received, and ECG signal detected by the electrocardiograph can be transmitted to other external equipment. Set the EXTINPUT RECORD as ON to turn on the function and OFF to turn off.

5.3.6 Key and QRS Beep Settings

KEY BEEP : ON

QRS BEEP : OFF

When KEY BEEP is ON, a short beep sound will be heard when press the control key. When KEY BEEP is OFF, there is no sound while pressing the key.

During the course of ECG recording, if QRS BEEP is ON, the unit will make a short beep sound when an R wave has been detected. So in normal recording, continuous and regular sound of beep will be heard.

5.3.7 Rhythm Lead Settings

RHYTHM LEAD : Π

Under AUTO 4 mode, ECG of one channel and a rhythm channel lead can be recorded. The rhythm lead can be anyone of 12 standard leads: I, Π, ΙΙΙ, AVR, AVL, AVF, V1, V2, V3, V4, V5, and V6.

5.4 Sensitivity Switching

There are five options of sensitivity:

×1 (10mm/mV) → ×2 (20mm/mV) → AGC → · 25 (2.5mm/mV) → · 5 (5mm/mV)

Press 

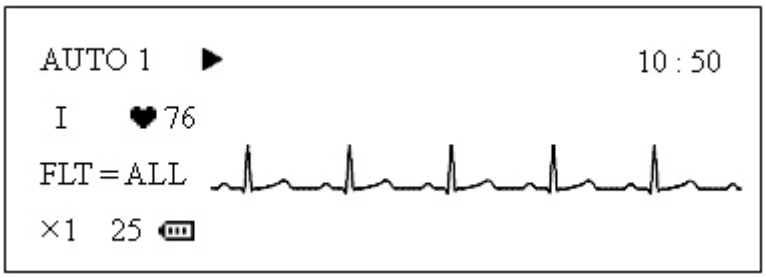
key to choose the appropriate sensitivity to achieve better ECG record according to the signal range that can be measured. Refer to **Section 3.1.2** for details about signal range under different sensitivity.

This key can be pressed during the course of examination or recording under manual mode while it is ineffective during the course of recording under automatic mode.

5.5 Automatic Mode Operation

Four automatic recording modes are provided by this electrocardiograph, AUTO 1, AUTO 2, AUTO 3 and AUTO4. Two channels, including a rhythm lead, can be recorded together under

AUTO 4 mode. The lead switching orders under different modes are listed in Table 3-1 in **Section 3.1.2**.



Under automatic mode, leads will be switched in order automatically while recording ECG. That means when ECG signal from one lead has been recorded for the set length such as 3 seconds, it will be switched to the next lead and begin recording another ECG signal. And there is a pause for several seconds before recording the next ECG signal under the modes of AUTO1, AUTO2 and AUTO3. Moreover, a 1mV calibration pulse will be printed on the record automatically before ECG of each lead.

Operation Procedures:

1) Press **MODE** key to choose automatic mode, which will be displayed in the left top corner on LCD screen;
2) If AUTO4 has been chosen, rhythm lead can be selected by pressing **MENU** key to set RHYTHM LEAD. The rhythm lead can also be set before selecting mode. Moreover there is no pause between different leads while recording.
3) Then press **PRINT/STOP** key to begin recording. The symbol ▶ means ECG is recorded now. It will stop automatically after a full 12-lead ECG printed out.

Pressing **PRINT/STOP** again during the course of recording can stop printing. However, when beginning record later, ECG will be recorded in order from the first lead again. And ID number will increase one automatically. If the ID number needs not to be changed, **ID** key should be pressed to adjust it before recording.

Note: Recording mode can not be changed during the course of printing. Stop recording before choose another recording mode.

5.6 Manual Mode

Under manual mode, users can determine the lead to be recorded and set the record settings or other parameters according to different leads.

Operation Procedures:

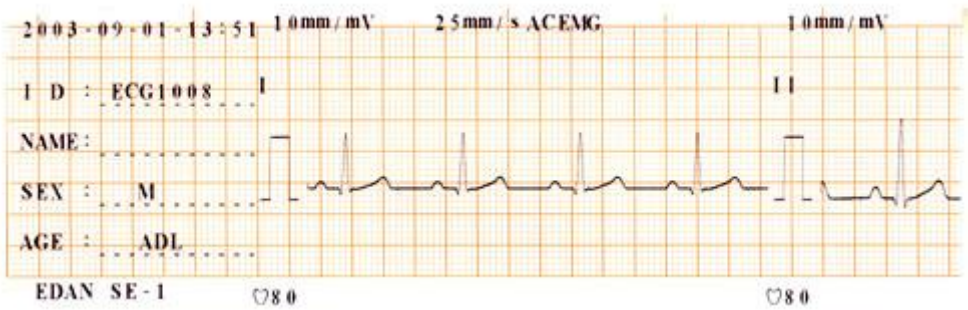
1) Press **MODE** key to choose MANU mode, which can be discerned by the identifier on

the left corner of LCD screen as MANU;

2) Press **LEAD** key left arrow or right arrow key to select the lead to be recorded;
3) Press **MENU** key to set the record settings or other settings. After setting, press **MENU** key again to confirm the settings;
4) Then press **PRINT/STOP** key to begin recording;
5) **1mV** calibration key can be pressed to print out 1mV pulse wave in the record while ECG recording;
6) Press **PRINT/STOP** key to stop printing after finishing ECG record.

Note: **LEAD** left and right arrow key can be pressed to switch the lead during the course of recording.

5.7 ECG Record



As the above figure shows, the ECG record includes: date and time, ID number, name (written by doctor later), sex, age, sensitivity, paper speed, filter settings, lead name, 1mV calibration pulse, ECG, heart rate, manufacturer and model of the equipment.

At the beginning of each lead's ECG, lead name and 1mV calibration pulse is printed. On the top of the ECG record of each lead, sensitivity is marked. The sensitivity may be different, for it can be changed during the course of recording.

5.8 Switch Off

When built-in battery pack used, press **ON/OFF** key directly to turn off the unit after finishing ECG record.

When mains supply used, press **ON/OFF** key first after finishing ECG record and then switch off the mains supply by pressing the switch on the left side of the unit. Pull off the plug from the outlet last.

6 Alarm Information

Alarm information will be displayed on the LCD screen when there is something wrong. Alarm information provided by the electrocardiograph and corresponding cause is listed in Table 6-1.

Table 6-1 Alarm Information and Causes

Alarm Information	Causes
LD OFF	Electrodes fall off from the patient or the patient cable falls off from the unit.
PAPER?	Record paper has not been loaded or it has been used out.
BATTERY WEAK	The built-in battery is weak.
--	The heart rate is over 250BPM.
--	The heart rate is below 30BPM.
--	Heart rate has not been detected in 2 seconds.
OVR	The ECG signal exceeds the measuring range under certain sensitivity.

7 Technical Specifications

Safety Standards	1) MDD93/42/EEC 2) IEC60601-1 3) EN 60601-1-4 4) IEC60601-2-25 5) EN 60601-2-51 6) EN ISO14971 7) EN 55011 8) ANSI/AAMI EC-11

Classification	Anti-electric-shock type:	Class I with internal power supply
	Anti-electric-shock degree:	Type CF with defibrillation proof
	Degree of protection against harmful ingress of water:	Ordinary equipment (Sealed equipment without liquid proof)
	Disinfection/sterilization method:	Refer to the user manual for details
	Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas
	Working mode:	Continuous operation
	EMC:	Group I, type A
Dimensions	288mm×210mm×70mm	
Weight	About 2.3kg	
Display	192 × 64 pixels color LCD	

		Transport	Storage	Working
Environment	Temperature	-20℃~50℃	-10℃~40℃	5℃~40℃
	Relative Humidity	25%~95% No Condensation	25%~95% No Condensation	25%~85% No Condensation
	Atmospheric Pressure	700hPa ~1060hPa	700hPa ~1060hPa	860hPa ~1060hPa

Power Supply	Mains Supply	Rated input voltage =100V~115V/220V~240V
		Rated frequency = 50/60Hz
		Rated input power = 35VA
	Built-in Lithium Battery Pack	Rated voltage = 14.4V
		Rated capacity = 1600mAh
		Charge mode: Constant current/voltage
		Charge current (standard) = $0.2C_5A$ (320mA)
		Charge voltage (standard) = (16.8±0.1V)
		Cycle life ≥ 300 times
	Power Consumption	35VA
	Fuse	T200mA Ø5×20 or T400mA Ø5×20

Recording	Recorder	Thermal dot-matrix printer
	Thermal Print Head	Dot structure: 384 dots/line Dot pitch: 0.125mm (8 dots/mm) Dot size: 0.125mm×0.12mm
	Record Paper	Rolled thermal paper
	Paper Width	50mm
	Effective Width	48mm
	Paper Speed	25mm/s, 50mm/s
	Accuracy	±3%

HR Recognition	Technique	Peak-peak detection
	HR Range	30BMP~250BMP
	Accuracy	±1BMP

ECG Unit	Leads:	12 standard leads
	Acquisition Mode:	One lead

	A/D Resolution:	12 digit
	Time Constant:	≥3.2s
	Frequency Response:	0.05Hz ~ 150Hz
	Sensitivity:	2.5, 5, 10, 20 (mm/mV)
	Input Impedance:	≥10MΩ
	Input Circuit Current:	≤50nA
	Input Voltage Range	<±5 mVpp
	Calibration Voltage:	1mV±3%
	Noise:	<15μVp-p
	Filter	EMG Filter: 35Hz (-3dB)
		AC/DFT Filter: 50Hz/60Hz (-20dB)
	CMRR	>90dB; >100dB (with AC filter)
Patient Leakage Current:		<10μA (220V~240V)
Patient Auxiliary Current:		<0.1μA (DC)
Dielectric Strength:		4000V rms

External Input/Output (Optional)	Input (Single ended)	≥100kΩ; Sensitivity10mm/V±5%;
	Output (Single ended)	≤100Ω; Sensitivity1V/mV±5%;
Communication Interface	RS232 (Refer to Section 3.2 for details)	

8 Cleaning, Care and Maintenance

8.1 Cleaning

CAUTION: Turn off the power before cleaning and disinfection. If mains supply used, the unit should be switched off first and the power cord should be plugged out of the outlet.

8.1.1 Cleaning the Main Unit and Patient Cable

The surface of the main unit and patient cable can be wiped with a clean soft cloth damped in soapy water or non-caustic neutral detergent. After that, remove detergent remainder with a clean dry cloth.

8.1.2 Cleaning the Electrodes

Remove the remainder gel from the electrodes with a clean soft cloth first. For chest electrodes, take the suction bulb and mental cup of chest electrodes apart, and for limb electrodes take the clamp and the metal part of the limb electrodes apart. Clean them in warm water and be sure there is no remainder gel. Dry the electrodes with a clean dry cloth or air dry naturally.

8.1.3 Cleaning the Print Head

Dirty and soiled thermal print head will deteriorate the record definition. So it should be cleaned at least once a month regularly.

Open the recorder casing and remove the record paper. Wipe the print head and printer platen gently with a clean soft cloth damped in 75% alcohol. For stubborn stain, soak it with a little alcohol first and wipe it off with a clean soft cloth. After air dried, load the record paper and shut the casing of the recorder.

CAUTION:

- Prevent the detergent from seeping into the main unit while cleaning. Do not immerse the unit or patient cable into liquid under any circumstances.
- Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes and thermal print head.

8.2 Disinfection

To avoid permanent damage to the equipment, disinfection can be performed only when it has been considered as necessary according to your hospital's regulations.

Before disinfection clean the equipment first. Then wipe the surface of the unit and patient cable with 70% isopropyl alcohol. Wipe the surface of electrodes with 70% alcohol or isopropyl alcohol. Never immerse the unit, cable or electrodes into disinfectant solution.

CAUTION: Do not use chloric disinfectant such as chloride and sodium hypochlorite etc.

8.3 Care and Maintenance

8.3.1 Recharge and Replacement of Battery

1) Capacity Identification

Current capacity of the rechargeable battery can be identified according to the battery symbol in the last row on LCD screen.

: Full capacity

: Not full but enough

: Capacity is limited, and recharge should be taken into account

: Battery is weak; and warning message "BATTERY WEAK" will be displayed on LCD screen. The battery should be recharged immediately

2) Recharge

The electrocardiograph is equipped with recharge control circuit together with built-in rechargeable lithium battery. Once the main unit is connected to mains supply with power cord, the battery will be recharged automatically. And then the battery recharge indicator ( ) and the mains supply indicator ( ) will be lit at the same time. When the capacity of battery is full, the battery recharge indicator ( ) will be black.

Because of the capacity consumption during storage and transport, the capacity of battery is not full while being used at the first time. Battery recharge is recommended before first usage.

3) Replacement

When the useful life of battery is over, or foul smell and leakage has been found, please contact with manufacturer or local distributor for replacement of battery.

⚠**WARNING**⚠:

- Only qualified service engineer authorized by EDAN can open the battery compartment and replace the battery. And the battery of same model and specification provided by manufacturer must be used.
- Danger of explosion -- Do not reverse the anode and cathode when connecting the battery.
- When the battery's useful life is over, contact with the manufacturer or local distributor for disposal or dispose the battery according to local regulations.

8.3.2 Record Paper

Storage requirements:

- Record paper should be stored in dry, dark and cool area, avoiding excessive temperature, humidity and sunshine.
- Do not put the paper under fluorescence for long time.
- Be sure that there is no polyvinyl chloride or other chemicals in the storage environment, which will lead to color change of the paper.
- Do not overlap the recorded paper long time, or else the ECG record may trans-print each other.

Note: Record paper provided by manufacturer should be used. Other paper may shorten thermal print head's life. And the deteriorated print head may lead to illegible ECG record and block the advance of paper etc.

8.3.3 Maintenance of Main Unit, Patient Cable & Electrodes

The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

a) Inspect the equipment and accessories for mechanical and functional damage.
b) Inspect the safety relevant labels for legibility.
c) Inspect the fuse to verify compliance with rated current and breaking characteristics.
d) Verify the device functions properly as described in the instructions for use.

e) Test the protection earth resistance according IEC 601-1/1988: Limit 0.2ohm.

f) Test the earth leakage current according IEC 601-1/1988: Limit: NC 500uA, SFC 1000uA.

g) Test the patient leakage current according IEC 601-1/1988: Limit: 10uA (CF).

h) Test the patient leakage current under single fault condition with mains voltage on the applied part according IEC 601-1/1988: Limit: 50uA (CF).

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

⚠**WARNING**⚠: Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

1) Main Unit

- Avoid excessive temperature, sunshine, humidity and dirt.
- Put on the dustproof coat after use and prevent from shaking violently when moving it to another place.
- Prevent any liquid from seeping into the equipment, for it will affect the safety and performance of the electrocardiograph.

2) Patient Cable

- Integrity of patient cable, including main cable and lead wires, should be checked regularly. And be sure that it is conductible.
- Do not drag or twist the patient cable with excessive stress while using. Hold the connector plugs instead of the cable when connect or disconnect the patient cable.
- Align the patient cable to avoid twisting, knotting or crooking in closed angle while using.
- Store the lead wires in bigger wheel to prevent any people from stumbling.
- Once damage or aging of the cable patient has been found, replace it with a new one immediately.

3) Electrodes

- Electrodes must be cleansed after use and be sure there is no remainder gel on them.
- Keep the suction bulb of chest electrode from sunshine and excessive temperature.

- After long-term use, the surface of electrodes will be oxidized because of erosion and other causes. By this time, electrodes should be replaced to achieve high-quality ECG.

CAUTION: The equipment and reusable accessories can be sent back to the manufacturer for recycling or proper disposal after their useful lives.

9 Service Warranty

Material and Manufacture

The warranty period for the main unit and the accessories is 12 months from the date of shipment.

EDAN warrant that there's no defect in material and manufacture. During the warranty period, EDAN will repair or replace the defective part free if the defect has been confirmed as material or manufacture defect.

Software or Firmware

For the software or firmware installed, EDAN will replace the software or firmware free if the defect has been confirmed during 12 months from the date of shipment. But EDAN can not warrant it will not interrupt the use of the product.

CAUTION: All services must be done by the engineers authorized by EDAN.

Limit of Warranty

The charges of freight and others are excluded under warranty.

The warranty is void in the case of

- Assembly, extensions, readjustments of any parts;
- Modification and repair by unauthorized persons;
- Subsequent damage caused by improper use or maintenance;
- Replacement or remove of the label of serial number and manufacturer.

10 Accessories and Ordering Information

The accompanying accessories of the electrocardiograph are listed in Table 10-1.

Table 10-1 Accessories List

No.	Accessory	Manufacturer / EDAN Part No.
1	Power cord	EDAN / M13-36014
2	Patient cable	Tsingtao KOHDEN / MS1-18503
3	Chest electrodes	Tsingtao KOHDEN / MS1-18504
4	Limb electrodes	Tsingtao KOHDEN / MS1-18505
5	Paper roller	EDAN / MS1-19927
6	Thermal paper	EDAN / MS1-19917

The following accessories can also be ordered according to some special usage.

No.	Accessory	Manufacturer / Part No.
1	Earth wire	EDAN / MS2-01952
2	Input/output signal cable	EDAN / MS1-19907
3	Cable for defibrillator-proof electrodes	EDAN / MS1-20035
4	ECG Electrodes	MSB LIMITED/ M15-40016

The main unit and accessories are available by contacting the manufacturer or your local distributor.

Manufacturer:

EDAN INSTRUMENTS, INC.

Address: 3/F - B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, shekou, Nanshan Shenzhen, 518067 P.R. China

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11 EMC Information - Guidance and Manufacture's Declaration

11.1 Electromagnetic Emissions - for all EQUIPMENT and SYSTEMS

<table>
<tr><th colspan="3">Guidance and manufacture's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The Electrocardiograph is intended for use in the electromagnetic environment specified below. The user of the Electrocardiograph should assure that it is used in such and environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Electrocardiograph uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class A</td><td rowspan="3">The Electrocardiograph is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

11.2 Electromagnetic Immunity - for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *Electrocardiograph* is intended for use in the electromagnetic environment specified below. The user of *Electrocardiograph* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±4 kV contact ±6 kV air	It is recommended the use of antistatic materials. If floor are covered with synthetic material, the relative humidity should be at least 50%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±1 kV for power supply lines ±0.5 kV for input/output lines	It is recommended the use of filters on power input lines and enough separation between signal lines and power lines.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

11.3 Electromagnetic Immunity - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity

The *Electrocardiograph* is intended for use in the electromagnetic environment specified below. The customer or the user of *Electrocardiograph* should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the *Electrocardiograph*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	1 V	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

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

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

11.4 Recommended Separation Distances

Recommended separation distances between

portable and mobile RF communications equipment and electrocardiograph

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.35**	**0.117**	**0.233**
0.1	**1.11**	**0.369**	**0.738**
1	**3.5**	**1.17**	**2.33**
10	**11.1**	**3.69**	**7.38**
100	**35**	**11.7**	**23.3**

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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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