

eCTG-8M
Fetal/Maternal Monitor
User Manual

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About User Manual

Shenzhen Luckcome Technology Inc., Ltd bears no responsibility or not guarantee for the occasional or indirect damage caused by using of eCTG-8M. Luckcome bears no responsibility for any result caused by using for other purpose.

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The information of this manual can be changed without prior notice.

Warning: This is not treatment device.

Warning: The computer with central station software can only work as a monitoring device. If user use it for other purpose, central station failed, Luckcome bears no responsibility of after-sale service.

Warning: Do not use the instrument in the presence of flammable gases such as anesthetic agents, or it may cause an explosion.

Warning: Do not rely solely on the alarm system of the Monitor when monitoring the patient. Clinicians should have a close observation of mother clinical situation.

Warning: Only authorized personnel by manufacture can repair this system.

Warning: Alarm silence, alarm off and other important setup can not be changed. Low alarm sound may bring dangers to mother.

Warning: Instrument and related accessories and parts disposal should follow local laws and regulations.

Special storage

This system should stay in dry, suitable storage environment with suitable humidity. It should avoid strong sunlight, with no erosion gas and with good ventilation.

Contraindications: Do not use during Defibrillation, Electrosurgery, or Magnatic Resonance Imaging(MRI).

Lifetime: Its lifetime is 5 years.

Remark:

Warning: User should know that how to avoid damage on patient and clinicians.

Caution: User should know that how to avoid damage on devices.

Note: User should know some important information.

IPX1 closed instrument with water drop proof function.



BF type applied part against electric shock.



: Refer to attached User Manual.



Waste Electrical and Electronic Equipment Directive 2002/96/EC (WEEE Directive).



: Non-Ionizing Radiation

SN

Manufacture's serial number.



class II equipment .

Registration Information:

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Product Model: eCTG-8M

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1 Prefix

1.1 Introduction

Fetal/Maternal Monitor is mainly composed of ultrasound probe, uterine contraction probe, charging seat and power adapter. It is suitable for continuous monitoring of fetal heart rate and uterine contraction pressure during perinatal period. The probe has a display screen to display the current fetal heart rate and uterine contraction pressure.

1.2 Safety Guidance

Probes in this system are devices of internal power supply. It is BF applied parts .

BF protection indicates that patient connection should comply with the requirements of IEC60601-1 on allowable leakage current and dielectric strength.

Ultrasound probe: IPX1 against water.

Before use it, please check its lifetime. Its lifetime is 5 years and manufacturing date is labeled at the bottom side of device.

Warning: Do not use the instrument in the presence of flammable gases such as anesthetic agents, or it may cause an explosion.

Warning: Do not throw battery into fire, avoiding explosion.

Warning: The instrument can be used on one patient at one time.

Warning: Do not use during Defibrillation, Electro surgery or Magnetic Resonance Imaging (MRI), avoiding causing damage to mother.

Warning: Please use Luckcome probes, otherwise instrument may fail to work.

Caution: This instrument must be maintained by qualified engineers.

Caution: This instrument is designed to work continuously, water drop proof type, pay attention to avoid to be splashed.

Caution: Keep this instrument clean and avoid vibrating.

Caution: No high temperature disinfection, electron beam or γ-ray sterilization.

Caution: Electromagnetic interference – ensure the operating environment of the instrument away from strong interference, such as wireless transmitters, mobile phones or other interference.

Caution: The following safety check is done by the authorized person, normally one time per two years or according to test regulation by the public organization.

- ✧ Check whether there are damages in the mechanical and functions.
- ✧ Check whether the relative safety label is easy to identify.
- ✧ Check whether the function is the same as described in the user manual.

Caution: After the effective life of this instrument, please send it back to the manufacturer according to local rules for recycling.

Caution: Disposal the battery properly according to local rules after the capability of battery run out.

Caution: This instrument can only be used by qualified personnel.

Caution: We recommend that exposure to ultrasound should be kept As Low As Reasonably Achievable. This is considered to be good practice and should be observed at all times.

Caution: The battery should be stored in a cool and dry environment.

Caution: When store battery, please don't mix it with metal objects to avoid short-circuit accident.

Caution: Don't use this instrument immediately when it is transferred from a cold environment to a warm and moisture place.

Caution: To ensure electric installation safety, the environment shall be reasonably dust free, without corrosive or combustible gas, or extreme temperature or humidity.

Caution: Please stop operating if this instrument is splashed or has water drops.

Caution: Although the instrument is robust and designed to withstand the clinical use, the unit does contain

delicate components and should be treated with care. This applies especially to the transducers which should not be dropped or knocked.

Caution: The use of water-based gel supplied by certificated suppliers is strongly recommended. Oil based gels can damage the transducer and must not be used. The use of oil based gels will invalidate your warranty.

Caution: Excess gel should always be wiped off after use. The transducer faceplate, transducer body and main unit can be cleaned with a damp cloth impregnated with a mild disinfectant or detergent.

Caution: A soft cloth dampened with 70% can be used for cleaning and disinfection.

Caution: The main unit, transducers and other accessories can't be disinfected by steam.

Caution: TOCO transducer is non-waterproof type, don't use Gel and avoid any liquids into it.

Caution: Do not turn off the volume during monitoring, it is very important to monitor fetal heart sound.

Caution: The accuracy of FHR is decided by machine itself and cannot be adjusted. If you are suspicious of accuracy of the result, you can verify it through other devices like a stethoscope, or you can contact local distributors or manufacturers for help.

1.3 It is needed to confirm fetal alive before using the monitor.

Current technology cannot distinguish fetal heart rate (FHR) signal source from maternal heart rate (MHR) signal sources in all circumstances. Therefore, before the monitoring, you must use a different method to confirm that the fetus is still alive, such as palpation fetal movement, a Fetal stethoscope or a pinard. If you can't hear the fetal heart sound, or fail to address the fetal movements, you will need to use the obstetric ultrasound to confirm fetal survival, and confirm that the fetus is the guardianship of the signal source.

Should have known:

- MHR traces and FHR traces can be rendered extremely similar characteristics, as well as acceleration and deceleration.
- Don't just rely on movement of the trace feature to identify sources of the fetal heart rate. There are only traces of the fetus fetal movement on curve (FM) marks does not always guarantee that the fetus is still alive. Deceased fetus also moves the body and lead to a mark of monitor fetal movements.

Here are a few examples, indicates how the MHR will be identified as FHR by error.

- When Ultrasonic transducer is used:
 - You can pick up signals from the mother source, such as a mother's heart, aorta or great vessels of other beats.
 - When the MHR higher than normal (especially above 100bpm), it is possible to identify where the error occurred.
- When enabling AFM curves (AFM):
 - the following may be causing fetal death and still appear in the context of FM tags:
 - dead fetus in utero during exercise or after exercise.
 - During and after manual palpation of fetal movements (especially if the pressure is too large), the dead fetus will be moving.
 - Movement of the ultrasonic transducer.
 - Ultrasonic transducer detects the motion signal source, such as its main artery.

To reduce the possibility of confusion between MHR and FHR, also recommended that monitoring of maternal and fetal heart rate simultaneously.

1.4 Intended Use

It is intended for monitoring physiological parameters of pregnant women during antepartum examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

It provides Non-Stress testing for pregnant women from the 28th week of gestation.

It is intended for continuous and auscultatory monitoring of uterine contraction pressure(TOCO), fetal heart rate(FHR)

Contraindications: Do not use during Defibrillation, Electrosurgery or Magnatic Resonance Imaging (MRI).

2 General Information

2.1 Product and Working principle

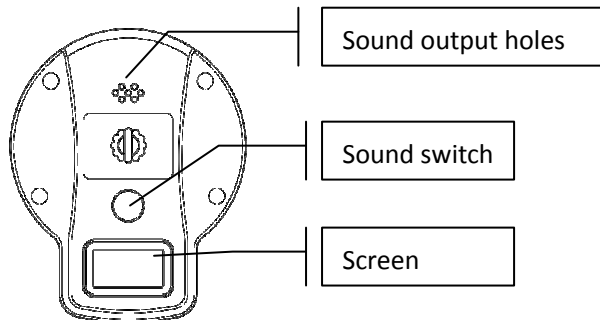
eCTG-8M consist of ultrasound probe, TOCO probe, Charging socket and power adapter.

This working principle: Ultrasound beams produced by ultrasound transducer reach the surface of fetal heart movement. Due to Doppler effect, the frequency of ultrasound frequency shifts. The frequency shifts are detected by the receiving transducer. After signal processing, the low frequency signals related to fetal heart are separated. After amplification and acquisition, the controller is displayed through the display screen.

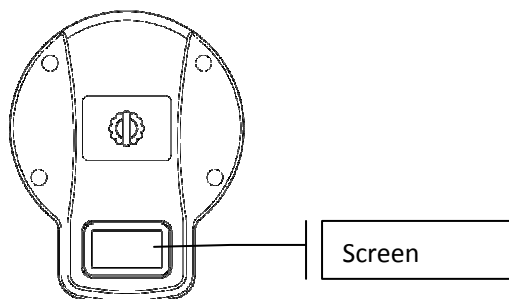
3 Probe

3.1 Probe and Charging Socket

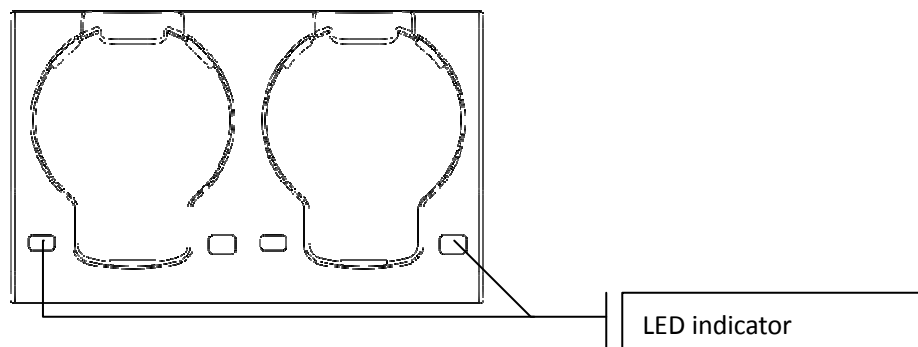
Ultrasound Probe



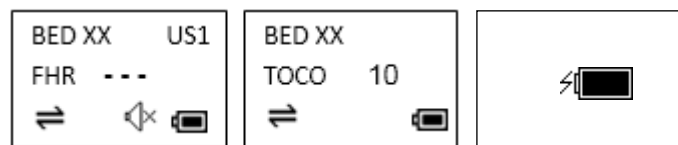
TOCO probe



Charging socket



3.2 Display



BED XX : Probe ID

US1: FHR Probe type

: Probe battery status

---: FHR or TOCO value

: Charging

: Turn off probe sound, : Turn on probe sound

Central software is not activated and running.

→ : Monitoring is not started yet. ⇌ : Started monitoring.

3.3 Charging

Probes are with rechargeable battery. If battery runs out of power, charge it.

Charging time: about 80minutes

Continuous working hour: about 5 hours.

Connect charging socket with AC power, put probe onto charging socket, start charging. During charging, charging grid on battery sweeps; After fully charging, stop sweeping.

Caution: During charging, instrument can not proceed monitoring. Discontinue charging, power on the device, then it start working. Input power is 5V.

4 Fetal Heart Monitoring

4.1 Fetal Heart Monitoring

FHR monitoring is achieved basing on the Doppler Effect. We know that a certain frequency of ultrasonic will be reflected when encountering obstacles in the transmission. If the object is stationary, the reflected wave and the transmitted wave have the same frequency. Once the object moves, the reflecting frequency will change. The reflecting frequency of the object facing the sound source becomes higher, and the reflecting frequency of the object back to the sound source becomes lower. The faster the object moves, the greater the frequency changes. This effect is called the Doppler Effect. Clinically, the ultrasonic sensor is used to emit ultrasonic waves to human body, the echo signal changes when encountering organs in motion, such as the heart, and the heart rate is derived by processing the echo signal.

Clinically, the best position for heart rate monitoring with Doppler is the fetus with its back toward the mother's abdomen. If the fetus is facing the abdomen, the hands and the feet will affect the echo, the fetal turn makes the heart deviate from the irradiation area of the probe, the echo signal will decay, and some of the Doppler components disappear.

4.1.1 Misidentifying MHR as FHR

It does not always mean that the fetus is still alive when the Monitor detects FHR. Before monitoring, confirm that the fetus is still alive, and then confirm that the fetus is the source of recorded heart rate (see 1.3 Confirming the Fetus is Still Alive before Monitoring).

The following examples indicate how MHR is misidentified as FHR.

- **When using an ultrasonic transducer:**

- △ The maternal signal source may be picked up, such as the beats of mother's heart, aorta or other large vessels.
- △ When MHR is higher than normal value (especially above 100bpm), misidentification may occur.

- **When fetal movement curve (FM) is enabled:**

Keep in mind that the only FM mark on the fetal trace does not always indicate that the fetus is still alive. For example, the FM mark still appears when the fetus is dead under the following conditions:

- △ Dead fetus moves during or after the mother moves.
- △ Dead fetus moves during and after manual palpation of fetal movement (especially if the applied pressure is too large).
- △ Movement of the ultrasonic sensor.

4.1.2 Fix FHR probe.

- 1) Remove the probe from the charging socket.
- 2) tie it onto mother belly.

4.1.3 Finding Fetus Heart location

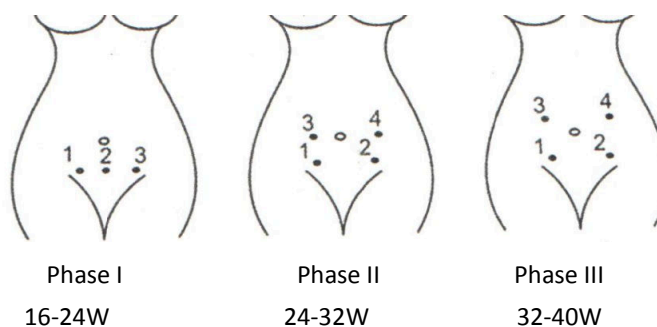
Find position where heart beats is strong by touch; Put appropriate gel on the surface of ultrasound probe and put it near the fetal heart, adjust the probe to get good fetal heart signal (the sound is clear and less noise). User can adjust the sound volume as per clinical requirement. Usually, for the earlier gestational weeks, the fetal heart position is always at 1/3 between navel and pubis, as the fetus grows up, the position will move up, and will be at left or right slightly due to different fetus position. When using the probe, please make sure it touch the skin completely.

Usually, when probe is at the back side of fetus left shoulder, the signal is best. Regular fetal heart sound

can be heard, the FHR value will be on display continuously. Then tie the probe here. If probe change its place during monitoring, adjust it to get best signal.

Note: Please use certified Gel.

Fetus Heart Location reference:



4.2 TOCO Monitoring

Uterine contraction pressure monitoring is to measure uterine activities by placing a TOCO transducer on the abdomen of pregnant woman.

Measure and record the relative pressure changes, as shown below.

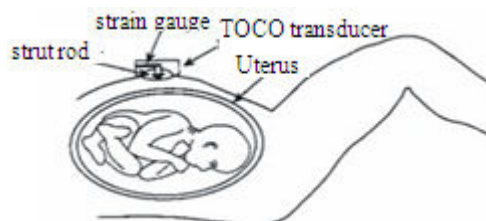


Fig. 6--1 Uterine Contraction Pressure Monitoring Diagram

UC pressure monitoring is to monitor the uterine contractions. UC pressure is the indicator of childbirth strength. Clinically, the uterine contraction has directly affected the fetal heart rate activities and childbirth. The curves recorded by pressure monitoring can provide a lot of information, such as the intensity, frequency and duration of uterine contraction, regularity and shape; the uterine contraction may cause FHR increased or reduced. At present, the FHR monitoring is accompanied by UC pressure monitoring, and the medical personnel can combine UC situation and FHR changes for diagnosis.

External pressure monitoring is to obtain UC pressure from the maternal abdomen. When a contraction occurs, the compression of the abdominal wall tension is applied on the pressure sensor, which will convert the pressure into electric signals. The resulting pressure signals are amplified and processed through the instrument, and finally output or printed.

4.2.1 TOCO Monitoring

Place the TOCO probe on mother's abdomen and fix with strap. The strap should have moderate elasticity. If it is too tight, the peak of uterine contraction may be flat topped and lower than 100 on the pressure gauge. If it is too loose, the probe may slip, causing abnormal readings. Adjust the strap pressure as required.

Warning:

Do not monitor patients underwater if probe is labeled with IPX.

[Note]:

Do not use ultrasonic coupling agent on the UC probe or probe contact area.

[Note]:

Pressure adjustment must be carried out between two uterine contractions.

5 Maintenance

5.1 Maintenance

Before using the instrument, please check if there is any damage of equipment that may affect the patient's safe or the instrument performance. If an obvious damage (broken enclosure or damaged cable) is found, it should be solved or replaced before use.

This instrument has passed professional Medical Testing Laboratory safety test. User can use without concern within its lifetime.

The accuracy of FHR is decided by machine itself and cannot be adjusted. If you are suspicious of accuracy of the result, you can verify it through other devices like a stethoscope, or you can contact local distributors or manufacturers for help.

Ultrasound probes are very fragile and sensitive. Please take it carefully and gently. After using, wipe off gels on time to extend its lifetime.

Display screen should avoid shock and vibration; the environment shall be reasonably dust free, without extreme temperature or humidity. Do not put other items on display screen. It is recommended not to touch screen with hand.

5.2 Cleaning

Before cleaning, turn off the instrument.

Keep instrument clean, without dust. Use dry and soft cloth to clean surface. If needed, use cloth damped with soap water or clean water to clean it.

Use soft cloth to wipe off excessive gel. Probe surface can only be cleaned by soft cloth damped with soap water or clean water.

Caution: Please do not use acetone or other strong solutions.

Caution: Forbid to use abrasive materials such as metal wool or silver polishing agent.

Caution: Do not let any liquid into the enclosure, do not let any part of enclosure immerse into liquid.

Caution: Do not pouring liquid into this instrument during cleaning.

Caution: Do not leave cleaning agent on the surface of this instrument after cleaning.

5.3 Disinfection

After cleaning surface and probe as per above mentioned method, then use 70% alcohol, clean probe, then

Use dry and soft cloth to clean the probe.

Caution:

Do not sterilize the instrument or probe with a pressure cooker or other ways.

5.4 Storage and Transportation

Storage Environment : $-10^{\circ}\text{C} \sim +55^{\circ}\text{C}$, relative humidity: not over 93% , no erosive gas, with good ventilation.

6 Specifications

Model: eCTG-8M

Type of against electrical shock: internal power device

Level of against electrical shock: BF applied part 

Degree of against liquid: Probe IPX1

Safety of anti-flammable gas: can not be used in flammable gas.

Working Mode: Continuous working

EMC: Class 1 B

General Information:

Size: 0.96 dual color OLED display

Resolution: 128*64

Battery: 3.7V rechargeable battery

Working environment: Temperature: +5℃ ~ +40℃; Humidity: ≤80%

Atmospheric pressure: 86kPa ~ 106kPa

Transport and storage temperature: Temperature: -10℃ ~ +55℃; Humidity: < 93%

Atmospheric pressure: 86kPa ~ 106kPa

Bluetooth:

4.0 dual mode

Working frequency range: 2402--2480MHz

Output Power: <10dBm

Sensitivity: -82dBm

Modulation Method :FHSS,GFSK,DPSK, DQPSK

Ultrasound Probe

Working Frequency±15%	Against Liquid	Speaker Power	Weight ±20g
2.0MHz	IPX1	500mW	124g

Transducer: Multi-crystals, Wide beam, pulsed doppler, high sensitivity.

Strength: <5mW/cm²

Probe acoustic output: In accordance with the provisions of 1992 IEC1157, negative peak sound pressure shouldn't exceed 1 MPa, and the beam intensity shouldn't exceed 20mW/cm². Spatial peak instantaneous average intensity density shouldn't exceed 100mW/cm². The sound intensity of this model does not exceed 5mW/cm². Sound output meets the conditions exempted from publication.

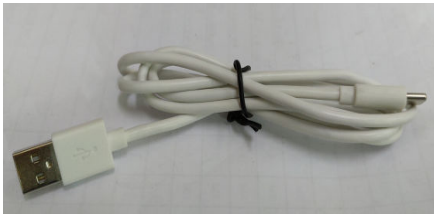
TOCO probe

Against Liquid	Weight ±20g
IPX1	120g

Measurement range: 0~100

Nonlinear error: ≤±10%

Appendix I Accessories List

ID	Name
	Ultrasound Probe
	TOCO probe
	Charging socket
	Power adapter
	USB Cable

Appendix 2 Acoustic Output Reporting Table

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

System Model: eCTG-8M

Transducer Model: US 1

Nominal Frequency: 2.0MHz

Operating Model: PW Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.021	0.083		0.24		N/A
Index component value			N/A	0.083	N/A	0.24	
Acoustic Parameters	$p_{r,s}$ at z_{MI} (MPa)	0.029					
	P (mW)		25.53		25.53		N/A
	P_{1x1} (mW)		N/A		N/A		
	z_s (cm)			2.85			
	z_b (cm)					2.85	
	z_{MI} (cm)	2.85					
	$z_{PIL,s}$ (cm)	2.85					
	f_{awf} (MHz)	2.00	2.00		2.00		N/A
Other Information	p_{rr} (Hz)	2663.00					
	s_{rr} (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa,s}$ at $z_{PIL,s}$ (W/cm ²)	0.033					
	$I_{spta,s}$ at $z_{PIL,s}$ or $z_{SIL,s}$ (mW/cm ²)	8.79					
	I_{spta} at z_{PIL} or z_{SIL} (mW/cm ²)	13.03					
	p_r at z_{PIL} (MPa)	0.035					
Operating control conditions	Focus(mm)	Fixed	N/A	Fixed	N/A	Fixed	N/A
	Depth(mm)	Fixed	N/A	Fixed	N/A	Fixed	N/A
	Frequency(MHz)	2.00	N/A	2.00	N/A	2.00	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Appendix 3 Guidance and Manufacturer's EMC Declaration

Guidance and manufacturer's declaration – electromagnetic emissions

The eCTG-8M is intended for use in the electromagnetic environment specified below. The customer or the user of the eCTG-8M should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The eCTG-8M uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The eCTG-8M is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity The eCTG-8M is intended for use in the electromagnetic environment specified below. The customer or the user of the eCTG-8M 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	±8 kV contact ±15 kV air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for Power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1kV differential mode ±2kV 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	0 % UT (100 % dip in UT) for 0,5 cycle 0 % UT (100 % dip in UT) for 1 cycles 70 % UT (30 % dip in UT) for 25/30cycles 0 % UT (100 % dip in UT) for 250/300 cycles	0 % UT (100 % dip in UT) for 0,5 cycle 0 % UT (100 % dip in UT) for 1 cycles 70 % UT (30 % dip in UT) for 25/30cycles 0 % UT (100 % dip in UT) for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the eCTG-8M requires continued operation during power mains interruptions, it is recommended that the eCTG-8M be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.



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

Recommended separation distances between Portable and mobile RF communications equipment and the eCTG-8M			
The eCTG-8M is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the eCTG-8M can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the eCTG-8M as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.16 \sqrt{P}$	80 MHz to 800 MHz $d = 1.16 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

To ensure your Warranty service, please fill in following Warranty Card:



Warranty Card

Product Name		
Model No.		
Serial No.		
Purchasing Date		
Warranty Expired date		
Customer Info	Name	
	Telephone	
	Fax	
	Address	
Information Source	☐ Network ☐ Exhibition ☐ Magazine ☐ Sales Recommendatin ☐ Others _____	
Note		



FCC Statement:

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help
- This device and its antenna(s) must not be co-located or operating in conjunction with any other antenna or transmitter.