Content

Instructions to User

Dear users, thank you very much for purchasing the CMS50K Wearable SpO_2/ECG Monitor.
This Manual describes, in accordance with the product's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. As well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.
Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment damage due to users' negligence of the operation instructions. The manufacturer’s warranty service does not cover such faults.
Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.
This product is medical device, which can be used repeatedly.

- Our company have the responsibility to provide qualified product which conform to company standard of this product.
- Our company have the responsibility to complete product installation, debugging and technical training according to the contract.
- Our company have the responsibility to complete product maintenance according to the contract.
- Our company have the responsibility to respond the requirements of user in time.

⚠ Note: before using this product, please read the User Manual carefully.

1 Precautions

1.1 General Precautions

1) Do not use the product in high temperature or high humidity environment, the operating temperature of the product is 10˚C~40˚C, the operating humidity of the product is 0%~75%RH.
2) Do not clean the product with water, if the device gets wet, please stop operating it.
3) When the device is carried from cold environment to warm or humid environment, please do not use it immediately.
4) Do not use or store the product in the following conditions:
   - areas near flame or fire;
   - areas with strong shock;
   - areas with strong electromagnetic field.
5) Do not disinfect the product in autoclaves or gas sterilizer.
6) The device has useful life for five years, when the device reach the end of life and can not be used, please do not discard it at will, the disposal should follow the local laws and regulations.
7) Keep the operation environment away from dust, vibration, corrosive substances, explosive materials, high temperature and humidity.
8) Strenuous action of the subject or extreme electrosurgical interference may affect the accuracy.
9) After using, refer to the relative chapter(7.1) in User Manual for instructions of cleaning and disinfection.
10) The device is worn on the arm, fixed position, too tight or too loose will affect the measurement accuracy.
11) Please don't measure this device with functional tester for the device's related information.
12) Please don't use the device during MRI or CT scanning.
13) The disposal of scrap instrument and its accessories and packings(including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.
14) The user must check that the equipment functions safely and see that it is in proper working condition before being used.
15) The patient is an intended operator.
16) A warning against servicing and maintenance while the ME equipment is in use.

1.2 Measurement Precautions

1) If subjects' skin is too dry to measure ECG, wipe them with disinfectant alcohol or electric salve so that the electric capability can be strengthened.
2) When measuring ECG, the subject should maintain a natural sitting posture with a straight back, and begin to measure after the waveform is stable.
3) When measuring ECG, the finger and arm electrodes should touch subjects' skin exactly, roundly and well.
4) When measuring SpO_2, the subject should entirely put a finger into the black pane on the

side of the device, the finger entirely touch the contact.

5) During exercise, it is not suitable for measuring ECG and SpO_2.
6) The device can only be matched with the compatible probe.
7) The product is not suitable for use in continuous supervision for patients. The problem of overrating would emerge when the patient is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this circumstance.

1.3 Safety Precautions

1) Do not use the device under the state of charging.
2) No servicing and maintenance while the ME equipment is in use
3) When the device is not used for a long time, it should be placed in a cool, dry room, and power it every three month.
4) Do not use the device in environment with inflammable gas such as some ignitable anesthetic agents.
5) The infrared is harmful to eyes, so the user and the maintenance man should not stare at the light part of the SpO_2 probe (the infrared is invisible).
6) Inspect periodically, make sure that there is no visible damage that may affect patient's safety and monitoring performance. It is recommended that the device should be inspected at least once a week. Please stop using the oximeter if there is obvious damage to the device.
7) When measuring SpO_2 with probe, subjects can not use enamel or other makeup.
8) Please refer to the correlative medicinal literature about the clinical restrictions and contraindications.
9) The disposal of scrap instrument and its accessories and packings(including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.
10) Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
11) The device cannot be used together with equipments not specified in User's Manual. Only the accessory that is appointed or recommendatory by manufacture can be used with this device.
12) The device is not intended for treatment.
13) The device has been calibrated before leaving factory.

1.4 EMC Statement

1) When using the device, EMC should be paid more attention, the device shall be used in the environment complied with the appended table.

FCC Cautions:

1) 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.

2) 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.

3) Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

4) The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

2 Overview

CMS50K Wearable SpO_2/ECG Monitor integrated functions of SpO_2, ECG and pedometer in one product.

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood. It is an important bio-parameter for the respiration. A number of diseases relating to respiratory system may cause the decrease of SpO_2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body, and the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. Serious symptoms might bring danger to human's life. Therefore, prompt information of patients' SpO_2 is of great help for the doctor to discover the potential danger, and is of great importance in the clinical medical field.

The ECG function of CMS50K Wearable SpO_2/ECG Monitor is a good helper in the prevention of cardiovascular disease, as it can monitor ECG with easy operation at any time and any place. The device can record, analyze and display users' ECG waveform, capture the pathological ECG waveform when users happen to transient heart attack or other unpleasant symptoms. The heart can be monitored not limited in the hospital, which saves money from the physical check-up for users. After connecting with a computer or APP in mobile phone, the device can provides data reference for doctors.

The pedometer function of CMS50K Wearable SpO_2/ECG Monitor is basing on counting steps by acceleration sensor, adopts the recognition principle of pace waveform and its acceleration and deceleration process for recognizing the waveform produced by person walking, finally gets the number of steps. Detailed method: use the acceleration sensor to collect user’s steps(more than five steps), via analyzing and calculating, obtain the peak value of step vibration waveform and the average value of acceleration difference value, and set it to the threshold value. Collect the user’s actual step waveform data, if it is in the threshold range, then it is considered that user walks one step forward.

2.1 Features

1) Compact shape, handsome appearance, easy to operate and carry.
2) Monitor and record real-time SpO_2 value, pulse rate value, ECG waveform, heart rate, step number and calories anytime and anywhere.
3) With real-time clock function, the device can display year, month, day, hour, minute and second, it can be used as an electronic clock when there is no measurement activities.

2.2 Range of Application

1) Applicable situations: the device applies to family, medical clinics and hospitals, and can't be used for clinic medical examination instead of conventional electrocardiograph.
2) Applicable object: people under high pressure and workload for long time, heart disease patients, the elderly and sub-health people.(The patient is an intended operator)
3) Purpose: the device does not belong to the therapy equipment, it is just for the measurement and storage of SpO_2, ECG and step number at anytime and anywhere. Operation is simple and less requirement for the operating personnel.

3 Main Technical Specification

3.1 Environment Requirements

1) Operating environment

- Temperature: 10˚C~40˚C
- Relative humidity: 0%~75%RH
- Power supply: built-in rechargeable lithium batteries, voltage is 3.7V

2) Transport and storage environment

- Temperature: -40˚C~+55˚C
- Relative humidity: ≤95%

3.2 Main Parameters

1) Measurement range of SpO_2: 0%~100%, error: 70%~100%: ±2%; 0%~69%: unspecified.
2) Measurement range of pulse rate: 30bpm~250bpm, error: ±2bpm or ±2%(select the larger).
3) Measurement range of heart rate: 30bpm~300bpm, display error is ±1bpm or 1%(select the larger);
4) The software revision level is V0.94, release date is Oct.19，2015.
5) The type of protection against electroshock: internally powered equipment;
6) The degree of protection against electroshock: type BF applied part;
7) The grade of protection against ingress of liquid: IP54;
8) Sterilization or disinfection: N/A
9) Category AP / APG equipment: N/A;
10) Mode of operation: Continuous.

3.3 Main Performance

1) Display of SpO_2 value.
2) Display of pulse rate value.
3) Display of heart rate value and ECG waveform.
4) Display of step number and calorie.
5) Low-battery indication.
6) Data storage function.
7) The data stored can be wireless uploaded to mobile terminal.
8) Clock function.
9) Charging function.

3.4 Product applied part

Name：ECG electrode slices 、lower shell、Watchband

Material: stainless steel, plastic, silica gel

BF applied type: type BF

4 Device Introduction

4.1 Appearance Introduction

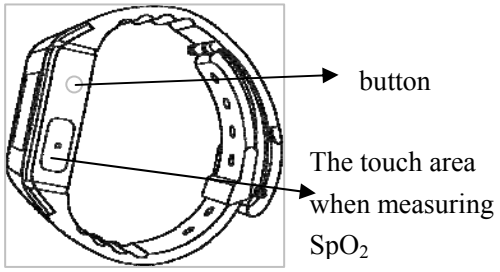


Figure 4-1

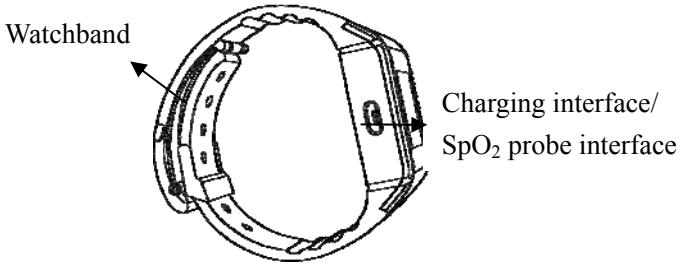


Figure 4-2

4.2 Interface Introduction

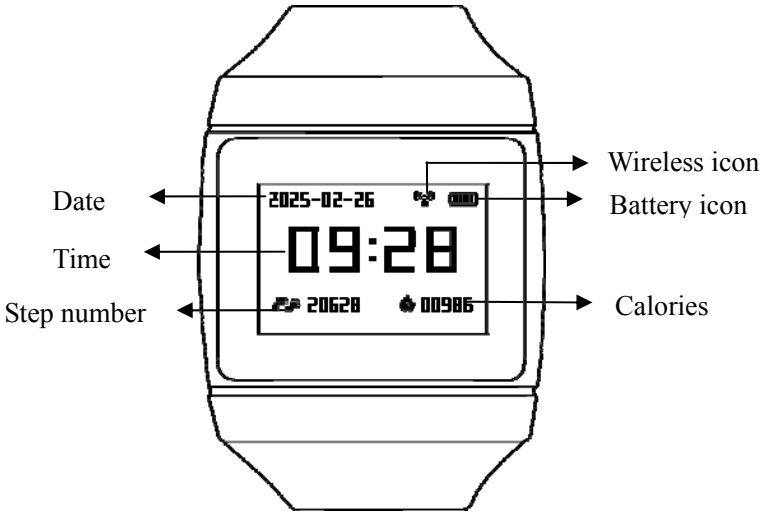


Figure 4-3 Pedometer interface

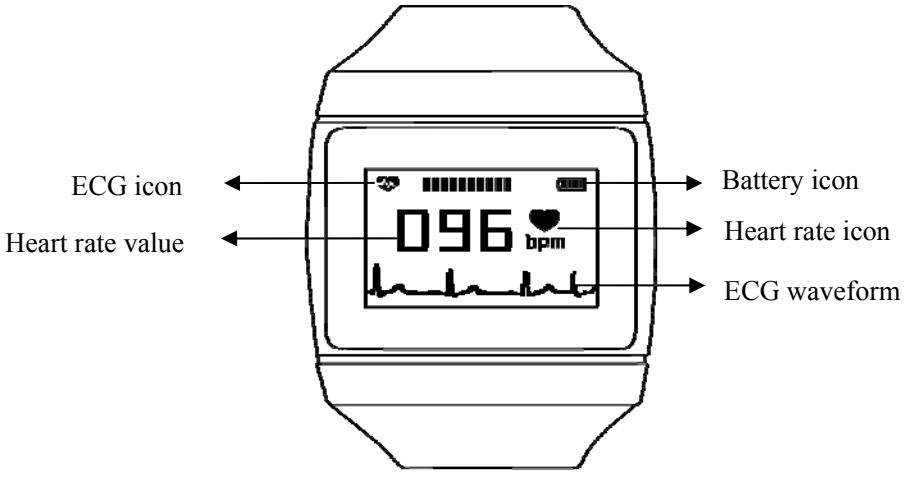


Figure 4-4 ECG measurement interface

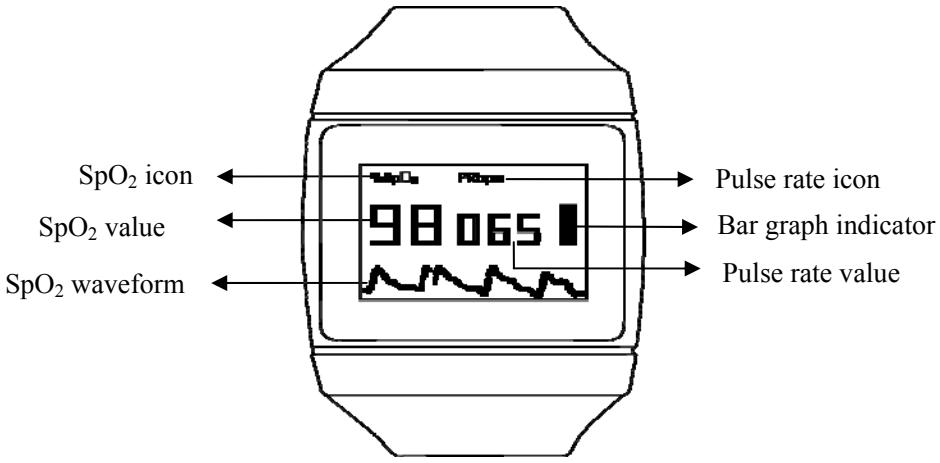


Figure 4-5 SpO_2 measurement interface

5 Operation Instruction

5.1 Power On and Power Off

For blank screen, press the button to turn on the device. In the state of power-on, the device will automatically enter the power-down mode if there is no operation for a while.

5.2 SpO_2 Measurement

After turning on the device, press the button to switch the device to the SpO_2 measurement interface, put a finger into the SpO_2 measurement area(as Figure 5-1) and fully touch the contact, then the SpO_2 value can be measured.

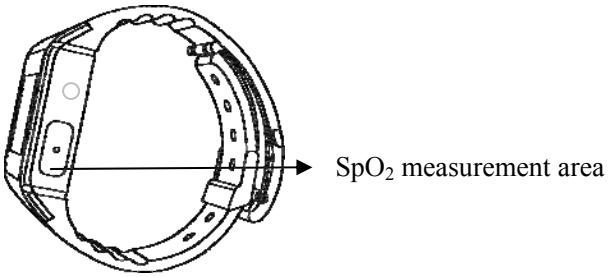


Figure 5-1 Measure SpO_2 through touching

After inserting the external probe into the USB interface on the left side of the device, insert a finger into the probe, then the SpO_2 value also can be measured, as Figure5-2.

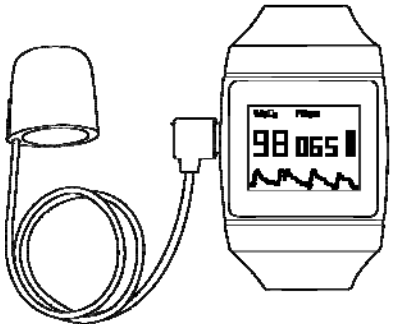


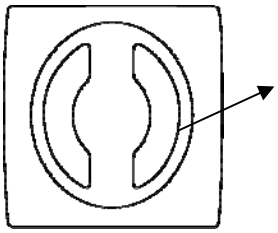
Figure5-2 Measure SpO_2 through the external probe

5.3 Pedometer

Press the button to switch the device to the pedometer interface(as Figure4-3). In the pedometer interface, users can measure step number and calorie, long press the button to begin the pedometer, long press the button again to end the pedometer. Users can view the date and time in this interface, and the device can automatically synchronize date and time when connecting with mobile phone APP.

5.4 ECG Measurement

Press the button to switch the device to the ECG measurement interface(as Figure4-4), after wearing the device, two ECG electrode slices(as Figure5-3) on the back of the device will fully contact with the arm, the ECG can be measured when a part(usually is a finger) of the body contact with the metal electrode slice(as Figure5-4) on the upper shell of the device.



ECG electrode slices on the back of the device

Metal electrode slices on the upper shell

Figure 5-3

Figure 5-4

The device will switch to pedometer interface after the body left the metal electrode slice on the upper shell.

5.5 Charge

Connect the device to an adapter (output current>500mA, 5V, general USB interface) complied with IEC 60950-1 at least, and it will take about 2~3 hours to complete charging.

5.6 Data Upload

After connecting with mobile phone APP, the device can automatically synchronize time, store and send values of SpO_2, pulse rate, heart rate, ECG waveform, step number and calorie to mobile phone client.

5.7 The Installation and Replacement of SpO_2 Probe

After inserting the external probe(as Figure5-5) into the USB interface on the left side of the device, the installation is completed.(as Figure5-2)

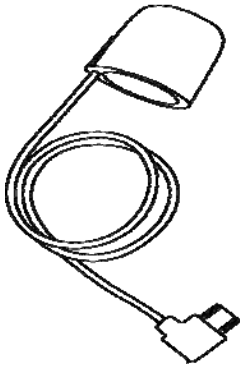


Figure 5-5 External SpO_2 probe

5.8 Accessories

- A unit of CMS50K Wearable SpO_2/ECG Monitor
- Three external SpO_2 probe
- A User Manual
- A data cable

5.9 Clinical Restrictions

1) As the SpO_2 measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding,or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
2) For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this device may be inaccurate.
3) The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor resulted in serious error of SpO_2 measure.
4) The SpO_2 value serves as a reference value for judgment of anemic anoxia and toxic anoxia, for some patients with serious anemia may also report good SpO_2 measurement.

6 Troubleshooting

If there is something wrong with the device, you can solve it according to the following table, if the problem not included in the following table and you can not solve it either, please contact with the customer service.

Problem	Cause	Solution
the device cannot be woke up again after appearing blank screen during use.	Battery is exhausted.	Please charge the device.
	The finger is not properly touch the contact on the side of the device.	Make the finger well touch the contact on the side of the device
	Misoperation	Only touch the contact on side can wake up the device after appearing blank screen.
The disturbance is too big or the waveform is random in ECG sampling process.	Your skin is dry.	Wipe skin with disinfectant alcohol or electric salve.
	There is unwanted movement in sampling process.	Please sit comfortably, and touch the electrode gently, do not squeeze the electrode.
	There is strong electromagnetic disturbance in sampling environment.	Please turn off interference source or resample in environment without strong electromagnetic field.
The SpO_2 or Pulse Rate cannot be displayed normally.	The finger is not properly touch the contact on the side of the device.	Put the finger properly and try again.
	The SpO_2 value of patient is too low to be detected.	Please try several times more; Go to a hospital for a diagnosis if you are sure the device works all right.
The display disappears suddenly.	Low power	Please charge the device in time.
	The device enters to standby mode automatically if there is no measurement for 1 minute.	Normal

7 Maintenance & Transportation & Storage

7.1 Cleaning and Disinfecting

Turn off the device before cleaning. Use medical ethanol to clean and disinfect the device, natural air-drying or clean it with a clean and dry cloth. Avoid any liquid entering to the device.

7.2 Maintenance

1) Any person who is not authorized by our company, could not open the enclosure of the device to avoid possible damage to internal components.
2) Any maintains and upgrades to this device must be carried out by personnel trained and authorized by our company.
3) Prevent any liquid from seeping into the device as it will affect the safety and performance of the device.
4) Avoid tempestuously vibration or hit when using the device.
5) Do not place other objects on the device, this could damage the touch screen.
6) Keep the device away from dust, high temperature and humidity, and avoid strong shaking and hitting.
7) If there are foreign bodies sticked on the surface of the device, please wipe it with neutral detergent, avoid using strong corrosive liquid, like alcohol and gasoline, etc.
8) Please clean and disinfect the device before using according to the User Manual (7.1).
9) Please charge the device in time when low-battery appears.
10) The device needs to be calibrated periodically (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

7.3 Transportation and Storage

1) The packed device can be transported by general vehicle or according to the order contract, avoid pounded, shake and splash by rain and snow in transportation.
2) The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40°C~+55°C; Relative Humidity: ≤95%; Atmospheric pressure: 500hPa~1060hPa.

8. Meaning of Symbol

Symbol	Meaning
	Refer to instruction manual/booklet
%SpO2	The pulse oxygen saturation(%)
PRbpm	Pulse rate(bpm)
	Low-power(please charge in time to ensure the accurate measurement)
	Full-power
	The bluetooth is ON
bpm	Heart rate
IP54	Ingress of liquids rank
	Step number
	Calories
	Type BF applied part
	ECG interface indicator
SN	Serial number
	Alarm inhibit
	WEEE (2002/96/EC)
EC REP	European Representative
CE 0123	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.

9. Specification

Display Information	Display Mode
The Pulse Oxygen Saturation(SpO_2)	2-digit digital OLED display
Pulse Rate(PR)	3-digit digital OLED display
Heart rate	3-digit digital OLED display
Pulse Intensity(bar-graph)	bar-graph OLED display
Calorie	5-digit digital OLED display
Step number	5-digit digital OLED display
Time	Year-month-day hour-minute OLED display
SpO_2 parameter	
Display range	0%~99%(resolution: 1%)
Pulse parameter	
Display range	30bpm~250bpm(resolution: 1bpm)
Pedometer	
Display range	0~65535steps(resolution: one step)
Safety classification	Internally powered equipment, type BF applied part
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicates the stronger pulse.
Power supply	
DC 3.7V	
Dimension and weight	
Dimension	50.4mm(L)*41.4mm(W)*14.7mm(H)
Weight	About 73g(not including accessories)

EMC Declaration

Guidance and manufacturer's declaration – electromagnetic immunity			
The CMS50K" is intended for use in the electromagnetic environment specified below. The customer or the user of the "CMS50K" should ensure 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	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output 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	±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. If the user of the "CMS50K" requires continued operation during power mains interruptions, it is recommended that the "CMS50K" be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The "CMS50K" is intended for use in the electromagnetic environment specified below. The customer or the user of the "CMS50K" should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the "CMS50K", including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** **d=1.2 √ P** d=1.2 **√ P** **80MHz to 800MHz** **d=2.3 √ P 800MHz 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

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 "CMS50K" is used exceeds the applicable RF compliance level above, the Medical CMS50K should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the "CMS50K".

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

Guidance and manufacturer's declaration – electromagnetic emissions

The "CMS50K" is intended for use in the electromagnetic environment specified below. The customer or the user of the "CMS50K" should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The "CMS50K" 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 "CMS50K" 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	

Recommended separation distances between portable and mobile RF communications equipment and the Medical CMS50K

The "CMS50K" is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Medical CMS50K can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the "CMS50K" 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 $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
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.