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REF **CA10M** M35048 Rev.00.09.25

EC REP

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PREFACE

Dear user, thank you very much for purchasing the Capnograph.
This device is a kind of medical product that can be used repeatedly.
This user manual contains instructions for use and technical notes of the device, and describes its features and requirements, main structure, performance, specification, as well as correct method of transportation, operation, maintenance, repair and storage, and also the safety precautions of protecting the operator and device. Refer to the following chapters for details.
Please read the User Manual carefully before using this product. The operating procedures specified in this User Manual should be followed strictly. This manual describes in detail the operation steps must be noted, the procedures may result in abnormal, and possible damage to the product or users. Failed to follow the User Manual may cause measuring abnormality, device damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues of such results due to user's negligence of this manual for using, maintenance or storage. The free services and repairs do not cover such faults either.
For product upgrade, the device you received may not exactly in keeping with the description in this user manual, and we sincerely apologize for that.
Content of this manual is subject to change without prior notice. Our company reserves the final explanation right to this user manual.
Warning
Reminding the things that may cause severe consequences to the patient, operator or environment:

- Do not use the device under flammable gases existing, such as anesthetic gas.
- Do not throw battery into fire to avoid explosion.
- Do not charge the dry battery to avoid current leakage, then causing fire or even explosion.
- The device can be only operated by the professional medical staff who has been trained and familiar with the user manual.
- Nitric oxide, high concentration of nitrogen, helium, xenon, halogenated gases and atmospheric pressure may affect the CO2 measurement.
- The device is not intended for use with parts, accessories or adapters that are not approved by the manufacturer.
- The gas path adapter is made of human affinity materials. It has no bad effect on patients.
- The measurement accuracy of CO2 is influenced by the following factors: gas path blockage, air leakage and sharp temperature changes.
- Avoid electrostatic discharge (ESD) and electromagnetic interference (EMI) from other equipment.
- In the presence of equipment with electromagnetic interference, such as soldering iron, the device may be subject to electromagnetic interference. When the electromagnetic field is higher than 20V/m, the performance of the module will be seriously affected.
- If the device is used in conjunction with a ventilator or with hazardous gas, such as N2O, it is necessary to check the air tightness of the gas path connection before use.
- Moisture and secretions in the gas path adapter can affect the optical transmission. When using the device in a hot and humid environment, keep the adapter upright, and replace it if necessary.
- Do not use the device together with a nebulizer, or else the optical transmission of the gas path adapter will be affected.
- The disposal of waste and residue should comply with corresponding national laws and regulations, otherwise it will cause pollution to the local environment.
- For the details of clinical limitations and contraindications, please refer to relevant medical literature carefully.
- Don't near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CA10M, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- This equipment is suitable for Professional Healthcare Facility Environment.
- The accuracy of the end-tidal carbon dioxide (ETCO2) and airway respiration rate (AwRR) is the Essential performance, Misjudgment may occur if the Essential performance is lost or degraded due to EM DISTURBANCES.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CHAPTER 1 OVERVIEW

1.1 About the Capnograph
1.1.1 Intended purpose
1.1.1.1 Equipment purpose
The device adopts mainstream method to measure the end-tidal carbon dioxide (ETCO2) and airway respiration rate (AwRR).
1.1.1.2 Patient population
The application population is adult, child and infant patients.
1.1.1.3 Applicable place
The device is applicable for use in emergency department, ICU, operating room and respiratory department.
1.1.2 Use requirement
It needs to be used with a ventilator or anaesthetic machine. It connects with patient's respiratory tract by the airway adapter (applied part) and breathing tube. The breathing tube except for airway adapter is not a part of the device. Ventilator or anaesthetic machine shall meet the CE requirements.
1.1.3 Contraindications: No found.
1.2 Accessories
★ CA10M Airway adapter

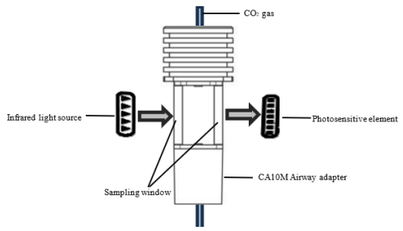
Model	Deadspace	Patient population	Manufacturer
MGN0011	<5cc	Suitable for 2 years old and above	Contec Medical Systems Co., Ltd.
MGN0012	<1cc	Suitable for 29 days to 2 years old	Contec Medical Systems Co., Ltd.

1.3 Working environment
a) Temperature: 5°C ~ 40°C
b) Relative humidity: 30% ~ 75%, no condensation
c) Atmospheric pressure: 700hPa ~ 1060hPa
d) Waterproof degree: IP22
e) Product safety type: BF with defibrillation protection function
f) Input voltage: DC 3V (2 AAA batteries)
1.4 Attentions

- The device should be inspected regularly in order to ensure there is
- no obvious damage that may affect the safety or monitoring performance. It is recommended to inspect the device at least once a week. Stop using the device if any damage found.
- Only the qualified maintenance person appointed by the manufacturer has the authority to maintain the device. Do not repair the device by yourself.
- The device is calibrated when leaving the factory.
- If the device alarms for low battery, it is recommended not to start the CO2 measurement function, otherwise the device may shutdown.
- Do not soak the device into liquid or directly spill liquid on the device.
- The device has automatic atmospheric pressure compensation.
- If the airway respiration rate or the ratio of expiratory time to inspiratory time exceeds specified range, the measurement accuracy of end-tidal CO2 may be reduced.
- Users should verify the function of the alarm system before each use, if the alarm prompt is abnormal, it means that the system cannot be used normally. Therefore, the user must contact with the manufacturer or the maintenance center.

CHAPTER 2 WORKING PRINCIPLE

During working, the infrared light source emits periodic infrared light according to the preset modulation frequency, the emitted infrared light irradiates the sampling window of the airway adapter, the CO2 in the adapter absorbs the infrared light of a specific wavelength. The infrared light passed through the sampling window is regarded as
measurement signal, which will be obtained from the photosensitive element.

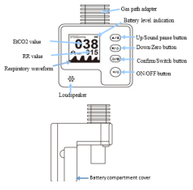


CHAPTER 3 TECHNICAL SPECIFICATION

3.1 Main functions
A. Able to measure the EtCO2
B. Able to measure the respiration rate
C. With over-limit alarm function for EtCO2 and RR
D. With low battery alarm function
3.2 Main parameters
A. ETCO2
Range: 0~150mmHg
Resolution: 1mmHg
Accuracy: 0~40 mmHg~±2 mmHg
41~70 mmHg~±5% of reading
71~100 mmHg~±8% of reading
101~150 mmHg~±10% of reading
B. Respiration rate
Range: 2 ~ 150 rpm
Resolution: 1rpm
Accuracy: ± 1rpm

CHAPTER 4 OPERATION GUIDE

4.1 Device structure



4.2 How to operate
4.2.1 Battery assembly
A. Remove the battery compartment cover on the rear of the device, as shown in Figure 1.

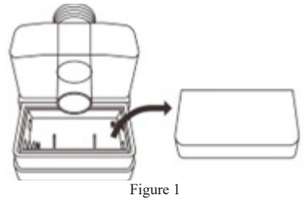


Figure 1

B. Gently press two 1.5V AAA alkaline batteries into the battery compartment according the positive and negative marks (consistent with the polarity marks in the battery compartment). As shown in Figure 2.
C. Load the battery compartment cover, as shown in Figure 3.

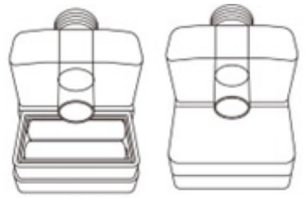


Figure 2 Figure 3

Note: Batteries must be loaded in accordance with "+" "-" marks, otherwise the device may be damaged.
Note: It is required to replace 2 new batteries of the same type at the same time.
4.2.2 Gas path adapter connection
4.2.3 Startup
Long press the ON/OFF button to enter the measuring interface. The interface after startup is shown as Figure 5.

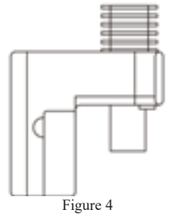


Figure 4

Long press the ON/OFF button to enter the measuring interface. The interface after startup is shown as Figure 5.

Figure 5

Under the measuring interface, long press the Confirm/Switch button to enter the setup interface. Short press Up or Down button to choose the item that need to be adjusted, and short press the Confirm/Switch button to confirm the selection, then use Up/Mute button and Down/Zero button to adjust the alarm limit value, as shown in Figure 6.

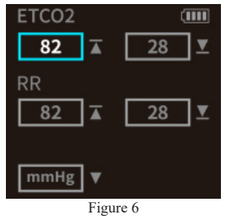


Figure 6

After replacing the battery, the alarm limit should be consistent with the value set previously.
If the alarm lower limit is turned off, the function of the alarm system may be affected.

4.2.5 Switch unit
Under the setup interface, short press Up/Mute button or Down/Zero button to move the cursor to the unit, short press the Confirm/Switch button to confirm the selection, then use Up/Mute button and Down/Zero button to change the unit, the options are "mmHg", "KPa" and "%".
4.2.6 Zero calibration
Each time the device uses a new gas path adapter, it should process zero calibration according to the following procedure:
Connect the gas path adapter with the respiratory circuit, then load the adapter on the device, and make sure the device is far away from all objects that may generate CO2, including air conditioner, patient and the operator. Long press the Down/Zero button, the interface as shown in Figure 7 appears, and the device starts zeroing. Normally, the zero calibration lasts 15~20 seconds. When it is finished, the interface as shown in Figure 8 appears. If the device does not reach the zero calibration condition (i.e. preheating is not finished, or the period of no breath detected is less than 12seconds), after pressing the Zero button, the failure interface of zero calibration appears, as shown in Figure 9. Wait a few seconds under the failure interface, the device will jump to the measuring interface. At this moment, the device needs to wait to reach the zero calibration condition (i.e. preheating is finished and the period of no breath detected is over 12 seconds), then perform another zero calibration.

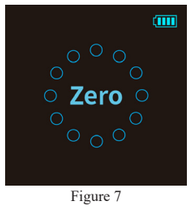


Figure 7

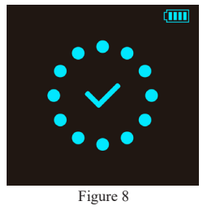


Figure 8

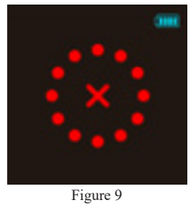


Figure 9

Note: The zero calibration can be performed only after the device has not detected breathing for 12 seconds.
Zero calibration adopts air as the gas without special treatment.
4.2.7 Measurement
Select the appropriate airway adapter and connect it to the card slot of the device. The device can be inserted into the breathing circuit to start the measurement after the preheat and zero setting is completed.
The position of CA10M airway adapter in the respiratory circuit is shown in Figure 10.
Note: The ventilator/anesthesia line and intubation pipeline should meet the requirements of ISO 5356 standard.

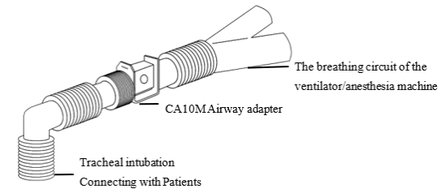


Figure 10

Note: The measurement can be affected by the following factors:
★Leakage or internal leakage of sample gas
★Mechanical shock;
★Excessive circulation pressure and abnormal pressure change of the gas path;
★Quantitative effect of temperature and condensation
★Gas or steam interference
★Periodic pressure rising to 10 kPa(100 cmH2O)
★Other interference sources
4.2.8 Alarms
4.2.8.1 Over-limit alarm
When the detected EtCO2 or RR value exceeds the preset limit, the device generates over-limit alarm. On the display interface, the parameter turns red, at the same time, the corresponding upper limit icon ▲ or lower limit icon ▼ appears and flickers continuously.
Figure 11 shows the alarm status that the detected RR value exceeds its lower limit.
Figure 12 shows the alarm status that the detected CO2 value exceeds its upper limit.

Figure 11

Figure 12

To verify whether the Over-limit alarm function is normal, user can setup the Alarm limits to see if the device generates an alarm.
4.2.8.2 Alarm for gas path adapter falling off
When the gas path adapter falls off or the connection between adapter and the device is bad, the device alarms for gas path adapter falling off, as shown in Figure 13.

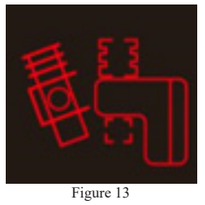


Figure 13

To verify the whether the alarm function is normal, user can remove the gas path adapter to see if the device generates an alarm.
4.2.8.3 Alarm mute
Long press the Mute button in the alarm state, the icon as shown in Figure 13 appears, at the same time, the alarm sound stops, and recovers automatically 2 minutes later. Under mute state, short press the sound pause button to exit Mute state. When the alarm disappears, Mute state will cancel automatically.

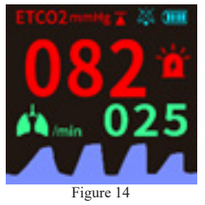


Figure 14

Physiological alarm

Alarm Type	Causes	Alarm level	Delay
ETCO2 upper limit alarm	ETCO2 value exceeds the upper limit	High	Less than 30s
ETCO2 lower limit alarm	ETCO2 value exceeds the lower limit	High	Less than 30s
RR upper limit alarm	RR value exceeds the upper limit	High	Less than 30s
RR lower limit alarm	RR value exceeds the lower limit	High	Less than 30s

Technical alarm

Alarm type	Causes	Alarm level	Delay
Disconnection alarm	Gas path adapter falls off from the device.	High	Less than 1s
Low battery alarm	Low battery	Low	Less than 1s

4.3 Software description
Software name: CA10M
Software specification: no
Release version: 1.0
Release time: Oct 23rd,2019
Naming rule for version:
<Major enhancive software upgrade>.
<Minor enhancive software upgrade>.
<Improvement software upgrade>.
<Improvement software upgrade>
Involved algorithm
Name: photoelectric ETCO2 detection technology
Type: mature arithmetic
Purpose: be used to calculate user's ETCO2 and respiration rate values.
Clinical function: the algorithm adopts photoelectric ETCO2 detection technology to calculate ETCO2 and respiration rate values, to make the user know the his physical condition.

CHAPTER 5 DISINFECTION, MAINTENANCE AND STORAGE

5.1 Disinfection
The CA10M host is reusable.
Remove batteries before cleaning and disinfecting, and do not directly immerse the device into liquid.
Gently wipe the device surface 5 times with medical gauze dipped in 70%medical alcohol, wipe for 3 minutes each time.
After thorough disinfecting, dry it with a clean soft cloth or air dry.
After the disinfecting step is complete, the device surface should be visually inspected to determine adequacy of disinfecting. If residues or stains are found, the entire disinfection process must be repeated as described above.
Do not directly spill liquid on the device to avoid the liquid entering the inside of device.
5.2 Maintenance

- The device should be inspected regularly in order to ensure there is no obvious damage that may affect the safety or monitoring performance. It is recommended to inspect the device at least once a week. Stop using the device if any damage found.
- Connect the device to the test device shown in Figure 201.101 of ISO80601-2-55. According to the values set on the fixed frequency cycle operator, alternately supply 5% CO2 standard gas and air to the equipment. Verify the accuracy of ETCO2 and respiratory rate of the equipment based on gas concentration and ventilation frequency.
- During the validation of ETCO2 and respiratory rate, set the alarm limit to make ETCO2 and respiratory rate exceed the limit, and verify whether the alarm system is normal.
- ETCO2, respiratory rate, and alarm system validation should be conducted at least every 6 months. The test results should meet the basic performance requirements.
- Please disinfect the device before or after using according to Section 5.1.
- Replace batteries when the device prompts low battery.
- Take out the batteries if the device is not used for a long time (over 3 months).
- 5.3 Transport and Storage
- The packed device can be transported by ordinary conveyance or according to transport contract. Avoid violent shock, vibration, rain and snow splash during transporting. Do not transport it mixed with toxic, harmful, corrosive material.
- The packed device should be stored in room with no corrosive gas and good ventilation. Atmospheric pressure: 500hPa ~ 1060hPa, Temperature: -40°C~+55°C; Relative Humidity: ≤95%.

CHAPTER 6 TROUBLESHOOTING

No.	Problems	Cause analysis	Solutions
1	Unable to turn on the device	1. Low battery or batteries run out. 2. Battery polarity is connected falsely. 3. Something wrong with the device.	1. Replace batteries. 2. Load the batteries correctly. 3. Contact the local customer service.
2	The display information disappears suddenly	1. Low battery. 2. Something wrong with the device.	1. Replace batteries. 2. Contact the local customer service.
3	The display of data is abnormal or unstable	1. The adapter of gas path is not properly loaded. 2. Air leakage in the gas path. 3. The working environment does not satisfy the requirements in this user manual. 4. Something wrong with the device.	1.Check the connection of adapter. 2.Check the connection of gas path. 3.Use the device under normal working environment condition. 4.Contact the local customer service.
4	The device prompts that the adapter of gas path is not connected.	The adapter of gas path is not connected.	Check the connection of adapter.

CHAPTER 7 SYMBOLS

Symbol	Meaning
	Refer to instruction manual/booklet
	ON/OFF button
	Confirm/Interface switch button
	Down/ Zero button
	Up/Mute button
	Mute icon
	Battery level icon
	Upper limit icon
	Lower limit icon
	"Caution", please refer to the accompanying document (this user manual)
ETCO2	EtCO2 concentration, unit: mmHg,kPa,%
	Respiration rate icon
	WEEE (2012/19/EU)
SN	Serial number
	Date of manufacture
	Manufacturer
	Type BF applied part with defibrillation protection function
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	This way up
	Fragile, handle with care
	Keep dry
CE 0123	Medical Device complies with Directive 93/42/EEC
MD	Medical device
	Do not use if package is damaged
	Do not re-use
LOT	Batch code
	Use by date
EC REP	Authorized Representative in the European Community
	Imported by

CHAPTER 8 SPECIFICATION

EtCO2	
Range	0 ~150 mmHg
Resolution	1mmHg
Accuracy	0~40 mmHg~±2 mmHg 41~70 mmHg~±5% of reading 71~100 mmHg~±8% of reading 101~150 mmHg~±10% of reading
Alarm range	Upper limit: 1~150 mmHg Lower limit: 0~149 mmHg
Alarm preset value	Upper limit:60 mmHg Lower limit:25 mmHg
Measurement accuracy drift	Meet the requirement of measurement accuracy
Respiration rate	
Range	2~150 rpm
Resolution	1 rpm
Accuracy	±1 rpm
Alarm range	Upper limit: 1~150 rpm Lower limit: 0~149 rpm
Alarm preset value	Upper limit:40 rpm Lower limit:15 rpm
Power requirement	
Two AAA batteries	
Battery life time	
4 hours	
Total response time of system	
0.5s	
Preheat time	
15s	
Dimension and Weight	
Dimension	55*52*59 mm
Weight	About 97g (with batteries)
Alarm sound pressure level	
40~60dB	
Data sampling rate	
5ms	
Service life of device	
10 years	
Shelf life of CA10M airway adapter	
2 years	

APPENDIX

Guidance and manufacturer's declaration - electromagnetic emissions	
The CA10M is intended for use in the electromagnetic environment specified below. The customer or the user of the CA10M should assure that it is used in such an environment	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Not applicable

Guidance and manufacturer's declaration - electromagnetic Immunity		
The CA10M is intended for use in the electromagnetic environment specified below. The customer or the user of the CA10M] should assure that it is used in such an environment		
Immunity Test	IEC 60601 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
NOTE UT is the a.c. mians voltage prior to application of the test level.		

Guidance and manufacturer's declaration - electromagnetic Immunity		
The [Code SI] is intended for use in the electromagnetic environment specified below. The customer or the user of the [Code SI] should assure that it is used in such an environment		
Immunity Test	IEC 60601 Test level	Compliance level
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz	3 V/m 80 MHz – 2,7 GHz
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 [Code SI] is used exceeds the applicable RF compliance level above, the [Code SI] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [Code SI]. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.		

Guidance and manufacturer's declaration - electromagnetic Immunity							
The CA10M is intended for use in the electromagnetic environment specified below. The customer or the user of the CA10M should assure that it is used in such an environment							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	380 –390	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
	810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
	1720 1845 1970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
	5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.							
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.							

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies.