Sunvou

Nano Coulomb Breath Analyzer

Sunvou-TM1100

User Manual

Sunvou Medical Electronics Co., Ltd.
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Sunvou Medical Electronics Co., Ltd.

Product name：Nano Coulomb Breath Analyzer
Product model：Sunvou-TM1100
Manufacturer and address：Sunvou Medical Electronics Co., Ltd.
#8 Jingxian Rd., Xinwu District, Wuxi, Jiangsu, 214000, China
Importer and address: See product label

Intended use

Sunvou-TM1100 measures Nitric Oxide (NO) in human breath.

Contraindications

There are no known contraindications.

Precautions

The instrument is a portable device for precision measurement. During use and storage, pay attention to:

- Use at room temperature: try to use the instrument at room temperature.
- The instrument is not suitable for use in outdoor and wild places without protection. Avoid excessive high/low temperature, Do not place the instrument in direct sunlight.
- Avoid dust and water: the instrument shall not be exposed to or splashed with liquid, and the container containing liquid shall not be placed on the instrument. Objects filled with liquid such as vases shall not be placed on the instrument. Neither the instrument nor consumables shall be immersed in water or other liquids.
- Avoid humidity: humidity will affect the performance and operating life of the instrument. Try to avoid placing the instrument in wet places. In case of fog or water drop in the breathing tube, please contact the technical person-nel of our company in time.
- Avoid dropping the instrument or subjecting it to any impact: avoid it in a high place. Be careful when handling the instrument.
- Avoid heavy pressure: heavy objects shall not be placed on the upper cover of the instrument to avoid crushing.
- Avoid open flames and burning: Keep the instrument away from open flames. The instrument will generate heat during normal operation, so it should be placed in an open or ventilated place. The temperature of the instrument may rise or be higher than the ambient temperature, so try to avoid placing the instrument on a bed, sofa, carpet or other soft surface.
- Avoid electric shock / lightning: to prevent electric shock, do not try to disassemble or repair the instrument by yourself. In case of lightning weather, try to disconnect the external power connection wire.
- The instrument shall be far away from all kinds of pollution sources, especially all kinds of interfering gases.

- Do not disinfect the product with disinfectant. Clean the surface of the instrument according to Maintenance of this manual.
- Avoid using ultraviolet light to illuminate the instrument.
- The mouthpiece shall not be used repeatedly and one mouthpiece shall be only used by one person. The company is not responsible for the measurement deviation or all other consequences caused by the repeated use or cross use of the mouthpiece.
- The built-in sensor in the instrument may cause damage to the environment or human body. Do not open the sensor in the instrument without permission or put the sensor into the mouth.
- The selection of spare parts or accessories other than our company may reduce the performance of the instrument and even damage the instrument or other parts. Any problems caused by the use of accessories provided by other companies are not included in the product quality assurance.
- When the instrument is not in use, the breathing tube must be connected to the breath filter at all times.
- Please do not disassemble the instrument privately, otherwise the maintenance and installation will not be provided, and the company will not be responsible for the adverse consequences.
- Abnormal shutdown may cause data or system errors. Please shut down the instrument normally after use.
- It is recommended to keep the transportation packaging. The possible equipment damage caused by the use of other packaging is manmade damage and does not belong to the scope of warranty service of the company.
- The user must handle and use the instrument in strict accordance with the methods indicated in this manual, otherwise the company will not be responsible for damage of the instrument or incorrect results.
- The button battery inside the sensor cannot be taken out by yourself
- Sensor operating life: Nano coulomb NO sensor is high sensitivity electrochemical sensor. In order to maintain the accuracy of the instrument, the instrument software will automatically check the number of uses of the sensor according to its characteristics after it is replaced. When the actual number of uses reaches the set value, the instrument will prompt to replace the sensor. The accompanying document of the sensor will give a notice of the number of uses.
- The instrument and sensor can be recycled and disposed in accordance with the environmental regulations of the place where the instrument is used.
- Disconnection from the network power supply of the instrument should be through power adapter.
- When necessary, the Company may provide corresponding circuit diagrams, component lists, drawing notes, calibration instructions, or other materials necessary for repairable equipment parts as required.
- If there is any problem, turn off the power first and contact the technical support personnel of the company as soon as possible.
- The following instructions in this manual are only applicable to this model. If other operating instructions are required, they will be provided separately.

CONTENTS

1. Parts and Accessories

（See attached photo of the object and related instructions）

SN	Name	Model / Strength	Application
①	Nano Coulomb Breath Analyzer	Sunvou-TM1100	Breath measurement, with online and offline test function
②	NO sensor	Sunvou-HD1101	Use with analyzer
③	Power adapter	5V ⎓ 2.0A	Device power supply
④	Filter	SV-EBFH	Use with analyzer，filter device for on-line breath sampling，Including handpiece（⑤,see label for user instructions）and disposable mouthpiece（⑥）

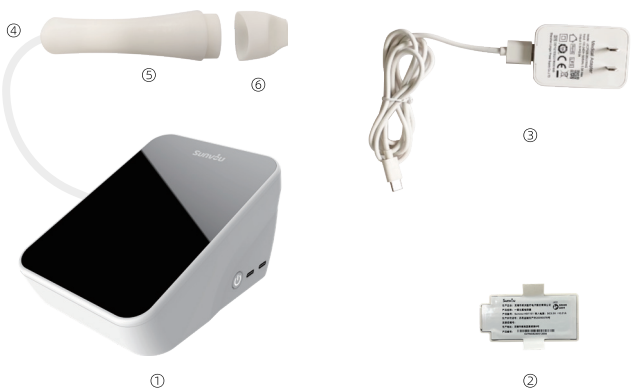

Figure1-1

2. Operation guide

2.1 Operating Conditions

Temperature：5℃～35℃

Humidity range：≤80% RH (non-condensing)

Atmospheric pressure: 700-1060hPa

Supply voltage: input AC100-240V ±10%; output DC5V 2.0A

Supply frequency：50Hz/60Hz ±1Hz

Internal power supply (lithium battery) voltage：DC3.635V

2.2 Test preparation

（1）Connect the breathing tube、Handpiece and power adapter with the device.

（2）Press the power switch on the right side of the instrument for 5s until the display screen lights up. Then resource loading information appears on the display.

（3）The instrument starts to initialize（Figure2-1）, And display the precautions, please read carefully.

（4）After initialization is complete，the main function page is displayed.（Figure2-2）

（5）One function icon button is on the main interface, the other two are put in upper right corner（battery and bluetooth display after opening）.

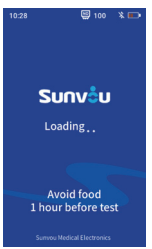

Figure2-1

Figure2-2

Figure2-3

2.3 $FeNO_{50}$ Test

This product adopts the patented technology of nitric oxide electric quantity detection developed by Sunvou, which is used for the analysis of nitric oxide in expiratory breath. The on-line sampling adopts the sampling expiratory flow rate, pressure and time as required by the international standard guidelines.

After the test is completed, press the power switch on the right side of the instrument until the display is off. The instrument will shut down automatically.

（1）On the home screen，after reading home screen test precautions ,press “ FeNO ” ，enter into “User management” interface（Figure2-4）；

（2）Swipe left and right to select serial number of patient，input age，select sex，press “ NEXT ” .

（3）Open a new mouthpiece and connect it to the handpiece as shown figure，cover the mouth with mouthpiece（Figure2-5），do not leak，waiting for quality inspection to be completed；

（4）Press “ ▶ ” ，continue exhaling to keep the ball in the green frame until the sample is successful（Figure2-6）；

（5）Analyze the sample after it is successfully sampled，analysis takes approximately 20 seconds，please wait patiently. Do not remove the mouthpiece during analysis；

（6）Display test results after analysis is complete. Press the “ ← ” in the upper left corner to return to breath interface（Figure2-7），you can exhale again, If you need to change the user to test, you can click “ ⌂ ” at the lower left corner to return to the home screen.

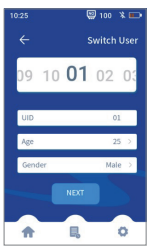

Figure2-4

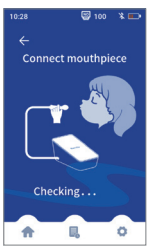

Figure2-5

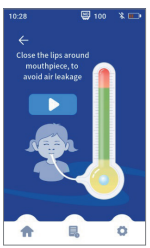

Figure2-6

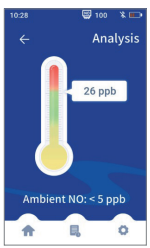

Figure2-7

2.4 Data

Press “ 📄 ” button at the bottom of the home screen，enter “Data interface” . To search historical test records of this user（Figure2-8）. Press "Switch User" in the upper right corner to view other users' historical test records.

Figure2-8

2.5 Settings

Press “ ⚙ ” button at the bottom of the home screen，enter “Settings” interface，Display five types of parameter settings and information：Language、Bluetooth、Data Sync、QC、System info（Figure2-9）.

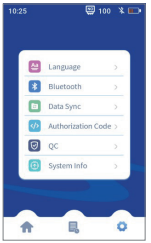

Figure2-9

2.5.1 Language

Enter Settings interface，press “Language” ，enter the interface of language selection（Figure2-10）.

2.5.2 Bluetooth

Enter Settings interface，press “Bluetooth” to turn on or off Bluetooth.After this function is enabled, you can query the Bluetooth connection status in the upper right corner of the screen（Figure2-11）.

2.5.3 Data Sync

Enter Settings interface，press “Data Sync” to sync the data（Figure2-12）.

Figure2-10

Figure2-11

Figure2-12

2.5.4 QC

2.5.4.1 Qualified User

（1）Enter Settings interface，press "QC"，input the password of Quality control，the service personnel authorized by the company shall enter "QC" interface（Figure2-13,Figure2-14）.Press " " enter the interface of Qualified User；

（2）Set the NO preset value and click to confirm（Figure2-15,Figure2-16）,Obtain a new mouthpiece and connect it to the breath filter，cover the mouth with mouthpiece，do not leak;

（3）press " " ，continue exhaling to keep the ball in the green frame until the sample is successful（Figure2-17）；

（3）Analyze the sample after it is successfully sampled，analysis takes approximately 20 seconds，please wait patiently（Figure2-18）；

（4）Display sensitivity correction after analysis is complete（Figure2-19）.Press the back button in the upper left corner to return to the "QC" interface.

Figure2-13

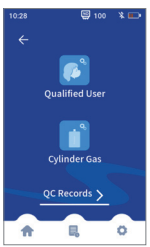

Figure2-14

Figure2-15

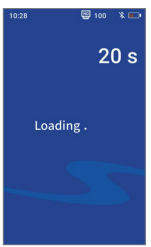

Figure2-16

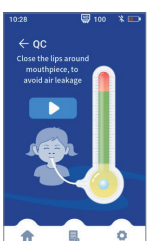

Figure2-17

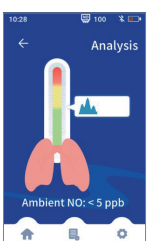

Figure2-18

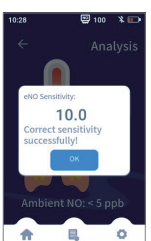

Figure2-19

2.5.4.2 Cylinder Gas

Enter Settings interface，press "QC"，input the password of Quality control，the service personnel authorized by the company shall enter "QC" interface（Figure2-13,figure2-14）.Press " " ,enter the interface of Cylinder Gas.

（1）Set the NO preset value and click to confirm（Figure2-15,Figure2-16）；

（2）Connect sample bag with the device，do not leak，press "Start"，the device starts pumping air until the sampling is successful（Figure2-20）；

（3）Analyze the sample after it is successfully sampled，analysis takes approximately 20 seconds，please wait patiently；

（4）Display sensitivity correction after analysis is complete（Figure2-21）.Press the back button in the upper left corner to return to the "QC" interface.

Figure2-20

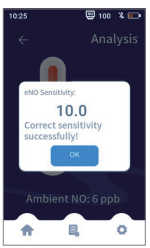

Figure2-21

2.5.5 System Info

Enter Settings interface，press "System info"．Information such as device number can be consulted（Figure2-22）.

Figure2-22

2.6 Sensor Replacement

If the remaining count is less than a certain number, please contact the distributor in time to order. When "The remaining count of NO sensor has expired" appears on the screen, it indicates that remaining count of sensor has reached the limit and can no longer be used. A new sensor needs to be replaced.

Before replacing the sensor, please make sure the device is turned off!

1.Remove the original sensor

（1）Turn device upside down, and use a flat-head screwdriver to remove the screws on the cover.（Figure2-23）

（2）Remove the sensor compartment, pinch the handle labels on both sides of the sensor with your hands, and pull out the sensor vertically（Figure2-24）;

Figure2-23

Figure2-24

2.Install new sensor

（1）Unpack the new sensor;

（2）Align the sensor cavity of the device, insert the new sensor, and press it tightly by hand(Figure2-25).Put the sensor compartment cover back on. Tighten the screws(Figure2-26).

The replaced sensor should be disposed according to local environmental protection requirements.

Figure2-25

Figure2-26

3. Maintenance

（1）If the internal parts of the device need to be maintained and repaired, please contact Sunvouor its local distributor.

（2）Each test should be equipped with another mouthpiece or equipped with accessory parts.

（3）Clean the device with a damp cotton cloth or damp absorbent cotton. Do NOT use ethanol, isopropanol or similar disinfectant to clean the device. Do not wipe the parts with wordings, so as to avoid illegibility. The mouthpiece is disposable and does not require cleaning.

（4）Clean and disinfect: Clean the device with a clean, soft, damp cloth. Do not use alcohol or strong cleaning agent.

（5）Instructions for transport and storage:

CAUTION!

Always use a sealed box for transportation and storage. Make sure there is no collision, falling from height and damage.

Temperature range: -40 ~ +55℃

Humidity range: ≤93%

Atmospheric pressure range: 700 to 1060 hPa

Make sure the storage conditions are appropriate. The device shall be stored in a well-ventilated room without corrosive gas. Make sure the storage room is rain proof, moisture-proof, dust-proof and pressure proof.

（6）FAQs and solutions

Please refer to the following table if the device cannot be used normally.

Code	Hint	Explanation
E01	Device self-checking failed. Restart the instrument. If the alarm code persists, contact customer support.	Self-checking failed
E02	NO sensor not connected	The sensor is not installed or is improperly installed
E03	NO sensor count has been used up	Sensor exception or alarm
E04	NO QC count has been used up	Sensor exception or alarm
E05	NO sensor validity period expires	Sensor exception or alarm
E06	The temperature sensor of NO sensor is not recognized	Sensor exception or alarm
E07	Low battery of NO sensor	Sensor exception or alarm
E08	NO sensor type error	Sensor exception or alarm
E09	NO sensor and device don't match	Sensor exception or alarm
E10	The lithium battery is low. Please connect the adapter	Connect the adapter
E11	The sampling phase is abnormal. Please restart the test	The sampling velocity is too low
E12	The sampling phase is abnormal. Please restart the test	Excess positive pressure

Code	Hint	Explanation
E13	The sampling phase is abnormal. Please restart the test	Low pressure
E14	Ensure that the ambient temperature ranges from +5℃ to +35℃. If necessary, move the instrument to another location and restart the device.	Device alarm ,breath test disabled
E15	Bluetooth connection error	Check Bluetooth connection and reconnect.

In order to enable you to use the instrument normally and maximize the benefit of the device, please pay attention to the normal and daily maintenance of the device.

4. Technical specifications

4.1 Main component composition

It is composed of host, nitric oxide sensor, power adapter (optional), embedded software (Software TM1100,V1), disposable mouthpiece, sampler(optional) and sample bag(optional).

4.2 Technical specifications and Symbols

（1）Classification by the type of protection against electric shock: Class II ⧈ internal electric source: DC3.635V

（2）Classification by the degree of protection against electric shock: Application part of Class B

（3）Classification according to the degree of protection for liquid inlet: IPX2

（4）Non-AP, APG type equipment

（5）Classification by operation mode: Continuous operation

（6）Input Voltage ~ 100-240V±10%,frequency 50Hz/60Hz, Output Voltage DC5V 2A

（7）Input Voltage DC5V 2A/ Input power: 35 VA

（8）Device does not have the application component of protection for defibrillation discharge effect

（9）Device has signal input/output components.

（10）Non permanently installed equipment.

（11）Dimensions: height140mm width100mm depth 78mm

（12）Weight: 0.7kg

（13）Electric safety:

Compliant EN61010-1:2010+A1:2019 、IEC61010-1:2010+A1:2016

Other specialized standard: IEC61010-2-081:2019 EN61010-2-081:2020

EN61010-2-101:2017 IEC61010-2-101: Relevant requirements in 2018 series standards

（14）Production date and service life: The production date, service life and frequency of the main engine and sensor shall be determined and marked in the corresponding product label.

Symbols and instructions used in the user manual

Symbol	Instruction
	Please refer to the attached document
	Application part of Class BF
	Class II
	Alternating current
	Direct current

4.3 Performance specifications

Performance specifications of Nano Coulomb Breath Analyzer (Sunvou-TM1100) are as follows:

Index	NO sensor
Measurement range	5 ~ 3000ppb
Lower Detection Limit	5ppb
Accuracy	±3ppb for Measured Value ≤30ppb ± 10% for Measured Value > 30ppb
Repeatability	≤3ppb for Measured Value ≤30ppb ≤ 10% for Measured Value > 30ppb

Appendix

Electromagnetic Compatibility requirements

Caution

Pay attention to the field electromagnetic environment, as the product may be affected by the field electromagnetic field .The installation and use of products should be far away from products or facilities that emit strong magnetic waves, such as radio towers, high-frequency electrotome, nuclear magnetic resonance equipment, etc.

This product may cause electromagnetic interference to other electrical equipment on site. However,this product meets the requirements of electromagnetic compatibility standards and the electromagnetic environment instructions.

Caution

Portable and mobile communication RF devices may affect the use of this product.

Caution

The device should not be used in close proximity to or stacked with other devices. If it must be used in close proximity or stacked with other devices, observe and verify that it can work properly under the configuration used.

Caution

With the exception of sensors and cables sold by the Company as spare parts for internal components, the use of non-specified sensors and cables may result in increased emission interference or reduced anti-interference of the equipment or system.

Basic performance description for EMC testing: The product performance meets the requirements and can ensure normal operation.

The product conforms toIEC61010-1:2010+A1:2016、IEC61010-2-081:2019、EN61010-2-101:2017、IEC61010-2-101:2018.

EMC

Guidance and manufacturer's declaration - Electromagnetic immunity and electromagnetic emissions

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions		
Nano Coulomb Breath Analyzer (Sunvou-TM1100) is intended for use in the electromagnetic environment specified below. The customer or the user of Nano Coulomb Breath Analyzer (Sunvou-TM1100) should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Nano Coulomb Breath Analyzer (Sunvou-TM1100) 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	Class B	Nano Coulomb Breath Analyzer (Sunvou-TM1100) is suitable for use in all establishments, including domestic establish- ments 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	Complies	

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity			
Nano Coulomb Breath Analyzer (Sunvou-TM1100) is intended for use in the electromagnetic environment specified below. The customer or the user of Nano Coulomb Breath Analyzer (Sunvou-TM1100) should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test	Compliance	Electromagnetic environment - guidance
Electrostatic discharge	± 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	± 2 kV for power supply	± 2 kV for power supply	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to	± 1 kV line(s) to	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 % Ur (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s <5 % UT(>95 % dip in UT)for 5s	Mains power quality should be that of a typical commercial or hospital environment.

Power frequency (50/60 Hz) 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 UT is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration-electromagnetic immunity - for life-supporting ME equipment and ME systems (Not Applicable)

Table 4

Guidance and manufacturer's declaration - electromagnetic immunity - for ME equipment and ME systems that are not life-supporting			
IMMUNITY test	IEC 60601 TEST	Compliance	Electromagnetic environment - guidance
IEC 61000-4-6 Radiated RF IEC 61000-4-3	150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of Nano Coulomb Breath Analyzer (Sunvou-TM1100), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2 $\sqrt{P}$ d = 1.2 $\sqrt{P}$ 80 MHz~800 MHz d = 1.2 $\sqrt{P}$ 800 MHz~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			
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 Nano Coulomb Breath Analyzer (Sunvou-TM1100) is used exceeds the applicable RF compliance level above, Nano Coulomb Breath Analyzer (Sunvou-TM1100) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Nano Coulomb Breath Analyzer (Sunvou-TM1100). b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Table 5

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment or ME system - for life-supporting ME equipment and ME systems (Not Applicable)

Table 6

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment or ME system - for life-supporting ME equipment and ME systems (Not Applicable)

Recommended separation distances between portable and mobile RF communications equipment and Nano Coulomb Breath Analyzer (Sunvou-TM1100)

The Nano Coulomb Breath Analyzer (Sunvou-TM1100) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Nano Coulomb Breath Analyzer (Sunvou-TM1100) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Nano Coulomb Breath Analyzer (Sunvou-TM1100) as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitter m		
	150 kHz~80 MHz d = 1.2 $\sqrt{P}$	80 MHz~800 MHz d = 1.2 $\sqrt{P}$	800 MHz~2.5 GHz d = 1.2 $\sqrt{P}$
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 metres (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.