MedSense®

Infrared Forehead & Ear Thermometer

MDS-TFE02

User Manual

Version 1.0. Updated July 2020.

Model number: PG-IRT1603

Contents

Symbols used in this manual

Caution - Consult instructions for use

Strictly prohibited

Disassembly prohibited

Type BF equipment

Water resistance, moisture resistance

Please read the instructions carefully before use

It means the package of this unit can comply with the requirements of green environmental protection.

This product and/or its materials are made of renewable materials that can be recycled.

This device is an electronic equipment and should not be disposed of in household waste. Please dispose of the device and its batteries in an environmentally safe way and in accordance with local laws and regulations.

IP Classification: IP22

Product introduction

Congratulations on the purchase of your new MedSense Infrared Ear/Forehead Thermometer. This thermometer has been clinically validated for accuracy and is a precision instrument that hygienically and accurately records temperature in a safe and non-invasive manner.

Features:

- Contactless measurement of body temperature
- Precise temperature readings within 1 second
- 9 sets of memory values
- Triple mode use for forehead temperature, ear temperature and object temperature
- Results in °C (default) or °F
- Multi-coloured backlight display
- On/off audible alerts
- Power-saving auto switch off after 30 seconds of inactivity

Statement of Intended Use

The MedSense IR Ear/Forehead Thermometer is intended for the measurement and monitoring of human body temperature from the forehead or the ear. This thermometer has been clinically tested and proven to be accurate and safe to use on all patients, irrespective of age, when used in accordance with this instruction manual. This thermometer is suitable for clinical or home use.

The MedSense IR Ear/Forehead Thermometer may also be used for the measurement of objects and surface temperatures within the home. It can measure the temperature of bath water, infants feeding bottle, air temperature and other applications.

User precautions

- Please read and follow the instructions in this user manual carefully before use.
- This thermometer has been clinically tested and found to be accurate and safe, when used in accordance with this instruction manual, for all patients irrespective of age.
- The measurement results of this device at any time should be a reference only and cannot replace the medical diagnosis of a doctor. If you have any questions about the measurement results, please consult a doctor.
- To avoid any harmful situation, this device should not be operated unsupervised by children and used only for the purposes described in this instruction manual.
- This thermometer is unsuitable for use in the presence of flammable anaesthetics or oxygen.
- This thermometer is intended for indoor use and should not be exposed to extreme environmental conditions outside of its operating and storage temperature and humidity conditions, as stated below:

Operating conditions	Storage conditions
10°C~40°C	-25°C~55°C
15%RH~93%RH	0%RH~93%RH

- If the device is not used within specified temperature and humidity ranges the technical accuracy cannot be ensured.
- If the thermometer is not stored within the specified ambient temperature range, allow the thermometer 30 minutes to equilibrate with room temperature before use.
- The probe sensor is the most delicate part of this thermometer and must be kept clean and undamaged to ensure accuracy.
- Do not touch the probe's lens with your fingers.
- Never splash or soak this device in any liquid including water.
- Ensure not to drop the device, as it is neither shock-proof nor impact resistant.
- Do not use equipment that generate electromagnetic fields near this device.
- Should a fault occur with the thermometer, do not disassemble or attempt to repair the device as this will void the warranty. Please contact Andatech for service.

Body temperature readings

Body temperature varies according to the site used to take the measurement. Therefore, readings taken from different body sites cannot be directly compared.

The World Health Organisation (WHO) provides normal human body temperature reference values. Please refer below for specific temperature differences:

Measurement site	Normal body temperature
Anal temperature	36.6°C~38°C
Oral temperature	35.5°C~37.5°C
Axillary temperature	34.7°C~37.3°C
Cochlear temperature	35.8°C~38°C

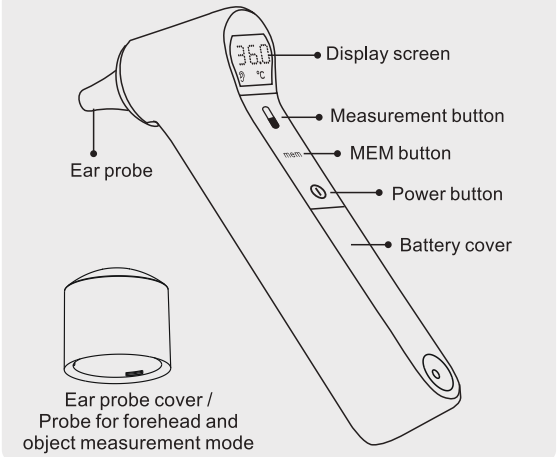
Additionally, human body temperature may change throughout the day. In the morning, body temperature is gradually increasing and is highest at noon after lunch. Body temperature gradually decreases in the afternoon until the evening, and is at its lowest at night due to decreased activity and sleep.

Each person's normal temperature may be defined by measuring body temperature several times during a day when illness is absent. Record these readings for future reference to use for comparison when a fever may be suspected.

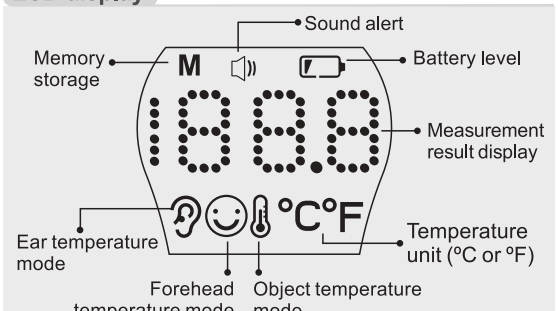
Seek medical help regarding the fever, when:

- The child is less than 6 months old
- The child refuses to drink
- The fever rises above 38.5°C or persists for more than 48 hours
- Other symptoms appear, including difficulty in swallowing, ear tugging, rash, etc.

Product layout



LCD display



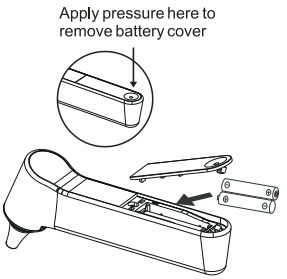
Backlight

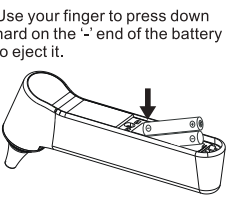
The LCD backlight changes colour based on the measured results and may show a warning.

Temp. Range	*Backlight Colour and Warning*	
Below 34°C	Red	"LO"
34~37.1°C	Green	
37.2~38.1°C	Orange	
38.2~43°C	Red	
Above 43°C	Red	"HI"

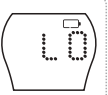
Battery installation

1. Press the battery cover at the round indentation - the cover will pop up for easy removal.
2. Insert two 1.5V AAA batteries (alkaline batteries are recommended) into the battery compartment, ensuring that their polarities are correctly positioned as illustrated inside the battery compartment.
3. Replace the battery cover and secure it into place.





Low battery: When the battery is low, the LCD display will show " LO " and the battery icon will always be on display, which signals the need to replace the batteries.



If the thermometer will not be used for an extended period of time, please remove the batteries before storage to avoid any battery leakage from damaging the device.

Used batteries are hazardous waste and should not be disposed of with normal household waste.

Setting thermometer parameters

Alert sounds

By default, the device will “beep” to indicate when a measurement is complete or when there is an error.

To enable or disable this sound, press the “MEM” button while the device is switched on.

The icon on the LCD display will indicate whether the sound has been switched on or off:

Alert sound **ON** Alert sound **OFF**

Setting the measurement unit (°C or °F)

When the device is switched off, press and hold the “MEM” button for 6 seconds.

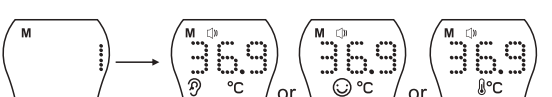
Then, press the power button to switch on the device. Otherwise, the device will switch on automatically after 8 seconds.

Memory recall

The device can store 9 readings in memory.

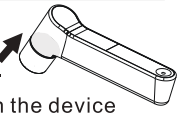
To recall temperature values from memory, press the “MEM” button while the device is switched off. The result will display as below. Each additional press of the “MEM” button will recall the next most recent measurement.

The number in the display indicates how many measurements ago this reading was taken and the icons indicate whether it was an ear, forehead or object temperature.



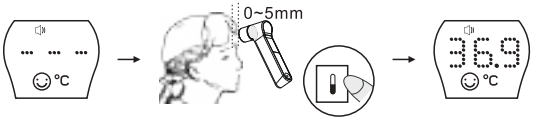
The device will switch off automatically after 30 seconds of inactivity. Alternatively, press the power button to switch off the device manually.

Measuring forehead temperature



1. Keep the ear probe cover attached.
2. Press the power button to switch on the device and enter measurement mode. The LCD screen will display the last measured test result.
3. Aim the device probe at the center of the forehead from a distance of 0 to 5mm from the skin, then press the "🌡" button to take a measurement.

   Note: Maintain this distance until the measurement completion sound is heard. If the device is in silent mode, maintain this distance for approximately 1-2 seconds.
4. After 1 second, the measurement result will display on the screen.



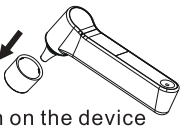
LCD flashing
Device waiting
to start measurement

Aim at forehead
and press button
to take measurement

Measurement
result

- If there is perspiration on the forehead, wipe the area dry before taking a measurement.
- Do not take temperature readings on areas where scars or skin disorders (eczema, dermatitis, etc) are evident.
- Avoid taking a measurement in close proximity with an air conditioner or immediately after a swim, shower or bath, as measurement results may be lower.
- It is important that patients remain still when a measurement is being taken as any movements could result in an inaccurate reading.
- Temperature measurements vary according to the measurement site. If several readings are taken consecutively at different points on the forehead, the manufacturer recommends accepting the highest reading as correct.
- When taking consecutive readings, wait 10 seconds between readings to allow the thermometer to reset itself.
- Ensure that the device maintains a 0 to 5mm distance from the forehead during measurement to ensure accurate readings.

Measuring ear temperature



1. Remove the ear probe cover.
2. Press the power button to switch on the device and enter measurement mode. The LCD screen will display the last measured test result.
3. Perform an ear tug to straighten the ear canal. This gives the thermometer a clear view of the eardrum. An ear tug is best performed using your free hand to grasp the outer edge of the top half of the ear.

Children under 1 year:
Pull the ear straight back.

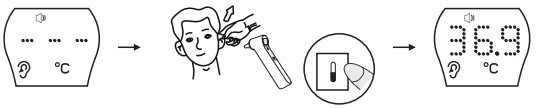
Children aged 1 year to adult:
Pull the ear up and back.

To take your own ear temperature, wrap your free hand around the back of your head and tug your ear from behind.

4. Place the ear probe snugly into the ear canal and press "" button to take a measurement.

   Note: Maintain this position until the measurement completion sound is heard. If the device is in silent mode, maintain this position for 1-2 seconds.

5. After 1 second, the measurement result will display on the screen.



LCD flashing
Device waiting to start measurement

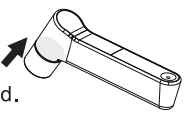
Tug ear, insert probe into ear canal and press button to take measurement

Measurement result

- Always take the measurement in the same ear as the temperature from the right ear may differ from that of the left ear.
- For accurate readings, ensure the ear is free from obstructions or excess earwax build-up.
- Do not use ear probe on patients suffering from otitis external, tympanitis and other ear diseases.
- If ear drops or other ear medications have been placed in the ear canal of one ear, take the temperature in the untreated ear.

- External factors may influence ear temperatures, such as when the patient has:
  - been lying on one ear or the other
  - had their ears covered
  - been exposed to very hot or very cold temperatures, or
  - been recently swimming or bathing.

  In these cases, remove the patient from the situation and wait 20 minutes prior to taking a measurement.



Measuring object temperature

1. Keep the ear probe cover attached.
2. Press and hold the power button for 6 seconds to enter the object measurement mode.
3. Aim the device at the target object, then press the "🌡" button to take a measurement.

   Note: Maintain the device's aim at the target object until the measurement completion sound is heard. If the device is in silent mode, maintain the aim for approximately 1-2 seconds.
4. After 1 second, the measurement result will display on the screen.

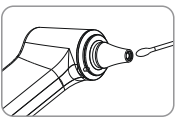
LCD flashing
Device waiting
to start measurement

Aim device at object
and press button
to take measurement

Measurement
result

Cleaning and storage instructions

It is recommended to clean the device probe before and after each use to ensure precise measurements and hygienic use each time.



1. Check the device probe before and after each use. If there is residue or dirt on the probe, please use a cotton swab dipped in 75% alcohol to gently clean it for about 5 seconds.
2. The other parts of the device can be wiped with a soft and dry cloth for about 10 seconds.
3. Ensure there is no visible dirt or residue on the device after cleaning.
4. Wait 10 minutes before using the device to take a measurement.

⚠
- Do not clean the device with organic solvents (such as thinners, acetone, etc) or abrasive cleaners.
- Never splash or soak this device in any liquid, including water.
- Ensure no liquid enters the interior of the device.
- The device probe can be cleaned for a maximum of 40,000 times

When storing the device:

- Store in a safe place away from direct sunlight, dust and pollutants.
- If the device will not be used for an extended period of time, please remove the batteries before storage to avoid any battery leakage from damaging the device.

Error messages

If an error occurs, the device will beep (if not in silent mode) and display an error message. Refer to the table below for their possible causes and solutions:

Error message	Cause	Solution
HI	Target object temperature is higher than the measurement range (43ºC for body temperature mode or 93.2ºC in object temperature mode)	Make sure the device probe is clean. Make sure the device probe is properly inserted into the ear canal, or that the device is within the suitable distance from the forehead or target object. Then, take a new temperature.
LO	Target object temperature is lower than the measurement range (34ºC for body temperature mode or 0ºC in object temperature mode)	
Er.H	Current temperature in the operating environment is too high (above 40°C)	Operate the device only in an environment with ambient temperature of 10°C~40°C
Er.L	Current temperature in the operating environment is too low below 10°C)	
Err	Environment temperature changed too rapidly at more than 5°C during object temperature mode. Device shuts down automatically.	Allow the thermometer 30 minutes to equilibrate with room temperature before use.

Troubleshooting guide

Issue	Cause	Solution
The screen will not display when the device is switched on	The battery power is too low	Replace with new alkaline batteries
	The batteries were inserted incorrectly	Ensure batteries are inserted with their polarities correctly positioned
The measurement result is too low	Measurement position is not correct	Follow the user manual instructions when taking a measurement
	There is dirt obstructing the ear canal or device probe	Clean the ear canal or device probe according to the cleaning instructions
Consecutive tests showing large temperature fluctuations	The time interval between measurements is too small	Wait 10 seconds before taking the next measurement test

Product specifications

Product name: Infrared Ear/Forehead Thermometer
Model number: PG-IRT1603
Product dimensions: 31×175×72mm
Product weight: about 77g (excluding batteries)
Measurement range:
Body temperature 34.0 - 43.0°C.(93.2 - 109.4°F)
Object temperature 0 - 93.2°C (32 - 199.7°F)
Resolution ratio: 0.1°C/°F
Measurement location: Laboratory
Accuracy: (35.0°C~42.0°C) ±0.2°C, (95.0°F~107.9°F) ±0.4°F, other temperature ±0.3°C.
Operating conditions:
Temperature 10.0°C~40.0°C(50.0°F~104.0°F)
Relative humidity 15%RH~93%RH
Atmospheric pressure 70kPa~106kPa
Transportation / storage conditions:
Temperature -25°C~55°C (-13°F~131°F)
Relative humidity 0%RH~93%RH
Atmospheric pressure 50kPa~106kPa
Display screen: LCD display screen, 4 bit numbers and special icons.
Sound: 1 short beep - Device switched on and ready
1 long beep - Measurement complete
3 short beeps - System error or fault
10 short beeps - Fever alert
* Alert sounds can be switched on / off
Memory: 9 tests
Automatic shut down: After 30 seconds of inactivity
Battery: 2 x 1.5V AAA batteries
(alkaline batteries are recommended)
Period of use: 5 years

Forehead mode:
Clinical bias, Dcb: 0.078
Limits of Agreement, LA: 0.243
Clinical Repeatability, σr: 0.069
Reference body site: forehead
Measuring site: forehead

Packing parts list
1. Main body
2. Product manual

Warranty Details

Register your warranty online now at **my.andatech.com.au**

Congratulations on your purchase! It is our aim to provide you with quality products that you can trust. Our products come with guarantees that cannot be excluded under the Australian Consumer Law.

You are entitled to a replacement or a refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

The Guarantee

The product is guaranteed to be free from defects in workmanship and parts for a period of 2 years from the date of purchase. Defects that occur within this warranty period, under normal use and care, will be repaired, replaced or refunded at our discretion, solely at our option with no charge for parts and labour. The benefits conferred by this warranty are in addition to all rights and remedies in respect of the product that the consumer has under the Trade Practices Act and similar state laws.

Proof of Purchase

This warranty is valid for the original purchase and is not transferable. Please keep your purchase docket or receipt as proof of purchase and as proof of date on which the purchase was made. The purchase docket (or a copy) or receipt must be presented with the warranty when making a claim under this warranty.

Service during the Warranty Period

To claim for warranty, contact us on 1300 800 200 or support@andatech.com.au to get an RA# (Return Authorisation Number). Ensure that the RA# is clearly stated on the outside of the packaging and that the product is properly packaged so that no damage occurs to the product during transit. Shipping of the product back to us for warranty will be at our cost. A product return without the RA# or proof of purchase will not be accepted.

Extent of Warranty

This warranty is limited to defects in workmanship or parts. All defective products or parts will be repaired or replaced. This warranty does not cover manuals and packaging.

Normal Wear and Tear

This warranty does not cover normal wear and tear to the product or parts.

Exclusions

This warranty does not cover:

- Any defect caused by an accident, misuse, abuse, improper operation, lack of reasonable care, unauthorised modification, loss of parts, tampering or attempted repair by a person not authorised by the distributor.
- Any product that has been damaged by a lightning strike either directly or indirectly or a main power surge or liquid ingress.
- The product if it is located outside of Australia.
- Any damage caused by improper power input or improper cable connection.

Andatech Pty. Ltd.
PO Box 3038, Nunawading VIC 3131, Australia.
Phone: 1300 800 200 Fax: 1300 883 802 Email: support@andatech.com.au

Appendix 1 Guidance and Manufacturer Declaration Tables

Guidance and manufacturer's declaration–electromagnetic emissions		
The Model PG-IRT1603 Infrared Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-IRT1603 Infrared Thermometer should assure that it is used in such an environment.		
Emissions	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The Model PG-IRT1603 Infrared Thermometer 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 Model PG-IRT1603 Infrared Thermometer is used in home and it's powered by DC 3V
Harmonic emissions IEC 61000-3-2	N. A.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N. A.	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model PG-IRT1603 Infrared Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-IRT1603 Infrared Thermometer 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 ±2 kV, ±4 kV, ±8 kV, ±15KV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	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 Model PG-IRT1603 Infrared Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-IRT1603 Infrared Thermometer should assure 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 Vrms150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Model PG-IRT1603 Infrared Thermometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHZ to 2.7 GHz	10 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.7GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range [b] Interference may occur in the vicinity of equipment marked with the following symbol:

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

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

a The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHZ, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c 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 Model PG-IRT1603 Infrared Thermometer is used exceeds the applicable RF compliance level above, the Model PG-IRT1603 Infrared Thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model PG-IRT1603 Infrared Thermometer.

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

Recommended separation distances between portable and mobile RF communications equipment and the Model PG-IRT1603 Infrared Thermometer

The Model PG-IRT1603 Infrared Thermometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model PG-IRT1603 Infrared Thermometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model PG-IRT1603 Infrared Thermometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output 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 2.7 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 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.

Andatech Pty Ltd
9 Trade Place, Vermont VIC 3133 Australia
andatech.com.au
1300 800 200

Shenzen Pango Electronic Co., Ltd
Main Site: No. 25 1st Industry Zone, Fenghuang Road, Xikeng Village, Henggang Town, Longgang District, Shenzhen, Guangdong China.
Additional Site: 2-4 Floor, No. 5 Shanzhuang Rd., Xikeng Village, Henggang Town, Longgang District, Shenzhen City, Guangdong Province, China.