Instruction For Use

CE 2764

Continuous Monitoring Thermometer

Model: Coola

- Version：A0
- No：WI-Coola-0014
- Release Date: 2018/09/12

Contents

1. Foreword

Thank you for purchasing the Continuous Monitoring Thermometer.
In order to use the product safely and correctly, please read the instructions carefully before use.
Before use, please check whether the accessories are complete according to the packing list, and check whether there is any breakage and damage to the product appearance and buttons. After installing the battery, turn on the power button and check whether the indicator flashes is in blue .

1.1 Security Information

⚠ Precautions

- Before using this thermometer, please read this manual carefully and fully understand the warnings and risks.
- This electronic thermometer is applied only to the underarm unless otherwise the measuring discrepancy will occur.
- The user's posture and physical conditions may affect measuring accuracy.
- When measuring, keep thermometer in your armpit tightly.
- Any move of the users will result in inaccuracy for measuring.
- Any move of the thermometer in use will make measuring inaccurate.
- The loose contact between the probe and the measuring position may result in inaccurate measurement.
- If the thermometer is taken out before the complete measurement, the measurement result will be inaccurate.

- Measurements will become abnormal right after the sports activities, diet, and bathing.
- Having a rest before taking the measurement.
- Ensuring thermometer measuring under proper and required conditions.
- The measuring results should not be based solely on personal experience but duly constancy with professional physicians

⚠ **Warning**

- Do not use this product in the environment of strong electromagnetic interference.
- This product is non-water proof and do not soak the thermometer directly in water.
- Please do not dismantle or repair yourself but contact the manufacturer for after-sale service when any damages or obstacles occur to this product
- Please remove the batteries when the product is in no use for some long time
- Do not put the product in a strong acid or alkali environment, or it may affect the product life and accuracy of measurement results.
- Improper replacement of lithium batteries may pose an unacceptable risk
- This app is applicable to phones with blue tooth 4.0, Android4.3 or above, IOS6.1 or above. In order to avoid any possible damage to your phone, please confirm that your phone system meets with the requirements before use
- Do not perform maintenance operations during use
- This product contains batteries and electronic components, do not close to fire or heat source.
- The product bears small parts and components , please keep it out of Children’ s reach. The use by

Children of this product must be under the guardian of adults

- The electronic thermometer has been ex-factory calibrated,
- do not calibrate it by yourself, but contact the factory for any calibration in need.
- The equipment or system shall not be used close to or stacked with other equipment.
- Unless otherwise it is so required, the user has to observe and prove this will work properly together
- In addition to cables sold by the manufacturer of the equipment or system as spare parts for internal components, the use of non-prescribed accessories and cables may result in increased emission or reduced immunity of the equipment or system.
- 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 device 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Do not store the product outside the rated storage temperature and humidity range;
- Do not use this product in environmental conditions outside the rated operating temperature and humidity range
- Severe impact, such as dropping, may damage the equipment and cause the accuracy of the equipment to decrease;
- When the patient's temperature is lower than the

ambient temperature, the measurement may not be accurate.

Attention

- The Electronic Thermometer conforms to the related requirements of electromagnetic compatibility of IEC60601-1-2 standard.
- Users shall install and use the electromagnetic compatibility information provided in the accompanied files with the sale of this product
- Avoid strong magnetic interference sources such as smart phones , micro ovens in order that the Electronic Thermometer function fully and properly
- Please refer to the guidance and manufacturer's statement attachments.
- The patient is the intended operator

1.2 Symbol

Symbol	Significance
	Attention,warnings
	Type B application device
	Caution
	The electronic waste should be disposed by professionals after use
	Manufacturer
	Lot Number

	Manufacturer
CE 2764	CE mark
IP22	2 Protected against solid foreign objects of 12,5 mm Ø and greater; 2 If keep the thermometer in 15 degree angle, it still can prevent the water drop.

2. Product description

2.1 Product name and model

Product Name: Continuous Monitoring Thermometer
Product model: Coola

2.2 Expected usage

The electronic thermometer is suitable for measuring the body temperature under the armpit

2.3 Indications for Use

Intended use:

The device is intended to be used for measuring the body temperature under the armpit for 48 hours. The device is intended to be used at home or healthcare facilities. The device is not intended for infants less than three months.

Contraindications:

The product is should not be used when accurate measurement of body temperature will influence clinical decisions and should not be used persons with an implanted pacemaker.

Side effects:

Skin rash or reaction due.

Patient Profile:

All patients(age: more than 3 months) who meet indications but do not meet contraindications.

User profile:

There is no specific user identification for the device. It can be used by experts or non-specialists in accordance with the conditions specified in the user manual.

2.4 Product Specifications and Parameters

Description		Electronic Thermometer
Model		Coola
Voltage		d.c.3.0V（lithium battery CR2016）
Temperature Sensor		thermistors
Measuring Method		actual measurement
Measuring Position		armpit
Temperature Display Model		3-digital display
Measuring Accuracy		lower than 35.3℃ ± 0.3℃； 35.3℃~36.9℃ ± 0.2℃； 37.0℃~39.0℃ ± 0.1℃； 39.1℃~41.0℃ ± 0.2℃； Higher than 41.0℃ ± 0.3℃。
Measuring Range		33℃~45℃
Measuring Time		10min
Minimum measurement time		2min
The time required from a cold or hot storage environment to 20 degrees Celsius equipment can work normally		2 hours
Working Conditions	working temp and humidity	5 ° C~40 ° C； ≤85%RH
	storing temp and humidity	-10 ° C~55 ° C； ≤95%RH
	operating air	70~106kPa

	pressure	
	Transit and storing air pressure	50~106kPa
Overall Dimension		38mm × 38mm × 4mm
Product life expectancy		3 years
Battery life expectancy		5 years
Typical usage time		120h
Electric Shock Protection		internal power supply ,type B application
Disinfection and Sterilization Method		as per recommended cleaning by the manufacturer
Safety Classification		Don't use in the presence of a mixture of flammable anesthetic gas and air or with oxygen or nitrous oxide.
Working system classification		continuous operation
Packing List		Thermometer x1 Battery x1 User’ s manual x1 Q.C certificate x1.

*The specs are subject to change without further notice

2.5 Product structure and composition

The electronic thermometer is complete with the main body of the thermometer and the smart phone application. The main body of the thermometer

comprises mainly the control circuit, battery and temperature detector.

3. Preparation before use

3.1 Open box to check

Please check the box carefully before unpacking.If you find any damage, please contact the carrier or the company immediately.If the package is complete, unpack the package in the correct way and carefully remove the device and other components from the box. Check the equipment for any mechanical damage and complete items.If you have any questions, please contact us immediately.

⚠ Warnings and precautions

- Please save the box and packing materials for future transportation or storage.
- Please save the warranty card for warranty use.
- When handling packaging materials, you must follow local regulations or the hospital's waste disposal system and place the packaging materials out of reach of children.
- The equipment may be contaminated by microorganisms during storage, transportation and use. Please confirm that the packaging is in good condition before use.
- The date of manufacture and the date of use of the product are listed on the label.

4. Instructions

4.1 Operation Instructions

※Without proper measuring method applied, never

would it be possible for users to obtain right measuring figures.

Please follow the measuring procedures well

(1) log in HTTP: select "download center" to download the corresponding mobile application.。

(2) battery installation or replacement: open the battery compartment of the thermometer and mount the battery onto the compartment door . The "+" side of the battery is on the same side of thermometer front then push it in with the door of the battery compartment.Switch on the thermometer power supply and turn on the smartphone bluetooth ,log on the mobile app, and add the device according to the operating instructions.

Figure 1 Schematic diagram of battery installation

(3) Pool power test method: body temperature sticking equipment returns 0 and 1, 0 means there is electricity, 1 means no electricity.

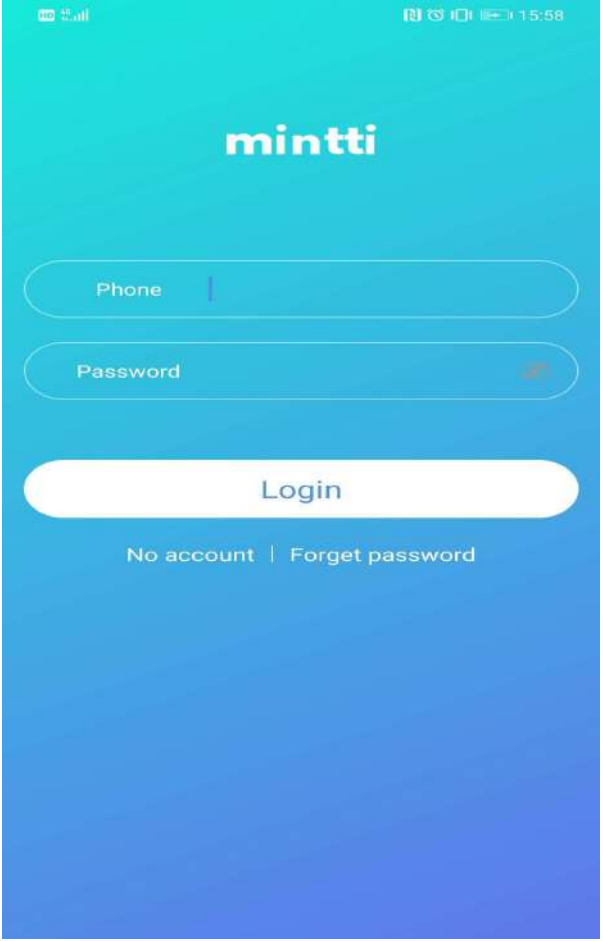
(4) APP operating instructions

1)Use a mobile browser to scan the QR code below,

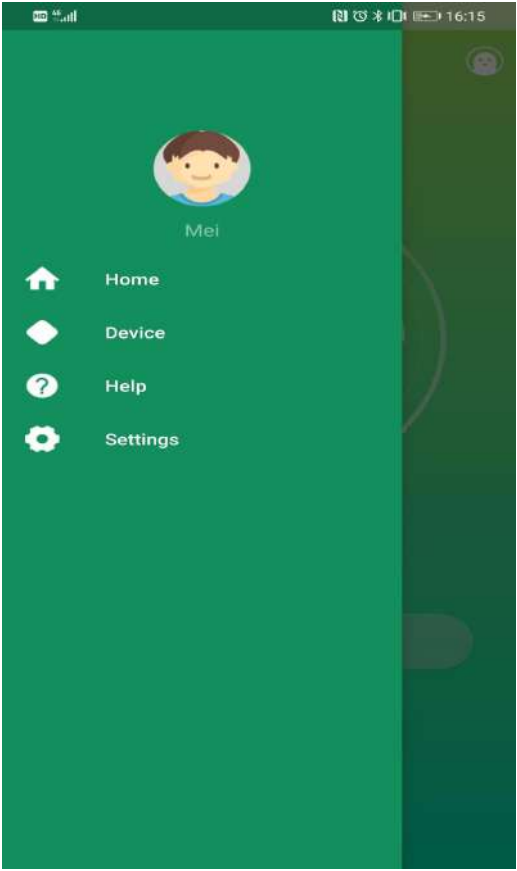
download and install the APP

Figure 2 APP download QR code

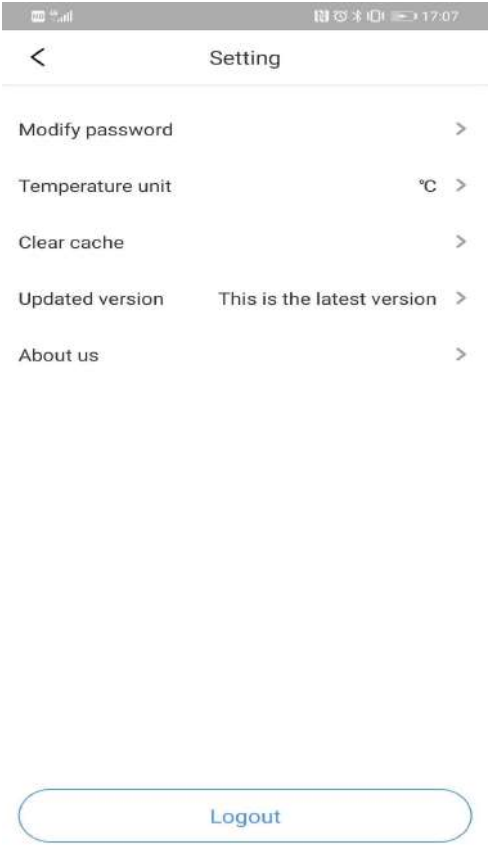
2) Open the temperature stick app on the phone, enter the login interface, and register an account to set a password


15:58
mintti
Phone
Password
Login
No account | Forget password

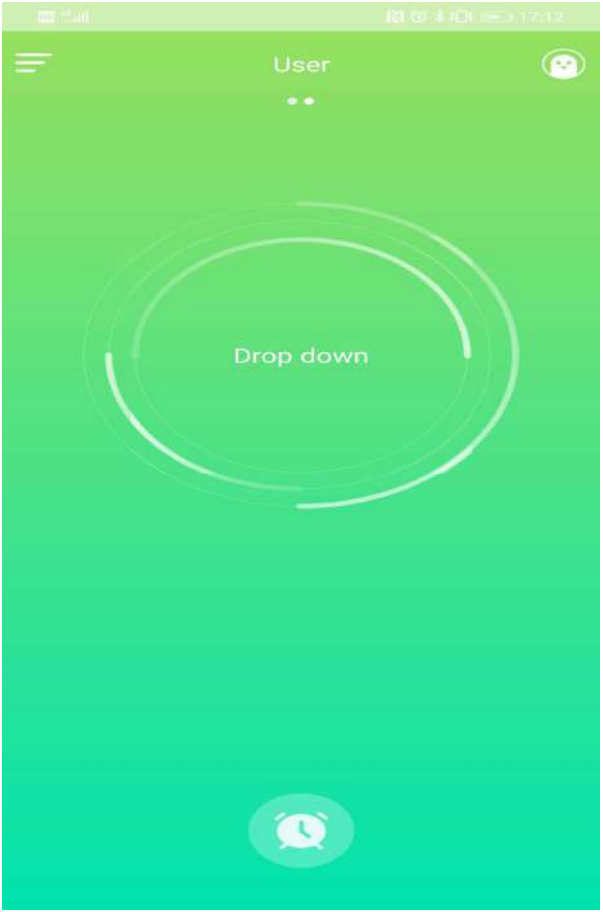
3）Click Settings



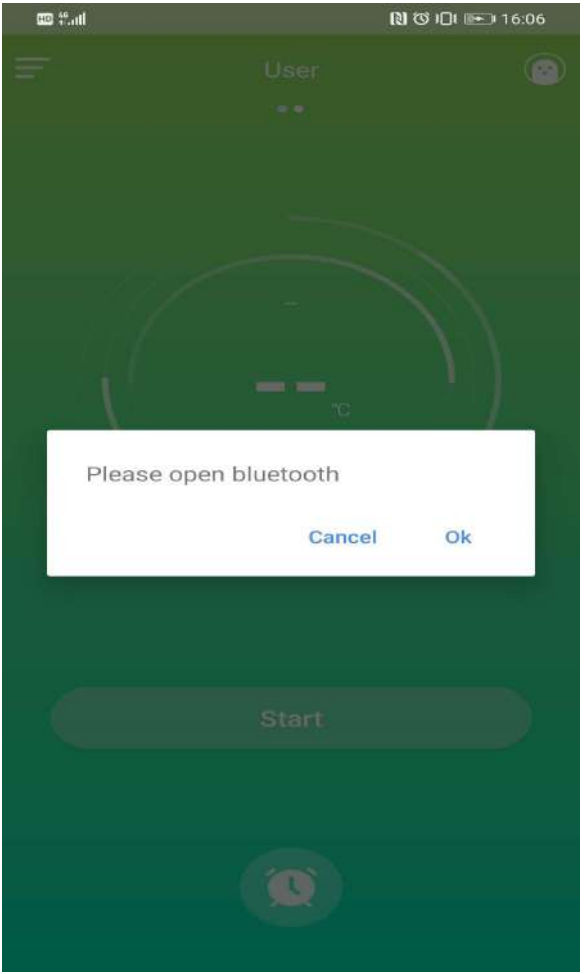
4）Here are the following functions



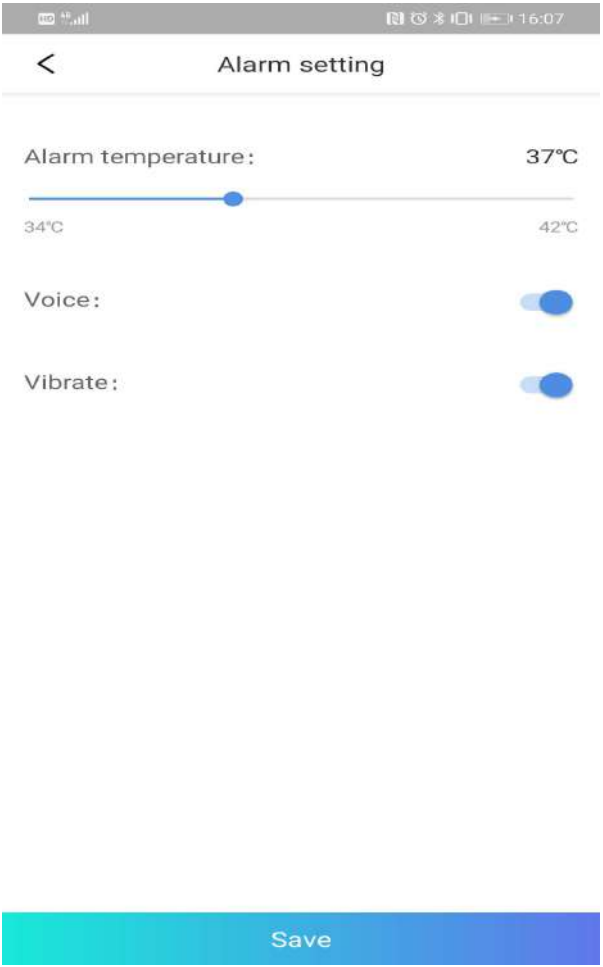
5）Press and hold the button of the temperature sticking device to boot, enter the APP homepage, pull down and bind the temperature sticking device



6）Turn on Bluetooth and bind the device



7）Set the alarm temperature and select the alarm prompt method



8）Clamp the thermometer directly under the armpit, or prepare medical tape to fix the thermometer under the armpit so that the metal temperature sensor points to the armpit.

9）And click to start measurement according to the instructions of the mobile app

The measured temperature is as follows: When the measured value is stable, the mobile application will trigger vibration / sound and display “End Measurement” on the mobile device. Remove the thermometer, long press the power button of the thermometer to turn it off, then clean and save. The measurement result will appear in the application.


User
36.0
℃
Normal
Stop

ur

Fever cooling method

Physical cooling method

1.Cold compress: wet the towel with cold water and apply it to the forehead. Replace it 5-10 minutes. Ice pillow may be used when the temperature is high, but local skin frostbite should be prevented;

2.Hot compress: use warm water to wipe the blood vessels more abundant parts, such as the neck, armpit, groin and so on, to promote blood circulation, to help dissipate heat;

3.Antipyretic plaster: apply a antipyretic patch on your forehead or other major blood vessel to achieve a physical cooling effect;

4.Add water: when heating, water easily lose, should be more water, drink plenty of water, is conducive to cooling.

Diet notes during the period of illness

When heating, excessive consumption of nutrients, should be eating light, and rich in vitamins, digestible foods, reducing the burden on the gastrointestinal tract. Eat more fruits and vegetables, eat less and eat more. Should not eat too full, so as not to cause vomiting or abdominal discomfort.

4.2 General Settings for Mobile Applications

(1) temperature display unit is ℃, resolution is 0.1℃.

(2) when the temperature point is stabilized, the measuring mode changes from "measuring" to "measuring ended".
(3)Variable Settings: reminder , medicine -taking, parameters , account and about us .etc.
(4)Reminder setting: the system default temperature setting at 37.5℃, and users can set optional temperature range between 37.0℃ and 38.4℃ to display. When the reaches the preset value, the mobile phone application will start vibrating or ringing while users can chose to set up either vibration or ringing
(5)Medicine-taking reminder:
Users can set the medication interval time and starting time and choose whether to turn on the reminder switch.
(6) parameter settings: users can switch units.
(7) account setting: users can set accounts accordingly and the data can be stored into corresponding accounts.
(8) about us: users can check the updates and enter the official website or official WeChat.
(9) History: the measured temperature can be stored and displayed, and the temperature curve can be drawn up.
(10)Tips: recommended physical cooling methods and dietary precautions during illness.
(11)high and low temperature reminder: when the temperature exceeds the temperature display range, a reminding signal will sound.

5. Maintanance and Cleaning

5.1 Cleaning and maintenance

Wipe the dirt on the thermometer with a soft dry cloth before and after each use.

If the dirt is more serious, please wring and wipe the cloth soaked with water or neutral detergent first, then wipe the dirt on the thermometer with a soft cloth.

Do not immerse the thermometer in alcohol

Do not use ultrasound for cleaning

5.2 Storage

This thermometer is non water proof. Do not use the thermometer in the conditions where water is available for it will cause malfunction.

Do not keep the thermometer in the place where high temperature, humidity and direct sunlight and heater and near the heat source or fire source etc are available.

Do not store in a tilt, vibrating or sever impacting conditions

Do not store where there are chemicals or corrosive gases

[waste disposal]

Please dispose of the used battery according to the relevant regulations in your city.

5.3 fault analysis and troubleshooting

Obstacles	Causes and	Solutions

	analysis	
Valued measured some lower	Temp sensor is off the center of armpit during the measurement	Position the temp sensor in the armpit center with sensor toward armpit and tight clamp
	The thermometer is taken out during the measurement	Do not raise up your arms often or take the thermometer out
	Measuring take places right after sports , shower or eating .	Start measuring after 30 minutes' rest
Value measures unstable	Possible move in the measuring position	Ensure the temp sensor toward armpit
	In a still or quite conditions or not during the measurement	Stay quiet and keep still during the measurement
Bluetooth disconnected	Application is far from thermometer	Use thermometer in the designed application range

Indicator off	Battery installation error	Install the battery correctly
	poor battery	Replace battery at once
Undiscoverable in the list of devices	Bluetooth signal too weak	Shut off the thermometer and add the device after rebooting

5.4 Warranty Services

This thermometer conforms to all of the requirements established in ASTM Standard E 1112. Full responsibility for conformance of this product to the specification is assumed by Suzhou Melodicare Medical Technology Co., Ltd.
Address：Building Room 301, no. 32 Hongxi road, Suzhou high-tech zone, Jiangsu province, China
The company renders limited warranty to the product of thermometer ： from the date of sale, the user is granted one year free warranty with proof of shopping invoice.
The limited warranty do not apply to :
Obstacles caused by randomly tampering with products
b) obstacles caused by proper maintenance
c) obstacles caused by improper operations against the instruction manual.

d) obstacles caused by repairmen in an authorized repairing shop

(3) repair and maintaining service outside warranty to be charged according to material and repair service

This term of warranty applies only to electronic thermometer but not to the easily consumable parts like battery and other accessories.

6. Appendix

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1	**Guidance and manufacturer´s declaration – electromagnetic emission**		
2	The model Coola is intended for use in the electromagnetic environment specified below. The customer or the user of the model Coola should assure that it is used in such an environment.		
3	**Emissions test**	**Compliance**	**Electromagnetic environment – guidance**
4	RF emissions CISPR 11	Group 1	The Model Coola 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.
5	RF emissions CISPR 11	Class B	The Model Coola is suitable for use in all establishments, including domestic establishments and those directly connected to
6	Harmonic emissions	Not applicable	

	IEC 61000-3-2		the public low-voltage power supply network that supplies buildings used for domestic purposes.
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer´s declaration – electromagnetic immunity			
The Model Coola are intended for use in the electromagnetic environment specified below. The customer or the user of the Model Coola 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, ±15 kV 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 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	N/A	N/A
Voltage dips, short interruptions and	0 % UT (100 % dip in UT) for 0.5 cycle at 0 , 45 , 90 ,	N/A	N/A

voltage variations on power supply input lines IEC 61000-4-11	135 ,180 , 225 , 270 , and 315 0 % UT (100 % dip in UT) for 1 cycle at 0 70 % UT (30 % dip in UT) for 25/30 cycles at 0 0 % UT (100 % dip in UT) for 250/300 cycle at 0		
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: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Coola is intended for use in the electromagnetic environment specified below. The customer or the user of the Coola 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 Vrms 150 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 Models Coola, 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  ncy 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 Coola is used exceeds the applicable RF compliance level above, the Coola should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Coola.

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 Coola

The Model Coola is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model Coola can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model Coola 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	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.7

10	3.7	1.11	2.22
100	11.7	3.5	7.0

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.

Recommended separation distances between RF wireless communications equipment

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $E = \frac{6}{d}\sqrt{P}$
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					

1970					Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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