VEGA TECHNOLOGIES INC.

INSTRUCTION MANUAL

Non-contacted Infrared forehead thermometer

Model No.: IR-08MT

V3.0

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Read this instruction manual carefully before use

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1. Introduction

Thank you very much for purchasing our Non-contacted Infrared forehead thermometer IR-08MT. To ensure safe and correct use of this device, please read this instruction manual carefully before using. We also recommend you to keep this manual at hand for future reference.

The Non-contacted Infrared forehead thermometer is intended for the intermittent measurement of human body temperature for people of all ages. It allows you quickly and easily to measure temperature, and values are saved automatically. The thermometer has been clinically tested and proven to be safe and accurate and no any side effects when used in accordance with the operating instruction manual.

Non-contacted Infrared forehead thermometer frontal temperature gun for measuring human body temperature. The product is widely used in schools, customs, hospitals, families. Easy to use, mode selection.

The Non-contacted Infrared forehead thermometer is intended for the intermittent measurement of human body temperature for people of all ages.

The device has direct mode(object temperature mode) and adjust mode(forehead temperature mode). The direct mode is designed for measuring object temperature, while the adjust mode is designed for measuring human body temperature. Since the direct mode is used to measure surface temperatures of objects, the direct mode does not fall under any medical function with defined target populations or indications.

2. Information about the device:

2-1. Intended use:

The Non-contacted Infrared forehead thermometer is intended for the intermittent measurement of human body temperature for people of all ages. It allows you quickly and easily to measure temperature, and values are saved automatically.

2-2. Intended User:

The Non-contacted Infrared Forehead Thermometer is intended for use by qualified medical professional and lay persons.

2-3. Intended patients: People of all ages.

2-4. Intended Environment:

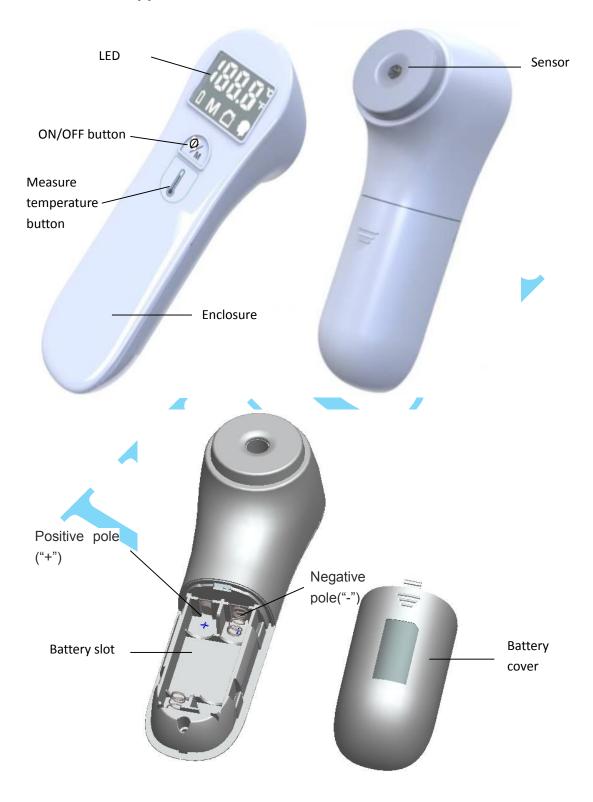
This product is intended for use in a medical facility, such as Hospital, clinic and doctors office, and in a room of general household.

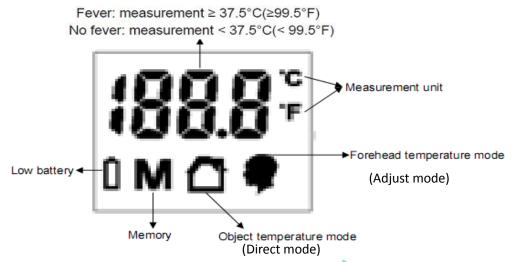
2-5. Precautions for use:

Warnings and cautions described in the instruction manual should be observed.

3. Product description:

3-1. Visual appearance and structure





3-2. Accessory:

AAA Size (LR03) alkaline battery: 2PCS

4. Product features:

- ♦ Ideal design for easy use;
- Ultra jumbo display, with backlight, easy to read;
- ♦ Non-contact, clean, safety and accurate;
- Automatic shut off;
- ♦ Beeper alarm;
- → Fast measurement within 1 second;
- ♦ 32 sets memories recall;
- ♦ °C & °F switchable;
- Two modes: Direct Mode(object temperature mode) and Adjust Mode(forehead temperature mode);
- ♦ Wide range of measurement;
- ♦ Low voltage indication;
- ♦ With AAA size (LR03) alkaline battery (2pcs);
- Optional storage case and carrying bag for easy storage.

5. Device specifications

NO	Item	Specification		
1	Operation mode	Continuous mode		
2	Measure mode	Non-contacted infrared forehead thermometer		
3	Product Type	Internally powered ME equipment		
4	Power supply	AAA size (LR03) alkaline battery		
5	Classification	Class II equipment, Type BF applied part		
6	Unit	$^{\circ}\mathrm{C}$ / $^{\circ}\mathrm{F}$ switchable		
		Direct Mode(object temperature mode):		
		0°C-93.2°C (32.0°F-199.9°F)		
7	Measuring range	Adjust Mode(forehead temperature mode):		
		32.0℃-43℃ (89.6°F-109.4°F)		
8	Laboratory accuracy	°C: 34.0≤T<35.5°C & 42.0≤T<43.0°C, ±0.3°C		

		1 20 20
		35.5≤T<42.0℃,±0.2℃
		0≤T<34.0℃ & 43.0≤T<70.1℃,±0.5℃
		70.1≤T≤100.0°C, ±1°C
		℉: 93.2℉≤T<95.9℉& 107.6≤T<109.4℉, ±0.6℉
		95.9°F≤T<107.6°F,±0.4°F
		32.0°F≤T<93.2°F& 109.4°F≤T<158.2°F,±0.8°F
		158.2≤T≤199.0°F,±1.6°F
9	Resolution	0.1°C /0.1°F
10	Measure position	Human forehead or the surface of object
11	Measure speed	about 2 s
11	ivieasure speed	≤3 cm (the distance between the sensor and being
12	Measure distance	measure person forehead or surface of object.)
		Direct Mode(object temperature mode):
		<0°C: display "Lo";
		>100°C: display "Hi "
	High and low	Adjust Mode(forehead temperature mode):
13	temperature warning	<34.0°C: display "Lo";
	temperature warring	>43.0°C: display "Hi";
		The symbol" Lo" represents low temperature; "Hi"
		represents high temperature.
	Fever temperature (adjust	represents high temperature.
14	mode)	≥37.5°C(99.5°F)
	mode)	Open the device: One "Bi" emits;
	Sound notice	
		Already for the test: One "Bi" emits;
4.5		Direct Mode(object temperature mode): One "Bi" emits
15		when finish the test
		Adjust Mode(forehead temperature mode): One "Bi" emits
		when body temperature $<$ 37.5°C; Six "Bi" emits when
		body temperature≥37.5°C
16	Automatic shut off	Stop operating the device, it wills automatic shut off after
		20 ± 5 seconds.
		ii ii
17	Low power display	The device will display 🔳 when the battery power is in
		the range 2.6V± 0.2V.
18	Memory function	32 sets
19	Working voltage	3V (2pcs AAA size (LR03) alkaline battery)
20	Work current	<60mA
21	standby current	<15uA
22	Battery life	At least 1500 measurement
23	Dimension (L x W x H)	135 x 43 x 42mm
		5°C to 40°C (41°F to 104°F);
	O	30% to 85% RH
24	Operating Temperature &	Atmospheric pressure:700 hpa~1060 hpa
	Humidity Range	Note: if the operation temperature is not in the range from
		5°C to 40°C (41°F to 104°F), the device will display "Err".
		-10°C to 60°C (14°F to 140°F)
25	Storage Temperature &	25% to 90 % RH
	Humidity Range	Atmospheric pressure:700 hpa~1060 hpa
26	lifetime	2years(300h)
27	Applied parts	Unit body enclosure
_,	Applica parts	one soay cholosure

6. Operating Instructions:

6-1. Function instructions:

Please read the following information carefully before measure the temperature.

6-1-1. Switch ON/OFF the unit

A. Power on and self-check function

- Press the [O/M] button to switch on the thermometer, it will go directly into self-check mode in 1 second and then the LED display from the shows the last memory temperature and after this, "--- °C" for "--- °F" will be showed, at the same time, a "Bi" sounds from the buzzer.
- → At this time, the measurement can start. Press the button to start the measurement.

B. Switch off:

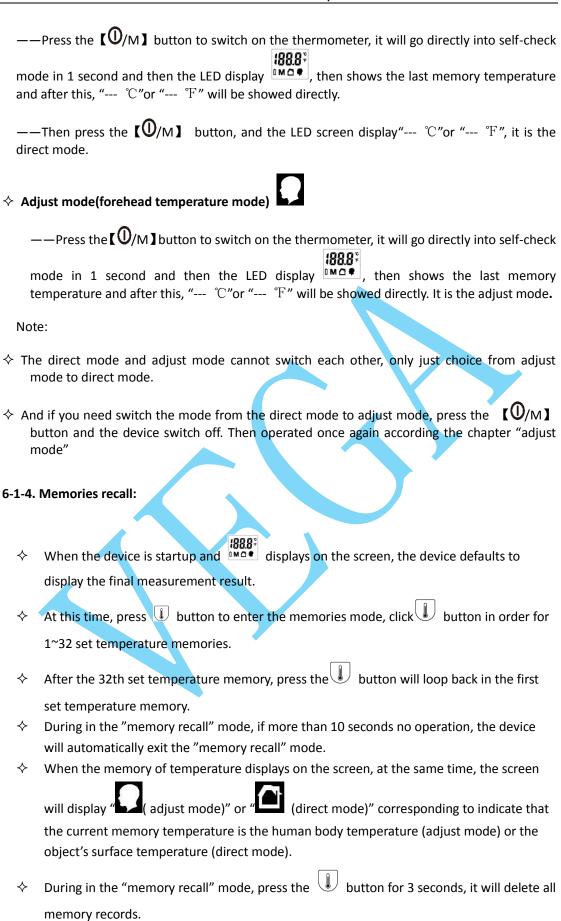
- ♦ After startup, press [0/M] button and then the unit turn off in the Direct Mode.
- ♦ After startup the unit will be shutdown automatically after 20 seconds if no any operation.

6-1-2.℃/ Fswitchable:

- \diamond Firstly, Press the **(**0/M**)** button for about 2 seconds while the device is in OFF state.
- \Leftrightarrow Secondly, the device will come into the switchable state, and display the original setting unit (°C or °F) for 0.5s.
- ♦ Then, the automatic switch the other unit as not same as the original setting unit.
- \diamond In the end, waiting for 5 seconds or press the **[O/M]** button, the switchable unit (°C or °F) operation is done.

6-1-3. Direct mode / adjust mode switchable:

Direct mode(object temperature mode)



6-1-5. Low power alarm:

When the battery power voltage is in the range 2.6V(±0.2V), the symbol will be light and display in the LED screen. It means that the user needs to replace new battery.

Note: Handle of the new battery need by the adult or the children under adult supervision.

6-2. Measure temperature.

- When the device is in the measure temperature mode, place the sensor head right in front of the measurement position (patient forehead or object) and the distance is not exceed 3cm.
- Secondly, press the button to measure the temperature. After 1 second, the buzzer makes a "Bi" sound, and the result will display in the LED screen.
- If you need to measure the person temperature, please choice the adjust mode, and the LED screen will display the symbol. (Please see the chapter" 6-1-3. Direct mode / adjust mode switchable)
- If you need to measure the object temperature, please choice the direct mode, and the LED screen will display the symbol. (Please see the chapter" 6-1-3. Direct mode / adjust mode switchable)

6-3. Replacement parts:

There is no part that needs to be replaced by the user except for the AAA size (LRO3) alkaline battery.

Note: If the device has a long time not to be used, please remove batteries from the device. Batteries replacement process:

Step1. Push down the battery cover;

Step2._ Take batteries out from the battery slot;

Step3._ Insert the new batteries into the battery slot correctly;

Step4._ Insert and pull up the battery cover.



7. Cleaning & Disinfecting

Please keep the device is clean after every use.

- Please use a clean soft cloth or cotton bud that can be moistened with 70% alcohol to clean the sensor.
- The measuring sensor is the most sensitive part of the thermometer, take great care of the measuring sensor when cleaning the device.
- Please use a soft cloth slightly moistened with a mild soapy solution to clean the entire device. Under no circumstances may liquid enter the device. Do not use the device again until it is completely dry.
- Never use abrasive cleaning agents, thinners or benzene for cleaning.
- ♦ Do not scratch the surface of the lens and the LED.
- ❖ Do not put the device into the water cleaning, in order to avoid damage to the device, use cotton swabs dipped in alcohol or using alcohol content of 70% cotton cloth or cotton to cleaning the enclosure and probe. Please note that don't let the liquid infiltration inside the thermometer, or use any corrosive cleaner, do not soak with water or other solvents or gasoline detergent.

8. Storage/Maintenance/Repair

8-1. Storage

To keep your device in the best condition and protect the device from damage follow these directions:

- Do not leave the device unattended with infants or persons who cannot express their consent.
- Do not subject the device or the parts to any strong shocks such as dropping the device on the floor.
- Do not use or store the device in extreme hot or cold temperatures, high humidity or under direct sunlight or dust.

 Dispose of the device and any used accessories or optional parts according to applicable local regulations.

8-2. Maintenance

- The manufacturer accepts no liability for unauthorized and incorrect reprocessing of this device by external companies!
- The replacement of the battery must only be performed by adult.
- The replacement of the parts must only be performed by the manufacturer or by the distributor.
 - This device is used only for the purposes described in the instruction. The manufacture shall not be liable for damage caused by incorrect use.

Note:

- Those parts of the device that shall not be serviced or maintained while in use with a PATIENT.
- The patient or the user can replace of batteries, and the children use or replace the battery need under the adult supervision.

8-3.Repair

- Never open or attempt to repair the device by yourself, as otherwise proper function is no longer guaranteed. Failure to observe this regulation shall void the warranty.
- The MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of ME EQUIPMENT
- If you need to repair the device, contact your equipment provider or that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

9. TROUBLESHOOTING

Problem/Question	Possible Cause/Remedy
The device does not work when the switch	The device does not assemble the batteries or
is pressed	the internal battery may run out of power and
	need to assemble or replace with new
	batteries.

The device measure result is not accurate.	 The measure sensor is dirty, and need to use a clean soft cloth or cotton bud that can be moistened with 70% alcohol. The patient uses the device immediately after exercising or walking a long time. And need to rest for 5 mins to 10mins to measure the temperature.
The device displays the symbol"Err".	The operation environment temperature changes suddenly, and the temperature difference is greater than 8°C, the device will display "Err". And it just needs to put the device in the operation environment for 20mins and more, after that to use the device.

10. Safety precaution:

——Indicates a potentially hazardous situation which, if not avoided, could result in serious injury.

Read all instructions carefully before use.

Warning:

- No modification of this equipment is allowed.
- Skin condition may affect measurement accuracy.
- Check the thermometer for signs of damage or wear before each use. Damaged or worn thermometer should not be used.
- Under any circumstances, the temperature taking result is ONLY for reference.
 Before taking any medical action, please consult your physician.
- MR UNSAFE: The device cannot be used in an MR environment.
- The user should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

10-1. Product cautions:

- The direct mode shall not be used to measure human body temperature.
- If the sensor is degraded or loosened, and the measure value is incorrectly, please stop using the device immediately and contact your equipment provider.
- To avoid electrical shock: Keep the unit away from water. Do not immerse the unit in liquid. Do not use while bathing. Do not reach for a unit that has fallen into water.

- Never operate the unit if it has any damaged parts, if it has been dropped or submersed in water. Promptly send it to a service center for examination and repair.
- If any abnormality occurs, discontinue use until the unit has been examined and repaired.
- Do not use other attachments unless recommended by manufacturer.
- This device is not a mirrored one.
- Children are not allowed to use the device unwatched, supervision is needed.
- This device is not waterproof and should not be immersed in water or other liquids. If cleaning is required, please follow the instructions in the "clean and disinfect" section. If you think this device is damaged or abnormal, please stop using this device and do not open it without permission.
- Failure to read and observe all precautions could result in personal injury or equipment damage.
- Do not use the device to treat the animals, and keep the device away from the pets to avoid damaging the device.
- If the device does not function correctly, stop using the device immediately.
- Switch the device off immediately if it is defective or malfunctioning.
- Keep the device out of the reach of unsupervised infants and children. The device may contain small pieces that can be swallowed.
- Keep children away from packaging materials risk of suffocation.
- Store the parts in a clean location for avoiding infection.
- Do not use the device after exercising, and need to rest for 5 mins to 10mins to measure the temperature.
- Make sure that the sensor is clean before use.
- The unit housing temperature is not exceeding 43° C.
- Protect the device from strong impacts.
- —Do not use the device if it has fallen or been dropped on the floor, been exposed to
 extreme humidity or is otherwise damaged in case of doubt, contact our customer service
 department or your local dealer

10-2. Operating Cautions:

- Close adult supervision is highly recommended when this unit is used by children or invalids.
- Never operate if this unit has a damaged part, and if it has been dropped into water.
- The operation environment temperature changes suddenly, and the temperature difference is greater than 8°C, the device will display "Err". Please put the device in the operation environment for 20mins and more, after that to use the device.

• Incorrectly selected the measuring temperature mode incorrectly should result in wrong data. Please operated the device according the chapter 6" operating instructions".

10-3. Storage Cautions:

- Do not store the unit under direct sunlight, high temperature or humidity.
- Keep the unit out of reach of small children.
- When you are not using the thermometer, please retain it in the storage box.
- Keep the unit stay away from fire and water. Do not test the high temperature or fire so as not to damage the body of the unit.

10-4. Cleaning Cautions:

- Use the cotton buds to clean the probe inside when it has dirt.
- Do not use water or fingers to contact with the probe directly.
- Do not immerse the unit in water. It may damage the unit.

11. SYMBOL GLOSSARY

	Refer to instruction manual/booklet		Manufacturer
LOT	LOT Batch code		Date of manufacture
SN	SN Serial number		Caution
Type BF applied part		-10℃	Temperature limitation
Keep away from sunlight			Protection class II
Humidity limitation		IP22	Ingress protection
=== Direct current		Ť	Keep away from rain

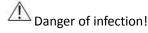
	"ON"/"OFF" (push-push)	\sim	Alternating current
C € ₀₁₂₃	This device complies with the requirements of Regulation (EU) 745/2017	QTY	Quantity
<u>††</u>	This way up	EC REP	Authorized representative
Ţ	Fragile; handle with care	70kPa → 106 kPa	Atmospheric pressure limitation
	In according with European directive 2002/96/EC on waste electrical and electronic equipment, this symbol indicates that the product must not be disposed of unsorted municipal waste, but should be collected separately	MD	Medical Device
	Use by date		

12. WARRANTY & DISPOLSAL

Warranty

Vega Non-contacted Infrared forehead thermometer's warranty period is 2 years from date of purchase from VEGA Technologies Inc. The warranty is limited to repair or replacement, at VEGA Technologies Inc. sole option, of any such component or equipment claimed to be defective when claim is shown to be bona fide by evaluation by VEGA Technologies Inc. This warranty does not extend to any components or equipment subjected to misuse, improper operation, accidental damage, or unauthorized repairs, and is not extended to charges of, or for, labor repairs. All items returned must be properly packaged and shipped, prepaid, by the distributor servicing the unit. VEGA Technologies Inc. shall not be liable to purchaser or others for loss of use of equipment or for indirect, or incidental or consequential damages that might arise.

Disposal



The device and accessories may come into contact with infectious material and be contaminated during their lifetime. For this reason the device and its accessories should be decontaminated before disposal or transportation.

Dispose of the device properly at the end of its service life. According to the European Directives 2002/96/EC (WEEE) and 2002/95/EC (RoHS) the device may not be disposed of with unsorted domestic waste. Look for a careful separation of materials. Consider the country-specific laws and regulations that apply to the disposal of the device. The proper disposal

of the device prevents environmental and human damage.

Outside the EU the appropriate national regulations for disposal must be observed.

13. Information about Electromagnetic Compatibility

Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC). The device needs to be installed and put into service according to the EMC information provided in this chapter.

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment. You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment (transmitters) and the device as recommended below.



The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Please avoid using the device immediately after taking a shower or in other scenarios that may impact skin condition and temperature, such as taking temperature readings immediately upon entering the room from outside in the summer or after exercise, as this can impact measurement accuracy. Additionally, please ensure that the sensor head does not exceed a distance of 3 cm from the patient's forehead during temperature measurement.

Table 1

Guidance and manufacturer's declaration –electromagnetic emissions					
	The device is intended for use in the electromagnetic environment specified below. The customer				
or the user of the device	e should assure the	at it is used i <mark>n s</mark> uch an environment.			
Emissions test	Compliance	Electromagnetic environment - guidance			
RF emissions CISPR 11	Group 1	The device 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 device is suitable for use in all establishments other than domestic and those directly connected to			
Harmonic emissions IEC 61000-3-2	Not applicable	the public low-voltage power supply network that supplies buildings used for domestic purposes.			
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable				

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity				
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.				
Immunity test IEC 60601 test level		Compliance level	Electromagnetic environment – guidance	

Electrostatic	①±6 kV contact	± 6 kV contact	Floors should be wood, concrete or	
discharge (ESD)	∄±8 kV air	± 8 kV air	ceramic tile. If floors are covered	
discridinge (ESD)	ELO RV UII	10 KV dii	with synthetic material, the relative	
IEC 61000-4-2			humidity should be at least 30 %.	
Electrical fast	±2 kV for power	Not applicable	Mains power quality should be that	
transient/burst	supply lines	Not applicable	of a typical commercial or hospital	
IEC 61000-4-4	+1 kV for		environment.	
120 02000 1 1	input/output		environment.	
	lines			
Surge	± 1 kV line(s) to	Not applicable	Mains power quality should be that	
	line(s)		of a typical commercial or hospital	
IEC 61000-4-5	± 2 kV line(s) to		environment.	
	earth			
Voltage dips,	<5 % UT	Not applicable	Mains power quality should be that	
short	(>95 % dip in		of a typical commercial or hospital	
interruptions and	UT)		environment. If the user of the	
voltage variations	for 0.5 cycle		device requires continued operation	
on power supply	40 % UT		during power mains interruptions, it	
input lines	(60 % dip in UT)		is recommended that the device be	
	for 5 cycles		powered from a continuous power	
IEC 61000-4-11	70 % UT		supply or a battery.	
	(30 % dip in UT)			
	for 25 cycles			
	<5 % UT			
	(>95 % dip in			
	UT)			
D	for 5 s		David Carres and Carles	
Power frequency	3 A/m	3 A/m	Power frequency magnetic fields	
(50/60 Hz)	374	37,4	should be at levels characteristic of a	
magnetic field			typical location in a typical commercial or hospital environment.	
•			commercial of hospital environment.	
IEC 61000-4-8				
NOTE UT is the a.c. mains voltage prior to application of the test level.				

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity					
The device is intended for use in the electromagnetic environment specified below.					
The customer or the user of the device should assure that it is used in such an environment.					
Immunity IEC 60601 Compliance Electromagnetic					
test	test level	level	environment – guidance		

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	Not applicable 3V/m	Portable and mobile RF 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 $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz 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 meters (m). Field strengths from fixed RF transmitters, 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:
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NOTE 1 At 80MHz and 800MHz, 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
- b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the device

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 portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated	Separation distance according to frequency of transmitter m				
maximum output power of transmitter W	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz		
	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$		
0.01	0.12	0.12	0.23		
0.1	0.38	0.38	0.73		

1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80MHz and 800MHz, 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.

Table 5 reference body site: axilla ; measuring site: forehead

Clinical bias(△cb)	-0.15 ~ -0.12	
Limits of agreement(LA)	0.73 ~ 0.81	
Clinical repeatability(or)	0.24 ~ 0.28	

Table6

Accessory battery description

Accessory name	Model	Specifications	Supplier	Photograph
battery	AAA size (LR03)	1.5V	Excell	EXCELL [®] ALKALINE ALKAL
battery	AAA size (LR03)	1.5V	Maxell	II BXEM

14. Contact information



Vega Technologies Inc.

No.505, Shengping Mid.Road, Yangwu, Dalang Town, 523789 Dongguan City, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

Website: www.vegamedical.com

EC REP

MedPath GmbH Mies-van-der-Rohe-Strasse 8,80807 Munich, Germany



