FORA® FocusTemp

Forahead Thermomter
Stirnthermometer
Thermomètre frontal
Termometro frontale
Termómetro de frente
Voorhoofdthermometer
Termómetro de leitura na testa
Termometru de frunte

Operating Instructions
Bedienungsanleitung
Mode d'emploi
Istruzioni per l'uso
Instrucciones de funcionamiento
Gebruiksaanwijzing
Instruções de funcionamento
Instrucțiuni de utilizare

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REF FORA IR42a

IP22

CE 0123 -20°C 60°C 85%

311-1242100-027

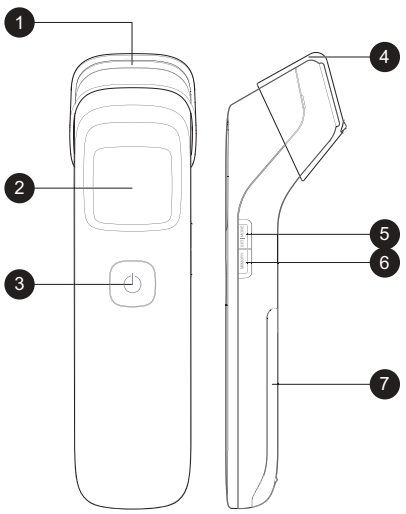
INTRODUCTION

Thank you for choosing FORA FocusTemp Forehead Thermometer. Please read this instruction manual first so that the thermometer can be used safely and correctly. Keep this instruction manual for future reference. This innovative medical device uses advanced infrared (IR) technology to measure temperature instantly and accurately on the forehead/any surface area. FORA FocusTemp Forehead Thermometer delivers a body temperature reading from the thermal radiation emitted from the forehead without any body contact.

INTENDED USE

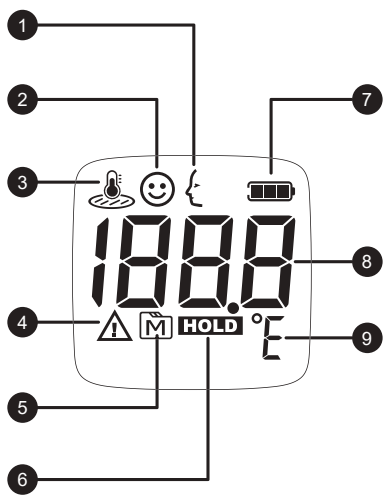
FORA FocusTemp Forehead Thermometer is intended for the intermittent measurement and monitoring of human body temperature from the forehead. The device is intended for use by people of all ages in the home or by healthcare professionals.

APPEARANCE AND KEY FUNCTIONS OF THE THERMOMETER



1. Probe lens
2. Display screen
3. Power/ Measure button
4. Protective sensor cap
5. Mode button
6. Memory button
7. Battery Cover

LCD SCREEN



1. Adult body temperature indicator
2. Child body temperature indicator
3. Object surface temperature indicator
4. Error message
5. Memory mode
6. Hold Symbol
7. Battery indicator
8. Temperature display
9. Temperature unit

IMPORTANT SAFETY INSTRUCTIONS

READ THIS BEFORE USING AND KEEP THESE INSTRUCTIONS IN A SAFE PLACE

1. Close supervision is necessary when the thermometer is used by, on, or near children, handicapped persons or invalids.
2. Use the thermometer only for the intended use described in this manual.
3. Do not use the thermometer if it is not working properly, or if it has sustained any damage.
4. Keep the sensor end clean and free of debris. See Maintenance section for instructions.
5. Do not use ethylene oxide gas, heat, autoclave, or any other harsh methods to sterilize the device.
6. Put in place the protective sensor cap on the sensor end when not in use.
7. Do not use the device shortly after exercise, bathing or coming indoors.
8. If coming from an environment of warmer or cooler temperature or after a period of exertion, allow the user and the thermometer to reach room temperature for 20 minutes prior to taking a measurement.
9. As the forehead temperature may be affected by sweat, oil and the surrounding temperature, the reading shall be taken as a reference only.
10. Do not use in presence of flammable anesthetic mixtures.
11. Do not use accessories which are not supplied or recommended by the manufacturer.
12. Proper maintenance is essential to the longevity of your device. If you are concerned about the accuracy of measurement, please contact the local customer service or place of purchase for assistance.

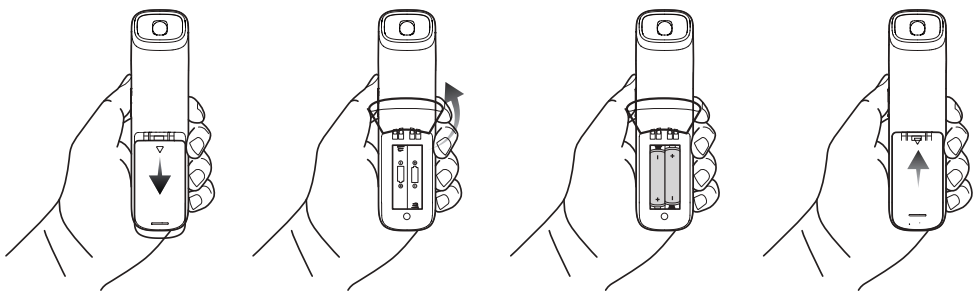
WARNING AND PRECAUTIONS

- ***As with any thermometer, proper technique is crucial to getting accurate temperature readings. Please read this manual thoroughly and carefully before use.***
- ***Always operate the thermometer in an operating temperature range 10°C to 40°C, and relative humidity of less than 85%.***
- ***Always store the thermometer in a cool and dry place: temperatures between -20°C to 60°C; relative humidity less than 85%. Avoid direct sunlight.***
- ***Avoid dropping the thermometer.***
- ***Basic safety precautions should always be observed, especially when the thermometer is used on or near children and disabled persons.***
- ***This thermometer is not intended to be a substitution for a consultation with your physician.***

USING THE DEVICE

Install Battery

1. Remove the battery cover by pressing down at the arrow mark and slide to the direction of the arrow as shown in the figures below.
2. Install (2) AAA alkaline batteries and close the battery cover.
3. Remove the batteries if the thermometer is stored and not in use.

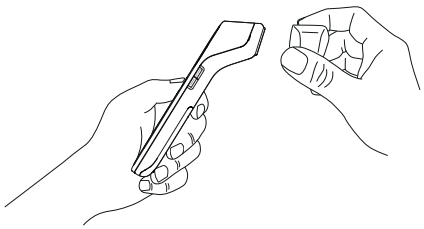


MEASUREMENT MODES

The default measuring mode is for the adult forehead temperature. Press the MODE button on the side of the thermometer to adjust the measuring mode.

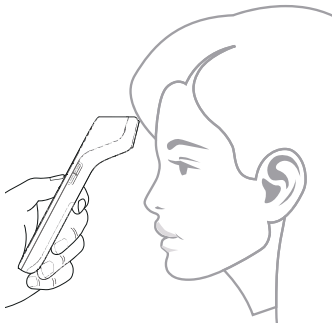
	Adult Forehead Mode: measuring the forehead temperature of adults
	Children Forehead Mode: measuring the forehead temperature of children (age: 3 ~ 36 months)
	Object Surface Mode: measuring the surface temperature of objects

MEASURING TEMPERATURE FOR ADULTS



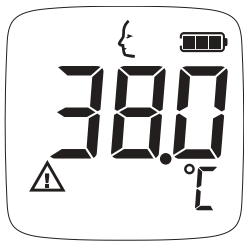
1. Remove the protective cap. The forehead should be clear of hair and perspiration.

2. Aim at the center of the forehead area 3 to 7cm away from and perpendicular to the surface of the skin.



3. Press and release the Measure button to take a measurement. A double “beep” sound indicates that a reading has been taken and displayed on the LCD screen.

When a reading is more than 38°C, a warning symbol will flash with a red backlight.



4. To take another measurement, follow steps 2 and 3.

5. The thermometer turns off automatically after 30 seconds. Replace the sensory cap when finished.

WARNING AND PRECAUTIONS

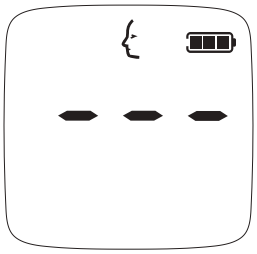
► *If the reading is < 31.9°C, “Lo” will be displayed.*

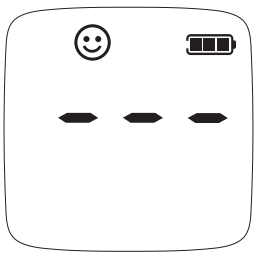
► *If the reading is ≥ 32.0°C and ≤ 37.9 °C, it will be displayed with a green backlight.*

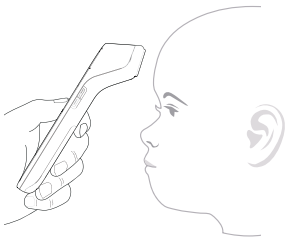
► *If the reading is ≥ 38°C and ≥ 43°C, it will be displayed with a red backlight.*

► *If the reading is ≥ 43.1°C, “Hi” will be displayed.*

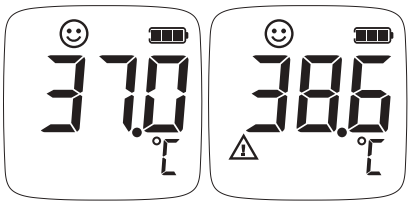
MEASURING TEMPERATURE FOR CHILDREN







1. Press the Power button to turn on the thermometer.
2. Press and hold the MODE button for 1 second before releasing. An adult facial profile should be flashing, indicating that the preset mode is for adults.
3. Press the MODE key to switch to Child mode which is indicated by a smiley face icon.
4. Aim the scanner at the center of the child's forehead 3 to 7cm away from and perpendicular to the surface of the skin. Press and release the Measure button to take a measurement.



A red backlight with a warning symbol indicates a reading more than 37.6 °C.

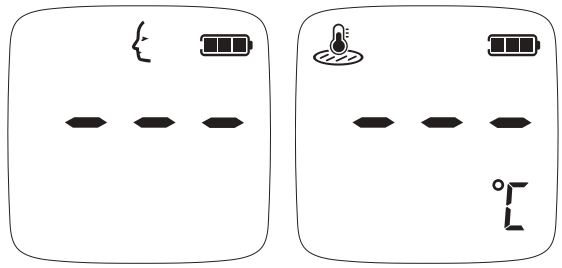
5. The thermometer will be switched off automatically when left idle for 30 seconds.
6. Replace the sensor cap when finished.

Note:

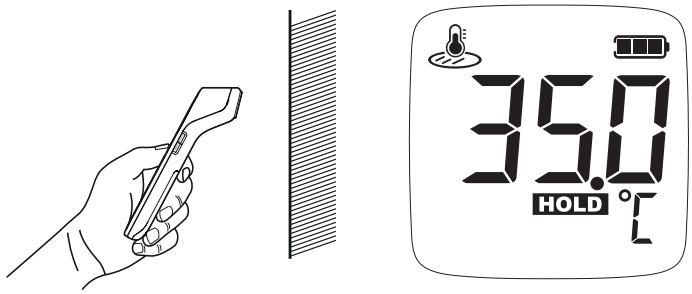
- If the reading is ≤ 31.9°C, "Lo" will be displayed.
- If the reading is ≥ 32°C and ≤ 37.6 °C, it will be displayed with a green backlight.
- If the reading is ≥ 37.7 °C and ≤ 43°C, it will be displayed with a red backlight.
- If the reading is ≥ 43.1°C, "Hi" will be displayed.
- Parents should not rely only on temperature readings. If you have concerns, please seek medical advice.

MEASURING SURFACE TEMPERATURE

1. Press the Power button to turn on the thermometer.
2. Press and hold the MODE button for 1 second before releasing. An adult facial profile should be flashing, indicating that the preset mode is for adults.
3. Press the MODE key to switch to Surface mode which is indicated by a thermometer icon.



4. Make sure the probe is flat and close to the surface of the object and not at an angle. The measurement should be taken within a distance of 5 cm. Press and hold the Measure button as you move the meter along the surface. The HOLD symbol flashes.



5. Release the button and read the result. If the reading is ≥ 0°C and ≤ 100.1°C, it will be displayed with a green backlight.

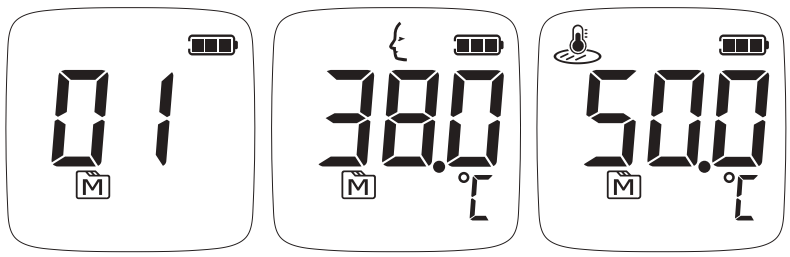
Note:

- If the reading is ≤ 0°C, “Lo” will be displayed.
- If the reading is ≥ 100.1°C, “Hi” will be displayed.

RECALLING PAST READINGS

FORA FocusTemp stores 30 of the most recent readings.

1. Press and release the Power button to turn on the thermometer.
2. Press and hold the MEMORY button for 1 second to enter the memory mode which is indicated by a flashing " M " symbol. The most recent reading which is stored will be displayed.



3. Press and release the MEMORY button to scroll through older readings.
4. When left idle for 30 seconds, the thermometer will be switched off automatically.

Note:
When the memory is full, the oldest result deleted as the new ones are added. While recalling previous readings, you may take a measurement by pressing the Measure button.

ABOUT NORMAL BODY TEMPERATURE & FEVER

Body temperature can vary from one individual person to the next. It also varies according to the location on the body and time of day. Fever indicates that the body temperature is higher than normal. This symptom may be caused by infection, overdressing or immunization. Some people may not experience fever even when they are ill. These include, but are not limited to, infants younger than 3 months old, persons with compromised immune systems, persons taking antibiotics, steroids or antipyretics (aspirin, ibuprofen, acetaminophen), or persons with certain chronic illnesses. ***Please consult your physician if you are concerned about your body temperature readings.***

MAINTENANCE

- FORA FocusTemp has no user serviceable internal parts except for the battery replacement.
- Always replace the Sensor Cap (or place in cradle) when not in use.
- Store in a dry location free of dust and away from direct sunlight.

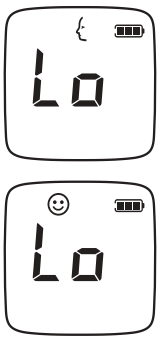
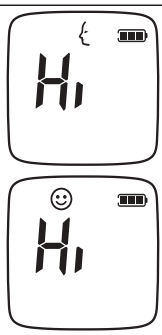
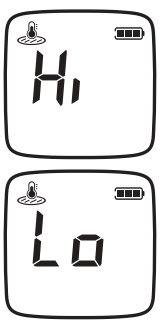
CLEANING AND DISINFECTION

- Use a soft dry cloth to clean the plastic casing or a cloth dampened with a solution of water and mild detergent. Occasionally, 70% isopropanol solution may be used. Never submerge in liquid.
- The sensor window is recessed to assist in keeping it clean and free of debris. Inspect the lens and remove any debris. Smudges may be cleaned by gently wiping the window with a small foam-tipped swab (non-linting) moistened with 70% alcohol. Wait 10 minutes prior to taking your temperature.

SYMBOL INFORMATION

Symbol	Referent
REF	Model number
	Consult instructions for use
	Caution, consult accompanying documents
	Temperature limitation
	Humidity limitation
	Keep away from sunlight
	Type BF Equipment
IP22	Ingress protection rating
SN	Serial number
CE	CE Mark
	Manufacturer
	Disposal of waste equipment

TROUBLESHOOTING

Message	What it means	What to do
	The ambient temperature is outside of the operating temperature range.	Only operate the thermometer within an ambient temperature range of 10°C to 40°C.
	Measured temperature below the measurement range (below 32°C).	Review instructions and repeat the measurement. Make sure the distance from the forehead is not further than 5cm, and that the forehead is clear.
	Measured temperature above the measurement range (above 43°C).	Review instructions and repeat the measurement. Consult a physician if the problem persists.
	Low or no power.	New batteries should be replaced.
	Surface temperature measured outside of the measurement range (0°C ~ 100°C).	Review the instructions and re-start the measurement procedure.

SPECIFICATIONS

Model No.:	FORA IR42a
Dimension & Weight	155.46 (L) x 40.14 (W) x 39.45 (H) mm, 61.8g (without battery)
Power Source	2 x 1.5V AAA alkaline batteries
Battery Life	With new batteries, approx. 5,000 measurements.
Displayed Temperature range	• Forehead: 32°C to 43°C • Object Surface: 0°C to 100°C
Display Resolution	0.1°C
Accuracy	The accuracy requirements specified in ASTM E1965-98 is met • Forehead: ±0.2°C for the range of 35.0°C to 42.0°C / ±0.3°C for the range of <35.0°C or >42.0°C • Object surface: ±1°C
Reference to Standards	ASTM E1965-98; IEC 60601-1; IEC 60601-1-2 (EMC)
Temperature Unit	°C
Operating Temperature Range	10°C to 40°C
Operating Humidity	85% RH or less
Storage / Transportation Temperature Range	-20°C to 60°C
Storage / Transportation Humidity	85% RH or less
Memory Capacity	30 measurements
Calibration method	Oral calibration/ sublingual

The specifications may be changed without prior notice.

WARRANTY TERMS AND CONDITIONS

With respect to disposable products, ForaCare Suisse warrants to the original purchaser that, at time of delivery, each standard product manufactured by ForaCare Suisse shall be free from defects in material and workmanship and, when used for the purposes and indications described on the labeling, is fit for the purposes and indications described on the labeling. All warranties for a product shall expire as of the product expiration date, or if none, after two (2) years from the original date of purchase, as long as it has not been modified, altered, or misused. ForaCare Suisse warranty hereunder shall not apply if:
(i) a product is not used in accordance with its instructions or if it is used for a purpose not indicated on the labeling; (ii) any repairs, alterations or other work has been performed by the buyer or others on such item, other than work performed with ForaCare Suisse's authorisation and according to its approved procedures; or (iii) the alleged defect is a result of abuse, misuse, improper maintenance, accident or the negligence of any party other than ForaCare Suisse. The warranty set forth herein is conditioned upon proper storage, installation, use and maintenance in accordance with applicable written recommendations from ForaCare Suisse.
The warranty furnished hereunder does not extend to damaged items purchased hereunder resulting in whole or in part from the use of components, accessories, parts or supplies not furnished by ForaCare Suisse.

Warning:
Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided. Careful consideration of this information is essential when stacking or collocating equipment and when routing cables and accessories.

Warning:
RF mobile communications equipment can affect medical electrical equipment.

Recommended separation distance between portable and mobile RF communications equipment and the FocusTemp

The FocusTemp is intended for use in an electromagnetic environment (for home healthcare and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the FocusTemp can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the FocusTemp as recommended below, depending on the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2,3\sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	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) depending on 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 to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic emissions		
The FocusTemp is intended for use in the electromagnetic environment (for home healthcare and professional healthcare) specified below. The customer or the user of the FocusTemp should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance** (for home healthcare and professional healthcare)
RF-emissies CISPR 11	Group 1	The FocusTemp uses RF energy only for internal use. Therefore, its RF emissions are very low and are not likely to cause any interference from nearby electronic equipment.
RF-emissies CISPR 11	Class B	The FocusTemp is suitable for use in all establishments, including domestic establishments 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	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration-electromagnetic immunity			
The FocusTemp is intended for use in the electromagnetic environment (for home healthcare and professional healthcare) specified below. The customer or the user of the FocusTemp should assure that it is used in the environment specified below.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare and professional healthcare environment)**
Electrostatic discharge(ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	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 transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/ output lines	Not applicable Not applicable	Mains power quality should be that of a typical home healthcare and professional healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV,± 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical home healthcare and professional healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % *UT*; 0,5 cycle 0 % *UT*; 1 cycle 70 % *UT*; 25/30 cycles Voltage interruptions: 0 % *UT*; 250/300 cycle	Voltage dips: Not applicable Not applicable Not applicable Voltage interruptions: Not applicable	Mains power quality should be that of a typical home healthcare and professional healthcare environment. If the user of the FocusTemp requires continued operation during power mains interruptions, it is recommended that the FocusTemp be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The FocusTemp power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare and professional healthcare environment.
NOTE: *UT* is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The FocusTemp is intended for use in the electromagnetic environment (for home healthcare and professional healthcare) specified below. The customer or the user of the FocusTemp should assure that it is used in the environment specified below.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare and professional healthcare environment)**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Not applicable Not applicable 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment must not be used close to any parts of the FocusTemp including cables, other 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 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,7 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 meters (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 to 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 FocusTemp is used exceeds the applicable RF compliance level above, the FocusTemp should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FocusTemp.

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

Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The FocusTemp is intended for use in the electromagnetic environment (for home healthcare and professional healthcare) specified below.

Test frequency (MHz)	Band [a] (MHz	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home and professional healthcare)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/ n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE To achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be the worst case.