

microlife[®] FR1DQ1-B

Infrared Forehead Thermometer



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Made in China

- ① Measuring sensor
- ② Tracking light
- ③ Display
- ④ START/IO button
- ⑤ MEMO button
- ⑥ MODE
- ⑦ Battery compartment cover
- ⑧ All segments displayed
- ⑨ Ready for measuring
- ⑩ Start the measurement
- ⑪ Measurement complete
- ⑫ Body mode
- ⑬ Object mode
- ⑭ Low battery indicator
- ⑮ Changing between Celsius and Fahrenheit
- ⑯ Recall mode
- ⑰ Recall the last 30 readings
- ⑱ Measured temperature too high
- ⑲ Measured temperature too low
- ⑳ Ambient temperature too high
- ㉑ Ambient temperature too low
- ㉒ Error function display
- ㉓ Blank display
- ㉔ Flat battery
- ㉕ Date/Time
- ㉖ Beeper function setting
- ㉗ Protective cap



Read the instructions carefully before using this device



Type BF applied part

Overview

This Microlife thermometer is a high-quality product incorporating the latest technology and tested in accordance with international standards. With its unique technology, this device can provide a stable, heat-interference-free reading with each measurement. The device performs a self-test every time it is switched on to always guarantee the specified accuracy

of any measurement. This Microlife thermometer is intended for measurement and monitoring not only the temperature of forehead of human body, but also the temperature of object. This thermometer has been clinically tested and proven to be safe and accurate when used in accordance to the operating instruction manual. Please read through these instructions carefully in order for you to understand all functions and safety information.

Indication For Use

The Microlife Infrared Forehead Thermometer Model FR1DQ1-B is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home. The device can be used in connection with a smart phone running the «Microlife Connected Health +» APP. The memory data can be transferred to the smart phone via Bluetooth.

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1. The Advantages of this Thermometer

Measures in a matter of seconds

The innovative infrared technology allows the measurement without even touching the object. This guarantees safe and sanitary measurements within seconds.

Measurement with distance control

The device will show good on display when the device detects the distance is appropriate within 5 cm.

Multiple uses (wide range of measurement)

This thermometer offers a wide range of measurement from 0.1 – 99.9 °C / 32.2 - 211.8 °F, meaning the unit can be used to measure body temperature or it also has a feature allowing it to be used to measure surface temperature of the following examples:

- Milk surface temperature in a baby's bottle
- Surface temperature of a baby's bath

Accurate and reliable

The unique probe assembly construction incorporates an advanced infrared sensor, ensuring that each measurement is accurate and reliable.

Gentle and easy to use

- The ergonomic design enables simple and easy use of the thermometer.
- This thermometer can even be used on a sleeping child without causing any interruption.
- This thermometer is quick, therefore child friendly.

Multiple readings recall

Users will be able to recall the last 30 readings with a record of both time and date when entering the recall mode, enabling efficient tracking of temperature variations.

Safe and hygienic

- No direct skin contact
- No risk of broken glass or mercury ingestion.
- Children should be used under the care of adults to avoid danger caused by accidental ingestion

Fever alarm

10 short beeps with a red LCD backlight for 5secs and time and date switch every 1 sec alert the patient that he/ she may have a temperature equal to or higher than 37.5 °C.

Guidance system for self-measurement

A blue tracking light shows the user that the device is at the right distance and ready to take a measurement.

Bluetooth function

This device connects to the «Microlife Connected Health+» App by using Bluetooth®4.2 and enables monitoring of temperature

2. Important Safety Instructions

- Follow instructions for use. This document provides important product operation and safety information regarding this device. Please read this document thoroughly before using the device and keep for future reference.
- This device may only be used for the purposes described in these instructions. The manufacturer cannot be held liable for damage caused by incorrect application.
- Never immerse this device in water or other liquids. For cleaning, please follow the instructions in the «Cleaning and Disinfecting» section.
- Do not use this device if you think it is damaged or notice anything unusual.
- Never open this device.
- A basic physiological effect called vasoconstriction can occur in the early stages of fever, resulting in a cool skin effect. The recorded temperature using this thermometer can, therefore, be unusually low.
- Please note that before measurement, the thermometer and the person whose temperature is to be measured should be in the room temperature for at least 30 minutes
- If the measurement result is not consistent with the patient's finding or unusually low, repeat the measurement every 15 minutes or double check the result by another core body temperature measurement.
- This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in the «Technical Specifications» section.
- Ensure that children do not use this device unsupervised; some parts are small enough to be swallowed.
- Do not use this device close to strong electromagnetic fields such as mobile telephones or radio installations. Keep a minimum distance of 3.3 m from such devices when using this device.
- Data Transmission: This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted, such as on an aircraft or in hospitals. Turn off this thermometer; remove batteries when in RF restricted areas. For further information on potential restrictions refer to documentation on the Bluetooth usage by the FCC.
- Protect it from:
 - Extreme temperatures
 - Impact and dropping
 - Contamination and dust
 - Direct sunlight
 - Heat and cold
- If the device is not going to be used for a prolonged period, the batteries should be removed.

- Ⓜ WARNING:** The measurement results given by this device is not a diagnosis. It is not replacing the need for the consultation of a physician, especially if not matching the patient's symptoms. Do not rely on the measurement result only, always consider other potentially occurring symptoms and the patient's feedback. Calling a doctor or an ambulance is advised if needed.

3. How this Thermometer measures Temperature

This thermometer measures infrared energy radiated from the forehead as well as objects. This energy is collected through the lens and converted to a temperature value.

4. Control Displays and Symbols

- **All segments displayed ⑧** : Press the START/IO button ④ to turn on the unit; all segments will be shown for 1 second, default body mode.
- **Ready for measuring ⑨** : after all segments have been show for 1 second, the unit is ready for measuring, the «°C» or «°F» icon will keep flashing while the mode (3s body / 1s body / object), time and beep icon will be displayed.
Taking a measurement: for 3s body mode ,when the device detect the distance is appropriate (within 5cm),the screen shows "good" ⑩ with 1 short beep ,then press START/IO button ④ to start measuring. For 1s mode, when the device detects the distance is appropriate (within 5cm), the screen shows "good" ⑩ with 1short beep, then press START/IO button ④ to start the measurement.
- **Measurement complete ⑪** : The reading will be shown on the display ③ with the «°C» or «°F» icon and the mode icon steady. The unit is ready for the next measurement as soon as the «°C» or «°F» icon is flashing again.
- **Low battery indicator ⑭** : When the unit is turned on, the «battery» icon will keep flashing to remind the user to replace the batteries.

5. Setting Date, Time, and Beeper Functions

- **Setting the date and time ⑮**

After the new batteries are fitted, device will enter time setting automatically. Under any status, hold "MODE" button for 8 seconds, will enter time setting mode. Under time setting mode, first will be year setting, then Date setting, following by time setting, (then jump back to year setting again as cycle, until "Start/IO" button be pressed to enter stand-by mode") with press MODE button.

1. The year number flashes in the display (1 time/per sec) to indicate year setting ⑮. Press "MEMO" ⑤ button to

select year (21~40), then Press "MODE" ⑥ button to confirm the years' setting, then move to month setting.

2. Press "MEMO" ⑤ button to select month (1~12), then press "MODE" ⑥ button to confirm the month setting. then move to day setting
3. Press "MEMO" ⑤ button to select day (1~31), Press "MODE" ⑥ button to confirm the day setting. then move to next setting
4. Follow the previously mentioned instructions to set the day, hours, and minutes.
5. Once you have set the minutes and pressed the START/IO button④, the date and time are set and the time is displayed.

☞ If no button is pressed for 20 seconds, the device will go back to stand-by for measurement with no date/time information display and then switches to ready for measuring.

☞ Press "Start/IO" button at any time-setting status, will allow to enter measuring stand-by mode directly. (If there is any item of time-setting have not been completed, they will be show with no-information--)

● Setting the beeper 26

At any status, press "MODE" ⑥ button for 3 seconds, will enter beep on/off setting

1. In "beeper on/off" setting mode press and hold the "MODE" button ⑥ for 3seconds to set the beeper 26.
2. Press the MEMO ⑤ to either turn the beeper on or off. The beeper is activated when the beeper icon 26 is shown without across. When the beeper setting has been chosen, press the START/IO button ④ to enter the stand-by measurement mode; otherwise, the device automatically switches to ready for measuring after 10 seconds.

6. Changing measurement mode

1. Press the START/IO button ④. The display ③ is activated to show all segments for 1second.
2. The default mode is 3S body mode. Press the MODE button ⑥ to switch between 3S, 1S body mode 12 and object mode 13.

7. Directions for Use

Always remove the protective cap 27 before use.

Measuring in 3S and 1S body mode with distance control

1. Press the START/IO button ④ . The display ③ is activated to show all segments for 1second.
2. A flashing «°C»/«°F» icon, the blinking blue tracking light ② and a beep indicate that the device is ready to take a measurement ⑩ .
3. Press the MODE button ⑥ to switch between 3S and 1S body mode.
4. Remove any hair, sweat or dirt from the forehead before measuring to ensure the accuracy of the readings.
5. 3S body mode: Aiming the thermometer at the center of the forehead with a distance no more than 5 cm. Once the display shows “good”, when the measuring sensor ① detects the distance is appropriate within 5 cm. Then press the START/IO button and slowly scanning from forehead to temple, a long beep will verify the completion of measurement.
6. 1S body mode: Aiming the thermometer at the center of the forehead with a distance no more than 5 cm. Once the display shows “good”, when the measuring sensor ① detects the distance is appropriate within 5 cm. Then press the START/IO button, a long beep will verify the completion of measurement.
7. Read the recorded temperature from the LCD display.
8. For the next measurement remove the thermometer from the forehead and wait until the «°C»/«°F» icon is flashing. Follow steps 4-5 above.
9. Press and hold the START/IO button ④ for 3seconds to enter stand by ambient mode or 6seconds to turn off the device totally; otherwise, the device will automatically switch off after approx. 30seconds

Measuring in object mode without auto measurement

1. Press the START/IO button ④ . The display ③ is activated to show all segments for 1second.
2. Press the MODE button ⑥ to switch to object mode.
3. A flashing «°C»/«°F» icon, the blinking blue tracking light ② and a beep indicate that the device is ready for measurement ⑨ .
4. Aim the thermometer at the center of the object you want to measure with a distance no more than 5 cm. Press the START/IO button ④ . After 1seconds a long beep will verify the completion of measurement.
5. Read the recorded temperature from the LCD display.
6. For the next measurement wait until the «°C»/«°F» icon is flashing and follow steps 4-5 above.
7. Press and hold the START/IO button ④ for 3seconds to turn off the device totally, otherwise the device will

automatically switch off after approx. 30seconds.

NOTE:

Patients and thermometer should stay in similar room condition for at least 30 minutes.

- Don't take a measurement while or immediately after nursing a baby.
- Don't use the thermometer in high humidity environments.
- Patients should not drink, eat or exercise before/while taking the measurement.
- Don't move the measurement device from the measuring area before hearing the termination beep.
- 10 short beeps and a red LCD backlight alert the patient that he/ she may have a temperature equal to or higher than 37.5°C.
- Always take the temperature in the same location since temperature readings may vary according to locations.
- Doctors recommend rectal measurement for newborn infants with in the first 6 months, as all other measuring methods might lead to ambiguous results. If using a Infrared Forehead Thermometer on those infants, we always recommend verifying the readings with a rectal measurement.
- In the following situations it is recommended that three temperatures are taken with the highest one taken as the reading:
 1. Children under three years of age with a compromised immune system and for whom the presence or absence of fever is critical.
 2. When the user is learning how to use the thermometer for the first time until he/she has familiarized himself/herself with the device and obtains consistent readings.
 3. If the measurement is surprisingly low.
- **Readings from different measuring sites should not be compared as the normal body temperature varies by measuring site and time of day**, being highest in the evening and lowest about one hour before waking up.

Normal body temperature ranges:

 - Axillar: 34.7 - 37.3 °C / 94.5 - 99.1 °F
 - Oral: 35.5 - 37.5 °C / 95.9 - 99.5 °F
 - Rectal: 36.6 - 38.0 °C / 97.9 - 100.4 °F
 - Microlife FR1DQ1: 35.4 - 37.4 °C / 95.7 - 99.3 °F

8. Changing between Celsius and Fahrenheit

This thermometer can display temperature readings in either Fahrenheit or Celsius. To switch the display between °C and °F, at any status, **press and hold** the MODE button (6) for 3 seconds will enter °C/°F setting, In “°C/°F” setting mode the °C/°F icon is shown on the display, change the measurement scale between °C and °F by pressing the MEMO button (5). When the measurement scale has been chosen, press the START/IO button (4) to enter the «ready for measuring» mode otherwise, the device automatically switches to ready for measuring after 10 seconds.

9. How to recall readings in Memory Mode

This thermometer can recall the last 30 readings with a record of both time and date.

- **Recall mode** 16: Press the MEMO button (5) to enter recall mode when the power is off or in measuring mode.

The memory icon «M» will display.

- **Reading the last reading** 17: Press and release the MEMO button (5) to recall the last reading. Number «1» and «M» are displayed.
- Pressing and releasing the MEMO button (5) after the last 30 readings have been recalled will resume the above sequence from reading.

After memory recall

1. Press “Start/ IO” button to go back to ready for measuring
2. Press “Start/ IO ” button for 3 seconds to switch off.
3. If no button be press for 30 seconds, the device will auto off.

10. Bluetooth® Function

This device can be used in conjunction with a smart phone running the «Microlife Connected Health+» App. The measurement results will be automatically transferred via Bluetooth®.

App Quick start guide

Please refer to APP quick start guide for more details **Downloading the «Microlife Connected Health+» App** Download «Microlife Connected Health+» App for free from Google Play™ (Android) or App Store (iOS) and install it on your smartphone.

Setup User Profile

1. Open the App and select “Start” to begin using the App.
2. Select “Settings” on the navigation menu (bottom) to enter “My profile”.
3. Edit profile information, then select “Save” to complete Profile setup.

Transfer Data

1. Turn on Bluetooth of Smartphone.
2. Open the app on the Smartphone, and select the Temperature Overview interface.
3. Make sure to FR1DQ1-B is within 5 meters of your Smartphone, and turn off other Bluetooth device if possible in case it interfere the data transfer.
4. Turn on FR1DQ1-B in Body Temperature mode. Bluetooth of FR1DQ1-B is activated (when not taking measurement) and automatically searches for Smartphone to connect to.
5. When FR1DQ1-B is connected to the App on a Smartphone, FR1DQ1-B will transfer data automatically if new data (hasn't been transferred previously) is available, while transferring. The LCD of FR1DQ1-B will show new data with “-” and 3 digits thermometer designated ID for 3 seconds, no new measurement can be start within this 3 seconds.
6. Upon data transfer, the App will display a message with “-” and 3 digits thermometer ID (MAC address) to confirm which Patient Log in the App the data should be assigned to. Be sure to check “-” and 3 digits thermometer ID is identical on FR1DQ1-B and APP then select the Patient Log and Confirm to complete the data transfer.
 - If “-” and 3 digits thermometer is not identical of both App and FR1DQ1-B, please discard the message show on the app to stop the data transfer, and record the temperature data into the App manually. Or take a new measurement and start Transfer Data from step 1 to 6 again.

- If no message showed on App to confirm which patient log the data should be assigned to, please record the temperature data showed on FR1DQ1-B into the App manually or takes a new measurement and start Transfer Data step from 1 to 6 again.

Bluetooth® Icon Indicator

The Bluetooth® icon indicator on your device, located in the middle right portion of the display, is designed to provide information about the connection between your device and smartphone.

- ✓ The Bluetooth® function is enabled: The Bluetooth® icon indicator 14 appears steady on the display.
- ✓ Connecting with a device or uploading the data: The Bluetooth® icon indicator 14 flashes.
- ✓ The Bluetooth® function is automatically switched off during measurement; after measurement the device will switch it on and upload the data to the «Microlife Connected Health+» App.

NOTES

The Bluetooth® of this thermometer is a medical device data system (MDDS) as its only function is for records and no additional functions. It does not modify the data or modify the display of the data, and it does not by itself control the functions or parameters of any other medical device. It is not active when the thermometer is recording data or during measurement. The thermometer will not sound any alarm with or without Bluetooth®. The Bluetooth® is used only to transfer data from point A to point B. The App on your smart devices cannot be used to start or stop the thermometer, nor update the firmware of thermometer via Bluetooth®.

Wireless communication interference

This product operates in an unlicensed ISM band at 2.4 GHz. In the event this product is used near other wireless devices such as microwave and wireless LAN, which operate on the same frequency band as this product, there is a possibility that interference may occur. If interference occurs, stop the operation of the other devices or relocate this product away from other wireless devices before attempting to use it.

11. Error Messages

- **Measured temperature too high 18** : Displays «ErrH» when measured temperature is higher than 43°C/109.4°F in body mode or Displays «H» when measured temperature is higher than 99.9°C /211.9°F in object mode.
- **Measured temperature too low 19** : Displays «ErrL» when measured temperature is lower than 34.0 °C / 93.2 °F in body mode or Displays «L» when measured temperature is lower than 0.1 °C / 32.2 °F in object mode.
- **Ambient temperature too high 20** : Displays «AH» when ambient temperature is higher than 40.0 °C / 104.0°F in body model and object model.
- **Ambient temperature too low 21** : Displays «AL» when ambient temperature is lower than 15.0 °C / 59.0 °F in body mode and 5.0 °C / 41.0 °F in object mode.
- **Error function display 22** :
 «Err»: The system has a malfunction.
 «Errd»: Device is over 5cm from forehead /object.
 «Er2»: Keep the measuring distance of 1-5 cm. **Do not touch the bottom side (sensing area) of the measuring sensor.**
- **Blank display 23** : Check if the batteries have been inserted correctly. Also check polarity (<+> and <->) of the batteries.

- **Flat battery indicator**  : If only «battery» icon is shown on the display, the batteries should be replaced immediately.

12. Cleaning and Disinfecting

Use an alcohol swab or cotton tissue moistened with alcohol (70% Isopropyl) to clean the thermometer casing and the measuring sensor. Ensure that no liquid enters the interior of the device. Never use abrasive cleaning agents, thinners or benzene for cleaning and never immerse the device in water or other cleaning liquids. Take care not to scratch the surface of the sensor lens and the display.

13. Battery Replacement

This device is supplied with 2 new, long-life 1.5V, size AAA batteries. Batteries need replacing when this icon

«battery»  is the only symbol shown on the display.

Remove the battery cover  by sliding it in the direction shown. Replace the batteries – ensure correct polarity as shown by the symbols in the compartment.

 Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

14. Guarantee

This device is covered by 5 years guarantee from the date of purchase. The guarantee is valid only on presentation of the guaranteed card completed by the dealer (see back) confirming date of purchase or the receipt.

- The guarantee covers the device. Batteries and packaging are not included.
- Opening or altering the device invalidates the guarantee.
- The guarantee does not cover damage caused by improper handling, discharged batteries, accidents or non-compliance with the operating instructions.

Please contact Microlife-service.

15. Technical Specifications

Type: Infrared Forehead Thermometer FR1DQ1-B

Measurement Range: Body mode: 34.0 °C -43.0 °C / 93.2 °F -109.4 °F,
Object mode: 0.1-99.9 °C / 32.2 °F-211.8.0 °F

Resolution: 0.1 °C / °F

Measurement accuracy (Laboratory): Body mode: $\pm 0.2^{\circ}\text{C}$ (35.0°C~42.0°C) / $\pm 0.4^{\circ}\text{F}$ (95.0°F~107.6 °F)
 $\pm 0.3^{\circ}\text{C}$ (34.0°C~34.9 °C and 42.1°C~43.0°C) / $\pm 0.5^{\circ}\text{F}$ (93.2°F~94.8 °F and 107.8°F~109.4°F)
Object mode: $\pm 1.0^{\circ}\text{C}$ (0.1°C~99.9°C) / $\pm 2^{\circ}\text{F}$ (32.2°F~211.8 °F)

Display: Liquid Crystal Display, 4 digits plus special icons

Acoustic: The unit is turned on and ready for the measurement: 1 short beep. Complete the measurement: 1 long beep (1 sec.) if the reading is less than 37.5 °C / 99.5 °F, 10 short «beep» sounds, if the reading is equal to or greater than 37.5 °C / 99.5 °F. System error or malfunction: 3 short «bi» sounds.

Memory: 30 readings recall in the memory mode with a record of both time and date.

Backlight: The display light will be GREEN for 5 seconds, when a measurement is completed with reading less than 37.5°C/99.5°F but equal to or higher than 34.0°C/93.2°F. The display light will be RED for 5 seconds, when a measurement is completed with a reading equal to or higher than 37.5°C/99.5°F but equal or lower 43.0°C/109.4°F .

Operating conditions: Body mode: 15-40.0 °C / 59-104.0 °F, Object mode: 5-40.0 °C / 41-104.0 °F 15-95% relative maximum humidity

Storing conditions: -25 - +55 °C / -13 - +131 °F / 15-95% relative maximum

Automatic Switch-off: Approx. 30 sec when power on without measurement & after measurement

Battery: 2 x 1.5 V alkaline batteries; size AAA

Battery Life: Approx. 2000 measurements (using new batteries)

Dimensions: 140 x 42.2 x 50 mm

Weight: 95.8 g (with batteries), 73.5 g (w/o batteries)

IP Class: IP22

Reference to standard: ASTM E1965; IEC 60601-1; IEC 60601-1-2 (EMC); IEC 60601-1-11

Expected service life: 5 years or 12000 measurements

This device complies with the requirements of the Medical Device Directive 93/42/EEC. Technical alterations reserved.

According to the Medical Product User Act a biennial technical inspection is recommended for professional users. Please observe the applicable disposal regulations.

16. www.microlife.com

Detailed user information about our thermometers and blood pressure monitors as well as services can be found at www.microlife.com

FCC

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications to the product are not approved by Microlife USA and could void the user's authority to operate the equipment under FCC jurisdiction. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: reorient or relocate the receiving antenna, increase the separation between the equipment and receiver, connect the equipment into an outlet on a circuit different from that to which the receiver is connected, consult the dealer or an experienced radio/TV technician for help.

This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance.

Trademark Usage:

Apple, the Apple logo, iPad, and iPhone are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc.

Android and Google Play are both trademarks of Google Inc.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks in this thermometer is under license. Other trademarks and trade names are those of their respective owners.

Appendix

Guidance and manufacturer's declaration – electromagnetic emissions		
The model FR1DQ1-B is intended for use in the electromagnetic environment specified below. The customer or the user of the model FR1DQ1-B should assure that it is used in such an environment.		
Emissions	Compliance	Electromagnetic environment-- guidance
RF emissions CISPR 11	Group 1	The model FR1DQ1-B 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 FR1DQ1-B is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power
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 FR1DQ1-B is intended for use in the electromagnetic environment specified below. The customer or the user of the model FR1DQ1-B 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 ±15 kV air	±8 kV contact ±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 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines and patient coupled lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) and neutral	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5s	N/A	Mains power quality should be that of a typical commercial or hospital environment. If a dips or an interruption of mains power occurs, the current of the model FR1DQ1-B may be dropped off from normal level, it may be necessary to use uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity

The model FR1DQ1-B is intended for use in the electromagnetic environment specified below. The customer or the user of the model FR1DQ1-B 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	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the model FR1DQ1-B, 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	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz 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).b 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. 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 FR1DQ1-B is used exceeds the applicable RF compliance level above, the model FR1DQ1-B 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 FR1DQ1-B.

b. 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 FR1DQ1-B

The model FR1DQ1-B is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model FR1DQ1-B can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model FR1DQ1-B as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{P_1}\right]\sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	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.