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Product instructions

FDTH3400

PN:6004213F001-03A
Description Version: V3.0
Revision date: April 2021
The production date is shown on the outer package.
For American please refer to "℉",
For European please refer to "℃".
Before using your device, please read these instructions and warnings completely.
FCC ID :PONFDTHB34

CONTENT

1. Product Description

Thank you very much for choosing our products!

This product is a high-tech electronic thermometer which is used to measure the temperature of human body by collecting the change of the temperature and energy of human body heat source.

This product has 8 seconds rapid measurement mode and direct measurement mode, so that you can easily and quickly know the health status of yourself and your family anytime and anywhere.

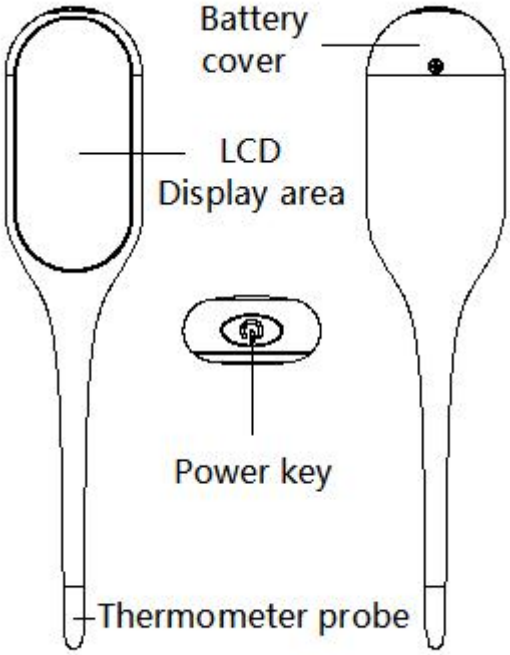
Product name:Digital Clinical Thermometer

Product model: FDTH3400

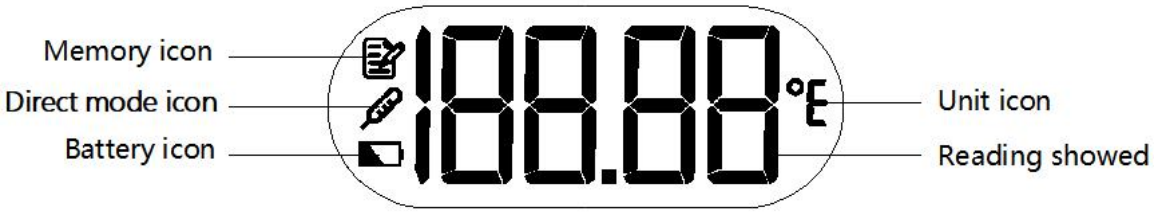
2. Product structure and components

The thermometer mainly consists of plastic shell, thermistor, PCBA, buzzer chip, LCD display,and battery.

Main appearance structure diagram description:



Display Description:



3. Product specifications

Product name	Digital Clinical Thermometer
Product model	FDTH3400
Power supply voltage	d.c. 3.0V, one CR1632 battery
Measurement type	Adjusted mode / Direct mode
Measuring part	Axillary / Oral / Rectal
Reference site	Oral cavity
Measuring range	32.00℃ ~ 42.90℃ (89.60℉~109.22℉)
Measuring accuracy	±0.10℃: between 35.00℃~42.00℃ (±0.18℉ between 95.00℉~107.60℉) ±0.20℃(or±0.36℉): outside this ranges
Display resolution	0.01℃(0.01℉)
Repeatability error	≤0.20℃ (±0.36℉)
Measurement time	Adjusted mode：Less than 8s (for water bath) Direct mode：Less than 50s (for water bath)
High body temperature hint	≥37.60℃(99.68℉)
Operation environment	Temperature:5℃~40℃ (41℉~104℉) Relative humidity:15%~95%RH，No condensing Atmospheric pressure:70 kPa~106 kPa
Transportation and storage environment	Temperature:-25℃~55℃ (-13℉~131℉) Relative humidity:15%~95%RH，No condensing Atmospheric pressure:70 kPa~106 kPa
Temperature unit	°C/°F
Memory group	Last time memory display
Battery life	1 year/1000 measurement
Product size	28mm×13mm×131mm
Net Product	17g（Battery free）
Period of validity	5 years (excluding vulnerable parts)
Software version	V1.0
Grade of waterproof	IP22
Electric shock	Internally powered ME equipment
Operational mode	Continuous operation
Applied part	Type BF applied part,including the whole unit.

*Statement: If stored or used outside the temperature, humidity or atmospheric pressure range specified by the manufacturer, the product may not achieve the claimed performance.

4. Intended use and scope of application

4.1 This product is used to measure the temperature of human body by collecting the change of the temperature and energy of Axillary,Oral,Rectal heat source.

4.2 Expected patients： and can be used for body temperature measurement in infants, children and adults.

4.3 Intended user： Doctor, nurse or regular user.（We recommend adults to operate the thermometer instead of babies and children.）

4.4 Expected Operating environment：Hospitals, clinics and home Settings

5. Contraindications

5.1 Do not use local lesions such as inflammation, trauma and postoperative.
5.2 It is forbidden for those who are allergic to stainless steel and ABS plastic.

6. Notes

6.1 Measurement

1. This product is only for monitoring and self-testing body temperature, can not be used for disease diagnosis, patients only through the results of self-judgment and treatment is very dangerous, so please follow the guidance of the doctor.
2. To ensure the accuracy of the measurement, please set the thermometer in the normal working environment for more than 30 minutes, so that it reaches the equilibrium state before measuring.
3. Please do not measure under strong electromagnetic interference environment (working microwave oven, induction cooker, mobile phone nearby, etc.), this may cause measurement is not correct or can not be measured.
4. Participants were measured after taking medications that change their body temperature (e.g. aspirin, acetaminophen, ibuprofen), which may cause measurement bias.
5. The subjects may cause temperature fluctuations after intense exercise, crying, eating, etc. It is recommended to keep quiet for 30 minutes before measurement.
6. When measuring, please keep the subject quiet and steady, according to the measurement method shown in the specification, so as not to cause the measurement deviation caused by improper operation.
7. Continuous measurement, the measurement results may have a small error, which is a normal phenomenon, it is recommended that the maximum continuous measurement in a unit of time 3 times.
8. The human body temperature fluctuates from time to time, and the body temperature collected from different parts will also vary. When observing the changes in body temperature, it is recommended to measure and observe the body temperature in the same part multiple times.
9. Different types and brands of temperature measuring products do not have comparative value. It is recommended to use the same temperature measuring product to observe temperature changes in order to better grasp the temperature changes.

6.2 About Products

1.Except for measurement of Axillary, oral and rectal temperature, don’ t use this product for other purposes.

2.Please do not force collision, fall, stampede or shake this product, may cause product failure or cause measurement deviation.

3. Do not disassemble, repair or modify the product.

4. Do not use in electromagnetic interference environment, which may affect the measurement results.

5. Please keep this product out of reach of children to prevent children from swallowing batteries or small parts. If swallowed, please contact the doctor immediately.

6. Please keep the product in accordance with the product transportation / storage conditions to avoid use problems or measurement deviations.

7. Do not put in direct sunlight, high temperature and humidity, dust, near the fire, vulnerable to vibration shock place custody.

8. The thermometer is not used for a long time, the battery should be removed to prevent battery leakage.

9. Do not place this product in a place with electric shocks.

10. Do not insert the metal probe end of the thermometer into the power socket. This may cause electric shock.

11. Do not throw the thermometer and its accessory batteries into the fire, which may cause an explosion.

12. Please dispose of waste or residue at the end of the product's service life in accordance with local laws and regulations.

13. The normal use of this product is the human body temperature measurement mode, if you need to enter the correction mode must contact the company's after-sales service agencies.

7. Installation and use

7.1 Installation of batteries

1.This product uses One CR1632 button battery and has been built into the thermometer body when it leaves the factory.(Note: The built-in battery in the thermometer is a trial battery. This battery may not provide the same life as the new battery.)

2.To replace the battery, turn the phillips screwdriver counterclockwise to remove the screw on the battery cover.

3.gently remove the battery cover, then take out the old battery.

4.Follow the battery polarity mark in the battery compartment and put the new battery into the battery compartment. When installing, pay attention to the positive and negative polarity.

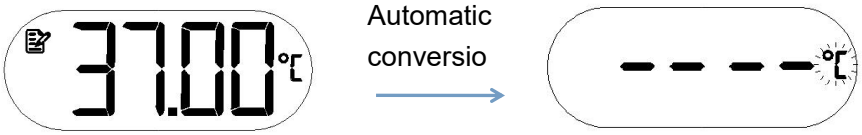
5.Reinstall the battery cover as is, and use a Phillips screwdriver to turn clockwise to tighten the fixing screws.

7.2 Measurement process

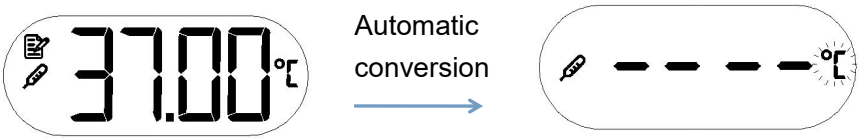
7.2.1 Adjusted mode / Direct mode

1. Tap the “power key”, the thermometer will display in full screen, and then display the effective memory temperature value measured last time.

2. If adjusted mode was used last time, then this measurement is also adjusted mode.



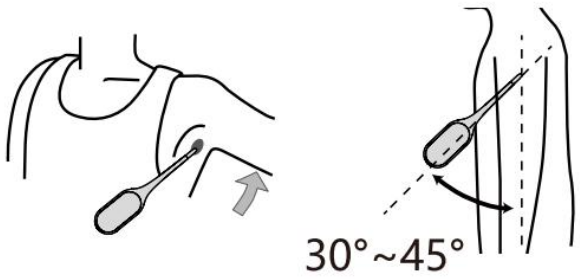
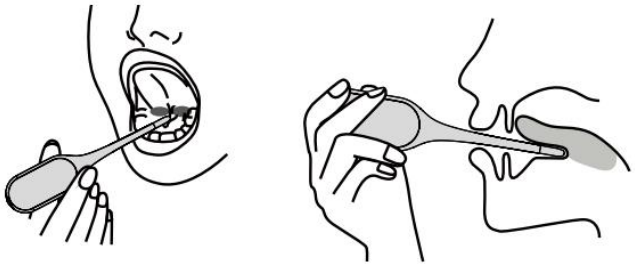
If direct mode was used last time, this measurement will also be in direct mode.



Note: In direct mode, the screen displays the "🖉" direct mode icon.

3.When the icon "℃" or"℉" on the screen begins to blink, place the temperature sensor of the thermometer in the following test parts:

Measuring part	Measuring method	Graphic

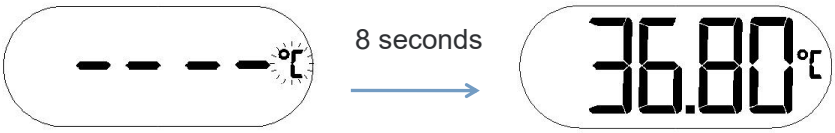
Axillary	• Raise your arm,Place the probe tip under the armpit parallel to the arm, pressing the arm against the body. • Make sure the metal probe of the thermometer is completely wrapped around the armpit.	
[a] Oral	• Place the thermometer in one of the two locations under the tongue, to the left or right of the root of the tongue. The measuring probe must be in good contact with the tissue. • Close your mouth and breathe evenly through the nose to prevent the measurement from being influenced by inhaled/exhaled air.	
[b] Rectal	• This is the most reliable measuring method, and is especially suitable for infants and small children. • Lay the baby on its back on a hard surface and lift its legs to an angle of approximately 90°. Hold them by the ankles in order to prevent their body from turning while taking the temperature. • Carefully insert the measuring probe of the thermometer 2 to 3cm into the anal aperture.Until the thermometer's metal probe is completely covered.	

[a] For some sensitive people, nausea may occur when mouth temperature is measured;

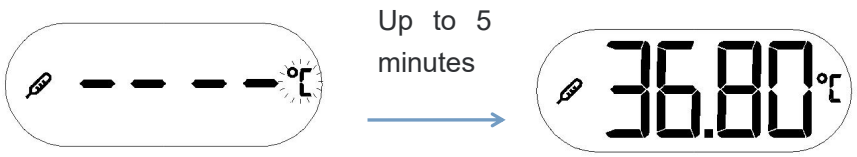
[b] After measuring rectal temperature, there may be a slight feeling of distension in the anus.These are all normal phenomena, and a rest may relieve them. If you are concerned that the measurement cannot be done correctly, please consult a professional physician for the measurement.

[c] To obtain more accurate measurement data, it is recommended to measure the oral and rectal temperature in direct mode.

4.Under the direct mode,after the thermometer detects the temperature of the human body, the measurement results will be displayed about 8s later with a prompt sound.



In direct mode, when the temperature value of human body is stable or the test time reaches 5min, the thermometer will display the measurement result with prompt sound.



5. Remove the battery of the thermometer and power it on again each time. The Adjusted mode is entered by default for the next measurement.

7.2.2 The mode switch

1. In the off state, press and hold “power key”for 5 seconds and release it, then it will automatically enter the measurement state different from that used last time.
2. If the adjusted mode was used last time, it will automatically change to direct mode and start temperature measurement.

If the direct mode was used last time, it will automatically change to adjusted mode and start temperature measurement.

7.3 Display and Sound Tips

After the measurement is completed, the following tips may appear in the thermometer:

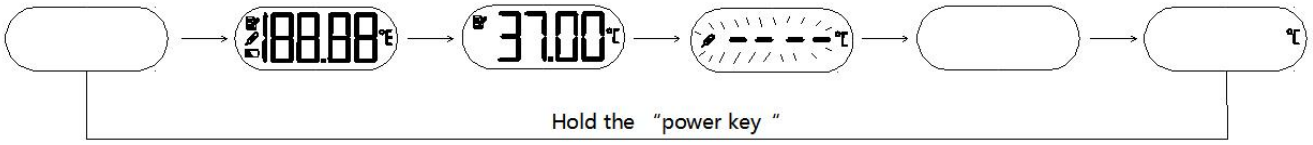
Screen display	Sound Tips	Representation of information
Temperature : 32.00℃~37.59℃ （89.60℉~99.67℉）	"beep"~	Target temperature values for this measurement
Temperature : 37.60℃~42.90℃ （99.68℉~109.22℉）	"beep beep beep"..."beep beep beep"..."beep beep beep"..."beep beep beep"..."beep beep beep"	Target temperature values for this measurement
Err	"beep "..."beep"..."beep "... " beep"	Abnormal temperature rise rule (e.g., measurement process shedding)
Hi	"beep "..."beep"..."beep "... " beep"	The measurement temperature is higher than the maximum value of the thermometer range
Lo	"beep "..."beep"..."beep "... " beep"	The measured temperature is below the minimum value of the thermometer range

7.4 Power off function

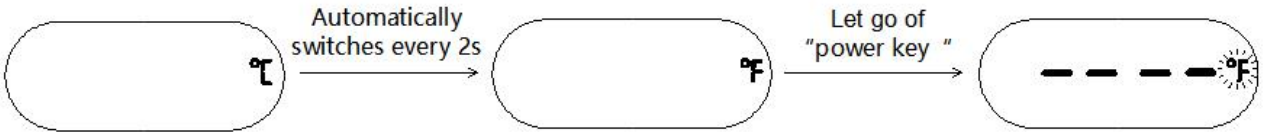
If the thermometer does not perform any operation within 30 seconds or press “power key” again, it will enter the shutdown state directly.

7.5 Temperature unit setting function

1. When the thermometer is off, hold down“power key” and do not release it. The product will start. Wait for 5 seconds after the screen turns off, and then enter the temperature unit setting interface.



2.Hold down the“power key” and do not release it. The unit of ℃or℉will be automatically switched,every 2s. When the required unit is displayed, release the hand, that is, select the current unit, and the thermometer immediately enters the state to be measured.



7.6 Low Voltage Prompt Function

1. The thermometer automatically detects the battery voltage every time it is turned on. When the battery voltage is insufficient but can continue to use, the“ ” icon appears on the display screen, but does not affect the operation.

2. When the battery voltage is too low to continue to use, the display screen appears separately “ ”icon and flashes, about 8 s after forced shutdown, thermometer need to replace the new battery to continue to use.

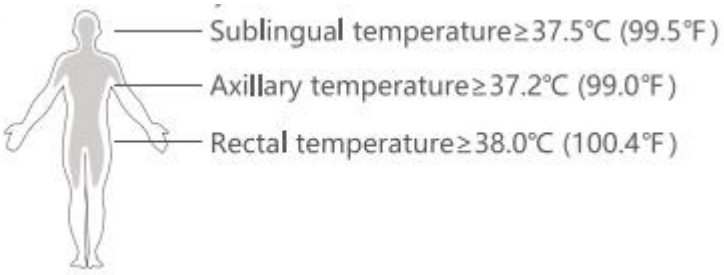
7.7 Initialization function

Remove the battery and repower the thermometer, and it will automatically restore to the factory setting.

8. Body Temperature

The normal body temperature of people is a range value, the normal body temperature of different people will be different, and the personal body temperature will also change at different times.

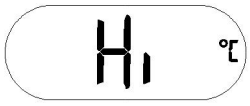
The following are the reference values for the definition of fever in various parts of the human body:



*Data sources: ISO 80601-2-56：2017/AMD 1：2018, for information only.

It is dangerous to make self-diagnosis and treatment according to the measurement results. Please consult a professional doctor with the measurement results.

9. Troubleshooting instructions

Fault Description	Possible causes	Solution
The screen does not react when the power is on or Equipped with batteries.	Battery runs out	Please replace the new battery and re-open
	Battery installation error	Please install the battery correctly according to the positive and negative pole mark in the battery bin.
	After reloading the battery, the screen remains blank	Please contact after sale
 All ICONS on the screen flicker	Hardware failure	Please contact after sale
 The battery icon appears on the screen and flashes	Too low battery voltage, Causing failure to boot.	Please replace the new battery and restart
 Battery icon appears on the screen	Battery power is running out	Please replace the new battery as soon as possible
	Abnormal temperature rise rule (e.g., measurement process shedding)	Please restart the measurement. The thermometer should be properly placed at the measuring site according to the instructions.
	The measurement temperature is higher than the maximum value of the thermometer range	Please check the measurement target is correct and re-measure again.
	The measured temperature is below the minimum value of the thermometer range	Please check the measurement target is correct and re-measure again.

10. Maintenance and maintenance

1. Please use a soft, dry cloth to gently wipe the dirt on the mainframe. If the surface is more serious dirty, you can dip some alcohol to wipe.Cleaning is recommended every 1 month.
Caution: Do not wash with water or use cleaners, diluents or volatile oils containing abrasives.
2. After the thermometer measuring probe is soiled, please use a soft cloth dipped in more than 75% concentration of medical alcohol to cover the measuring probe end and gently wipe it. If the wipe is still not clean, please contact customer service.
3. If the thermometer measuring probe, button, display and other parts are damaged, please contact the after-sales service.
4. Do not put in direct sunlight, high temperature and humidity, dust, near the fire, vulnerable to vibration shock place custody.
5. When the thermometer is not used for a long time, the battery should be removed to prevent battery leakage.
6. When the “ ” icon appears on the thermometer display screen, it indicates that the battery power is about to run out. Please replace the battery as soon as possible.
7. We do not authorize any organization or individual to carry out maintenance, please do not disassemble and adjust the thermometer.
8. The thermometer has been tested and calibrated at the time of manufacture. If you have any questions about the function or measurement accuracy of the product, please contact the dealer or manufacturer.

11. List of accessories

Use only original accessories to check whether the received accessories are complete.

Quantity	Components
1 pcs	FDTH3400 host
1 pcs	CR1632 batteries (Placed inside the mainframe）
1 pcs	User Manual

*The technical data should be combined with the user manual.

*In addition to specifying the use of CR1632 batteries, replacing existing components with non-manufacturer supplied components may cause measurement errors and reduce safety.

12. Final disposal

At the end of the product lifecycle, do not throw this product into the normal household garbage, but bring it to a collection point for the recycling of electronic equipment.
Waste Electrical and Electronic Equipment can have potentially harmful effects on the environment. Incorrect disposal can cause harmful toxins to build up in the air, water and soil and can be harmful to human health.

13. Information on critical parts

Name	Model	Supplier
Thermistor	XWTH002	A041
IC	XWIC036	A102
Thermometer casing	ABS	D004

14. Explanation of standardized symbol

CE 1639	Complies with the European Medical Device Directive (93/42/ EEC). Notified Body is SGS Belgium NV
EC REP	Authorized representative in the European Community.
	Attention: see Instructions for use!
	Caution! Consult accompanying documents.
	Type BF applied parts
LOT	Batch code
SN	Serial number
	Manufacturer information:
IP22	IP code of the device: this device's grade of against ingress of solid foreign objects .
	Disposal in accordance with Directive 2002/96/EC (WEEE).
MD	Medical Device
REF	Catalogue number
UDI	Unique Device Identifier
	Temperature limit
	Humidity limitation
	Date of manufacture

15. Electromagnetic compatibility information

15.1 FCC STATEMENT

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.

FCC CAUTION
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note:
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 transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines. This equipment has very low levels of RF energy that are deemed to comply without testing of specific absorption ratio (SAR).

15.2

WARNING:
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.
Not use of accessories, transducers and cables other than those specified or provided by the manufacturer of this the FDTH3400 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 FDTH3400, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and manufacturer´s declaration – electromagnetic emission

– for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic emission		
The FDTH3400 is intended for use in the electromagnetic environment specified below. The customer or the user of FDTH3400 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The FDTH3400 uses RF energy only for its internal function. There for, 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 FDTH3400 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	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity

– for all EQUIPMENT and SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic immunity			
The FDTH3400 is intended for use in the electromagnetic environment specified below. The customer or the user of the FDTH3400 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 %. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	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	0 % U_T (100 % dip in UT) for 0,5 cycle 0 % U_T (100 % dip in UT) for 1 cycles 70 % U_T (30 % dip in UT) for 25/30cycles 0 % U_T (100 % dip in	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FDTH3400 requires continued operation during power mains interruptions, it is recommended that the FDTH3400 be powered from an uninterruptible power supply or a battery.

	UT) for 250/300 cycles		
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U^T is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration – electromagnetic immunity –

for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer´s declaration – electromagnetic immunity			
The FDTH3400 is intended for use in the electromagnetic environment specified below. The customer or the user of the FDTH3400 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 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz.[a]	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the FDTH3400, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[b] should be less than the compliance level in each frequency range.[c]

			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 is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz 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] 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 FDTH3400 is used exceeds the applicable RF compliance level above, the FDTH3400 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary,such as such as reorienting or relocating the FDTH3400.

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

Recommended separation distances between portable and mobile

RF communications equipment and the EQUIPMENT or SYSTEM -for EQUIPMENT and SYSTEMS

Recommended separation distances between portable and mobile RF communications equipment and the FDTH3400				
The FDTH3400 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FDTH3400 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FDTH3400 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 outside ISM and amateur radio bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d = [\frac{12}{V_2}]\sqrt{P}$	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	N/A	N/A	0.035	0.07
0.1	N/A	N/A	0.11	0.22
1	N/A	N/A	0.35	0.7
10	N/A	N/A	1.1	2.21
100	N/A	N/A	35	70

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.

16. Standard List

FDTH3400 complies with the following standards

IEC 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-11	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 15223-1	Medical device –symbols to be used with medical device labels, labeling and information to be supplied –Part 1; General requirements
ISO 80601-2-56	Medical electrical equipment – Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

17. Warranty

We provide one year warranty starting from the date of purchase. Please refer to the followings situations that are excluded from the free repair services within the warranty period.

1. All damages caused by disassembly and repair of the device by yourselves.
2. All damages caused by dropping the device during usage, or transport.
3. All damages caused by improper usage of the device and not following the instructions on the user manual.

Please contact after-sales service and support and enclose your product purchase receipt while claiming for warranty services.

Location of purchase:

Contact number:

Date of purchase:

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EC REP

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