choiS TECHNOLOGY

# USER MANUAL
# Electronic Thermometer (XST200)

EC REP

OBELIS S.A
Bd. Général Wahis 53 1030 Brussels, BELGIUM
Tel : +32 (0)2.732.59.54, Fax : +32 (0)2.732.60.03

CHOISTechnology Co., Ltd.
Manufactured for KM HELATCARE
7811 N. Shepherd Dr, Ste# 215-A, Houston,
Texas 77088, USA

CE 0123

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## Chapter 1. Introduction

### 1.1 summary

This product is Class II, Non-Invasive Device.
The electronic thermometer is a device that measures the body temperature using the thermistor resistance change.
The body temperature display must be connected to the mobile app installed on the smartphone, so that it can be displayed. Smartphones are not provided as components of this product.

### 1.2 Intended Use

Measuring instrument for measuring the body temperature of a patient by using the electrical properties

### 1.3 Intended Operator

#### 1.3.1 Education

At least 11 years - 5 years of intensive reading experience (school)

#### 1.3.2 Knowledge

Be able to distinguish body position (measurement site, chest, armpit)

#### 1.3.3 Understanding languages

To understand English or user manual.

#### 1.3.4 experience

No experience required

#### 1.3.5 Acceptable faults

No specific information

### 1.4 Indications

- No record.

### 1.5 Side Effects and Contraindications

- No record.

### 1.6 Before Use

1) Be sure to read and use the user manual.
2) Do not use for other purposes.
3) Stabilize the state of the person before the measure ment and make the measurement in the correct state.
4) The temperature detecting unit of the body temperature sensor is brought into close contact with the skin. Use in body cavity is prohibited.



## Chapter 2. Safety (Cautions and Warning)

### 2.1 Danger

1) Be sure to use the specified rated battery and check the polarity of the battery.

### 2.2 Warning

1) If an abnormality is found in the instrument, immediately stop the operation of the instrument, remove the instrument from the human body and ask the manufacturer for inspection.
2) Do not exchange battery arbitrarily.

### 2.3 Caution

1) This electronic thermometer can be used for all ages. However, please be sure to use as directed by your doctor if you have severe high fever.
2) Be careful not to use the device by not intended operator.
3) Be careful not to cause damage to the device.
4) Be careful not to let liquid or foreign matter get into the body.
5) Please contact the manufacturer if any of the following situations occur.
   - If you have a skin reaction (urticaria, allergies, etc.)
   - If something is wrong with the whole device
   - In case of using in parallel with other medical devices, change of measured body temperature occurs remarkably
6) If the unit detects a heat, be sure to remove it from your body.
7) It should not be used in the same place where there is equipment with strong electromagnetic wave(e.g. X-ray, MRI etc.)

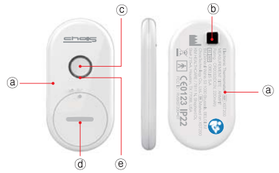
### 2.4 Notice

1) Since this electronic thermometer should be used in conjunction with a smartphone, operation may not be smooth depending on the location and power status of the smartphone. Please observe the followings.
   - Maintain the power supply status of the smartphone by using auxiliary battery or adapter for continuous measurement of body temperature.
   - Since the normal temperature measurement range is within 15m from the thermometer, be careful not to let the smartphone deviate more than 10m.
   - When using in two connected rooms, distance to use may be significantly reduced. Use in one independent space if possible.
2) This electronic thermometer can be used for all ages, but please be aware of the following when using Young or Infant.
   - Measures should be taken after 30 minutes or more after the infant enters the room from outside or moves the thermometer to a different temperature environment.
   - The sensor part on the back of the product is very sensitive and should always be kept clean and intact for accurate measurement.
   - In case of body temperature measurement for infants, in case of severe strangulation, distance between skin and sensor may not be kept constant, so measurement error may occur.
   - Do not allow infants or children to touch the thermometer sensor and battery with their mouths or with wet hands.
3) This electronic thermometer attached to the body, please note the following points.
   - limitation for contact duration : 24hour - 30days



## Chapter 3. Specifications

### 3.1 System, Contents, Feature Description




| NO. | Name | Function |
|---|---|---|
| ⓐ | Case | Protect PCB ASS'Y, shape product |
| ⓑ | Temperature Sensor | Detect human body temperature and convert it to digital signal |
| ⓒ | Button | ON / OFF button to operate the product |
| ⓓ | Battery cover | So that the battery can be easily attached and detached. |
| ⓔ | LED Indicator | Display the Device status<br>LED OFF : Sleep mode<br>LED ON(every 3sec blinking) : Active mode |

### 3.2 Product Performance

| Section | Specification |
|---|---|
| Battery | CR2032 (DC 3V) |
| Measurement Range | 50.36°F ~ 139.82°F |
| Accuracy | ± 0.18°F (93.2°F ~ 107.6°F)<br>± 0.54°F (50.36°F ~ 93.02°F, 107.7°F ~ 139.82°F) |
| Minimum unit | 0.01°F |
| Measurement Method | Thermistor / Direct mode only |
| Measurement site | armpit |
| Measurement Display | Bluetooth communication with your smartphone to show in your mobile app |



| | |
|---|---|
| Measurement Transient time | After 15-20 minute |
| Use Distance | Max 15m |
| Lift time | Max 5days |
| Software Version | Firmware : Ver. 1.0.0<br>Mobile App : Ver. 2.0.9 |

### 3.3 Product Characteristics

1) Protection for electric shock
   Internal Power device, BF type applied part

2) Waterproof grade
   IP22 (according to IEC529)
   - Protected against a solid object grater than 12.5mm, such as a finger.
   - Protected against water drops at a 15degree angle.

### 3.4 Label


### 3.5 Pictogram

| | |
|---|---|
| CE | Community European |
| 0123 | Notified Body |
| REF | Catalogue number |
| SN | Serial number (Marked on XST200 ) |
| | Manufacturer |
| EC REP | Authorized representative in the European Community |



| | |
|---|---|
| | Date of manufactured |
| | Keep dry |
| | DC |
| | Class II Equipment |
| | BF type applied part |
| | Caution |
| | Consult Instruction for use |
| | Do not dispose of with domestic waste |

### 3.6 Environmental condition(Storage, Transfer, Operation)

1) Storage Condition
   Temperature : 50°F ~ 158°F
   Humidity : 0 - 93 % RH
   Air pressure : 700 - 1,060 hPa
2) Transfer Condition
   Temperature : 50°F ~ 158°F
   Humidity : 0 - 93 % RH
   Air pressure : 700 - 1,060 hPa
3) Operation Condition
   Temperature : 41°F ~ 140°F
   Humidity : 15 - 93 % RH
   Air pressure : 700 - 1,060 hPa

## Chapter 4. Operation

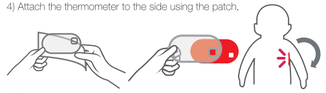
### 4.1 Preparation before use (before operation)

1) Stabilize the state of the person before the measurement and make the measurement in the correct state.
2) The temperature detecting unit of the body temperature sensor is brought into close contact with the skin. Use in body cavity is prohibited.



### 4.2 How to operation

1) Install a mobile app (name: Thermosafer) on your smartphone.
2) Activate the Bluetooth function of the smartphone.
3) Place the operating button of the device on and check whether the LED indicator is on. If LED is blinking every 3sec then operation is active.
4) Attach the thermometer to the side using the patch.



5) Run the mobile app and select the thermometer you searched for.
6) Check that the temperature is displayed on the mobile app when the thermometer is normally connected.
7) Changes in body temperature information will be stabilized after about 15 to 20 minutes.

### 4.3 Precautions when operation

1) If there is any problem with the device, stop operation and contact the manufacturer.

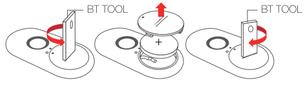
### 4.4 After operation management methods

1) Avoid contact with water. Do not store near water.
2) Do not use in places subject to adverse influences such as air pressure, temperature, humidity, wind.
3) Pay attention to the stable state such as vibration and shock (including in transportation).
4) Do not store in chemical storage area or gas generating place.

## Chapter 5. Routine maintenance

### 5.1 Routine check

1) Please check the battery remaining in the mobile app and replace the battery.
   * Battery replacement is as follows.




2) Be sure to clean the surface of the product with a cloth
3) Please check the storage conditions and usage conditions of the product.
4) You do not need to take a separate calibration.



## Chapter 6. Trouble shootings

| Symptom | Possible Reason | Solution |
|---|---|---|
| The temperature data cannot be displayed properly. | 1. Low battery of Instrument | 1. Turn on again<br>2. Please replace battery. |
| Cannot turn on Instrument | 1. May the battery power is shortage or no electricity<br>2. There are some problems of the instrument. | 1. Turn on again<br>2. Please replace battery<br>3. Contact customer service |
| Unusual temperature data | 1. The position of Instrument is not correct<br>2. There are some problems of the instrument. | 1. Check the position of Instrument<br>2. Contact customer service |
| Mobile App error<br>1. User data not saved.<br>2. Wrong data received,<br>3. Measurement error<br>4. Alarm error<br>(High temp, Low temp, Lowbattery, Disconnection.) | 1. The app may not install properly or may not be compatible with your smartphone. | 1. Contact customer service |

## Chapter 7. Shop for supplies, A/S

### 7.1 Supplies list and Purchase path

| Item | Purchase path |
|---|---|
| Patch | Contact customer service |
| Battery | Contact customer service |

### 7.2 A/S explanation

If you have any problems while using the product, or if you need to improve things, please contact the following contact details and we will kindly consult you.
Email: cs@kmact.com / Fax: 281-405-0891
Homepage: https://kmact.com

### 7.3 Warranty

1) The warranty period for this product is 3 years.
   Any defect of the product caused by materials and mechanical problems will be covered for free for a year. If our model you purchased is found to be defective within that time, we will promptly repair or replace it. owever, this warranty does not cover problems or damages resulted from unauthorized repair, modification or disassembly. In case of defect or failure of the product that occurred after one year of purchase during the warranty period, paid repair is possible.
2) If any of the following situations occur within 1 year during the warranty period, it will be charged.
   - In case of malfunction due to user's mistake
   - failure or damage caused by the arbitrary disassembly, modification of structure, performance, and function
   - failure or damage caused by the use of the product other than its intended purpose
   - In case of malfunction due to carelessness such as dropping and flooding after purchase
   - failure due to natural disaster(earthquake, fire, flood, lightning)

## Chapter 8. EMC Compliance



### 8.1 Electromagnetic Emission

The product is suitable for use in an specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

| Emission Test | Compliance | Electromagnetic Environment Guidance |
|---|---|---|
| RF-emission CISPR 11 | Group 1 | The product use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. |
| RF-emission CISPR 11 | Class A | The product 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 purpose. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Complies | |

### 8.2 Electromagnetic Immunity

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

| Immunity Test | IEC 60601- Level | Compliance Level | Electromagnetic Environment Guidance |
|---|---|---|---|
| Electrostatic discharge(ESD) IEC61000-4-2 | ± 6kV contact<br>± 15kV air | ± 6kV contact<br>± 15kV air | Floor 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 IEC61000-4-4 | ± 2kV for power supply lines<br>± 1kV for input/output lines | ± 2kV for power supply lines<br>± 1kV for input/output lines | Mains power quality should be that of a typical commercial and/or hospital environment |
| Surge IEC61000-4-5 | ± 1kV differential mode<br>± 2kV common mode | ± 1kV differential mode<br>± 2kV common mode | Mains power quality should be that of a typical commercial and/or hospital environment |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11 | <5% U. (>95% dip in U.) for 0.5 cycle<br>40% U. (60% dip in U) for 5 cycles<br>70% U. (30% DIP IN U.) for 25 cycles<br><5% U. (>95% dip in U.) for 5 sec | <5% U. (>95% dip in U.) for 0.5 cycle<br>40% U. (60% dip in U) for 5 cycles<br>70% U. (30% DIP IN U) for 25 cycles<br><5% U. (>95% dip in U.) for 5 sec | Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |



| | | | |
|---|---|---|---|
| Conducted RF IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance:<br>d = 1.2√P<br><br>d = 1.2√P<br>for 80 MHz to 800 MHz<br><br>d = 2.3√P<br>for 800 MHz to 2.5 GHz<br>where P is the maximum output power rating of the transmitter in Watt (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[b] in each frequency range. Interference may occur in the vicinity of equipment marked with the symbol described literal. |
| Radiated RF IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 Vrms | |

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, people and animals.

[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 product is used exceeds the applicable RF compliance level above, the product should be observed, additional measures may be necessary, such as reorienting or relocating the product.
[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.



### 8.3 Recommended Separation Distances between portable and mobile HF- communications equipment and the product

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product - according on output power and frequency of the communications equipment - as recommended in the following table.

| Rated maximum output power of transmitter in watts (W) | Separation distance according to the frequency of transmitter in meter (m) | | |
|---|---|---|---|
| | 150 kHz to 80 MHz<br>d = 1.2√P | 80 MHz to 800 MHz<br>d = 1.2√P | 800 MHz to 2.5 GHz<br>d = 2.3√P |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note 1: At 80 MHz and 800MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

## Chapter 9. Wastes

### 9.1 Instructions for waste procedure

#### 9.1.1 Disposal of Electronic Thermometers

- Follow local laws, standards and guidelines for disposal of used electrical equipment.
- Do not allow parts to be contaminated during disposal.

#### 9.1.2 Disposal of packaging materials

- All packaging materials can be disposed of or recycled in an environmentally friendly manner.
- Please send the old packing materials to the recycling collection companies for the prevention of waste and recycling of raw materials.



Radio Regulations :
FCC Part 15 standard(s) ISO/IEC 60601-1-2 Electromagnetic Compatibility

FCC Statement and Legal Notices

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 WARNING: any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment under FCC regulations.

FCC RF Radiation Exposure Statement: This equipment complies with FCC RF Radiation exposure limits set forth for an uncontrolled environment. This device and its antenna must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC ID: RVBXST200-BT
Model: XST200
Responsible Party: KM HEALTHCARE 7811N. Shepherd Dr. Ste#215-A, Houston, Texas 77088, USA, TEL: (281) 405-0888