Instruction for use

1. Product name: Mercury free clinical thermometer

2.model specifications: CR.W00

3. Contact information



Wuxi Medical Instrument Factory Co., Ltd.
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SRN: CN-MF-000002277



Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands. SRN: NL-AR-000000121

4. Storage requirements

The temperature should keep -10°C to 42°C when it is stored and transported.

5.WARNING

- Warn patients against chewing, speaking and playing when the clinical thermometers are below the tongue of patients;
- Need to let sick children lie quietly and help them to hold another end of the clinical thermometers for rectal use in case it is inserted too deep, or it slips from the anus.
- Avoid having a bath, eating or smoking half an hour before taking body temperature:
- It is not designed for special applications (e.g. thermometers for premature babies, ovulation thermometers):
- Always disinfect thermometer and fall The liquid column below the lowest numbered scale mark after use;
- Care should be taken to avoid any potential risk or damage during measuring;
- Children aged 10 and under who need to use a thermometer to measure their temperature can only use it with the assistance of an adult;
- Use of this thermometer is not intended as substitute for visiting your doctor.
 Persistent fever, especially in children must be treated by a health professional;
- any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established:

6.Intended use

6.1 Intended purpose including any clinical claims

Measure the temperature of human.

6.2 Expected operating environment:

1/3

Minimum measuring temperature range should be 35.5 $^{\circ}$ C to 42 $^{\circ}$ C, and the environment temperature (for mercury free thermometer only)should be 20 $^{\circ}$ C to 30 $^{\circ}$ C; if the temperature for storage is less than 20 $^{\circ}$ C, please put the thermometers in the temperature $^{\circ}$ 20 $^{\circ}$ C to 30 $^{\circ}$ C for at least 1-2 hours or 30 $^{\circ}$ C to 35 $^{\circ}$ C for ten minutes before use or test.

6.3 Use method

Notice for swing: catch the tail part of the thermometer by thumb and forefinger tightly and carefully, swing the thermometer lightly several times until the liquid down.

Operation procedures

- [1] The liquid column shall fall below the lowest numbered scale mark before use, then clean and disinfect the clinical thermometer in medical alcohol or put on a sterilized plastic tube.
- [2] Be careful to put it below the tongue of patients if measuring oral position and tell them to close their mouth tightly.
- [3] A clinical thermometer for rectal use is applied some lubricator before inserting it in the anus.
- [4] Be careful to put it below the armpit of patients if measuring armpit position and tell them to tight it tightly.
- [5] Disinfect thermometer and fall The liquid column below the lowest numbered scale mark after use;

Please read the number of the clinical thermometer about 4 minutes after above measuring steps.

7.CLEANING INSTRUCTIONS

The thermometer has hermetically sealed hygienic glass housing and can be disinfected without restrictions.

The thermometer of disinfectants and cleaning agents shall not exceed 42 $^\circ\!\!\!\mathrm{C}$. Clean the glass thermometer with a medical alcohol (if measuring site is mouth or anus, please use 75% Medical Ethanol Alcohol and without this limit for disinfectant if measuring site is armpit) before and after use. Disinfect the thermometer with a cotton pad or cloth soaked in alcohol or immersed in a disinfectant solution (immersion time must be in accordance with its manufacturer's instructions).

8. waste disposal

The metallic liquid is an alloy consisting of gallium, indium and tin. this clinical thermometer should be handled with care. In particular, care should be taken to avoid dropping the instrument or treating it in any way that could result in damage. When the clinical thermometers are broken, cleaning split metallic liquid by a damp cloth with soap suds. and the product can be disposed together with other household waste.

9.Shelf life

N/A

10. Main performance indicators of the product:

a. Minimum measuring range: 35.5 $^{\circ}\text{C}$ -42 $^{\circ}\text{C}$, min interval is: 0.10 $^{\circ}\text{C}$

b. size of thermometers:

2/3

flat type, large size, length: 120+8-5 mm; H/W: 12±0.4mm x9±0.4mm

c. Accurate: 37°C and 41°C: ± 0.10 °C and ± 0.15 °C, It is recommended to measure 37°C and 41°C:

d. Storage requirement: temperature will keep -10 °C to 42 °C

e. Operating temperature: 20 °C to 30 °C

f. Standard: EN12470:2000+A1:2009

11. Symbol

| 11. Symbol | | | |
|------------|--|-------------|---|
| ••• | Manufacturer | EC REP | Authorized representative in the European Community/ European Union |
| <u></u> | Date of manufacture | | Use-by date |
| LOT | Batch code | # | Model number |
| []i | Consult instructions for use or consult electronic instructions for use | \triangle | Caution |
| MD | Medical device | C€xxxx | CE marking |
| Hg | Mercury Free | | |

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3/3

Size: 80x130mm