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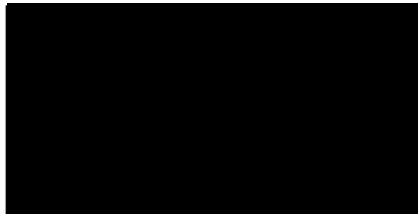
Product Service

EC Certificate

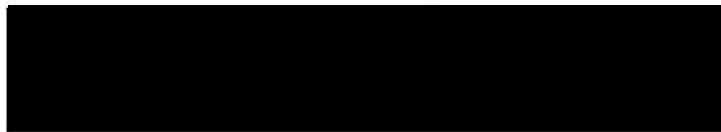
Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 082883 0014 Rev. 00

Manufacturer:



Facility(ies):



Product Category(ies): Non-contact Infrared Thermometer, Digital Thermometer, Ear Thermometer, Nasal Aspirator

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: GZ19049CN01

Valid from: 2019-05-15

Valid until: 2023-07-28

Date, 2019-05-15

Stefan Preiß

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES**



MANUFACTURER:

MEDICAL DEVICE: Non-contact Infrared Thermometer
JXB-182, JXB-178, JXB-179, JXB-180, JXB-181, JXB-183, JXB-185, JXB-186, JXB-188, JXB-189, JXB-190, JXB-191, JXB-192, JA001, JXB-301, JXB-302, LMP001, JXB-195, JXB-303, JXB-307, JXB-308, JXB-182B, JXB-311

CLASSIFICATION - ANNEX IX: CLASS IIA, RULE 10

CONFORMITY ASSESSMENT ROUTE: ANNEX II.3

WE, THE MANUFACTURER, IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY, HERewith DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. (NOTE: IT IS SUGGESTED THAT THIS LIST STATE THE STANDARDS' FULL NAME AND DATE OF ISSUE AND INCLUDES ALL AMENDMENTS. A CROSS REFERENCE TO THIS STANDARDS LIST FROM THE ESSENTIAL REQUIREMENTS CHECKLIST MINIMISES DOCUMENT CHANGES IN THE EVENT OF STANDARDS RE-ISSUE OR AMENDMENT).

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER **CE** 0123

(EC) CERTIFICATE(S): EC CERTIFICATE(S) NUMBER(S) NO. G1 082883 0014 Rev.00
SHOW ONLY THE EC CERTS WITH A SCOPE THAT COVERS THE PRODUCTS LISTED



EUROPEAN REPRESENTATIVE: Wellkang Ltd; Addr: The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland;
Tel: +353(1)4433560
E-mail: AuthRep@CE-marking.eu

(THERE MAY BE ONLY ONE EC REP FOR EACH PRODUCT TYPE FOR ALL THE EU)

START OF CE-MARKING: 2012-09-07

PLACE, DATE OF DECLARATION: GUANGZHOU 511470, 2019-05-15

SIGNATURE:



NAME: KEN GUO

POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)



Non-contact Infrared Thermometer Model: JXB-178

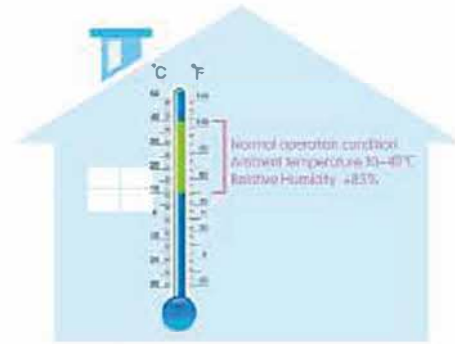
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THE MANUFACTURER RESERVES THE RIGHT TO ALTER THE SPECIFICATIONS OF THE PRODUCT WITHOUT PRIOR NOTIFICATION

Quick guide

● 1. Measure Temperature Indoors



● 2. Before measuring

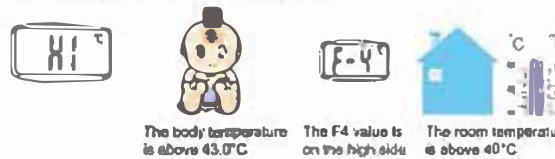


● 3. Note:

1. Lo may display due to following circumstances



2. Hi may display due to following circumstances



Temperatures are measured by the energy emitted by humans. Thermometer does not emit radiation as it is harmless.

I. Safety precautions

- Follow the maintenance advice stipulated in this instruction manual.
- This device may be used for professional purposes or for personal home use.
- This device must only be used for the purposes described in the instruction manual.
- This device must only be used in an ambient temperature range of between 10°C and 40°C.
- This device must always be kept in a clean, dry area.
- Do not expose this thermometer to electric shocks.
- Do not expose this thermometer to extreme temperature conditions of >55°C or <-20°C.
- Do not use this device in relative humidity higher than 85%.
- The protective glass over the lens is the most fragile part of the thermometer.
- Do not touch the glass of the infrared lens with your fingers.
- Clean the glass with a cotton bud lightly moistened with 95% alcohol.
- Do not expose the thermometer to sunlight or to water.
- Never drop the device.
- Should a problem occur with your device, please contact your retailer. Do not attempt to repair this device yourself.

II. Intended use

The device is an infrared thermometer intended to measure forehead temperature of infants and adults without contacting human body. It can be used by consumers in household environment and doctor in clinic as reference.

III. Introduction

The JXB-178 Non-contact Infrared thermometer has been developed by using the latest infrared technology. This technology allows temporal artery (TA) temperature to be taken at a distance of about 3cm-5cm away from the forehead. Precise, instantaneous and without contact, the JXB-178 is, up to now, the most suitable thermometer for no risk on temperature measurement. It has been demonstrated that this method of TA temperature measurement is more precise than the tympanic thermometry and better tolerated than rectal thermometry (1). However, as with other types of thermometer, it is essential to use the JXB-178 properly in order to obtain reliable and stable results. You are therefore advised to read this instruction manual and the safety precautions carefully before use. (1)Greenes D, Fleisher G. Accuracy of a Noninvasive Temporal Artery Thermometer for Use in Infants. Arch Pediatr Adolesc Med 2001;155:376.

IV. Precautions before use

The JXB-178 is preset at the factory. It is not necessary to calibrate the device when starting it up.

In order to obtain reliable and stable results, you are advised each time there is a significant change in the ambient temperature due to a change in environment, to allow the JXB-178 to acclimatize to this ambient temperature for 15 to 20 minutes before using it. It is important to allow 3-5 seconds interval between two measurements.

V. Operating principle

All objects, solid, liquid or gas, emit energy by radiation. The intensity of this energy depends on the temperature of the object. The JXB-178 infrared thermometer is therefore able to measure the temperature of a person by the energy that the person emits. This measurement can be taken thanks to an external temperature probe on the device which permanently analyses and registers the ambient temperature. Therefore, as soon as the operator holds the thermometer near the body and activates the radiation sensor, the measurement is taken instantly by detection of the infrared heat generated by the arterial blood flow. Body heat can therefore be measured without any interference from the heat of the surrounding environment.

THE DIFFERENT METHODS OF TEMPERATURE MEASUREMENT

Core temperature

Core temperature is the most precise measurement and involves measuring the temperature in the pulmonary artery by means of a catheter equipped with a thermal probe which can read the temperature in situ. The same method is employed for probes measuring the oesophageal temperature. However, such invasive temperature measurement methods require specific equipment and expertise.

Rectal thermometry

Rectal temperature adjusts slowly in comparison to the evolution of the body's internal temperature. It has been demonstrated that rectal temperature remains raised long after the internal temperature of the patient has started to drop and vice versa. Furthermore, rectal perforations have been known to occur as a result of this method and without appropriate sterilisation techniques, rectal thermometry can spread germs often found in faeces.

Oral thermometry

Oral temperature is easily influenced by recent ingestion of food or drinks and by breathing through the mouth. To measure oral temperature, the mouth must remain closed and the tongue lowered for three to four minutes which is a difficult task for young children to accomplish.

Axillary (earpit) temperature

Although it may be easy to measure axillary temperature, it has been proven that it does not provide an accurate measurement of the child's internal temperature. To take this type of temperature, the thermometer must be wedged tightly over the axillary artery. Despite the low sensitivity and relative inaccuracy of axillary temperature in detecting fever, this method is recommended by The American Academy of Pediatrics as a screening test for fever in newborns.

Tympanic thermometry

In order to obtain a precise temperature reading, good command of the measurement technique is required. The thermometer probe must be placed as close as possible to the warmest part of the external ear canal.

Normal temperatures according to measurement method

MEASUREMENT METHOD	NORMAL TEMP°
RECTAL	36.6°C ~ 38°C
ORAL	35.5°C ~ 37.5°C
AXILLARY	34.7°C ~ 37.3°C
AURICULARY	35.8°C ~ 38°C
TEMPORAL	35.8°C ~ 37.8°C

The temperature of the human body varies throughout the day. It can also be influenced by numerous external factors: age, sex, type and thickness of skin...

Advantages of temporal artery (ta) temperature

Infrared arterial temperature can be measured using a device placed on the forehead, in the temporal artery region. It has been demonstrated that this relatively new method of measuring temperature is more precise than tympanic thermometry and better tolerated than rectal thermometry. The JXB-178 thermometer has been designed to produce an instant forehead temperature reading after any contact with the temporal artery. As this artery is quite close to the surface of this skin and therefore accessible and given the blood flow is permanent and regular, it allows precise measurement of the temperature. This artery is linked to the heart by the carotid artery which is directly linked to the aorta. It forms part of the main trunk of the arterial system. The efficiency, speed and comfort of taking a temperature from this area make it ideal compared with other temperature measurement methods.

Normal temperature according to age

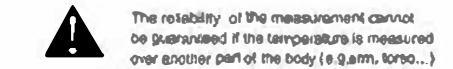
Age	°C	°F
0-2 years	36.4-38.0	97.5-100.4
3-10 years	36.1-37.8	97.0-100.0
11-65 years	35.9-37.6	96.6-99.7
> 65 years	35.8-37.5	96.4-99.5

Practical considerations when taking a temperature

- In order to ensure that precise and accurate temperature measurements are obtained, it is essential that each user has received a adequate information on and train in the temperature measurement technique when using such a device.
- It is essential to remember that although procedures such as taking a temperature may be simple they must not be trivialised.
- Temperature should be taken in a neutral context. The patient must not have undertaken vigorous physical activity prior to taking his/her temperature and the room temperature must be moderate.
- Be aware of physiological variations in temperature which must be taken into consideration when evaluating the results: ion temperature increases by 0.2° between am and 3 pm. Women have a temperature that is higher, on average, by around 0.2°C. Their temperature also varies in accordance with their ovarian cycle. It rises by 0.5°C in the second half of the cycle and at the early stages of pregnancy.
- When sitting, temperature is lower by about 0.3°C to 0.4°C than when standing.

How to take a temperature

Aim at the middle of forehead, from a distance of about 3cm-5cm, press the thermometer's measurement button and the left temperature is instantly displayed.

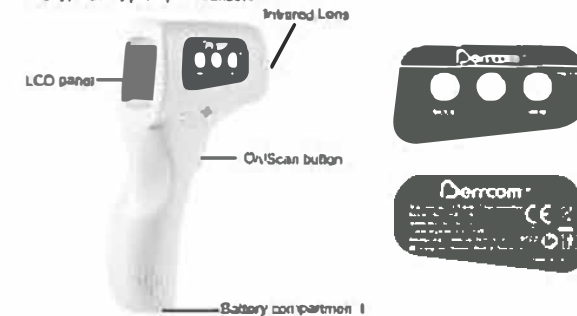


Constraints

- Please observe the following before any temperature measurement to ensure a stable and reliable result.
- Push back hair from the forehead.
 - Wipe away any perspiration from the forehead.
 - Avoid any drafts (e.g. from nasal specs, air conditioning...)
 - Allow a 3-5 seconds interval between two measurements.
 - Each time there is a significant change in the ambient temperature due to a change in environment, to allow the JXB-178 to acclimatise to this ambient temperature for at least 15 minutes before using it.

VI. Basic instrument

The type BF applied part: Sensor.





- Measurement of body/object/room temperature
- Hygienic and safe-measure without skin contact
- Measurement in <1 second Infrared measurement technology
- Display in Centigrade or Fahrenheit
- Free high temperature alarm setting

Unit size: 155 x 100 x 40 mm (L x W x H)

Unit weight (including batteries): 105g

Temperature display resolution: 0.1°C and 0.1°F

Measuring range: - In body mode: 32°C ~ 43°C (89.6°F ~ 109.4°F) -

Under body mode, there is three color backlist:

Green color backlit : $\leq 37.3^{\circ}\text{C}$ (99.1°F), means normal temperature.

Orange color backlit: $37.4\sim 37.9^{\circ}\text{C}$ (99.3~100.2 °F), means low fever.

Red color backlit: $\geq 38^{\circ}\text{C}$ (100.4°F), means high fever.

In surface temp mode: $0^{\circ}\text{C} \sim 60^{\circ}\text{C}$ (32°F ~ 140°F) -

In room mode: $0^{\circ}\text{C} \sim 40^{\circ}\text{C}$ (32°F ~ 104°F)

Precision: $32.0^{\circ}\text{C} \sim 34.9^{\circ}\text{C}$ (89.6°F ~ 94.8°F) : $\pm 0.3^{\circ}\text{C}$ ($\pm 0.6^{\circ}\text{F}$)

$35.0^{\circ}\text{C} \sim 42.0^{\circ}\text{C}$ (95°F ~ 107.6°F) : $\pm 0.2^{\circ}\text{C}$ ($\pm 0.4^{\circ}\text{F}$)

$42.1^{\circ}\text{C} \sim 43^{\circ}\text{C}$ (107.8°F ~ 109.4°F) : $\pm 0.3^{\circ}\text{C}$ ($\pm 0.6^{\circ}\text{F}$)

Consumption: ≤ 300 Mw

Accuracy: $\pm 0.3^{\circ}\text{C}$ (0.6°F)

Measuring distance: 3cm ~ 5cm (1.2in ~ 2in)

Automatic power-off: ≤ 30 secs

Memory: 32 sets