McKESSON

Digital Thermometers

OWNER'S MANUAL

For use with MFR #'s 16-412GM-00, 16-413BGM-00, 16-413RGM-00, 16-413BGM, 16-413RGM, 16-413BKGM, 16-413RKGM, 16-415GMHT, and 16-415GMST.

WARNING

- Read instructions thoroughly before using digital thermometer.
- Choking Hazard: Thermometer cap and battery may be fatal if swallowed. Do not allow children to use this device without parental supervision.
- Do not use thermometer in ear. Designed use is for oral, rectal, and armpit (axilla) readings only.
- Do not place thermometer battery near extreme heat as it may explode.
- Note: Use of the probe cover may result in a 0.2ºF(0.1ºC) discrepancy from actual temperature.
- The use of temperature readings for self-diagnosis is dangerous. Consult your doctor for the interpretation of results. Self-diagnosis may lead to the worsening of existing disease conditions.
- Do not attempt measurements when the thermometer is wet as inaccurate readings may result.
- Do not bite the thermometer. Doing so may lead to breakage and/or injury.
- Do not attempt to disassemble or repair the thermometer. Doing so may result in inaccurate readings.
- After each use, disinfect the thermometer especially in case the device is used by more than one person.
- Do not force the thermometer into the rectum. Stop insertion and abort the measurement when pain is present. Failure to do so may lead to injury.
- For children who are two years old or younger, please do not use the devices orally.
- If the unit has been stored at temperatures over 104ºF (40ºC), leave it in 41ºF~104ºF (5ºC~40ºC) ambient temperature for about 15 minutes before using it.

PLEASE READ CAREFULLY BEFORE USING

This digital thermometer provides a quick and highly accurate reading of an individual's body temperature. The digital thermometer is intended to measure the human body's temperature in regular mode orally, rectally or under the arm, and the device is reusable for clinical or home use on people of all ages. To better understand its functions and to provide years of dependable results, please read all instructions first.

This appliance conforms to the following standards:

ASTM E1112 Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature,

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,

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 and complies with the requirements of IEC 60601-1-2(EMC), AAMI/ANSI ES60601-1(Safety) standards. And the manufacturer is ISO 13485 certified.

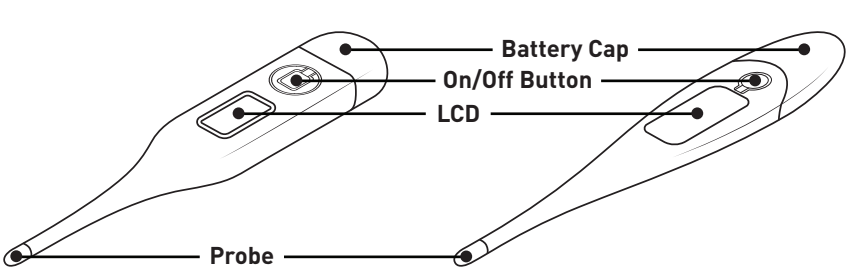
CONTENTS

MFR #s 16-412GM-00, 16-413BGM-00, 16-413RGM-00, 16-413BGM, 16-413RGM, 16-415GMHT, and 16-415GMST come with 1 thermometer, 1 owner's manual, 1 storage case, and 5 probe sheaths.

MFR #s 16-413BKGM and 16-413RKGM come with 1 thermometer, 1 owner's manual, 1 storage case, and 20 probe sheaths.

PRODUCT ILLUSTRATION

16-412GM-00, 413 SERIES **415 SERIES**



PRECAUTION

*The performance of the device may be degraded should one or more of the following occur:

- Operation outside the manufacturer's stated temperature and humidity range.
- Storage outside the manufacturer's stated temperature and humidity range.
- Mechanical shock (for example, drop test) or degraded sensor.
- Patient temperature is below ambient temperature.

*Portable and mobile RF communications can affect the device. The device needs special pre-cautions regarding EMC according to the EMC information provided in the accompany documents.

*Do not use the devices in the MR environment.

SYMBOL EXPLANATION

⎓	Direct Current
	Type BF Applied Part
	Consult accompanying documents
LOT	Batch code
MFD	Manufacture date

SPECIFICATIONS

Type	Digital Thermometer (Not predictive)
Measure range	90.0ºF-109.9ºF (32.0ºC-42.9ºC)(ºC/ºF chosen by manufacturer)
Accuracy	±0.2ºF (±0.1ºC) during 95.9ºF~107.6ºF (35.5ºC~42.0ºC) at 64.4ºF~82.4ºF (18ºC~28ºC) ambient operating range ±0.4ºF (±0.2ºC) for other measuring and ambient operating range
Operating mode	Direct Mode
Display	Liquid crystal display, 3½ digits
Memory	For storing the last measured value
Battery	One 1.5V DC button battery (size LR41 or SR41, UCC 392)
Battery life	Approximately 200 hours of continuous operation or 1 year with 3 measurements per day
Expected service life	Three years
Ambient operating range	Temperature: 41ºF~104ºF (5ºC~40ºC) Relative Humidity: 15%~95%RH Atmospheric Pressure: 700hPa~1060hPa
Storage and transportation condition	Temperature: -4ºF~131ºF (-20ºC~55ºC) Relative Humidity: 15%~95%RH Atmospheric Pressure: 700hPa~1060hPa
Ingress Protection Rating	MFR # 16-412GM-00: IPX0 All remaining MFR #'s: IP27
Classification	Type BF

ºF/ºC SWITCHABLE

Temperature readings are available in the Fahrenheit or Celsius scale (ºF/ºC; located in the upper right corner of LCD.) With the unit off, press and hold the On/Off Button for approximately 2 seconds to change the current setting.

DIRECTIONS

1. Press the On/Off Button next to LCD display. A tone will sound as the screen shows 188.8ºF, followed by last recorded temperature. After showing the self-test temperature, the thermometer is now in the testing mode.
2. Position thermometer in desired location (mouth, rectum, or armpit.)
   a) Oral Use: Place thermometer under tongue as indicated by"√" position shown in Figure 2. Close your mouth and breathe evenly through the nose to prevent the measurement from being influenced by inhaled/exhaled air. Normal temperature between 96.3ºF and 99.1ºF (35.7ºC and 37.3ºC).

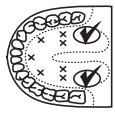


Figure 2

b) Rectal Use: Lubricate silver probe tip with petroleum jelly for easy insertion. Gently insert sensor approximately 1cm (less than 1/2 in) into rectum. Normal temperature between 97.2ºF and 99.9ºF (36.2ºC and 37.7ºC).

c) Armpit Use: Wipe armpit dry. Place probe in armpit and keep arm pressed firmly at side.

3. The degree sign flashes throughout the testing process. When flashing stops an alarm will beep for approximately 10 seconds. The measured reading will appear on the LCD simultaneously. The minimum measurement time until the signaling tone (beep) must be maintained without exception. The measurement continues even after the buzzer notification. So that in order to achieve better body temperature measurement result, recommend to keep the probe in mouth and rectum about 2 minutes, or in armpit about 5 minutes regardless of the beep sound and at least 30 seconds measurement interval should be maintained.

*Note: Normally the buzzes are "Beep-Beep-Beep-Beep-"; Alarm beeps more rapidly when temperature reaches 100ºF (37.8ºC) or higher, and the buzzes are"Beep-Beep-Beep-------Beep-Beep-Beep-------Beep-Beep-Beep"

4. To prolong battery life, press the On/Off Button to turn unit off after testing is complete. If no action is taken, the unit will automatically shut off after around 10 minutes.

Error Message	Problem	Solution
Lo	Temperature taken is lower than 90.0ºF (32.0ºC)	Turn off, wait one minute and take a new temperature via close contact and sufficient rest.
Hi	Temperature taken is higher than 109.9ºF (42.9ºC)	Turn off, wait one minute and take a new temperature via close contact and sufficient rest.
Err	The system is not functioning properly	Unload the battery, wait for 1 minute and repower it. If the message reappears, contact the retailer for service.
	Dead battery: Battery icon is flashing, can't be measurable	Replace the battery.

BATTERY REPLACEMENT

1. Replace battery when " " appears in the lower right corner of LCD display.
2. Pull battery cover off as shown in Figure 3.
3. Gently pull out plastic circuit board with battery chamber approximately 1 cm (slightly less than1/2 in.) (See Figure 4)
4. Use pointed object such as a pen to remove old battery. Discard battery lawfully. Replace with new 1.5V DC button type LR41 or SR41,UCC392, or equivalent. Be sure battery is installed with "+" polarity facing up. (See Figure 5)
5. Slide battery chamber back into place and attach cover.

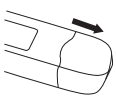


Figure 3

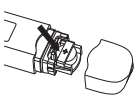


Figure 4

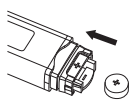


Figure 5

CLEANING AND DISINFECTION

Wipe the thermometer with a soft clean cloth.

For stubborn stains, wipe the thermometer with a cloth that has been dampened with water or a neutral detergent solution and then wring thoroughly. Finish by wiping with a soft dry cloth. For disinfection, 75% Ethanol or Isopropyl alcohol can be used.

Observe the following to prevent damage to the thermometer.

- Do not use benzene, thinner, gasoline or other strong solvents to clean the thermometer.
- Do not attempt to disinfect the sensing section (tip) of the thermometer by immersing in alcohol or in hot water (water over 122ºF (50ºC)).
- Do not use ultrasonic washing to clean the thermometer.

CALIBRATION

The thermometer is initially calibrated at the time of manufacture. If the thermometer is used according to the use instruction, periodic readjustment is not required. However, we recommend checking calibration every two years or whenever clinical accuracy of the thermometer is in question. Turn on the thermometer and insert into the water bath and then check the laboratory accuracy. Please send the complete device to the dealers or manufacturer. ASTM laboratory accuracy requirements in the display range of 98.6 to 102.2°F (37.0 to 39.0°C) for electronic thermometers is ±0.2°F(±0.1°C).

The above recommendations do not supersede the legal requirements. The user must always comply with legal requirements for the control of the measurement, functionality, and accuracy of the device which are required by the scope of relevant laws, directives or ordinances where the device is used.

FCC INFORMATION

Caution: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user 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. 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 and correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to 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.

Disposal of this product and used batteries should be carried out in accordance with the national regulations for the disposal of electronic products.

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Questions? Call 1-800-777-4908

Satisfaction Guaranteed

If you are not completely satisfied with any McKesson Brands product, you may return it for a full refund or credit.

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