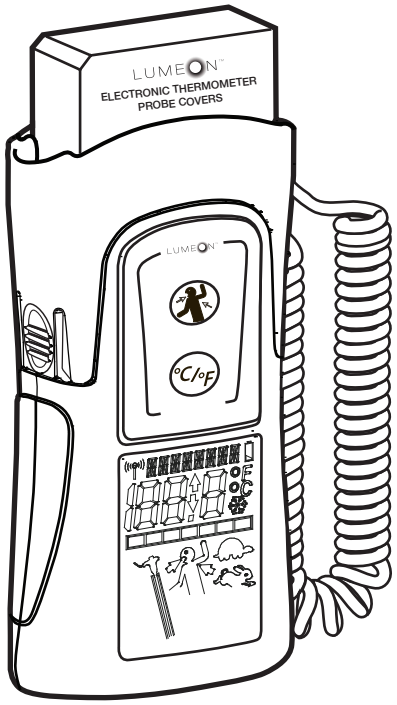
LUMEON™

ELECTRONIC THERMOMETER W/PROBE

OPERATION MANUAL

FOR USE WITH REORDER #S 3073 & 3074



Comments or Questions about Lumeon Products? 800-777-4908
Manufactured for PSS World Medical, Inc.
4345 Southpoint Blvd., Jacksonville, FL 32216
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Section I — Body Temperature Information

It is a common myth that 98.6°F (37°C) is the "normal body temperature." The truth is that 98.6°F (37°C) is an average body temperature. Normal body temperature is actually a range that varies with age, gender, and measurement site. Body temperatures also fluctuate through out the day, typically cooler temperatures in the morning, warmer in the afternoon, and cooling down again in the evening. Other factors that can influence body temperature are: the patient's recent level of activity, metabolism rate or medications. Normal body temperatures also tend to decrease with age.

Please see the chart below for normal temperature ranges by patient age and site. Readings from different body sites, even when taken at the same time, should not be directly compared; body temperatures will vary by site.

Site	Normal Body Temperatures by Patients Age			
	0-2 Years	3-10 Years	11-65 Years	>65 Years
Ear	97.5°- 100.4°F 36.4°- 38°C	97.0°- 100.0°F 36.1°- 37.8°C	96.6° - 99.7°F 35.9°- 37.6°C	96.4° - 99.5°F 35.8°- 37.5°C
Oral	- -	95.9° - 99.5°F 35.5°- 37.5°C	97.6° - 99.6°F 36.4°- 37.6°C	96.4° - 98.5°F 35.8°- 36.9°C
Core	97.5° - 100.0°F 36.4°- 37.8°C	97.5° - 100.0°F 36.4°- 37.8°C	98.2° - 100.2°F 36.8°- 37.9°C	96.6° - 98.8°F 35.9°- 37.1°C
Rectal	97.9° - 100.4°F 36.6°- 38°C	97.9°- 100.4°F 36.6°- 38°C	98.6° - 100.6°F 37°- 38.1°C	97.1° - 99.2° 36.2°- 37.3°C
Axillary	94.5° - 99.1°F 34.7°- 37.3°C	96.6° - 98.0°F 35.9°- 36.7°C	95.3° - 98.4°F 35.2°- 36.9°C	96.0° - 97.4°F 35.6°- 36.3°C

References:

Chamberlain, J, Terndrup, T., et al. (1995) Determination of Normal Ear Temperature with an Infrared Emission Detection Thermometer. Annals of Emergency Medicine, Volume 25, Issue 1, Pages 15-20

Braim. S., Preston, P., and Smith, R. (1988) Getting a better read on thermometry. RN. 1998 Mar; 61(3):57-60

Munk, P, Woods, S, Leduc, D., et al Canadian Paediatric Society Statement; Temperature Measurement in Paediatrics; Paediatric Child Health Vol 5 No 5: July/August, 2000

Brunner, L. and Suddarth, Dl, et.al. (1982) The Lippincott Manual of Nursing Practice, Third Edition; J. B. Lippincott Company, Philadelphia, PA; 1982; p.1145

Houdas, Y. and Ring, E. F. J.. Human Body Temperature, Its Measurement and Regulation; Plenum Press, NY, 1982; p.81-87.

Section II — General Information

1. The Lumeon™ electronic thermometer is a fast, highly accurate and an easy to use clinical instrument for measuring patient temperatures by oral, axillary or rectal means.
2. The electromagnetic compatibility of this device has been verified by test according to the EN60601-1-2:2005 requirements.
3. This device requires no user maintenance other than periodic cleaning and replacement of expired batteries.

Features

- Fast temperature measurements.
- Measurement range: 30°C to 43°C (86°F to 109°F)
- Push button alternates Celsius/Fahrenheit scale.
- Audible indication of completion ("beep" sound).
- Interchangeable, color-coded isolation chambers with matching probes helps keep probe covers and probes together for aiding in infection control (blue: oral/axillary; red: rectal).
- Easily wiped clean.
- Uses four standard disposable "AA" batteries.

- “Auto-On” when probe is withdrawn from the probe well.
- “Auto-Off” conserves battery life.
- Low battery and dead battery indicators.
- Last temperature recall.
- Easily accessible probe cover box.
- Easy to read LCD display with backlight.
- Optional direct mode lock.

Section III — Safety and Warnings

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

1. Read this booklet thoroughly before using the Lumeon™ Electronic Thermometer w/Probe.
2. Do not use this device near flammable anesthetics. Not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
3. Do not use this thermometer without first installing a new Lumeon™ Electronic Thermometer Probe Cover.
4. Use only Lumeon™ Electronic Thermometer Probe Covers with this device. Use of any other probe cover will result in erroneous temperature readings.
5. The device and probe covers are non-sterile. Do not use on abraded tissue.
6. To limit cross contamination, use blue devices for oral and axillary temperature taking only.
7. Use red devices only for rectal temperatures.
8. Thoroughly dry all electrical contacts on both probe and thermometer after washing, or device may fail to function properly.
9. For re-calibration, service or integrity checks, refer to a qualified biomedical technician or return to manufacturer.
10. Do not open unit. No user-serviceable parts inside. Opening of device may affect calibration and voids warranty.
11. Disposal of used probe covers must be performed in accordance with current medical practices or local regulations regarding disposal of infectious, biological medical waste.
12. Removal of the batteries is recommended if the unit is not going to be used for an extended period of time.
13. Dispose of batteries in a manner consistent with local environmental and institutional policy for Lithium or Alkaline battery disposal.
14. Dispose of old battery-powered electronic equipment in a manner consistent with institutional policy for expired equipment disposal.
15. Cleaning frequency and practices must be consistent with institutional policy for cleaning of non-sterile devices.
16. Device to be used by trained personnel.

NOTE:

Even though this device has been designed to minimize the effects of electromagnetic interference, it does generate radio frequency energy. If not used in accordance with the instructions, the device could cause interference in other equipment operating within its vicinity. If the device is causing interference, the following actions may be taken in an attempt to correct the interference:

- Re-orient or re-locate the receiving device.
- Increase the separation between the devices.
- Consult a customer service representative.

Section IV — Icon Identification

Type BF Equipment
Degree of protection against electrical shock – no conductive connection to the patient.

Date of Manufacture

Dispose of as Electrical and Electronic Waste.

See Accompanying Documents

Manufacturer Serial Number

Direct Mode
Non-predictive temperature measurement mode.

Oral Temperature Mode
Works only with blue probe and isolation chamber.

Axillary Temperature Mode
Works only with blue probe and isolation chamber.

Rectal Temperature Mode
Works only with red probe and isolation chamber.

Install/Remove Probe Cover
Flashing probe cover reminder to install probe cover prior to use and remove cover after use.

Out of Range - High
Temperature measurement is above 109°F (43°C).

Out of Range - Low
Temperature measurement is below 86°F (30°C).

Low Battery
Battery voltage is low. Replace batteries as soon as possible.

Dead Battery
Unit will not operate until new batteries are installed.

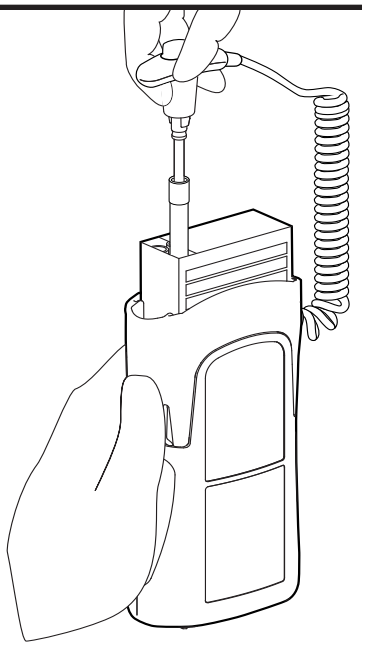
Progress Bar
Temperature measurement status indication.

°C/°F Button
Use to change temperature scale.

Site Button
Use to change measurement location.

Medical Electrical Equipment Infrared Tympanic Electronic Thermometer
(1) Classified with respect to electical shock, fire and mechanical hazards in accordance with UL60601-1
(2) Classified with respect to electrical shock, fire, mechanical and other specified hazards in accordance with CAN/CSA C22.2 No. 601.1

Section V — Instructions For Use

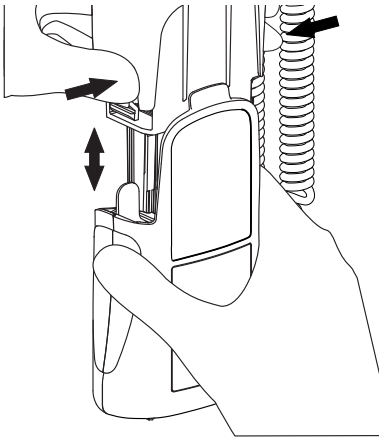


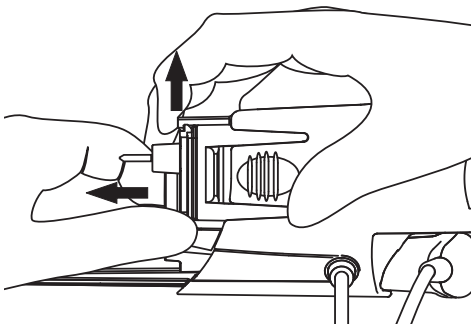
Applying & Removing Probe Covers

1. Open probe cover box by lifting tab at top corner and pulling to remove top panel.
2. Insert box of probe covers into top of isolation chamber. (To aid infection control, never switch boxes between blue and red isolation chambers. Also, never switch probes between blue and red isolation chambers. Keep like colors together.)
3. Remove probe from the probe well. This automatically turns on the thermometer.
4. To help remind the user to apply or remove a probe cover, a probe icon with flashing probe cover will be displayed when the probe is withdrawn from the probe well and following a completed temperature measurement.
5. Insert the probe end into a cover in the box. Push the handle firmly until you feel the cover “snap” into place.
6. Take appropriate temperature measurement (oral, axillary or rectal).
7. Eject the used cover into bio-waste container by pressing top button.
8. Remove, discard and replace box when empty.

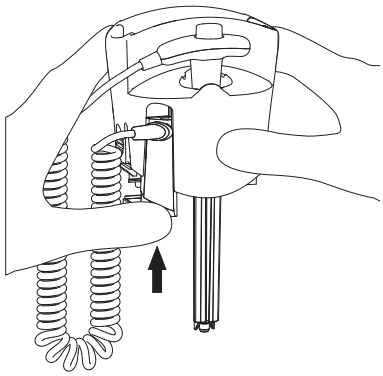
Changing Isolation Chambers and Probes

1. For aiding in infection control, use only the blue probe and blue isolation chamber for oral and axillary temperature taking. The red probe and red isolation chamber must only be used for rectal temperature taking.
2. Do not attach a red probe to a blue isolation chamber or vice-versa.
3. To remove or replace any isolation chamber/probe assembly, grasp the isolation chamber from each side as shown.
4. Squeeze inward releasing the snaps and slide the isolation chamber up to pull off.
5. To replace, align probe well finger with opening in the top of the unit.
6. Slide the isolation chamber down until the side snaps “click” into place.

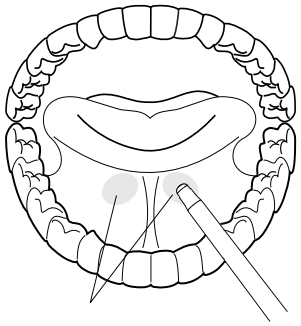




7. The probe is connected to the thermometer automatically.
8. To change probes, remove the isolation chamber as described previously.
9. Grasp the sides of the L-shaped connector piece with one hand and then using other hand pull backward on the latch holding the end of the L-shaped connector.
10. Once free of the latch, slide the L-shaped connector out of isolation chamber.
11. To replace, properly align the top of the L-shaped connector to the slot on the back of the isolation chamber.
12. Then slide the connector up into the slot pressing firmly on the bottom of the connector until it “clicks” into place.



Oral & Axillary Temperature Taking

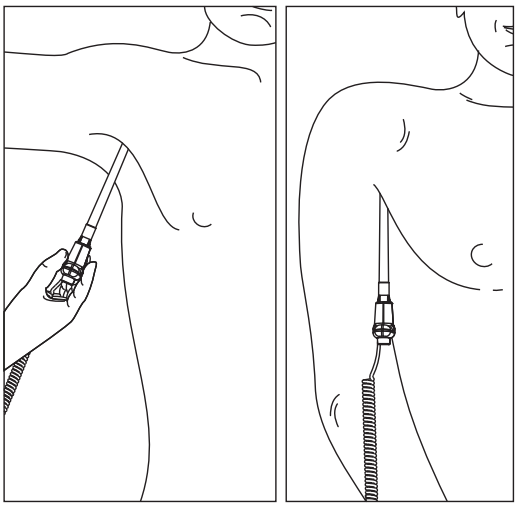


Heat Pockets

1. Make certain that the blue isolation chamber/probe unit is attached.
2. Withdraw probe and apply a probe cover. The thermometer turns on automatically.
3. An icon identifying oral or axillary mode is displayed. The rectal icon can not be displayed when a blue isolation chamber/probe is attached.
4. Press the site button on the front panel to select either the oral or axillary mode.
5. For oral temperatures, insert the probe tip deep into the sublingual pocket next to the frenulum linguae, (vertical fold of tissue in middle of tongue), on one side or the other, toward the back of the mouth.

   Note: Accurate body temperature readings can only be obtained in one of these two “heat pocket” locations as shown. Temperatures taken in other mouth locations will result in inaccurate body temperature readings.

6. Patient’s mouth must be closed.
7. Securely hold the probe in place until the temperature is displayed.*
8. For axillary temperatures, have the patient raise the arm, then place the probe tip in the axilla. Press gently to assure good contact. For the most accurate temperature the probe tip should be placed directly against the patient's skin.
9. Have the patient then lower the arm and remain as still as possible. Hold the probe parallel to the arm as shown.*
10. If two short beeps are heard, it means the unit switched to direct (slow) mode for this temperature only.
11. A “long beep” is sounded when measurement is complete and the final temperature is displayed.
12. To change between Celsius and Fahrenheit scales, press the °C/°F button. Press again as needed.
13. Eject the used cover into a bio-waste container by pushing top button.
14. After returning the probe to the probe well, the temperature is stored for recall until the probe is once again withdrawn. If the probe is returned to the probe well before the “long beep” is heard, no temperature will be stored for the recall function.



Rectal Temperature Taking

1. Make certain that the red isolation chamber/probe unit is attached.
2. Withdraw the probe and apply a probe cover. Thermometer turns on automatically.
3. An icon identifying rectal mode is always displayed provided the red isolation chamber/probe assembly is attached. Pressing the site button on the front panel to change modes has no effect.
4. Apply lubrication if desired.
5. Insert the probe into the patient’s rectum. To ensure proper tissue contact, angle the probe slightly after insertion.*
6. Depth of insertion is recommended at 1/2” to 3/4” (12 mm - 19 mm) for adults and 1/4” to 1/2” (6 mm - 13 mm) for children.
7. If two short beeps are heard, it means the unit switched to direct (slow) mode for this temperature only.
8. A “long beep” is sounded when measurement is complete and the final temperature is displayed.
9. To change between Celsius and Fahrenheit scales, press the °C/°F button. Press again as needed.
10. Eject the used cover into a bio-waste container by pushing top button.
11. After returning the probe to the probe well, the temperature is stored for recall until the probe is once again withdrawn. If the probe is returned to the probe well before the “long beep” is heard, no temperature will be stored for the recall function.

*Probe movement during a measurement can affect the thermometer's ability to accurately measure the site temperature and may lengthen the time required to obtain a reading.

Direct Mode

1. The Lumeon™ Electronic Thermometer w/Probe normally operates in predictive mode for accurate temperature measuring. In certain cases, such as with a hypothermic patient, the thermometer will automatically shift to direct (slow) mode and will then act as a temperature monitor.
2. The Lumeon™ Electronic Thermometer w/Probe can be set to operate exclusively in direct mode (disable predictive mode). See the direct mode lock section for instructions on configuring the thermometer to operate exclusively in direct mode.
3. In direct mode the device may require up to 60 seconds to reach equilibrium and display patient temperature.
4. A turtle icon will be continuously displayed whenever the thermometer is functioning in direct mode.
5. To change between Celsius and Fahrenheit scales, press and release the °C/°F button. Press and release again as needed.
6. An up or down arrow will appear on the display whenever the current temperature reading is out of range, either high or low, respectively.
7. The direct mode auto feature is always functional regardless of red or blue isolation chamber/probe.
8. A “long beep” is sounded when measurement is complete and the final temperature is displayed.
9. After returning the probe to the probe well, the temperature is stored for recall until the probe is once again withdrawn. If the probe is returned to the probe well before the “long beep” is heard, no temperature will be stored for the recall function.

Direct Mode Lock

1. To configure the thermometer so it always operates in direct mode, press and hold the site and °C/°F buttons at the same time for 4 seconds. A long “beep” will be sounded. On the LCD, the turtle will flash and “ON” will be displayed for approximately 2 seconds before the unit turns off. (Note: The thermometer must be off before configuring direct mode lock.)
2. In this mode of operation, the turtle icon will be continuously displayed during use to indicate direct mode operation.
3. To exit direct mode lock and return to normal operation, again press and hold the site and °C/°F buttons at the same time for 4 seconds. A long “beep” will be sounded. On the LCD, the turtle will flash and “OFF” will be displayed for approximately 2 seconds then the unit will turn off.

Recall Last Temperature

1. After each temperature measurement, a “long beep” is heard. The “beep” indicates the temperature measurement has been completed and stored and is available for recall. This temperature can be recalled after the probe is returned to the probe well.
2. To recall the most recent temperature measurement, press and release °C/°F button on the front panel. The last measurement taken will appear for several seconds.
3. While the recalled measurement is displayed, the user may press and release the °C/°F button again to change between the Celsius and Fahrenheit scales.
4. Withdrawing the probe from the probe well erases last temperature memory.
5. If the most recent temperature measurement was incomplete or out of range, dashes will appear on the display during the recall operation.

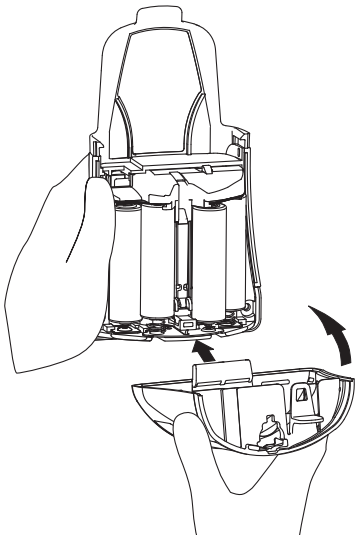
Section VI — Cleaning and Sterilization

1. The entire device may be easily wiped clean. Water temperature should not exceed 130°F (55°C). Do not submerge or soak under water.
2. A mild detergent may be added to water. Use of cleaners such as Spray Nine™*, Phisohex™*, Hibiclens™*, or Vesta-Syde™* Cidex™* may result in damage to the thermometer case.
3. Use of 10:1 water and hypochlorite mixture or a damp isopropyl alcohol wipe occasionally, is acceptable. Prolonged and repeated use of these chemicals may result in damage to the thermometer case and display area.
4. Use of a cloth or sponge is recommended for cleaning. Abrasive pads may result in damage to the thermometer case and display area.
5. This thermometer is provided non-sterile. Do not use ethylene oxide gas, heat, autoclave, or any other harsh methods to sterilize this unit.

6. Isolation chambers may be replaced inexpensively instead of cleaning.
7. After cleaning the unit, shake the probe handle to drain out any excess solution. Thoroughly dry the electrical contacts on both probe and thermometer.

Section VII — Battery Replacement / Installation

1. To access the batteries, remove the isolation chamber by depressing the tabs on the sides of the unit and slide off upwardly.
2. Pull back on the finger tab on the top of the battery door. The battery door should hinge open to expose the batteries.
3. The batteries may be removed by pressing firmly on the positive end (opposite the compressed spring) and lifting up.
4. Be certain to dispose of used batteries in a manner consistent with local environmental and institutional policy for lithium or alkaline battery disposal.
5. To install new batteries, place the negative end on the spring. Press down firmly to compress spring and tilt battery into place.
6. To replace the battery door, insert the tab on the bottom of the door into the slot on the bottom of the unit to create a hinge. Swing the top half of the door upwards pressing firmly on the top of the door until the small tab on the main unit “clicks” into the catch on the battery door.
7. Reinstall isolation chamber with probe attached.



Section VIII — Troubleshooting

1. If device fails to function properly after washing & reconnecting probe, rinse all contacts in de-ionized water and blow dry.
2. Icons indicate all other possible errors and remedies.
3. Device Error Codes:
   - E01 - System error during synchronization
   - E02 - System error during patient thermistor calibration
   - E03 - System error during heater thermistor calibration
   - E04 - System timing error
   - E05 - Heater error
   - E06 - LCD communication error
   - E07 - Shut off error
   - P01 - Probe configuration (or no probe connected) error
   - P02 - Direct mode patient thermistor unstable or out of range
   - P03 - Direct mode heater thermistor unstable or out of range
   - P04 - Predict mode patient thermistor unstable or out of range
   - P05 - Predict mode heater thermistor unstable or out of range
   - P06 - Unable to pre-heat probe tip
4. No user-serviceable parts inside.
5. Refer to a factory or qualified biomedical technician for service.

Section IX — Specifications

Classified with respect to electrical shock, fire, and mechanical hazards only in accordance with UL60601-1.
Classified with respect to electrical shock, fire, and mechanical hazards only in accordance with CAN/CSA C22.2 NO.601.1.

Dimensions (Approximate, without Base):
3.2 w x 6.0 h x 2.1 d"; 84 w x 152 h x 56 d mm
Dimensions (Approximate, with Base):
4.1 w x 7.5 h x 3.1 d"; 105 w x 190 h x 79 d mm
Weight (Approximate, without base):
13.5 Ounces; 385 Grams

Temperature Measurement Range:
30°C to 43°C; (86°F to 109°F)

Normal Prediction Measurement Range:
35°C to 43°C (95°F to 109°F)

Ambient Operating Temperature Range:
10°C to 40°C; 50°F to 104°F at 10% - 95% RH, non-condensing.

Average Prediction Times (After Insertion into Measurement Site):
Oral (EZ model): 3-5 seconds (non-fever temps), 8-10 seconds (fever temps)
Oral (EZA model): 6-10 seconds
Axillary Mode: 8-12 seconds
Rectal Mode: 10-14 seconds
Direct Mode (All Sites): 60-120 seconds

Typical Times for Switch to Direct Mode:
If ambient temperature is greather than 35°C (95°F); Immediate.
If no measurement site detected: 60 seconds (after pulling probe from probe well).
If temperature does not stabilize: 70 seconds (after measurement site insertion).

Pulse Timer:
60 Second count with a “beep” at 15 seconds, 2 “beeps” at 30 seconds, 1 “beep” at 45 seconds and 2 “beeps” at 60 seconds.

Water Bath Accuracy (35.5°C to 42.0°C):
Direct Mode (All Sites): ±0.1°C (±0.1°F)
Standard Prediction Mode (All Sites)**: ±0.1°C (±0.1°F)
Quick Prediction Mode (EZ model- Oral Only)**: ±0.3°C (±0.3°F)

**Greater than 95% of the prediction mode readings will be within the specified accuracy

Patient Accuracy:
In standard predict mode, thermometer accuracy meets EN 12470-3. A standard prediction mode reading and a direct mode reading will differ by less than ±0.2°C (±0.4°F) on 98% of tested patients

Batteries:
Four “AA” batteries required. Standard IEC package size. Alkaline 1.5 Volt. Approximately 6000 temperature readings

Probe:
Replaceable. For probe integrity/safety checks, refer to qualified Biomedical Technician or return to PSS World Medical

Isolation Chamber:
Removable, replaceable, washable, Polycarbonate-polyester blend

Device Materials:
Thermometer Case: Flame retardant polycarbonate-polyester blend
Isolation Chamber: Flame retardant polycarbonate-polyester blend
Probe Handle: Flame retardant polycarbonate-polyester blend
Probe Shaft: Flame retardant polyester
Probe Cable: Polyurethane jacket with TPE over mold
Tip: Aluminum

Type of Protection Against Electrical Shock:
Internally Powered Equipment.

Degree of Protection Against Electrical Shock:
Type BF

Mode of Operation:
Continuous use, hand held use.

Degree of Safety of Application in the Presence:
Not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.

Transport and Storage:
Not to exceed 30 days. Transport and store this device between temperatures of -25°C to 55°C (-13°F to131°F).
Relative humidity range should be between 10%-95% RH, non-condensing. Return unit to the factory if the device is dropped and performance appears degraded, or in the event that the environmental conditions for transport, storage and operation are exceeded.

Regulatory and Safety Standards:
The Lumeon™ Electronic Thermometer w/Probe is in compliance with the following international standards:

- UL60601-1
- EN60601-1:2005
- EN 12470-3:2000
- BS EN980:1997
- CAN/CSA C22.2 No. 601-1
- EN60601-1-2:2005
- MDD 93/42/EEC
- ASTM E 1112: 2006

Section X — Customer Service

The circuitry of the Lumeon™ Electronic Thermometer w/Probe is not customer serviceable. In particular, electronic assembly re-work will likely affect accuracy.
All service personnel must be properly trained, qualified and familiar with operation of the thermometer. Improper service may impair proper operation of the thermometer
Probe accuracy can be checked in any mode using a calibrated water bath.
The thermometer should provide direct mode accuracy to within ±0.1°C of the calibrated water bath temperature.
The thermometer should have a standard predict mode accuracy within ±0.1°C of the calibrated water bath temperature.
The thermometer should have a quick predict mode accuracy within ±0.3°C of the calibrated water bath temperature.
The probe cable connector is designed to exceed 1,000 insertions. Do not lubricate or solvent clean. Replace the probe if the connector is thought to be faulty.

In the event that it becomes necessary to return a unit for service, please contact PSS World Medical customer information desk at **800-777-4908.**

Parts Listing
To order parts, contact our customer service center or your sales representative for the parts listed below.

Part Description	Order Number
Electronic Thermometer Probe Covers	3072

Note: Use of any other brand or style probe cover will result in erroneous temperature readings.

Rectal Electronic Thermometer w/Probe.....3073
Includes electronic thermometer with red rectal isolation chamber and red rectal probe with 4-foot (1.2m) cord and operation manual CD.

Oral/Axillary Electronic Thermometer w/Probe.....3074
Includes electronic thermometer with blue oral/axillary isolation chamber and blue oral/axillary probe with 4-foot (1.2m) cord and operation manual CD.

Section XI — Warranty

LIMITED WARRANTY: Your Lumeon™ electronic thermometer is manufactured exclusively for PSS World Medical by Kendall, a Tyco Healthcare Group LP company. Kendall warrants to the original purchaser ("Customer") that this product will be free of defects in materials and workmanship, under normal use, for one (1) year from the date of original purchase from PSS World Medical. If this product does not operate as warranted above during the applicable warranty period, Kendall may, at its option and expense, replace the defective part or product with a comparable part or product, repair the defective part or product, or, if neither replacement nor repair is reasonably available, refund to Customer the purchase price for the defective part or product. Dated proof of original purchase will be required.

Comments or Questions about Lumeon™ Products? 800-777-4908
Manufactured for PSS World Medical, Inc.
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Made in the USA • www.myselectonline.com

For Use with Reorder#s 3073 & 3074

One or more U.S. Patents (when used with a thermometer probe cover 6,619,837); 6,634,789, 6,839,651; 7,316,507; 7,494,274; 7,549,792; D532,710; D535,202; D548,626; D554,008

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