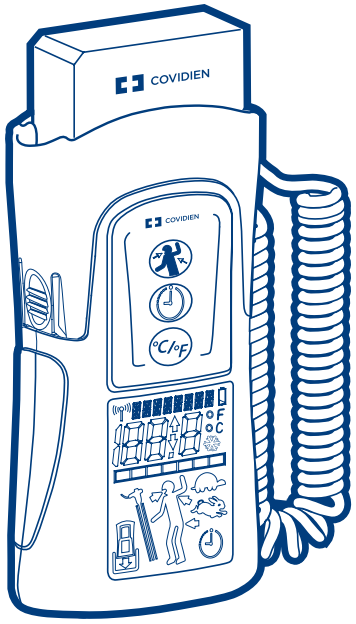
COVIDIEN™

Operating Manual

Filac™

3000 AD/ADA Electronic Thermometer



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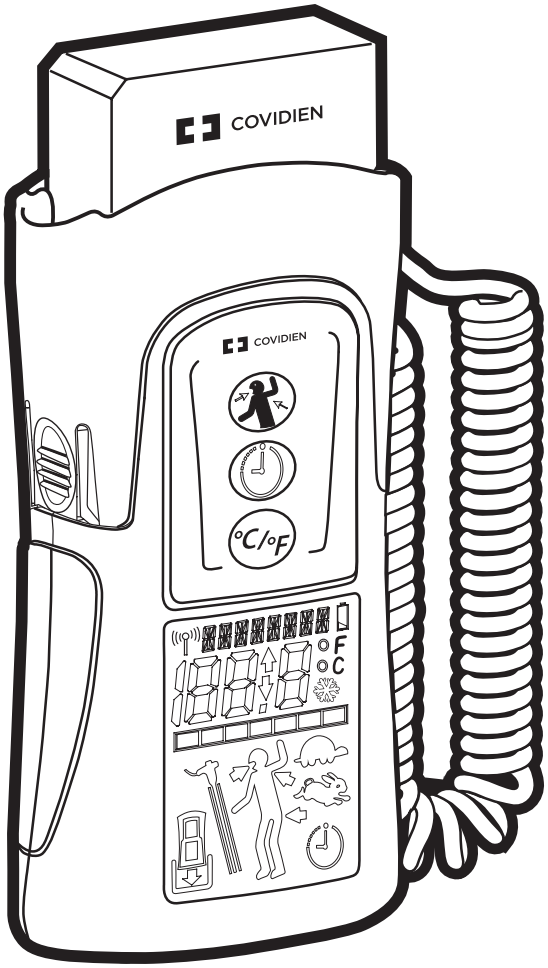

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I. About Body Temperature

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.

Temperature Site	Normal Body Temperatures by Patients Age			
	0-2 Years	3-10 Years	11-65 Years	> 65 Years
Ear	97.5°- 100.4°F 36.3°- 38.0°C	97.0°- 100.0°F 36.1°- 37.7°C	96.6° - 99.7°F 35.8°- 37.6°C	96.4° - 99.5°F 35.7°- 37.5°C
Oral	- -	95.9° - 99.5°F 35.3°- 37.5°C	97.6° - 99.6°F 36.7°- 37.8°C	96.4° - 98.5°F 35.7°- 36.9°C
Core	97.5° - 100.0°F 36.3°- 37.7°C	97.5° - 100.0°F 36.3°- 37.7°C	98.2° - 100.2°F 36.7°- 37.8°C	96.6° - 98.8°F 35.8°- 37.1°C
Rectal	97.9° - 100.4°F 36.6°- 38.0°C	97.9°- 100.4°F 36.5°- 38.0°C	98.6° - 100.6°F 37.0°- 38.1°C	97.1° - 99.2° 36.1°- 37.3°C
Axillary	94.5° - 99.1°F 34.7°- 37.2°C	96.6° - 98.0°F 35.8°- 36.6°C	95.3° - 98.4°F 35.1°- 36.8°C	96.0° - 97.4°F 35.5°- 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

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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.

II. General Information

1. The Filac 3000 AD/ADA Electronic Thermometer is a fast, highly accurate, and 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 EN60601-1-2:2001 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
- 15, 30, 45 and 60 second pulse Timer
- Easily accessible probe cover box
- Easy to read LCD display with backlight
- Cold Mode – lower pre-heat temperature option provides quicker, accurate readings for post-OR patients
- Theft prevention lock out and anti-theft accessories

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 Filac 3000 AD/ADA Electronic Thermometer.
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, or in an oxygen rich environment.
3. Do not use this thermometer without first installing a new Filac 3000 AD/ADA Electronic Thermometer probe cover.
4. Use only Filac 3000 AD/ADA 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. **Warning:** No modification of this equipment is allowed. 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. Do not use lithium batteries with this device.
13. Do not mix alkaline and rechargeable batteries.
14. Removal of the batteries is recommended if the unit is not going to be used for an extended period of time.
15. Dispose of batteries in a manner consistent with local environmental and institutional policy for Alkaline battery disposal.
16. Dispose of old battery-powered electronic equipment in a manner consistent with institutional policy for expired equipment disposal.
17. Cleaning frequency and practices must be consistent with institutional policy for cleaning of non-sterile devices.
18. Device to be used by trained personnel.

Note:

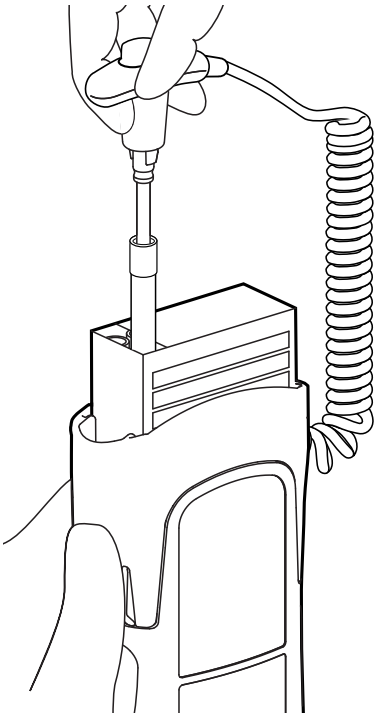
Even though this device has been designed to minimize the effects of electromagnetic interference, it does generate radio frequency energy. If not used in accordance with the instructions, the device could cause interference in other equipment operating within its vicinity. If the device is causing interference,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

IV. Icon Identification

ORAL Temperature Mode Works only with BLUE probe and isolation chamber	**Low Battery** Battery voltage is low – replace batteries as soon as possible	**Follow instructions for use -** This manual must be read prior to use of the thermometer (Symbol appears blue on device)
AXILLARY Temperature Mode Works only with BLUE probe and isolation chamber	**Dead Battery** Unit will not operate until new batteries are installed	95% 10% **Humidity limitations**
RECTAL Temperature Mode Works only with RED probe and isolation chamber	**Progress Bar** Temperature measurement status indication	131°F 55°C -13°F -25°C **Temperature limitations**
Site Button Use to change measurement location	**Return to Base** Return unit to Anti-theft base to clear anti-theft lock out feature	**Keep away from sunlight**
°C/°F Button Use to change temperature scale	**Out of Range - High** Temperature measurement is above 109°F (43°C)	**Keep dry**
Pulse Timer Button Use to start and stop pulse timer	**Out of Range - Low** Temperature measurement is below 86°F (30°C)	**EN 50419** Dispose of as Electrical and Electronic waste
Pulse Timer 15 or 30 second timer	NON STERILE **Non-Sterile**	**Type BF Equipment** Degree of protection against electrical shock – no conductive connection to the patient
Quick Mode Fast predictive measurement mode – displays temperature measurement in 3.5 seconds	LATEX **Latex-free**	**Non-ionizing electromagnetic radiation**
Cold Mode Post-operative mode. Pre-heat temperature of 91°F (33°C)	**Single use**	TÜV SÜD NRTL C US **Medical Electrical Equipment**
Direct Mode Non-predictive temperature measurement mode	Rx ONLY **By prescription only**	CE 0123 **CE mark**
Install/Remove Probe Cover Flashing probe cover reminder to install probe cover prior to use and remove cover after use	DEHP **DEHP-free**	SN **Manufacturer Serial Number**
EC REP **Authorized representative in the European Community**	**Manufacturer**	**Date of Manufacture**

V. Instructions For Use

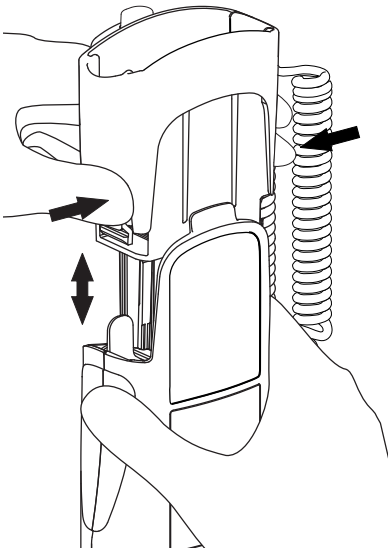


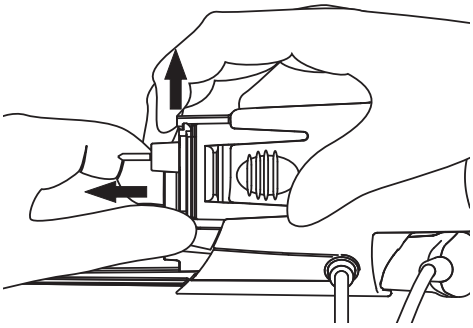
Probe Covers — Applying & Removing

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

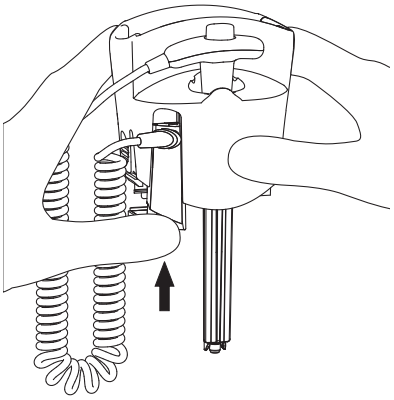
Changing Isolation Chambers and Probes

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.

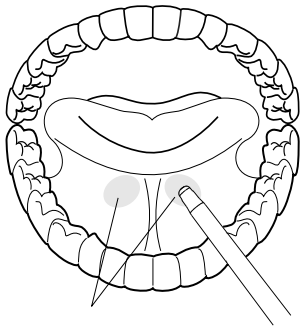




9. Grasp the sides of the L-shaped connector piece with one hand and then using other hand pull backward on the latch holding the end of the L-shaped connector.
10. Once free of the latch, slide the L-shaped connector out of isolation chamber.
11. To replace, properly align the top of the L-shaped connector 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

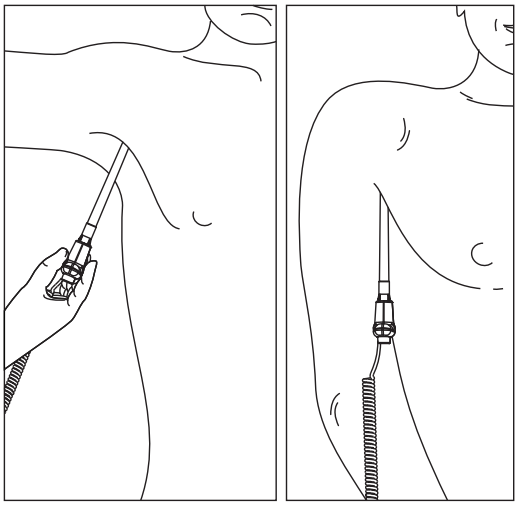


Heat Pockets

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 patients 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. If desired, apply medical grade lubricant as per institutional protocol.
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 Filac 3000 AD/ADA Electronic Thermometer 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 Filac 3000 AD/ADA Electronic Thermometer can be set to operate exclusively in Direct mode (disable Predictive mode). See instructions within the Bio-Tech Mode section for information on how to lock Direct mode on.
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.

Quick Mode (Oral Only)

1. Quick Mode is provided for more rapid, time consistent, oral temperature predictions. This mode is indicated by a rabbit icon on the display. In this mode, a temperature measurement prediction is provided in approximately 3.5-4 seconds.
2. See instructions within the Bio-Tech Mode section to turn this feature On or Off.
3. Quick Mode is not available with Axillary or Rectal Body Sites, with Cold Mode, or when in Direct Mode.

Cold Mode

1. Cold Mode is provided for use in applications where body temperatures may be lower than normal, such as for patients recently out of surgery.
2. See instructions within the Bio-Tech Mode section to turn this feature On or Off.
3. When selected, as indicated by the snowflake on the display, the probe preheats to 91°F (33°C). All other functions are unchanged.
4. Cold Mode is not available with Quick Mode or when in Direct Mode.

Recall Last Temperature

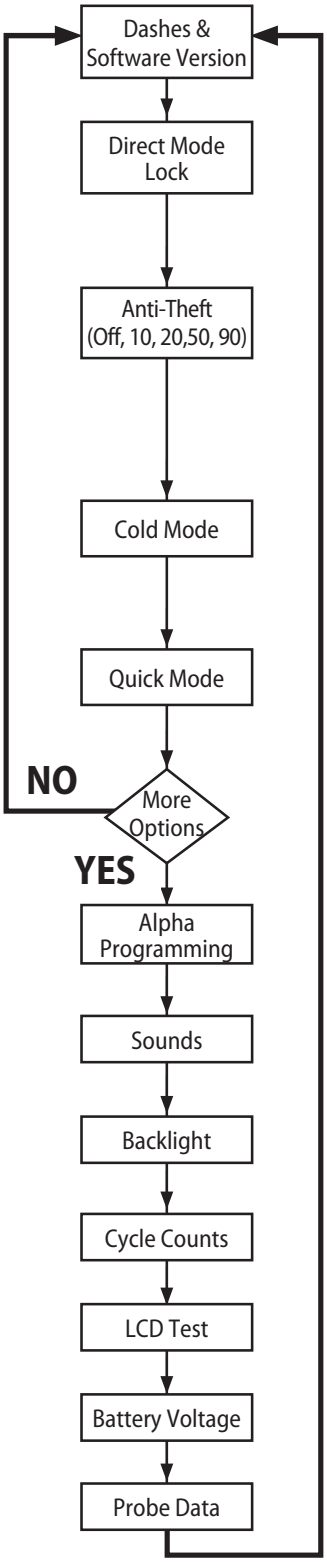
1. After each temperature measurement, a "long beep" is heard. The "beep" indicates the temperature measurement has been completed and stored and is available for recall. This temperature can be recalled after the probe is returned to the probe well.
2. To recall the most recent temperature measurement, 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.

Pulse Timer Mode

1. The Filac 3000 AD/ADA Electronic Thermometer may also be used to help measure a patient's pulse rate.
2. To access, do not remove probe from the probe well.
3. Press and release the Timer button on the front panel. The Clock icon and 0.0 will be displayed.
4. Press and release the Timer button a second time to start the timer and elapsed time display.
5. A "beep" is sounded at 15 seconds, 2 beeps at 30 seconds, 1 beep at 45 seconds and 2 beeps at 60 seconds. The count stops at 60 seconds.
   Pressing the Timer button again will shut the unit off.
6. The Timer mode will turn off automatically, 5 seconds after stopping at 30 or whenever the probe is removed from the probe well.

Bio-Tech Mode (Option Configuration Menu)

1. To enter Bio-Tech mode, the thermometer must be in sleep mode (probe securely in place with blank screen).
2. Press and hold the Site and °C/°F buttons at the same time for 4 seconds. A "beep" is heard and a dash scrolls in the display. The software version of the device will be shown in the alpha-numeric section of the display
3. The thermometer is now in Bio-Tech mode. To navigate the Bio-Tech mode menu, follow the chart below.
4. The Pulse Timer button is used to move forward through the different configuration options. °C/°F button is used to change an option configuration.
5. To exit Bio-Tech mode and resume normal operation, press the Site and °C/°F buttons at the same time and hold for 1 full second. Last settings are saved.
6. Bio-Tech mode also exits automatically after 20 seconds of inactivity. The last settings are saved.



What You See or Hear	Option Configuration
X, YZ with moving dash	No Function
DIR with Blinking	☒ ON ☐ OFF
THEFT with Blinking	(blank) ☐ OFF 10 ☒ ON 20 ☒ ON 50 ☒ ON 90 ☒ ON
COLD with Blinking	☒ ON ☐ OFF
FAST with Blinking	☒ ON ☐ OFF
MORE	☒ ON ☐ OFF
8 programmable characters, selected alpha-numeric characters blinking	Step to next character location*
BEEP with Beeper Beeping Continuously	☒ ON ☐ OFF
LIGHT with Backlight Blinking Continuously	☒ ON ☐ OFF
°C/°F CFLOCK button toggles between °C and °F	☒ ON ☐ OFF
LCD Test	Start test••
A. BC V	No Function
PROBE SN	View Serial Number

* The Pulse Timer button is used to move forward through the different configuration options. Press the °C/°F button to step to next character location

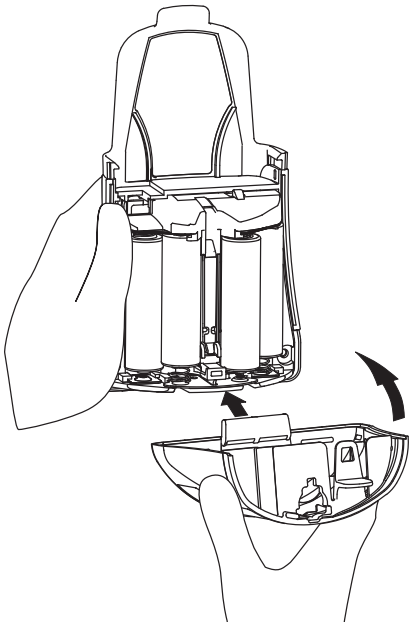
** Press the Site button to return to the initial LCD Test screen

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™*, Vesta-Syde™*, or Cidex™* may result in damage to the thermometer case.
3. Use of 10:1 water and hypoclorite 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.

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.



VIII. Mounting Instructions

1. To mount the Filac 3000 AD/ADA Electronic Thermometer onto any vertical surface, a convenient mounting base is provided.
2. For hollow wall mounting, locate a stud and use the 2 screws provided. If mounting between studs, substitute 2 standard hollow wall anchors.
3. Rolling stand mounting brackets and pole clamps are also available for this device.

IX. Anti-Theft Features & Options

1. The Filac 3000 AD/ADA Electronic Thermometer is equipped with an electronic system that deters casual theft by disabling the thermometer after a preset number of temperatures have been taken.
2. A Filac 3000 AD/ADA Electronic Thermometer Mounting Base is required in order for this option to function.
3. To reactivate the thermometer it must be momentarily returned to any Filac 3000 AD/ADA Electronic Thermometer Mounting Base when indicated by a displayed icon.
4. The anti-theft option is normally disabled as shipped from the factory.
5. Key-locking is also possible where a more positive anti-theft deterrent is desirable.

X. 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.

XI. Specifications

Medical Electrical Equipment
Filac 3000 AD/ADA Electronic Thermometer

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. 60601-1-08

Dimensions (Approximate, without base):	in.- 3.2 W x 6.0 H x 2.1 D ; mm - 84 W x 152 H x 56 D	
Dimensions (Approximate, with base):	in.- 4.1 W x 7.5 H x 3.1 D ; mm - 105 W x 190 H x 79 D	
Weight (Approximate, without base):	13.5 Ounces; 385 Grams	
Temperature Measurement Range:	30°C to 43°C; 86°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 (Quick Mode):	3-5 seconds (non-fever temps), 8-10 seconds (fever temps)
	Oral (Standard Mode):	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 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/95.9°F to 42.0°C/107.6°F):	Direct Mode:	+/-0.1°C - +/- 0.2°F
	Standard Prediction Mode**:	+/-0.1°C - +/- 0.2°F
	Quick Prediction Mode (Oral Only)**:	+/-0.3°C - +/- 0.5°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" 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 Covidien.

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

All materials are latex-free.

Type of Protection Against Electrical Shock: Internally Powered Equipment. 4 AA Batteries.

Degree of Protection Against Electrical Shock: Type BF

Degree of Protection Against Ingress of Fluids: Not Protected-IPX0

Mode of Operation: Continuous Use . Intended for 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.

The Filac 3000 AD/ADA Electronic Thermometer is in compliance with the following International Regulatory and Safety standards:

UL60601-1	CAN/CSA C22.2 No. 60601-1-08	EN60601-1:2005
EN60601-1-2:2001	EN 12470-3:2000	MDD 93/42/EEC
EN980:2008	ASTM E 1112: 2006	

XII. Customer Service

The circuitry of the Filac 3000 AD/ADA Electronic Thermometer is not customer serviceable. In particular, electronic assembly re-work.

will likely affect accuracy. Certain replacement items such as probes and isolation chambers are available from the service centers listed below.

All service personnel must be properly trained, qualified and familiar with operation of the thermometer. Improper service may impair proper operation of the Filac 300 AD/ADA Electronic Thermometer.

A Filac 3000 AD/ADA Electronic Thermometer Calibration Plug (reorder number 500099) is available to check accuracy of the

Filac 3000 AD/ADA Electronic Thermometer. It replaces the regular probe and verifies the accuracy of the main unit electronics.

Replace the main unit if accuracy is deficient. Follow the instructions that accompany the Filac 3000 AD/ADA Electronic Thermometer Calibration plug.

Probe accuracy can be checked in any mode using a calibrated water bath.

A Filac 3000 AD/ADA Electronic Thermometer should provide direct mode accuracy to within ±0.1°C of the calibrated water bath temperature.

A Filac 3000 AD/ADA Electronic Thermometer should have a standard predict mode accuracy within ±0.1°C of the calibrated water bath temperature.

A Filac 3000 AD/ADA Electronic 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 follow these instructions:

1. Call the appropriate phone number listed below for an Authorized Return Number and shipping instructions.
2. Pack the instrument carefully and ship insured parcel to the appropriate location:

United States
Covidien
5920 Longbow Drive
Boulder, CO 80301,
USA
Phone: 1-800-448-0190

Canada
Covidien
7300 Trans Canadian Hwy
Pointe-Claire, QC H9R 1C7,
Canada
Phone: 1-877-664-8926

Outside US & Canada
Covidien
Unit 2 Talisman Business
Center, London Road
Bicester, OX266HR, UK
Phone: +44-1869-328065

Covidien llc (Italy)
Laboratorio
AssestenzaTecnica
Via Rivoltana 2/D
Segrate – MI,
Italy 20090
Phone: (0039) 0270308131

Covidien llc (Germany)
Service Centre
Raffineriestr. 18, GEB.II
Neustadt/Donau,
Germany 93333
Phone: (0049) 09445 959374

Covidien llc (Spain)
A/A Servicio Técnico
C/Fructuós Gelabert, 6, pl.
Sótano
Sant Joan Despi,
Barcelona, Spain 08970
Phone: (0034) 934758669

Covidien llc (France)
Parcd'affaires Technopolis
3 Avenue du Canada,
LP851-LES Ulis, Courtaboeuf,
France 91940
Phone: (0033) 0810787590

If not listed please contact Covidien Customer Service or representative for details of your nearest service center.

To Order/Reorder/Replace device components and accessories, specify one or more of the following Reorder Numbers:

Probe Covers	Case of 500	Reorder No. 500500
	Case of 2,000	Reorder No. 502000

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

Complete Oral /Axillary Thermometer

Includes electronic thermometer with Blue - Oral/Axillary isolation chamber and Blue - Oral/Axillary probe, with 4-foot (1.2 m) cord, and global manual on CD

Filac 3000 EZ	Reorder No. 504000
Filac 3000 EZA	Reorder No. 504003
Filac 3000 AD	Reorder No. 505000
Filac 3000 ADA	Reorder No. 505003

Complete Rectal Thermometer

Includes electronic thermometer with Red - Rectal isolation chamber and Red - Rectal probe, with 4-foot (1.2 m) cord, and global manual on CD

Filac 3000 EZ	Reorder No. 504005
Filac 3000 EZA	Reorder No. 504008
Filac 3000 AD	Reorder No. 505005
Filac 3000 ADA	Reorder No. 505008

Isolation Chamber

Blue - Oral/Axillary	Reorder No. 500028
Red - Rectal	Reorder No. 500038

Probe (with 4-foot standard cord)

Blue - Oral/Axillary	Reorder No. 500026
Red - Rectal	Reorder No. 500036

Probe (with 9-foot standard cord)

Blue - Oral/Axillary	Reorder No. 500027
Red - Rectal	Reorder No. 500037

Calibration Plug	Reorder No. 500099
Mounting Base for Wall	Reorder No. 500046
Mounting Base for Rolling Stand	Reorder No. 500047
Mounting Base with Pole Clamp	Reorder No. 500048
Rolling Stand	Reorder No. 303059
Rolling Stand Basket	Reorder No. 8884813711

XIII. Warranty

Limited Warranty: Covidien warrants to the original purchaser ("Customer") that this product will be free of defects in materials and workmanship, under normal use, for three (3) years from the date of original purchase from Covidien or its authorized distributor. If this product does not operate as warranted above during the applicable warranty period, Covidien 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.

Covidien does not assume any liability for loss arising from unauthorized repair, misuse, neglect, or accident. Removal, defacement, or alteration of serial lot number voids warranty. Covidien disclaims all other warranties, expressed or implied, including any implied warranty of merchantability or fitness for a particular purpose or application other than as expressly set forth in the product labeling.

Section XIV – Electromagnetic Conformity Declaration

The Filac 3000 Electronic Thermometer has been build and tested according to IEC 60601-1, CAN/CSA C22.2 No. 60601-1-08 and EN 60601-1-2 Standards.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The FILAC 3000 Electronic Thermometer is intended for use in the electromagnetic environment specified below. The user of the FILAC 3000 Electronic Thermometer should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>RF emissions
(CISPR 11)</td><td>Group 1</td><td>The FILAC 3000 Electronic Thermometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
(CISPR 11)</td><td>Class B</td><td rowspan="2">The FILAC 3000 Electronic Thermometer 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 purposes.</td></tr>
<tr><td>Harmonic emissions
(IEC 61000-3-2)</td><td>Not applicable</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The Filac 3000 Electronic Thermometer is intended for use in the electromagnetic environment specified below. The user of the Filac 3000 Electronic Thermometer should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) (EN 61000-4-2 per EN 60601-1-2: 2001)	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors 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 IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	not applicable not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	not applicable not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Filac 3000 Electronic Thermometer requires continued operation during power mains interruptions, it is recommended that the P-STIM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field (EN 61000-4-8 per EN 60601-1-2: 2001)	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.
Note UT is the a. c. mains voltage prior to application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the Filac 3000 Electronic Thermometer			
The Filac 3000 Electronic Thermometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Filac 3000 Electronic Thermometer can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communications			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 1,2\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
2	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 800 MHz, the separation distance for the higher frequency range applies. **Note 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Filac 3000 Electronic Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Filac 3000 Electronic Thermometer should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Conducted RF IEC 61000-4-6 Radiated RF (EN 61000-4-3 per EN 60601-1-2: 2001)	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	Not applicable 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Filac 3000 Electronic Thermometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** Not applicable **d** = 1,2√**P** 80 MHz to 800 MHz **d** = 2,3√**P** 800 MHz to 2,5 GHz Where **P** is the maximum output power rating of the transmitter in watts (**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 in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
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 and people.			
[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 Filac 3000 Electronic Thermometer is used exceeds the applicable RF compliance level above, the Filac 3000 Electronic Thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Filac 3000 Electronic Thermometer. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Identification of a substance that is not contained or present within the product or packaging.

COVIDIEN

Manual No. SMF0212-004

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; 7,648,268; 7,654,735; D532,710; D535,202; D548,626; D554,008.

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