

Dry Bath Operations Manual

List Number 8B29-01

Foreword

The Abbott LCx[®] Dry Bath is a component of the Abbott LCx[®] Probe System.

The LCx Dry Bath is backed by dedicated professionals with

The LCx Dry Bath is backed by dedicated professionals with expertise in engineering, training, and technical information. Abbott will teach you how to operate, maintain, and troubleshoot your system when you attend our PACE accredited training program at our Dallas, Texas facility.

This manual should also serve as a reference to all aspects of instrument operation. Please familiarize yourself with its contents. Technical assistance from our Customer Support Center staff is also available. We look forward to serving your needs.

Customer Support Center (CSC)

United States: 1-800-527-1869

Abbott Laboratories Diagnostics Division

Canada: 1-800-387-8308 (Ontario and Quebec: 1-800-387-4378)

International: Call your local Customer Service Representative

International: Call your local Customer Service Representative.

Intended Use

The Abbott $LCx^{\mathbb{B}}$ Dry Bath is intended for use as an accessory of the Abbott $LCx^{\mathbb{B}}$ Probe System.

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ABBOTT LCx® DRY BATH Operations Manual

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All operating instructions must be followed. In no event shall Abbott be responsible for failures, errors, or other liabilities resulting from customers' noncompliance with the procedures and precautions outlined herein.

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Pictorial Disclaimer

Illustrations contained in this manual are for informational purposes only. They are not to be used for clinical or maintenance evaluations.

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Please direct all inquiries concerning information in this manual to Abbott Laboratories at the following address:

Probe Diagnostics Business Unit Abbott Diagnostics Division Abbott Laboratories 100 Abbott Park Road Abbott Park, IL 60064

Trademark Statement

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Warnings

Electrical Shock Hazard



WARNING: To avoid electrical shock:

- Use a properly grounded electrical outlet of correct voltage and current handling capacity.
- Disconnect the LCx Dry Bath from the power supply prior to maintenance and servicing.
- Do not spill liquid into the LCx Dry Bath.
- Do not immerse the LCx Dry Bath in liquid.

Personal Injury Hazard



WARNING: To avoid personal injury:

- Do not operate in the presence of flammable or combustible materials; fire or explosion may result. This device contains components which may ignite such materials.
- To avoid burns, turn off the power to the LCx Dry Bath and wait for the heating blocks to cool to 35°C or below.
 - Refer servicing to qualified personnel.

Biohazard



WARNING: Potential Biohazard.



Biosafety Level 2¹ or other appropriate biosafety practices^{2,3,4}, should be used for materials that contain or are suspected of containing infectious agents. These practices include, but are not limited to the following: wear gloves when handling specimens or reagents, do not pipette by mouth, and do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.

The LCx Dry Bath must be equilibrated at the operating temperature before samples are loaded.

Verification of the temperature of the LCx Dry Bath must be performed before heating specimens.

Hazardous Materials



WARNING:

This product contains refractory ceramic, refractory ceramic fiber, or fiberglass (glass wool) insulation which can produce respirable fibers and dust when handled. These fibers or dust can cause irritation and can aggravate pre-existing respiratory diseases. Refractory ceramic insulations may contain or may form crystalline silica (crystobalite) which may cause lung damage (silicosis).

The International Agency for Research on Cancer (IARC) has classified refractory ceramic fiber and fiberglass as group 2B (possibly carcinogenic). IARC has classified crystalline silica as group 2A (probably carcinogenic).

Do not disturb, replace, or repair insulating material in the LCx Dry Bath. Contact your LCx Customer Support Center (CSC) for help with maintenance and service.

Introduction

Use and Function

To provide a controlled dry heat environment at a constant temperature for tubes containing *in vitro* diagnostic specimens used in qualitative test procedures. Please refer to your LCx assay-specific package insert for the time required to heat the specimens in the LCx Dry Bath.

Installation Procedure

- Remove the LCx Dry Bath from the carton.
- Place the three heating blocks into the LCx Dry Bath chamber.
- Verify that the blocks are centrally placed and are not touching the sides of the dry bath.
- Check the voltage specifications located on the back of the LCx Dry Bath to ensure compatibility with local power supply.
- Plug the supplied power cord into the back of the LCx Dry Bath and into a 3-wire grounded outlet.



WARNING: Do not use three-to-two plug adapters.

• Follow steps 1 through 5 of the procedure in the *Operating Instructions* to ensure that the LCx Dry Bath functions correctly.

Principles of Operation

The LCx Dry Bath is designed to heat thermally conductive blocks. The blocks have wells that conform to tubes containing *in vitro* diagnostic specimens. The unit is constructed to uniformly conduct the heat produced by a resistive heater upon which the blocks rest. The output of the heater is controlled by a precision temperature sensor. Operating temperature is factory set.

The unit is equipped with an ON-OFF switch and light to indicate that the power is "ON" as shown in Figure 1. The unit operates on nominal 100, 120, or 220 volt AC power sources.

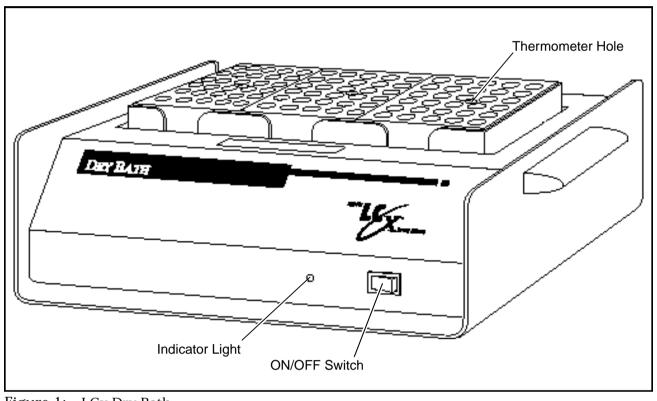


Figure 1: LCx Dry Bath

Characteristics and Specifications

Mechanical Characteristics

Dimensions 9 in D X 11.75 in W X 3.75 in H

(23 cm D X 30 cm W X 9.5 cm H)

Weight Approximately 11 lbs (5 kg)

Heating Blocks

Number 3

Configuration 5 X 6 wells (holes)

Dimensions 4 in D X 3 in W X 2 in H

(10.25 cm D X 7.5 cm W X 5 cm H)

Thermometer

Position 1 in each block

Thermometer

Position Diameter 0.25 in (0.6 cm)

Electrical

List Number	Volts	Amps	Watts	Hz
08B23-14	100	2.50	250	50/60
08B23-10	120	2.08	250	50/60
08B23-17	220 – 240	1.04	250	50/60

Temperature

Operating Range	95° – 99°C
Temperature Uniformity	± 2°C
Temperature Stability	± 2°C
Ambient Operating Range	20° – 30°C

Thermometer

Calibrated thermometer, list number 04A83-01 or 05C93-01.

NOTES

Operating Instructions

Perform the following steps to verify that your LCx Dry Bath is performing properly.

1. Turn the LCX Dry Bath ON.



CAUTION: The LCX Dry Bath must be at the proper temperature prior to placing the specimen tubes in the bath. Refer to the assay-specific package insert.

2. Allow approximately 30 minutes for the dry bath to heat up.

NOTE: Heat-up time for an unloaded LCx Dry Bath containing three blocks from a cold start is approximately 30 minutes. Heat-up time depends on voltage. Heat-up time for a fully loaded dry bath will vary between 20 and 40 minutes.

- 3. For digital thermometer users only: Remove thermometer probe cover and turn the thermometer ON (see Figure 2).
- 4. Insert the calibrated thermometer into its hole at the center of each block.
- 5. For each block, verify that the thermometer reading is $97^{\circ} \pm 2^{\circ}$ C.
- 6. If the temperature is out of range, refer to *LCx Dry Bath Calibration*.
- 7. Insert specimen tubes in the wells in the heated blocks. Allow heated blocks to stabilize to 97°C.
- 8. Refer to your LCx assay-specific package insert for specimen heating time.



WARNING: Hot Surface. Use care in loading and unloading specimen tubes. Avoid touching the LCx Dry Bath heating blocks as they may cause severe burns.



WARNING: To avoid burns, turn the power to the LCx Dry Bath OFF and wait for the heating blocks to cool before handling them. Do not use the dry bath in the presence of flammable or combustible chemicals; fire or explosion may result. This device contains components which may ignite such materials.

For digital thermometer users only: Turn the thermometer OFF if no more specimens are to be processed.

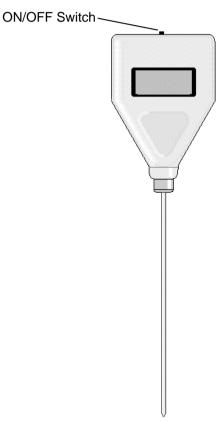


Figure 2: Digital Thermometer, Probe Cover Removed

Calibration

Digital Thermometer Calibration (for digital thermometer users only)

Calibrate the digital thermometer every six months.

Equipment required:

- 3/32 inch (2 mm) screwdriver
- Calibrated reference thermometer accurate to ± 1°C between 90° - 100°C, with accuracy traceable to a recognized national standard.
- Remove the battery cover from the rear of the digital thermometer by lifting the cover at the slot (see Figure 3).
- Move the calibration switch to the down (ON) position. The display should read -0.4° to 0.4°C.
- 3. If the display is outside -0.4° to 0.4°C, use the screwdriver to turn T1 to adjust as required.
- Turn the calibration switch OFF.
- Insert the reference thermometer into the LCx Dry Bath. NOTE: A water bath set between 95° – 100°C may be used instead of the LCx Dry Bath.
- 6. Verify that the indicated temperature is $97^{\circ}C$ ($\pm 1^{\circ}C$) in the LCx Dry Bath or between 95°C - 100°C in a water bath after 15 minutes. Note the indicated temperature.
 - Remove the reference thermometer. Remove the digital thermometer's probe cover and insert the digital thermometer into the LCx Dry Bath or the water bath.
- 8. Note the temperature indicated on the digital thermometer after 15 minutes.
- If necessary, adjust T2 (see Figure 3), until the display reads the same temperature as indicated on the reference thermometer.
- 10. Remove the digital thermometer and replace the battery cover. Turn the digital thermometer OFF.

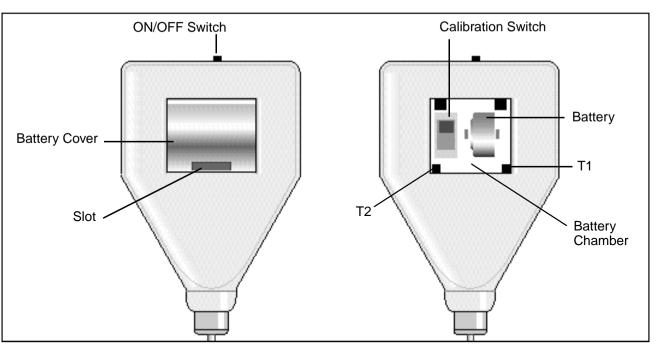


Figure 3: Digital Thermometer, Back View

LCx Dry Bath Calibration

Equipment required:

- Regular flat tip, 7/32 inch (4 mm) screwdriver.
- Calibrated reference thermometer accurate to ± 1°C between 90° 100°C, with accuracy traceable to a recognized national standard.

NOTE: Always place three blocks in the LCx Dry Bath during calibration.

If the temperature indicated on the thermometer is not 97°C (± 2°C) during operation, the LCx Dry Bath should be calibrated as follows:

- 1. Insert the reference thermometer into the thermometer hole of the center block.
- 2. Turn the LCx Dry Bath ON.
- 3. Allow the temperature to fully stabilize.

NOTE: For digital thermometer users only: If the reference thermometer reads 97°C (± 1°C), proceed to Digital Thermometer Calibration.

- 4. If the indicated temperature is not 97°C (± 1°C) turn the adjustment screw located on the rear of the LCx Dry Bath (see Figure 4). Turning the adjustment screw clockwise increases the temperature setting.
- 5. Allow the temperature to stabilize.
- 6. Verify the temperature reading.
- 7. Repeat steps 4 through 7 as necessary, until temperature stabilizes at 97°C (± 1°C).
- 8. If temperature does not stabilize at 97°C (± 1°C), contact your LCx Customer Support Center.

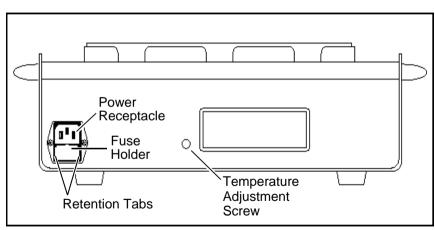


Figure 4: Rear View of LCx Dry Bath

NOTES

Service and Maintenance



WARNING:

Electrical Shock Hazard. Disconnect from power supply before performing any maintenance steps. Contact your LCx Customer Support Center for service.



WARNING:

The LCx Dry Bath must be decontaminated prior to shipment or transfer from the laboratory.



WARNING:

To avoid burns, turn off the power to the LCx Dry Bath and wait for the heating blocks to cool to 35°C or below.



WARNING:

Do not use the LCx Dry Bath in the presence of flammable or combustible chemicals; or explosion may result. This device contains components that may ignite such materials.

Daily Maintenance

Visually verify preset temperature prior to performing specimen preparation.

As Required Maintenance

Cleaning

Use a moist cloth to clean the case and aluminum blocks. Dry thoroughly.

Biohazard Decontamination

- 1. Unplug the LCx Dry Bath and allow to come to room temperature.
- 2. To decontaminate the LCx Dry Bath surfaces, heating blocks and wells, use a cotton swab or cloth dipped in a 0.5% Sodium Hypochlorite solution (10% chlorine bleach).
- 3. Moisten a cloth or swab with distilled water and thoroughly wipe the surfaces of the LCx Dry Bath, heating block and wells until chlorine residue is no longer visible.

DNA Decontamination

wells with a cloth or swab moistened with 1% sodium hypochlorite solution (20% chlorine bleach). Moisten a cloth or swab with distilled water and thoroughly wipe the surfaces of the LCx Dry Bath, heating block and wells until chlorine residue is no longer visible.

Wipe the surfaces of the LCx Dry Bath, the heating block, and

Fuse Replacement

- To replace a fuse, turn off the power, allow the LCx Dry Bath to cool to room temperature, and disconnect the power cord from the rear of the LCx Dry Bath. 2. Locate the fuse holder below the power receptacle (see Figure 4).
- Remove the fuse holder by squeezing the retention tabs and pulling the fuse holder out of the LCx Dry Bath. The fuse holder contains 2 fuses.
- Replace the defective fuse(s).
- Place the fuse holder back into the LCx Dry Bath.

Digital Thermometer Battery Change (for digital thermometer users only)

- Remove the battery cover from the rear of the digital thermometer by lifting the cover at the slot (see Figure 3).
- Remove the old battery (see Figure 3).
- Insert the new battery (type P675-NR44) in the correct orientation.
 - Perform the digital thermometer calibration as described in Digital Thermometer Calibration.

Troubleshooting

Problem	Possible Cause	Corrective Action	
Will not heat.	Power not available.	Ensure that power is available to the LCx Dry Bath.	
	Power fuse blown.	Replace the fuse. See Service and Maintenance.	
	Defective circuit board.	Contact LCx Customer Support Center (CSC).	
	Defective triac.	Contact LCx CSC.	
	Thermal fuse open.	Contact LCx CSC.	
Temperature out of range.	Digital thermometer defective (for digital thermometer users	See Digital Thermometer Calibration.	
	only).	2. Replace thermometer battery.	
		3. Contact LCx CSC.	
	LCx Dry Bath not calibrated.	See Calibration.	
	Heating blocks not seated properly.	Check for foreign objects between heating blocks and heating chamber.	
	Fluctuating power source.	Contact LCx CSC.	
Erratic temperature.	Unit under heating or cooling duct.	Move unit to a draft-free area.	
	Heating blocks not placed correctly.	Check to be sure the three heating blocks are touching each other and centered in the dry bath well so the blocks are not touching the dry bath walls.	
	Fluctuating power source.	Contact LCx CSC.	

Defective circuit board.

To ensure constant and accurate performance of your LCx Dry Bath, be aware that:

Contact LCx CSC.

- Placing the unit in drafts, sunlight, or near equipment which emits heat may result in fluctuating temperatures.
- Use only Swab Specimen Transport Tubes and LCx Urine Specimen Resuspension Tubes supplied for use with the Abbott LCx Probe System.

If the LCx Dry Bath continues to malfunction, contact your LCx Customer Support Center.

NOTES

Bibliography

- 1. U.S. Department of Health and Human Services, Biosafety in Microbiological and Biomedical Laboratories HHS publication number (CDC) 93-8395.
- 2. World Health Organization. Laboratory Biosafety Manual. Geneva. World Health Organization, 1993.
- 3. National Committee for Clinical Laboratory Standards. Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue: Tentative Guidelines. NCCLS Document M29-T2. Villanova, PA: NCCLS, 1991.
- 4. U.S. Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens; final rule. Fed Register, 1991, 56: No. 235:64175-82.

NOTES