

Covered Dry Bath Operations Manual

List Number 05C74-01

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Foreword

Foreword

The Abbott LCx Covered Dry Bath is a component of the Abbott LCx Probe System.

The LCx Covered Dry Bath is backed by dedicated professionals with expertise in engineering, training, and technical information. As a valued customer, we 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 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)

Abbott Laboratories Diagnostics Division

United States: 1-800-527-1869

Canada: English 1-800-387-8378 French 1-800-465-2675

International: Call your local Customer Service Representative.

Intended Use

The Abbott LCx Covered Dry Bath is intended for use as an accessory of the Abbott LCx Probe System, for heat treatment of specimens.

Proprietary Statement

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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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Trademark Statement

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NOTES

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 Covered Dry Bath.

Installation Procedure

- 1. Remove the LCx Covered Dry Bath from the carton.
 - NOTE: Be sure the following items have been shipped with your unit: forceps, tweezers, block handlers, and fuse. If any items are missing or damaged, contact your LCx Customer Support Center.
- 2. Allow the LCx Covered Dry Bath to come to room temperature.
- 3. Place the heating block into the LCx Covered Dry Bath and verify that the block is centrally located.
- 4. Check the voltage specifications located on the back of the LCx Covered Dry Bath to ensure compatibility with local power supply.
- 5. Plug the supplied power cord into the back of the LCx Covered Dry Bath and into a 3-wire grounded outlet.



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

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

Principles of Operation

The LCx Covered Dry Bath is constructed with a precision temperature controlled, resistive heater. An aluminum block, machined to hold in vitro diagnostic specimens conducts heat from the heating element to the specimens. When closed, the insulated cover helps assure that the specimen tubes are uniformly heated.

The LCx Covered Dry Bath is equipped with an ON/OFF switch that illuminates when the power is "ON" as shown in Figure 1. The indicator light turns on in conjunction with the operation of the heating element. LCx Covered Dry Bath units are available that operate on nominal 100, 120, or 220 volt AC power sources.

The LCx Covered Dry Bath is electrically protected by two fuses and also by a thermal fuse set to cut power at 107°C.

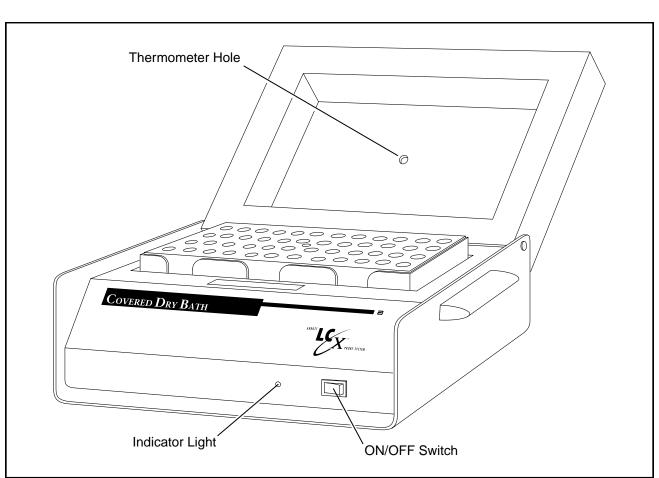


Figure 1: LCx Covered Dry Bath

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 Covered Dry Bath from the power supply prior to maintenance and servicing.
- Do not spill liquid into the LCx Covered Dry Bath.
- Do not immerse the LCx Covered 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 Covered Dry Bath and wait for the heating block to cool to 35°C or below.
- Refer servicing to qualified personnel.
- Use care when moving the LCx Covered Dry Bath. Carry it by the handles provided and in an upright position, taking care not to drop the unit or tilt the unit excessively or the heating block may fall out.

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 Covered Dry Bath must be equilibrated at the operating temperature before samples are loaded. The cover must be closed during sample heating.

Verification of the temperature of the LCx Covered Dry Bath must be performed before and after 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 Covered Dry Bath. Contact your LCx Customer Support Center (CSC) for help with maintenance and service.

Characteristics and Specifications

Mechanical Characteristics

Dimensions 9.75 in D X 14.25 in W X 9.25 in H

(24.8 cm D X 36.2 cm W X 23.5 cm H)

Weight 13.2 lbs (5.9 kg)

Heating Block

Number 1

Configuration 4 X 12 wells (holes)

Dimensions 4 in D X 9 in W X 2 in H

(10.16 cm D X 22.86 cm W X 5.08 cm H)

Thermometer

Hole In the center of the block

Thermometer

Hole Diameter 0.28 in (0.71 cm)

Electrical Requirements

List Number	03C53-10	03C53-14	03C53-17
Voltage	120	100	220/240
Voltage Range	108 – 132	90 – 110	198 – 242
Amps	2.08	2.5	1.04
Watts	250	250	250
Maximum Heat Output (Btu/hour)	853	853	853
Frequency (Hz)	50/60	50/60	50/60
Frequency Range (Hz)	45 - 66	45 - 66	45 - 66
Power Fuses (2) Type	5 x 20 mm 250 V	5 x 20 mm 250 V	5 x 20 mm, time delay, 250 V
Fuse Amperage	4	4	1.6

Temperature

Operating Range	93° – 97°C Measured through thermometer hole.
Temperature Uniformity	86° – 97°C Throughout the aluminum block.
Temperature Stability	± 2°C

Environmental Requirements

Maximum

Altitude 8000 feet (2438 meters) above sea level

Ambient

 $Temperature 17^{\circ} - 30^{\circ}C$

Relative

Humidity 10 – 85% non-condensing

Thermometer

Calibrated, digital thermometer, list number 05C93-01

Operating Instructions



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.

Perform the following steps:

- 1. Turn the LCx Covered Dry Bath ON.
- Close the cover.
- 3. Pull the plastic cover off the digital thermometer. Insert the digital thermometer into the thermometer hole (see Figure 1) and turn the thermometer ON (see Figure 2).
- 4. With the cover down, allow the LCx Covered Dry Bath to equilibrate to 95°C (± 2°C). This may take up to 60 minutes depending on line voltage.



CAUTION: The LCx Covered Dry Bath temperature must be verified with the cover down before placing specimen tubes in the LCx Covered Dry Bath. Heat up time varies with available line voltage.

- 5. Verify that the temperature is 95°C (± 2°C).
- 6. Remove the digital thermometer and open the cover.
- 7. Insert specimen tubes in the wells of the LCx Covered Dry Bath, close the cover and place the digital thermometer into the thermometer hole.

NOTE: If the temperature is not 95°C (± 2°C) do not place specimens into the LCx Covered Dry Bath. Refer to your LCx assay-specific package insert for specimen handling information, and to the Calibration, Service and Maintenance and Troubleshooting sections of this manual.



WARNING: Hot Surface.

Use care in loading and unloading specimen tubes. Avoid touching the LCx Covered Dry Bath heating block as it may cause severe burns.

- 3. Refer to the LCx assay-specific package insert for specimen heating time.
- 9. Verify that the temperature is at 95°C (± 2°C) at the end of the heating time.



CAUTION: If the temperature of the LCx Covered Dry Bath is outside 95°C (± 2°C), refer to your LCx assayspecific package insert for specimen handling information. Also refer to the Calibration, Service and Maintenance and Troubleshooting sections of this manual.

- 10. Remove the digital thermometer and open the cover.
- 11. Remove specimen tubes using forceps.
- 12. Turn the LCx Covered Dry Bath and digital thermometer OFF if no more specimens are to be processed.

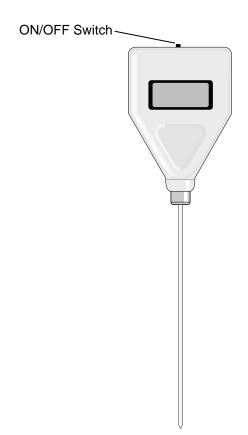


Figure 2: Digital Thermometer

Calibration

Digital Thermometer Calibration

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.
- 1. Verify that the digital thermometer is turned on and remove the battery cover from the rear of the digital thermometer by lifting the cover at the slot (see Figure 3).
- 2. 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.
- Close the cover of the LCx Covered Dry Bath and insert the reference thermometer into the LCx Covered Dry Bath.

NOTE: A water bath set between 95° – 100°C may be used instead of the LCx Covered Dry Bath.

- 6. Verify that the indicated temperature is 95°C (± 1°C) in the LCx Covered Dry Bath or between 95°C 100°C in a water bath after 15 minutes. Note the indicated temperature.
- 7. Remove the reference thermometer and insert the digital thermometer into the LCx Covered Dry Bath or the water bath.
- 8. Note the temperature indicated on the digital thermometer after 15 minutes.
- 9. 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.

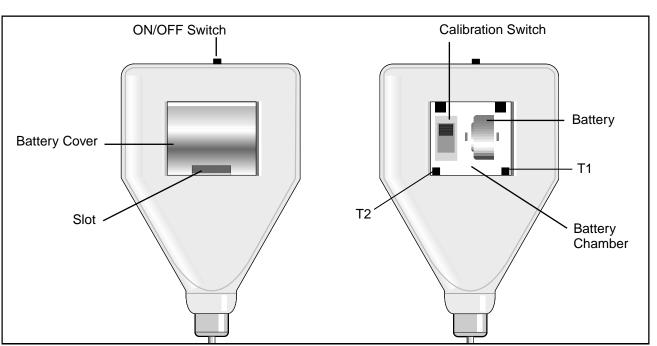


Figure 3: Digital Thermometer, Back View

LCx Covered Dry Bath Calibration

Equipment required:

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

If the temperature indicated on the digital thermometer is not 95° C (\pm 2°C) during operation, the LCx Covered Dry Bath should be calibrated as follows:

- 1. Ensure the aluminum heating block is in place.
- 2. Close the cover.
- 3. Insert the reference thermometer into the thermometer hole.
- 4. Turn the LCx Covered Dry Bath ON.
- 5. Allow the temperature to fully stabilize.

NOTE: If the reference thermometer reads 95°C (± 1°C), proceed to Digital Thermometer Calibration.

- If the indicated temperature is not 95°C (± 1°C) turn the adjustment screw located on the rear of the LCx Covered Dry Bath (see Figure 4). Turning the adjustment screw clockwise increases the temperature setting.
- Allow the temperature to stabilize. This may take up to 60 minutes depending on line voltage.
- 8. Verify the temperature setting.
- Repeat steps 5 through 8 as necessary, until temperature stabilizes at 95°C (± 1°C).
- 10. If temperature does not stabilize at 95°C (± 1°C), contact your LCx Customer Support Center.

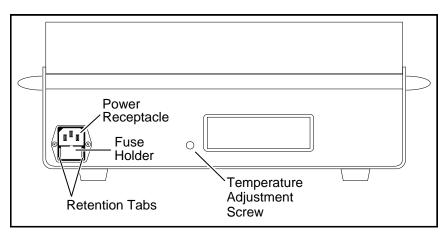


Figure 4: Rear View of LCx Covered Dry Bath

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



WARNING:

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



WARNING:

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

As Required Maintenance

Cleaning

Use a moist cloth to clean the case, cover and aluminum block. Dry thoroughly.

Biohazard Decontamination

- 1. Unplug the LCx Covered Dry Bath and allow to come to room temperature.
 - To decontaminate the LCx Covered Dry Bath surfaces, heating block 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 Covered Dry Bath, heating block and wells until chlorine residue is no longer visible.

DNA Decontamination

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

To replace a fuse, turn off the power, allow the LCx

Wipe the surfaces of the LCx Covered Dry Bath, the heating block, and wells with a cloth or swab moistened with 1%

Fuse Replacement

- Covered Dry Bath to cool to room temperature, and disconnect the power cord from the rear of the LCx Covered Dry Bath.

 2. Locate the fuse holder below the power receptacle
- 3. Remove the fuse holder by squeezing the retention tabs and pulling the fuse holder out of the LCx Covered Dry Bath.

(see Figure 4).

- 4. Replace the defective fuse.
- 5. Place the fuse holder back into the LCx Covered Dry Bath.

Digital Thermometer Battery Change

- 1. Remove the battery cover from the rear of the digital thermometer by lifting the cover at the slot (see Figure 3).
- 2. Remove the old battery (see Figure 3).
- 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 Covered 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.	See Digital Thermometer Calibration.
		2. Replace thermometer battery.
		3. Contact LCx CSC.
	LCx Covered Dry Bath not calibrated.	See Calibration.
	Heating block not seated properly.	Check for foreign objects between heating block and heating chamber.
	Cover not seated properly.	Check for foreign objects between cover and LCx Covered Dry Bath.
	Fluctuating power source.	Contact LCx CSC.
Erratic temperature.	Fluctuating power source.	Contact LCx CSC.
	Defective circuit board.	Contact LCx CSC.

NOTES

Bibliography

- 1. U.S. Department of Health and Human Services, Biosafety in Microbiological and Biomedical Laboratories HHS publication number (CDC) 93-8395.
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- 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.

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