

ThermoBrite®

Slide Denaturation/Hybridization System

Operator's Manual



Operator's Manual

ThermoBrite®

Model Number S500

For in-vitro diagnostic use

REF 3800-004852-001 - *ThermoBrite Slide Denaturation/Hybridization System 120V*

REF 3800-004852-002 - *ThermoBrite Slide Denaturation/Hybridization System 240V*

REF 3800-004970-001 - *Humidity Card, 10pk*

REF 3800-006418-001 - *ThermoBrite Temperature Verification Kit*

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How to use this manual

This manual along with information contained on product labels should provide you with all the information you need to operate and maintain the ThermoBrite.

Cautions and Warnings appear in boxes with symbols to the left of the text. Notes also appear in boxes to highlight information.

Cautions and Warnings

A **WARNING** is a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the instrument.

A **CAUTION** is a statement that alerts the user to the possibility of a problem with the instrument associated with its use or misuse. Such problems include instrument malfunction, instrument failure, damage to the instrument or damage to other property. The **CAUTION** statement includes the precaution that should be taken to avoid the hazard.

Please pay close attention to the instructions that accompany the notes and symbols as well as the standard laboratory practices outlined by your facility and local regulatory agencies. The table below lists all the **CAUTIONS** and **WARNINGS** for the ThermoBrite.



CAUTION: Plug the instrument into a properly grounded outlet supplying the voltage and frequency indicated on the serial number label.



CAUTION: Outside of North America: Inspect that the supplied Line Cord has local electrical compatibility. Installation outside of the USA: Use power cord with an IEC320/CEE22 female connector and male connector suitable for the power outlet to be used. Cord must meet standards.



WARNING: Unplug the ThermoBrite from the wall outlet before performing maintenance.



CAUTION: Do NOT expose the ThermoBrite to strong or concentrated acids, bases, esters, aromatic or halogenated hydrocarbons, ketones or strong oxidizing agents.



BIOLOGICAL HAZARDS: Universal precautions should be followed on all specimens, regardless of whether a specimen is known to contain an infectious agent (see Biohazard references).



WARNING: Risk of electric shock: The instrument contains no user serviceable parts other than fuse and cover gasket replacement. Removal of housing will expose potentially lethal voltage. Refer service to qualified service personnel.













WARNING: Hot Surface: The interior surface of the instrument may be HOT, use caution to avoid potential burn.



CAUTION: Do NOT use paper towels or any other filter card in card positions. This may change the humidity and may decrease the intensity of the probe, potentially causing assay failure.



CAUTION: Please use the system as intended. Improper use of the ThermoBrite may cause damage to the system, inaccurate results, or potentially nullify warranties.

Symbol	Meaning	Definition
	Catalog Number	Indicates the product/catalog number
	Warning/Caution	Statement of caution/warning, read instruction carefully
	Biological Hazards	Statement of caution/warning, read instruction carefully
	Caution, risk of electric shock	Statement of caution/warning, read instruction carefully
	Warning, hot surface	Statement of caution/warning, read instruction carefully
	EC Representative	European Community Authorized Representative
	For in vitro diagnostic use	Clarifies for use as <i>in vitro</i> diagnostic only
	Serial Number	Indicates instrument serial number code
	Manufacturer	Indicates manufacturer of the instrument
	CE marking of conformity	Indicates conformance to CE

Leica Biosystems Contact Information

Customer opinion and input is extremely important to us.
Comments on this manual should be directed to:

Leica Biosystems Richmond, Inc.
5205 Route 12
Richmond, IL 60071
USA
Website: www.LeicaBiosystems.com

North America Phone Contacts:
Customer Service: 1-800-248-0123
Technical Support: 1-800-248-0123

Outside of North America, contact your local Leica representative.

Authorized European Representative | | | |----|-----| | EC | REP | |----|-----|

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Manufacturer



Leica Biosystems Richmond, Inc.
5205 Route 12
Richmond, IL 60071
USA
1-815-678-2000

Section 1

Warranty

Leica Biosystems Warranty

Leica Biosystems, warrants that the instruments shall be free from defects in material and/or workmanship, under normal use and service, for the period expiring twelve (12) months from the date of installation. Leica Biosystems will, at its discretion, repair or replace any unit covered under this warranty returned to Leica Biosystems with shipping costs prepaid. Repaired or replaced instruments supplied under this warranty carry only the remaining portion of the original warranty and repairs shall not interrupt or prolong this warranty. For warranty terms and conditions outside the United States, contact your Authorized Leica Biosystems Distributor.

No warranty extended by Leica Biosystems shall apply to any instrument that has been damaged due to misuse, negligence, accident, or damage resulting from unauthorized repairs, alterations, or improper installation.

Leica Biosystems makes no warranty other than the one set forth herein. This warranty is given expressly in lieu of all other warranties, expressed or implied. The purchaser agrees that there is no warranty of merchantability or of fitness for any intended purpose and that there are no other remedies or warranties, expressed or implied, which extend beyond the description on the face of the agreement. No agent or employee of Leica Biosystems is authorized to extend any other warranty or assume for Leica Biosystems any liability except as set forth above. This warranty is only applicable to the original purchaser.

Limitation of Liability

Leica Biosystems shall not be liable for any loss of use, revenue or anticipated profits, or for any consequential or incidental damages resulting from the sale or use of the products. The purchaser shall be deemed liable for any and all claims, losses, or damages incurred by the use or misuse of the Leica Biosystems instrument by the purchaser, its employees or others, following receipt of the instrument or other items.

Section 2

Unpacking and Installation

Inspect Packaging

The ThermoBrite and its accessories are delivered in one carton. If the instrument or accessories have suffered any damage in transport, please inform your carrier immediately.

NOTE: Save original shipping carton and foam inserts. Original packaging is required for returns and service to prevent damage during transport.

Verify Contents

The package contains:	
1	ThermoBrite
1	Line Cord
1	Operator's Manual
2	Humidity Cards

Installation Instructions

1. Place the ThermoBrite on a level surface suitable for laboratory instrumentation.
2. The ThermoBrite has an intake fan located underneath the instrument; ensure no obstruction exists on the intake fan.
3. Ensure the ThermoBrite is placed at least 12" (30 cm) from the wall to allow for proper cooling.
4. Position the ThermoBrite away from direct sunlight and sources of heat or cold.

5. Verify voltage requirements located on serial number label on the rear of the instrument.
6. Plug the instrument into a grounded outlet supplying the voltage and frequency indicated on the serial number label.
7. The main power switch is located on the rear of the instrument, next to the line cord power entry module.
8. Installation is complete.



CAUTION: Plug the instrument into a properly grounded outlet supplying the voltage and frequency indicated on the serial number label.



CAUTION: Outside of North America: Inspect that the supplied Line Cord has local electrical compatibility. Installation outside of the USA: Use power cord with an IEC320/CEE22 female connector and male connector suitable for the power outlet to be used. Cord must meet standards.

Section 3

System Overview

Principle and Intended Use





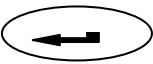


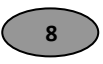
For in vitro diagnostic use in denaturation/hybridization of slide-based FISH procedures



The ThermoBrite is a microprocessor controlled small bench top hot plate with lid. The ThermoBrite allows storage of 40 programs, three operating modes, Fixed Temperature, Hybridization Only or Denaturation and Hybridization, capacity for twelve slides and a maximum temperature of 99°C. The instrument is UL/cUL listed and CE marked.

Keypad



Keypad Symbols and Definitions		
	Up	Move cursor up; Enter character A-Z for program name
	Down	Move cursor down; Enter character A-Z for program name
	Enter	Accept or Enter
	Backspace	Move cursor back to previous screen
	Stop	End a program in process
	0-9	Enter numeric values for time and temperature or for program name

Display Abbreviations

Abbreviation	Expansion
PGM	Program
Denat & Hyb	Denaturation & Hybridization
Denat Temp	Denaturation Temperature
Denat Time	Denaturation Time
Hyb Temp	Hybridization Temperature
Hyb Time	Hybridization Time
Hyb Only	Hybridization Only
Fixed Temp/Fxd	Fixed Temperature

Audible Indicators - NORMAL

Single beep:	All legal keystrokes.
Two short beeps:	Upon accepting a field and cursor has moved to next field.
Five beeps:	Completion of process.

Section 4

Operating Instructions

Opening and Closing the Lid



WARNING: The plate may be hot. Use caution and check temperature on display before handling slides. Improper precaution can cause a burn.

NOTE: Depressions located on either side of the lid allow user to simply lift lid into position. The lid should offer some resistance when opening. To close, reverse process. Assure front is completely down and no obstructions prevent the cover gasket from sealing on housing base.

Turning Unit On

The ThermoBrite main power switch is located on the rear panel. Assure unit is plugged into a grounded outlet. Move switch to ON (I) position. Instrument will beep to announce power has been turned on. Main Menu will be displayed when the instrument has reached the default temperature of 37°C.

Indicators on power switch: I=ON O=OFF

Run a PGM
Edit a PGM
Create a PGM
Present Temp: 37°C

Run a Program

Turn unit on and wait for the Main Menu screen. Cursor highlights “Run a PGM” line.

Press “Enter” button to accept.

With the arrow keys, scroll through program numbers 1 to 40 / program names. Alternately, use the keypad to enter desired program number. If no programs have been saved advance to programming section of this handbook. To accept, press “Enter” button.

Enter PGM no. or Scroll (arrows) PGM 01 namexxxxxx
--

Display will confirm PGM number, name, incubation time(s) and temperatures. Cursor highlights “Run PGM” line. Press “Enter” button to accept.

Hyb Only	Denat & Hyb	Fixed Temp
PGM 02 EBV Hyb: 55°C 01:30 Run PGM Main Menu	PGM 01 HER2 82°C :05; 45°C 20:00 Run PGM Main Menu	PGM 03 BAKE FIXED: 65°C Run PGM Main Menu

The display prompts to “Add Slides and Close Lid”. Before adding slides, saturate two Humidity Cards with distilled or deionized water, and insert into the inside lid. Now place the slides to instrument. (see **Humidity Cards**). Move cursor to highlight “Start” line. Press “Enter” button to run the program. To return to the Main Menu instead, move the cursor to highlight “Main Menu” line and then press the “Enter” button.

PGM 02 EBV Add Slides – Close Lid Start Main Menu	PGM 01 HER2 Add Slides – Close Lid Start Main Menu	PGM 03 BAKE Add Slides – Close Lid Start Main Menu
--	---	---

Denaturation and Hybridization:

Display indicates present temperature of the slides.

```
PGM 01 HER2
**Heating**
Denat: 82°C :05
Present Temp: 42°C
```

Once temperature reaches denaturation set point, the ThermoBrite will beep twice and denaturation time will count down from the set time.

```
PGM 01 HER2
Denat in Process
Denat: 82°C 02:28
Present Temp: 82°C
```

The ThermoBrite will automatically cool to hybridization set temperature once denaturation is completed.

```
Please Wait

Cooling to Hyb 45°C
Present Temp: 58°C
```

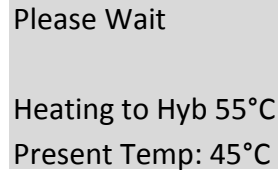
Hybridization time will count down from the set time once temperature reaches hybridization set point.

Upon program completion the ThermoBrite will beep five times and the display will show **“PROCESS COMPLETE”**. Hybridization temperature will be maintained until **“End PGM/Main Menu”** is accepted by pressing **“Enter”** button. Before pressing **“Enter”** button, remove slides for further processing. If **“End PGM/Main Menu”** is not accepted within the first minute of program completion, the ThermoBrite will add the time accrued since completion of the original hybridization program to the time of the original hybridization program to give the Total Time at the hybridization temperature.

```
PGM 01 HER2
PROCESS COMPLETE
Total Hyb Time 21:05
End PGM/Main Menu
```

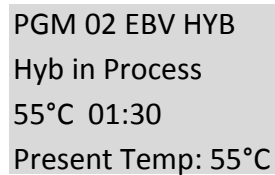
Hybridization Only:

Display indicates present temperature of the slides.



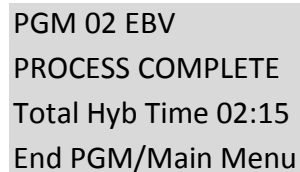
Please Wait
Heating to Hyb 55°C
Present Temp: 45°C

Once temperature reaches hybridization set point, the ThermoBrite will count down from the set time.



PGM 02 EBV HYB
Hyb in Process
55°C 01:30
Present Temp: 55°C

Upon program completion the ThermoBrite will beep five times and the display will show **“PROCESS COMPLETE”**. Hybridization temperature will be maintained until **“End PGM/Main Menu”** is accepted by pressing **“Enter”** button. Before pressing **“Enter”** button, remove slides from instrument for further processing. If **“End PGM/Main Menu”** is not accepted within the first minute of program completion, the ThermoBrite will add the time accrued since completion of the original hybridization program to the time of the original hybridization program to give the Total Time at the hybridization temperature.



PGM 02 EBV
PROCESS COMPLETE
Total Hyb Time 02:15
End PGM/Main Menu

Fixed Temp:

Display indicates present temperature of slides.

```
Please Wait  
Heating to Fxd: 65°C  
Present Temp: 30°C
```

Once temperature reaches target, timer counts elapsed time.

```
PGM 03 APPL FIXED  
Fixed Temp: 65°C  
Reset Timer 01:18:10  
End PGM/Main Menu
```

To end program, use the arrow keys to move to “**End PGM/Main Menu**” line and press “**Enter**” button to accept.

NOTE: If ambient temperature is programmed the fan will continually cycle until the program is aborted. The lowest temperature that may be programmed is ambient + 5°C or 30°C (whichever is higher).

NOTE: The temperature can be increased or decreased as the unit is running by using the up/down arrows from the “**Fixed Temp**” line.

Abort Program in Process

To end a program in process press “**STOP**” button, three beeps will sound.

Use arrows to move cursor to “**Yes**” line and press “**Enter**” button to accept. The program will continue to run until “**Yes**” or “**No**” has been accepted.

NOTE: The ThermoBrite prompts, “**Are You Sure?**” This measure is to prevent accidental disruption of a program in process.

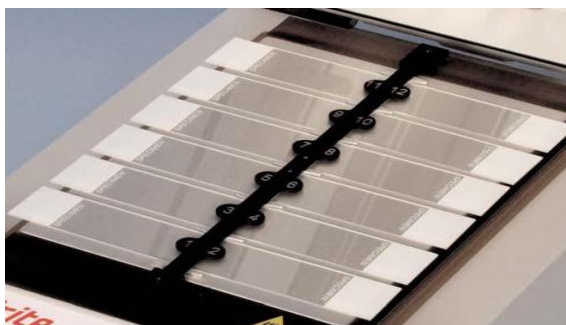
ABORTING!
Are You Sure?
No
Yes – Main Menu

Fan will turn on. If the slide temperature is above 37°C, the fan will cool to 37°C.

Slide Installation

Temperature uniformity across the heater is within 1°C of set point across all slide positions. The ThermoBrite allows up to a maximum of 12 slides to be installed. When prompted simply lift the lid and load the slide(s) onto the plate. The frosted edge of the slides(s) should hang over the edge of the plate. Move the slide toward the middle of the plate by positioning the slide(s) into the slide separator.

NOTE: Be sure the slide(s) rests flat on the heater plate before closing the lid or the lid may break slide(s).



Humidity Cards

Located in the lid, Humidity Cards act to prevent evaporation of probe mixture from prepared slides.

Instructions for use:

Saturate the Humidity Cards with distilled or deionized water (~13 mL for new cards).

Instructions for re-use:

- After the run has ended, keep the lid closed between runs to avoid drying out of the cards.
- Do not reuse cards that have been dried out after initial saturation.
- Resaturate the cards before starting a new run.
- The amount of water needed to resaturate the card depends on the program and the time in between runs.
- For each subsequent program, resaturate the cards with 3-10 mL to maintain moisture.
- Cards should be replaced every 1-2 weeks as they will deteriorate over time and with use.

Replacement instructions:

To replace cards, lift lid and remove. Slide card into slot positions and allow tabs in lid to support cards.



CAUTION: Do NOT use paper towels or any other filter card in card positions. This may change the humidity and may decrease the intensity of the probe, potentially causing assay failure.

Section 5

Programming

Overview

The ThermoBrite is capable of storing 40 different programs. Each program can be one of three program types:

- Denaturation and Hybridization (Denat & Hyb),
- Hybridization Only (Hyb Only) or
- Fixed Temperature (Fixed Temp).

Programming is simple. From the Main Screen, arrow down to “**Create a PGM**”, choose a program type and follow screen prompts to enter run times and set temperatures. The ThermoBrite maintains set temperatures for the duration of the protocol.

Run a PGM	Select PGM Type
Edit a PGM	Denat & Hyb
Create a PGM	Hyb Only
Present Temp: 37°C	Fixed Temp

NOTE: At the end of the program the display will show “Process Complete”. The temperature will be maintained and the timer will continue to run until End PGM/Main Menu is accepted by pressing “Enter” button.

NOTE: If all 40 program numbers have been used “Create a PGM” line in the Main Menu will no longer appear. An existing program must be edited, see “Editing a Program”.

Predefined Limits

Program Mode	Temperature Range	Timer Limits
Denature	50°C to 99°C	00:00-00:30 minutes
Hybridization	Room temp: 30°C to 70°C	00:00 - 99:59 hours and minutes
Fixed Temp	Room temp: 30°C to 99°C	00:00 - 99:59 hours and minutes

Creating a Denaturation and Hybridization Program (Denat & Hyb)

From the Main Screen, use the arrow keys to move cursor to **“Create a PGM”** and press **“Enter”** button to accept.

Cursor highlights **“Denat & Hyb”** line; press **“Enter”** button to accept.
The ThermoBrite will advance to the next available program number.

The ThermoBrite allows the user to create a program name. The cursor highlights the first name character position. Use the arrow keys to move through character set and press **“Enter”** button to accept the characters. All 10 character positions must be filled. Press **“Enter”** button to accept blank characters. For numeric characters use keypad 0-9.

Character set: A-Z; 0-9; period, - and blank (**“Enter”** button or move arrow)

The cursor will advance to **“Denat Temp”**. With numeric keypad enter a two-digit temperature value in degrees Celsius (50-99°C).

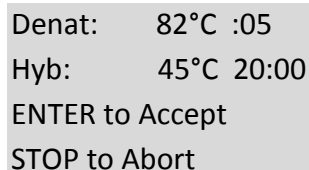
The cursor advances to **“Denat Time”**. With numeric keypad enter a two-digit time value in minutes (0 – 30).

The cursor advances to **“Hyb Temp”**. With numeric keypad enter a two-digit temperature value in degrees Celsius (30-70°C). The instrument allows a temperature of 30°C or ambient temp + 5°C (whichever is higher) for the lowest hybridization temperature.

For room temperature hybridization (ambient temp +5°C) enter the two-digit value 00.

The cursor advances to **“Hyb Time”**. With the numeric keypad enter a two-digit time value in hours (0 – 99) followed by a two-digit value in minutes (0-59).

The Display will now show entered program values. The cursor highlights **“Enter to Accept”** line.



```
Denat: 82°C :05
Hyb: 45°C 20:00
ENTER to Accept
STOP to Abort
```

Press **“Enter”** button to accept the program values; or press **“Backspace”** button to return to previous screen to modify program values; or press the **“Stop”** button to abort.

Creating a Hybridization Only Program (Hyb Only)

From the Main Screen, use the arrow keys to move cursor to **“Create a PGM”** and press **“Enter”** button to accept.

The cursor highlights **“Hyb Only”** line; press **“Enter”** button to accept. The ThermoBrite will advance to the next available program number.

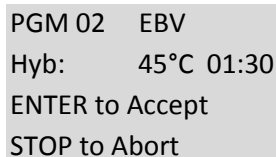
The ThermoBrite allows the user to create a program name. The cursor highlights the first name character position. Use the arrow keys to move through character set and press **“Enter”** button to accept the characters. All ten character positions must be filled. Press **“Enter”** button to accept blank characters. For numeric characters use keypad 0-9.

Character set: A-Z; 0-9; period, - and blank (**“Enter”** button or move arrow).

The cursor advances to **“Hyb Temp”**. With numeric keypad enter a two-digit temperature value in degrees Celsius (30-70°C). The instrument allows a temperature of 30°C or ambient temperature + 5°C (whichever is higher) for the lowest hybridization temperature. For room temperature hybridization (ambient temperature +5°C) enter the two-digit value 00.

The cursor advances to “**Hyb Time**”. With the numeric keypad, enter a two-digit time value in hours (0 – 99) followed by a two-digit value in minutes (0-59).

The display will now show entered program values. The cursor highlights “**Enter to Accept**” line.



```
PGM 02  EBV
Hyb:    45°C 01:30
ENTER to Accept
STOP to Abort
```

Press “**Enter**” button to accept the program values; or press “**Backspace**” button to return to previous screen to modify program values; or press “**Stop**” button to abort.

Creating a Fixed Temperature Program (Fixed Temp)

From the Main Screen, use the arrow keys to move the cursor to “**Create a PGM**” and press “**Enter**” button to accept.

With the arrow keys, move the cursor to “**Fixed Temp**” line and press “**Enter**” button to accept. The ThermoBrite will advance to the next available program number.

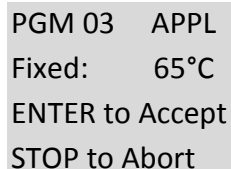
The display will now show entered program values. The cursor highlights “**Enter to Accept**” line.

The ThermoBrite allows the user to create a program name. The cursor highlights the first name character position. Use the arrow keys to move through character set and press “**Enter**” button to accept the characters. All 10 character positions must be filled. Press “**Enter**” button to accept blank characters. For numeric characters, use keypad 0-9.

Character set: A-Z; 0-9; period, - and blank (“**Enter**” button or move arrow).

The cursor advances to “**Fixed Temp**”. With numeric keypad, enter a two-digit temperature value in degrees Celsius (30-99°C). The instrument allows a temperature of 30°C or ambient temperature + 5°C (whichever is higher) for the lowest fixed temperature. For room temperature fixed (ambient temperature + 5°C) enter the two- digit value 00.

The display will now show entered program values. Cursor highlights “Enter to Accept” line.



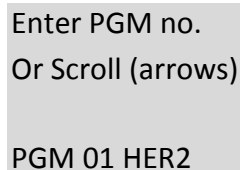
```
PGM 03  APPL
Fixed:   65°C
ENTER to Accept
STOP to Abort
```

Press “Enter” button to accept the program values; or press “Backspace” button to return to previous screen to modify program values; or press “Stop” button to abort.

Editing a Program

From the Main Screen, use the arrow keys to move the cursor to “Edit a PGM” and press “Enter” button to accept.

With the arrow keys, scroll through the program numbers 1 to 40 / program names. *If no programs have been saved, advance to programming section of this manual.* To accept, press “Enter” button.



```
Enter PGM no.
Or Scroll (arrows)

PGM 01 HER2
```

The cursor highlights existing program type: “Denat & Hyb”, “Hyb only” or “Fixed Temp”. Press “Enter” button to accept existing program type or use arrow keys to move the cursor to a different program type. Press “Enter” button to accept.

Use the numeric keypad to enter new values for Temperatures and/or Time. The procedure and limits are the same as those for creating a program.

NOTE: The ThermoBrite allows 40 programs to be entered and stored. Once all program numbers have been used, an existing program must be edited.

Section 6

Maintenance

Overview

Leica Biosystems recommends that instrument operators perform periodic inspections and maintenance on all Leica Biosystems instruments. Contact Leica Biosystems's technical support department or distributor if, at any time, the instrument is not functioning properly. Contact Leica Biosystems's technical support or distributor for more information.



WARNING: Unplug the ThermoBrite from the wall outlet before performing maintenance.



CAUTION: Do not expose the ThermoBrite to strong or concentrated acids, bases, esters, aromatic or halogenated hydrocarbons, ketones or strong oxidizing agents.

Cleaning

- The ThermoBrite is supplied with a removable slide separator.
- To remove, pull the separator back releasing the top from its holder (the separator is spring loaded to hold it in position).
- Lift the slide separator up and remove from spring holder at bottom.
- Set on the bench top.
- Clean the outside surfaces and switch overlay panel with a water-dampened cloth and mild detergent.
- Clean the inner surface with a mild detergent, and if necessary, a disinfectant, wiping surfaces with a dampened cloth using 70% alcohol or 10% bleach solution.

To replace a damaged or lost slide separator, contact customer service.

REF 3801-004928-001 – Assy Separator



CAUTION: Do NOT use harsh abrasives or scouring pads, this will scratch the heating surface.

Fan Filter

The fan filter, located on the underside of the ThermoBrite, should be removed from the ThermoBrite, rinsed with water and air-dried as needed. When dry, reinsert fan filter back into the underside of the ThermoBrite.

Temperature Verification

Leica Biosystems recommends users verify temperature of the ThermoBrite with the ThermoBrite Temperature Verification Kit. The ThermoBrite Temperature Verification Kit is available as an accessory to the ThermoBrite, and is purchased separately.

REF 3800-006418-001 - *ThermoBrite Temperature Verification Kit*

The ThermoBrite Verification Kit is a digital thermometer with a Type K thermocouple attached to a standard glass slide. Users should adhere to local guidelines for frequency of temperature verification.

Temperature Verification Kit Instructions For Use:

1. Insert the battery per thermometer user guide to activate the digital thermometer.
2. Insert the Type K thermocouple into T1 digital thermometer; be sure the +/- match up on both the meter and the thermocouple. Refer to the thermometer's user guide for additional information.
3. Insert two humidity cards into the ThermoBrite lid and saturate the cards with distilled/deionized water.
4. Place the glass slide onto the ThermoBrite with the thermocouple facing up, making sure the glass slide is in full contact with the hot plate.
5. Close the ThermoBrite cover.
6. Turn on the digital thermometer by pressing the button with the red circle.
7. Turn on the ThermoBrite and allow the ThermoBrite to warm up for 30 seconds.
8. Set the ThermoBrite temperature to a fixed temperature.
9. Once the fixed temperature is reached, wait up to 2 minutes for the temperature to equilibrate.
10. Repeat steps 8 and 9 to measure different temperatures, if desired.
11. The temperature readout on the digital thermometer should be within +/- 1°C of the ThermoBrite display.



CAUTION: If the temperature readout on the digital thermometer is not within +/- 1°C, contact your local technical support.

NOTE: The ThermoBrite Temperature Verification Kit's digital thermometer should be recalibrated per manufacturer recommendations. Refer to thermometer's user guide for more information.

Service

There are no user-serviceable parts except for fuses and the cover gasket. Refer all other service to technical support. Reference the Leica Biosystems Warranty for further instruction.

Decontamination is required before returning instrument for service

Any instrument or accessory containing accumulated blood and/or other biological or chemical deposits must be cleaned prior to shipment to the manufacturer/dealer for service. This decontamination is required by Federal Law (Title 48 and 49 of the Federal Regulations) and in accordance with the Environmental Protection Agency's Regulations for Biohazard Waste Management. Leica personnel cannot perform this decontamination.

Fuses:

REF 3801-004915-001 Fuse 3.0 A (120V)

REF 3801-004915-002 Fuse 1.6A (240V)

Fuses are located in the rear of the ThermoBrite between the main power plug and the On/Off switch.



Fuse Drawer



Fuse(s)

Fuse Replacement Instructions:

Unplug the ThermoBrite. Use a small flat screwdriver to carefully disengage the two snap-locks securing the fuse holder. Remove the fuse holder and inspect the type and value of the fuse. Replace existing fuse(s) with the same type and value. Insert the fuse drawer and push until two snaps are heard.

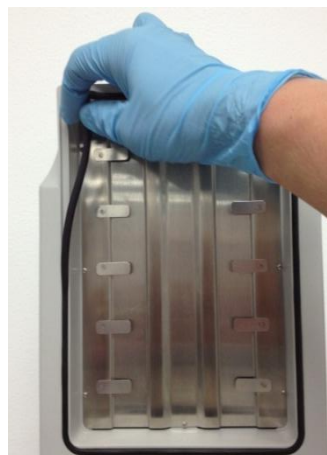
Cover Gasket:

REF 3801-004931-001 Cover Gasket

The cover gasket is located on the underside of the lid.



Cover Gasket Removal



Cover Gasket Insertion



Cover Gasket Replacement Instructions:

Remove the existing cover gasket from the groove in the lid underside. Insert the new cover gasket with fingers. Be sure it is properly seated in the groove.

Troubleshooting Guide

Issue	Possible Cause/Remedy
Unit does not turn on or no power	Check both cord ends are plugged in
	Check fuses located on rear panel next to On/Off switch If necessary, replace with same type and value (see label on back of instrument)
	If not resolved, contact technical support
Poor results on slides	Verify programmed protocol against probe manufacturer's recommendation
	Ensure Humidity Cards are in place and saturated with distilled or deionized water
	Humidity Cards should be replaced every 1-2 weeks as cards cease retaining water
	Verify the ThermoBrite is heating using the Temperature Verification Kit
	Ensure lid is properly closed and verify that the cover gasket seal is properly seated and free of damage
	Ensure the ThermoBrite has the proper amount of ventilation clearance
	Ensure the fan filter is clean and free of debris
Temperature on display does not match surface temperature of slides	Clean the slide heating plate with 70% ethanol or 10% bleach; remove any sealant/rubber cement
	Ensure the thermometer used to verify the temperature has current calibration
	If not resolved, contact technical support

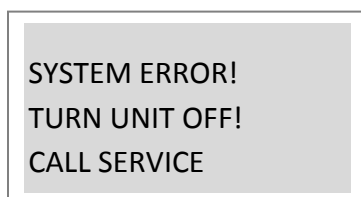
Issue	Possible Cause/Remedy
Cannot set temp above 70°C	Verify the program mode, you cannot exceed preset limits
	Denature Limits: 50-99°C, 00:00-00:30 minutes Hybridization Limits: 30-70°C, 00:00-99:59 hours and minutes (Note: hotplate will hold 37°C after protocol end) Fixed Temp Limits: 30-99°C, 00:00-99:59 hours and minutes
Can't find "Create a Program"	If the maximum of 40 programs have been stored, only an existing program can be edited.
Keypad not functioning properly	Contact technical support
High temperature error	Ensure there is no obstruction of the fan on the underside of the unit
	Ensure the unit is positioned a minimum of 12" (30 cm) from the wall
	Ensure the ambient temperature is not greater than the lowest programmed temperature, + 5°C
	If not resolved, contact technical support
Loose cover gasket	Ensure rubber cement/sealant is not causing cover gasket to stick; clean and reinsert gasket
	Replace with a new cover gasket

Audible Indicators - ERROR

Three short beeps:	Entering of illegal or non-functioning keystrokes.
Low tone beep:	Attempt to enter a value out of acceptable range.
Continuous beep:	Instrument is not performing within acceptable range or program condition. Turn off main power and restart. If beep continues, discontinue use and contact technical support.

Error Messages

If the instrument cannot achieve a set temperature by heating within 10 minutes an error message appears to inform user to turn unit off and call service. A constant beep will sound.



If the instrument cannot measure the temperature, the software will automatically turn off the heating. An error message will appear to inform the user to turn off the unit and call service. A constant beep will sound.

High ambient temperature condition:

The instrument will attempt to achieve process set temperatures. However, if the cooling fan cannot achieve the set temperature within 10 minutes, an error message will appear to inform the user that the ambient temperature is high. A constant beep will sound. The counter will continue to count. The present temperature will be displayed. Hitting the “Stop” button will allow the user to abort the process. A new screen will be displayed asking user if they are sure they want to abort.

For Hyb Only:

Please Wait
Cooling to Hyb --°C
Present Temp --°C
 (“Ambient Temp High! Flashes
alternately on this line)

For Fixed Only:

Please Wait
Cooling to Fxd --°C
Present Temp --°C
 (“Ambient Temp High! Flashes
alternately on this line)

Abort Screen Message:

ABORTING!
Are You Sure?
No
Yes – Main Menu

If the ambient temperature changes during a process and causes the instrument process set temperature to change beyond the +/- 1°C specification for more than two minutes, a message will appear to inform the user that the ambient temperature is high. A constant beep will sound. The counter will continue to count. The present temperature will be displayed. Hitting the “Stop” button will allow user to abort the process. A new screen will be displayed asking user if they are sure they want to abort.

For Hyb Only:

```
PGM – namexxxxxx  
Hyb In Process (“Ambient Temp  
High!” flashes alternately on this  
line)  
Hyb--°C --:--  
Present Temp: --°C
```

For Fixed Only:

```
PGM – namexxxxxx  
Fxd Temp --°C (“Ambient Temp  
High!” flashes alternately on this  
line)  
Reset Timer 00:00:00  
End PGM/Main Menu
```

Abort Screen Message:

```
ABORTING!  
Are You Sure?  
No  
Yes – Main Menu
```

If the ambient temperature changes after a process is completed, but before the user removes the slides and causes the instrument process set temperature to change beyond the +/- 1°C specification for more than two minutes a message will appear to inform the user that the ambient temperature is high. A constant beep will sound. The counter will continue to count. The present temperature will be displayed. Hitting the “**Stop**” button will allow user to abort the process. A new screen will be displayed asking user if they are sure they want to abort.

For Hyb Only:

```
PGM – namexxxx  
PROCESS COMPLETE (“Ambient  
Temp High!” flashes alternately on  
this line)  
Total Hyb Time --:--  
End PGM/Main Menu
```

Abort Screen Message:

```
ABORTING!  
Are You Sure?  
No  
Yes – Main Menu
```

NOTE: If 40 programs have been created or edited the software will blank out the “**Create a PGM**” mode on the main menu screen. This will only allow users to edit existing programs.

```
Run a PGM  
Edit a PGM  
  
Present Temp:--°C
```

Section 7

Specifications

Product No.	3800-004852-001	3800-004852-002
Model No.	S500-12	S500-24
Capacity	Up to 12 slides	
Temperature Range	30°C -99°C Lowest programmable temperature is 30°C or ambient temperature+5°C (whichever is higher)	
Processing Time	00:00 - 99:59 hr:min	
Number of Programs	40	
Ramp Time	37-95°C in less than 3 minutes	
Cooling Time	95-45°C in less than 6 minutes	
Electrical	120 VAC 50/60 Hz @ 3.0 A	240 VAC 50/60 Hz @ 1.6 A
Dimensions	Depth 45.1 cm/17.8 in Width 22.8 cm/9.0 in Height 13.5 cm/5.3 in Weight 8.5 kg/18.7 lb	
Environmental	Indoor Use	
	Altitude up to 2000m	
	Temperature 15°C to 40°C	
	Maximum relative humidity 80% for temperatures up to 15°C decreasing linearly to 50% relative humidity at 40°C	
	Main supply voltage fluctuations not to exceed +/- 10% of the nominal voltage transient over-voltages according to installation category II Pollution degree 2	

Biohazard References

1. NCCLS. "Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Second Edition." NCCLS document M29-A2 [ISBN 1-56238-453-8]. NCCLS, 940 West Valley Rd, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.
2. CDC. Recommendations for prevention of HIV transmission in health care settings. MMWR (Suppl. No. 2S):2S-18S, 1987.
3. CDC. Updated: US Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV and Recommendations for Post Exposure Prophylaxis. Appendix A and B. MMWR 50 (RR-11): 1-42, June 29, 2001.
4. NCCLS. Fluorescence *in situ* Hybridization (FISH) Methods for Genetics; Approved Guideline. NCCLS document MM7-A (ISBN 1-56238-524-0). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

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