

# Contents

<b>Preface</b> . . . . .	<b>1-1</b>
The COBE Spectra Apheresis System <i>Operator's Manual</i> . . .	1-1
The COBE Spectra <i>Essentials</i> . . . . .	1-2
COBE Spectra <i>Essentials</i> Contents . . . . .	1-2
The COBE Spectra Procedural Guides . . . . .	1-6
Document Conventions . . . . .	1-7
Definitions . . . . .	1-7
Text Conventions . . . . .	1-7
Abbreviations Used in these Guides . . . . .	1-8
Indications . . . . .	1-10
Contraindications . . . . .	1-10
Warnings . . . . .	1-10
For Both the Spectra System and the SpectraTHERM Warmer . . . . .	1-10
For the Spectra System Only . . . . .	1-11
For the SpectraTHERM Warmer Only . . . . .	1-13
Cautions . . . . .	1-15
For Both the Spectra System and the SpectraTHERM Warmer . . . . .	1-15
For the Spectra System Only . . . . .	1-16
For the SpectraTHERM Warmer Only . . . . .	1-17
Adverse Effects . . . . .	1-19
Symbols and Certifications . . . . .	1-20
For the COBE Spectra Apheresis System . . . . .	1-20
For the COBE SpectraTHERM™ Blood/Fluid Warmer . . . . .	1-21
Service Information . . . . .	1-22
For Service or to order Parts in the United States, contact: . . . . .	1-22

For Parts and Service outside the United States,  
contact: . . . . . 1-22

<b>Introduction</b> . . . . .	<b>2-1</b>
Spectra System Description . . . . .	2-2
Spectra System Components . . . . .	2-4
Centrifuge Chamber . . . . .	2-5
Front Panel . . . . .	2-8
Control Panel . . . . .	2-12
Return Flow Controller . . . . .	2-18
Disposable Tubing Sets . . . . .	2-23
Functional Description . . . . .	2-25
Separation . . . . .	2-25
Fluid Flows (General) . . . . .	2-26
Modes of Operation . . . . .	2-27
Anticoagulation . . . . .	2-28
Automatic and Manual Mode . . . . .	2-29

## **Installing, Moving, and Returning the Spectra System** . . . . . **3-1**

Environmental Requirements . . . . .	3-1
Packing List . . . . .	3-2
Storage . . . . .	3-2
Return Flow Controller . . . . .	3-3
Packing List . . . . .	3-3
Installing the Return Flow Controller . . . . .	3-3
Moving the Spectra System . . . . .	3-7
Returning the COBE Spectra Apheresis System . . . . .	3-7

## **Loading and Removing the Disposable Tubing Set and other common operations . . . . . 4-1**

Setting up the Spectra System . . . . .	4-1
Removing and Installing the Filler . . . . .	4-2
Loading the Disposable Tubing Set . . . . .	4-4
Placing Tubing on the Front Panel . . . . .	4-4
Installing the Channel in the Filler . . . . .	4-7
Starting Rinseback . . . . .	4-11
Removing the Disposable Tubing Set . . . . .	4-14

## **Software Options and Configuration . . . . . 5-1**

Menu/Software Navigation Basics . . . . .	5-2
Configuring the Spectra System . . . . .	5-2
Configuring the Height/Weight Units . . . . .	5-3
Configuring the Decimal Point/Thousands Separators . . . . .	5-3
Configuring the AC Infusion Rate . . . . .	5-4
Configuring Total Plasma Removed (Platelet Collection Procedures) . . . . .	5-4
Configuring Procedure End Points . . . . .	5-4
Configuring the Inlet:AC Ratio . . . . .	5-5
Configuring the Harvest and Chase Volume (AutoPBSC Procedures) . . . . .	5-6
Configuring the High Flow (ELP Procedures) . . . . .	5-6
Configuring the Centrifuge Step Down (ELP Procedures) . . . . .	5-6
Enabling the Single-Needle Option . . . . .	5-6
Enabling the LeukoReduction System . . . . .	5-6
Configuring the Yield Scaling Factor (YSF) . . . . .	5-6
Other Important Options . . . . .	5-7
Entering Donor/Patient Data . . . . .	5-7
During Prime . . . . .	5-7

Donor/Patient Data Entry After Prime . . . . .	5-7
Changing Entered Data During the Run . . . . .	5-9
The MENU ON/OFF Key . . . . .	5-10
Data Entry During the Run . . . . .	5-10
Pressure Display . . . . .	5-12
CCM . . . . .	5-13
Air Remove . . . . .	5-14
Strobe . . . . .	5-15
Configuration . . . . .	5-15
SN (Single-Needle) . . . . .	5-15
The VALVE Key . . . . .	5-16
First Valve Selection Screen . . . . .	5-16
Invalid Valve Position Changes . . . . .	5-19
The CHANGE MODE Key . . . . .	5-20
Mode Change Selection Screen . . . . .	5-20
Invalid Mode Changes . . . . .	5-20

## **Automatic and Manual Mode . . . . . 6-1**

Automatic Mode . . . . .	6-2
Manual Mode . . . . .	6-4
Single-Needle Flow Control . . . . .	6-6

## **Alarm Tests . . . . . 7-1**

Overview . . . . .	7-1
Starting the Alarm Tests . . . . .	7-2
Access Pressure Alarm Test . . . . .	7-3
Primary Return Air Alarm Test . . . . .	7-3
Return Pressure Alarm Test . . . . .	7-3
Secondary Return Air Alarm Test . . . . .	7-3
Leak Detector Alarm Test and Door Safety System Test . . . . .	7-4

<b>Anticoagulation</b> . . . . .	<b>8-1</b>		
Terminology . . . . .	8-2		
System Operation and Anticoagulant Management . . . . .	8-2		
AC Infusion . . . . .	8-2		
Inlet:AC Ratio . . . . .	8-4		
Managing Symptomatic Hypocalcemia . . . . .	8-5		
Managing Clumping . . . . .	8-6		
<b>Fluid Volumes</b> . . . . .	<b>9-1</b>		
Fluid Shifts . . . . .	9-4		
Extracorporeal Volume . . . . .	9-6		
Determining Net Additional Saline Returned to Donor/Patient . . . . .	9-6		
<b>General Maintenance</b> . . . . .	<b>10-1</b>		
Operator Maintenance of the COBE Spectra Apheresis System . . . . .	10-1		
Cleaning . . . . .	10-1		
Disinfecting . . . . .	10-2		
Once a Week . . . . .	10-2		
Every Month . . . . .	10-2		
Every Six Months . . . . .	10-4		
Operator Maintenance of Return Flow Controller . . . . .	10-4		
Cleaning . . . . .	10-4		
Disinfecting . . . . .	10-4		
Technician Maintenance for COBE Spectra Apheresis System . . . . .	10-5		
Internal Adjustments . . . . .	10-6		
Preventive Maintenance . . . . .	10-6		
<b>Helpful Hints and Recovery Procedures</b> . . . . .	<b>11-1</b>		
Correcting Incorrectly Entered Disposable Tubing Set . . . . .	11-3		
		Using an Alternative Single-Pass Prime Procedure . . . . .	11-3
		Speeding or Slowing Rinseback . . . . .	11-5
		Determining Net Additional Saline Returned to Donor/Patient . . . . .	11-5
		Calculating Collect/Plasma Bag Tare Weights . . . . .	11-6
		Calculating Spectra System Fluid Volumes . . . . .	11-6
		Manually Overriding the Centrifuge Cover and Door Latches . . . . .	11-6
		Manual Rinseback Procedure . . . . .	11-8
		Power-Up Tests Failure . . . . .	11-9
		Repositioning the Access Pressure Sensor Diaphragm . . . . .	11-10
		Repositioning the Return Pressure Sensor Diaphragm . . . . .	11-11
		Dual-Needle Procedure . . . . .	11-11
		Single-Needle Procedure . . . . .	11-12
		<b>General Alarms and Troubleshooting</b> . . . . .	<b>12-1</b>
		Safety System . . . . .	12-1
		Shutdown Alarms . . . . .	12-2
		Warnings and Operator-Attention Alarms . . . . .	12-2
		Multiple Alarms . . . . .	12-3
		Repeated Single-Needle Alarms . . . . .	12-3
		Clearing Alarms . . . . .	12-3
		Warnings and Alarms . . . . .	12-4
		Invalid Valve Position Changes . . . . .	12-7
		AC infusion rate configuration was changed last run . . . . .	12-9
		AC infusion rate exceeds allowable limits . . . . .	12-10
		AC PUMP ERROR! . . . . .	12-11
		ACCESS PRESSURE ERROR! . . . . .	12-12
		ACCESS PRESSURE LOW . . . . .	12-13
		ACCESS PRESSURE LOW! Check access line and needle . . . . .	12-14
		ACCESS PRESSURE OCCLUSION ERROR! . . . . .	12-15

ACCESS PRESSURE SENSOR DID NOT REACH		NO SALINE SEEN AT INLET AIR SENSOR! . . . . .	12-42
ALARM LIMIT!. . . . .	12-16	NO SALINE SEEN AT RETURN AIR SENSOR!. . . . .	12-43
ACCESS PRESSURE SENSOR NOT ZERO!. . . . .	12-17	OUT OF ANTICOAGULANT!. . . . .	12-44
AIR IN INLET CHAMBER! . . . . .	12-18	OVERTORQUE ON _____ PUMP!. . . . .	12-45
AIR IN RETURN CHAMBER! . . . . .	12-19	Plasma and collect pumps running faster than inlet pump .	12-46
ALARM TEST FAILED!. . . . .	12-20	Plasma collection volume exceeds pump speed limit . . . . .	12-46
CCM CALIBRATION FAILURE . . . . .	12-20	PLASMA PUMP ERROR! . . . . .	12-47
CCM not operational - this run only . . . . .	12-21	PLASMA VALVE NOT OPERATING CORRECTLY!. . . . .	12-48
CENTRIFUGE COVER OPEN! . . . . .	12-22	POWER INTERRUPTED! . . . . .	12-50
CENTRIFUGE PRESSURE ERROR! . . . . .	12-23	PUMPS OFF OVER 3 MINUTES. . . . .	12-50
CENTRIFUGE PRESSURE HIGH! . . . . .	12-24	PUMPS OFF TOO LONG . . . . .	12-51
Centrifuge up to speed. . . . .	12-26	PUMPS OFF TOO LONG! Centrifuge turned off for donor/ patient safety. . . . .	12-51
Check the CCM for proper loading. . . . .	12-26	Ratio configuration was changed last run. . . . .	12-52
COLLECT PUMP ERROR!. . . . .	12-27	RBCs DETECTED. . . . .	12-52
COLLECT VALVE NOT OPERATING		RBCs LOST!. . . . .	12-53
CORRECTLY!. . . . .	12-28	Restarting centrifuge . . . . .	12-53
Diagnostic failure prevents operation. . . . .	12-29	RETURN FLOW TOO SLOW! . . . . .	12-54
Disconnect donor/patient . . . . .	12-29	RETURN PRESSURE HIGH . . . . .	12-55
Donor/Patient Disconnected???. . . . .	12-30	RETURN PRESSURE HIGH! Check return line and needle . . . . .	12-56
Ensure return flow scale is in the prime position . . . . .	12-30	RETURN PRESSURE HIGH! Decrease return flow scale	12-58
EXCESSIVE LOAD ON CENTRIFUGE!. . . . .	12-31	RETURN PRESSURE OCCLUSION ERROR! . . . . .	12-59
EXCESSIVE VIBRATIONS! . . . . .	12-32	RETURN PRESSURE SENSOR DID NOT REACH	
FAILURE #3: __Display Comm. . . . .	12-33	ALARM LIMIT!. . . . .	12-60
FAILURE #20: _____ . . . . .	12-34	RETURN PRESSURE SENSOR NOT ZERO!. . . . .	12-61
FAILURE #__: _____ . . . . .	12-35	RETURN VALVE BAD . . . . .	12-61
FAILURE IN -5V POWER SUPPLY! . . . . .	12-35	RETURN VALVE POSITION ERROR! . . . . .	12-62
FLUID LEAK IN CENTRIFUGE!. . . . .	12-36	Service mode enabled. . . . .	12-62
INLET AND AC PUMP FLOWS NOT BALANCED!. . . . .	12-38	Total plasma collected (collect and plasma bags) exceeds specified limit . . . . .	12-63
INLET PUMP ERROR! . . . . .	12-39	Valve held in place by alarm! . . . . .	12-63
INVALID VALVE MOTION! . . . . .	12-40		
_____ key failure . . . . .	12-40		
NO RBCs DETECTED . . . . .	12-41		

Valve motion canceled . . . . . 12-63  
 Valve will be moved at end of return cycle . . . . . 12-63  
 WASTE VALVE NOT OPERATING CORRECTLY! . . . . . 12-64

**Specifications . . . . . 13-1**

Physical . . . . . 13-2  
 Environmental . . . . . 13-2  
 AC Power . . . . . 13-3  
 Electrical Safety . . . . . 13-3  
 Safety Certifications . . . . . 13-4  
 Pump Flow Rates and Speeds . . . . . 13-4  
 Return Flow Controller . . . . . 13-5  
 Disposable Tubing Sets . . . . . 13-6  
 Residual Plasma Volumes . . . . . 13-7  
 Centrifuge . . . . . 13-7  
 Safety . . . . . 13-7  
 Sensors . . . . . 13-8  
 AC Pump Alarm Responses . . . . . 13-10

**Data Input Limits . . . . . 14-1**

**COBE SpectraTHERM™ Blood/Fluid Warmer**

**Operator's Guide . . . . . 15-1**

Indications for Use . . . . . 15-1  
 Contraindications . . . . . 15-1  
 Warnings . . . . . 15-1  
 Cautions . . . . . 15-1  
 Adverse Effects . . . . . 15-2  
 Symbols and Certification . . . . . 15-2  
 Return of Used Product . . . . . 15-2  
 Introduction . . . . . 15-2  
 System Description . . . . . 15-3

Installing the SpectraTHERM Warmer . . . . . 15-6  
 Environmental Requirements . . . . . 15-6  
 Packing List . . . . . 15-6  
 Installation . . . . . 15-6  
 Storage . . . . . 15-7  
 Operating the SpectraTHERM Warmer . . . . . 15-7  
 Equipment and Supplies . . . . . 15-7  
 Basic Setup and Use Instructions . . . . . 15-8  
 Installing the SpectraTHERM Tubing Set . . . . . 15-9  
 Starting the SpectraTHERM Warmer . . . . . 15-18  
 Priming the Warmer Tubing . . . . . 15-19  
 Performing Apheresis Procedures . . . . . 15-19  
 Turning Off the SpectraTHERM Warmer . . . . . 15-20  
 Removing the SpectraTHERM Tubing Set . . . . . 15-20  
 Troubleshooting . . . . . 15-21  
 Heat Exchanger has exceeded Safety Cutoff  
 Temperature . . . . . 15-22  
 Warmup exceeds five minutes . . . . . 15-23  
 Power to SpectraTHERM Warmer cut off briefly . . . . . 15-24  
 Green Power Switch light is On, but SpectraTHERM  
 Warmer does not heat . . . . . 15-24  
 Alarm occurs while Heat Exchanger is heating . . . . . 15-24  
 After Alarm, SpectraTHERM Warmer can be restarted  
 but only when temperature is between 20 and 35° C . . . . . 15-25  
 Heat Exchanger temperature exceeds 37° C . . . . . 15-25  
 Current Temperature Display obviously incorrect . . . . . 15-26  
 SpectraTHERM Warmer dropped or its housing is  
 damaged . . . . . 15-26  
 Power to SpectraTHERM Warmer cut off . . . . . 15-27  
 SpectraTHERM Warmer is plugged in but green Power  
 Switch light is off . . . . . 15-27  
 Sales and Service Information . . . . . 15-28

Maintenance and Quality Control . . . . . 15-29

- Operator Maintenance . . . . . 15-29
- Quality Control . . . . . 15-29
- Repairing the SpectraTHERM Warmer . . . . . 15-31
- Internal Adjustments of SpectraTHERM Warmer . . . . . 15-31

Specifications . . . . . 15-32

- Physical . . . . . 15-32
- Environmental . . . . . 15-32
- AC Power . . . . . 15-32
- Electrical Safety . . . . . 15-33
- Safety Certifications . . . . . 15-33
- SpectraTHERM Performance Data . . . . . 15-34
- SpectraTHERM Performance Data . . . . . 15-36
- SpectraTHERM Tubing Set . . . . . 15-36
- Safety . . . . . 15-36

**Index . . . . . i-1**

**The Spectra Seal Safe System™ . . . . . 16-1**

- Components . . . . . 16-2

Installation . . . . . 16-3

Operation . . . . . 16-4

- Cutting and Sealing . . . . . 16-4
- Sealing Only . . . . . 16-7

Maintenance . . . . . 16-7

- Topical Cleaning of the Cutter/Sealer Jaw Cavity . . . . . 16-7
- Servicing . . . . . 16-12

Splash Guards . . . . . 16-12

- Replacing a Splash Guard . . . . . 16-12

Specifications . . . . . 16-14

- Physical Specifications . . . . . 16-14
- Environmental Specifications . . . . . 16-14
- Performance Specifications . . . . . 16-14
- Safety Certifications . . . . . 16-14