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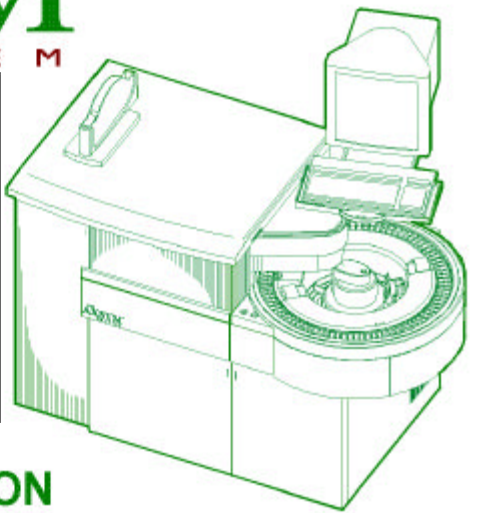

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Installation
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Sequencer
General Information
Theory of Operation
Block Diagrams

ELECTRONIC SERVICE DOCUMENTATION

ABBOTT DIAGNOSTICS
A DIVISION OF ABBOTT LABORATORIES
ABBOTT PARK, IL 60064

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046 New Process Carousel
045A Diluent Supply Tubing and Tubing Connectors
044 2.10 Software
043A Software Version 2.33
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041B Upgrade for the Caged Syringes
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038A Software Version 2.00/2.05 Upgrade
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1.1 PRODUCT DESCRIPTION OVERVIEW

The Abbott AxSYM System is an automated immunoassay diagnostic instrument that incorporates continuous and random access, stat capability, and high testing capacity in a stand-alone analyzer. It is targeted for medium to high volume hospital and reference laboratories that process 100 to 300 assays per eight hour shift.

The instrument offers a broad array of tests based on Microparticle Enzyme Immunoassay (MEIA), Fluorescence Polarization Immunoassay (FPIA), and Radiative Energy Altenuation (REA) technologies, allowing samples containing both large and small molecular weight analytes to be intermixed and quantified on a continuous basis.

Product groups from the diagnostic assay sectors include:

- Cardiovascular
- Thyroid
- Metabolic
- Fertility/Pregnancy
- Endocrinology
- Cancer
- Therapeutic Drug Monitoring
- Drugs Of Abuse / Toxocology
- Hepatitis
- Retrovirus
- Congenital

The AxSYM Instrument provides a high degree of process flexibility, allowing assays to be optimized for both performance and throughput. Continuous and stat process capability is achieved by separating areas of the system requiring operator interaction from those involved with actual process.

1.1 PRODUCT DESCRIPTION OVERVIEW, cont.

All areas are independently controlled by software, so that samples, reagents, or consumables can be added or removed at any time with no interruption of process. Reagent pack, bulk solution, and consumable capacities are balanced with throughput, providing operator completion time of approximately one hour. For most routine assays, test results are received in 15 to 25 minutes.

1.2 HOW TO USE THIS MANUAL

The purpose of this service document is to provide information useful for servicing the Abbott AxSYM® System and is composed of eleven (11) chapters, system block diagrams, ISAs and TSBs.

Chapter 1. General Data

This chapter contains a product overview, information on manual usage, manual revision marks, accident prevention symbols, and system specifications.

Chapter 2. Troubleshooting

This chapter contains normal operation of system, followed by procedures to be used by FSE/FSR in identifying and isolating problems. The procedures are presented in flowchart format and are accompanied by illustrations for added clarity. A detailed explanation of flowchart usage is given at the first of the chapter.

Chapter 3. Parts Lists

This chapter provides the Supplemental Tools and Supplies list, exploded view drawings of all field spared parts (and their configuration) which are indexed to the item number and description on the spared Parts Lists (PL).

Chapter 4. Removal and Replacement

This chapter contains Removal & Replacement procedures which are indexed by number to related Parts Lists in Chapter 3. For example, RR - A1.5 is Removal & Replacement procedure for Parts List PL - A1, item #5.

Chapter 5. Verification Procedures

This chapter contains adjustments, calibrations, checks tests and additional procedures required to verify instrument

1.2 HOW TO USE THIS MANUAL, cont.

operation after repairs are complete. Verification Procedures (VPs) are also used to assist in troubleshooting.

Chapter 6. PM/Total Call

This Chapter contains preventative maintenance (PM) procedures, Total Call procedure, and a PM/Total Call check list for the instrument.

Chapter 7. Installation

This chapter outlines the responsibilities of the Field Service Engineer/ Representative (FSE/FSR) in setting up the AxSYM System from preinstallation to installation and relocation.

Chapter 8. Diagnostic Software

This chapter provides information on the AxSYM Laptop Diagnostic Software. Information includes procedures to install and use the diagnostic software as well as a detailed description of the function and capabilities of the diagnostic routines.

Chapter 9. Sequencer

This chapter provides information on the AxSYM Sequencer Software. Information includes procedures to install and use the diagnostic software as well as a detailed description of the function and capabilities of the diagnostic routines.

Chapter 10. General Information

This chapter provides a quick reference of materials that may not be found in other sections of the service documentation, such as breakdowns of system diagnostic reports, log-on levels, and motor parameters.

1.2 HOW TO USE THIS MANUAL, cont.

Chapter 11. Theory of Operation

This chapter provides general and detailed theory of operation on the primary subassemblys, subsystems, and general operation of the AxSYM Instrument. An overview of key software components and the command line interface commands are also provided.

Block Diagrams

Block and wiring diagrams are available for the subsystems in the AxSYM Instrument.

Manual Revision Marks

AxSYM Service Documentation revision pages keep the manual up to date with configuration changes and servicing techniques. The actual changes will be identified as follows:

Identification of Unique Items

If either information, a procedure or a spare part is unique to United States Field Service only, then **(US)** is noted beside item. If the item is unique to International Field Service only, **(INTL)** is noted beside item. If the information, a procedure or spare part is unique to another country, the country is listed in parenthesis beside that item.

Example:

Item	Part No.	Description
11	LN09A84 - 17	Fax/Modem (Canada)
	LN09A83 - 04	Fax/Modem (Denmark)
	LN09A83 - 46	Fax/Modem (France)
	LN09A83 - 07	Fax/Modem (Germany)

1.2 HOW TO USE THIS MANUAL, cont.

TSB/ISA Symbols

Two symbols are used to show areas or sections in service documentation which have been affected by a TSB or an ISA. Refer to this TSB or ISA in AxSYM Service Documentation for additional information.

These symbols are used to show a particular part or area which has been, or has not been, modified by TSB number within symbol.

T-25	~~T-25~~
TSB 83-025 Installed	TSB 83-025 Not Installed

Example: TSB Modifications

This symbol is used to identify the ISA containing additional information about a part or area. I-25

Danger, Warning, Caution, and Note Tags

Danger, Warning, Caution, and Note tags are inserted throughout the manual to warn, assist, and inform user. The following examples identify format and give information included for each tag type.

DANGER

Denotes serious injury or possible death. Failure to comply will expose operator/FSE/FSR to significant risk of serious injury or death.

1.2 HOW TO USE THIS MANUAL, cont.

NOTE: *Denotes general information and helpful hints. Failure to comply will not affect safety, effectiveness, or performance.*

WARNING

Denotes clear and present danger or questionable result effectiveness. Failure to comply may result in incorrect instrument performance leading to instrument failure, erroneous results, or hazard to operator/FSE/FSR.

CAUTION

Denotes a minor, non-immediate, or potential hazard. Failure to comply may result in unexpected instrument performance or may expose operator/FSE/FSR to potentially hazardous conditions.

1.2 HOW TO USE THIS MANUAL, cont.

Definition of Symbols

> Greater than.
< Less than.
≈ Approximate.

Removal & Replacement Procedure (RR).

Verification Procedure (VP).

Both Removal & Replacement and Verification Procedures.

T-25 TSB 83-025.

I-25 ISA 83-025.

The biohazard symbol identifies an activity or area where operator may be exposed to potentially infectious materials or substances.

The electrical warning symbol alerts user to the possibility of electrical shock in noted activity or at posted location.

The general warning symbol identifies a physical, mechanical, or procedural situation where operator may be exposed to hazards such as sharp edges, hot surfaces, pinch points, awkward or heavy lifting, etc. and must be aware, alert, and cautious to prevent injury.

1.2 HOW TO USE THIS MANUAL, cont.

The electrostatic discharge symbol identifies an activity or area where operator must wear a ground strap while servicing system.

The laser warning icon identifies an activity or area where operator may be exposed to a potential eye hazard and implies following caution:

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser light exposure.

Do not stare directly into laser beam or into a reflection from a mirror-like surface. Remove power from Bar Code reader prior to cleaning or replacement.

(L) (Low) < + 1.00V.

(H) (High) + 4.75V to + 5.25V.

GND Chassis GND (Ground) unless otherwise stated.

1.2 HOW TO USE THIS MANUAL, cont.

Laser Caution Labels

The following laser caution label will be affixed to rear of instrument. (Figure 1 - 1)

Figure 1 - 1: Laser Caution Label on System Back Panel

The following laser caution label will be affixed to Sample Bar Code Reader Cover located in center of Sample Center carousels. (Figure 1 - 2)

Figure 1 - 2: Laser Aperture Label on Sample Bar Code Reader

1.2 HOW TO USE THIS MANUAL, cont.

Biohazards

Safety

Consider all clinical specimens, reagent controls, and calibrators, etc. that contain human blood or serum as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices.

CAUTION

The probe is sharp and may be contaminated with potentially infectious materials. Avoid contact before decontamination.

Disposal

Dispose of all clinical specimens, reagents, controls, calibrators, and disposables that may be contaminated, according to local, state, and federal, regulations governing treatment of regulated medical waste. The probe must be placed in an appropriately marked puncture resistant container prior to disposal.

Spills

Clean spills of potentially infectious materials in accordance with established biosafety practices. Absorb spill with absorbent material, pour liquid disinfectant over the spill, wipe area with detergent solution, then wipe area with disinfectant (not less than 10% chlorine bleach solution or 0.525% Sodium Hypochlorite).

1.3 SYSTEM SPECIFICATIONS

This section contains instrument dimensions, space, computer and interface specifications, electrical, environmental, printer, optical specifications and capacities requirements.

Physical Dimensions

Width	63" (160 cm)
Depth	33.5" (85 cm)
Height	51" (130 cm) to top of monitor
Weight	661.5 lbs. (300 kg)

Clearances

Left	24" (61 cm)
Right	24" (61 cm)
Rear	10" (25 cm)
Overhead	25" (63.5 cm) from top of monitor
Front	36” (91.4 cm)

Computer and Interface Specifications

Processor	Motorola® 68030, 25 MHz, 16 MB RAM.
Hard Drive I-62	270 MB, SCSI bus interface to CPU.
Disk Drive I-61	3.5", 21 MB Floptical®, SCSI bus interface to cpu.
Operator Interface Display	Full color VGA CRT, 14" diagonal (35.5 cm).
Touchscreen Type	Resistive overlay, RS-232 connection.
Keyboard	101 - key, custom, IBM compatible.
Bar Code Wand	Code 128, RS-232 connection.
Host Interface	Bi-directional, RS-232 serial communication port, 1200, 2400, 4800, or 9600 baud, ASTM standard, DCE or DTE configurable.

1.3 SYSTEM SPECIFICATIONS, cont.

Computer and Interface Specifications, cont.

Service (CLI) Port	RS-232 serial connection.
Spare Port	RS-232 serial connection.
Bar Code Reader, Sample	Code 128, Interleaved 2 of 5, Code 39, or Codabar (includes NW7).
Bar Code Reader, Reagent Pack	Code 128.
Printer	80 column parallel, Centronix connection.

Environmental Requirements

Instrument For Indoor Use Only.	
Operating Altitude Limit	6600 ft (2000 m).
Location	Flat, level surface. No direct sunlight or drafts. Remove from sources of direct heat, moisture. Do Not place next to a heat generating device.
Temperature - Ambient	Minimum 62° F (17° C). Maximum 86° F (30° C).
Humidity (non-condensing)	15 - 85% @ 77° F (25° C).
BTU Output	6551 BTU/Hr.
External Drain (if used)	At floor level, within 15 ft. (7.62 m).

1.3 SYSTEM SPECIFICATIONS, cont.

Electrical Specifications I-39

- For 220VAC Areas 187.2 - 264 VAC
- For 110VAC Areas 90 - 137 VAC.
- 50/60 Hz ± 1%.
- Ampere Breaker/16 Amp Fuse.

Dedicated Power Line

- Separate Circuit Breaker/Fuse.
- No other electrical devices can be supplied from dedicated breaker and power lines. Wire size to conform to local code.

Dedicated Ground

Clamp on ammeter reads zero (0.000A).

Conduit or BMx (Flexible Metal Conduit)

No other electrical wires are present.

Breaker Located in Customer's Distribution Panel

Identified as ABBOTT AxSYM.

Receptacle (U.S./Canada)

The receptacle shall be a dedicated duplex, NEMA reference 6-20R, (Example: Hubbel 5462) series mounted alone in a metal electrical box. The 6-20R consists of a 2 pole, 3 wire receptacle. (Figure 1-3)

Receptacle Mounting

- The electrical box containing the receptacle shall be mounted within 12 ft. (3.7 m) of right side of instrument.

1.3 SYSTEM SPECIFICATIONS, cont.

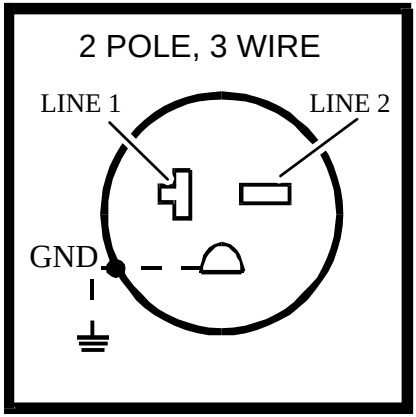

Figure 1 - 3: 220 VAC Receptacle

Power Connection

Power Cord (U.S./Canada)	UL/CSA-approved, SJT type 12 AWG.
Power Cord (Outside U.S./Canada)	(3 x 1.5 mm) meeting national electric code of installation site.
Instrument Connector	IEC320, UL/CSA-rated 20A/250 VAC, IEC-approved for 16A/250 VAC.

1.3 SYSTEM SPECIFICATIONS, cont.

Printer

Service Connector (U.S./Canada)	UL/CSA-approved NEMA 6-20P.
Service Connector (Outside U.S./ Canada)	Plug on power cord, mating with utility service must be rated and IEC-approved for at least 16 A, 250 VAC and be of a type meeting national electrical code of country of final destination; to be attached at final destination if other than supplied "schuko" style plug.
Maximum Line Loss Duration	0.03 sec.

Required Measurement At 220V Outlet

U.S.	Breaker Closed	Breaker Open
Line 1 to Line 2 =	187.2 - 264 VAC	≤ 0.5 VAC
Line 1 to GND =	90 - 132 VAC	≤ 0.5 VAC
Line 2 to GND =	90 - 132 VAC	≤ 0.5 VAC
GND to Conduit =	less than 0.5 VAC	≤ 0.5 VAC

INTERNATIONAL	Breaker Closed	Breaker Open
Line to Neutral =	180 - 264 VAC	≤ 0.5 VAC
Line to Earth =	180 - 264 VAC	≤ 0.5 VAC
Neutral to Earth =	0.5 VAC	≤ 0.5 VAC
Neutral to Case =	less than 0.5 VAC	≤ 0.5 VAC

1.3 SYSTEM SPECIFICATIONS, cont.

Optical Specifications

MEIA Lamp Type	Mercury vapor fluorescent
Output power	28 µw
Peak wavelength	360 nm
FPIA Lamp Type	Tungsten-halogen quartz
Output power	200 µw
Output wavelength	480 - 490 nm
Standards	
MEIA absorption wavelength	362 nm
MEIA fluorescence emission	448 nm
FPIA absorption wavelength	485 nm
FPIA fluorescence emission	525 - 550 nm

Capacities

Data Storage	
Released Patient Test Results	2,500
Released Control Results	5,000
Unreleased Test Results	1,500
Spooled Results	1,500
Tests Ordered	1,000
Message History	2,000
Temporary Messages	1,500
Carousels	
Reaction Vessel	90 RVs
Reagent	20 packs
Sample	6 segments
Process	36 RVs
Matrix Cell	32 cells
Matrix Cell Hopper	250 cells

1.3 SYSTEM SPECIFICATIONS, cont.

Sample Segments	
Sample cup segment	15 cups
Primary tube segment	10 tubes
Aliquot tube segment	10 tubes
Sample Vessels	
Sample cup	2 ml
Primary tube	10 ml
Aliquot tube	7 ml
Bulk Solution Containers	
Solution 1 (MUP)	250 mL
Solution 3 (matrix cell wash)	1 L
Solution 4 (line diluent)	10 L
Syringe, Sample or Process	1200 µl
Liquid Waste Container	12 L
Consumable Waste Container	300 RVs and /or matrix cells

Flow Rate to Drain (if used)	
Average	0.64 L/hr, maximum
Peak	7 ml/sec for 5 sec duration (purge)

Allowable Tube Sizes And Types I-52	Aliquot Tube Segments	Primary Tube Segments
Height		
(1) Minimum	64 mm	93 mm
(2) Maximum	76 mm	102 mm
Outer Diameter		
(1) Minimum	12 mm	12 mm
(2) Maximum	16 mm	16 mm
Inner Diameter		
(1) Minimum	9.5 mm	9.5 mm
Shape	Continuous Cylinder	Continuous Cylinder
Fluid Level	Bottom Justified	Bottom Justified