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PREFACE

The Abbott Diagnostics Division of Abbott Laboratories developed this manual as a reference guide for field service personnel for use during maintenance and repair of the Abbott COMMANDER® Flexible Pipetting Center (FPC). Technical information in the manual was written at a level assuming the service person has attended an Abbott-approved COMMANDER® FPC Service Training course. The Abbott Diagnostics Division recommends successful completion of the entire course by the service person before any servicing of the instrument.

INTRODUCTION

The Flexible Pipetting Center (FPC), along with the Parallel Processing Center (PPC), Dynamic Incubator (DI), and COMMANDER® Dynamic Incubator Monitor (CDIM) provide a “Good Manufacturing Practice” environment since blood products are considered a pharmaceutical (i.e., injectable). The Food and Drug Administration mandates persons handling blood products provide traceability for every step of the blood testing process. Blood handlers must be able to provide documentation for all steps of the manufacturing process showing proper following of procedures.

The Total Process Control™ (TPC™) System was created to assist with this tracking. The FPC is the front-end sample handler for the TPC concept. Along with its current capabilities of pipetting and data management, FPC Version 2.5 also has a component library. The component library manages information regarding reagents, guides the operator through use of proper reagents, and produces a summary report of all pertinent reagent data used on a particular tray or carousel.

While the FPC 2.5 Base version remains available, a TPC version has been added. FPC 2.5 software is available in various configurations as listed below:

1. **Base V2.5:** This version includes all Base and Plus features from Version 2.0, as well as software enhancements for Version 2.5. The operator interface was modified from FPC Version 2.0 to incorporate system changes necessary for TPC.

2. **TPC™ V2.5:** This is an available packaged option including TPC features besides all features in the V 2.5 Base Version.

There are three distinct levels of process control available through TPC. Assays are configured in three modes:

- **Verify**, where the FPC ensures that the operator uses appropriate reagent components and reports reagent and pipetting data.
- **Record**, where the FPC accepts and reports any reagent and pipetting data provided by the operator.
- **Off**, where no questions are asked of the operator about reagents and processing, and no reporting of reagent and pipetting data occurs.

WORK FLOW PROCESS

FUNCTIONAL FLOW PROCESS FOR SAMPLE HANDLING

The following section compares how a pipetting run would be set up in the three TPC™ modes available (Verify, Record, and Off) on the FPC:

In **TPC VERIFY MODE**, checks are performed against the component library to verify component usage. A pipetting run setup for a TPC Verify assay occurs in the following manner:

1. ☐ The operator enters the Technician ID number.
2. ☐ The operator selects the assay(s) to be pipetted.
3. ☐ The system displays a pop-up menu so the operator may select or enter a master lot for the assay(s). The master lot is then verified against the component library.
4. ☐ After confirming there are enough components to pipette into the trays for the run, the operator selects the components to be pipetted.
5. ☐ The operator enters a component lot number(s) and the system verifies master lot and expiration date. The operator then places the component(s) into the control bottle and diluent bottle rack(s), and verifies component location(s) with the system.

6. ☐ The operator enters the destination ID(s), places destination(s), and verifies platform location(s) with the system.
7. ☐ The operator prepares the Pipettor for pipetting by placing sources and tips, priming, etc.

In **TPC RECORD MODE**, no checks are performed against the component library. The FPC accepts all data entered. A pipetting run setup for a TPC Record assay occurs in the following manner:

1. ☐ The operator enters the Technician ID.
2. ☐ The operator selects the assay(s) to be pipetted.
3. ☐ The operator enters the master lot number for the assay(s), if desired.
4. ☐ After the operator has confirmed that there are enough components to pipette into the trays for that run, the operator selects the component(s) to be pipetted.
5. ☐ The operator then enters component lot number(s) if desired, places the component(s) into the control bottle and diluent bottle rack(s), and verifies component location(s) with the system.

Section 1

Total Process Control™

6. The operator next enters destination ID(s), place destination(s), and verifies platform location(s) with the system.
7. The operator then prepares the Pipettor for pipetting by placing sources and tips, priming, etc.

In **TPC OFF MODE**, no data is requested on component usage. No component data is printed on reports. This is similar to how the FPC operates in Version 2.0. A pipetting run setup for all assay(s) with TPC Mode OFF occurs in the following manner:

1. The operator enters the Technician ID.
2. The operator selects the assay(s) to be pipetted.
3. After the operator has confirmed that there are enough components to pipette into the trays for that run, the operator selects the components to be pipetted.
4. The operator then places component(s) into the control bottle and diluent bottle rack(s).
5. The operator next enters the destination ID(s) and places destination(s).
6. The operator then makes the Pipettor ready for pipetting by placing sources and tips, priming, etc.

Refer to Figure 1-1 for a block diagram of how a pipetting run would be set up in the three TPC modes (Verify, Record, and Off) from an operator's perspective.

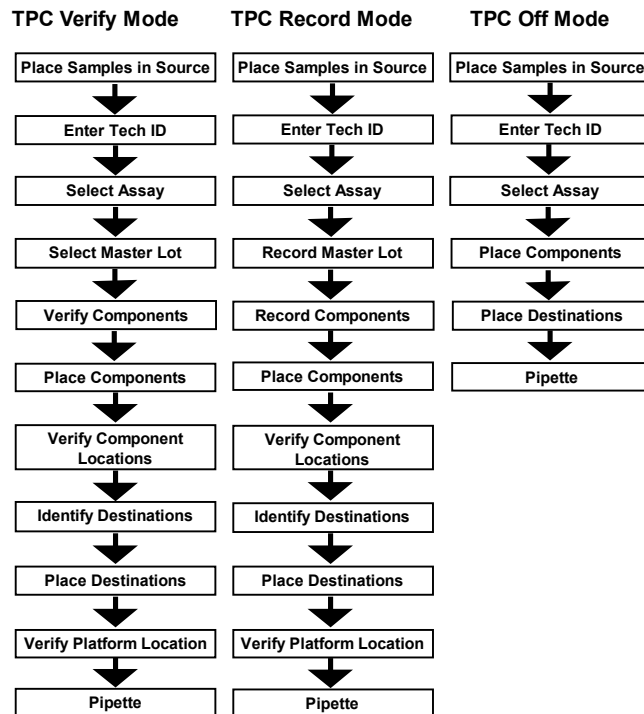


Figure 1-1. TPC Mode Flow Diagram

FUNCTIONAL FLOW PROCESS FOR COMPONENT LIBRARY

The component library stores the component/reagent data. The operator enters the list number of the reagent kit, the master lot number, the components that link to that master lot, and expiration dates. The component library is used to warn the operator if there is an attempt to use inconsistent or expired components (in Verify mode only). Depending on the error condition, the operator may either override the warning (using a password), or correct the situation before proceeding. Refer to Figure 1-2 for a flow chart of the component library.

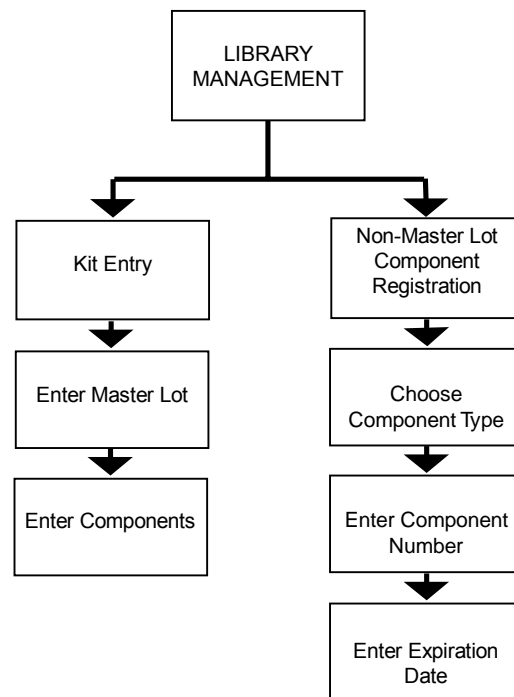


Figure 1-2. Component Library Flow Diagram

DATA FLOW (VERIFY MODE)

The master lot and components are first entered at a data entry point in the component library. If the assay is set to Verify Mode during assay protocol configuration, the operator queries the system for allowable master lots available for a given assay. When the operator selects a master lot, the system allows the operator to use components from within that master lot only (other master lot components may be used if an override password is entered). Each time the operator enters a component, the system checks the component library to verify if the component is acceptable for use. When the operator enters component information into the PPC, a message is sent to the FPC to check that component against the component library for all PPCs connected to the FPC Computer. The system sends a message to the PPC indicating whether or not the component is acceptable for use. In Verify Mode, the FPC accepts and stores information received from the PPC on components used and process deviations. Refer to Figure 1-3 to view the data flow diagram that exhibits communication with the component library.

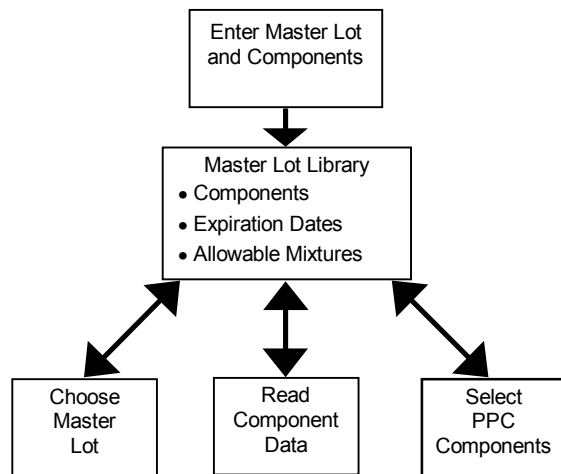


Figure 1-3. Component Library Data Flow Diagram

NOTE:

The double arrow indicates data flows in both directions. An operator interface is required. The single arrow indicates the data flows in that direction only.

HARDWARE

The following hardware components were added to the FPC system with the release of FPC 2.5, TPC™.

BAR CODE READER

The Bar Code Reader reads bar code label identifications from racks, sample tubes, trays, and boxes and transfers them to the COMMANDER® FPC. The Bar Code Reader is connected to the Sensor Module (F-Link) or ABC by a cable. Data read by the Bar Code Reader is transferred to the system database for storage.

BAR CODE ACCESSORIES

- ☐ Bar Code Label Set
- ☐ Bar Code Reader Extension Cable

Bar Code Label Set

The Bar Code Label Set identifies various locations in the equipment. It is used for tracking reagent and location data.

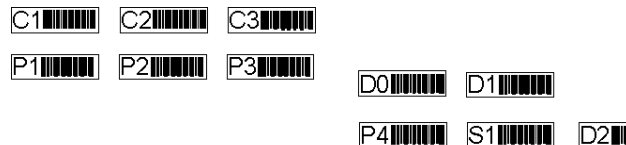


Figure 1-4. Bar Code Label Set

NOTE:

This is an illustrative representation of a Bar Code Label Set. The bar codes depicted cannot be scanned. Sizes shown are not to scale.

Bar Code Reader Extension Cable

The Bar Code Reader Extension Cable allows the hand-held Bar Code Reader to be extended for reading bar code data on the platform.

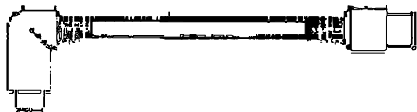


Figure 1-5. Bar Code Reader Extension Cable

PIPETTOR

PIPETTOR COMPONENTS

Control Bottle Rack

Controls in bottles and tubes are placed in appropriate positions in the Control Bottle Rack attached to the pipetting platform. Each position, marked X1 through X5, can hold a 5 ml, 10 ml, 12 ml, 35 ml, and 1 dram bottle or a 13 mm diameter tube. Positions are assigned by the computer depending on assays included in the process run.

NOTE:

This pre-labeled component comes with the TPC™ kit.

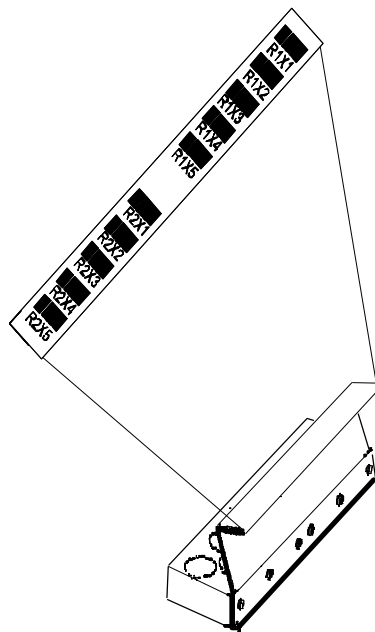


Figure 1-6 Control Bottle Rack with Labels

PIPETTOR ACCESSORIES

- Diluent Bottle Racks
- Carousel Adapters

Diluent Bottle Racks

Appropriate diluents are placed in positions marked D0, D1, and D2 in the Diluent Bottle Rack on the Pipetting platform. Positions are assigned by the computer depending on assays included in the process run.

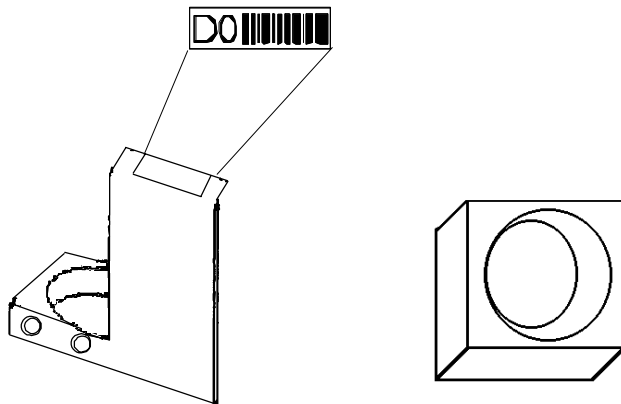


Figure 1-7 Diluent Bottle Racks

Carousel Rack Adapters And Carousel Rack Adapter Tray

The Carousel Rack Adapter Tray contains the Carousel Adapter and Control Rack. The Carousel Rack Adapter holds the MEIA or FPIA carousel.

NOTE:

This pre-labeled component comes with the TPC™ Carousel Kit.

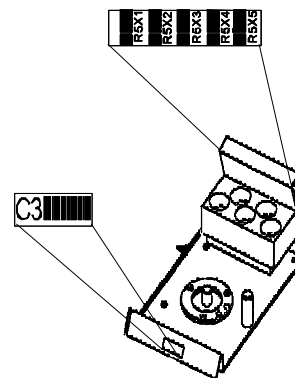


Figure 1-8 Carousel Rack Adapter with Labels

Guard Bars

The Guard Bars are movable. They allow the operator access to read all bar code labels in the pipetting area.

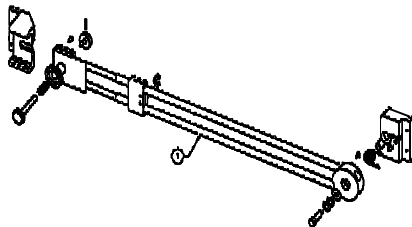


Figure 1-9. Guard Bars

SYSTEM PREPARATION

To prepare the FPC for operation, perform the following procedures:

LABEL APPLICATION

The artwork on the pipetting platform provides a guide for the correct placement of each FPC component. The designators on the artwork correspond to the designators on the bar code labels. Refer to the platform designators when applying the bar code labels to the FPC.

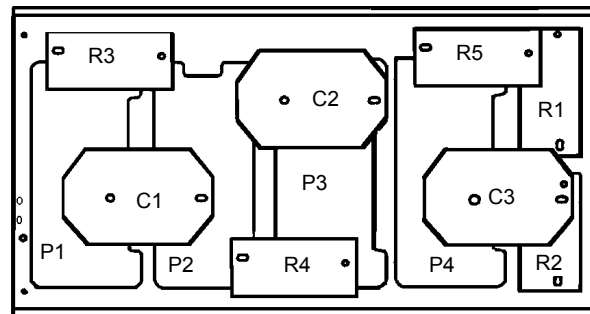


Figure 1-10. Platform Designators

APPLYING BAR CODE LABELS TO THE TRAY PLATFORM

To apply bar code labels to the tray platform, perform the following procedure:

1. Locate the short labels with the PX designator in the Bar Code Label Set.
2. Refer to the pipetting platform to determine which label to use.
3. Remove the label from the adhesive backing.
4. Apply the label to the Tray Platform as shown in Figure 1-11.

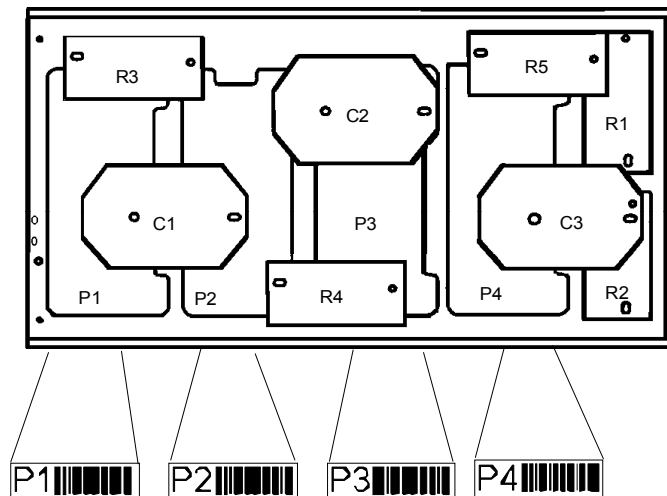


Figure 1-11. Applying Bar Code Labels to the Tray Platform

APPLYING BAR CODE LABELS TO THE DILUENT BOTTLE RACK

To apply bar code labels to the Diluent Bottle Rack, perform the following procedure:

1. ☐ Locate the short labels with the DX designator in the Bar Code Label Set.
2. ☐ Remove the labels from the adhesive backing.
3. ☐ Apply the D1 and D2 labels to top of Tip Injector Plate as shown in Figure 1-12.

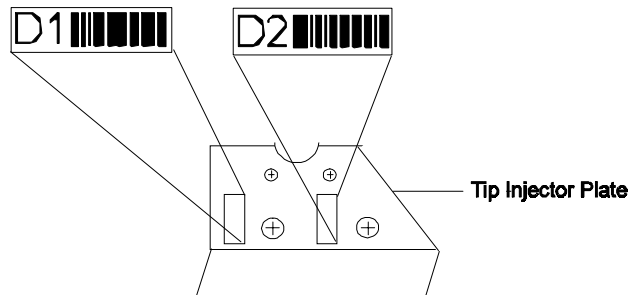


Figure 1-12. Applying Bar Code Labels to the Diluent Bottle Rack

APPLYING BAR CODE LABELS TO THE PLATEN EXTENSION ASSEMBLY

To apply bar code labels to the Platen Extension Assembly, perform the following procedure:

1. Locate the short label with the S1 designator in the Bar Code Label Set.
2. Remove the label from the adhesive backing.
3. Apply the S1 label to the front of the Platen Extension Assembly as shown in Figure 1-13.

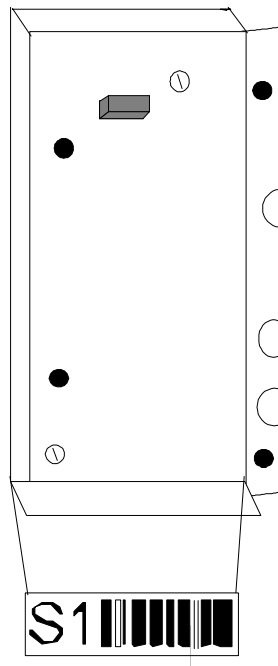


Figure 1-13. Applying Bar Code Labels to the Platen Extension Assembly

SOFTWARE FLOWCHARTS

This section describes the menu structure for FPC 2.5 and TPC™. Refer to Figures 1-14 through 1-25.

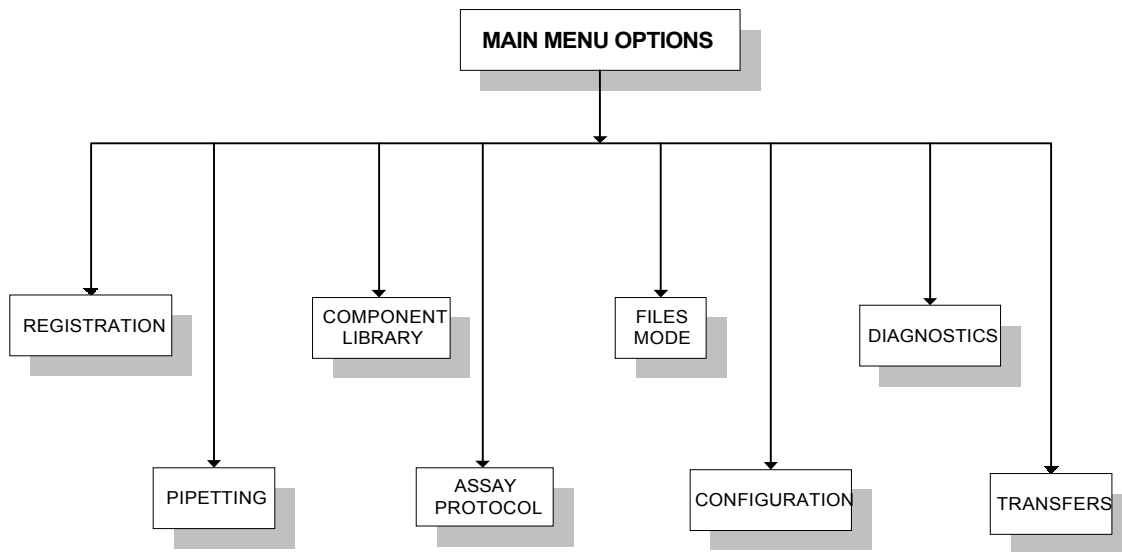
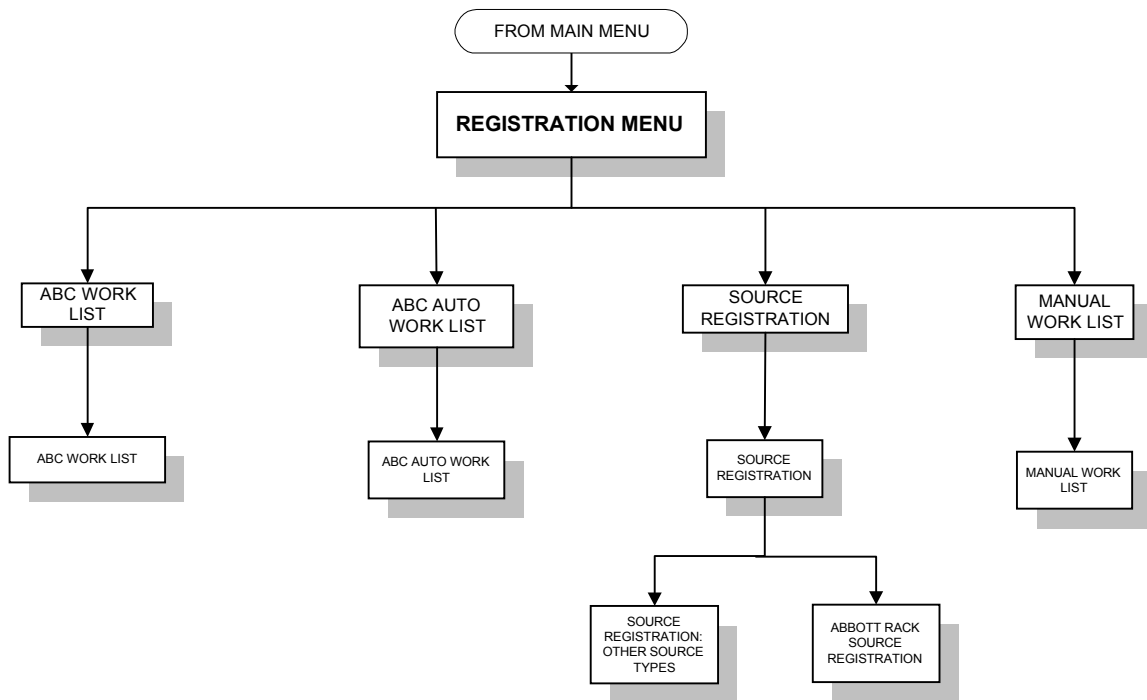
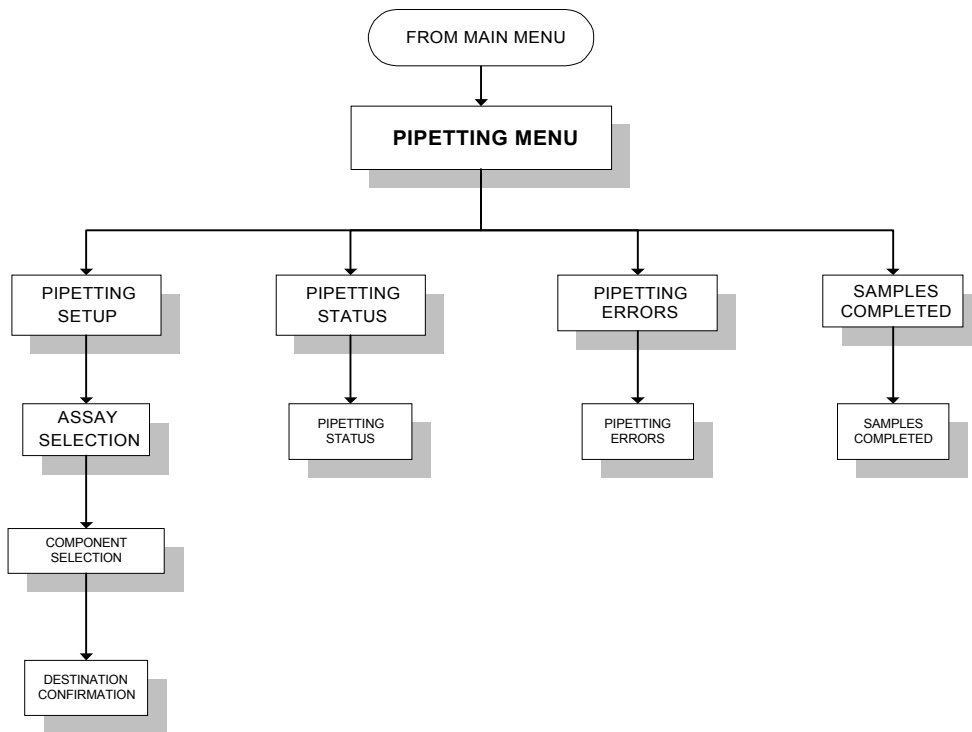


Figure 1-14. Main Menu Options

*Figure 1-15. Registration Menu*

*Figure 1-16. Pipetting Menu*

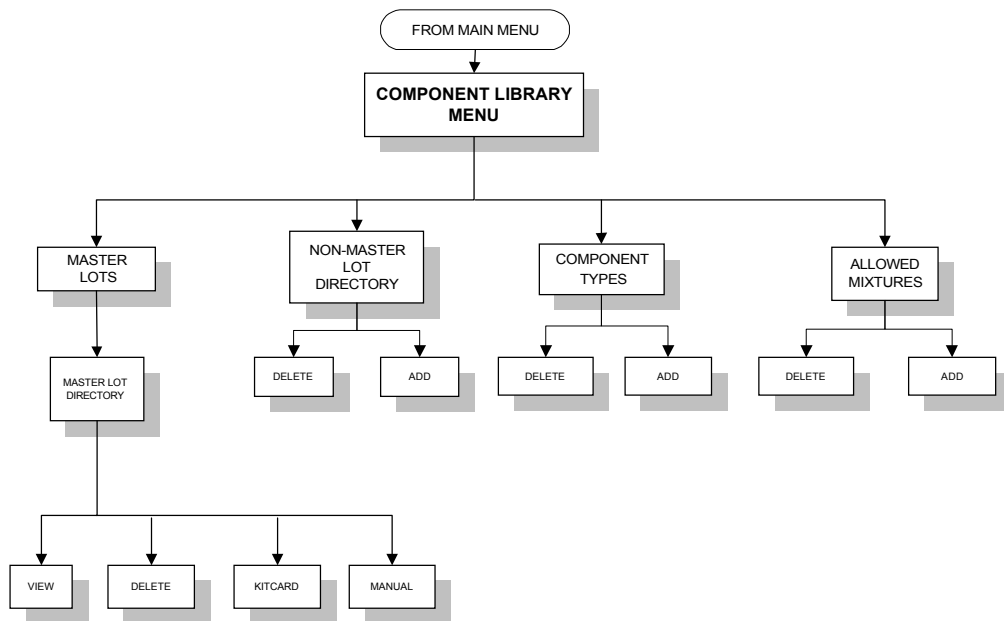
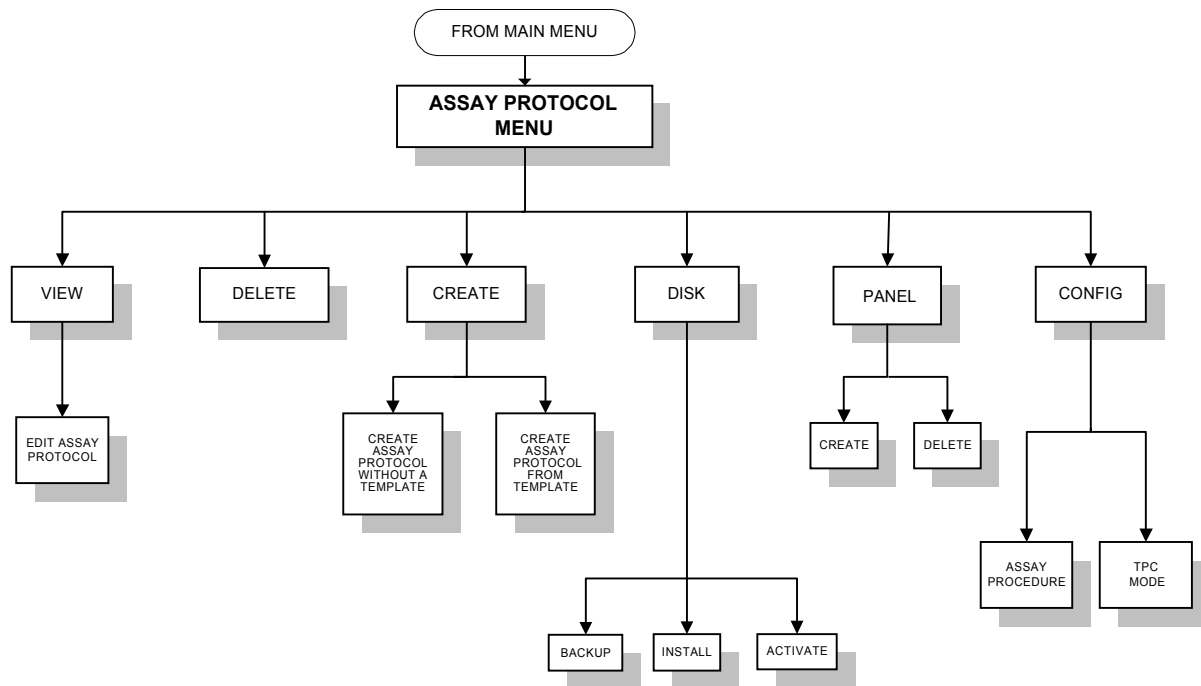
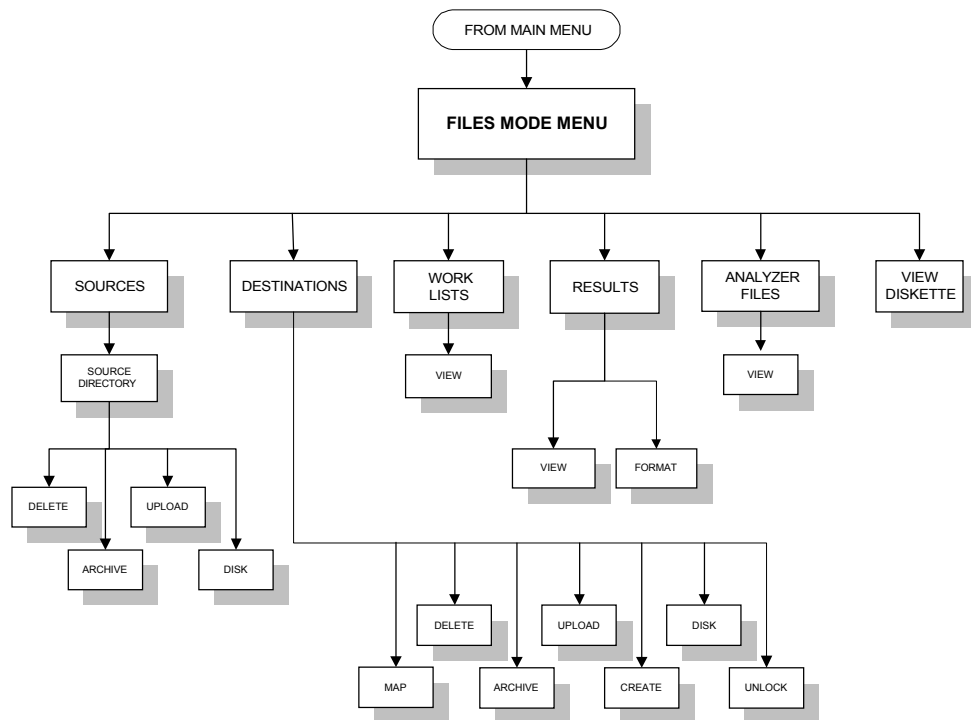
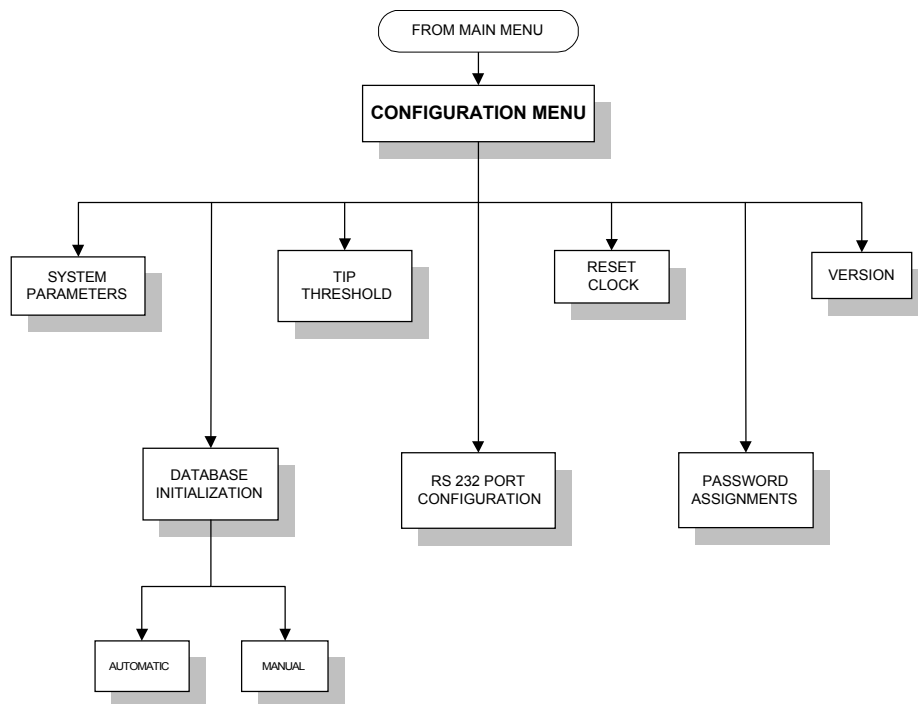
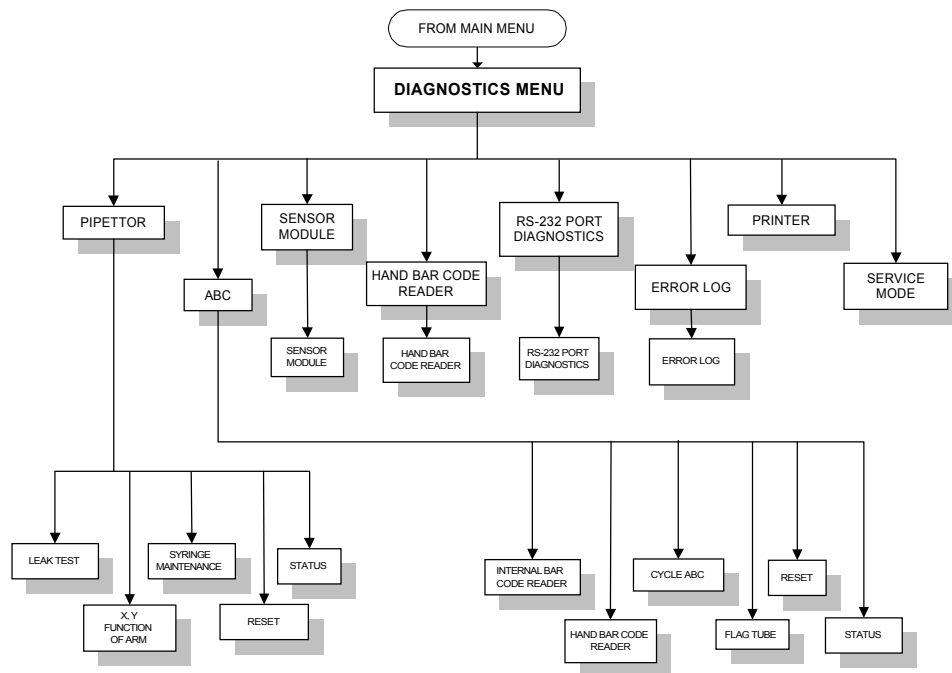


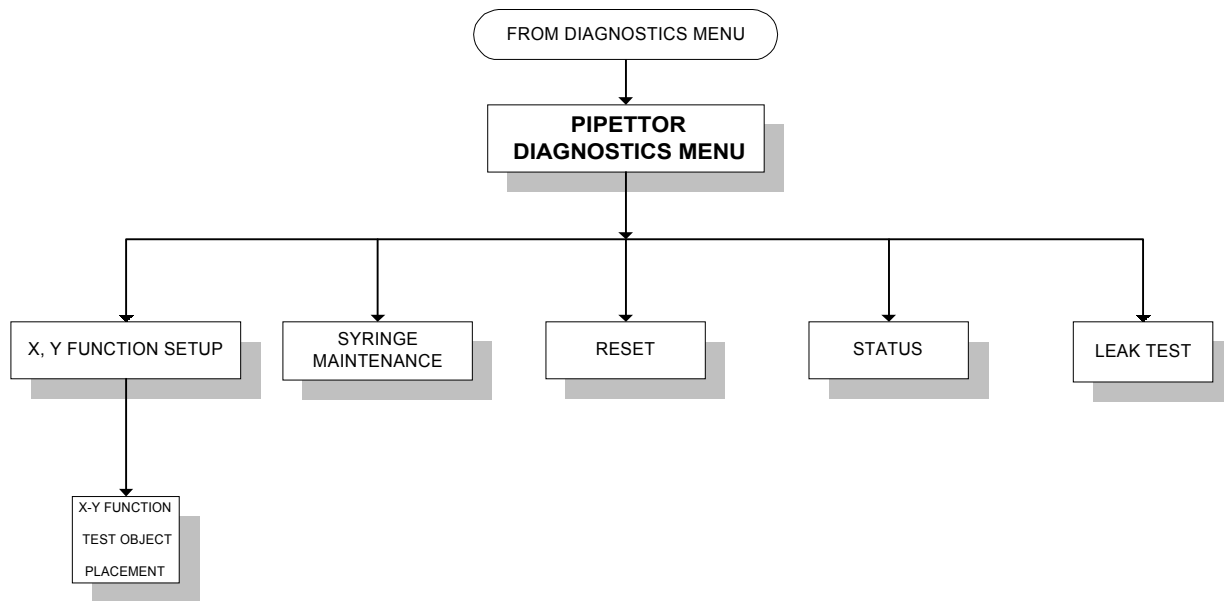
Figure 1-17. Component Library Menu

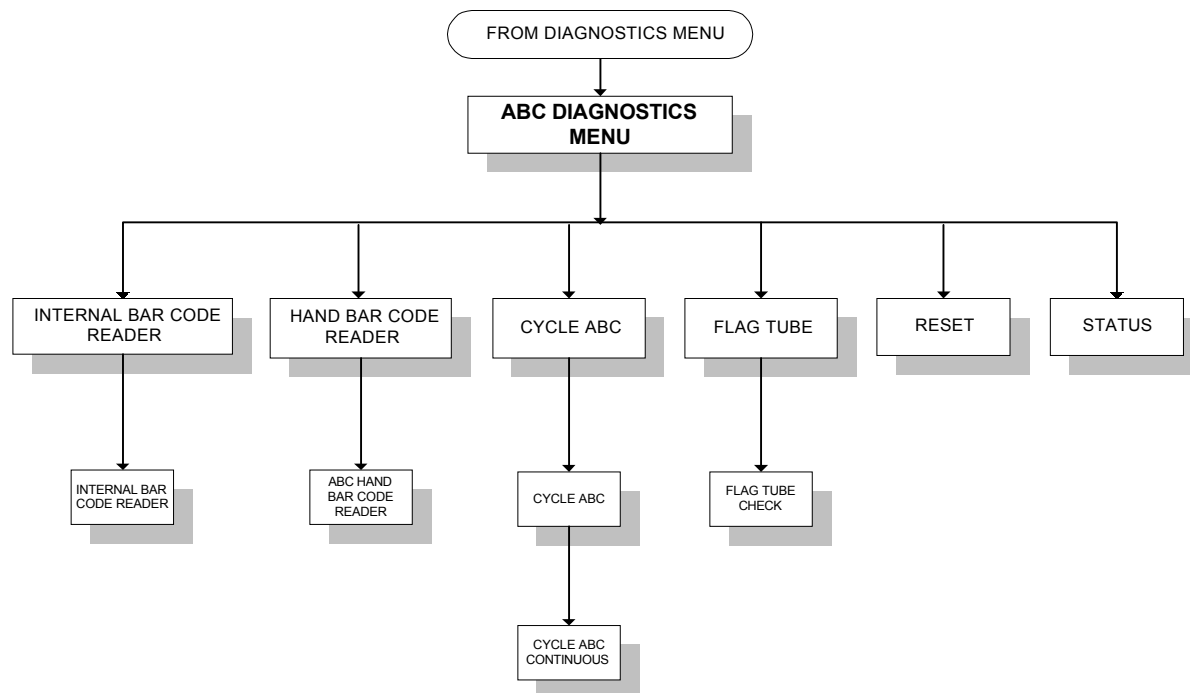
*Figure 1-18. Assay Protocol Menu*

*Figure 1-19. Files Mode Menu*

*Figure 1-20. Configuration Menu*

*Figure 1-21. Diagnostics Menu*

*Figure 1-22. Pipettor Diagnostics Menu*

*Figure 1-23. ABC Diagnostics Menu*

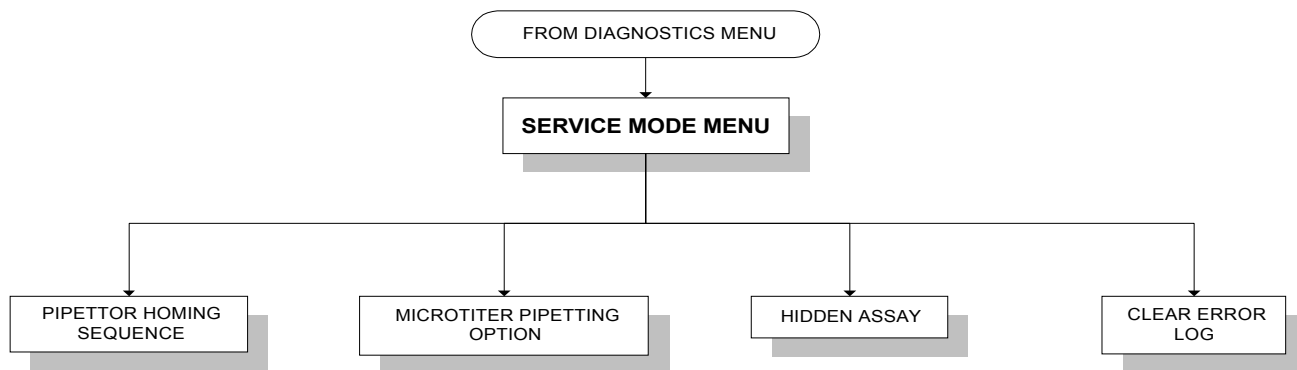


Figure 1-24. Service Mode Menu

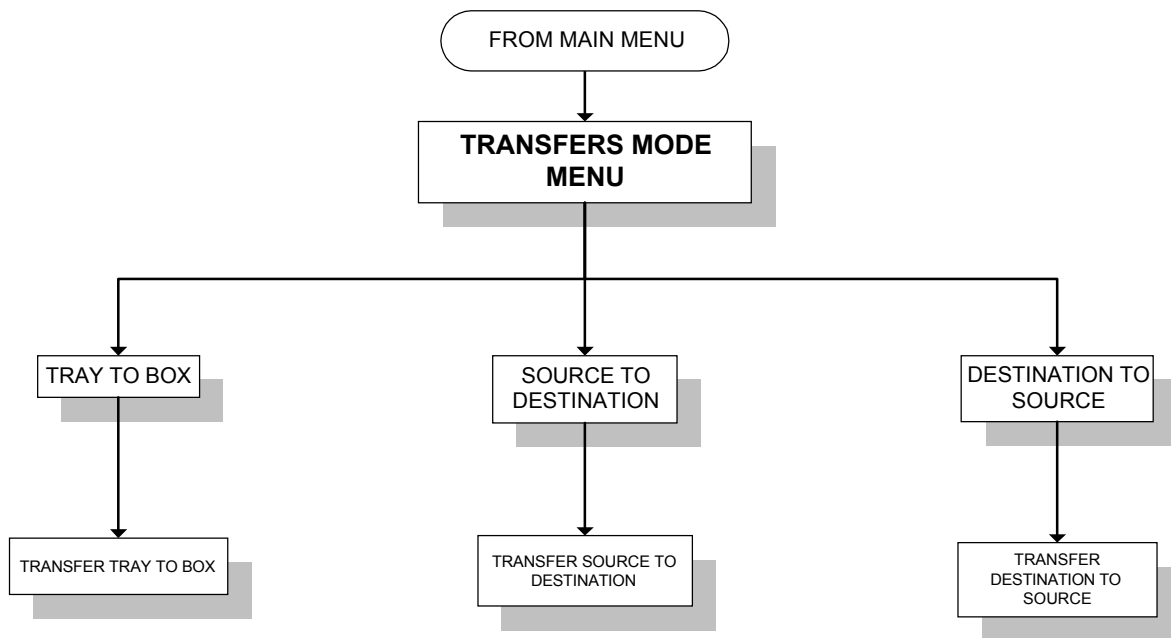


Figure 1-25. Transfers Mode Menu