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|  ABBOTT ADD | INDEX INSTRUMENT SERVICE ADVISORY |
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| PRODUCT: TDxFLx® (67) | DATE: 07-JUL-98 |
|--|----------------------------------|

| ISA # | SUBJECT | EFFECTIVITY DATE |
|--------------|--|-----------------------------|
| 67-025 | TDxFLx® Service Manual | 07-JUL-98 |
| 67-023 | A C Htr Brk Fail or A H Htr Brk Fail on the TDxFLx® Analyzer | 30-NOV-95 |
| 67-022 | Barcode Alignment Flowchart | 05-JUN-95 |
| 67-021 | TDx®/TDxFLx® DT Manual | 07-FEB-95 |
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| 67-019 | PENDING | PENDING |
| 67-018 | PCB Retainer Brackets | 20-AUG-93 |
| 67-017 | Barcode Scanner Upgrade/Downgrade | 20-AUG-94 |
| 67-016A | TDxFLx Wash Station Alignment | 26-AUG-94 |
| 67-015 | ONEAC Line Conditioner | 20-AUG-93 |
| 67-014A | FPIA Optics Diagnostic Procedure | 20-AUG-93 |
| 67-013 | Thermal Printer Upgrade | 22-SEP-92 |
| 67-012 | Ribbon Post and Card Cage Fan | PENDING |
| 67-011 | Metal Optics Assemblies | 20-APR-92 |
| 67-010 | "Mean Time Between Failure" Counter | 22-APR-92 |
| 67-009A | Number of Tests in TDxFLx Wedge Reagent Pack | 08-DEC-93 |
| 67-008 | Power Entry Assembly | 03-DEC-91 |
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| 67-005 | Reagent Wedge Z-Boom Calibration Procedure | INCORP. |
| 67-004 | New Factory Set Password | 08-NOV-91 |
| 67-003A | TDxFLx Serial Number Clarification | 16-AUG-93 |
| 67-002 | Improved Waste Container | 14-AUG-91 |
| 67-001 | Front Panel Assembly Removal | 26-JUL-91 |

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|-----------------------|---|
| PENDING - | ISA index number has been reserved for a future ISA. |
| CANCELLED - | ISA index number is cancelled. |
| INCORPORATED - | ISA was incorporated into another document or manual. |
| OBSOLETE - | ISA no longer applies. |
| COMPLETE - | ISA is complete. |

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| SUBJECT: TDxFLx® Service Manual | ISA#: 67-025 |
| ORIGINATOR: Eric Tormos | PRODUCT: TDxFLx® (67) |
| APPROVED: Jack B. Hall 7/7/98 | EFFECTIVITY DATE: 07-JUL-98 |

TDxFLx® is a registered trademark of Abbott Laboratories.

I. DISTRIBUTION:

Worldwide

II. PURPOSE:

This ISA is to notify the field of a revised TDxFLx® Analyzers Total Service Call Procedure. This procedure has been developed from customer site visits made to correct various customer issues. The purpose of this new procedure is to reduce the number of preventive maintenance procedure requirements, while continuing to maintain optimum performance of the instrument.

The Total Service Call Procedure makes sure that the three major subsystems, i.e., temperature, photo and dispense, are checked. Solving an error on one of the subsystems should result in checking the other two as well.

III. PARTS:

None.

IV. PROCEDURE:

6.1 PM/TOTAL SERVICE CALL PROCEDURE

Suggested PM/Total Service Call Procedure

1. Verify proper TSB level.
2. Obtain printout of System Parameters 1, 2, 3, 6, 7, 9, 10 and 11.
3. Wipe analyzer base and cover with 95% ethanol or methanol.
4. Clean and inspect optics and lamp housing with compressed air.
5. Remove air duct cover, clean dust form heater coils and thermistor with compressed air

- or vacuum cleaner.
- 6. Prime buffer 5 times and inspect instrument and accessories for leaks in tubing or multivalve block.
- 7. Run boom calibration (only if it was not yet requested as a verification procedure).
- 8. Run temperature check (only if it was not yet requested as a verification procedure).
- 9. Run photo check (only if it was not yet requested as a verification procedure).
- 10. Run pipe check (only if it was not yet requested as a verification procedure).
- 11. Run assay of customer's choice with controls.
- 12. Obtain printout of System Parameters 1, 2, 3, 6, 7, 9, 10 and 11.

6.2 PM/TOTAL SERVICE CALL CHECKLIST

Suggested PM/Total Service Call Procedures Performed

| | | |
|-----|--|---|
| 1. | | Verify proper TSB level. |
| 2. | | Obtain printout of System Parameters 1, 2, 3, 6, 7, 9, 10 and 11. |
| 3. | | Wipe analyzer base and cover with 95% ethanol or methanol. |
| 4. | | Clean and inspect optics and lamp housing with compressed air. |
| 5. | | Remove air duct cover, clean dust from heater coils and thermistor with compressed air or vacuum cleaner. |
| 6. | | Prime buffer 5 times inspect instrument and accessories for leaks in tubing or multivalve block. |
| 7. | | Run boom calibration (only if it was not yet requested as a verification procedure). |
| 8. | | Run temperature check (only if it was not yet requested as a verification procedure). |
| 9. | | Run photo check (only if it was not yet requested as a verification procedure). |
| 10. | | Run pipe check (only if it was not yet requested as a verification procedure). |
| 11. | | Run an assay of the customer's choice with controls. |
| 12. | | Obtain printout of System Parameters 1, 2, 3, 6, 7, 9, 10 and 11. |

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| SUBJECT: A C HTR BRK FAIL or A H HTR BRK FAIL on the TDxFLx® Analyzer | ISA#: 67-023 |
| ORIGINATOR: Louis Valich | PRODUCT: TDxFLx® (67) |
| APPROVED: Mark Slater 11/30/95 | EFFECTIVITY DATE: 30-NOV-95 |

TDxFLx is a registered trademark of Abbott Laboratories.

I. **PURPOSE:**

There has been a software issue identified with the TDxFLx Rev. 2.0/2.1 which will cause the customer to encounter the error message "A C HTR BRK FAIL" or "A H HTR BRK FAIL". If the sequence of steps the customer completes is as detailed below, the run will terminate without results, and these error messages may be generated. Please follow the corrective action steps as outlined below if this sequence of events is encountered. This should resolve the error messages. The CSC and TSO organizations have been notified of this and they should be able to resolve this situation over the phone with the customer, avoiding sending out of an FSR/FSE on a service call.

TDxFLx assay run ends abruptly with no results

This error will occur if the operator performs the following steps when one wedge reagent pack is loaded on a reagent carousel and a run is initiated. The sequence of events that will generate the error messages are:

1.

BARCODE FAIL

 OR

INVALID BARCODE

 is displayed for approximately one (1) second.
2. BARCODE FAIL or INVALID BARCODE is printed on tape.

3. Display reads: REAGENT LIST OK?

4. Operator incorrectly responds by pressing: STORE/YES

NOTE: The correct operator response when a BARCODE failure has occurred with only one wedge reagent pack on a carousel is NEXT/NO. Enter reagent ID with the barcode scanner or by the keypad. Run should go to completion, and the error should not be generated.

5. The run terminates without pipetting and concentration values are not printed.

6. A sample load list may be printed with : NO RGT LOADED

7. The display reads: DONE REMOVE RPAK

8. Operator presses: STOP

9. Display changes to: READY

10. Display may change to: TEMPERATURE STABILIZING or A C HTR BRK FAIL or A H HTR BRK FAIL and the heater shuts off.

11. If the operator presses: STOP again, sequence in steps 9-10 repeats

Corrective Action

Even if the error message(s) in Step 10 are not displayed, the following steps should be performed:

1. Turn the instrument off
2. Wait 30 seconds and turn the instrument on
3. Attempt to reinitiate the run using the barcode override

If a barcode failure was encountered, perform troubleshooting to resolve barcode fail or invalid barcode error.

If, after this corrective action, the error message(s) in Step 10 returns, there is a possible hardware problem and you should begin troubleshooting there.

The TDxFLx Operations Manual will be updated to include this corrective action for the error messages in the troubleshooting section in the next revision.

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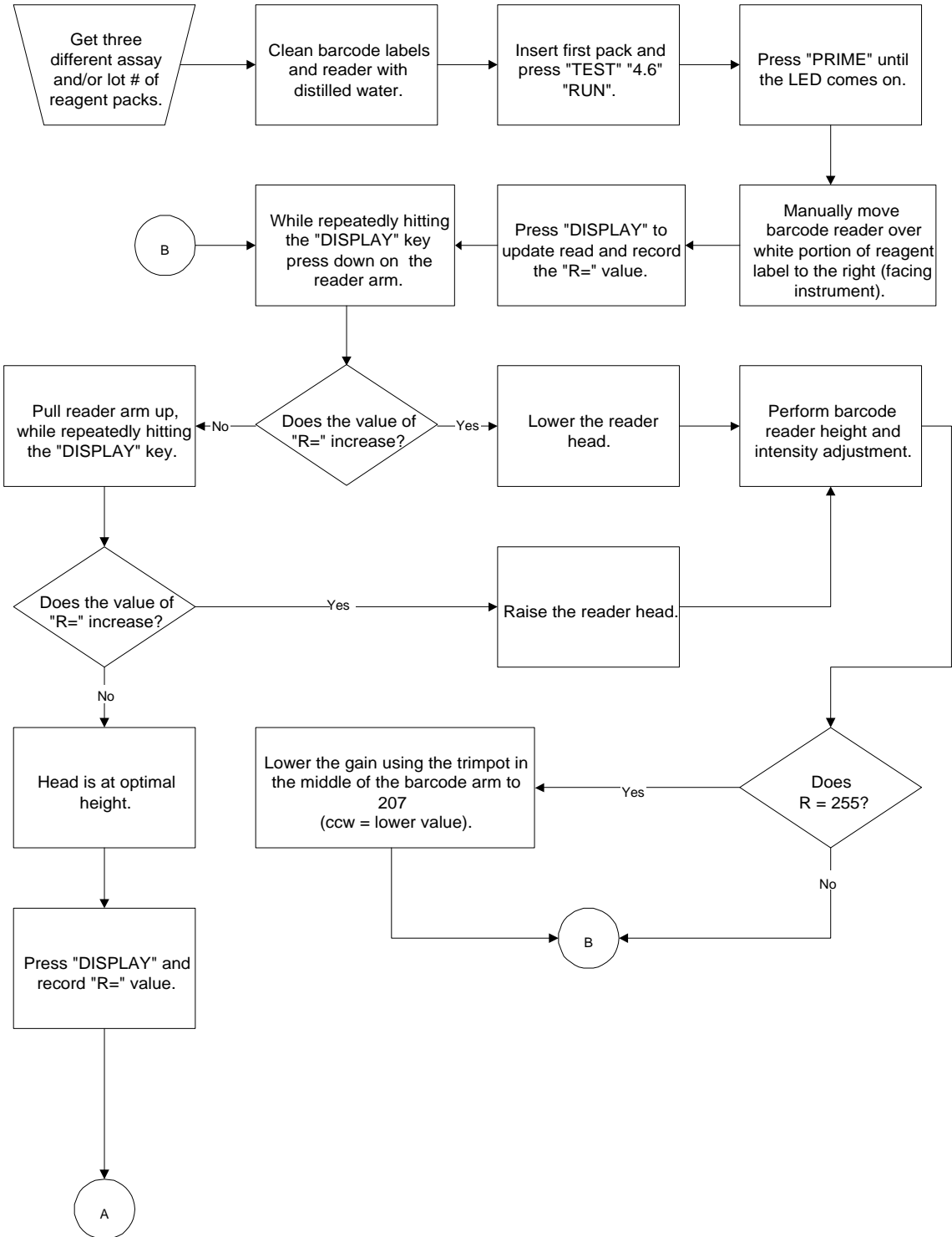
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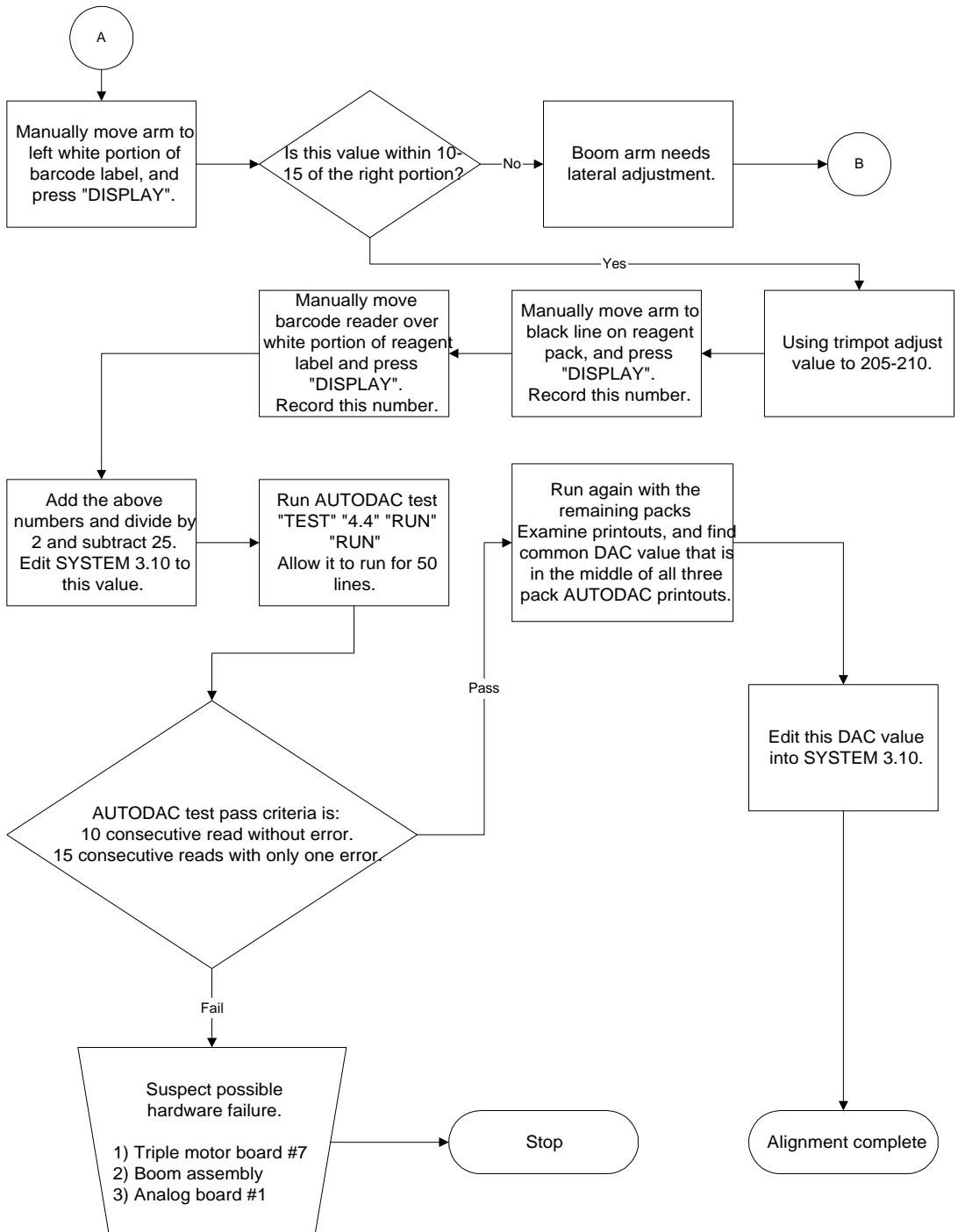
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| SUBJECT: Barcode Alignment Flowchart | ISA#: 67-022 |
| ORIGINATOR: Michael Mowen | PRODUCT: TDxFLx® (67) |
| APPROVED: Bob Schabel 5/June/95 | EFFECTIVITY DATE: 05-JUN-95 |

TDxFLx is a registered trademark of Abbott Laboratories.

- I. **DISTRIBUTION:**
International and USA
- II. **PURPOSE:**
To provide the field with a guide to adjust the barcode reader for proper operation, and to save time and repeat calls.





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INSTRUMENT SERVICE ADVISORY

SUBJECT:
TDx®/TDxFLx® DT Manual

ISA#:
67-021

ORIGINATOR:
Michael A. Mowen

PRODUCT:
TDxFLx® (67)

APPROVED:
Bob Schabel 02/08/95

EFFECTIVITY DATE:
07-FEB-95

TDx, IMx, and TDxFLx are registered trademarks of Abbott Laboratories.

I. DISTRIBUTION:

United States: If a new manual is needed, it can be ordered via a FieldWatch message to Field Service Logistics. The cost of the manual will be charged to the district department number.

International: International locations should forecast requirements for the manual to their responsible logistics organization.

II. PARTS :

To order the complete TDx®/TDxFLx® DT-size manual use the following number:

3-45331-02 Complete manual (binders both volume one and two, tabs, text)

This manual replaces the previously released manual for the TDx®/TDxFLx® System, 3-45331-01.

III. PURPOSE:

The New TDx®/TDxFLx® DT-size Service Manual is now available.

IMPROVEMENTS:

The manual is now in the small binder format and updates the previous manual to include TDxFLx Rev. 2.0/2.1, the digital centrifuge, thermal printer, VDE information, and other new information. Volume One corresponds to the IMx® DT service manual, but with text based troubleshooting only. Volume Two contains the reference material, such as the schematics, theory, RS232 specifications, etc. Feedback from FSE/FSRs, has prompted the binders to have locking rings and Mylar reinforced holes, on all pages.

The following TSBs and ISAs were incorporated into the text as follows:

TSBs

TDx

- 09-039 TDx REV. 15.1 Software
- 09-037B Lamp Socket Assembly
- 09-035 TDx REV 15.0 Software

TDxFLx

- 67-011 TDxFLx REV. 2.1 Software
- 67-009 TDxFLx REV. 2.0 Software
- 67-008B Lamp Socket Assembly
- 67-007 Thermal Printer
- 67-005 VDE Instrumentation
- 67-002A Improved Waste Container Sensor

ISAs

TDx

- 09-110 NOVRAM Copier Tool
- 09-108 Motor Board Diagnostic Test (Test 5.7)
- 09-107 RS232 Port and REV. 15.0
- 09-106 ONEAC Line Conditioner
- 09-105A FPIA Optics Diagnostics Procedure
- 09-104 Ribbon Post and Card Cage Fan
- 09-098 New Factory Set Password

TDxFLx

- 67-020 NOVRAM Copier Tool
- 67-018 PCB Retainer Brackets
- 67-016 Wash Station Alignment
- 67-015 ONEAC Line Conditioner
- 67-014A FPIA Optics Diagnostics Procedure
- 67-013 Thermal Printer Upgrade

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| 67-010 | MTBF Counter |
| 67-004 | New Factory Set Password |

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| SUBJECT: TDxFLx WASH STATION ALIGNMENT | ISA#: 67-016A |
| ORIGINATOR: Kyle Hranitzky | PRODUCT: TDxFLx® (67) |
| APPROVED: Bob Schabel 08-26-94 | EFFECTIVITY DATE: 26-AUG-94 |

TDxFLx is a registered trademark of Abbott Laboratories.
TEFLON is a registered trademark of E.I. duPont de Nemours & Co., Inc.
TYGON is a registered trademark of U.S. Stoneware, Inc.

This ISA supersedes ISA 67-016.

I. PURPOSE:

This ISA provides the FSR with instructions to properly replace and align the wash station on the TDxFLx® System. Proper alignment of the wash station is essential for sufficient washing of the probe during panel and abused drug runs and for minimizing splashing.

II. PROCEDURE:

The wash station/waste system is composed of the following parts (listed in order of assembly):

| <u>Component</u> | <u>P/N</u> |
|------------------|------------|
| Wash station | 3-45048-01 |

| | |
|---------------------------------------|------------|
| TEFLON®tape | 14246-030 |
| Connector, Fitting, barb 90 degree | 14603-112 |
| Screw, with washer, 6-32x.50 PHP | 14494-110 |
| Tubing, TYGON® 0.19 I.D. | 3-45183-01 |
| Drain, Waste (behind buffer platform) | 3-45067-01 |
| Waste container | 3-45047-01 |

Inspect the Wash station for cracks or leaks. Replace as necessary. If replacement is not required proceed with alignment.

REPLACEMENT:

1. Carefully move the boom arm to the center of the instrument . CAUTION: The probe and electrodes are sharp. Use caution when moving the boom arm.
2. Remove the wash station screw securing the wash station to the instrument.
3. Disconnect the tubing from the waste drain (located behind the buffer platform).
4. Lift the wash station - barb fitting - tubing assembly out of the instrument.
5. Use a wrench to disassemble the barb fitting from the wash station.
6. Remove the old TEFLON® tape from the threads of the fitting and replace with 2-3 wraps of new tape.
7. Reassemble the new wash station to the barb fitting. DO NOT OVERTIGHTEN as the wash station may crack.
8. Place wash station assembly into instrument. If the waste drain spout is touching the left edge of the waste container, loosen the drain mounting screw behind the buffer platform and move the drain to the right. If slide bar is present , move the drain just enough to keep the drain spout off the container opening.
9. Secure tubing to the waste drain.

NOTE: Replace the tubing if it does not securely attach to the waste drain. If tubing is not securely attached to waste drain or if waste drain is pulled out of alignment leakage may occur.

10. Remember that the barb fitting, tubing and waste drain must be straight in alignment to facilitate consistent draining to the waste container. Use a wrench to move waste station clockwise or counter-clockwise so that the barb fitting spout remains in a straight line with the tubing and waste drain.
11. Attach wash station assembly to reagent platform assembly using wash station screw.

ALIGNMENT:

GOAL: Probe assembly should be aligned: (1) left-to-right in the wash station, (2) front-to-back such that washing occurs in the front half of the wash station and (3) vertically so that at least the tip of the electrodes, but no higher than the top of the coating free area on the electrode, is washed. No splashing should be observed during priming of the instrument.

1. Perform either an Auto Boom Calibration (TEST 3.10) or Boom Calibration (TEST 3.2).
 - a. After the carousel barcode has been read and the probe has been centered over the reagent vials, the boom moves the probe over the wash station.
 - b. Carefully remove the batch reagent pack and batch pack adapter.
 - c. Align the probe left - to - right over the wash cup using the "0" or "." keys.
 - d. Align the probe front - to - back in the wash station so that the probe is a probe width (1-2 mm) from the front inside wall of the wash cup, at approximately the 6 o'clock position (Figure 1).
 - e. Loosen the wash station screw and move the wash station front-to-back as required. **DO NOT** loosen the thumb screws that secure the probe holder to the boom arm to align front-to-back.

- f. Tighten the wash station screw when alignment is achieved and press the "STORE" key.

- g. Continue with the carousel probe positioning and level sense portion of the boom calibration.
- 2. After the boom calibration has been performed, the probe should be positioned vertically such that only the tips (non-coated area) of the electrodes are washed when the "PRIME" key is pressed. Edit System parameter 10.6, WSTE ZBM, to adjust vertical height. Increase the parameter value to lower the probe further into the wash station; decrease the parameter value to raise the probe.
- 3. Press the "PRIME" key 3 times. Probe should not hit the inside wall of the wash station as it descends into the wash cup. No splashing should be observed. During washing, the buffer should not rise to the coating on the electrodes.
- 4. If probe hits the inside wall of the wash station or if splashing occurs, repeat the alignment procedure. If splashing still occurs when alignment has been optimized consider replacing the probe, valve block or tubing. Check and tighten all dispense components. Check valve tang alignment. If further troubleshooting is required, consider replacing the pump assembly or board #8.

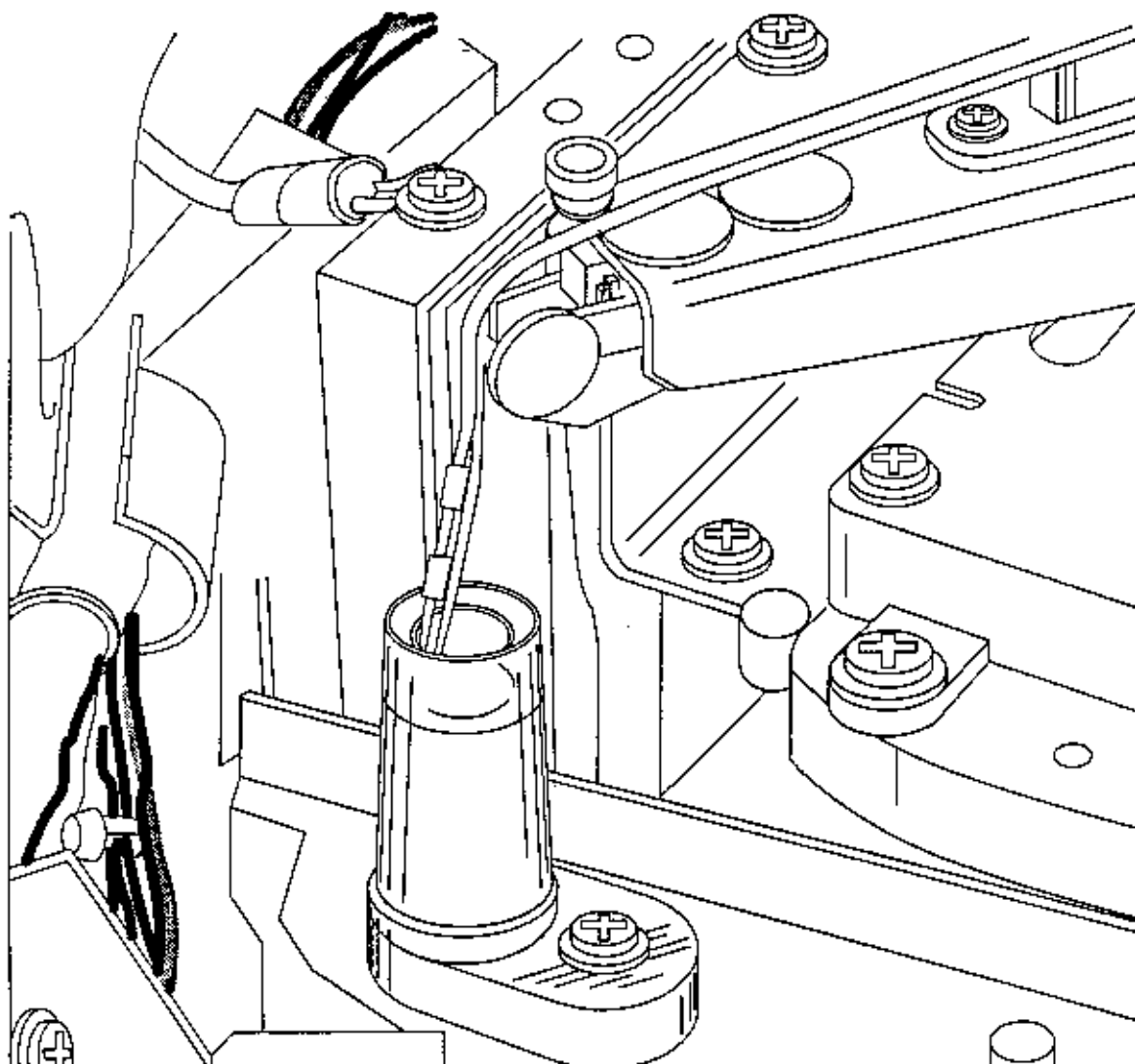


Figure 1

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| SUBJECT: ONEAC® Line Conditioner available on RZZ for TDxFLx® System | ISA#: 67-015 |
| ORIGINATOR: Ron Elston/Louis Valich | PRODUCT: TDxFLx® (67) |
| APPROVED: Bob Schabel 8/20/93 (<i>signature on file</i>) | EFFECTIVITY DATE: 13-AUG-93 |

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| TDxFLx is a registered trademark of Abbott Laboratories. ONEAC is a registered trademark of ONEAC Corporation, Bannockburn, IL. |
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This ISA is to inform the FSE in the USA that the ONEAC Line Conditioner can now be ordered by the FSE through Dallas Parts and invoiced to the customer. The following is the list number.

| Product Code | List Number | Spec: Amps/Volts | ONEAC Model # |
|--------------|-------------|------------------|---------------|
| 67 | 4A55-39 | 6.25A/120V | CP1107 |
| 09 | 4A55-37 | 4.6A/120V | CP1105 |

I will also give you information about Uninterruptible Power Supplies. These CAN NOT be ordered through the RZZ system or Dallas Parts. The customer will need to contact the ONEAC Corporation directly. For pricing information or to order call:

312-816-6000

| Product Code | List Number | Spec: Amps/Volts | ONEAC Model # |
|--------------|-------------|------------------|---------------|
|--------------|-------------|------------------|---------------|

| | | | |
|----|-----|-----------|--------|
| 67 | N/A | 7.5A/120V | ON1300 |
| 09 | N/A | 5.0A/120V | ON900 |

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