YALE-NEW HAVEN HOSPITAL	TITLE: **Tecan Freedom EVO 100**		DEPT OF LAB MEDICINE Policy and Procedure Manual DOCUMENT# IMM 170 Page 1 of 8
WRITTEN BY: Katelyn Marreiros	**EFFECTIVE DATE:** September 15, 2011	**REVISION Date:** 10/02/2012	**SUPERCEDES:** NEW

I. Intended Use:

The Freedom EVO is an open automation platform product for general laboratory use. It is intended for routine laboratory tasks, such as general purpose pipetting and general purpose liquid handling and robotic processes.

II. Summary and Explanation of the Tecan:

The Freedom EVO is an open automation platform product that will be used in the laboratory setting for several different pipetting options. It will be used in pipetting serum from patient sample tubes into their intended aliquot tubes to assist our laboratory assistants in the spinning area. Further functionality of the Tecan Freedom Evo will be determined at a later date.

III. Reagents and Materials Supplied with Instrument:

1. Disposable tips (1000 µL)
2. Carriers for 10 mm, 13 mm and 16 mm tubes (holds 16 sample tubes per rack)
3. DiTi Carrier (holds up to 3 trays of 96 disposable tips)
4. Disposable Reagent Troughs (holds up to 100 mL of liquid)
5. Quality Control Vial Rack (holds 16 QC vials per rack)
1. Falcon Tube Rack (holds 8 sample tubes per rack).

Additional Reagents Required But Not Provided

1. CLRW (Clinical Lab Reagent Water)
2. Reagent Grade Denatured Ethanol (Cardinal) made into a 70% solution
3. Chix Sports Towels
4. Biohazard bags
5. System liquid container
6. Waste container
7. Weekly maintenance rinse and wash container
8. Sample caps for large and small red top tubes
9. Cap tray

V. Maintenance

Useful Abbreviations
DiTi = Disposable Tips
FWO = Fast Wash Option
LiHa = Liquid Handling Arm
PosID = Positive Identification/barcode scanner

Supplies Needed
70% ethanol solution
CLRW
Sports Towels
Tecan System Hardware Tools

Start-up

a. Turn instrument on (green triangle on front of instrument).

b. Turn on computer.

c. Open Evoware Standard software program.

d. Log in using your Soft Username.

e. Run Maintenance.
   i. Select appropriate Maintenance program from drop down menu. (Start day maintenance)

f. Select Start your Selection.

g. Select Run: The system initializes.

h. Follow system prompts.

i. Tighten disposable tip adaptor cones. If tip adaptor cones are loose or broken follow instructions below. **Clean DiTi adaptor cones with alcohol pad.**

To replace a DiTi adapter:

1. *Switch off instrument.*
2. *Open the front safety panel.*
3. *Manually move all Z-racks up to their top most position, towards the front of the instrument and spread all the way out.*
4. *Hold the ejector tube while unscrewing the DiTi cone using the supplied cone wrench.*
5. *Remove the tip ejector tube.*

6. *Unscrew the adapter cylinder.*
7. *Pull the tubing extension and the pipetting tubing approx. 1 inch out of the tip adaptor.*
8. *Separate the tubing extension from the pipetting tubing*
9. *Remove the tubing extension together with the adapter cylinder.*

To Install the DiTi adapter:

10. *Carefully pull the pipetting tubing approx 1 inch out of the tip adapter.*
11. *Put the adapter cylinder on the tubing extension (knurled part pointing upwards).*
12. *Seize the two parts and push the conical part of the tubing extension 6-8mm into the tubing.*
13. *Screw the adapter cylinder onto the tip adapter and tighten slightly.*
14. *Slide the separator ring and then the O-ring onto the lower part of the tubing extension.*
15. *Shift the tubing into the adapter cylinder.*
16. *Slide the tip ejector tube (outer rim pointing upwards) on the adapter cylinder, hold it with one hand and screw the DiTi cone into the adapter cylinder.*
17. *Tighten the DiTi cone carefully, using the supplied cone wrench.*

j. Tighten syringes and plunger screws and check for leaks: Check syringes and plunger lock screws and tighten if necessary.

If there are leaks present

1. *Make sure the liquid container is full.*
2. *Tighten the lock nut and DiTi cones.*
3. *Tighten syringe and plunger lock screw.*
4. *Flush the liquid system until air is removed.*
5. *Observe the DiTi cones for 1 minute. If no droplets are formed the liquid system is tight.*
6. *If the system is still leaking, remove the top cover of the instrument by loosening the two outer screws. Tighten the tubing connection where the tubes leave both wheels and where the connect to the system.*
7. *Flush the liquid system.*
8. *Observe the DiTi cones for 1 minute. If no droplets are formed the liquid system is tight.*

9. *If problems still occur, call Tecan.*

k. Replace and fill tip racks:
    i. Check to make sure you have enough and replace empty positions. Check to make sure they are regular and straight when taking them out of the box. Also check the box for bacteria or abnormal particles. If you fill all of the tip locations, select yes at the system prompt. If you chose to start at the last position, select no at the system prompt.

l. Fill system liquid container with CLRW. Parafilm hose tightly into container.

m. Instrument Homes PosID and LiHa and flushes water through the system.
    i. Check for air bubbles in tubing. If any are seen, select the fast wash option to flush the system. To access the Fast Wash Option (FWO) go to main screen, choose maintenance and "flush between runs" option.

n. Click Cancel to navigate to main screen.

<u>During the Day</u>

a. Check the Liquid System: Flush the tubing prior to each run to remove any bubbles or air pockets. On the main screen, select run maintenance and choose "flush between run" option.

b. Check DiTi Waste: Check the waste bag and replace if it gets full. Lift the fastener to remove the bag housing. Remove the waste bag and dispose of appropriately and install a new one in its place.

<u>End of Day</u>

a. Run maintenance: Select End Day Maintenance.

b. Click Run.

c. Fill System Liquid container with CLRW if volume is < 1/4.

d. Empty liquid waste container.

e. Replace tip waste bag.

f. Clean DiTi Waste Slide:
    a. Open the front safety panel. Remove the cover and the waste slide. Soak in hot soapy water for a few hours or overnight. Use a

toothbrush or Q-tip applicator sticks to remove precipitated serum from the waste slide. Dry thoroughly with a sports towel.

g. System will flush to eliminate bubbles before shutdown.

h. Hit Cancel.

i. Load tips into empty spots for next day run.

j. Clean the safety panel screen with 70% ethanol solution or CLRW using a sports towel.

k. Clean carriers and racks using CLRW or alcohol wipes if necessary.

l. Unload drivers and exit.

m. Check Yes when it asks you if you want to move all arms to their home positions.

n. Turn off power on Tecan (hold down for 2 secs).

o. Shutdown PC.

p. Clean the worktable with 70% ethanol washing solution.

q. Wipe down counters with bleach or cleaning wipes.

Weekly Maintenance: PERFORMED EVERY FRIDAY

1. Save Logfiles from entire week:
    a. Go to Start, My Computer, O Drive, Immunology, Tecan Output Logfile
    b. Go to File, New Folder. Type in the "Week of" with the Month and dates of the week and the year
    c. Go to Tecan Logfiles Shortcut Folder on Desktop, Edit, Select All, Edit, Copy
    d. Go back to Tecan Output Logfile to the appropriate "Week of" folder and paste the copied logfiles in.
    e. Open the folder to make sure the files are present. If not repeat steps A thru E
    f. Go to Tecan Output Logfile, Edit, Select All
    g. On left sidebar, click the red X to delete the select items
2. Liquid System Check: Cleans the system to prevent growth of bacteria. Takes approx. 15 minutes. Use a mild detergent of 70% ethanol (600 mL). Under the "run maintenance" option, select weekly maintenance. Place the liquid system tubing in the weekly maintenance bottle A with the detergent and select run. The detergent will sit in the system for approximately 10 minutes. Put the liquid system tubing into the

weekly maintenance bottle B with CLRW and select run. Put the tubing back into the system liquid container and run the end of day maintenance.

3. System Liquid Container: Empty and clean with 70% ethanol. Rinse with CLRW to eliminate any remaining ethanol

4. Waste Container: Empty and clean with 70% ethanol. Rinse with CLRW to eliminate any remaining ethanol

5. LiHa: Clean front arm guide with a damp sports towel.

6. PosID: Clean laser output window and "No Tube" sensor. Clean PosID work area of the worktable with a lint free cloth and alcohol wipe.
    a. *To clean laser output window:*
        i. *Switch off the instrument.*
        ii. *Remove any carriers in the way of the PosID.*
        iii. *Visually check the laser output window for cleanliness.*
        iv. *Moisten a lint-free tissue with alcohol and clean the output window if necessary.*
    b. *To clean "no tube" sensor:*
        i. *Switch off the instrument.*
        ii. *Remove the carriers in the way of the PosID.*
        iii. *Slide PosID gripper back to gain access to the "no tube" sensor.*
        iv. *Moisten a lint-free tissue with alcohol and clean the front surface of the sensor.*

VII. Methodologies

1. ***To run Patient Sample Aliquoting***
    a. Select Run existing script from main menu
    b. To aliquot Large Red tubes – select "Clean_Aliquot _ Large Red"; to aliquot Small Red Tubes – Select "Clean_Aliquot _ Small Red".

NOTE: Cannot combine Large and Small Red sample tubes together on same rack; must be loaded separately.

    c. Select appropriate program and click Run.
    d. Load patient sample tubes.
    e. Load aliquot tubes into appropriate racks.
    f. Click Run (make sure door is closed).
    g. If clot is detected chose the most appropriate option to continue pipetting.
    h. At the end of the run, click cancel.
    i. Log files are stored on the desktop in a folder with a date and time stamp. Refer to these files if there are any patient sample aliquoting and pipetting errors.
    j. If an error occurs during the script, the "clean" portion of the selected program cleans out any data stored from that run, ensuring that the subsequent run is new

data with new patients. The previous run with errors will not restore previous data and continue where the script left off.

k. If more than 30 minutes passes between each run, go to the main screen. Select "Run Maintenance" and choose "flush between run" option. This will eliminate any bubbles that had formed in the tubing lines while in standby.

VIII. Quality Control

Quality control is performed by the Tecan manufacturer during the yearly preventative maintenance session. Gravimetric calibration is performed on the pipets onboard the system during preventative maintenance, as well. This applies when methodologies other than "Patient Sample Aliquoting" are being utilized. An internal verification script will be run every six months to verify source and aliquot tube mapping.

IX. Limitations of the Procedure

1. For Patient Sample Aliquoting:

a. Large Red Tubes: As of March 26, 2012, Work Groups 1, 2, 3 and 4 are in operation on the Tecan.

b. Small Red Tubes: As of March 26, 2012, Work Groups 1, 2, 3 and 4 are in operation on the Tecan.

X. Method Validation

1. For Patient Sample Aliquoting:

To validate the Tecan, test samples with CLRW were evaluated first, followed by patient serum. Test tubes filled with CLRW were given a test barcode specific to Work Groups 1 and 4. CLRW was dispensed into the corresponding aliquot tube. This was performed in several trial runs before serum patient samples were run. A total of 3 samples were validated in 2 runs using CLRW. Using patient samples, serum was dispensed into the corresponding aliquot tube. A total of 23 samples were validated in 5 runs using serum. The output data for all of the executed runs were analyzed. One hundred percent accuracy for the Tecan was achieved for patient sample aliquoting. This method occured without any discrepancies and was deemed successful for instrumentation use.

XI. Appendix

a. Tecan Maintenance Chart (Doc Imm # 170-A)
b. Tecan Rack and Work Group Charts (Doc Imm #170-B)
c. Tecan Training Checklist (Doc Imm # 170-C)
d. Tecan Training Quiz (Doc Imm #170-D)
e. Tecan Method Validation (Doc Imm #170-E)
f. Tecan QNS Chart (Doc Imm #170-F)

XII. References

1. Tecan Freedom Evo Operating Manual. Tecan Schweiz, AG, Switzerland. July 30, 2003 Version 6.0.

Tecan Daily/Weekly Maintenance																															
Month_____	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
DAILY MAINTENANCE																															
At Start of Day																															
Liquid System Check																															
Syringe																															
Tips																															
DiTi Cones																															
System Liquid Container																															
Waste Container																															
Liquid System Flush																															
Tech Initials																															
During Day																															
Liquid System Check																															
DiTi Waste																															
At End of Day																															
Safety Panel																															
Liquid System Flush																															
Tips																															
Carriers and Racks																															
Waste Container																															
DiTi Waste																															
DiTi Waste Slide																															
Worktable																															
System Liquid Container																															
Tech Initials																															

WEEKLY MAINTENANCE	Week 1	Week 2	Week 3	Week 4
Date				
Clean System & Containers				
LiHa				
PosID				
Tech Initials				

Supervisor Review/Date _____

Tecan Rack Chart

Rack Name	Tube Type
Big Red S	Large Red Top Tubes
Small Red	Small Red Top Tubes
1	DSX, Access, ANA, etc
2	Immunocap, IBT
3	Aliquot/freezer tubes
4	Send-outs (Mayo, Quest, ARUP)

Tecan Work Group Chart

Work Group #	**Rack #**	**Tube Type**	**Big Red Volume (µL)**	**Small Red Volume (µL)**
Work Group 1	1	DSX, Access, ANA, etc	500	400
Work Group 2	2	Immunocap, IBT	2000	2000
Work Group 3	3	Freezer/Aliquot Tubes	500	500
Work Group 4	4	Send Outs (Mayo, Quest, ARUP)	500	500

Tecan Training Checklist

Tech_____

Training Start Date_____

	Assisted	Un-Assisted
1. Can start up instrument & log in		
2. Can run & perform start up & start day maintenance		
3. Can perform a run a. Can load samples & aliquot tubes into appropriate work groups & racks b. Can back up system files		
4. Knows terminology & instrument parts		
5. Can run & perform Fast Wash Option		
6. Can perform minimal troubleshooting if/when necessary a. Can fix leaks b. Can assemble/disassemble DiTi cone apparatus c. Knows how to use the log file and explain the aliquot protocol		
7. Can run & perform end of day maintenance		
8. Can run & perform weekly maintenance		
9. Passed Tecan Training Quiz (+80%)		

Comments:

_____

Tech Signature/Date

_____

Trainer Signature/Date

Document Author
Katelyn Marreiros
September 12, 2011

Signature Approval for Annual Review
Name: Tecan Freedom EVO 100
Document #: Imm 170

Name (Print)	Title	Signature	Date of Review	Revision Page and Section # (Use Procedure Review Log to document staff review)	Issue Date for Training if Applicable	Effective Date for Use
TEODORICO LEE	LAB MANAGER	Teodorico Lee	10/5/12	Revised "Tecan Rack + Work Group Charts" (IMM 170B) and "Limitations of the Procedure" to reflect changes made on chart. Revised "End of Day Maintenance" under the Maintenance section. Changed Large and Small Red scripts under Methodologies.	N/A	10/02/12
BRIAN SMITH	LAB DIRECTOR	[illegible]	10/5/12			