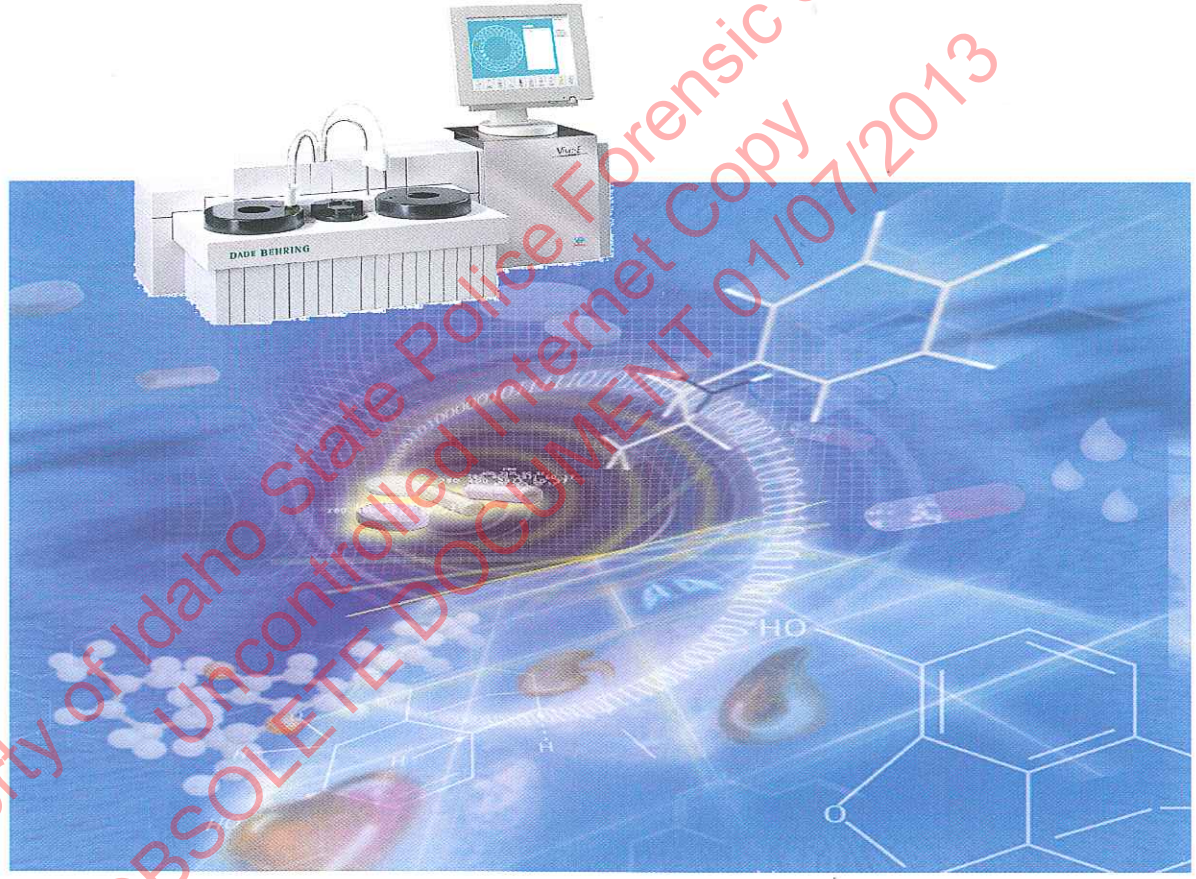
Viva·E®



Viva-E® System Operations Guide

T216 6/4/07

D01320

The Viva-E® Analyzer is manufactured by
Vital Scientific N.V.
and distributed by Dade Behring Inc.

Viva-E® is a registered trademark of Dade Behring

For Technical Assistance, please contact the
Dade Behring Technical Assistance Center at
800-227-8994

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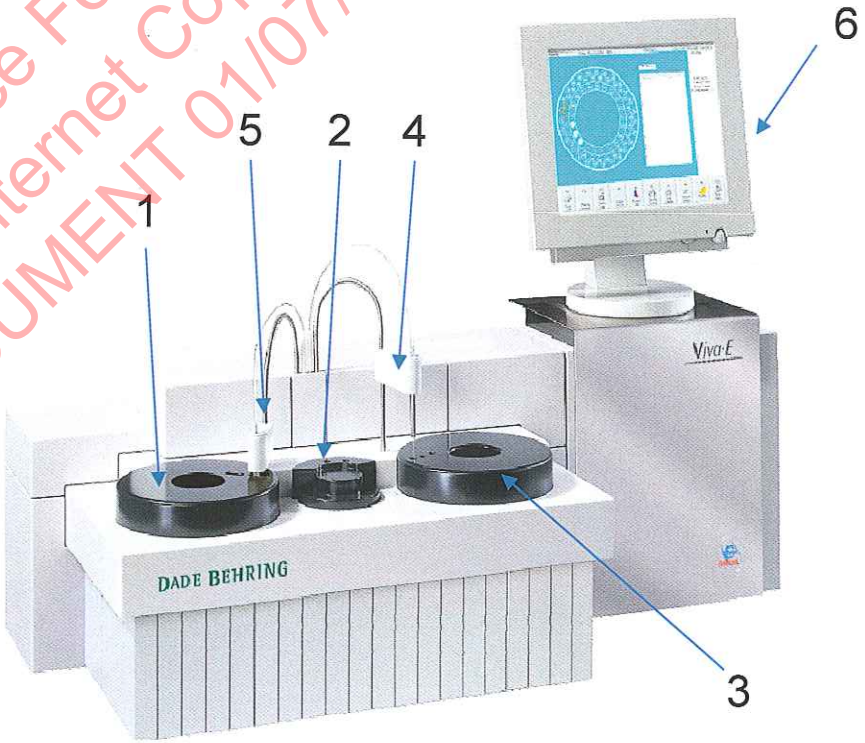
Viva-E® System Overview

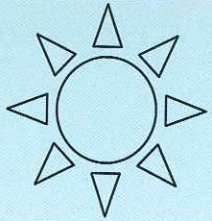
Main components of the system:

1. **Reagent Rotor**
2. **Cuvette Rotor**
3. **Sample Rotor**
4. **Sample Probe**
5. **Reagent Probe**
6. **Monitor**

The following components are not shown:

Cooling Unit
CPU
Syringes
Printer
Keyboard and Mouse





Daily Start Up

1. Fill water container **(10L DIH2O + 25mL System Solution)**.
2. Empty waste container(s).
3. Check cuvette rotor blank (refer to maintenance section and change measurement disk if there is an SD error or >10,000 tests)
4. Check printer paper.
5. Fill HCL bottle in reagent rotor **(0.1N Hydrochloric Acid)**.
6. Fill W position of sample rotor with Needle Rinse **(Sodium Hypochlorite)**.
7. Remove cuvette cover and check wash arm, mixers and cuvette rotor visually.
8. Replace cuvette cover.
9. Check that the cooling unit is on and operating correctly.
10. Check off daily start up items for today's date on the maintenance checklist and initial at the bottom box.
11. Perform Fill system (see instructions, page 20)
12. During Fill system, remove reagent caps.
13. Archive results: Select **[F7] Evaluate Samples,** select **[F2] Historic Results** and click Archive Results

Request and Run Calibration

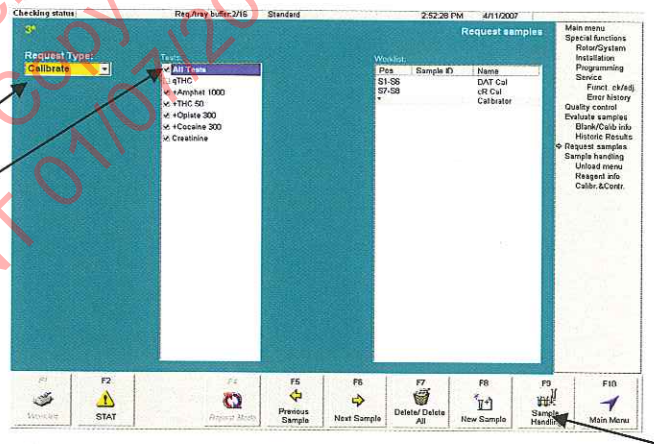
Prior to requesting calibration, print previously stored calibration to compare with new calibration:

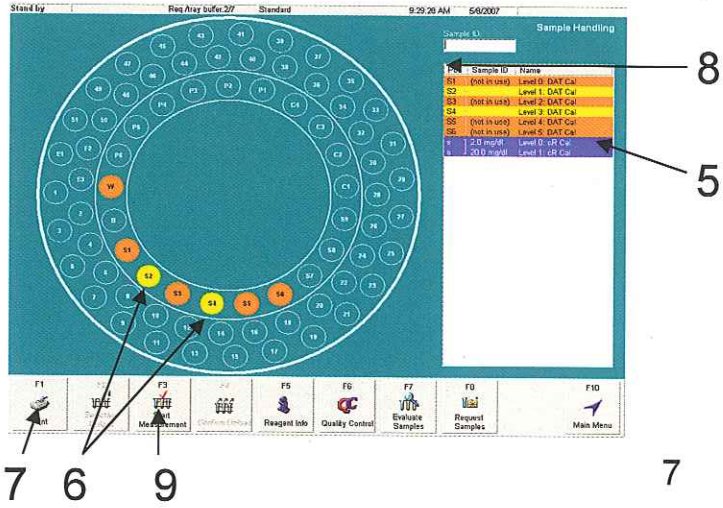
From the Main menu select [F7] Evaluate Samples, [F3] Blank/Calib Info, [F1] Print

To request calibration:

1. From the Main menu select **[F8] Request Samples**
2. Select Request Type **Calibrate**
3. Check tests or profile to select
4. Select **[F9] Sample Handling**
5. Calibrator(s) will be highlighted in blue on the worklist. Double click on the blue or press the enter key
6. The system assigns the calibrator(s) to available positions ***S1-S9** indicated in yellow on the rotor
7. Optional: **Select [F1] Print** and click Print Load List
8. Load the calibrator(s) on the rotor. Note assigned positions on the worklist under POS
9. Request controls (Page 9) **or** select **[F3] Start Measurement**

***Note: DAT calibrators Levels 0 to 5 not in use are placed in reserved positions indicated in orange on the rotor.**





Evaluating Qualitative DAT Calibration

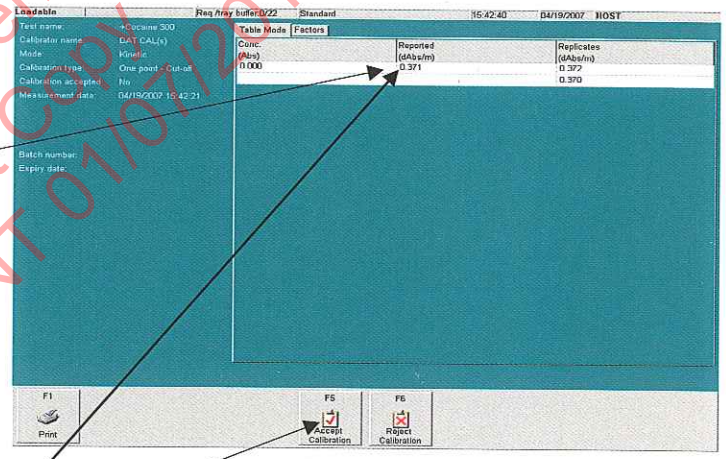
1. When the calibration screen appears, review result under "Reported dAbs/m"
2. Click **[F5] Accept Calibration** if:
   - result is relatively comparable to previous stored calibration

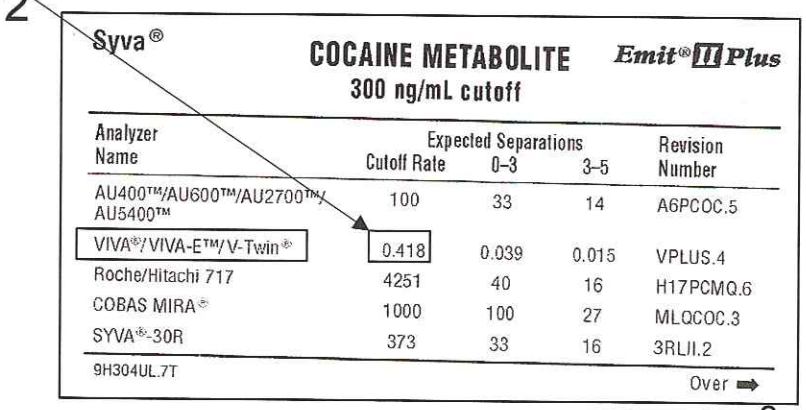
   or

   - result is relatively comparable to the number shown on the Assay Specific Guidelines card under "Cutoff" for Viva® analyzers.

   Click **[F6] Reject Calibration** if:
   - the result is a negative number or "0.000", or if calibration doesn't meet acceptable criteria

Controls must be run daily to verify calibration is acceptable.



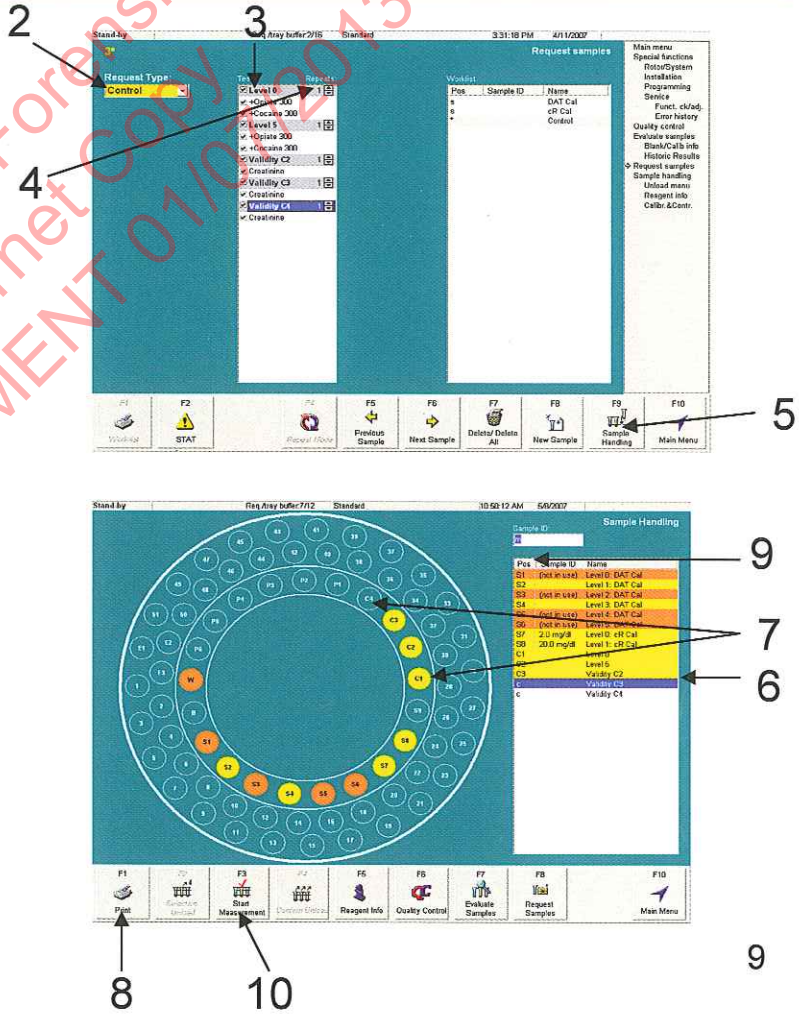


Analyzer Name	Cutoff Rate	Expected Separations 0–3	3–5	Revision Number
AU400™/AU600™/AU2700™/ AU5400™	100	33	14	A6PCOC.5
VIVA®/VIVA-E™/V-Twin®	0.418	0.039	0.015	VPLUS.4
Roche/Hitachi 717	4251	40	16	H17PCMQ.6
COBAS MIRA®	1000	100	27	MLQCOC.3
SYVA®-30R	373	33	16	3RLII.2

9H304UL.7T Over ➡

Request and Run Controls

1. From the Main menu select **[F8] Request Samples**
2. Select Request type **Control**
3. Select control name(s) to order all tests assigned to the control or select individual tests
4. If running the control more than one time, select the number of repeats by clicking on the up arrow located to the right of the control
5. Select **[F9] Sample Handling** after control(s) are ordered
6. Double click on the control(s) or press the enter key
7. The system assigns the control(s) to the first available position **C1-C4** on the rotor *(additional controls will be assigned to sample positions)*
8. Optional: **Select [F1] Print** and click Print Load List
9. Load the controls on the rotor. Note assigned positions on the worklist under POS
10. Select **[F3] Start Measurement**



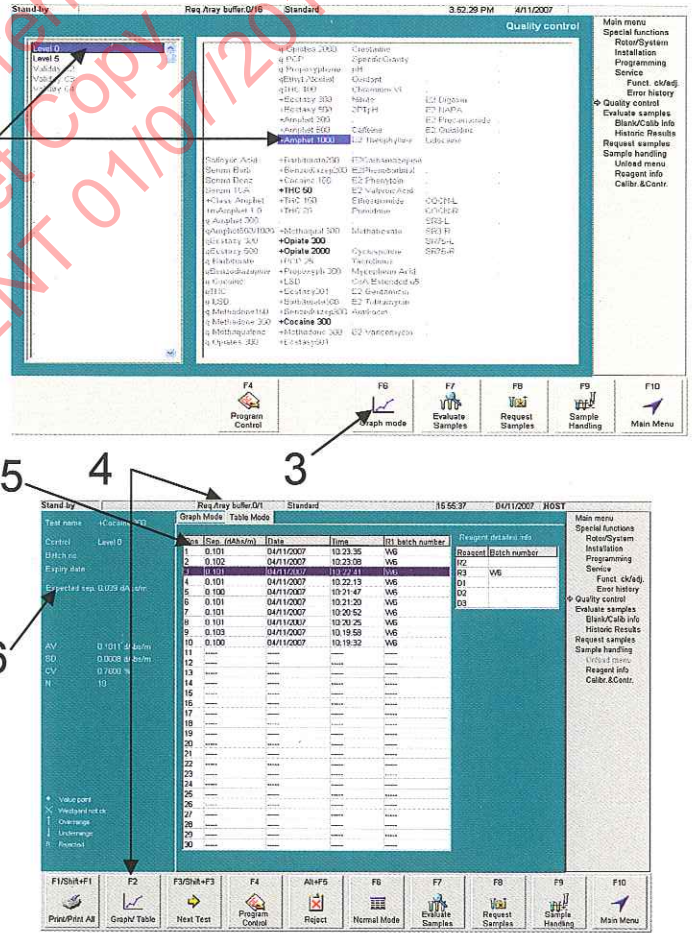
Evaluating Qualitative DAT Controls

1. From the Main menu select [F6] Quality Control.
2. Click on the control on the left and click on the assay or test on the right.
3. Press Enter or click on [F6] Graph mode.
4. Click [F2] Graph/Table or click on the Table Mode tab at the top of the screen.
5. The most recent control result will be displayed at the top of the table.
6. Result should be relatively comparable to previous run controls displayed on the table.

and

Level 0 should flag negative and its separation should be greater than the expected separation

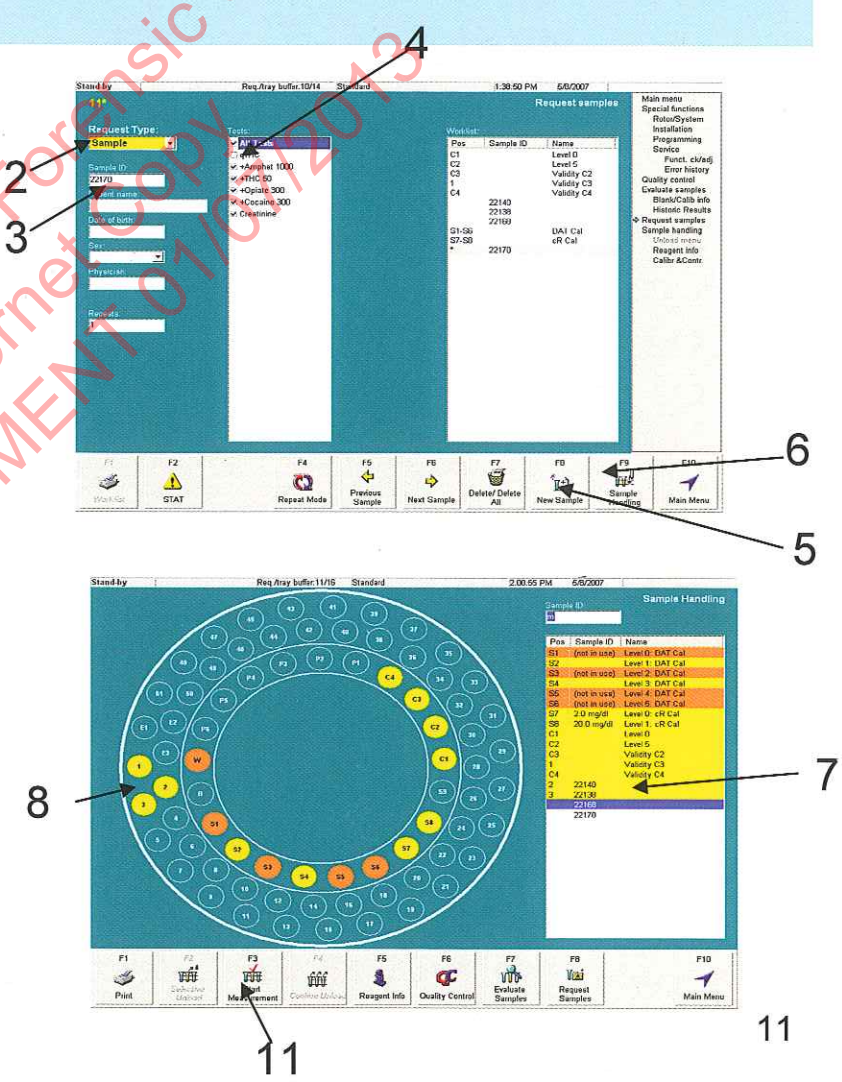
Level 5 should flag positive and its separation should be greater than the expected separation



Request and Run Samples

Non Barcoded

1. From the Main menu select **[F8] Request Samples**
2. Request Type displays Sample. If sample is a STAT or emergency request, click on down arrow to select STAT or select **[F2] STAT**
3. **Enter sample ID**. Name, date of birth, sex and physician are optional
4. Select individual tests or profile
5. Select **[F8] New Sample** to request next sample and repeat steps 2-5
6. Select **[F9] Sample Handling**
7. Double click on the first sample or press the enter key
8. The system assigns the sample to the first available position **1-51** on the rotor STAT samples are assigned to positions **E1-E3**
9. Repeat step 7 to complete work list assignment
10. Load samples on the sample rotor
11. Select **[F3] Start Measurement**



Request and Run Samples

Interfaced with a Non-Host Query Data Management System (DMS)

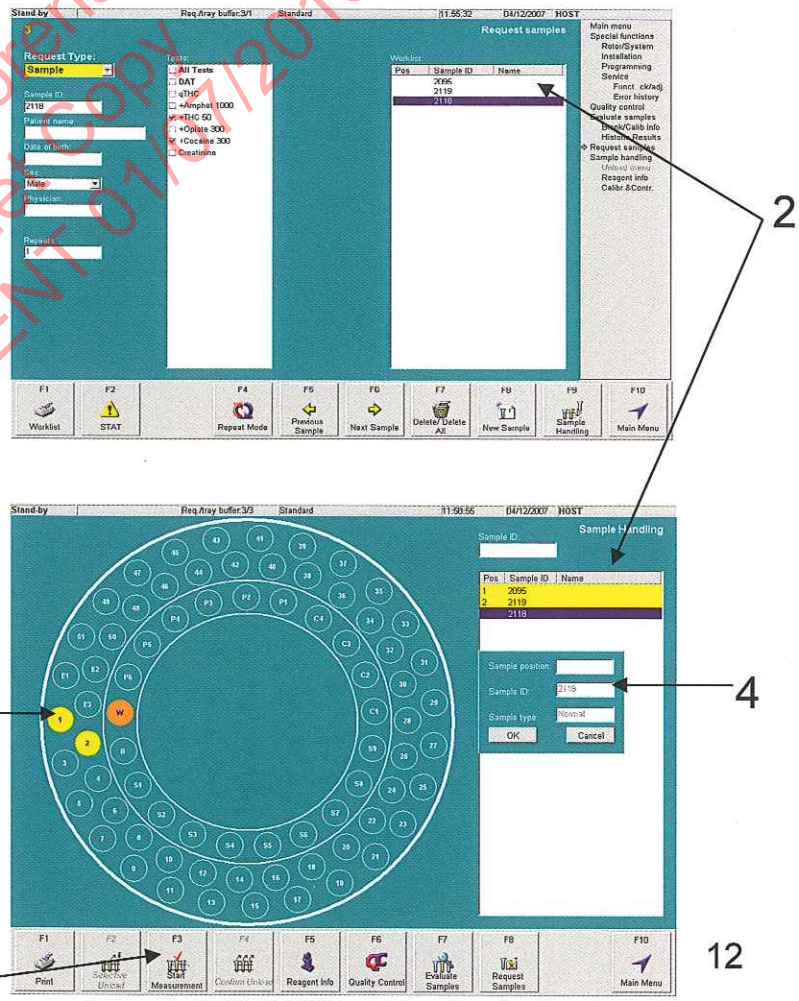
Samples and test requests must first be requested at the host computer

Barcoded

1. Select **[F9] Sample Handling** from the Main Menu
2. See the downloaded work list from the host computer.
3. Double click on the sample ID to assign to the first open position **or**
4. Right click on the mouse to assign to a single position
5. Repeat steps 3 or 4 to complete work list assignment.
6. Load barcoded samples in assigned sample rotor positions (1-51)
7. Select **[F3] Start Measurement** to begin sample testing.

No interface

See Request and Run Samples Non Barcoded (page 11)



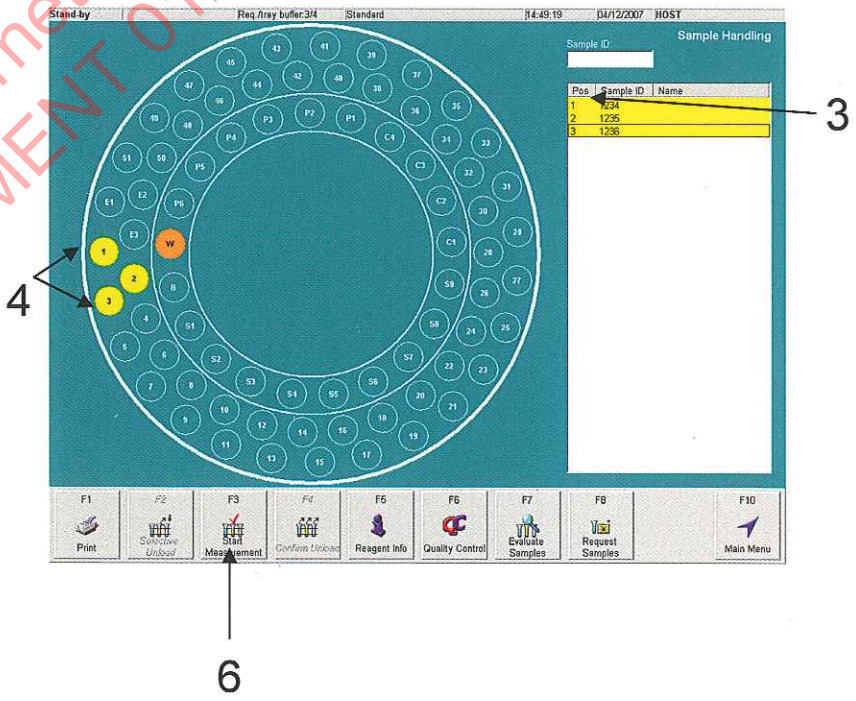
Request and Run Samples

Interfaced with a Host Query Data Management System (DMS)

Samples and test requests must first be requested at the host computer and sample tubes must have barcode labels

Barcode Scanner is required

1. From the Main menu, press **[F9] Sample Handling**
2. Scan the barcode on the sample tube. The analyzer will query the DMS for the sample order
3. The sample will be automatically assigned to the first free position on the rotor. The worklist will reflect the newly assigned position
4. Load corresponding sample on sample rotor in the correct position
5. Repeat steps 2-4 to complete work list assignment
6. Select **[F3] Start Measurement**

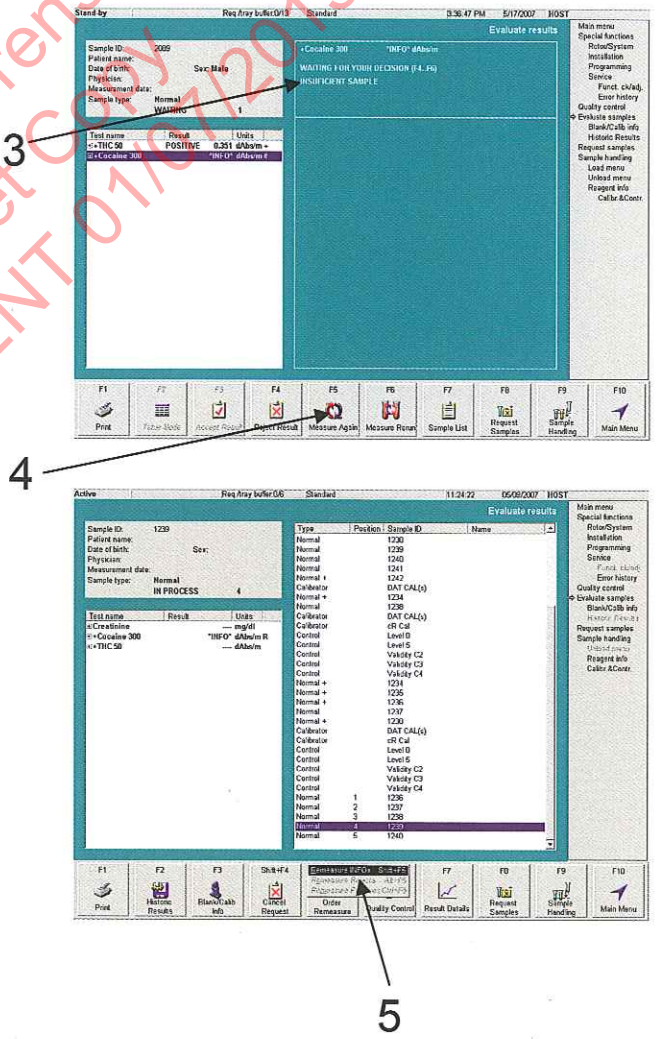


Empty with White Border | Position is free | Remeasure INFOs/ Positives/Rejects | Unload Calibrator/ Control/Sample

Remeasure INFOs

All tests flagged INFO are remeasured from the analyzer

1. Select **[F7] Evaluate Samples**
2. View **[F7] Result Details** for samples that are marked INFO
3. Correct the error that generated the INFO. INFOs can be accepted, rejected or remeasured.
4. To remeasure **a test** select **[F5] Measure Again**
   or
5. To measure **all tests** flagged INFO, select **[F7] Sample List,** select **[F5]Order Remeasure** and scroll to Remeasure INFOs
6. The system will automatically resume to the Active status.



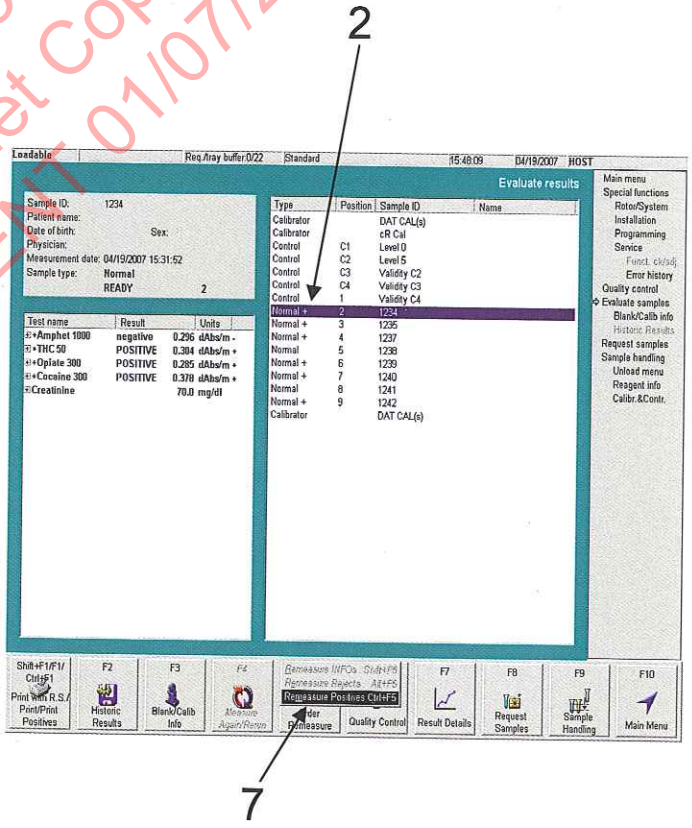
Empty with White Border | Position is free | Remeasure INFOs/ Positives/Rejects | Unload Calibrator/ Control/Sample

Remeasure Positives

Customers ***not*** connected to a Data Management System (DMS) such as a WinTOX or a Laboratory Information System perform the following

1. Select **[F7] Evaluate Samples**
2. View results that are positive by looking for samples with a "+" next to the sample ID
3. Mark a clean sample tube with the sample ID and pour a fresh aliquot of the sample into the marked tube
4. Remove and discard the initial positive sample tubes
5. Place the new aliquot for each sample into it's original position on the sample rotor. *(Sample positions are indicated in the Evaluate Samples screen)*
6. Select **[F5]Order Remeasure**
7. Scroll to Remeasure Positives option and select
8. The system will automatically begin the run and will enter the Active status

Note: Customers connected to a DMS/WinTOX can be set to automatically reorder positive samples from their DMS/WinTOX



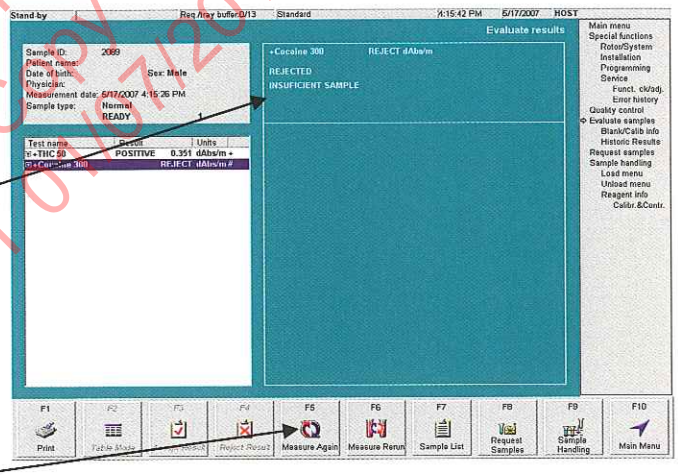
Empty with White Border | Position is free | Unload Calibrator/ Control/Sample

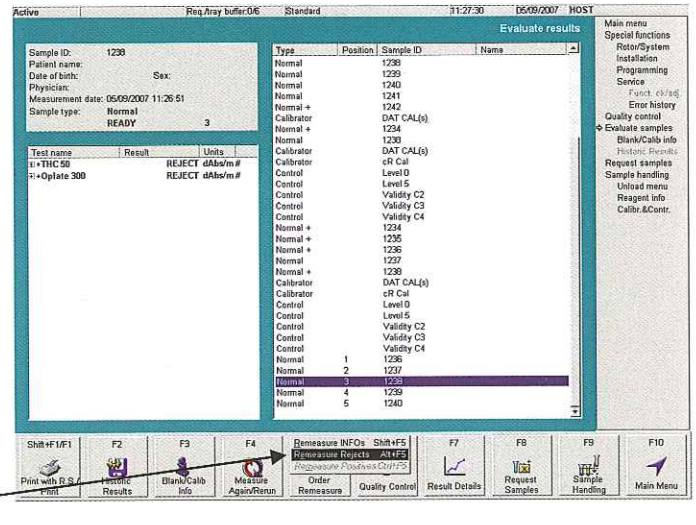
Remeasure Rejects

Customers ***not*** connected to a Data Management System, WinTOX or LIS* should rerun rejects using the following steps

1. Select **[F7] Evaluate Samples**
2. View **[F7] Result Details** for samples that are flagged REJECT
3. Correct the error that generated the rejected test result.
4. To remeasure **a test** select **[F5] Measure Again**
   or
5. To measure **all tests** flagged REJECT, select **[F7] Sample List**, select **[F5]Order Remeasure** and scroll to Remeasure Rejects
6. The system will automatically resume to the Active status.

Note: Customers connected to a DMS/WinTOX are to reorder rejected results from the DMS/WinTOX





Empty with White Border | Position is free

Unload Calibrator/ Control/Sample

Unload Calibrator/Control/Sample

In the sample handling screen, there are two different options for unloading samples, calibrators or controls

Unload All Completed Samples, Calibrators or Controls

1. Select [F4] Confirm Unload from the Sample Handling screen
2. Remove all sample tubes from the rotor

or

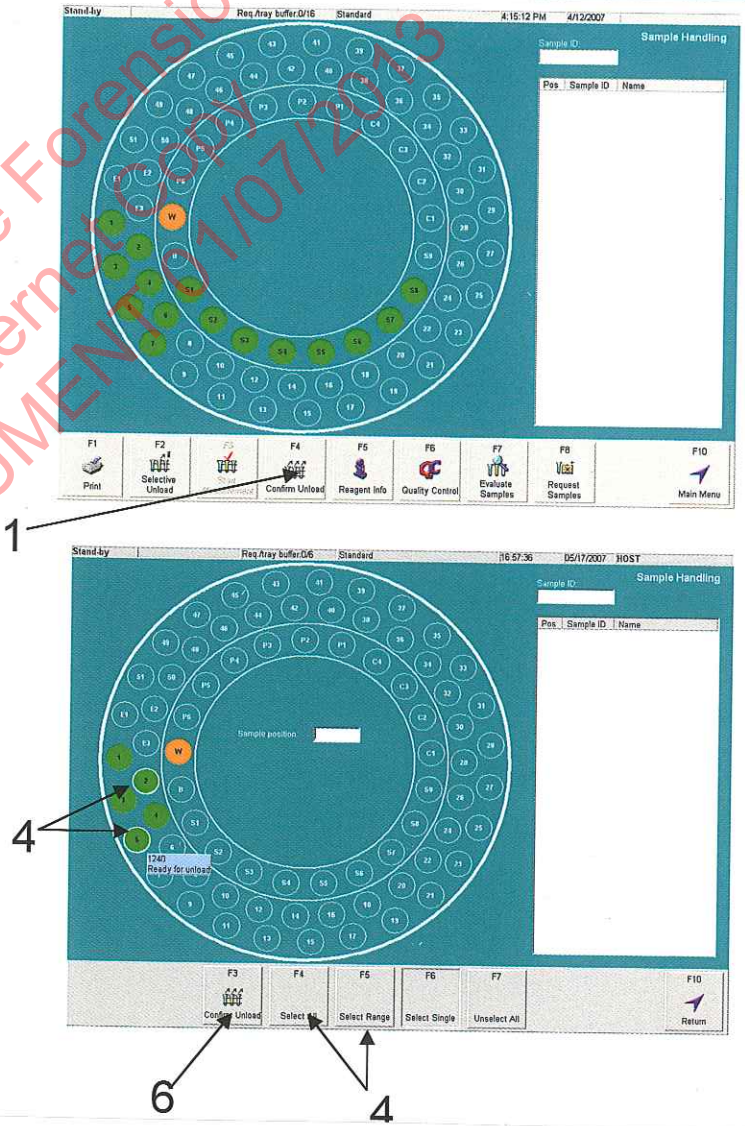
Selective Unload

3. In the Sample handling screen, select [F2] Selective Unload
4. Use the mouse to select sample positions to be unloaded (note samples selected are circled in white)

or

to select multiple samples to unload, select [F5] Select Range or [F4] Select All to unload selected samples, calibrators or controls

5. Remove selected tubes from sample rotor
6. Select [F3] Confirm Unload to confirm the samples were unloaded from the sample rotor



Empty with White Border | Position is free

Color codes for sample rotor positions

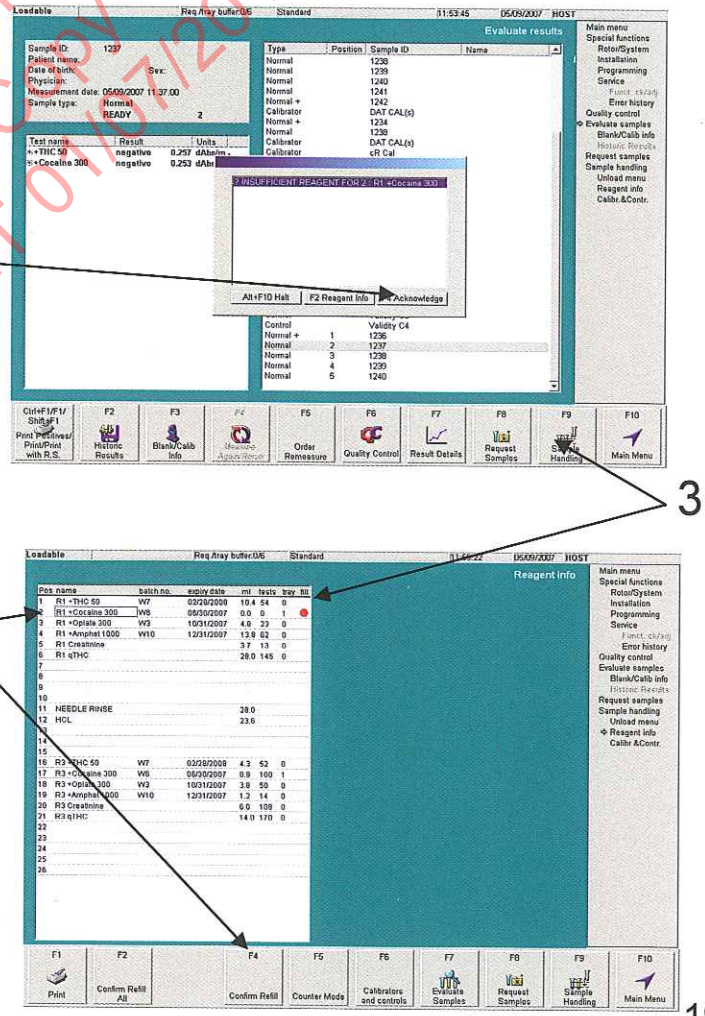
Orange	Reserved position for calibrators not in use. Do not load in these positions.
Green with **Orange Border**	Processed and flagged INFO -- requires operator interaction Go to **F7 Evaluate Samples** to accept, reject or remeasure
Green	Processed and the results were accepted or rejected. Ready to unload.
Green with **Light Green Border**	Processed however **not** ready to unload.
Black	In process
Gray	Started, about to be measured
Yellow	Position is assigned but not started
Yellow with **Green Border**	A host query request is pending
Yellow with **Red Border**	Sample ID scanned but no tests requested. Select and Unload
Green with **White Border**	Selected for Unload
Empty with **White Border**	Position is free

Insufficient Reagent Error

1. Read message inside pop-up box indicating which reagent bottle and position is empty. Select **[F4] Acknowledge** and wait for system status to go into **"Loadable"**.
2. Remove reagent rotor cover and refill empty reagent bottle. Replace reagent rotor cover.
3. Select **[F9] Sample Handling** and **[F5] Reagent Info.** Red dot indicates an empty bottle.
4. Click on the bottle that was refilled and select **[F4] Confirm Refill.**
5. Another pop-up box asks "Accept calibration curve for *the reagent that was empty"* Select **F5 Accept curve** if refilling with the same lot number or **F6 Reject curve** if refilling with a new lot of reagent.

Note : It is recommended to run controls after refilling the same lot of reagent and after calibrating.

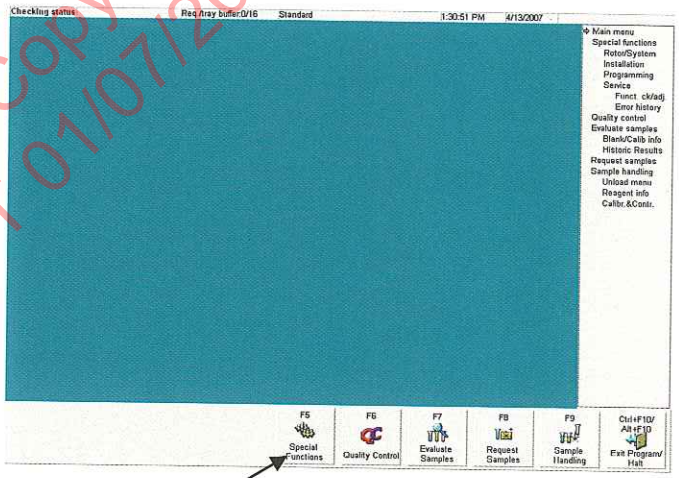
OR F6 System Reset to Standby →

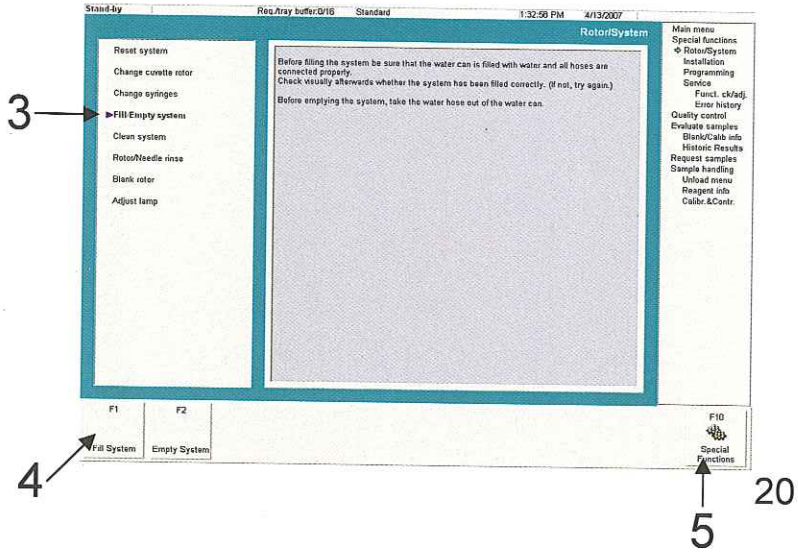


Fill System

To prime the lines and perform Fill system for Daily Start Up:

1. From the Main menu select **[F5] Special Functions**
2. Select **[F1] Rotor/System**
3. Select **Fill/Empty system**
4. Select **[F1] Fill System**
5. **Select [F10] Special Functions**
6. **Select [F10] Main Menu**

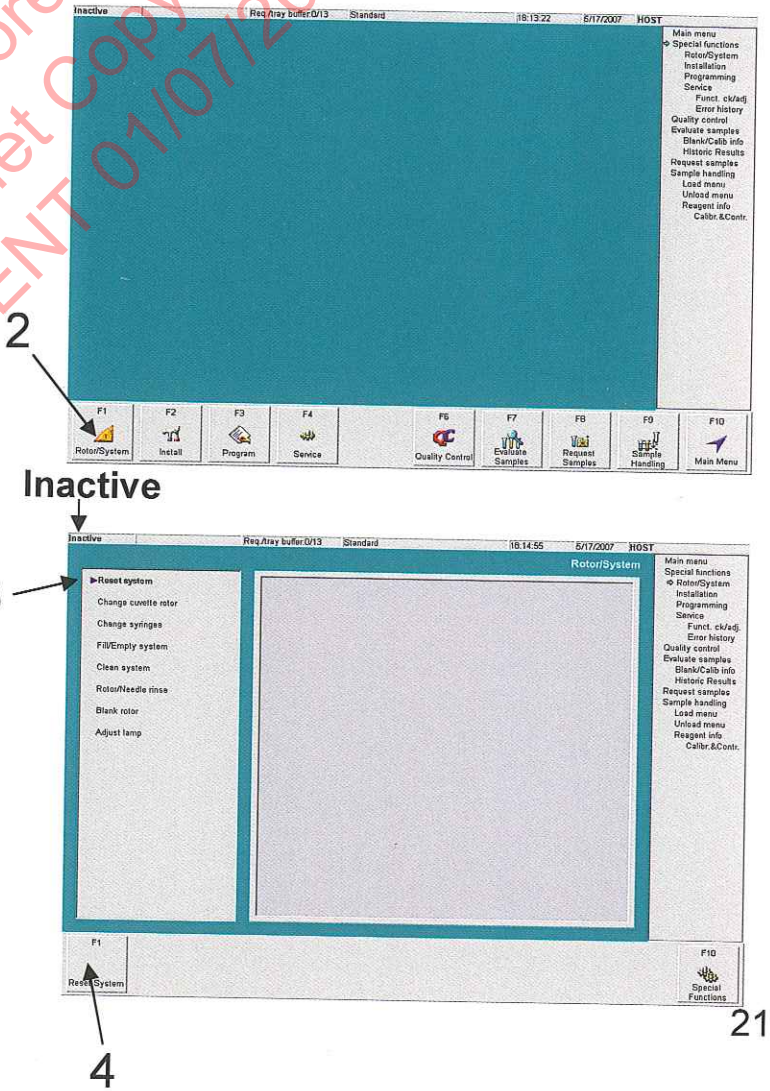




Inactive--Reset System

The analyzer needs to be reset when you have an "**Inactive**" message appear in the upper left corner

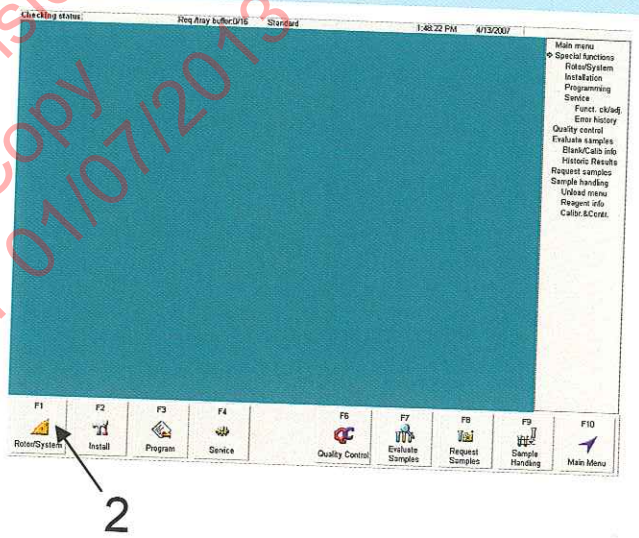
1. From the Main menu select **[F5] Special Functions**
2. Select **[F1] Rotor/System**
3. Select **Reset system**
4. Select **[F1] Reset System**
5. System returns to **"Stand By"**

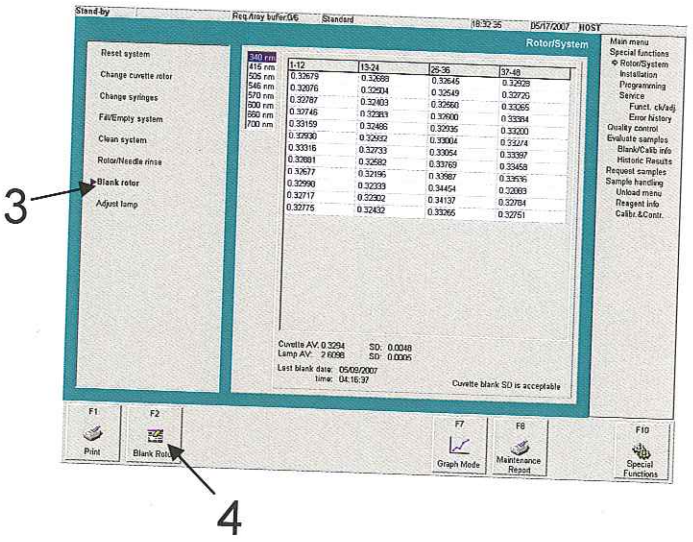


Cuvette Blank Rotor

To manually perform a cuvette blank rotor:

1. From the Main menu select **[F5] Special Functions**
2. Select **[F1] Rotor/System**
3. Select **Blank rotor**
4. Select **[F2] Blank Rotor**





Preventive and As Needed Maintenance

Weekly

- Perform needle rinse procedure
- Exit and restart analyzer and computer

Monthly

- Clean water and waste containers
- Exit and shutdown analyzer

Quarterly

- Replace water filter
- Replace mixer belts
- Replace drying blocks

As needed

- Replace cuvette rotor
- Change reagent bottles on the rotor

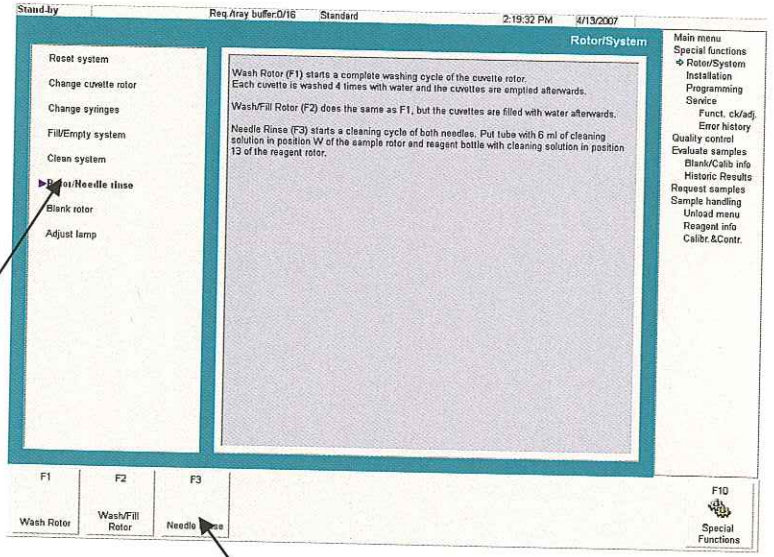
Weekly Maintenance

Needle Rinse

Fill the needle rinse bottle (full) on the reagent rotor and fill a tube (full) placed in position W on the sample rotor, with fresh Sodium Hypochlorite solution (Needle Rinse)

2

1. From the Main menu select **[F5] Special Functions**
2. Select **[F1] Rotor/System**
3. Select **Rotor/Needle rinse**
4. Select **[F3] Needle Rinse**



3

4

Weekly/Monthly Computer Maintenance

Weekly

1. Select **[F10] Exit program**
2. From the windows desktop, select Start, Shutdown and click drop down arrow to select Restart. Click OK
3. Double click Viva-E analyzer icon

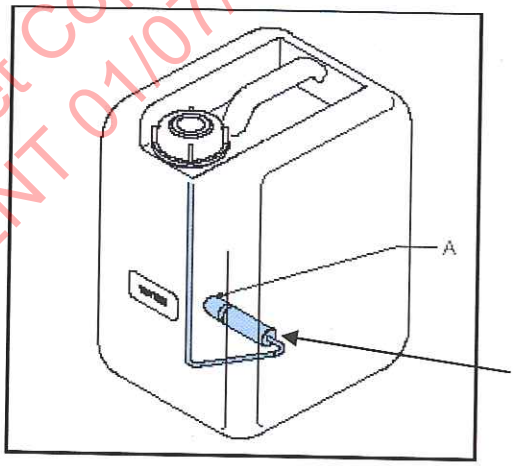
Monthly

1. Select **[F10] Exit program**
2. From the windows desktop, select Start, Shutdown and click OK
3. Turn off analyzer power button in the back
4. Wait about 10 seconds and turn analyzer power button back on
5. Turn on the computer by pressing the power button located in the front of computer
6. Double click Viva-E analyzer icon

Monthly/Quarterly Maintenance

Monthly

Clean water and waste
containers with 0.1 N NaOH
(**Sodium Hydroxide**)

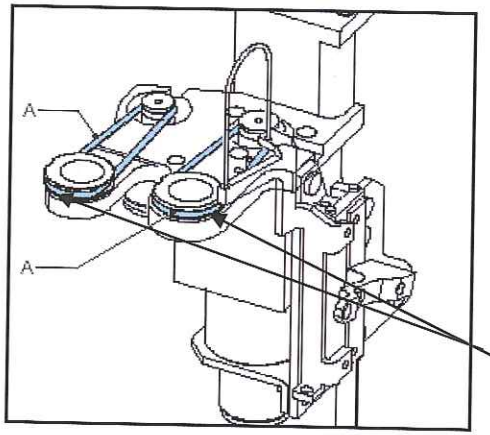


Water Filter

Quarterly

Replace water filter by unscrewing and replacing with new filter

Replace mixer belts by removing and replacing with new belts

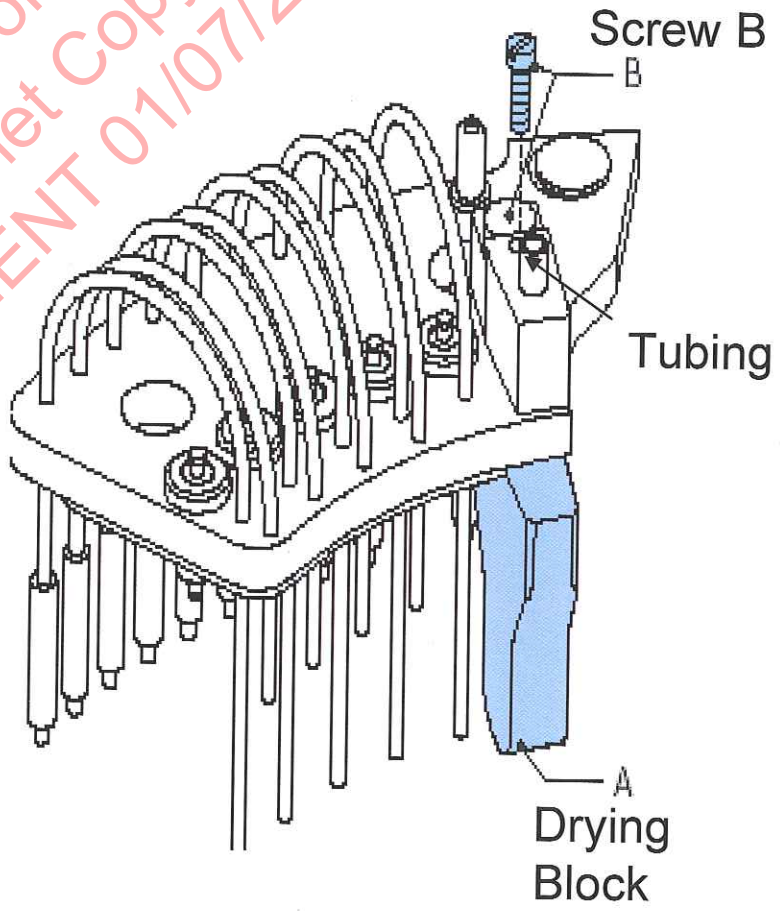


Mixer Belts

Quarterly Maintenance Con't

Replace drying block on wash arm

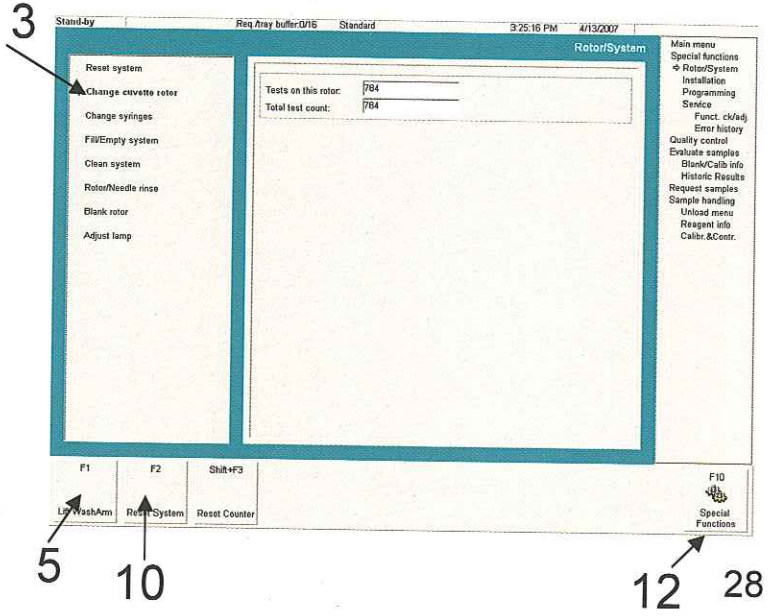
1. Remove the cover of the measurement disk .
2. From the main menu, select **[F5] Special Functions.**
3. Select **[F4] Service.**
4. Double click **Functional checks/adjustments.**
5. Double click **Wash Arm.**
6. Select **[F1] Reset Wash Arm.**
7. Press arrow up key on your keyboard to lift the wash arm.
8. Disconnect the tube from the drying block.
9. Loosen screw B and replace the drying block A of the wash arm with a new one, but do not tighten screw B yet. Be careful not to drop the loose screw into the analyzer. Use a screwdriver with a magnetic tip.
10. Press arrow down key on your keyboard to lower wash arm.
11. Wait for the wash arm to go to the correct location.
12. Press arrow down key on the keyboard to put the drying block in the correct position.
13. Tighten the screw B of the drying block.
14. Connect the tube to the drying block.
15. Select **[F10] Return.**
16. Select **[F10] Special Functions.**
17. Select **[F1] Rotor/System.**
18. Click **Reset System.**
19. Select **[F1] Reset System.**
20. Replace the cuvette cover.



As Needed Maintenance

Replace cuvette rotor:

1. From the Main menu select **[F5] Special Functions**
2. Select **[F1] Rotor/System**
3. Click **Change cuvette rotor**
4. Remove cuvette rotor cover
5. Select **[F1] Lift WashArm**
6. Select **[F1] Yes** to reset counter
7. Manually lift mixer tray and remove cuvette rotor
8. Carefully replace new cuvette rotor by lining up the notches to the slits of the rotor (Do not touch the sides of the disk; hold it by its center)
9. Manually lower the mixer tray
10. Select **[F2] Reset System**
11. Replace cuvette rotor cover
12. Select **[F10] Special Functions and [F10] Main Menu**
13. Perform cuvette blank rotor (refer to Cuvette Blank Rotor instructions page 22)



As Needed Maintenance

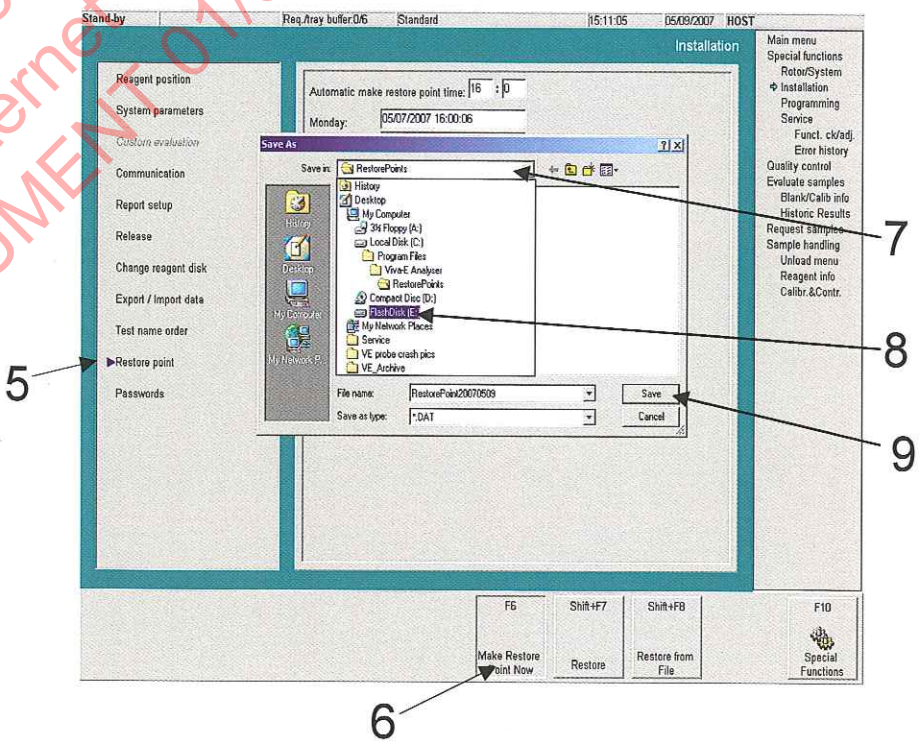
Change reagent bottles on the rotor:

1. Discard on-board 28 mL and 14 mL bottles* after one month or when a new lot of reagent is used.
2. Replace with new bottles.
3. Discard any unused reagent inside of the bottles.

**Applies to bottles which reagent is poured into*

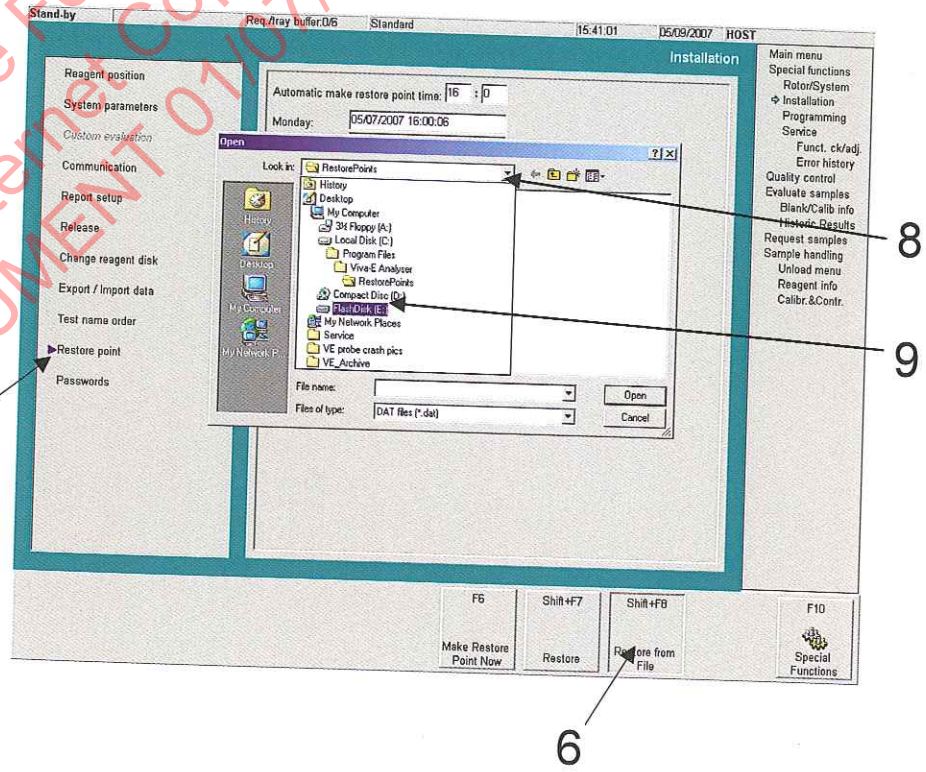
System Back Up

1. Access the Main Menu screen
2. Insert a USB stick into a USB port of the analyzer's computer
3. Select **[F5] Special Functions**
4. Press **[F2] Install**
5. Select "Restore point"
6. Select **[F6] Make Restore Point Now**
7. From "Save In" box, click down arrow
8. Select Removable Disk (E:)
9. Click "save" and click "OK"
10. Select **[F10] Special Functions**
11. Select **[F10] Main Menu**
12. Select **Cntl + [F10] Exit Program** and click Exit Program
13. To properly remove the USB stick, at the bottom right of the screen next to the clock, click the green arrow and click on "Stop USB…" and follow the prompts



System Restore

1. Access the Main Menu
2. Insert a USB stick into a USB port of the analyzer's computer
3. Select **[F5] Special Functions**
4. Select **[F2] Install**
5. Select "Restore point"
6. Select **[F8] Restore from File**
7. Click "Yes"
8. Use drop down arrow to expand folders
9. Select Removable Disk (E:)
10. Select recent "restore file" and double click
11. Select OK – Viva-E will reboot
12. To properly remove the USB stick, minimize the Viva-E screen by pressing the Windows and M key simultaneously. At the bottom right of the screen next to the clock, click the green arrow, click on "Stop USB…" and follow the prompts



Data Back Up

Already Done

Set-Up

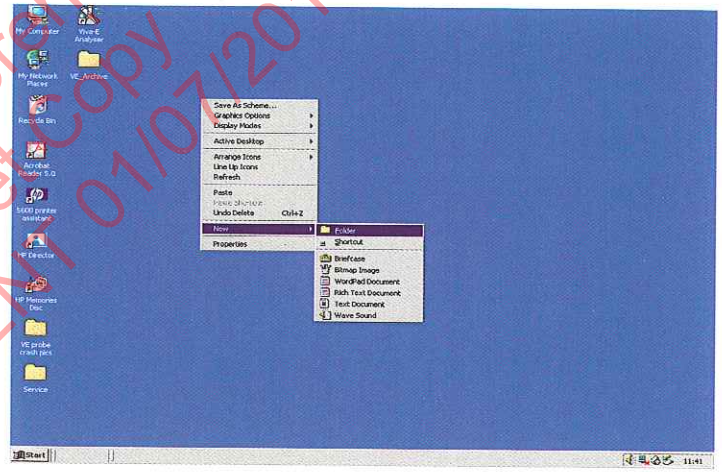
1. On the analyzer's computer desktop, create a new folder named VE_Archive: Right click anywhere on the Desktop. Highlight "New" and click on "Folder", type VE_Archive
2. Open the Viva-E analyzer. From the Main Menu, select **[F5] Special Functions, [F2] Install** and select System parameters
3. Select **[F5] Change Disk Results Location**
4. Highlight the VE_Archive folder and click OK

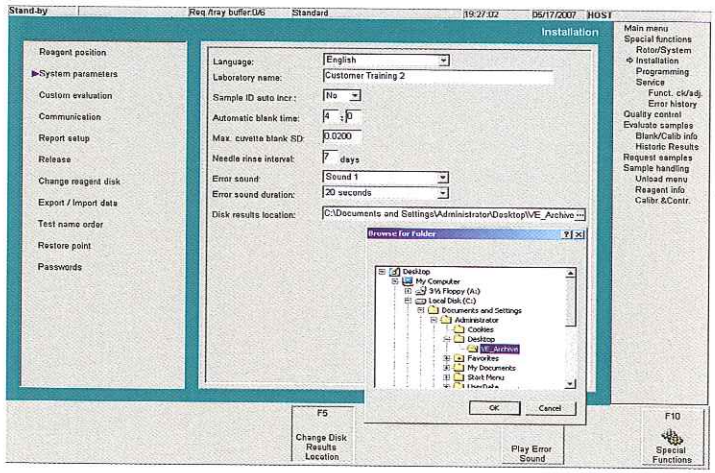
Archive Results (perform daily)

1. From Main menu, select **[F7] Evaluate Samples**
2. Select **[F2] Historic Results** and scroll to Archive Results

Weekly Data Back Up

1. Insert a USB stick into a USB port of the analyzer's computer
2. From the Main Menu select **[F10] Exit Program**
3. Right click on the VE_Archive folder on your desktop and select Copy
4. Double click on My Computer
5. Right click on Removable Disk (E:) and select Paste
6. Select "Yes to All"
7. Close screen by clicking on X in the upper right corner
8. To properly remove the USB stick click on the green arrow down by the clock in the lower right hand-side of the computer screen, click on "Stop USB…" and follow the prompts
9. Start the Viva-E analyzer by double clicking on the icon on the desktop.





Data Restore

1. Insert **Data Back Up** USB stick into a USB port of the analyzer's computer
2. Double click on My Computer and double click Removable disk (E:)
3. Right click on the VE_Archive folder and select copy
4. Close all open windows
5. Right click on the desk top and select paste
6. To properly remove the USB stick, at the bottom right of the screen next to the clock, click the green arrow, click on "Stop USB…" and follow the prompts
7. Start the Viva-E analyzer by double clicking on the icon on the desktop.
8. Set the system parameters disk results location to the VE_Archive folder on the desktop *(see page 32 under Set-Up)*