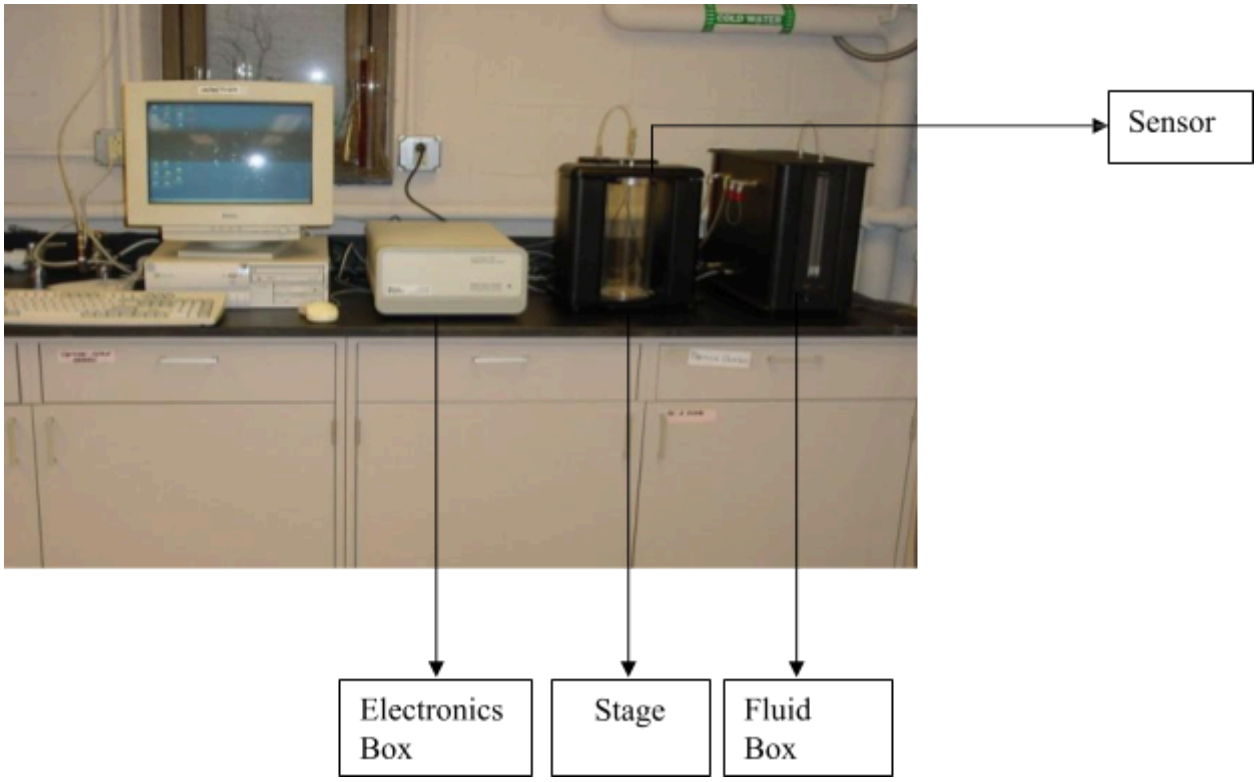
Pressurized Automated Liquid System



The Pressurized Automated Liquid System has three main parts:

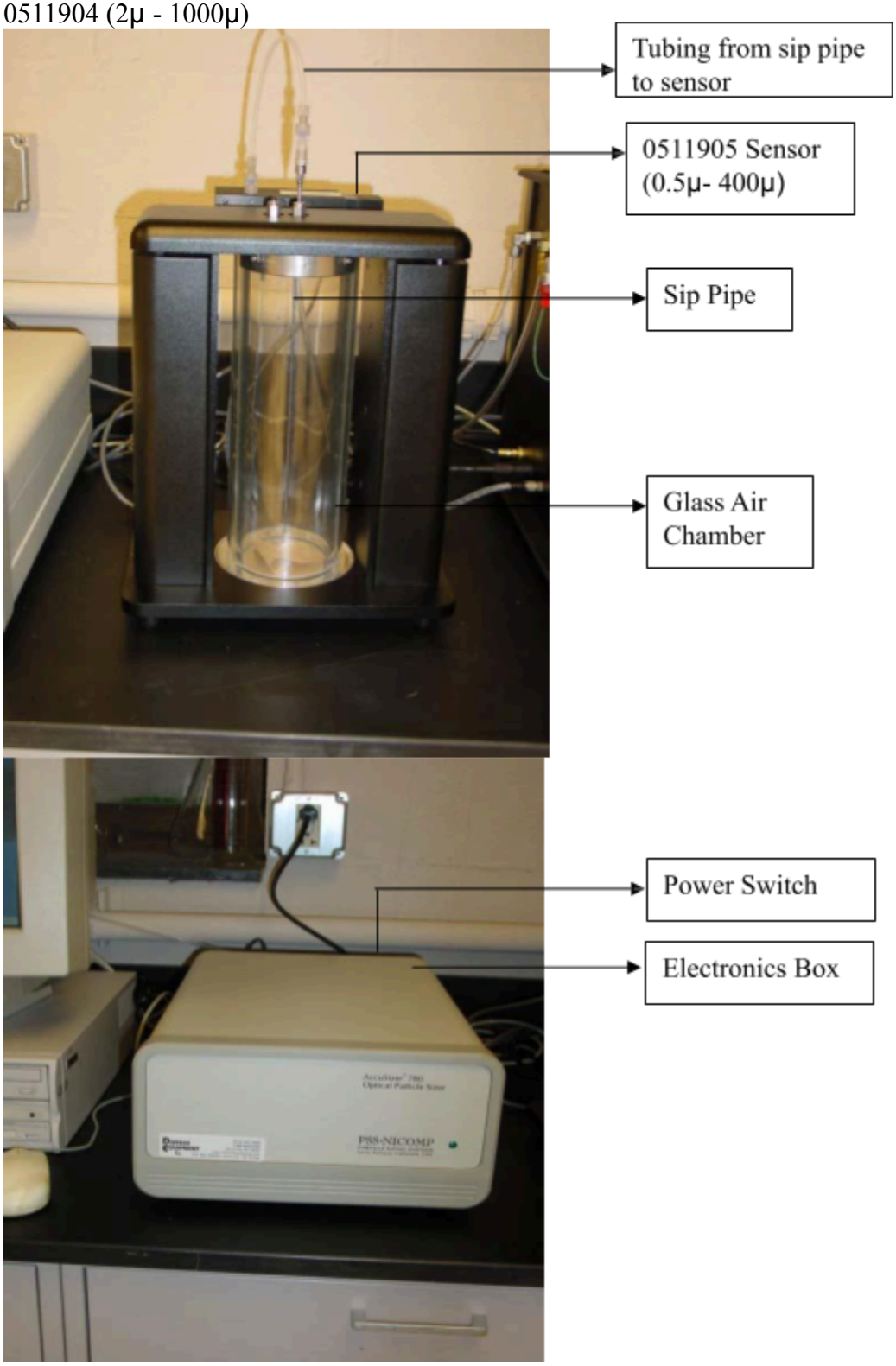
1. Electronics to process sensor data
2. Stage
3. Fluid Box

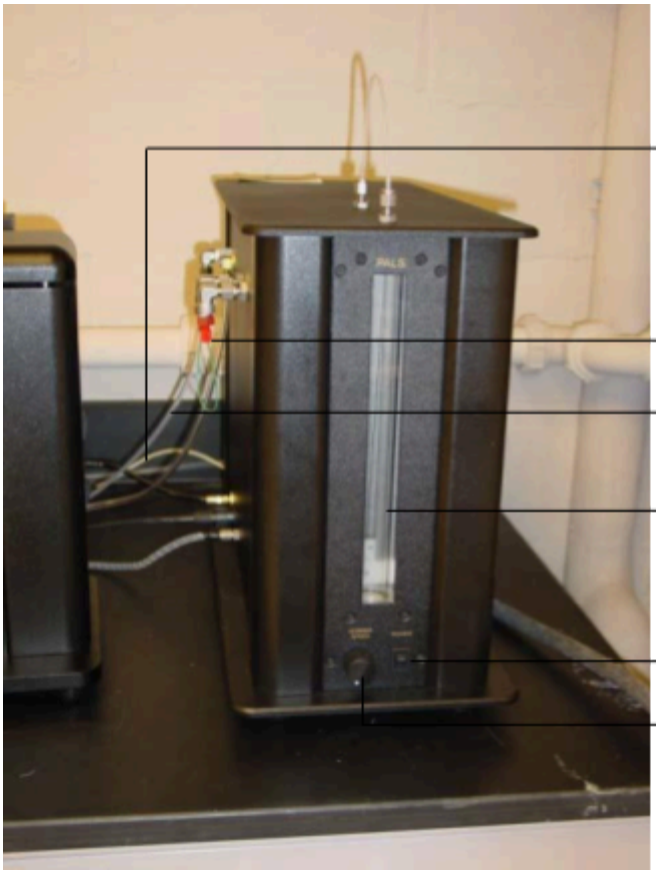
Principle:

A known volume of an emulsion containing particles whose size distribution is to be determined is taken in a glass chamber which is pressurized by air. The solution is then sent through the sip pipe from which the solution flows through the sensor which counts the particle. And accordingly passes the analog signal to the electronics box which converts the analog signal to the digital one and provides the particle distribution curves. Based on the particle size there are two sensors which are provided:

Sensor 1
0511905 (0.5µ- 400µ)

Sensor 2
0511904 (2µ - 1000µ)





Drain Pipe

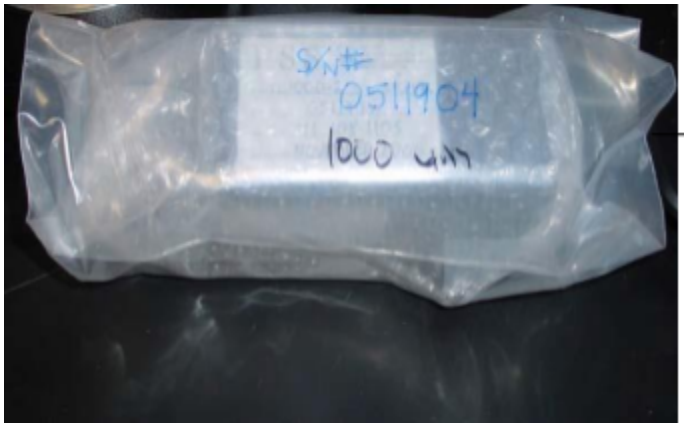
Restriction Loop

Chamber Pressure

Burette

Power Switch

Magnetic Stirrer



0511904 Sensor
2µ - 1000µ

Pressurised Automated Liquid Sampler

1. Turn instrument on and allow the instrument to warm up for ½ hour.
2. Start Software
3. Verify that the reported sensor voltage (see the sensor status screen from the View pull down menu) is within 10% of the maximum observed voltage. If not remove sensor and clean.
4. Set the minimum detected size of the instrument to 0.56 um (lower threshold is set by using the up and down cursor keys when the screen in blank and can be observed in the right most box of the status bar).
5. Flush the instrument with clean (filtered) water until the cumulative count > 0.56µm is less than 20ml.
6. If counts do not decrease to < 20ml replace the sip tube with a new one and try again.
7. Verify the volumetric accuracy of the SIS as instructed in the manual.
8. Set analysis parameters:
    - Flow rate for the liquid selected
    - Pre Analysis Dead Volume
    - Sample per run
    - No of Runs

9. Prepare the PQ standard for immediate introduction into the instrument.
    - Mix the bottle by inverting 25 times
    - Sonicate the sample by placing the bottle in a sonic bath for 30 seconds

    Note: if the sample rests for more than 60 seconds before sample extraction prepare the sample again.
10. Sample bottles have a stir bar inside. Set stir speed to 25% and place sip tube such that the stir bar does not hit it nor is it in the vortex.
11. Click on the start measurement from the tool bar.
12. Ensure the data file saved to the computer for analysis.

Analyzing the Data:

13. Read one of the data files just created (not the *.cb file).
14. Move to the data display to population distribution (128 channels).
15. Press Ctrl +B and choose to display the data in 512 channels.
16. Press M to activate the user defined peak option. A window will appear at the bottom of the screen displaying data on the full range of the distribution.
17. Place the mouse cursor over the graph and click. This produces a cross hair on the graph , use the cursor <left> and <right> keys on the keyboard to move the cross hair to the first lower channel size as defined by the attached certificate of analysis and press < Enter>.Position of the cross hair is displayed on the status bar.
18. Then move the cross hair to the upper channel size as defined by the attached certificate of analysis and press <Enter>
19. The software places a vertical black line on each side of the peak indicating the range of the sizes you wish to examine. The window at the bottom of the screen now contains intermation at this range. Ensure the range is correct and record the “mean diameter” and the particles in range. Repeat this for each peak in the count standard.
20. The software allows 3 user defined peaks to be defined and can be printed by choosing “Cumul Result Table” from the print menu.
21. To calculate the concentration of particles in #ml for each peak, divide the # of particles in the range by they sample size (in this case 5ml).
22. Compare the mean and total counts obtained for each peak with the expected results and range as defined by the certificate of analysis. Counts should fall within the defined range.
23. The mean size should fall within the defined range

NOTE:

1. Do not rely on the exact counts in the bottle after the liquid level has reduced below 50% of the original bottle volume as the statistical confidence of the counts may be below acceptable values.
2. Factors such as stirring speed, sip tube location, and sample volume have an influence on the spatial distribution of the particles within the bottle, which determines the particles that are actually sampled.