

Preparing Your Dissolution Instruments for Use After Shutdown

In case your organization has suspended laboratory operations, Agilent has some suggestions for getting your dissolution instrumentation up-and-running once again without any surprises.

Hopefully, your equipment was cleaned in place before shutdown (see Agilent publication [Preparing Your Dissolution Instruments for Shutdown](#) on the Agilent Dissolution Community) and the necessary power cords, cables, tubing, and other components have remained nearby so they are reunited with the original equipment. The following steps should help restore all instrumentation to its pre-shutdown status.

Note: It is important that the qualification status of the equipment is considered during startup phase to keep the apparatus from being moved which could result in the need for requalification. If the equipment has been moved or if any of the dedicated components (paddle and basket shafts, baskets and vessels) have been replaced, the apparatus should be labeled out of service until the equipment is restored for use and requalified before testing product.

Dissolution Apparatus Startup

1. Heater/Circulator and Water Bath

The following steps should be considered when restoring the dissolution apparatus for use. If the water bath appears dirty from non-use, clean it as well as the vessels, shafts, and baskets. The heater/circulator and the water bath should be reconnected with the tubing if it has been disconnected. If it appears damaged, or is discolored from previous growth, consider replacing it from the spare parts list at the bottom of this section. Save and measure the old tubing to cut the proper lengths of new tubing and attach with the clamps originally provided.

After the heater/circulator tubing is reconnected, check that the vibration isolators are on the legs of the heater/circulator and place it behind the water bath in the holes provided in the base plate of the apparatus. Fill the water bath half full of water and check for leaks. Gently lift the heater/circulator to allow it to fill with circulator water; you should see bubbles in the water bath as water fills the circulator and tubing.



Note: It is important that the heater/circulator is full of water prior to applying power or it may damage the heating elements in the circulator.

If no leaks are detected, fill the water bath up to the appropriate line indicated on the front-left of the water bath. Next, connect the communication cable to the proper jack in the heater/circulator and the other end to the proper jack marked "heater circulator" on the rear of the dissolution apparatus. Ensure that the heater/circulator is dry and connect the power cable to the heater/circulator first, then plug into the power source.

Spare Parts:

- Heater/circulator tubing (Agilent part number 4005-0016)
- Tubing clamps for water bath (Agilent part number K3060-0005)

2. Setting up the Dissolution Apparatus and Components

Even if the components (paddle and basket shafts, baskets, and vessels) appear clean, it is prudent to wash them according to your established cleaning procedures prior to use. Ensure that the proper dedicated components are reunited with the corresponding apparatus and in their appropriately assigned positions. Ensure that evaporation covers and any optional components – such as DDMs and sampling equipment – are in place and clean.



Ensure that communication cables to the apparatus are restored to their proper locations as indicated on the rear of the drive unit of the apparatus. Similarly connect any other equipment, such as an autosampler, to restore the desired configuration. Lastly, connect the power cable to the jack in the rear of the apparatus drive unit and plug into the power source.

Turn power to the apparatus on and allow to initialize. Turn the power on to the heater/circulator and ensure that the water is flowing forcefully. If water is not circulating, immediately shut off and lift the heater/circulator from its position and tilt from side-to-side until fluid appears to fill the heater/circulator and repeat the power-up. If there are any issues, warnings or if the display is not illuminated on the dissolution apparatus, turn power off and consult the troubleshooting suggestions in the [708-DS Dissolution Apparatus Operator's Manual](#).

Autosampler Setup

To restore the autosampler to the dissolution apparatus, account for all the sampling components including manifold, tubing, cannulas, and fittings if they have been disconnected. If tubing is damaged or discolored, you may wish to replace it at this time (see the [Agilent Dissolution Source Book](#) for part number assistance or contact dissolution.hotline@agilent.com.) First, reconnect the sample and return lines to the apparatus. Then, if applicable, connect the rinse, waste, and media replacement tubing to the corresponding ports on autosampler (e.g., 850-DS) and place the lines in the corresponding reservoirs for rinse, waste, and media replacement as required.



Once the liquid connections have been completed, connect the communication cables to the proper jacks in the rear of the autosampler and the dissolution apparatus drive unit. Finally, connect the power cord to the appropriate jack on the rear of the autosampler and then plug into the power source. (See the [850-DS Sampling Station Operator's Manual](#) for assistance.)

Turn power to the autosampler on and allow the system to initialize. After successful power-up, locate the diagnostics tab on the display and individually check control of the applicable components – e.g., sampling manifold, pump and optional equipment that has been installed as originally configured.

Note: If the sample tubing has been disconnected and replaced during a shutdown period, a verification of each sampling line should be performed to ensure that individual positions are consistent from the vessel, cannula, sample line connections and that it returns to the corresponding vessel via the return cannula. Each line must be verified and documented that it is correct and there are no sample line mix-ups or crossovers. The sample lines and connections should be checked for leaks at the same time. A review should be conducted to determine if portions of the autosampler IQ or OQ should be repeated to document these verification steps.

Once the autosampler has properly initialized, sample line connections have been verified, and diagnostic tests have been performed as needed, we recommend that the sampling lines are thoroughly cleaned. If applicable, ensure that the rinse reservoir is filled with a proper cleaning solution (e.g., purified water).

For cleaning, we recommend the following sequence:

1. Fill appropriate rinse containers with purified (DI) water
2. Remove any Full Flow filters from sampling cannulas if attached
3. Perform 2 clean cycles of purified water
4. Perform 2 cycles of 60:40 water to alcohol
5. Perform 2 clean cycles of purified water
6. Pump the lines dry until no additional liquid emerges



After cleaning, again inspect the system for leaks and resolve any issues. If any issues remain, consult the troubleshooting suggestions in the autosampler operator's manual ([850-DS Operator's Manual](#)).

Note: After all equipment is reconnected and checked, it is recommended that the appropriate documentation be logged into each instruments' maintenance logs to properly document the actions performed to bring each component back online. Agilent also recommends that a final review should be conducted by the appropriate level of laboratory management to determine if further qualification should be performed to document that the instrument is restored for use and meets requalification requirements prior to testing product.

With the successful restoration of your dissolution apparatus and autosampler – and proper review of the actions performed – your system should now be ready for use as reflected by a current calibration sticker. If problems arise, please do not hesitate to contact us at dissolution.hotline@agilent.com.

Keywords: equipment, faq, dissolution, startup, restart, 708-DS, 850-DS

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Agilent Dissolution Systems Digital Source Book

www.nxtbook.com/nxtbooks/agilent/dissolution_sourcebook/index.php



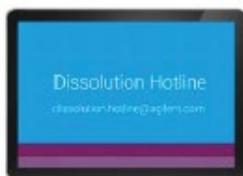
Dissolution Community

<https://community.agilent.com/community/technical/dissolution>



Dissolution 1-on-1 Training

<http://dissolution.chem.agilent.com/learn/dissolution-1-on-1>



Dissolution Hotline (Email Address)

dissolution.hotline@agilent.com



Dissolution Discussion Group (DDG)

www.dissolution.com