

10 tips for improving reagent and bulk fluid handling in IVD equipment

The role of fluid connectors in designing for instrument productivity and reliability

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The in vitro diagnostics (IVD) market continues to grow at an almost breakneck pace, along with laboratory demands for increasingly complex and efficient equipment. Whether designing for immunoassay, clinical chemistry, hematology, molecular diagnostics or infectious disease applications, OEMs and contract manufacturers are all feeling the pressure to make their next-generation diagnostic instruments more productive and more reliable than ever. On top of this, IVD instruments are being used closer to the point-of-care, often by undertrained operators, so new equipment designs need to build in ease of use, safety and error prevention.

At the nexus of these demands for testing productivity and reliability lie the fluid handling systems that facilitate diverse testing, buffering, washing and waste removal. Connectors are a critical component fluid handling systems, and using the connectors and other system components can increase ease of use, minimize operator error and increase testing—all important factors in the drive toward high productivity and reliability.

KEY FEATURES AND TECHNOLOGIES

Below are 10 tips for applying advanced connector features and technologies to help device manufacturers design world-class fluid handling systems for diagnostic instruments.

1. Ensure material and media compatibility: Material compatibility between connectors or other fluid handling components and the fluids used in the test setting is often overlooked and a mismatch can be the root cause of costly maintenance due to leaks, contamination or corrosion. In IVD applications, consider any cleaning solutions or other chemicals (for example bleach, hydrogen peroxide or isopropyl alcohol) that may be flushed through the fluid lines or wiped on the exterior. Some high-end applications involving stronger acids or solvents may require components to be made of engineered polymers such as PEEK or PVDF to maintain compatibility.



Figure 1: Adding quick disconnects to fluidics designs improve the serviceability of an instrument and maximizes “up time”.

2. Specify non-spill or “dry break” valved connection points: Connectors with integral valves create a cleaner and safer connection, eliminating the need for clamps and secondary shutoff valves and enhancing the overall perception of the instrument. Valved connectors prevent spills upon disconnection and also prevent the entry of air into the system. There are many styles of valves, with varying flow rates and pressure drops.

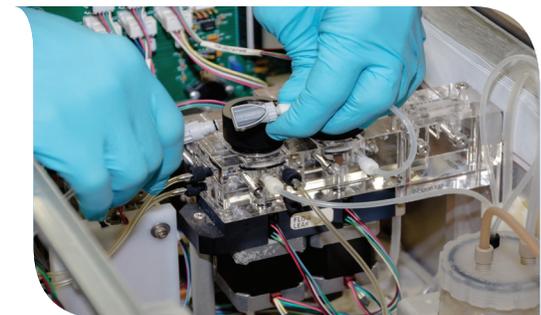


Figure 2: Non-spill connectors should be used when even drops of liquid pose a problem. These types of connectors effectively eliminate spills, enhance operator safety and prevent air inclusions into closed systems.

Material compatibility is often overlooked and can be the root cause of costly maintenance due to leaks, contamination or corrosion.

For example, adding non-spill quick disconnects to the critical assemblies of high-volume chemistry analyzers ensures easy access for serviceability. By using non-spill connection to pumps and other critical components, lab technicians can easily replace components without fear of damaging sensitive electrical assemblies.

3. *Track reagent batches at the point of use:* Facilitate safe and efficient fluid connections while avoiding harmful and expensive mistakes, reducing liability and improving process management by incorporating Radio Frequency Identification (RFID). Intelligent RFID-enabled coupling applications include: real time reagent inventory monitoring, batch identification, brand and product protection, and expiration date tracking.

These types of couplings are currently being used with clinical diagnostic lab equipment. Thanks to the RFID-enabled connection, labs can track the amounts of reagents used on each piece of equipment to confirm appropriate inventory levels, and ensure the availability of sufficient reagent to complete the testing cycle. In addition, the couplings confirm that the right reagent is being used with the diagnostic equipment, which eliminates errors and mitigates equipment downtime due to the use of “off brand” consumable products.

4. *Connect multiple fluid lines at once:* Consolidating multiple fluid lines into a single connection can greatly improve serviceability and prevent misconnections. Lines can include dissimilar fluids or gases and use either pressure or vacuum to drive fluid through an instrument. Multi-line connections on waste containers are particularly valuable in providing the necessary supply, empty and vacuum lines all in a single interface. New technology even allows electrical lines to be integrated into a hybrid connection point where fluids and data can be hooked up in a single quick operation.



Figure 3: Multiple fluid lines can be color-coded or even vary in material or tubing size to fit the application.

As an example, flow cytometry—routinely used in the diagnosis of health disorders especially blood cancers—uses large volumes of reagents and requires secure connections to ensure proper reagent delivery and waste collection. A hybrid-style coupling on the end of an umbilical line enables using a single connection to the cytometer for carrying electronics and sheath or waste fluid. The hybrid coupling provides a quick and easy way to replace consumable fluids, and at the same time eliminates exposure to potential bio-hazardous spills on waste containers.

5. *Use disposable packaging (bottles, bag-in-box, puncture seals):* Although reagents are typically packaged in disposable packaging with easy access ports, it often makes sense to implement a similar packaging strategy on bulk fluid or waste containers as well. Using bag-in-box style packaging to store bulk reagents, wash or buffer solutions eliminates inaccessible fluid below a dip-tube and allows for nearly 100% fluid utilization. It can also mean eliminating expensive, reusable caps or port fittings in exchange for cost-effective puncture seal connectors that streamline interchanges.

6. *Implement gravity fed plumbing with shutoff valves:* Why specify expensive and complex pumps onto the instrument when gravity can feed on-board fluidics? Using couplings with shutoff valves eliminates the risk of spilling fluids



Figure 4: Eliminate the potential for spills when changing fluid by threading quick disconnects directly in standard laboratory caps.

during inverted installation and ensures 100% evacuation of fluids from the bottle or reservoir. In this setup, non-spill valves minimize air inclusion (the volume of air introduced into the system each time the coupler is connected.) Venting to the bottle can easily be accomplished with a similar dip-tube as right-side up bottle systems.

7. *Color code or physically key multiple fluid lines:* Another critical variable that plays into human factors engineering is the potential for misconnecting dissimilar fluid lines. This can be a costly mistake that leads to extensive washing and flushing of supply lines if a biohazardous waste line is inadvertently connected to a reagent line heading to test vessels. Using color-coded or physically keyed connectors to prevent connection errors is especially critical on fluid lines in large automated immunoassay instruments where multiple reagent supply lines are co-located with rinse and waste lines.

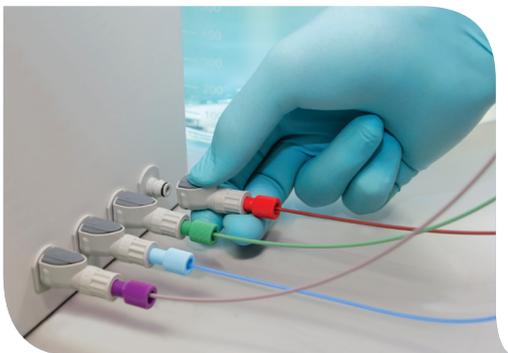


Figure 5: Quick disconnect couplings can be color-coded or physically keyed to ensure the correct connections are made every time.

8. *Don't let particulates clog your system:* Along with the obvious concern over invalidating a test due to foreign particulate, fluid systems also rely on clean flow paths. Pumps, filters, valves and microbore tubing are at risk of becoming clogged by particulate that can originate from fluid system components. It is important to review

component supplier quality standards and ensure that machining burrs or other foreign particulates will not contaminate fluid lines and wreak havoc on instrument components downstream.

CONNECTOR TYPES FOR IVD INSTRUMENT FLUID HANDLING SYSTEMS

Coupling Type	Description
Quick Disconnect	A general description of couplings; the coupling body and insert can be disconnected quickly and easily
Coupling Body	The body is the female half of a coupling which contains the locking latch
Coupling Insert	The insert is the male half of a coupling that contains a sealing o-ring; the insert fits into the coupling body
Fittings	Single component or assembly affixed to tubing or a vessel of some sort; removal requires prying and pulling the tubing off the barb
Microbore Tubing	A coupling that enables connections to be made to microbore tubing (tubing with an OD less than 10mm (0.3937"))
Non-Spill	Couplings designed to minimize the amount of spillage that occurs when the coupler is disconnected; also known as dry-break connectors
Multi-tube	Couplings with multiple flow paths that are connected and disconnected with a single connection
Physically Keyed & Color-Coded	Custom couplings that have features that only allow connections with the proper mating component; couplings can also be customized to color code mating parts to facilitate proper connections
Panel Mounted	Couplings that are designed to be mounted to a panel (or bulkhead) to make connections easier; these couplings can also be installed on bottle caps to provide a quick disconnect option for liquid consumable products
Hybrid	Couplings that connect air lines, electrical connections and fluid lines into a single connection point; these couplings are ideal for use in level sensing applications
RFID-enabled	Radio Frequency Identification (RFID) electronic intelligence is embedded into the coupling enabling the exchange of rewritable data once the coupling halves come close together; examples of information that may be exchanged includes connection validation, operational control settings, usage, media validation, track and trace
Puncture Seals	Found on the outlet neck of a bag-in-box or similar container of liquid product, the closure cap has a coupling insert which is sealed by a thin membrane across the opening; the coupling body connects to the closure cap and punctures the membrane so that the liquid product can flow
Bottle Caps	45mm GL caps with integral couplings, dip tube, and fill vent

Have a fluid handling question? Ask the experts at fluid handling companies for advice on common issues, improving fluidics designs or customizing standard products to meet your needs.

9. *Install cost-effective level sensing for bulk fluids:* Detecting fluid levels in bulk solutions and waste containers is essential to avoid instrument downtime and extra operator maintenance time. Float switches provide cost-effective, single-point detection when a bottle is full/empty or can be used in a modular design to detect multiple critical points in a bottle. Alternatively, many systems use load cells or conductive probes that provide continuous level detection and more precise measurements. For applications that require level sensing capabilities but involve particularly caustic media or are sensitive to microbial contamination, products like capacitance and optical sensors can provide non-contact level sensing. These products can be particularly valuable when handling fluids with a tendency to produce salt build up or bottles that are extra vulnerable to damage from a user.

10. *Seek help from supplier experts:* Have a fluid handling question? Ask the experts at fluid handling companies for advice on common issues, improving fluidics designs or customizing standard products to meet your needs. Suppliers usually employ design and engineers application specialists who can answer your questions and help design seamless fluid handling solutions for specific instruments needs.

Meeting today's and tomorrow's market demands for high-productivity, high-reliability IVD equipment will depend in part on efficient, effective fluid handling systems. Smart fluid handling component choices such as technologically advanced fluid connectors will help equipment manufacturers maximize instrument productivity and reliability—and make IVD testing faster and easier for labs and operators.

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About CPC

CPC is the leading provider of quick disconnect couplings, fittings and connectors for use with tubing in low-pressure fluid-handling applications. Employed in a broad range of applications, CPC's 10,000+ innovative standard products allow flexible tubing to be quickly and safely connected and disconnected. CPC also engineers custom solutions to improve the overall functionality and design of equipment and processes for life sciences, bioprocessing, specialty industrial and chemical-handling applications.



Smart fluid handling to take you forward, faster.