Using “RFID-enabled” fluid couplings to verify and track critical IVD consumable fluids

There has been much discussion lately about the “internet of things” (“IoT” and its role within the medical industry. Like many other IVD instruments, fluidic connectors have gotten “smart”. Equipped with a control unit and RFID technology, it is possible to communicate data that ensures the proper consumable fluids are being used as well as their status inside the instrument.

A select group of fluid connectors can now be found in the growing ranks of “intelligent” products. In addition to moving fluids, these high-tech connectors move data, thanks to the innovative use of wireless communications technology.

In medical or analytical laboratories, data transferring intelligent couplings can play many valuable roles. These include keeping track of instrument usage to anticipate preventative maintenance required as well as alerting lab technicians when consumable fluids need to be replaced. RFID-enabled couplings can also help protect brand integrity by ensuring the use of OEM-supplied reagents and media.

RADIO FREQUENCY COMMUNICATION
To add intelligence to fluid couplings, two ingredients are necessary: a brain (such as a PC or controller) to run the system and some means of wireless communication. In intelligent quick disconnect coupling systems, the wire technology of choice is radio frequency identification, or RFID.

Intelligent couplings communicate by sending RFID signals between the two separated coupling halves attached to different devices or lines. Data is stored on an RFID tag embedded in the passive half of the coupling, known as the insert. Looking for the tag is an RFID reader housed in the active half of the coupling, called the body. When the two coupling halves are brought within a few centimeters of each other, the reader detects the tag, reads it, and send the tag data to the control unit running the system. The control unit can also tell the reader to write new information to the tag.

IVD instruments and their reagents equipped with RFID technology can store and/or transfer important information such as product data (date of manufacture, batch/serial number, date/time of installation, number of uses remaining, etc.), auto-calibration parameters (identification of media, expiration date, etc.), and process control (number of tests completed, notification of test completion). Electronic data capture and automatic documentation are faster and more efficient than manual processes, and eliminate inaccuracies caused by human error.

RFID-equipped quick disconnect couplings perform many key functions that are beyond the capability of ordinary fluid connectors. As a part of IVD or analytical instrumentation, they can:

- Prevent connection errors in multiple port systems. Before a physical connection is
made, the RFID reader "reads" the tag and tells the control unit what is being connected to the instrument port. If a misconnection is attempted, the control unit can display an error message, trigger an alarm, or shut down the instrument until the error is corrected. Thus, the couplings ensure that each line is connected to the correct port, preventing misprocessing of tests and potential damage to the instrument.

- **Ensure correct operational settings.** Once the identification data on the tag has been read, the control unit automatically sets testing parameters such as pressure, flow rate, and operating time to match the requirements for the media that has been connected. Operational control settings reduce the risk of human error in setting operating variables to prevent harm to the instrument or invalidate tests.

- **Enforce required limits on reagent usage.** The controller tells the wireless connector to write to the tag on the consumable product each time the product is used. If it is a limited use consumable, the controller keeps track of the usage and will not allow a test to be processed once the threshold is reached. This prevents testing from being performed with media that is potentially outdated.

- **Validate connected media.** Intelligent quick disconnect couplings can ensure that OEM supplied consumable products are being used on the test instrument. The reader in the connector reads the identification data on the consumable package and verifies that inferior or incorrect media is not being connected. This prevents potential damage to the instrument, and provides brand protection for proprietary reagent solutions.

- **Monitor consumption of media.** RFID-enabled couplings can also be used to monitor the amount of reagent used for each test. The amount of reagent required for each test is specified in the control settings of the instrument. Each reagent container contains an RFID tag that is programmed with the initial volume of reagent. As tests are run the controller writes to the consumable product tag, and deducts the amount of reagent used for each connected line. When a container is close to empty, the control unit will alert the operator that additional reagents are required before a test can be started.

### CONSIDERATIONS WHEN DESIGNING A WIRELESS CONNECTOR SYSTEM

When contemplating the use of communicating connectors in an instrument design, it is best to work with a company with wireless communication and application experience. While it may be tempting to implement radio frequency communications in-house, it is often more time-efficient and cost-effective to partner with an experienced supplier. Here are some reasons why:

- **Component complexity** – Although wireless communication is a maturing technology, the tag and reader components used in fluid handling need to be specialized for the demands of the application. The majority of RF communication devices are designed to sense from as far away as possible. In fluid coupling applications, however, the goal is for the two halves to communicate only when the tag and reader are in close proximity.

- **Radio frequency tuning** – Critical to the success of any wireless communication
application is the ability to deal with RF noise in the environment. Specific to communicating with fluid couplers, however, is the challenge of controlling the distance at which the coupler halves talk to each other; in applications involving fluid connectors, data communication between the tag and the reader is desired only within a specific proximity.

- **Security** – An experienced supplier of fluid connectors with wireless capabilities will be familiar with security issues and can work with machine builders to ensure that products will cope with today’s and tomorrow’s wireless security challenges.

- **Integrated components** – In-house instrument builders can sometimes source RF/RFID parts from various vendors and get them to perform “tolerably” together. However, an experienced supplier of wireless fluid connectors rigorously tests the quality of its readers, tags, and fluid connectors as a total system, ensuring better mating of wireless devices and fluid couplings.

- **Economics** – Proven suppliers of wireless fluid connectors usually purchase components in volume and can offer economies of scale not available to individual, one-off users.

- **Industry and market expertise** – A knowledgeable supplier of wireless fluid connectors will understand the current and future trends in the RF market and be able to provide IVD instrument designers and manufacturers with forward-looking solutions backed by experience.

**CONSIDERATIONS IN IVD APPLICATIONS**

RFID-equipped quick disconnect couplings can withstand both ethylene oxide and autoclave sterilization, though they are not recommended for uses involving five or more autoclave cycles. On the other hand, the couplings cannot be sterilized with gamma radiation, since gamma rays erase data from the memories of current RFID tags.

IVD instrument designers must also bear in mind that metal placed near an RFID tag will affect the resonant frequency of the tag, which adversely impacts the processes of reading and writing to the tag. Designers can easily prevent metal-related tag problems by enlisting the help of a qualified “intelligent” coupling supplier. If a design calls for the tags to be placed within a certain distance from metal components, a supplier can “tune” the tags to compensate for the nearby metal. Once the tags are properly “tuned” there should be no problems when the device is in use.

Another issue designers should consider is whether the added cost of choosing intelligent quick disconnect couplings is justified by the benefits offered by RFID communication in a particular IVD application. In some cases, the decision to opt for intelligent couplings is a fairly easy one because the extra cost involved is insignificant compared to the overall cost of the IVD instrument being designed.

**CONCLUSION**

The concept of fluid connectors that “talk” is an elegantly simple solution for enhancing instrument function, tracking consumable media, and preventing operator errors. However, this solution is not simple in execution. The development path for applying couplers that exchange data wirelessly requires both connector and RF expertise.

RFID capability can be added to popular coupling lines or be part of custom connector solutions that meet the needs of unusual applications. Either way, users of IVD instruments most advanced connectors will quickly see the value of adding “smarts” to their fluid-handling processes and consumable products.