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JADAK Case Study

# RFID FOR MEDICAL DEVICES
# Iris Diagnostics Uses RFID for Authentication

## Situation

Iris Diagnostics (a division of Beckman Coulter, NYSE: BEC), a California manufacturer of medical diagnostic devices, wanted to integrate an RFID-based authentication system into its iQ200 Automated Urinalysis System to ensure that only the certified reagent formula Lamina, which Iris produces, is used with the machine.

The company decided to develop an authentication system to protect against counterfeit reagents. If a counterfeit reagent were introduced to the Iris urinalysis system, it could raise serious safety and financial concerns for the company. If counterfeit reagents were used, Iris Diagnostics would not be able to verify the validity of the urinalysis test results. This could pose a serious threat to patients, since it could lead to a misdiagnosis based on faulty test results. Thus requiring patients to revisit hospitals and have tests rerun. To avoid the potential financial and reputational impact of counterfeit reagents to the company, Iris proactively reached out to JADAK to identify a RFID solution.

## Results

Iris Diagnostics' iQ200 Automated Urinalysis System draws a measured amount of the reagent Lamina into the main analysis machine through plastic tubing. A stock of Lamina bottles is held in a carriage next to the machine. When all of the Lamina is drawn out of a bottle, a technician removes it and places the tube in a new bottle.

The company wanted to use high frequency RFID tags for the application because it wanted a short read range to ensure that only the tag on the bottle closest to the reader was read.

Iris worked with JADAK to integrate the Skyetek M2 high-frequency RFID reader module into the urinalysis system. JADAK also made RFID tag recommendations to Iris. Then Iris, JADAK, and the provider of the RFID-enabled labels and printer-encoders collaborated to identify a solution that utilized placement of RFID-enabled labels on each bottle of Lamina.

The printer-encoder used the Skyetek M2 reader to encode labels with embedded ICODE SLI transponders. The reader was ISO 13485 certified, and the transponders were compliant with the ISO 15693 standard and designed for item-level tracking and security applications.

The JADAK solution implemented a unique security/key exchange algorithm to prevent backwards engineering of the interface. The solution also allowed for remote field upgrading of the cryptographic keys and algorithms, in the event they were ever compromised.

The Skyetek M2 interrogator reads the data encoded to the inlay inside each bottle's label, checking for a digital signature encoded to the label when it was printed at the Iris manufacturing facility. The reader can unlock this signature using a master key, with cryptography based on a keyed hash-message authentication code, or HMAC. If it doesn't see the digital signature, the interrogator will prohibit the system from drawing the reagent out of the bottle and send an alert to the machine's technician, raising the possibility that the reagent is counterfeit.

Iris and JADAK partnered to write the software for the authentication system, which runs on JADAK's reader software. The system also runs the urinalysis reader and others used in the printer-encoders, since they share a cryptographic key infrastructure.



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