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DASH® Rapid PCR System Connectivity Options



Cloud-Based Nuclein Customer Portal

- ✓ Available option for the DASH® Rapid PCR System when running the FDA-cleared, CLIA-waived DASH® SARS-CoV-2 & Flu A/B Test
- ✓ Hosted by Galen Data, a leading provider of medical device connectivity solutions
- ✓ Individual customer accounts are HIPAA-compliant and highly secure
- ✓ Wi-Fi and hardwired Ethernet cable connectivity options
- ✓ Use of the Nuclein Customer Portal is required for the following functions:
 - Multiple user account setup within an organization
 - Review of previous test results
 - EMR/LIS/Middleware integration (via Galen Connect)
 - Over-the-air software updates
 - Advanced remote troubleshooting
 - Administrator oversight of multiple instruments within an organization



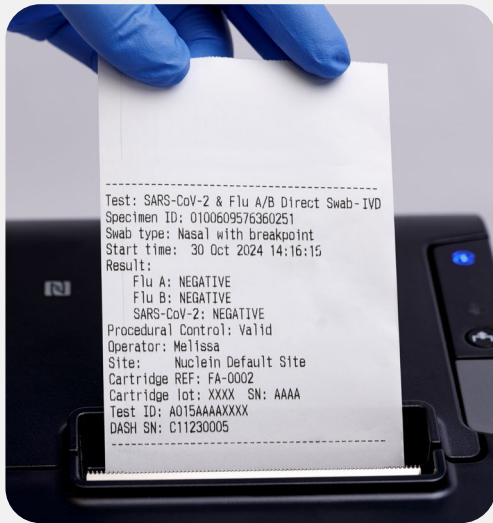
Cyber Security and HIPAA

- ✓ HIPAA and GDPR compliant
- ✓ HITRUST CSF r2 certified
- ✓ FDA, CE IVDD/IVDR, EU MDD/MDR, Health Canada, and Australia TGA compliant
- ✓ ISO 13485 Medical Device Quality Management certified
- ✓ ISO/IEC 27001 and IEC 62304 compliant
- ✓ UL-2900-01 compliant
- ✓ US state data protection law compliant
- ✓ Data access controls

All of the listed certification and compliance documentation is held by Galen Data.

Data Transmission Options

- ✓ Wi-Fi
- ✓ Hardwired via Ethernet cable
- ✓ Cloud-based Nuclein Customer Portal (hosted by Galen Data)
- ✓ EMR/LIMS/Middleware integration (via Galen Connect)
- ✓ Results automatically displayed on screen
- ✓ Results automatically printed at the conclusion of every test



DASH® Rapid PCR System Printer

The DASH® Rapid PCR System includes a printer. When installed, results are automatically printed at the end of each test, without user intervention. Test results are provided with or without use of the printer.

Operate the DASH® Rapid PCR System Without Connectivity

The DASH® Rapid PCR System is **fully capable of performing patient testing** without any optional connectivity, with the following limitations:

- Only one default administrator user for the instrument
- Over-the-air updates are not available
- Troubleshooting, if needed, from Nuclein Customer Support is more limited
- Past test results cannot be viewed
- Connection to an EMR/LIMS/Middleware requires connecting to the Nuclein Customer Portal and Galen Connect
- The DASH® SARS-CoV-2 & Flu A/B Test can be performed **with or without** use of optional connectivity