e-Connectivity™—White Paper

Integrated Design for Confidentiality and Security

Ortho AutoVue® Innova/Ultra

Ortho Clinical Diagnostics' e-Connectivity™ Interactive System Management feature provides a real-time, secure, interactive connection between the Ortho AutoVue® Innova/Ultra and Ortho Clinical Diagnostics Technical Support.

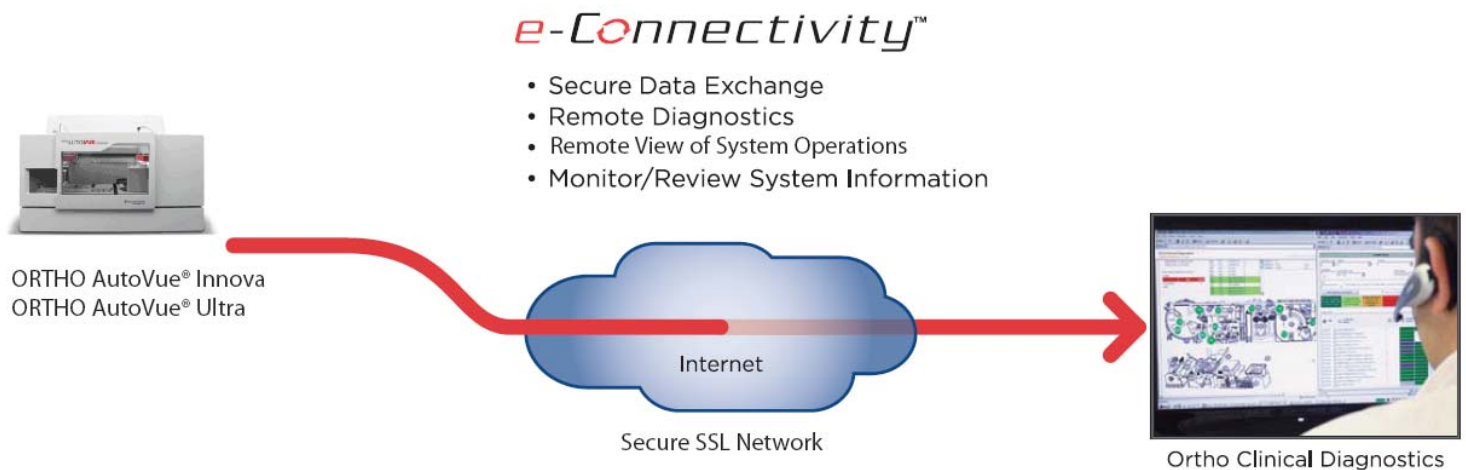The features provided by e-Connectivity™ include:

- Automatic Data Exchange; the ability to automatically send data from the system to Ortho Clinical Diagnostics Technical Support.
- Pro-Active Alerting; the ability to Alert Ortho Clinical Diagnostics Technical Support when specific events or statistical trends have been observed.
- Remote Connectivity ; connection of the System to Ortho Clinical Diagnostics that enables Remote Diagnostics, including the ability for our Technical Support personnel to remotely view System operations, as well as monitor and review system configuration, data, and performance information.

These features provide for automatic transfer of data regarding multiple aspects of system performance to Ortho Clinical Diagnostics Technical Support for real-time analysis.

Ortho Clinical Diagnostics Technical Support can be provided access to the Ortho AutoVue® Innova/Ultra to perform Remote Diagnostics, including Remote View of system operations, so that technical challenges can be solved more efficiently.

e-Connectivity™ provides comprehensive security and privacy through the application of the following features to help support patient and laboratory confidentiality:

- Only the operator can establish a connection for Technical Support. Ortho Clinical Diagnostics cannot connect to the system.
- The operator controls when the system is connected to and accessed remotely by Ortho Clinical Diagnostics Technical Support.
- Ortho Clinical Diagnostics Technical Support cannot change results, information or data.
- e-Connectivity™ makes use of web protocol communication technology; therefore, Ortho Clinical Diagnostics Technical Support does not have the ability to connect to any laboratory systems, computers, or networks.

e-Connectivity™
- Secure Data Exchange
- Remote Diagnostics
- Remote View of System Operations
- Monitor/Review System Information

ORTHO AutoVue® Innova
ORTHO AutoVue® Ultra

Internet

Secure SSL Network

Ortho Clinical Diagnostics

e-Connectivity™ Integrated Design for Confidentiality and Security

The primary features to help support security, privacy and confidentiality:

Exclude Patient Information from Data Logger Files

OCD is committed to protecting the privacy of the data that you provide to us and we do not require access to confidential patient-identifying information. Patient information, including Patient ID, Last name, First name, Gender, Birth date, Medical record, National ID, and Other ID, is excluded from the data files before being transmitted to OCD.   However, as part of an automatic data exchange, the System will upload files containing the Sample ID field.   OCD does not recommend the use of confidential, patient-identifying information such as patient name or government identifier as part of the Sample ID.

Information Systems

The e-Connectivity™ solution does not have access to the local network unless explicitly configured to allow LIS information transfer.
The e-Connectivity™ feature uses a TCP/IP network protocol with ASTM.IP. This is implemented by configuring the embedded hardware FIREWALL to allow port forwarding from the device to the IP address and port of the hospital network as configured by local IT. Port forwarding is configured and active only when ASTM/IP has been enabled on the instrument. The security of e-Connectivity™ remains unchanged as port forwarding is only allowed between the instrument and the LIS.

Secure Socket Layer Network Technology

e-Connectivity™ establishes a highly secure connection between the Ortho AutoVue® Innova/Ultra and Ortho Clinical Diagnostics for transfer of data via the Internet using Secure Socket Layer (SSL) technology. A SSL is a combination of industry standard network tunneling, encryption, authentication, access control and auditing technologies/services used to securely transport data over the Internet. In essence a SSL creates a protected closed system connecting two networks.   All data exchanged is encrypted, secure and confidential using Secure Socket Layer technology.

Connection Authorization

Ortho AutoVue® Innova/Ultra Systems must be authorized with Ortho Clinical Diagnostics Technical Support Centers prior to receiving permission to establish a connection to Ortho Clinical Diagnostics. The enabled systems must be registered with Ortho Clinical Diagnostics Technical Support before establishing a connection between the system and Ortho Clinical Diagnostics Technical Support and before Ortho Clinical Diagnostics Technical Support can access the system remotely.

Automatic Connection Timeout

An automatic connection timeout feature is included with e-Connectivity™. A timeout of 15 minutes is provided. This feature automatically monitors the time length of a connection and will automatically end the connection if activity is not detected.

Asset Identification

To enable the e-Connectivity™ feature, each System is assigned a name, password, unique identifier, and pre-configured IP route. The asset IP's are internal and non-routable internet addresses that have no capability to be used externally.

Data Exchange Database

When Ortho Clinical Diagnostics Technical Support receives data during an Automatic Data Exchange, the data is accessible only by authorized Ortho Clinical Diagnostics technical support personnel. The database is located in an Ortho Clinical Diagnostics affiliate and utilizes anti-virus protection software.

Virus Protection

e-Connectivity™ uses a closed process that minimizes exposure to viruses. Ortho AutoVue® Innova/Ultra Systems use the Windows XP Operating system. Anti-virus protection software is actively used at the Ortho Clinical Diagnostics Technical Support Centers and on the servers and databases supporting e-Connectivity™.

e-Connectivity™ Frequently Asked Questions

Q   Where can more information be obtained regarding e-Connectivity™?
A   More information is available in the Ortho AutoVue® Innova/Ultra section at orthoclinical.com

Installation and Configuration

Q   What is required to enable my Ortho AutoVue® Innova/Ultra for e-Connectivity™?
A   A standard on-site service call will be required to install and e-Connectivity™.

In addition, the lab network requirements are:
- Customer LAN, cable modem or DSL
- Continuous broadband connection or direct connection to the customer LAN with access to the Internet at a speed greater than or equal to 128 kbps
- Support the following local area network port speeds: Automatic, 100 and 10 Mbps with full-duplex, half-duplex and automatic detection of duplex
- Support SSL traffic to the Internet Port 443

Note: SSL utilizes port 443 outbound and inbound. This port must be open in the local area network's firewall.

- Female RJ45 connector on the network port within 6 meters of the center of the System.
- I.P. Address, Network Mask and Gateway I.P. Address either supplied automatically via DHCP (Dynamic Host Configuration Protocol) or statically assigned by the Information Technology (IT) department and provided to Ortho Clinical Diagnostics Technical Support

Q   Can another network device be used to connect the Ortho AutoVue® Innova/Ultra to Ortho Clinical Diagnostics?
A   No. e-Connectivity™ was developed with security integrated into the design. The internal NIC device that connects the Ortho AutoVue® Innova/Ultra System to the Internet provides a hardware firewall that is configured to connect only to OCD and enables specific port forwarding for LIS communications (if configured)

Q   Will e-Connectivity™ interfere with the performance of my system?
A   No. e-Connectivity™ is fully integrated into your systems so that routine system operation is maintained.

Q   How will e-Connectivity™ be priced?
A   Currently there is no charge for e-Connectivity™.

Q   How will Ortho Clinical Diagnostics use the collected data?
A   Our Technical Support Centers and Field Engineers will analyze it for existing or potential issues in individual systems, so service can be performed as quickly and conveniently as possible. In addition, analysis from analyzer performance data from multiple systems may point to needed software updates as well as feature development needs for future systems.

Q   Can I use a DSL/Cable internet connection?
A   Yes, you will need a local service provider to install the DSL/Cable line in your laboratory. The DSL/Cable line must support an Ethernet Connection. In addition, some service providers may require a login for the internet connection. The OCD e-Connectivity™ solution supports this model; the service engineer can configure the system with this information during the install of e-Connectivity™.

Security and Privacy

Q   How secure and private is e-Connectivity™?
A   e-Connectivity™ was designed with a focus on security and is integrated into the design to help support confidentiality, security, and privacy. Ortho Clinical Diagnostics is committed to protecting patient privacy and data security in all customer interactions and recognizes the legal and ethical obligations to protect patient privacy and data security.

Q   What data is transmitted through the SSL during a data exchange?
A   Ortho AutoVue® Innova/Ultra Systems transmit files that contain data associated with the sample IDs, results, condition codes, and other data that may be useful to troubleshoot the system. The data also includes verification information that helps ensure your system is operating within specification. All of this data is encrypted during transmission through the SSL tunnel.

Q   Will Ortho Clinical Diagnostics be able to access any other computers on my Network?
A   No. The Ortho AutoVue® Innova/Ultra Systems have SSL software with built in SSL/Firewall capabilities that are pre-configured to build a single SSL tunnel to a server located in Raritan NJ. Other than the tunnel, the devices are completely isolated from any other local or Internet network traffic. The devices also may support LIS connections via TCP/IP with ASTM/IP when port

forwarding has been enabled.

Q What type of encryption and authentication is provided for e-Connectivity™?

A The SSL tunnel is secured using open SSL with a minimum 128 bit encryption.   Encryption is accomplished by using a symmetric key for both communicating parties (the SSL Device and the computing affiliate's certificate) to encrypt and decrypt the data they exchange.

Agreement Method

Q Is a firewall in place to prevent unauthorized access to the Ortho AutoVue® Innova/Ultra Systems?

A Yes. The systems contain a Network interface device (NIC)   that features an ICSA (International Computer Security Association) certified dynamic firewall. This device prevents any unauthorized access to the System. It only allows communication from the system through the SSL tunnel to the Ortho Clinical Diagnostics server. The system is not exposed directly to the Internet.