

# e-Connectivity® Technology Integrated Design for Confidentiality and Security

Ortho Clinical Diagnostics' e-Connectivity® Technology Interactive System Management feature provides a real-time, secure, interactive connection between the ORTHO VISION™ Analyzer and Ortho Clinical Diagnostics Technical Support.



## The features provided by e-Connectivity® Technology include:

### Manual and/or Automatic Data Exchange

The ability to automatically send data from the system to Ortho Clinical Diagnostics (Ortho) Technical Support.

### Increased Uptime

Predictive alerts and remote analyzer monitoring alert Ortho support staff of potential problems - before they happen, allowing users to continuously maximize analyzer uptime.

### Remote Connectivity

The ability for an operator to enable a connection of the System to Ortho that enables Remote System Diagnostics, including the ability for Ortho Technical Support personnel to remotely view System operations, as well as monitor and review system configuration, analyzer performance logs and information.

### Remote Observe

Ortho Technical Support is able to remotely view the analyzer screen, using an encrypted VNC connection carried over the SSL. Ortho cannot manipulate the analyzer remotely using Remote Observe. Each time before Ortho can use Remote Observe, the Operator has to enable it on the analyzer and generate a password.

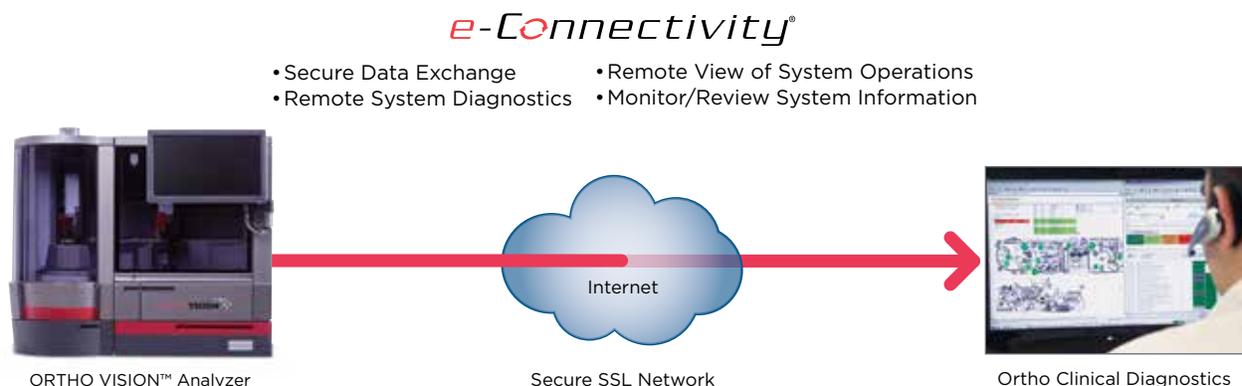
### Software updates

The ability to download Ortho validated software updates.

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

e-Connectivity® Technology 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 cannot connect to the system without customer assistance.
- The operator controls when the system is connected to and accessed remotely by Ortho Technical Support.
- Ortho Technical Support cannot change results, information or data.
- e-Connectivity® Technology makes use of secure web protocol communication technology; therefore, Ortho Technical Support does not have the ability to connect to any other laboratory systems, computers, or networks.



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

### Exclude Patient Information from Data Logger Files

Ortho is committed to protecting the privacy of the data that customers provide and does 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 specifically excluded from the data files before being transmitted to Ortho. However, as part of an automatic data exchange, the System will upload files containing the Sample ID field. Sample IDs are encrypted by default and there is an option for users to provide their own key logic for encryption. Ortho recommends against the use of confidential, patient-identifying information such as patient name or government identifier as part of the Sample/Donor ID field.

### Information Systems

The e-Connectivity® Technology solution does not have direct access to the local network. e-Connectivity® Technology only leverages the local network as a path through to tunnel SSL traffic. If enabled, the instrument LIS interface may leverage the local network to interact with the LIS. Refer to the instrument networking guide for specifications on the LIS interface.

The LIS interface may be implemented by configuring the Instrument FIREWALL to allow port forwarding from the instrument 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® is isolated from LIS interfaces as port forwarding is only allowed between the instrument and the LIS.

### Secure Socket Layer Network Technology

e-Connectivity® Technology establishes a secure connection between the ORTHO VISION™ Analyzer and Ortho 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 industry-standard, 2048 bit key encryption and up to 256-bit AES content encryption.

### Connection Authorization

The ORTHO VISION™ Analyzer must be authorized with Ortho Technical Support Centers before receiving permission to establish a connection to Ortho. The enabled systems must be registered with Ortho Technical Support before establishing a connection between the system and Ortho Technical Support and before Ortho Technical Support can access the system remotely.

### Asset Identification

To enable the e-Connectivity® Technology feature, each system is uniquely identified (ie: serial number) and pre-configured with a defined destination DNS/IP route.

### Data Exchange Database

When Ortho Technical Support receives data during an Automatic Data Exchange, the data is accessible only by authorized Ortho Technical Support personnel. The infrastructure is located in an Ortho affiliate and utilizes Intrusion prevention and anti-virus protection software.

### Virus Protection

PRODUCT: e-Connectivity® Technology uses a closed process that minimizes exposure to viruses. ORTHO VISION™ Analyzer uses the Windows 7 Embedded Operating system and associated configured firewall.

ORTHO INFRASTRUCTURE: Firewall and Antivirus protection software are actively used at the Ortho Technical Support Centers as well as on the infrastructure supporting e-Connectivity®.

### Secure Infrastructure

Our ISO-27001: 2005 certified data centers undergo an annual SSAE-16 SOC 2 audit and are built on state-of-the-art equipment, technology investments and operational expertise.

## e-Connectivity® Technology Frequently Asked Questions

**Q:** Where can more information be obtained regarding e-Connectivity®?

**A:** More information is available in the ORTHO VISION™ Analyzer section at orthoclinical.com.

### INSTALLATION AND CONFIGURATION

**Q:** What is required to enable my ORTHO VISION™ Analyzer for e-Connectivity®?

**A:** e-Connectivity is automatically installed on the analyzer, activating e-Connectivity can be done independently by the customer or through an on-site service call.

For specific connectivity and/or regulatory connectivity requirements, please contact your local Ortho representative.

In addition, the lab network requirements are:

- Customer LAN,
- 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 VISION™ Analyzer to Ortho Clinical Diagnostics?

**A:** No. e-Connectivity® Technology was developed with security integrated into the design. The ORTHO VISION™ Analyzer provides a software firewall that is configured to connect only to Ortho and enables specific ports for specific use cases (ie, LIS communications, remote review, and backups).

**Q:** Will e-Connectivity® interfere with the performance of my system?

**A:** No. e-Connectivity® Technology is fully integrated into your systems so that routine system operation is maintained.

**Q:** How will e-Connectivity® Technology be priced?

**A:** Currently there is no charge for e-Connectivity® Technology, and it is considered part of the product offering package with the purchase of an analyzer.

**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 anonymized 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, with exception. The DSL/Cable line must support an Ethernet Connection. The Ortho e-Connectivity® Technology solution currently does not support password input as required by some service providers.

### SECURITY AND PRIVACY

**Q:** How secure and private is e-Connectivity® Technology?

**A:** e-Connectivity® was designed with a focus on security and is integrated into the design to help support confidentiality, security, and privacy. Ortho is committed to protecting patient privacy and data security in all customer interactions and recognizes our 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 VISION™ Analyzers transmit files that contain data associated with the 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. Sample IDs are further encrypted by default and there is an option for customers to provide their own key logic for encryption.

**Q:** Will Ortho Clinical Diagnostics be able to access any other computers on my Network?

**A:** No. The ORTHO VISION™ Analyzers have built in SSL/Firewall capabilities that are pre-configured to build a single SSL tunnel to a secured infrastructure. Other than the tunnel, the devices are completely isolated from any other local or Internet network traffic. The devices also may support other connections via TCP/IP with ASTM/IP when ports have been enabled, such as a LIS connection.

*continued*

# e-Connectivity® Technology Frequently Asked Questions

**Q:** What type of encryption and authentication is provided for e-Connectivity®?

**A:** The e-Connectivity® Enterprise Solution encrypts message contents sent between the device and the enterprise, so that only the applications at each end can decode them. Ortho uses Secure Socket Layer (SSL), the same method banks use for secure online transactions, to provide secure transmission of data. SSL provides a protocol for transmitting private data via the Internet. In addition to encrypting data, the SSL standard also provide authentication to ensure that both the sender and receiver of data are known to each other. Ortho can also enable secret key AES 256-bit message encryption, which may be used with SSL to encrypt data beyond the Demilitarized Zone (DMZ). In addition to providing SSL, Transport Layer Security (TLS) is used to provide security at the communications level.

**Q:** How often does the ORTHO VISION™ Analyzer exchange data with the e-Connectivity infrastructure at Ortho?

**A:** Under normal conditions an upload of data will take place on configurable intervals. However, the user can initiate an additional data upload at any time, typically when contacting Ortho for support.

**Q:** How much data (size) is normally exchanged between the ORTHO VISION™ Analyzer and the e-Connectivity® Technology infrastructure at Ortho?

**A:** Under normal conditions the size of the daily upload will be ~25MB. S/W downloads may occur a few times per year and could be ~500MB.

**Q:** Do my LIS and e-Connectivity® talk through the same Ethernet connection?

**A:** LIS connection can be connected through the Ethernet port to share a link with e-Connectivity®, or may be routed through the Serial Port using a Serial to Ethernet adaptor. If routed through the Serial Port, the customer will need to provide two network ports

## AGREEMENT METHOD

**Q:** Is a firewall in place to prevent unauthorized access to the ORTHO VISION™ Analyzers?

**A:** Yes. The systems contain a software firewall. This solution prevents any unauthorized access to the System. It only allows communication from the system through the SSL tunnel to the Ortho Clinical Diagnostics e-Connectivity® Technology infrastructure. The system is not exposed directly to the Internet.

