

e-Connectivity[®] Technology for ORTHO VISION[®] Analyzers

Ortho Clinical Diagnostics e-Connectivity Technology Interactive System Management feature provides real-time, secure two-way interactive connection between the ORTHO VISION[®] Systems* and Ortho Care[™] Services.

Benefits of e-Connectivity Technology



Increased Uptime

Customers with connected analyzers save 1.5 calls/year leading to improved analyzer availability.



Faster Resolution

Ortho Care Representatives have information to resolve issues either by phone, or in advance of a service visit. Automatic scheduled transfer of system performance data is provided to the Ortho Care team for proactive analysis and resolution.



Time-Saving Updates

Receive the latest software version and assay information when released. A system notification is sent through the analyzer and is installed by the user when convenient.



Informative Tools

View laboratory efficiency and operation through analyzer-level performance data, including: key performance graphs, testing breakout, reagent usage, and maintenance.

Commitment to Cyber Security

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 the legal and ethical obligations to protect patient privacy and data security.

SECURE TLS

e-Connectivity Technology establishes a secure connection between the ORTHO VISION Systems and Ortho for transfer of data via the Internet using Transport Layer Security (TLS) technology.

EXCLUDE PATIENT INFORMATION

The Sample ID assigned to the patient sample is encrypted by the software. No other PHI is transmitted to e-Connectivity servers.

LIMITED ACCESS

To provide high security level and maintain patient data privacy and confidentiality, e-Connectivity limits access to specific hard drive directories. Only analyzer and assay performances data logger files can be collected.

*ORTHO VISION[®]



e-Connectivity Connection Model

e-Connectivity Technology establishes a secure connection between the ORTHO VISION Systems and Ortho for transfer of data via the Internet using **Transport Layer Security (TLS)** technology.

TLS technology is a combination of industry standard network tunneling, encryption, authentication, access control and auditing technologies/services used to securely transport data over the Internet.

e-Connectivity Technology was developed with security integrated into the design:

- Does not require an extra network device.
- No email server or internet browser available to the user.
- Fully integrated into your systems eliminating routine system operation.

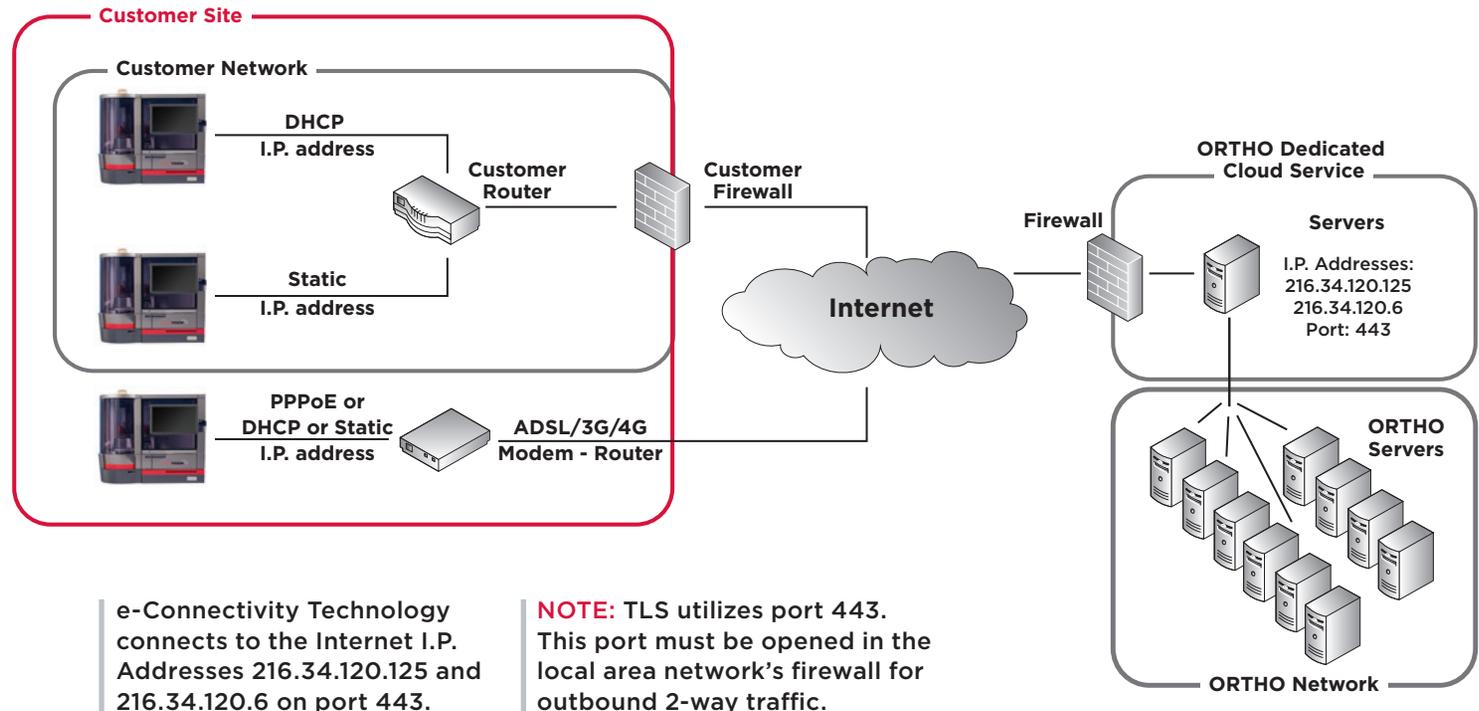
For specific use cases where internet access is required (e.g. LIS communications), the ORTHO VISION systems provide a firewall that is configured to connect only to Ortho and only enables specific ports.

On ORTHO VISION systems, the TLS tunnel is secured using a minimum 256-bit encryption. Encryption is accomplished by using a server side certificate from an authorized authority to encrypt the data exchanged.

TLS (default version 1.2)

How to Connect Your Analyzer

e-Connectivity Technology requires a continuous broadband connection or direct connection to the customer LAN with access to the Ortho Clinical Diagnostics e-Connectivity server at a speed greater than or equal to 128 kbps.



Transmitted Data & Encryption

ORTHO VISION systems transmit files containing data associated with the results, condition codes, and other data that may be useful to troubleshoot the system along with verification information to ensure your system is operating within specification.

ORTHO VISION systems data logger files are automatically processed and managed with restricted access during their transfer to Ortho e-Connectivity servers. **Only designated Ortho employees with passwords have access to the e-Connectivity data.**

e-Connectivity delivers software safely and securely to the analyzers. All software downloaded is verified prior to notifying the operator that an upgrade is available. Software installation is always performed by system operator and cannot be done automatically.

Personally Identifiable Information (PII)

By default, all sample IDs are encrypted (independently from the TLS encryption) and can only be decrypted at the analyzer

interface. Encryption is unique to each analyzer. Customers are reminded to use only anonymized sample IDs.

Network & Systems Security

The ORTHO VISION systems have built in firewall capabilities that are pre-configured to allow TLS secure access

to Ortho Infrastructure only. The devices may also be configured by customers to support other connections via

TCP/IP with ASTM/IP, when ports have been enabled.

Virus and Malware

ORTHO VISION uses a closed process that minimizes exposure to viruses. ORTHO VISION uses the Microsoft Windows 10 IoT Enterprise operating

system. ORTHO VISION boots directly into the analyzer software, providing an Operator with no access to the Operating System, no access to internet browser,

nor access to email, etc. Antivirus updates and OS patches are managed by Ortho.

Standard and References

The Ortho dedicated Cloud Service is certified ISO 27001.

In compliance with electronic record 21 CFR Part 11.

Ortho Clinical Diagnostics  ~~utilizes a partner, Parametric Technology Corporation (PTC), to host the cloud solution.~~

The e-Connectivity capability is designed to exclude both patient personally identifiable information and patient personal health information from being processed and sent to Ortho when implemented according to the Instruction For Use (IFU).

The e-Connectivity model is approved by the English National Health Service (NHS).



Frequently Asked Questions

1

What's the charge for e-Connectivity?

▶ There is no charge for e-Connectivity.

2

How do I prepare my ORTHO VISION Systems for e-Connectivity?

▶ You will need to provide a broadband connection with access to the Internet at a speed greater than or equal to 128 kbps. The Internet connection can be DSL, cable or provided through a Local Area Network (LAN). Ortho provides the hardware and software necessary for e-Connectivity. See e-Connectivity Network Connection Specifications and Network Form for further information.

3

How is e-Connectivity installed?

▶ Your ORTHO VISION System requires a standard on-site service call for installation or configuration of the components necessary for e-Connectivity. It is often part of instrument installation. You will need to provide local network information so that the Ortho Service Representative can configure the e-Connected Systems. This information is collected on the e-Connectivity Network Connection Specifications and Network Form, which can be completed and returned to Ortho Care Technical Support.

4

Will e-Connectivity interfere with the performance of my ORTHO VISION Systems?

▶ No. e-Connectivity is fully integrated into your system so that routine system operation is maintained. For example, Automatic Two-Way Data Exchange, including software downloads, can occur without interruption to continuous system operation, including during sample and assay processing.

5

How will Ortho use the collected data?

▶ Our Ortho Care Technical Support centers and field engineers will analyze system performance data for current and potential issues on individual systems, enabling service to be performed as quickly and conveniently as possible. In addition, aggregated data from multiple systems may point to needed software updates, as well as feature development needs for future systems.

VIRTUAL PRIVATE NETWORK (VPN)

6

Will I need a VPN on my hospital network (LAN)?

▶ No, you need to assign an IP address (Static or DHCP) and allow bidirectional traffic over port 443 through the site firewall. The assigned IP address will be configured by the Ortho Care installation team. The IP address and a working connection are needed at the time of installation.

7

Will I need to configure the instrument's connection?

▶ No. An Ortho Care Service Representative will configure the e-Connected Systems with local network information provided by you. However, a Key Operator password allows you to control and modify this configuration as well.

LOCAL AREA NETWORK CONNECTION CONFIGURATION

8

Will I need to configure my firewall(s)?

▶ Possibly. You will need to ensure that the e-Connected System on your network can communicate with Ortho (216.34.120.125 and 216.34.120.6) on TCP port 443 outbound 2-way traffic. This is the standard port used for TLS connections. If you have multiple firewalls, this configuration must be done for each firewall involved in the route. **It is extremely important that these ports are open for a timely and successful install of e-Connectivity and support to your System.**

DSL/CABLE CONFIGURATION

9

How is DSL/Cable installed in my laboratory?

▶ You will need a local service provider (typically the telephone company or cable company) to install the DSL/Cable line into your laboratory. The provider should supply the equipment necessary to connect the Systems to the Internet. Please note that the equipment must support an Ethernet connection (i.e. not USB only).

10

How do I ensure the DSL/Cable line is working?

▶ You should communicate with the service provider regarding how best to determine that the DSL/Cable line is functioning correctly. Several providers will perform all of the necessary work. Other providers will deliver the equipment and you will be required to make the connections and configure the equipment. If the service provider does the latter, then follow their instructions to install, configure and test it before Ortho connects the System.



Frequently Asked Questions

11

How do you configure the connection if IT requires a login to the Internet Service Provider?

▶ The Ortho Care Service Engineer can enter the appropriate information into the e-Connected System. Some hardware (DSL and Cable modems) can support the configuration of this information. If this is the case, Ortho would prefer that the information is stored in the hardware supporting the connection.

OPERATING SYSTEM

12

What operating system is used on the ORTHO VISION Systems?

▶ ORTHO VISION systems use Microsoft Windows 10 IoT Enterprise Operating System.

CONFIDENTIALITY, SECURITY AND PRIVACY

13

How secure and private is e-Connectivity?

▶ Ortho Care Technical Support cannot change or access results, patient information or data. By default, all sample IDs are encrypted when they are copied in data logger files. If the Sample ID encryption is disabled, Ortho Clinical Diagnostics strongly recommends to not use Patient Information in the Sample ID field.

14

What data is transmitted through e-Connectivity?

▶ e-Connected systems transmit logged System information that can assist in ensuring your system is operating within specification. The system may also be capable of receiving software upgrades and assay information. All of this data is encrypted during transmission through the TLS connection.

15

Is a firewall in place to prevent unauthorized access to the ORTHO VISION Systems?

▶ **Yes.** All ORTHO VISION systems include a firewall that blocks all incoming network traffic to prevent any unauthorized access. Only customer configured outbound traffic to Ortho e-Connectivity server and customer configured LIS servers is allowed.

16

Are my e-Connected Systems protected from viruses or other computers that may attempt to access the systems?

▶ e-Connectivity uses a secure connection mode. All assets at Ortho that could access this connection are maintained with the latest anti-virus and patches available per Ortho corporate standards and policies. The use of a firewall on the ORTHO VISION Systems prevents any unauthorized access to the system. It only allows communication from the ORTHO VISION System through the TLS connection to Ortho. The system is not exposed directly to the Internet and is protected by a firewall.

