

INCREASE UPTIME WITH REMOTE SUPPORT

Frequently asked questions for
O-arm™ O2 Surgical Imaging System



FEATURES & BENEFITS

Remote Diagnostics

When your team calls us with a problem, Medtronic's Technical Support team can remotely obtain diagnostic logs on the system to identify and resolve many system issues without waiting for on-site support.

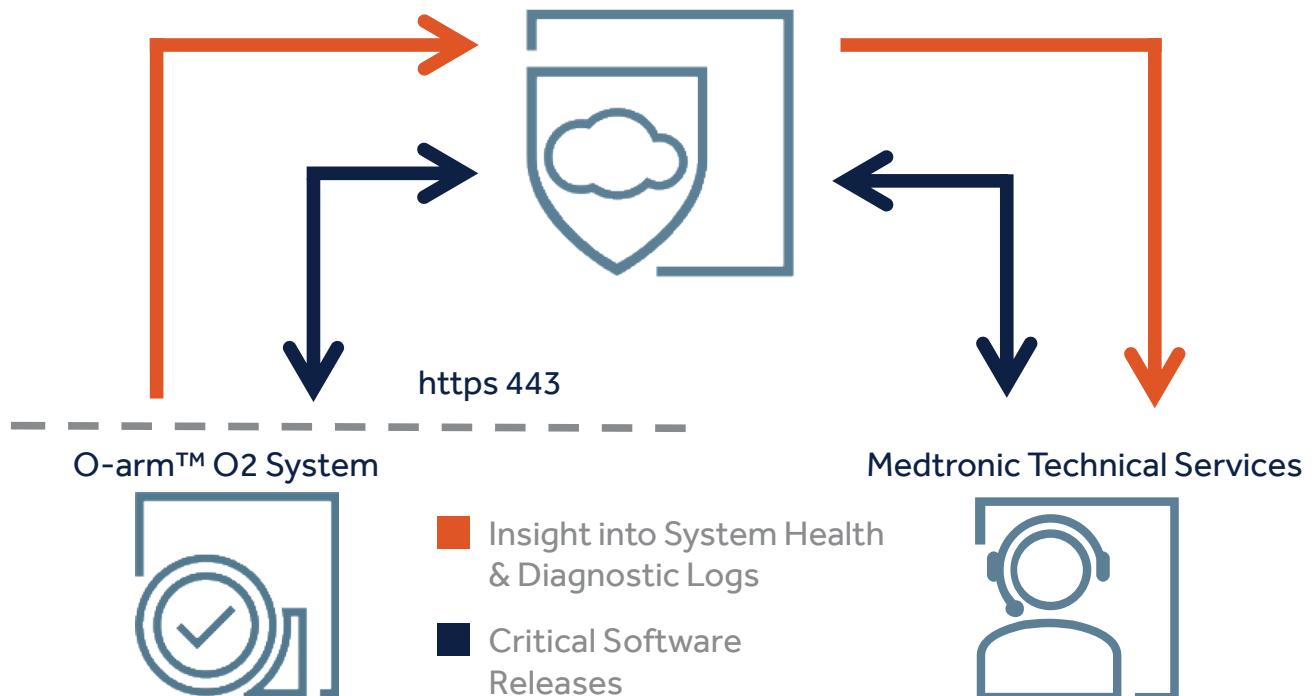
Pro-Active Fix

With remote insight into system health and usage, we can pro-actively detect certain part failure.

Update Critical Software

When convenient for your staff, Medtronic can remotely deliver software.*

MEDTRONIC PATHWAY CONNECT™ CLOUD SOLUTION



FREQUENTLY ASKED QUESTIONS

SYSTEM, CONNECTION, & COMMUNICATION

<p>What is the O-arm™ O2 System?</p>	<p>The O-arm™ O2 system is an intraoperative 2D/3D imaging system that is designed to meet the workflow demands of the surgical environment. It can be used in a variety of procedures including spine, cranial, and orthopedics. The O-arm™ system is not a patient implantable device and it is not easily portable outside of your facility.</p>
<p>What is Medtronic Pathway Connect™ server?</p>	<p>The Medtronic Pathway Connect™ server is a secure digital service cloud solution providing a connection between your Medtronic non-implantable equipment and Medtronic. The Medtronic Pathway Connect™ server enables numerous digital services to increase system up-time and develop analytical solutions to help your leadership make informed purchasing decisions.</p> <p>With the Medtronic Pathway Connect™ server we are providing you, our hospital IT partners with a secure and traceable connection to provide remote services on equipment within your hospital, and to save you time and to simplify engagement. The Medtronic Pathway Connect cloud server is non-burdensome, meaning it does not require any maintenance from you or your team.</p> <p>For more information on Medtronic Pathway Connect™ server and how Medtronic's commitment to security aligns directly with the National Institute of Standards and Technology (NIST) cyber security framework, please see Medtronic Pathway Connect™ Technical Brief.</p>
<p>How does the communication work?</p>	<p>Medtronic Remote Support is connected to the Medtronic Pathway Connect™ server, Medtronic's digital service cloud solution, through an outbound connection initiated from the system. The Medtronic Pathway Connect™ server uses the standard HTTPS (Secure Sockets Layer) communication protocol. Additionally, Remote Support uses the industry standard WebSockets protocol (RFC 6455), which runs on top of the secure and encrypted TLS Protocol. All communication originates from the device on-site to Medtronic Pathway Connect™ server as an outbound HTTPS connection on port 443.</p> <p>The O-arm™ system will attempt to communicate with the Medtronic Pathway Connect™ server every 30 seconds when the following conditions are met:</p> <ol style="list-style-type: none"> 1. System is powered on. 2. System is connected to network via Ethernet.
<p>What servers will the device access?</p>	<p>For the O-arm™ System, the Medtronic Pathway Connect™ server requires outbound access to a Domain Name Server (DNS), which is available upon request and can be white listed to allow the device to only communicate with this address.</p>

SERVICES BEING PERFORMED REMOTELY

<p>Remote diagnostics: How does it work?</p>	<p>The person troubleshooting a problem on the system will call Medtronic Technical Support. Upon completion of initial troubleshooting, Medtronic Technical Support can remotely request diagnostic logs from the system in order to diagnose many system issues and prevent a physical on-site call when possible. Only trained and authorized Medtronic specialists have access to diagnostic logs. Diagnostic files will not contain patient health information (PHI) on the O-arm™ system.</p>
<p>Proactively detect certain part failure: How does this work?</p>	<p>When the system is connected to Medtronic Pathway Connect™ server, Medtronic can collect data on the health of the system specific to certain critical parts. Parts such as hard drives send status messages. On other parts, we collect utilization files and use historical data to predict part failure. Depending on the level and status of your Service & Support Plan, Medtronic may replace certain parts before they break. Part status messages and utilization files will not contain patient health information (PHI).</p>
<p>Remote software delivery: How does this work?</p>	<p>Depending on the level and status of your Service & Support Plan, Medtronic can remotely deliver software. Non-clinical software releases can be remotely delivered in response to a request initiated by a Medtronic field representative operating the O-arm™ system.</p>

FREQUENTLY ASKED QUESTIONS

PROTECTING PHI & DATA

What data is being collected with the Remote Support service?	<p>With the Remote Support service, Medtronic will collect the following files from the O-arm™O2 system.</p> <ul style="list-style-type: none">▪ Diagnostic files. Diagnostic files are used to remotely identify and resolve many system issues. Only trained and authorized Medtronic specialists have access to diagnostic logs. Sometimes these logs contain sensitive patient data. Medtronic does not sell patient data or share it with other entities.▪ Part status messages, to provide insight into system health. Part status messages do not contain PHI.▪ Utilization files, which combined with historical data, tells Medtronic when certain parts may need to be proactively replaced. Utilization files do not contain PHI.▪ List of installed software, which do not contain PHI.
Who has access to this data?	<ul style="list-style-type: none">▪ Medtronic's Technical Support team, who are trained and authorized, may have access to diagnostic logs to troubleshoot a problem.▪ Medtronic's Research and Development team, who are trained and authorized, may have access to diagnostic logs, part status messages, and utilization files to develop design changes.▪ Your facility's leadership team may request utilization files to determine future equipment needs.

If you have questions about Remote Support, contact Technical Services at 800-595-9709 or 720-890-3160

Medtronic Remote Support is enabled by Medtronic Pathway Connect,™ digital service cloud solution. For more information on Medtronic's commitment to security, check-out Medtronic Pathway Connect™ Technical Brief. Please see Medtronic's pledge to privacy and security at www.medtronic.com/us-en/privacy-statement.html.

Caution: Federal Law (USA) restricts these devices for sale by or on the order of a physician. Refer to product instruction manual/package insert for instructions, warnings, precautions and contraindications. Healthcare professionals must review the product technical manual prior to use for detailed disclosure. For information on Indications, Safety, and Warnings, call Medtronic at 800.328.0810. For further information, please contact Medtronic Neurosurgery at 877.242.9504, or consult Medtronic's website at www.medtronic.com.

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www.medtronic.com/Oarm

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