

IEC 80001 Summary

ENGLISH

General Information

The following information is intended for the Medical IT-Network Risk Manager within the responsible organization (to perform tasks according to IEC 80001-1:2010 and IEC 60601-1:2005+AMD1:2012).

This information applies to the following Brainlab products:

	Products
Platforms	<ul style="list-style-type: none"> • Buzz • Buzz Navigation CM • Cirq Robotic Alignment Module • Curve Navigation 17700 • Curve Ceiling-Mounted • Curve Navigation Station • Digital Lightbox • Digital OR Computer for Barco Integration • Kick EM Navigation Station • Kick Navigation Station • iPlan Net (3.6, 3.7) • iPlan Server (3.x) • Kolibri Navigation Station 2.x • VectorVision Compact • VectorVision Sky • VectorVision²
RT Patient Positioning	<ul style="list-style-type: none"> • ExacTrac
Software	<ul style="list-style-type: none"> • All Brainlab Elements • All Brainlab navigation software • DICOM Viewer for Touchscreen PC • iPlan 3.0 (Cranial/ENT/CMF/Stereotaxy/Flow/Spine/View) • iPlan RT (4.1, 4.5) • Quentry

PEMS Intended to be Incorporated into an IT-Network

Connecting a Brainlab product to an IT-network that includes other equipment could result in previously unidentified risks to patients, operators or third parties.

The responsible organization should identify, analyze, evaluate and control these risks. Subsequent changes to the IT-network could introduce new risks and require additional analysis. Changes to the IT-network include:

- Changes in the IT-network configuration
- Connection of additional items to the IT-network
- Disconnecting items from the IT-network
- Updating/upgrading equipment connected to the IT-network

Applicable Group Policy Settings

To ensure correct function of the system, do not change the following Windows 10 Group Policy settings when the system is integrated into a hospital network (e.g., by a domain controller).

This applies to the settings found in the path **Computer/Policies/Administrative Templates:**

- Control Panel/Personalization
- Control Panel/User Accounts
- System/Device Installation
- System/Logon
- System/Internet Communication Management
- System/Power Management
- System/Shutdown
- Windows Components/AutoPlay Policies
- Windows Components/Desktop Window Manager
- Windows Components/Even Log Service
- Windows Components/Internet Explorer/Security Features/Add-on Management
- Windows Components/Windows Defender/Exclusions
- Windows Components/Windows Update

Technical Specifications of the Network Connection

Brainlab platforms feature the following IT-network connections:

	All Platforms	Some Platforms
Link layer	≥ 1 Ethernet port, compatible with 100/1000BASE-T networks	<ul style="list-style-type: none"> • Ethernet ports, compatible with 1000BASE-T networks • WLAN compatible with IEEE 802.11b/g/n/ac
Internet layer	IPv4 connectivity	IPv6 connectivity

NOTE: For detailed compatibility, refer to the relevant user guides.

Product Configurations

Products installed and configured by a Brainlab service engineer are compliant with the Microsoft Baseline Security Analyzer (MBSA) for IT security (wherever technically and reasonably applicable).

Please be aware that subsequent modifications can affect the safety and effectiveness of the product.

Required IT-Network Configurations

Firewalls must be configured according to the IT-Network Specifications listed in this document.

Brainlab considers a network that is not protected from unauthorized access as fault-prone.

Risks Resulting from IT-Network Failure

When performing non-time-critical surgical planning, failures do not result in hazardous situations.

However, if the IT-Network connection fails, it is possible that the treatment cannot be continued or must be repeated. If **ExacTrac** is used during this failure, this could lead to unnecessary KV imaging of the patient.

Additionally, if the intraoperative DICOM push (from the modality or C-arm) to the Brainlab product fails, it will no longer be possible to use the Brainlab product for patient treatment.

Technical Descriptions and User Guides

The following documents are available upon request for your product platform:

- DICOM Conformance statements: (<https://www.brainlab.com/dicom>)
- FDA and CE declarations
- IT Network Planning
- Navigation Software User Guide
- System and Technical User Guide
- Clinical User Guide
- Technical specification sheet

Product Recalls

Brainlab will inform every customer in case of identified anomalies.

Cyber Security Notices

Brainlab will inform every customer in case of identified cyber security issues and provide software updates accordingly.

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Intended Information Flow and IT-Network Specifications

PRODUCTS INVOLVED	PURPOSE OF CONNECTING TO THE IT-NETWORK	IT-NETWORK REQUIREMENTS		SECURITY SPECIFICATIONS				
		AVAILABLE BANDWIDTH	ADDITIONAL	PROTOCOL	PORT			
All products	Loading medical imaging data	≥ 100 Mbit/s (recommended: 1 Gbit/s)	Disk space: ≥ 250 GB (recommended: SSD)	DICOM	• 104/TCP (closed from external connections) • 11112/TCP		inbound & outbound	
	Storing medical imaging data			CIFS	445/TCP			
	Remote access to HTML5 applications	≥ 10 Mbit/s	Latency < 100 ms	• HTTP • HTTPS	• 44388/TCP/UDP • 55581/TCP/UDP		inbound	
	Remote support	≥ 2 Mbit/s	• Internet access • Latency < 100 ms	iHelp® (Axeda)	443/TCP	Authentication Server	support.brainlab.com	outbound
						Europe	gas-de2.axeda.com gas-de3.axeda.com gas.ie1.axeda.com gas.ie2.axeda.com	
North and South America						ghsom1.axeda.com gas-bo3.axeda.com gas-bo7.axeda.com ghsj1.axeda.com ghsj2.axeda.com		
Asia/Pacific						ghjap1.axeda.com ghjap2.axeda.com gas-aus2.axeda.com gas-aus3.axeda.com gas-cne4.axeda.com gas-cne6.axeda.com		
Platforms	Quentry cloud access	≥ 2 Mbit/s (recommended: 10 Mbit/s)	N/A	Quentry	443/TCP	US v01-us1.quentry.com v02-us1.quentry.com	inbound	
	Buzz remote control	≥ 15 Mbit/s	WLAN connection	Brainlab remote control		55578/TCP		
	Communication with Cirq Robotic Alignment Module via Medineering Positioning Arm	≥ 1 Mbit/s	Latency < 100 ms	• HTTP • HTTPS		• 80/TCP • 443/TCP		outbound
	Establishing data links	N/A	N/A	mDNS / DNS-SD	5353/UDP (Multicast 224.0.0.251)		inbound & outbound	
	Imaging modality connections	≥ 1 Mbit/s	Connections within the same broadcast domain for minimum latency	BK Medical OEM Interface	7915/TCP			
				Brainlab C-arm	• 44445/TCP/UDP • 55555/TCP/UDP • 56666/TCP/UDP			
	Transferring navigation information			NTP	123/UDP		outbound	
	Session sharing	≥ 1 Gbit/s		• Brainlab flex • Backbone	• 57575/TCP • 57574/TCP • 50001/TCP • 57581/TCP • 50002/UDP • 57578/TCP/UDP		inbound	
Video streaming, recording, conferencing	≥ 40 Mbit/s	N/A	• HTTP • HTTPS • SDP • RTP	• 80/TCP • 443/TCP • 3396/TCP • 57581/TCP • 55588/TCP • 55500/UDP		inbound		
Remote desktop connections (only available using Origin Server)	≥ 1.5 Mbit/s	Latency < 100 ms	• RDP • HTTPS	• 3389 (configurable)/TCP • 443/TCP • 8080/TCP				
• Platforms • RT Patient Positioning	User authentication	N/A	Microsoft Active Directory®	• LDAP • LDAP SSL • LDAP GC • LDAP GC SSL • Kerberos • DNS • Microsoft-DS • Kerberos change password		outbound		
	Windows® domain integration			• Microsoft-DS • Kerberos • LDAP • DNS				
RT Patient Positioning	Connecting to third-party computers	≥ 1 Mbit/s	N/A	VNC	5900/TCP		inbound	
	Connecting to linac	N/A	• Latency < 100 ms • Fully switched network	Varian ADI	56050/TCP		inbound & outbound	
				Elekta	• 135/TCP • 1801/TCP • 2101/TCP			
	Configuring firewalls		Third-party device	Varian	56050/TCP			
Elekta (e.g., NSS)				9090/TCP				