Safety Communication   رسالة سلامة

Instructions to Prevent Cybersecurity Vulnerability

Device/ Product Description:	iLab Intravascular Ultrasound Imaging Systems and POLARIS Multimodality Guidance Systems
Manufacturer:	Boston Scientific Ltd
Problem Summary:	The optional network security device (NSD) firewall provided with the above systems to help prevent the inadvertent transfer of viruses and other malware from the hospital network to the above systems may either be at its end of life and may require replacement or may be due for software patching. For more information, check the below attached document. If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center

	AR name:	FAROUK, MAAMOUN TAMER & COMPANY
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Dear, Valued Customer.

As a provider of the iLab® Intravascular Ultrasound Imaging System and the iLab POLARIS Multi-modality Guidance System, Boston Scientific realizes that the security of patient case data and Local Area Networks are important to medical care and service providers, particularly when the System is connected to the hospital PACS network.

Users should adhere to their organization's policies and procedures pertaining to patient privacy and comply with all applicable laws regarding where patient data is stored, used and disclosed. It is assumed that the iLab system is used within a secured network and environment to prevent data loss, tampering and contamination from a malicious invasive code such as viruses or other malware. It is assumed that a secured environment includes at a minimum:

- Firewall or router protection to ensure that only approved external hosts have network access to the iLab System
- Firewall or router protection to ensure that the iLab network access is limited to approved external hosts and services
- Any communication with external hosts and services outside the locally secured environment use appropriate secure network channels such as a Virtual Private Network (VPN)

To provide additional security to the iLab System, Boston Scientific has previously provided you an optional Network Security Device (NSD) firewall to help prevent the inadvertent transfer of viruses and other malware from the hospital network to the iLab System. **One of the devices below was sent to you and is now either end of life and may require replacement or is due for software patching.**

TZ-100 first generation NSD   SOHO second generation NSD

Please contact the Technical Assistance Center (TAC) so that we may assist you in determining your security needs. Prior to calling TAC, please use the enclosed document to identify your iLab serial number and the type of NSD connected (if still in use).
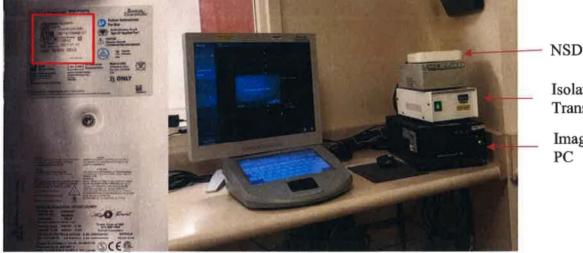
We look forward to speaking with you,
Capital Equipment Technical Support Team

Identify and locate your iLab Serial Number and NSD (if in use):

Mobile Cart System – The NSD is installed internally and requires removing the 4 screws on the lower back panel, see image below.

Integrated Systems – The serial number is found on the on the top of the isolation transformer. In typical installations the isolation transformer as well as the NSD are located in the control room.

Technical Support Numbers

Country / Continent	Telephone Number	Email
Asia Pacific	-64188813	CETechSupportAPAC@bsci.com
Australia/New Zealand	+61 1800 676 133 (option 5)	CapitalEquipmentANZ@bsci.com
Austria	+43 1608 1037	CEtechsupportEMEA@bsci.com
Denmark	+45 80253429	CEtechsupportEMEA@bsci.com
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Finland	+358 800770055	CEtechsupportEMEA@bsci.com
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Italy	+39 022 698 3218	CETechSupportEMEA@bsci.com
Netherlands	+31 45 5467707	CETechSupportEMEA@bsci.com
Norway	+47 80014236	CEtechsupportEMEA@bsci.com
Spain	+34 917 619 999	CETechSupportEMEA@bsci.com
United Kingdom	+44 1442 411 686	CETechSupportEMEA@bsci.com
U.S.	1-800-949-6708	CETechSupportUSA@bsci.com