



X-Link

EMR Integration for the **NMS450 Series**

Instructions for Use
Software Version 1.0.3 or higher



XM400-21XEN04-02

27 May 2026

Manufacturer



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Sponsors

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Teleflex Medical
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Caution

Federal (US) law restricts
this device to sale by or on
the order of a physician.



Warnings

- ♦ Read the entire User Manual before attempting to use the device.
- ♦ Opening of the device may only be performed by the qualified persons explicitly authorized and trained by the manufacturer.
- ♦ When the X-Link is used adjacent to or stacked with other equipment, monitor the device to ensure it functions normally in the intended configuration.
- ♦ Do not modify this equipment without authorization of the manufacturer.
- ♦ The X-Link is NOT to be used in the presence of flammable anaesthetic agents or oxygen enriched atmospheres.



Cautions

- ♦ The device shall only be used with the region specific power adapter supplied.
- ♦ The device shall be used in a "trusted network" such that the network has been secured prior to installing the X-Link.
- ♦ The product must be stored and used at the specified environment conditions only.
- ♦ Inspect all parts for any damage or manipulation before use. Never use any damaged or manipulated part.
- ♦ If an electrically conductive surface of the STIMPOD device or its accessories are exposed, such electrically conductive surface may shock a person handling it. Do not use such a device or accessory, please contact the manufacturer for repair.

- ♦ Do not drop the device or subject it to unnecessary forces which may cause damage. If this occurs and the device does not operate as expected, please contact the manufacturer for repair.
 - ♦ The device shall optimally be used with a CAT 5 ethernet cable.
 - ♦ The device shall be installed following the instructions in the User Manual prior to use in a clinical setting.
 - ♦ The supplied ingress protection caps shall be used when a specific interface port is not in use.
 - ♦ No calibration of the device is required.
 - ♦ Basic network knowledge and access is required to install the X-Link. Access to the Smart Lynx server shall be required to connect the X-Link to the EMR system.
 - ♦ The X-Link is not a diagnostic or therapeutic device.
 - ♦ Ensure that all devices on the network are free of malware, including all devices that are used to configure the X-Link
 - ♦ Ensure that the X-Link is used on a network that requires device whitelisting, ensuring that only known devices have access to the network environment.
 - ♦ Ensure that the network assigns a static IP to each X-Link device.
 - ♦ Where hospital managed certificates are used, ensure that certificates are generated using an RSA 2048 key pair or a more secure alternative.
 - ♦ Ensure that device certificates are not distributed or made publicly available.
 - ♦ For optimal security, ensure that server authentication is enabled on the DDI interface and either application or hospital managed certificates are used. Further, ensure that regular (every 2 years) certificate rotation is employed.
 - ♦ Ensure that the X-Link is not left in public places unattended where it might be tampered with without the knowledge of the intended operators.
 - ♦ In the event of any cybersecurity event, immediately quarantine the affected devices and email cybersec@xavant.com for steps to safely recover the devices.
 - ♦ Connecting X Link to an IT network that includes other equipment could result in previously unidentified risk to patient, operators or third parties. It is the responsibility of the hospital to identify and control these risks.
 - ♦ Any changes or modifications in IT-network configuration, connecting or disconnecting items from IT-network or upgrades to the network equipments could introduce new risks to the system that must be analysed and controlled by the responsible hospital IT management.
- Note:** The X-Link is able to obtain an IP Address on the network through DHCP. It is only recommended that the IP address assigned statically by the network to allow for easier device management.

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1 | The X-Link

1.1 Intended Purpose/Intended Use

The X-Link is intended to transmit data collected by the STIMPOD NMS450 series devices during NMT monitoring to a hospital's EMR (Electronic Medical Records) system via the hospital's network. This facilitates seamless integration of patient monitoring data into the hospital's digital records, improving workflow efficiency and reducing manual entry errors. Additionally, the X-Link provides the capability to charge the STIMPOD NMS450X+ device when it is not in use and is disconnected from the patient, enhancing workflow efficiency in its operating environment. The product does not control any functionality of the STIMPOD devices.

1.2 Indications for Use

The X-Link is intended to enable secure data transmission of NMT data from a STIMPOD NMT monitor to hospital information systems via standard HL7 wired protocol. It is not intended for real-time monitoring or diagnostic decision making.

1.3 Intended User

The intended user/operator for X-Link is a clinical professional that has been trained and has working knowledge and terminology required to operate this equipment and use the clinical information it provides in accordance with its intended use. Operators include anaesthetist, CRNAs, CRN and healthcare technicians.

1.4 Target Population

The target population for X-Link is the same as that for the STIMPOD NMS450 series devices.

1.5 Medical Conditions to be treated, diagnosed and/or monitored

X-Link is not directly used for the diagnosis, treatment or monitoring of any medical condition.

1.6 Clinical Benefits

X-Link does not have any clinical benefits due to the nature of the device intended application.

1.7 Device Description

The X-Link facilitates communication between the STIMPOD NMS450X or NMS450X+ (henceforth referred to as STIMPOD NMS450 devices) and a hospital's EMR system. The X-Link acts as an intermediary for data transmission; converting and relaying data from the STIMPOD to the hospital's network during neuromuscular transmission (NMT) monitoring procedures. Thus ensuring that patient information is accurately and automatically recorded in the EMR without any user intervention. The X-Link does not alter the content of the data or provide any analysis or interpretation of data. It is supplied as a Medical Device Data System (MDDS) accessory to the STIMPOD NMS450 devices.

1.8 X-Link Quick Start Guide

If the X-Link has already been configured, complete the following three steps to transmit NMT data to the EMR. If not refer to [Section 2](#) to configure the device

1. Connect your STIMPOD and sensor accessory cable to the X-Link.
2. Ensure the X-Link has two Green Status LED's, indicating that it is on and connected to both a Stimpod and the EMR.
3. Use the Stimpod to monitor the case using your normal workflows.
4. After use, shut down the STIMPOD using the power button. If an NMS450X+ is connected to the system, automatic charging will commence. The NMS 450X+ will charge until the battery is full and will then automatically power down
5. Press the power button on the NMS450X+ to exit charging mode and begin NMT monitoring if the device is currently charging.
6. Note that the X-Link should always be left powered on and does not need to be powered down after use.



1.9 Parameters transmitted by the X-Link to the EMR

The X-Link transmits the following NMT data to the EMR system:

- ♦ TOF results (counts and ratios).
- ♦ PTC results.
- ♦ DB results.
- ♦ DEP results as a ratio of the reference result.
- ♦ Individual pulse values for TOF, DEP and DB.
- ♦ Reference pulse data when a valid SMC was obtained (DEP and AUTO modes).
- ♦ Sensor type used to measure case data (AMG or EMG).
- ♦ Stimulus current for each result.

The X-Link, further, transmits contextual information to the EMR, ensuring that NMT results can be attributed to a patient and procedure. This includes:

- ♦ A unique serial number for every X-Link.
- ♦ A hospital configurable Device ID.
- ♦ A configurable device location.
- ♦ The patient ID (optionally set on a case-by-case basis).

Note: The X Link does not store, transmit or process any confidential or protected patient health information.



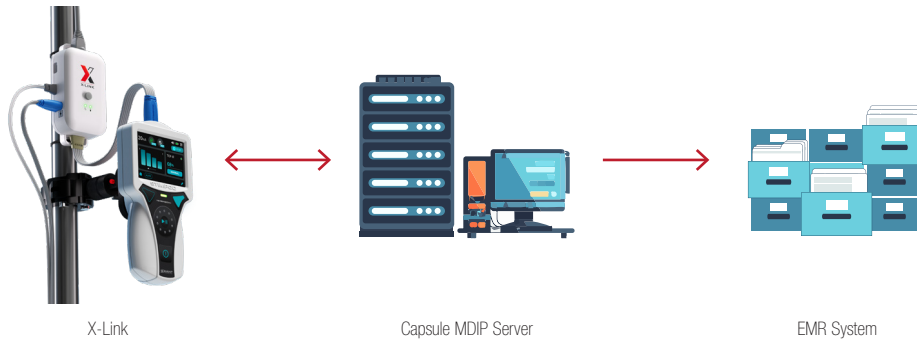
1.10 X-Link Installation Diagram

The X-Link connects directly to the hospital network via an Ethernet connection.

1. The X-Link transmits NMT data using the standardized HL7 message format to the Capsule MDIP, which forwards the data to the EMR system.
2. This allows for seamless EMR integration of existing and new NMS450 series devices, requiring little to no user interaction once the device has been successfully installed.

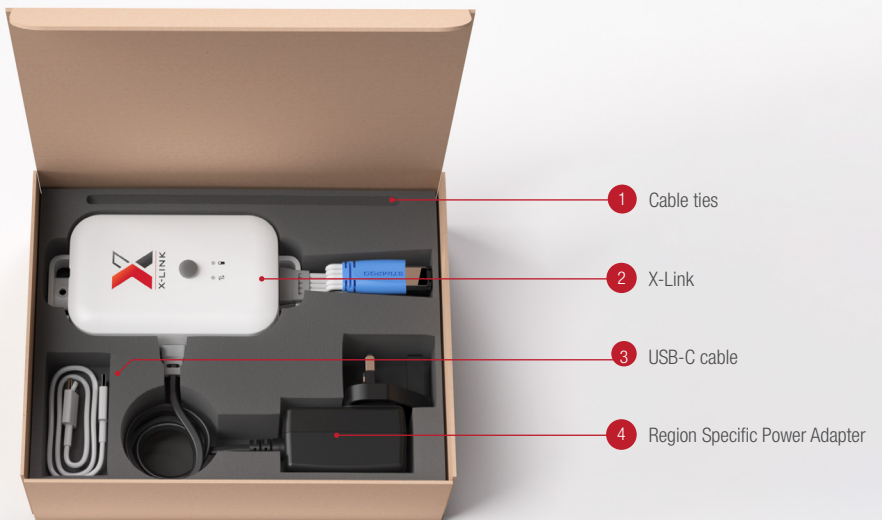
Notes:

- A. Do not connect to a capsule Neuron, connect the X-Link directly to the hospital's network.
- B. Direct connection to a Capsule Neuron can be achieved with Latest Neuron (3 4s2e).



1.11 Unboxing the X-Link

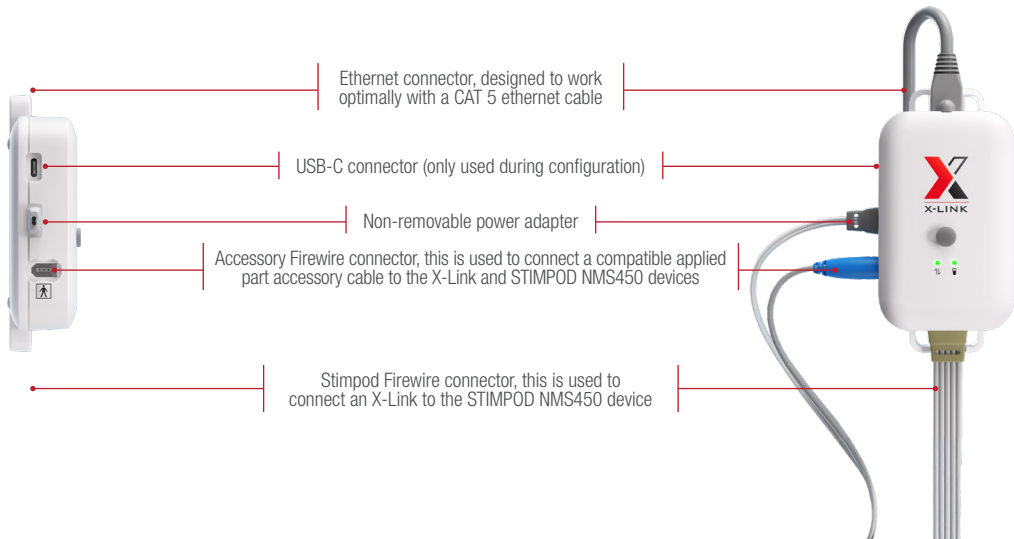
The content of the X-Link packaging is listed below. Note that an ethernet cable is not provided with the X-Link and will have to be purchased separately if required.



* Ingress caps placed on the Ethernet and USB ports.

1.12 The X-Link interfaces

The X-Link has several interfaces that serve specific purposes.



1.13 X-Link Status Indicators

The X-Link has two LED's that provide information around aspects of the device's functioning as follows:

Configuration LED

Indicates different device states. The different states indicated are:

- ♦ **White:** The X-Link is starting up.
- ♦ **Green:** The X-Link has established a connection and is sending data to the EMR.
- ♦ **Blue:** The X-Link's ethernet interface has been initialized and has obtained an IP address on the local network.
- ♦ **Red:** The X-Link's ethernet interface has been initialized, but it has not obtained an IP address.
- ♦ **Flashing blue:** The X-Link is in configuration mode and is ready to communicate with the Setup Application.



Stimpod LED

Indicates the X-Link's connectivity status with a connected Stimpod. The different states indicated are:

- ♦ **Red:** A Stimpod has not been connected to the X-Link.
- ♦ **Green:** A Stimpod has been connected to the X-Link and Stimpod communications are being received by the X-Link.
- ♦ **Blue:** The Stimpod is being charged by the X-Link.
- ♦ **Off/ No Colour:** The device is either in setup mode (if the configuration LED is flashing blue) or is starting up (the configuration LED is White).

1.14 X-Link Multi Function Button

The X-Link has been designed to minimize required user interactions. Its button provides two functions and serves as the primary user interaction available when using the X-Link. The functions are:

1. Pressing the button for more than 3s turns the device on or off.
2. Pressing the button twice within 2s initializes or disables the setup functionality of the X-Link. This shall be indicated by the flashing blue configuration LED (the LED on the left) and a clear Stimpod LED (the LED on the right) when setup mode is enabled.

Note that entering setup mode will stop charging the NMS450X+ if it was being charged before the button was pressed.



2 | Setting Up The X-Link

■ 2.1 Hardware and IT measures

The X-Link needs to be installed on a hospital network that is air-gapped from the external internet. The network should require device onboarding to access the network. Device onboarding should involve white listing MAC addresses before devices can access the network or a similarly strict requirement. These requirements ensure that the X-link exists on a secure network.

The MAC address of the X-Link can be accessed via the Device info tab of the configuration application. See [Section 4](#) for more details around this.

■ 2.2 Configuration Requirements

1. Each X-Link requires a first time set up before it is installed in an Operating Room or similar environment. Some equipment and information is required for the setup:
1. Your X-Link.
2. The included USB-C Cable.
3. A Windows PC with the X-Link Setup Application available via [this link](#).

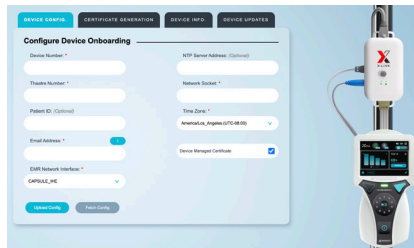
4. Device information including:
 - ♦ TLS certificates if hospital managed certificates are required.
 - ♦ Where the device shall be installed.
 - ♦ Optional: The Server address of the Hospitals NTP server, if one is available and will be used.
 - ♦ The EMR system that is used, this shall be Capsule when a Capsule MDIP is used at the facility.
 - ♦ Optional: The unique device name that shall be assigned to the X-link if the facility uses internal names to identify devices.
 - ♦ Optional: The Patient ID. If this is used, it needs to be configured before every case.

Notes:

- A. PC needs to have access to the internet during initial setup.
- B. The X-Link is able to obtain an IP Address on the network through DHCP.
- C. It is only recommended that the IP address assigned statically by the network to allow for easier device management.

I. Installing the X-Link Setup application

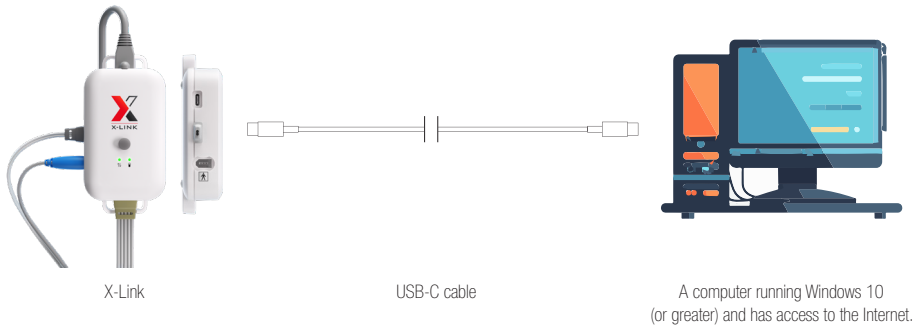
4. The X-Link Setup application is required to configure the X-Link. The X-Link needs to be configured before it can communicate with the EMR system. The application can be downloaded from [this link](#).
5. Once the application has downloaded, double click on the executable to install it.
6. After installation has been completed, a desktop icon shall be created for the X-Link Setup GUI Application; the icon has the same logo that appears on the front of the X-Link. Open the application by double clicking on the icon. Alternatively, open the X-Link Setup application from the Windows menu.
7. If an application update is available, it shall be automatically installed. The application shall evaluate if an update is available when it starts up.
8. The X-Link Setup Application shall open and appear as follows. The application needs to communicate over a USB-C connection with the X-Link.



■ 2.3 Entering Setup mode on the X-Link

Connecting the setup application with the X-Link requires two steps:

1. Connect the USB-C cable to the corresponding port on the X-Link (and connect the other side of the cable to your PC).



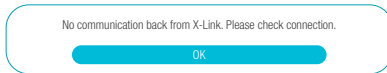
2. Ensure the X-Link has been powered on and is ready for use, the configuration LED is no longer white. The configuration light should be blue if you are generating a certificate using the application, this means that it has initialised and obtained an IP address on the local network. If the LED is not blue, ensure that an ethernet cable has been plugged into the X-Link and is connected to the facility's network.
 3. Once this has been achieved, press the X-Link's button twice to enter setup mode, as described in [Section 1.8](#). The configuration light should begin flashing blue, indicating that the X-Link is in setup mode. Further, the Stimpod LED shall be clear/off.
- Note:** Entering setup mode will disable charging the NMS450X+ if it was being charged before the X-link was placed in setup mode.

2.4 Configuring device onboarding fields

- I. Open the **DEVICE CONFIG.** tab of the application.
- II. With the X-Link in setup mode click the **Fetch Config** button on the application. If the X-Link has been correctly placed in setup mode, this shall populate the fields with the configuration values currently configured on the device. If this is the initial setup of the X-Link, it shall indicate that no values have been loaded using the following popup message:



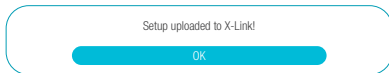
The application shall indicate if it cannot communicate with the X-Link using the popup message shown below. If this occurs, follow "Setup Communication troubleshooting" in [Section 5](#).



Once communication has been established with the X-Link, fill in the relevant Setup fields to configure the X-Link. Please see the description of each field in the following table. The fields with an asterisk are required. The values represent the following:

Field	Description	Max Length
Device number	The internal hospital configurable device number assigned to the X-Link.	20
Theater Number	The Location in which the X-Link shall be installed.	10
Patient ID	The Patient ID for a specific operation. Note that if this is configured it will need to be removed after every operation.	25
Email address	The email address of the person/unit in charge of managing the X-Link. This shall be used to notify you around device updates and features that are added in the future.	50
EMR Network Interface	The Network interface responsible for receiving data from the X-Link. This can only be CAPSULE_IHE.	-
NTP Server address	The NTP server address if an internal hospital has been configured. This shall ensure that data from the X-Link is accurate.	20
Network Socket	The network socket exposed on the X-Link. This is the Network socket / port connected to from the Capsule system. It is recommended to use port 8080 for all X-Link devices. This will not cause any issues on the Capsule server as the port is exposed on the X-link Device. Valid Sockets need to be greater then 1000.	20
Time Zone	The local time-zone of the facility, in case time should be synchronized to the time zone of the facility.	-
Device managed certificates.	Use device managed certificates. If this is selected the X-Link shall manage it's own certificates and no further certificate onboarding shall be required. More information around certificates will be provided in Section 2.5.	-

- III. Once the setup values have been updated press the **Upload Config** button. The Application will indicate when the setup values have successfully been loaded to the X-Link using the popup message shown below:



- IV. After setting the configuration values, continue to configure the TLS certificates used by the X-Link. This is only required if Device managed certificates were not selected when configuring the X-Link.

2.5 Certificate onboarding

- ♦ The X-Link requires a certificate to securely communicate with the Capsule MDIP Server over an encrypted connection.
- ♦ Unencrypted certificates are supported on the X-Link. The source of the certificate can be:
 1. Self-signed, this is a certificate created or generated on the device if device managed certificates are selected when configuring the device using the setup application.
 2. Hospital/ facility managed where the certificates are managed by the hospital. The setup application can be used to deploy these certificates to the X-Link.

2.5.1. Device managed certificates

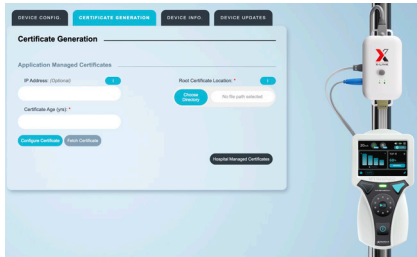
Device managed certificates are enabled when configuring the device on the Device Config. tab. If the Device managed certificate checkbox has been selected the X-Link shall generate and manage its own certificates. No further manual intervention will be required. As such, device managed certificates require no manual intervention after installation, while application and hospital managed certificates will require rotation after the onboarded certificates expire.

If a certificate is uploaded using the certificate generation tab, the device will revert to using the uploaded certificates and device managed certificates will be disabled.

Note: If device managed certificates are selected, the root certificate will not be uploaded to the MDIP server, as outlined in [Section 2.7](#). Further Server authentication will not be possible and should not be selected on the DDI. Device managed certificates are the least secure option of the three certificate management methods available, while it still provides an encrypted exchange of data to the EMR.

2.5.2 Application Managed Certificates

- ◆ Open the **CERTIFICATE GENERATION** tab of the application to generate and configure application managed certificates.
- ◆ To create a self-signed certificate using the application, you will need:



1. The IP address of the Connected X-Link.

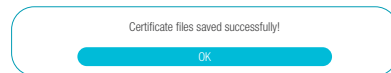
- If the X-Link already has an IP Address you can leave this field empty. You can confirm if it has an IP address by clicking the **Fetch Device Info** on the device information tab of the GUI.
- If the X-Link does not have an IP address you will need to input the IP address that you will assign to the device on the hospital's network. This is the same IP Address that will be configured on the Capsule MDIP system.

2. The chosen Certificate Age

- This is the time, in years, that the certificate will be valid. After this has elapsed, you will need to repeat this process to update the certificate. It is recommended to use a period of less than 2 years for optimal security, however a value up to 100 years is accepted if you do not want to replace the certificates on a regular basis. The minimum period allowed is 1 year.

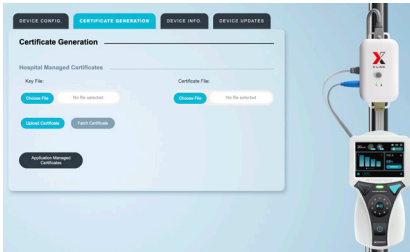
3. A directory to save the certificate to.

- ◆ Select a directory where the generated certificates will be saved.
- If this is not the first device onboarded, ensure that the RootCA.crt file is present in the selected directory. It is important that only one RootCA.crt is generated to ensure a minimal administrative burden when adding the file to the windows trust store on the Capsule MDIP server. RootCA.crt should be together
- If devices have previously been onboarded, or you need to onboard devices from multiple computers, copy the RootCA.crt used to the selected location on any computer configuring certificates on X-Link devices.
- ◆ Enter the details on the application and click on **Configure Certificate**. The application shall indicate when it has successfully deployed the certificate pair to the X-Link as shown in the popup message below.



2.5.3 Hospital Managed Certificates

Open the **CERTIFICATE GENERATION** tab of the application and click on the Hospital Managed Certificates button to configure hospital managed certificates.



Hospital managed certificates can be uploaded to the device in two easy steps:

1. Use the Key and certificate file addition elements to upload the relevant files.
 2. Click the **Upload Certificate** button. This shall send the certificate pair to the X-Link and ensure that the certificate has been correctly onboarded to the device. Both files should have the .pem extension and should not be encrypted.
- ♦ If the Key File and Certificate File needs to be fetched from the X-link, click the **Fetch Certificate** button. A popup will ask for the appropriate file path to save the files. Choose a file path and confirm. The X-link Key File and Certificate File will save to the appropriate file path afterward.

2.6 Saving configured values:

Configuration has been completed once the device onboarding fields and certificates have been set.

Press the multi-function button on the X-Link twice to exit setup mode and save the configured values. The Configuration LED shall return to either a solid blue or solid red colour, indicating that either an IP has or has not been obtained. Further, the Stimpod LED shall either be green or red, depending on whether a Stimpod is connected. See [Section 1.13](#) for more information on the LED colours and their meaning.

2.7 Uploading the root certificate to the MDIP

Once all devices have been onboarded, install the RootCA.crt file to the windows trust store as per the: Capsule MDIP System Administrator's Guide. This will need to be done for the Application and hospital managed certificates.

1. Copy the RootCA.crt to the Capsule MDIP server where the other certificates are stored.
2. Press the Windows button on the Capsule MDIP server.
3. Enter certlm.msc and press enter.
4. Navigate to Trusted Root Certification Authority/Certificates.
5. On the top bar, click on Action/All Tasks/Import and follow the prompts to load the RootCA.crt certificate to the trust store.

3 | Connecting The X-Link

3.1 Connecting to the X-Link from the MDIP

Add the device with the following configuration:

1. Add the DDI instance as a TLS client.
2. The device IP address should be the IP address assigned to the device. This can be retrieved using the [DEVICE INFO](#) tab on the configuration GUI.

3. If a self signed certificate or hospital managed certificate was uploaded to the device, enable server authentication.
 - If a self signed certificate was used, the "Trusted certificate common name" Shall be Xavant.
 - If a hospital managed certificate was used, add the common name of the hospital managed certificate.

Note: It is not required to enable server authentication on the DDI. However, it increases the security of the connection



■ 3.2 Installing the X-Link in the OR

The X-Link can be fastened to an IV Pole above the STIMPOD NMS450 device as shown in the image. Further instructions can be seen in the images below.



3.3 Charging the Stimpod through the X-Link

The X-Link can charge the NMS450X+, this is only available for NMS450X+ devices with software versions $\geq 10.6.8$.

- ♦ To enable charging, switch off your NMS450X+ device using the power button while it is connected to the X-Link. The NMS450X+ will automatically enter charging mode, as indicated on the screen. Charging will stop automatically once the battery is fully charged and the NMS450X+ will power down.
- ♦ To disable charging, press the power button, the NMS450X+ will restart, ready for use.

Notes:

- A. The NMS450X+ cannot perform NMT monitoring while simultaneously being charged by the X-Link.
- B. Charging will not commence if STIMPOD is in a closed circuit condition.
- C. Charging will halt if the X-Link enters configuration/setup mode.

3.4 Managing your X-Link

The X-Link application has two tabs that assist with managing the device past configuration. These tabs are:

- ♦ Device info:

The screenshot shows the 'Device Requests' screen in the X-Link application. The top navigation bar includes four tabs: 'DEVICE CONFIG', 'CERTIFICATE GENERATION', 'DEVICE INFO', and 'DEVICE UPDATES'. The 'DEVICE INFO' tab is currently active. The main content area is titled 'Device Requests' and contains several input fields: 'IP Address', 'MAC Address', 'OS Version', and 'Firmware Version'. A 'Fetch Device Info' button is located at the bottom left of the form.

- ♦ Device Updates:

The screenshot shows the 'Device Updates' screen in the X-Link application. The top navigation bar includes four tabs: 'DEVICE CONFIG', 'CERTIFICATE GENERATION', 'DEVICE INFO', and 'DEVICE UPDATES'. The 'DEVICE UPDATES' tab is currently active. The main content area displays a message: 'Device update available. Press "Proceed" to update your device.' Below the message is a 'Proceed' button.

To use these features:

- ♦ Put the X-Link into setup mode, see [Section 2.2 Entering Setup mode on the X-Link](#).
- ♦ Open the application and navigate to the tab.

4 | Technical Notes

■ 4.1 Supported Software Versions

NMS450X+	≥ 10.6.8 allows charging in addition to NMT data acquisition.
NMT Monitoring Cable (EMG)	All Software versions.
NMT Monitoring Cable (AMG)	All Software versions.

■ 4.2 Supported Hardware

STIMPOD NMS450X+	XT-45030
NMT Monitoring Cable (EMG)	XT-45003, XT-45003B , XT-45003A
NMT Monitoring Cable (AMG)	XT-45025, XT45025B , XT-45025A

4.3 Specifications

Physical specifications

Dimensions	121mm (L) x 62mm (W) x 31mm (H)
Mass	203.5 g
Operating Temperature	10-40 °C
Storage & Transport Temperature	0-50 °C
Operating Humidity	90% RH
Storage & Transport Humidity	90% RH
Operating Atmospheric Pressure	80-106 kPa
Storage & Transport Atmospheric Pressure	80-106 kPa

Power supply

Supply Voltage (V)	5 ± 0.5
Supply Current (A)	2.4 (max)
Supply Power (W)	12 (max)
Cable length	2.5 m

Current Consumption

Minimum (mA)	113
Average (mA)	280
Maximum (mA)	1500

Interface (firewire) Cable

Length (mm)	220
-------------	-----

USB Cable

Length (m)	1
Type	Type-C to Type - C

4.4 Symbols



Manufacturer



Date of manufacture
(Year only)



Caution



Recycle: Electronic Equipment
(Applicable to EU community only)



Serial
Number



Authorized Representative in
the European Community/
European Union



Catalogue
Number



Authorized Representative
in Switzerland



Prescription
only



Type BF
Applied Part



Ingress Protection
Rating



Humidity
limitation



Temperature
limit



Refer to instruction
manual / booklet



CE marking



Importer



Batch Code



Medical Device



Unique Device Identification
carrier contains UDI DI+PI



Warning



Xavant Youtube



Xavant X



Xavant University

4.5 Cleaning and Disinfecting X-Link

Cleaning

- ♦ Cleaning should be performed after each use and before disinfection.
- ♦ Wipe all parts with cleaning wipes or a soft lint-free cloth moistened in soap and water or a detergent-based disinfectant until visually clean.
- ♦ Allow the surface to dry, then wipe off traces of the cleaning agent with a soft lint-free cloth moistened in water.
- ♦ Visually inspect that the surface is clean and free of any residue. Repeat the cleaning procedure if required.



Caution

- ♦ Soap and water should only be applied with a damp cloth - under no circumstances should the X-Link or any of its parts or accessories come into direct contact with, be immersed in, or filled with liquid.
- ♦ Do not place the X-Link or any of its parts or accessories inside an autoclave.
- ♦ The X-Link is not sterile and should not be placed in close proximity from surgical site.

Disinfecting

- ♦ Any commercially available methanol-free disinfectant in an ethyl alcohol base can be used for disinfection.
- ♦ The surfaces of the X-Link and its accessories should be cleaned with a lint-free cloth moistened with a methanol-free disinfectant in an ethyl alcohol base. Before using a disinfectant, refer to the manufacturer's documentation and test on a small area.

Examples of recommended products include:

- Meliseptol® fluid and tissues from the manufacturer B. Braun.
- mikrozid® AF from the manufacturer Schülke.
- Oxivir Excel Wipe (0.36% Hydrogen Peroxide).
- Sodium Hypochlorite in a diluted 1% (v/v) concentration.

Check with your local authorized distributor or the manufacturer for approved products available in your country.

- ♦ Let the surface dry in air.
- ♦ Ensure to use a soft lint free cloth moistened in water to wipe off the traces of the disinfectant



Caution

- ♦ The X-Link must not come into direct contact with, be immersed in, splashed, or filled with liquid and should be cleaned in the same manner as the STIMPOD NMS450 Devices.

4.6 Guidance and Manufacturers Declaration

Guidance and Manufacturers Declaration – Electromagnetic Emissions– for All Equipment and Systems

The X-Link is intended for use in electromagnetic environment specified below. The customer or user of the X-Link should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 2 – Class A	The X-LINK must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. The X-LINK is suitable for use in all establishments, other than domestic establishments and may be used in domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: WARNING: This equipment/system is intended to be used by healthcare professional only. This equipment/system may cause radio interference or disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re- orienting or re-locating the X-LINK or shielding the location.

Guidance and Manufacturers Declaration – Electromagnetic Immunity- for All Equipment and Systems

The X-Link is intended for use in the electromagnetic environment specified below. The customer or the user of the X-Link should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	50 Hz 30 A/m (Effective)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The X-Link is intended for use in the electromagnetic environment specified below. The customer or the user of the X-Link should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3V at 0.15 - 80MHz and 6V at ISM Frequency. Home Healthcare: 3V at 0.15-80MHz, and 6V at ISM and Radio Amateur Frequency.	3V at 0.15 - 80MHz and 6V at ISM Frequency. Home Healthcare: 3V at 0.15-80MHz, and 6V at ISM and Radio Amateur Frequency.	Portable and mobile RF communications equipment should be used no closer to any part of the X-LINK, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2 \sqrt{P} \quad 80 \text{ MHz} - 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \quad 800 \text{ MHz} - 2.5 \text{ GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.
Radiated RF IEC 61000-4-3	3 V/m (10V/m Home Healthcare) at 80-2,700MHz, AM Modulation. And 9-28V/m at 385-6000MHz, Pulse Mode and other Modulation (upon Risk Analysis).	3 V/m (10V/m Home Healthcare) at 80-2,700MHz, AM Modulation. And 9-28V/m at 385-6000MHz, Pulse Mode and other Modulation (upon Risk Analysis).	 Interference may occur in the vicinity of equipment marked with this symbol.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the X-LINK is used exceeds the applicable RF compliance level above, the X-LINK should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the X-LINK.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the X-Link

The X-Link is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X-Link can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the X-Link as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz - 80 MHz Not Applicable	80 MHz - 800 MHz $d = 1.2 \sqrt{P}$	800 MHz - 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	-	0.12	0.23
0.1	-	0.38	0.73
1	-	1.2	2.3
10	-	3.8	7.3
100	-	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturers Declaration – Electromagnetic Immunity – for Equipment and Systems That Are Non-Life Supporting

The X-Link is intended for use in the electromagnetic environment specified below. The customer or the user of the X-Link should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated immunity 80MHz - 2.5GHz	80MHz – 1GHz @ 3V/m & 10V/m 1GHz – 2.5GHz @ 10V/m	80MHz – 1GHz @ 3V/m & 10V/m 1GHz – 2.5GHz @ 10V/m	Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT and should be used no closer to any part of the equipment, including cables, than the recommended separation distance.

Standards and Regulations Applied:

- ◆ IEC 60601-1:2005/AMD1:2012/AMD2:2020
- ◆ IEC 60601-2-10: 2012/AMD1:2016/AMD2:2023 CISPR 11 Group 1 Class A
- ◆ IEC 60601-2-40:2024
- ◆ IEC 62366-1:2015/AMD1:2020
- ◆ IEC 60601-1-6:2010/AMD1:2013/AMD2:2020
- ◆ ISO 13485:2016, EU MDR 2017/745

4.7 Waste Management and Disposal

According to the WEEE Directive 2012/19/EU, all waste electrical and electronic equipment (EEE) should be disposed of and collected separately, and treated using environmentally friendly techniques. EEE contains hazardous substances and valuable resources, making separate collection important. Proper disposal of this product conserves resources and prevents negative impacts on health and the environment resulting from improper waste handling.



Dispose of the Device and Accessories at an electronics recycler, and contact your local authority or nearest collection site for proper disposal. If you are uncertain about your country's disposal regulations, contact your local authority, dealer, or supplier for more information. Penalties may apply for incorrect disposal. Dispose of used electrodes as medical waste.

4.8 Product Lifetime

The lifetime of the product is 5 years.

4.9 Warranty

- ◆ The X-Link carries a 6 month warranty against manufacturing defects, provided that the device was used in accordance with the operating instructions.
- ◆ Unauthorized attempts to open, repair, or modify the device may void the warranty and compromise safety.
- ◆ Always follow the guidelines in this manual and reach out to customer support for any assistance.
- ◆ This device is not designed for service, maintenance, or repair by the user or unauthorized third parties in the field.

4.10 Periodic Checks



Warnings

- ♦ Always inspect the device and the cables prior to use for any broken or damaged parts.
 - ♦ If device performance changes or degrades from the specifications stated, take the device out of use immediately.
 - ♦ Do not attempt to service any damaged parts. Contact the Xavant authorised service center, dealer or Xavant.
-
- ♦ Switch off the device and remove from main connection before performing routine checks.
 - ♦ Examine if there are any visual signs of damage as follows:
 - Cracks on display or on enclosure.
 - Corroded surfaces.
 - Dents, sharp edges or broken parts.
 - ♦ Examine cables for any cracks, kink, signs of debris, wear or exposed internal wires.
 - ♦ Examine for any damage in cable insulation and connectors.
 - ♦ Always ensure that the device and cables are cleaned thoroughly, free from residues before and after use, including storage.
 - ♦ The routine checks are recommended to be performed once in 12 months.

4.11 Decommissioning X-Link Devices

When decommissioning X-Link devices ensure that:

- ♦ The X-Link devices are removed from the networks whitelisted devices.
- ♦ If all X-Link devices are removed from the facility ensure that the RootCA.crt certificate is removed from the Windows Trust store of the MDIP server.

5 | Troubleshooting

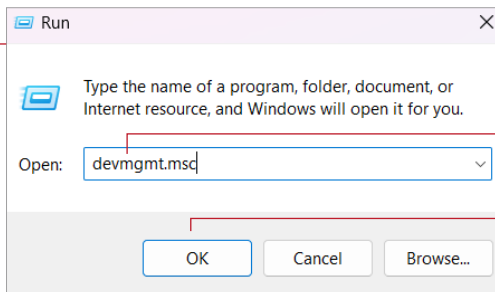
■ 5.1 Setup Communication troubleshooting

- ◆ Ensure the USB-C cable has been connected to the PC and X-Link.
- ◆ Ensure the X-Link is powered on and is in setup mode (indicated by flashing blue configuration LED).
- ◆ Ensure that the USB-C cable has been recognized by your PC. The instructions for performing this check can be seen on the following page.
- ◆ If all above checks fail, restart the X-Link and setup application and perform the steps to communicate with the application again.

1. Follow these steps to open the Device Manager. Alternatively, you can search for Device Manager using Windows Search.

Step 1:

Press Windows + 'R' on Keyboard. The following message box will be displayed



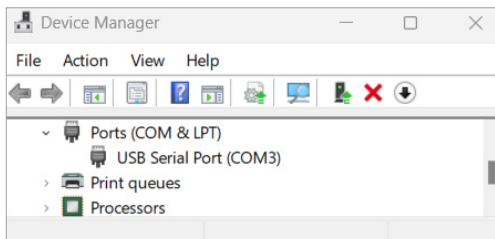
Step 2:

Type "devmgmt.msc" in the text box

Step 3:

Press the "OK" button to open the "Device Manager" Window

2. With the X-Link connected to the PC, scroll down to "Ports (COM & LPT)"¹, the COM Port name shall appear as shown in the image below.



3. If the port does not appear as above, download and install the drivers from the following link:
https://ftdichip.com/wp-content/uploads/2021/08/CDM212364_Setup.zip

¹ The COM port numbers might differ from those indicated in this document.

6 | Inside The Box

- ♦ XT-45300 X Link (supplied with non removable power adapter)
- ♦ XT-45205 USB Type C Cable 1m
- ♦ Cable ties (consumable)
- ♦ Instructions for Use





7 | Appendix A: Reporting Adverse Events to the FDA

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is not required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA at www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see [MedWatchLearn](#). The form is available at www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf.

Call FDA at 1-800-FDA-1088 to report by telephone.

Reporting Form FDA 3500 is commonly used by health professionals. The form is available at <https://www.fda.gov/media/76299/download>



8 | Appendix B: Reporting Adverse Events in EEA (European Economic Area)

If a serious incident occurs in relation to the use of this device, it is important to report it promptly. Adverse events include, but are not limited to, serious reactions or injuries, product safety issues and death or serious deterioration to health to patient/user.

Any adverse event should be reported to Xavant Technology as well as to the competent authority of the Member State (for Europe) or the relevant health authority in the country where the user and/or patient is located.

Reporting Adverse Events to Xavant Technology

To report an adverse event to Xavant Technology, please contact us through the following channels:

Email: compliance@xavant.com
Phone: +27 743 5959
Mail: Xavant Technology, 102 Tannery Industrial Park, 309 Derdepoort Road, Silverton, Pretoria, South Africa



Unit 102, The Tannery Industrial Park, 309 Derdepoort Rd
Silverton, Pretoria, South Africa, 0184
Tel: +27 (0) 12 743 5959, E-mail: support@xavant.com
Web: www.xavant.com
For feedback : customer@xavant.com