STIMPOD NMS 450 X+

Quantitative NMT Monitor Precision Nerve Locator

Instructions for Use

Software Version 10.6.x or higher

XAVANT TECHNOLOGY

FDA CLEARED CE 1639 | XM400-21ENP04-04
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Manufacturer

Xavant Technology (Pty) Ltd
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

Authorised Representatives

EC REP

Emergo Europe
Westervoortsedijk 60,
6827 AT Arnhem
The Netherlands

CH REP

MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

Europe
MedEnvoy
Prinses Margrietplantsoen 33
Suite 123
2595 The Hague, The Netherlands

Switzerland
Anandic Medical Systems AG
Stadtweg 24,
CH-8245, Feuerthalen - Schweiz

Sponsors

Australia
Teleflex Medical Australia
Level 4, 197 Coward St
Mascot NSW 2020
Australia

Caution

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

Applicable Software Versions

STIMPOD V10.6.x or higher

Intended Use

This product is a nerve stimulation device designed to be used by an anaesthetist during

- General Anaesthesia, for the purpose of establishing the efficacy of a Neuromuscular Blocking Agent using non-invasive surface electrodes.
- Regional Anaesthesia for the purpose of:
  - Nerve mapping using the non-invasive Nerve Mapping Probe (supplied).
  - Nerve locating using invasive electrodes/needles (not supplied).

Indications for Use

The STIMPOD is a quantitative NMT monitor that is indicated for monitoring the patient's muscle relaxation when neuromuscular blocking agent is administered.

Intended Users

The intended users of the STIMPOD include Anaesthesiologists, and Certified Registered Nurses Anaesthesia and used in accordance with approval clinical practices, local guidelines and recommendations.

Clinical Benefits

The STIMPOD offers significant clinical benefits both intra-operatively and postoperatively by allowing practitioners to monitor and control neuromuscular blockade and diagnose residual neuromuscular block while used in NMT mode. It helps avoid complications during intubation or extubation, adjust NMBA doses for each patient, detect residual neuromuscular weakness, and ensure the timely administration of reversal agents. In Nerve Map/Loc mode, it offers benefits through accurate detection of regional nerves. The data from the STIMPOD NMS450X+ should be used as supplementary information for patient management decisions.

Contraindications

- Infection of the puncture site.
- Known neurological disorders.
- Severe coagulation disorders.

⚠ Warnings

- Read the entire User Manual before attempting to use the device.
- Use of cables or accessories other than those supplied with the STIMPOD may result in serious injury.
- Maintenance on this device may only be performed by the manufacturer or persons explicitly authorized by the manufacturer.
- Do not use the STIMPOD in close proximity to equipment that produces strong electromagnetic fields, such as high frequency surgical equipment. The cable leads could act as antennae and dangerous currents could be induced as a result.
- Do not apply the STIMPOD to patients with implanted electrical devices, such as cardiac pacemakers, without first consulting with an appropriate medical specialist.
- The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- The patient should avoid contact with metallic objects that are grounded, produce an electrical conductive connection with other equipment and/or enable capacitive coupling.
- The cables and electrodes should be positioned in such a way that they do not come in contact with other patient cables that are simultaneously connected to the patient.

- Simultaneous connection of a patient to high frequency surgical ME equipment and the STIMPOD may result in potential interferences to the STIMPOD functionality leading to inaccurate measurements and risk of burns to patient.
- Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy ME equipment may produce instability in the stimulator output.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart. Avoid trans thoracic stimulation.
- No modification of this equipment is allowed.
- Do not modify this equipment without authorization of the manufacturer.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- The STIMPOD is NOT to be used in the presence of flammable anaesthetic agents or oxygen enriched atmospheres.
- Reuse of electrodes is not permitted as this may result in high impedance, poor stimulation, inaccurate monitoring, superficial skin burns and risk of cross contamination.

⚠ Cautions

- The use of batteries, that do not comply with stated recommendations could lead to electric shock or injury to the patient and damage to the STIMPOD.
- Long terms effects of electrical stimulation is unknown.
- Do not twist or pull a patient cable to disconnect it from STIMPOD as this could damage the integrity of the cable.
- No parts of the equipment are serviceable and/or requires special routine maintenance.
- Disconnect the patient cables, electrodes and STIMPOD from the patient and switch off the STIMPOD safely after the procedure.
- Avoid any accidental connection between the conductive surface of patient applied parts of STIMPOD with ESU devices or other devices with a protective earth connection.
- If surgery is conducted on any arm/foot, the STIMPOD patient electrode should be placed on the opposite limb to avoid subjecting the electrode to sterile surgical site.
- Prior to changing the batteries be sure to switch off the device and remove all the cables.
- Remove elements which may adversely affect the connection between the electrodes and the skin, e.g., dirt, hair, oil.
- Prior to placing any applied part (such as the AMG sensor, or ECG/EMG Electrodes), inspect the skin area for any pre-existing conditions and sensitivity to avoid if possible.
- Ensure that electrodes are not damaged or dried out.
- Ensure to check the expiry date of the electrodes prior to patient use.
- Large current densities associated with failing electrodes may cause superficial burns.
- For acceleromyography, the STIMPOD is designed to be compatible with standard ECG electrodes, however, for high currents the use of a dedicated NMT electrode such as the Xavant XT45008 is recommended.
- Electrodes that have current densities exceeding 2mA/cm2 may require special attention of the operator.
- The STIMPOD and its accessories must be stored and operated only within the specified recommended environment limits
- This product must be transported in the carry case provided.
- This product and all the accessories are latex free.
- Inspect all parts for any damage or manipulation. Never use any damaged or manipulated part!
- If an electrically conductive surface of the STIMPOD device or its cables 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.
- The refractory period delay is set at a default value to prevent the user from repeating stimulation while the nerve synapse is recovering from effects of the previous stimulation. A refractory period of less than 12 seconds in TOF mode is not advisable as measurements might not represent the effect of blocking agents on the neuromuscular junction.
- Do not place the STIMPOD stimulation electrodes in close proximity to other sensing electrodes i.e. EEG or ECG electrodes.
- Do not immerse the STIMPOD or its accessories in water or other liquids during cleaning or disinfection.
- Do not use abrasive cleaners on the display.
- Ensure the conductive parts of the patient cable or electrodes are in contact with patient only.

Application Specification

- The patient population includes patients of all ages, weight and nationality (excluding neonates). Patient health and state is described in contraindications, warnings and cautions.
- The user must be a medical professional with knowledge of anatomy.
- The use environment requirements of the device.
- The device can be used on any part of the body except the specific exclusions described in warnings and cautions.

Warranty

- The Stimpod (device only) carries a 24 month warranty against manufacturing defects, provided that the device was used in accordance with the operating instructions.
- The cables included in the Stimpod kit carry a 6 month warranty against manufacturing defects, provided that the cables were used in accordance with the operating instructions.
- The Stimpod enclosure should not be opened under any circumstances. Opening the unit will void the warranty.
- The warranty does not cover device failures that occur due to misuse, accidents, operator negligence, modifications, tampering or unauthorised repairs that have been performed during the warranty period by any personnel other than the manufacturer or its authorised agent.

Standards and Regulations Applied

- IEC 60601-1:2005/AMD2:2020, IEC 60601-2-10:2012/AMD2:2023,
- IEC 60601-1-2:2014/AMD1:2020 CISPR 11 Group 1 Class A,IEC 61000-4-2; IEC 61000-4-3
- IEC 60601-2-40:2016
- IEC 62366-1:2015/AMD1:2020
- IEC 60601-1-6:2010/AMD1:2013/AMD2:2020
- ISO 13485:2016, EU Directive 93-42-EEC

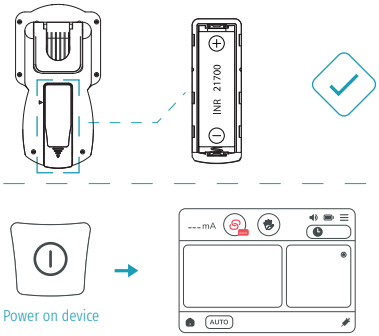
Note on Warnings and Cautions

- Warning is when a situation, if not avoided could result in serious injury or illness.
- Caution is when a situation, if not avoided could result in minor injury to patient or damage to STIMPOD.

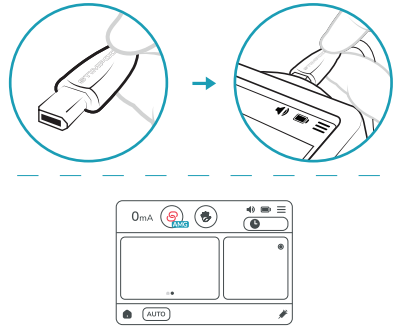
Quick Start Guide
AMG & EMG

NMT Monitoring I AMG Patient Setup

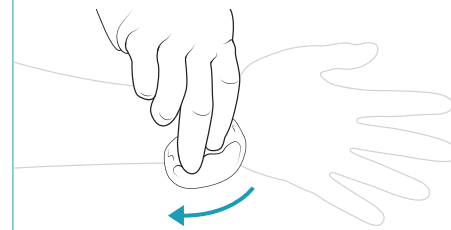
1 Check Batteries & Switch Device On



2 Connect NMT Monitoring Cable AMG



3 Prepare Patient's Skin for Monitoring

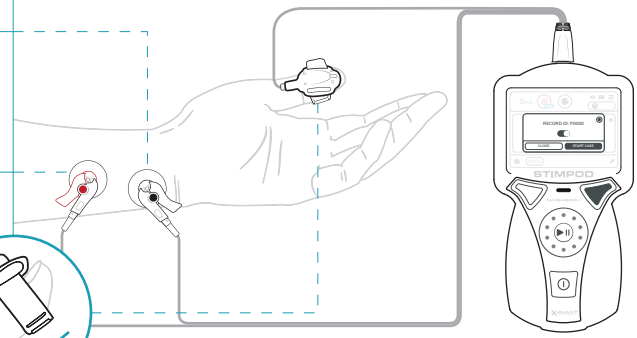


4 Attach Electrodes

5 Connect Clips to the Electrodes

6 Attach Accelerometer to Appropriate Contracting Appendage

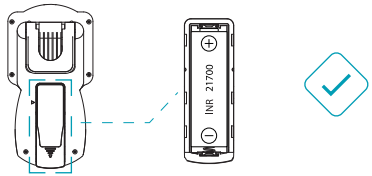
Patient Setup



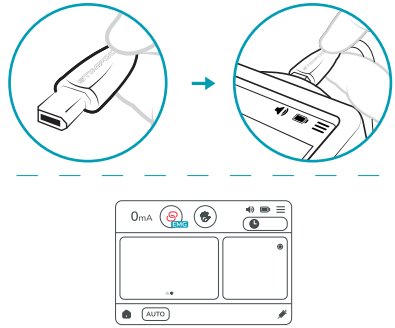
Setup Ready

NMT Monitoring I EMG Patient Setup

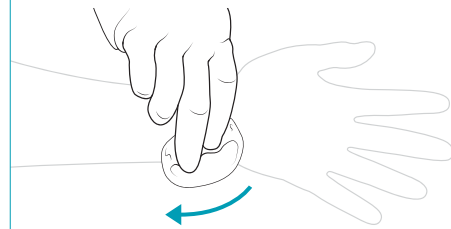
1 Check Batteries & Switch Device On



2 Connect NMT Monitoring Cable EMG



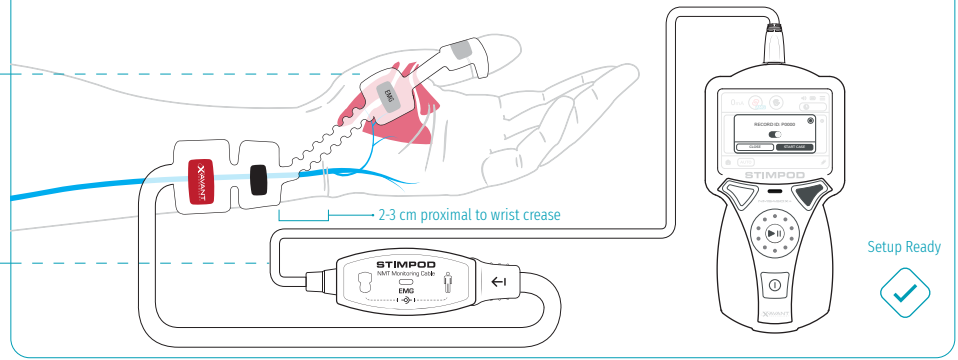
3 Prepare Patient's Skin for Monitoring



4 Attach EMG Electrode to Patient

5 Connect EMG Electrode to the NMT Monitoring Cable EMG

Patient Setup



Patient Stimulation Options for Patient NMT Monitoring

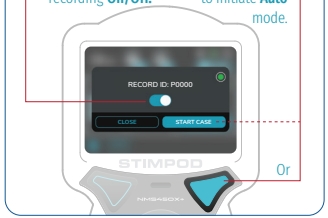
Option A: OneTouch NMT (AUTO Mode)

1 Start Case

Toggle case recording **On/Off.**

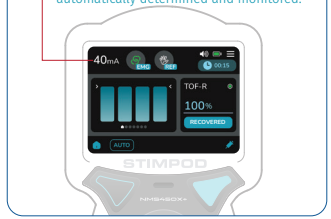
Select **START CASE** to initiate **Auto** mode.

Or



2 Full Case Monitoring Initiated

Reference current and **Depth of Block** automatically determined and monitored.

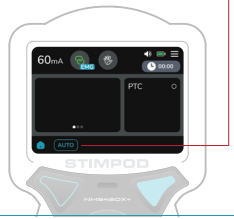


3 Select Desired View

Swipe to navigate through the available waveforms/views

Option B: Manual Stimulation

1 Press the **Mode** button to select mode

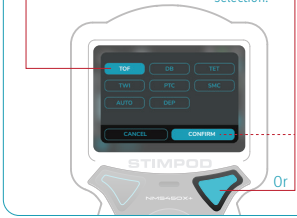


2 Select Stimulation Mode

Select **TOF** mode.

Confirm mode selection.

Or



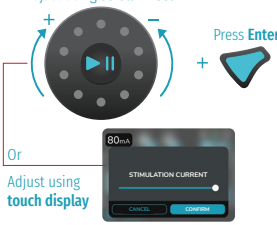
3 Adjust current as required

Adjust using **scroll wheel**

Press **Enter**

Or

Adjust using **touch display**



4 Press Play to Initiate Stimulation

Press **Play** key

Short Press for **Single Stimulation**
Or
Long Press (>2sec) for **Repeat Stimulation**

Contents

1 | Getting to Know the STIMPOD NMS450X+

1.1 | Device Description

The STIMPOD NMS450X+ is a quantitative Neuromuscular Transmission (NMT) monitor utilizing either tri-axial accelerometry or electromyography to provide real-time quantitative feedback.

The STIMPOD NMS450X+ is also a precision nerve mapping and locating tool. Transcutaneous mapping of nerves by electrical stimulation involves connecting the nerve stimulator to a conducting pen in order to ascertain the most superficial aspect of a motor nerve - indicated as the specific point on the surface of the skin where the strongest evoked neuromuscular response to electrical stimulation is observed. Percutaneous nerve locating involves connecting the nerve stimulator to a conducting anaesthetic needle in order to determine the subcutaneous location of a nerve - indicated as the specific point beneath the surface of the skin where the lowest threshold current required to elicit a neuromuscular response to electrical stimulation is observed.

⚠ **Caution:** This device should only be used by a qualified and competent physician with appropriate knowledge in anaesthesia. The sale or purchase of the device is restricted to licensed medical practitioners, as governed by the law of the country/state in which he/she practices, or where the device is to be used.

1.2 I Device Layout

1. **Cable Connector**
   Insert the combined Nerve Mapping/ Locating Cable or the NMT cable to activate the relevant mode.

2. **Display Screen**
   Full colour LCD display with capacitive touch and dimmable backlight control.

3. **Right Function Key**
   Context sensitive selection key - corresponds with buttons on the display that are blue in colour.
   Adjustment & Scroll key - provides for fine incremental increases in current and for scrolling waveform views.

4. **Left Function Key**
   Context sensitive selection key - corresponds with buttons on the display that are black in colour.
   Adjustment & Scroll key - provides for fine incremental decreases in current and for scrolling waveform views.

5. **Stimulating LED Indicator**
   Flashes Green - Stimulus pulse delivered.
   Flashes Red - Open Circuit or Stimulation Error.

6. **Play/ Pause Key**
   Press to start/stop stimulation or case.

7. **Scroll Wheel**
   Capacitive touch, radial slider - provide an alternative means for adjusting the stimulation current in all stimulation modes (also adjustable via touch screen).

8. **On/Off Key**
   Short press to turn unit on, Long press (>2 secs) to turn unit off. “ON”/ “OFF” (push-push).
   Note: Each position, “ON” or “OFF”, is a stable position

1.3 I Screen Layout

1 Electrode Placement Control
Indicates location and placement of stimulation and Monitoring electrode/s - Tap to set electrode location.

2 Open/Closed Circuit Indicator
Indicates open/closed circuit status of the currently connected stimulation cable.
Green: Closed Circuit, **Red**: Open Circuit
Tap to identify location of open circuit condition.

3 Current Setting Control
Indicates stimulation current intensity - Tap to adjust the current intensity. Measured current also displayed if it differs from current setting by more than 10%.

4 Stimulation Cable Identifier
Indicates the type of stimulation cable connected to the STIMPOD.

5 Waveform Display Window
Displays graphical stimulation results and waveforms.

6 Waveform Carousel
Indicates when multiple graph or waveform views are available - swipe left and right over the window to navigate between the available views.

7 Home Control
Tap to return to the main display screen for the currently selected stimulation mode.

8 Stimulation Mode Control
Indicates the currently selected stimulation mode - Tap to set or to change the desired stimulation mode.

9 Reference Indicator
Indicates that a stimulation reference value has been acquired and stored

10 Device Settings Control
Indicates speaker volume & battery status - Tap to set or change speaker volume and display brightness, and to view battery charge state.

11 Menu Settings Control
Tap to set or change user settings, NMT Settings, LOC Settings and data recording options.

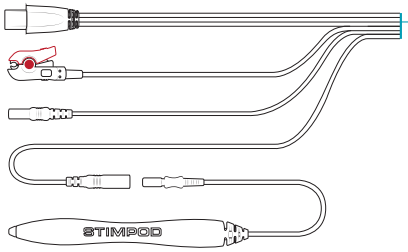
12 Timer Settings Control
Indicates active countdown timer - Tap to enable/disable repeat timer and to adjust timer settings.

13 Numerical Results Display Window
Displays numerical stimulation results.

14 Warning Message Control
Displays most recent warning message - Tap to clear warning message.

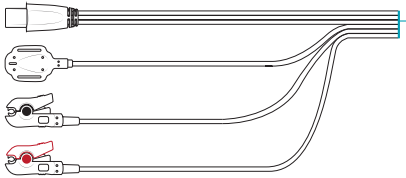
1.4 I Accessories

WARNING: Use of cables or other accessories other than those supplied with the STIMPOD may result in serious injury.
NOTE: ECG Electrodes and Nerve Locating needles are not included in this package.
CAUTION: A sterile wipe should be applied to the Nerve Mapping Probe prior to use.



Nerve Mapping/ Nerve Locating Cable *(XT-41014):*

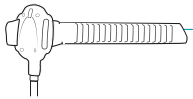
- This cable is used to activate the Nerve Mapping/Locating mode on the STIMPOD.
- The red (anode) connector is designed to clip on to a standard ECG electrode.
- The ergonomically designed cutaneous Nerve Mapping Probe presents the user with a simple and reliable Nerve Mapping solution.
- The 2mm needle connector will accommodate various makes of needles.



AMG Accessories

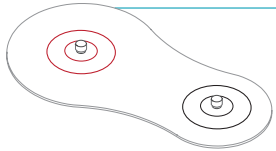
NMT Monitoring Cable AMG *(XT-45025)* **and 3.0m** *(XT-45025B):*

- The AMG cable is used to enable AMG based NMT Monitoring on the STIMPOD.
- The red (anode) and black (cathode) connectors are designed to clip onto the Xavant NMT electrode *(XT-45008)* or onto a standard ECG electrode.
- The accelerometer is designed to attach to the contracted appendage (in the case of the ulnar nerve, this will be the thumb).



Accelerometer Strap *(XT-45007)* **and Accelerometer Strap** *(XL) (XT-45007A):*

- The strap attaches and secures the accelerometer sensor on the AMG cable to the patient's thumb during monitoring.
- The strap is available in two sizes (short and long).



NMT Electrode *(XT-45008):*

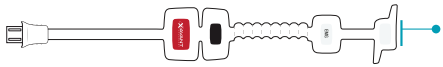
- The colour coded connections indicate the polarity for the NMT cable connections
- The larger surface area of the red (anode) electrode reduces the current density of the anode and prevents hyperpolarization.
- The proprietary gel and gel interface was specifically designed for transmission of large currents.

⚠ Warning
The electrode is single-use only. Reuse may result in high impedance, poor stimulation, skin burns and risk of cross contamination.

EMG Accessories

NMT Monitoring Cable EMG 1.8m *(XT-45003)* **and 3.5m** *(XT-45003A):*

- The EMG cable is used to enable EMG based NMT Monitoring on the STIMPOD.
- The EMG cable connects directly to the EMG Electrode.



EMG Electrode Large *(XT-45009L)* **and Small** *(XT-45009S):*

- The disposable EMG Electrode is applied directly to the patient for EMG based NMT Monitoring using the EMG cable.
- The proprietary connector interface was specifically designed for direct connection to the NMT Monitoring Cable (EMG).
- The proprietary gel and gel interface was specifically designed for transmission of large currents.
- The electrode is single-use only. Reuse may result in high impedance, poor stimulation and EMG recording, skin burn and risk of cross contamination.

⚠ Warning
The electrode is single-use only. Reuse may result in high impedance, poor stimulation, skin burns and risk of cross contamination.

Smart Data Cables

Smart Data Cable Philips RS232 *(XT-45100C-PHI):*

- Interface AMG/EMG data directly to a compatible Philips monitor.

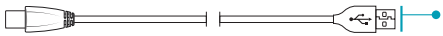
Smart Data Cable NMShow USB *(XT-45100A-NMS):*

- Interface AMG/EMG data directly to a PC/Monitor using the NMShow Protocol.

Smart Data Cable NMShow RS232 *(XT-45100C-NMS):*

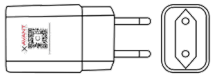
- Interface AMG/EMG data directly to a PC/monitor using the NMShow protocol.

Charging Accessories



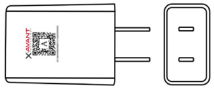
Charging Cable *(XT-45202):*

- The charging cable is used to connect the STIMPOD NMS50X+ to a power adapter for direct internal charging of the battery.



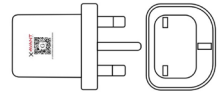
EU Power Adapter *(XT-45201-EU):*

- European Power Adapter for internal Charging.



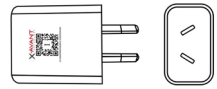
US Power Adapter *(XT-45201-US):*

- American Power Adapter for internal Charging.



UK Power Adapter *(XT-45201-UK):*

- British Power Adapter for internal charging



AU Power Adapter *(XT-45201-AU):*

- Australian Power Adapter for internal Charging.

1.5 I Warnings & Information Messages

Warning and information messages are raised on the display screen in response to a given error or condition related to the operation and use of the device.

1.5a Event Based Information Messages

These messages are raised on the main display screen in response to an operator input or an operational condition during NMT Monitoring. The message is raised for a short period of time (2-3 secs) before being removed from view again.

Refractory Delay Active

Refractory Delay Active
This warning message is raised when the play key is pressed to start a new stimulation while a refractory timer is in progress.

Stimulation In Progress

Stimulation In Progress
This warning message is raised when the play key is pressed to start a new stimulation while a stimulation is already in progress, or when the display is manipulated.

Abnormal NMT Data

Abnormal NMT Data
This warning message is displayed during NMT modes of operation when sensor data has not been received or is corrupted, or when the TOF/DB Ratio exceeds 150%.

Memory 95% Full

Memory 95% Full
This warning message is raised when the internal device memory for saving case data is 95% full.

Memory Full

Memory Full
This warning message is raised when the internal device memory for saving case data is full.

1.5b Case Management Information Messages

These messages are raised in response to specific conditions associated with NMT Case Monitoring. These messages are initially displayed in the docking area at the bottom of the display area but can be cleared by simply tapping on them.

SMC Not Found
Default 60mA

SMC Not Found
This warning message is raised when the SMC fails to find a valid supramaximal current value. Stimulation Current is default to 60mA for non-facial stimulation sites, and to 30mA for facial stimulation sites.

Paralytic Detected
Default 60mA

Paralytic Detected
This warning message is raised when the device has determined that a neuromuscular blocking agent has been administered to the patient before NMT Monitoring was started.

Stimulation Artefact

Stimulation Artefact
This warning message is raised when the effects of a stimulation pulse is detected in an EMG signal.

1.5c Shutdown Warning Messages

These messages are raised on the main display screen in response to a safety concern or condition of the device that requires operator intervention, and remains on the display screen for a short period of time (2-3 secs) before the device is automatically shutdown.

Recharge Device

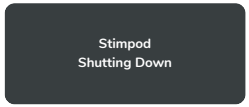
This warning message is raised when the batteries are depleted - device will shut down.

Device Overheating

This warning message is raised when device temperature is too high - device will shut down.

Device Error

This warning message is raised when an internal fault has occurred, and the device needs to shut down as a safety precaution.



STIMPOD Shutting Down

This warning message is raised just before the device shuts down due to a safety concern, a condition that requires operator intervention or no operator activity for 10 mins.

1.5d General Warning Messages

These messages are raised on the display screen in response to operational conditions and will remain in view until the condition that triggered the message is removed.

Cable Not Recognized

This warning message is raised when a cable is inserted that is not supported by the device.

EMI Warning

This warning message is raised when external electrical interference is detected.

Stimulation Aborted

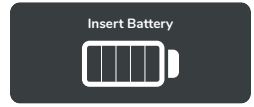
This warning message is raised when the delivered current in SMC differs from the set current by more than 10% or stimulation has been interrupted.

Low Battery

This warning message is raised when the battery is low and needs to be recharged, but the device is still usable.

High Device Temperature

This warning message is raised when the battery temperature is rising above normal operating temperature, but the device is still usable.



Insert Battery

The battery is not detected while the charging cable is connected for internal charging.

1.6 | Open / Closed Circuit Detection

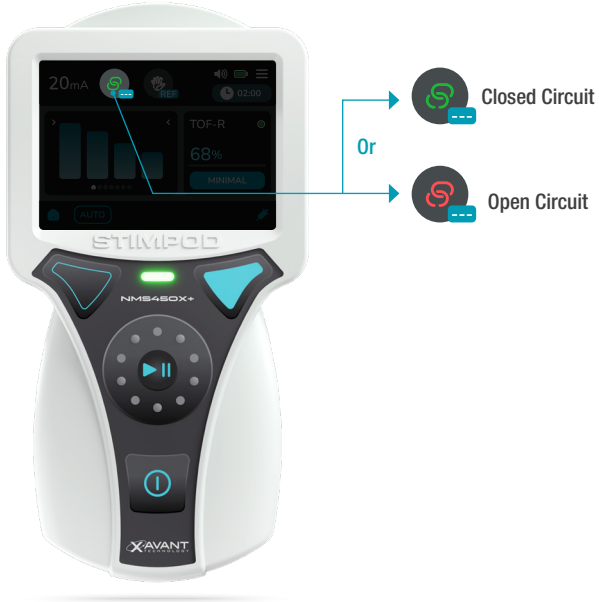
The STIMPOD performs impedance measurements at regular intervals to detect whether the connection between the STIMPOD and the patient comprises a closed circuit.

Closed Circuit Detected:

- Stimulation pulses are delivered to the patient.
- The speaker emits a beeping sound and the LED indicator pulses green with each successfully delivered stimulus pulse.
- The Open/Closed Circuit Indicator on the display screen is illuminated in green.

Open Circuit Detected:

- No stimulation pulses are generated or delivered to the patient.
- The speaker remains silent and the LED indicator pulses red for each stimulus pulse not delivered to the patient.
- The Open/Closed Circuit Indicator on the display screen is illuminated in red.



1.7 | Auto Shutdown

The device is designed to automatically shut down if no user or patient interaction occurs, or if a closed-loop patient circuit is not detected within 10 minutes.

1.8 | Symbols


Manufacturer


Date of manufacture (Year only)


Caution


WEEE Recycle: Electronic Equipment (Applicable to EU community only)

Serial Number

Authorized Representative in the European Community/European Union

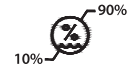
Catalogue/Model Number

Authorized Representative in Switzerland

Prescription only


Type BF Applied Part

Non-sterile



Humidity limitation

Temperature limit


Refer to instruction manual / booklet

Medical Device


Importer

MR Unsafe


CE marking

Ingress Protection Rating

Product is not made with natural rubber latex

Batch Code


Use-by Date


Do not use if package is damaged

CE mark and notified body number


Keep product dry


Do not reuse


Warning

UDI - Unique Device Identification

2 | Nerve Locating/Mapping
NMS450X+

Locating Mode (LOC)

Localisation of nerves by electrical stimulation involves connecting the nerve stimulator to a conducting, locating needle (not supplied) through which local anaesthetics can be administered. This procedures involves subcutaneous stimulation of the motor component of the relevant peripheral nerve, to locate the nerve.

- Select this mode by inserting the Nerve Locating / Mapping cable.
- The STIMPOD will automatically default to the Nerve Locating current range (0.00 - 5.00 mA) and display the LOC indicator.

When Using the Nerve Locating Needle

1. **LOC Mode Indicator**
   Indicates Loc Mode when the Mapping/Locating cable is connected and the stimulation needle is in contact with patient skin.

2. **Current Setting**
   Indicates stimulation current intensity.

3. **Proximity Indicator**
   Indicates proximity of the needle relative to nerve based on strength of response vs charge delivered.

4. **Waveform Display Window**
   Displays waveform of stimulation pulse delivered to the stimulating needle.

5. **Pulse Width Indicator**
   Indicates pulse width setting of stimulation pulse.

6. **Device Settings Control**
   If enabled, the speaker will beep each time a stimulus is delivered. The pitch of the beep will increase and decrease with the current intensity setting.

7. **Pulse Settings Control**
   Indicates the currently selected stimulation Frequency - Tap to set or change the frequency and/or the pulse width.

8. **Charge Indicator**
   Indicates the charge delivered for the last successful stimulation pulse.

Mapping Mode (MAP)

Transcutaneous nerve mapping enables the anaesthesiologist to map out a particular superficial nerve prior to nerve location with the needle. This is accomplished by stimulating the motor component of the relevant peripheral nerve Transcutaneously with the nerve mapping probe. This technique ensures a higher success rate for directing the needle to the correct nerve.

- This mode is selected when the Nerve Mapping / Locating cable is inserted and the mapping probe is in a closed circuit condition over the patient's skin.

This mode offers the user the means to do nerve mapping and locating without having to switch or unplug cables.

When inserting the Nerve Mapping / Locating Cable, the STIMPOD will default to the Nerve Locating current range (0-5mA). Current will be directed to the Nerve Locating needle and the STIMPOD will attempt to stimulate. If the mapping probe touches the patient, the STIMPOD will switch to the nerve mapping mode and start monitoring the mapping probe (0-20mA). Whenever the nerve mapping probe and the nerve locating needle simultaneously make contact with the patient the needle will have first priority.

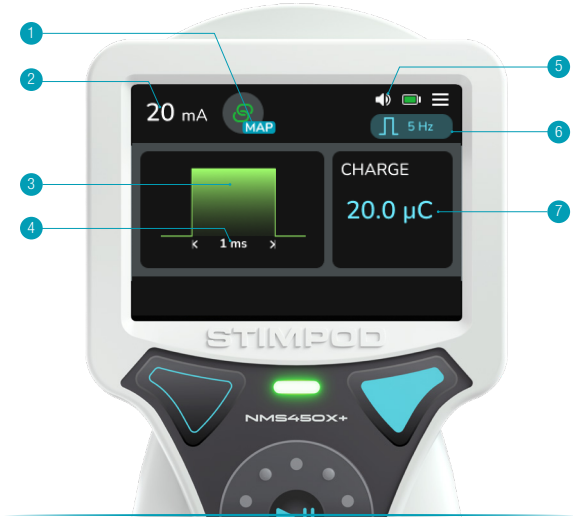
When using the Nerve Mapping Probe

1. **MAP Mode Indicator**
   Indicates Map Mode when the Mapping/Locating cable is connected and only the stimulation pen is in contact with patient skin.

2. **Current Setting**
   Indicates stimulation current intensity.

3. **Waveform Display Window**
   Displays waveform of stimulation pulse delivered to the stimulating pen.

4. **Pulse Width Indicator**
   Indicates pulse width setting of stimulation pulse.



5. **Device Settings Control**
   If enabled, the speaker will beep each time a stimulus is delivered. The pitch of the beep will increase and decrease with the current intensity setting.

6. **Pulse Setting Control**
   Indicates the currently selected stimulation Frequency - Tap to set or change the frequency and/or the pulse width.

7. **Charge Indicator**
   Indicates the charge delivered for last successful stimulation pulse.

2.1 | Adjusting Current in LOC and MAP

The stimulation current in LOC and MAP mode can be adjusted in predefined increments by using the left and right function keys or the scroll wheel on the keypad.

Current Adjustments Using Function Keys

Current Adjustments Using Scroll Wheel

2.1a | Current Adjustments in LOC Mode

Default Current range: 0.00 - 5.00mA
Adjustable in the following default increments:

- 0.0 - 0.6mA Default 0.1mA
- 0.6 - 2.0mA Default 0.2mA
- 2.0 - 5.0mA Default 0.5mA

2.1b | Current Adjustments in MAP Mode

Default Current range: 0.00 - 20.00mA
Adjustable in 1mA increments.

2.2 | Adjusting the Pulse Width

Options: 0.05ms, 0.1ms, 0.2ms, 0.3ms, 0.5ms, 1ms
Default: 0.05ms
Tap on the Pulse Settings Control icon on the display screen to select the desired pulse width from a list of supported pulse width settings.

2.3 | Adjusting the Stimulation Frequency

Options: 1Hz, 2Hz, 5Hz
Default: 2Hz
Tap on the Pulse Settings Control icon on the display screen to select the desired stimulation frequency from a list of supported frequency settings.

2.4 | Proximity Indicator

This is only relevant for Locating Mode

The proximity indicator notifies the user that the required charge limits have been reached. This function allows the user to set up an upper and lower limit of charge. When contraction is elicited at the set charge, this indicator should indicate to the user that the needle has reached the desired proximity to the nerve. This proximity is indicated both visually and audibly.

Visual Indication:

- Visually indicated in the Waveform Window by two dashed lines.
- Top Line indicates Upper Limit.
- Bottom Line indicates Lower Limit.

Audible Indication:

- A successful stimulus above the proximity range will make a single ‘beep’.
- A successful stimulus within the proximity range will make a double ‘beep’.
- A successful stimulus below the proximity range will make a triple ‘beep’.

3 | Neuromuscular Transmission (NMT) Monitoring NMS450X+

3.1 | Introduction to NMT Monitoring

NMT Monitoring is used to determine the depth of block of a Neuromuscular Blocking Agent (NMBA) by electrically stimulating a peripheral nerve on a periodic basis, and then quantitatively and objectively measuring the strength of the resulting neuromuscular response for each stimulation.

In terms of NMT Monitoring the relative strength of the evoked response for a periodic stimulus of given shape, magnitude, duration and repetition rate changes as the depth of block of an NMBA changes - making it an effective means for assessing the degree of neuromuscular blockade in the OR, PACU and ICU.

The STIMPOD NMS450X+ provides support for the following stimulation modes for purposes of NMT Monitoring: Auto, Train-of-Four, Post TetanicCount, Supra Maximal Current, Depolarising Muscle Relaxant Monitoring, Twitch, Tetanus and Double Burst Modes.

⚠ Warning
Use only Xavant-supplied cable accessories with the STIMPOD device. Using unauthorized accessories may affect device performance or patient safety.

3.2 | Cables and Sensors for NMT Monitoring

The STIMPOD NMS450X+ makes provision for two different sensor technologies for NMT Monitoring namely Acceloromyography (AMG) and Electromyography (EMG).

NMT Monitoring Cable (AMG)

In this case, the NMT Monitoring Cable is fitted with a tri-axial accelerometer that is attached to a contracting appendage whose associated muscle is innervated by a peripheral motor nerve of interest.

Stimulation of the motor nerve will result in a contraction of the appendage (an observable muscle twitch) the strength of which is measured by the accelerometer.

NMT Monitoring Cable (EMG)

In this case, the NMT Monitoring Cable allows for the attachment of a surface electrode to the muscle of a contracting appendage innervated by a peripheral motor nerve of interest.

Stimulation of the motor nerve will result in the establishment of an action potential in the muscle, the strength of which is measured by the electrode.

3.3 | Patient Skin Preparation

- Remove hair, dirt, oil from skin if necessary.
- Clean thoroughly and dry skin surface area completely before application.

3.4 | Removing the Electrodes

- Switch off the STIMPOD.
- For *AMG monitoring,* disconnect the AMG cable from the electrode by gently releasing the cathode and anode terminal clips.
- For *EMG monitoring,* disconnect the EMG cable from the electrode by gently pulling the connector tab.
- Remove the electrode from the patient skin by gently peeling it off from its edges.
- Ensure to remove any gel residue from the skin.
- Dispose of the used electrodes safely as clinical waste.

3.5 | Stimulation Sites for NMT Monitoring

The stimulation electrode should be placed so that the cathode terminal (black in colour) is located as close to the most superficial aspect of the target motor nerve as possible in order to effectively depolarize the nerve.

The anode terminal (red in colour) should be placed as far away from the target nerve as possible. Ensure that no other equipment, device, or material is in contact with the electrodes. Verify that the sensors and electrodes are only in contact with clean and healthy skin.

Anatomical Stimulation Sites are Chosen Based on:

- Their accessibility during surgery.
- The ability to observe neuromuscular response clearly and unmistakably.
- The relative distance of the cathode terminal from the responding muscle.

Stimulation Sites Suitable for AMG

AMG: Anatomically Ideal Stimulation Sites		
Targeted Nerve	**Affected Muscle**	**Contracting Appendage**
Ulnar nerve	Adductor pollicis muscle	Thumb
Posterior tibial nerve	Flexor hallucis brevis muscle	Big toe
Facial nerve (Zygomatic Branch)	Orbicularis oculi muscle	Eye lid
Facial nerve (Temporal Branch)	Corrugator supercili muscle	Eye brow

Stimulation Sites Suitable for EMG

EMG: Anatomically Ideal Stimulation Sites		
Targeted Nerve	**Affected Muscle**	**Contracting Appendage**
Ulnar nerve	Adductor pollicis muscle	Thumb

Notes:

1. ASA/ESAIC practice guidelines recommend stimulation of the distal ulnar nerve and monitoring of the evoked response at the adductor pollicis muscle.
2. ASA/ESAIC practice guidelines recommend extubating at a depth of block greater than 90% during reversal.

3.6 I Verifying Electrode Placement

- Tap on the Open/ Closed Circuit control icon, when a closed circuit condition occurs in NMT Mode, for visual guidance on correct placement of electrodes:

AMG Electrode Placement

EMG Electrode Placement

- Tap on the Open/Closed Circuit control icon, when an open circuit condition occurs in NMT Mode, for visual guidance on where the open circuit condition has been detected.

⚠ Warning
Incorrect Electrode placement could cause erroneous measurements, resulting incorrect interpretation of results.

AMG Open Circuit Errors

Open Stim Circuit

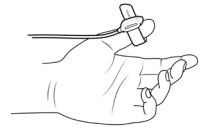
Open Stim Circuit

EMG Open Circuit Errors

Open Sense Circuit

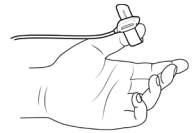
Open Circuit

3.7 I Accelerometer placement



Correct Positioning

Place the AMG sensor on the dorsal side of the thumb, over the distal phalanx (near the thumbnail)



Incorrect Positioning

Do not place the sensor above the nail area

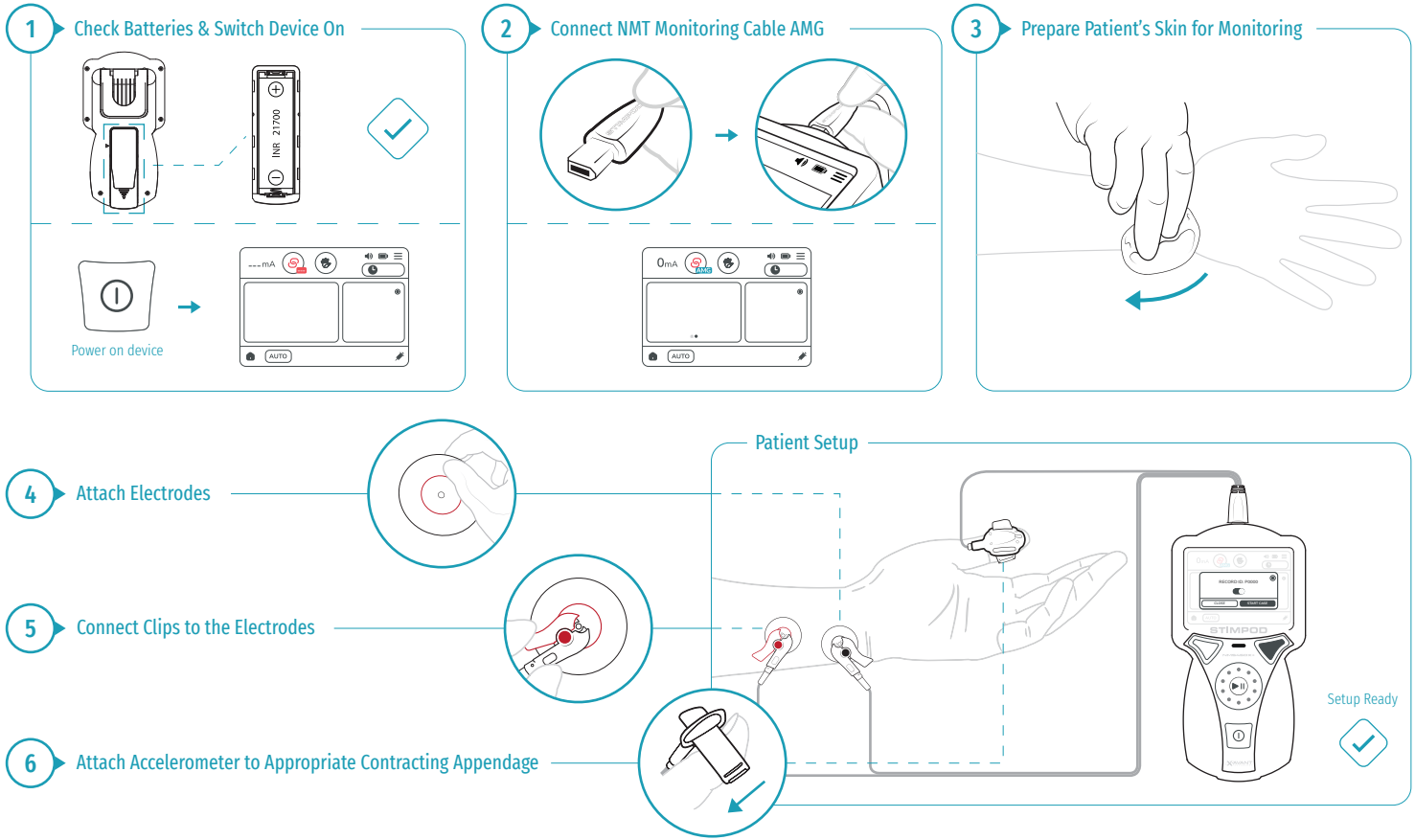
Incorrect Positioning

Do not place the sensor too proximal to the base of the thumb

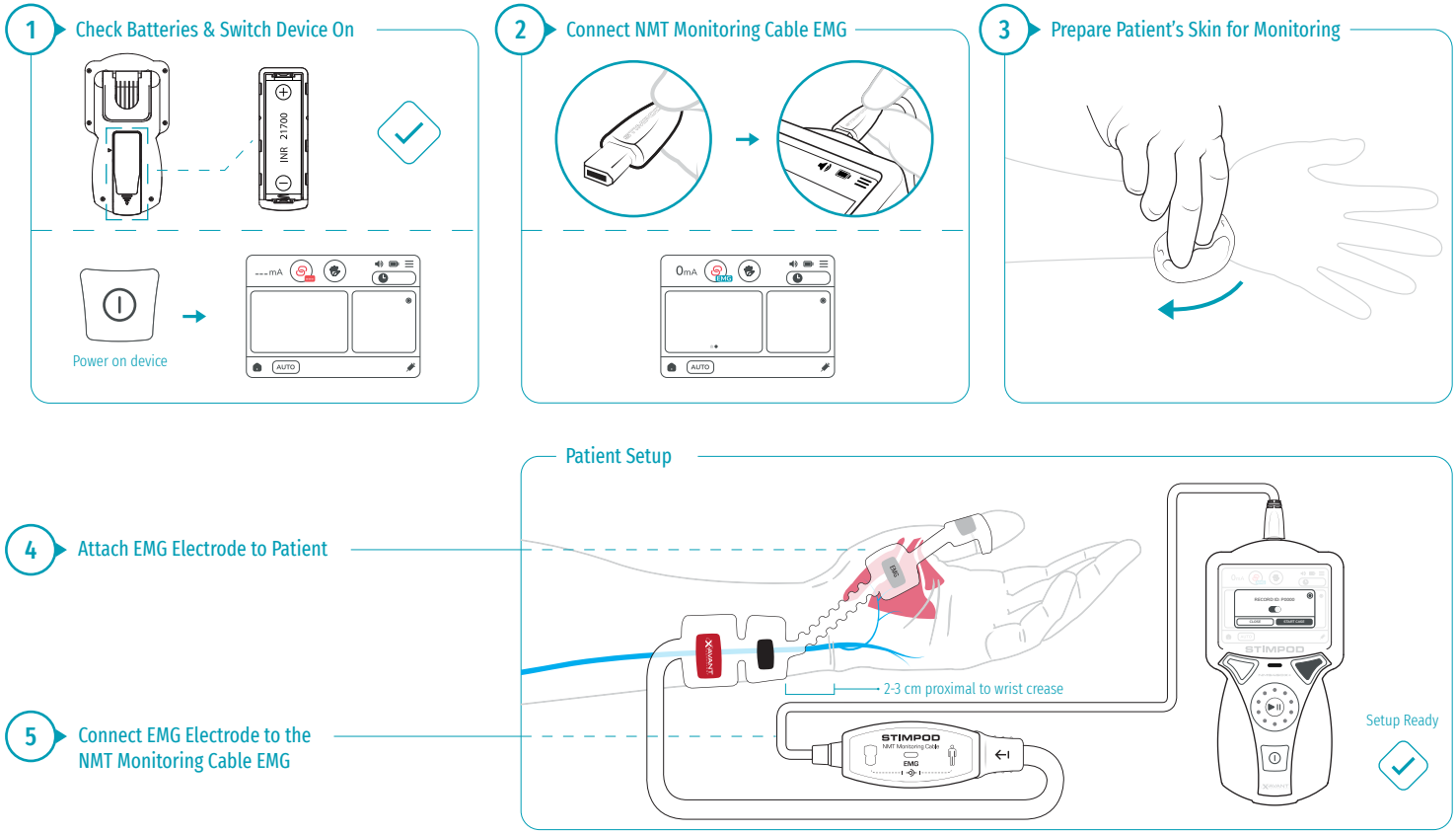
Notes:

- Secure the sensor firmly using the accelerometer strap, ensuring that the natural movement of the thumb is not restricted.
- Ensure the thumb is free to move as it is essential for accurate readings.
- The hand should rest comfortably with the palm facing upward or in a neutral supine position, allowing unrestricted thumb flexion/extension.

3.8 I AMG Patient Setup



3.9 I EMG Patient Setup



When using the NMT Mode

1. **Electrode Placement Control**
   Indicates location and placement of stimulation and Monitoring electrodes - Tap to set and view the electrode placement.
2. **Open/Closed Circuit Indicator**
   Indicates open/closed circuit status of the currently connected stimulation cable.
   Green: Closed Circuit **Red**: Open Circuit
   Tap to identify location of open circuit condition.
3. **Current Setting Control**
   Indicates stimulation current intensity - Tap to adjust the current intensity.
4. **Stimulation Cable Identifier**
   Indicates whether an AMG or EMG stimulation cable is connected to the STIMPOD.
5. **Reference Level Indicator**
   Indicates magnitude of measured reference value.
6. **Evoked Response & Waveform Display Window**
   Displays NMT evoked Response Bars for TOF, DB and PTC stimulation modes, the Depth of Block Trend Graph in TOF, PTC & AUTO modes, and EMG Waveforms when the EMG stimulation cable is used.
7. **Waveform Carousel**
   Indicates when multiple graph or waveform views are available - swipe left and right over the window to navigate between waveforms.
8. **Home Control**
   Tap to return to the main display screen for the currently selected stimulation mode.
9. **Stimulation Mode Control**
   Indicates the currently selected stimulation mode - Tap to set or to change the desired stimulation mode (AUTO, TOF, DB, PTC, SMC, TWI, TET, DEP).

NMT Main Screen

10. **Reference Indicator**
    Indicates that a stimulation reference value has been acquired and stored. Results in TOF, DB, PTC, DEP and AUTO Modes will be scaled to this value.
11. **Device Settings Control**
    If enabled, the speaker will beep each time a stimulus is delivered. The pitch of the beep will increase and decrease with the current intensity setting.
12. **Menu Settings Control**
    Tap to set or change NMT Settings and data recording options.
13. **Timer Settings Control**
    Indicates active refractory and/or repetition timers - Tap to implement quick timer changes.
14. **Data Recording Control**
    Indicates data recording status. Tap to enable/ disable recording.
15. **NMT Result Type Indicator**
    Indicates type of NMT result obtained - TOF/ DB Ratio, TOF Count or PTC Count.
16. **Numerical Results Display Window**
    Displays numerical stimulation results.
17. **Depth of Block Indicator**
    Displays Depth of Block in TOF, PTC & AUTO Modes.
18. **Dose Marker Control**
    Tap to indicate on Depth of Block graph when a neuromuscular blocking agent or reversal agent has been administered.
19. **Warning Message Control**
    Displays most recent warning message - Tap to clear warning message.

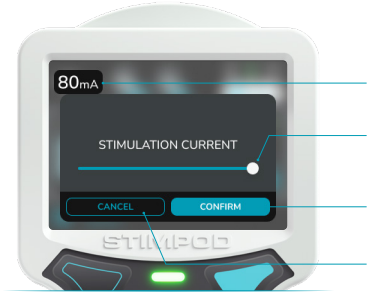
3.10 I Adjusting the Current

Default Current Range: 0 - 80 mA
Use the scroll wheel on the keypad or the current setting control on the display screen to adjust current.

The current intensity setting will automatically default back to the last used value as soon as the NMT Mode of operation is entered.

Touch the scroll wheel to set the current intensity on the keypad - a popup screen will appear on the display. Drag over the scroll wheel in an clockwise or anti-clockwise direction to increase and decrease the current in 5mA increments respectively. The current setting displayed on the screen will change accordingly - tap the confirm button once the desired current intensity has been reached.

Tap on the current settings control icon to set the current intensity on the display screen - a popup screen will appear on the display. Drag the linear slider on the popup screen to the right or to the left to increase and decrease the current in 5mA increments respectively. The current value displayed on the screen will change accordingly - Tap the confirm button or the right function key once the desired current intensity has been reached. Tap on the cancel button or left function key to dismiss any changes and return back to the main screen.



Current Setting
Increase/decreases in 5mA Increments.

Linear Slider
Touch and drag left/right to set current.

Confirmation Button
Tap to save current setting and close.

Cancelation Button
Tap to abort setting and close.

3.11 I Adjusting Stimulation Mode

Stimulation Mode: Auto, TOF, PTC, SMC, TWI, TET, DEP and DB
Default: Auto
Tap on the Stimulation Mode Control icon to set the active NMT Stimulation Mode.

NMT Stimulation Modes
Tap to select required Mode.

Confirmation Button
Tap to confirm mode selection and close.

Cancelation Button
Tap to abort Mode Selection and close.

3.12 I Refractory Period Delay

A minimum delay period must be observed between any two consecutive stimulation patterns in the TOF, DB and PTC stimulation modes. This minimum delay period,referred to as the refractory period, provides the nerve synapse adequate opportunity to recover from one stimulation pattern to the next.

The STIMPOD NMS450X+ displays a countdown value next to the timer control on the display screen that is initially equal in value to the refractory period. The countdown value will start decrementing immediately after a stimulation pattern has come to an end and represents the time remaining in seconds till the refractory period expires.

This will occur for each stimulation pattern that is started manually by pressing the play/pause key on the keypad.

If an attempt is made to start a new stimulation while the refractory period is still being counted down, a warning message will be raised on the display screen as a reminder that the refractory period has not expired yet.

Default Refractory Period Delays:
TOF: 15 seconds
DB: 1 minute
PTC: 2 minutes

Refractory Timer
The Timer Settings Control Icon is displayed in white.
Countdown timer value - decremented in 1s intervals immediately after a stimulation is completed.

Note: Further stimulations are permitted when the timer value reaches 00:00 - the timer is reset to the refractory time when the play/pause key is pressed again to start a new stimulation.

3.13 I Single Stimulus vs. Repeated Stimulation

A repeat stimulation sequence automatically initiates a TOF, DB, PTC or DEP stimulation pattern at regular time intervals without any further user intervention.

The time interval between consecutive stimulation patterns can be adjusted in the settings menu but cannot be set to a value that is less than the refractory period - the STIMPOD NMS450X+ will not allow such a setting to be made.

- An automated repeat stimulation sequence can be started by pressing down on the play/pause key for at least 2 seconds or, alternatively, by tapping on the timer control icon on the display screen and setting the toggle switch to the on position.
- Repeat stimulation sequences that are started via the play/pause key will adopt the repetition period that has been setup in the settings menu. If started via the timer control, the repetition period can be changed by simply selecting one of the options from a list of predefined timer values.
- The STIMPOD NMS450X+ displays a count down value next to the timer control icon on the display screen that is initially equal in value to the repetition period. The countdown value will start decrementing immediately after a stimulation pattern has come to an end and represents the time remaining in seconds till the next stimulation pattern is started.
- Repetitive time sequences can be disabled by pressing down on the play/pause key for at least 2 seconds or, alternatively, by tapping on the timer control icon and setting the toggle switch to the off option.

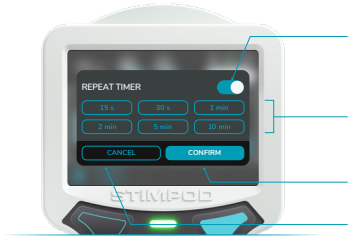
Repeat Timer
The Timer Settings Control Icon is displayed in blue.
Countdown timer value - decremented in 1s intervals immediately after a stimulation is completed.

Note: A new stimulation is started each time the timer value reaches 00:00 - the timer is reset to the repetition period immediately after the stimulation is started.

3.14 I Adjusting Quick Timers

Applicable Stimulation Modes: Auto, TOF, PTC, DEP, DB
The Default value for each applicable stimulation mode is set in the NMT menu.
Tap on the timer Settings Control icon to select the repetition period from a list of available options.

Default, 15 seconds, 30 seconds, 1 minute, 2 minutes, 5 minutes and 10 minutes.



Enable/Disable Button
Tap to enable/disable repetition timer.

Repeat Timer Quick Settings
Tap to select timer setting.

Confirmation Button
Tap to confirm repetition timer setting and close.

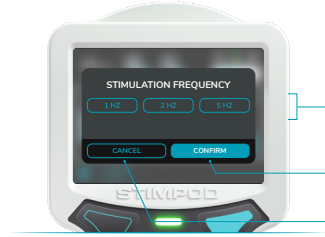
Cancelation Button
Tap to abort repetition timer setting and close.

3.15 I Adjusting Twitch / Tetanus Frequency

Frequency Setting Control
In the Twitch and Tetanus Stimulation Modes the Timer Settings Control is replaced with a Frequency Settings Control.

Twitch Mode Stimulation Frequency Options: 1Hz, 2Hz, 5Hz
Default: 2 Hz
Tetanus Mode Stimulation Frequency Options: 50Hz, 100Hz
Default: 50Hz
Tap on the frequency Settings Control icon to select the stimulation frequency from a list of available options. The list of available options will be appropriately configured for the active Stimulation Mode.

TWI: Default, 1Hz, 2Hz, 5Hz

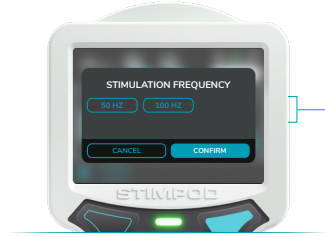


Stimulation Frequency Settings
Tap to select frequency setting for Twitch Mode.

Confirmation Button
Tap to confirm frequency setting and close.

Cancelation Button
Tap to abort frequency setting and close.

TET: Default, 50Hz, 100Hz



Stimulation Frequency Settings
Tap to select frequency setting for Tetanus Mode.

3.16 I Auto Mode

Auto mode is used to conduct Full Case NMT Monitoring. This is achieved through a series of alternating TOF and PTC stimulation sequences to determine the depth-of-block throughout the duration of the procedure.

Selecting Auto Mode:

- Ensure that an NMT Monitoring Cable (AMG/EMG) is inserted in the STIMPOD.
- Tap on the Stimulation Mode Control icon and select AUTO Mode on the popup screen.

Note: The device will default to AUTO Mode when it is turned on.

Managing Auto Mode

1. Starting a Case

- The AUTO Mode will only start when the cable in a closed circuit condition.

- The AUTO Mode will raise the default popup screen to start a case as illustrated
- Tap on the toggle switch to enable or disable data recording - If enabled the data recording indicator will be turned on and the STIMPOD will record data for the case, saving it to internal memory using the indicated recording ID as reference.
- Tap on the Start Case button to start monitoring the case, or alternatively, on the close button to continue using the device normally.
- The case will first start with an SMC stimulation to determine the supramaximal current value.

- If an SMC value cannot be determined the current setting defaults to 60mA ,or 30mA if the facial nerve is stimulated, and the following warning message is displayed.

- Tap on the warning message in the docking area to clear it - The warning will appear on the main display for a further 3s before it is automatically removed.
- The first TOF stimulation pattern is performed immediately after the stimulation current has been established.

- If the TOF Ratio is less than 90% the following warning message is displayed, to indicate that the case had been started after NMBA had been administered.

- Tap on the warning message in the docking area to clear it - The warning will appear on the main display for a further 3s before it is automatically removed.

2. Monitoring a Case

- The AUTO mode will commence with a series of alternating TOF and PTC stimulation sequences to determine the depth-of-block throughout the duration of the case.

- The Depth of Block states are defined as follows:
  - Recovered: Identified by a TOF Ratio greater than 90%.
  - Minimal: Identified by a TOF Ratio between 40% and 90%.
  - Shallow: Identified by a TOF Ratio between 10% and 40%.
  - Moderate: Identified by a TOF Ratio below 10% or a TOF Count between 1 to 3.
  - Deep: Identified by a PTC Count of 1 or more.
  - Profound: Identified by a PTC count of 0.

Real-time Patient Data Displayed

- The TOF and PTC stimulation results are displayed on the screen whenever they are active as illustrated below

- Swipe left over the display area at any time to view the depth of block trend graph.

Moderate → Recovered
TOF-R: 0-100%

Deep → Moderate
TOF-C: 0-4

Profound → Deep
PTC: 0-20

Depth of Block (DOB) Trend Graph
Indicates the change in Depth of Block over time.

Depth of Block
ASA/ESAIC Nomenclature for Depth of Block.

Dose Marker Control
Tap to indicate on Depth of Block graph when a neuromuscular blocking agent or reversal agent has been administered.

- Tap the dose marker control icon each time a muscle relaxant or reversal agent is administered to mark the point on the trend graph where it occurred.

Dose Marker
Indicates point where NMBA or reversal agent was administered.

- If an EMG monitoring cable is being used, the CMAP waveforms for each of the evoked responses measured during TOF and PTC stimulations can be seen by swiping left over the graph area.

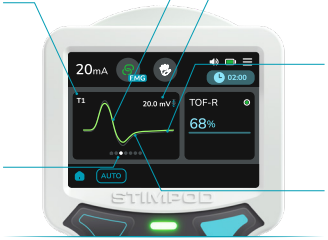
Note: EMG waveforms only available for EMG Cables with software version 2.3.x and above

Evoked Response & Waveform Display Window
Composite View: CMAP Waveform for all evoked responses.

CMAP Voltage Range
Indicates the maximum peak to peak voltage range of the measured CMAP waveforms.

Waveform Carousel
Displays the position in the carousel of the currently selected waveform view.

Multiple evoked response waveform View



Response Waveform
Measured CMAP waveform for the identified response.

CMAP Voltage Range
Indicates the maximum peak to peak voltage range of the measured CMAP waveform.

Response Identifier
T1-T4: T1 corresponds with the first stimulation pulse in a TOF stimulation, and T4 corresponds with the fourth.

Evoked Response & Waveform Display Window
Single View: CMAP Waveform for a single evoked response.

Reference Waveform
CMAP waveform for measured reference pulse taken before NMBA is administered.

Waveform Carousel
Displays the position in the carousel of the currently selected waveform view.

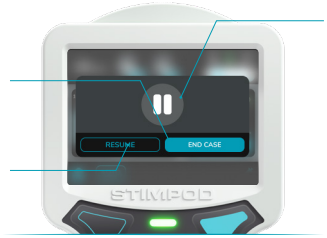
Single Identified evoked response waveform view

3. Closing a Case

- The Auto Mode is paused when the pause/play key on the keypad is pressed or an open circuit condition persists for more than 2 minutes.
- Tap the End button to close the case and its recording - the start case popup will be raised again for the next case.
- Tap the Resume button to continue with the current case and its recording.

End Case Button
Terminate the current case including recording.

Resume Case Button
Continue with the current case including recording.



Pause Case Indicator
Indicates that the current case is on pause.
Open Circuit: Current case pauses if open circuit condition persists for longer than 2 minutes.
Pause Key: Current case pauses if the play/pause key on the keypad is pressed.

3.17 I Train of Four Mode (TOF)

Evoked Response & Waveform Display Window
Default View: Evoked Response Magnitude for each stimulation pulse.

NMT Result Type Indicator
TOF-R: Displayed when 4 evoked responses are available.
TOF-R = (T4/T1) × 100 %
TOF-C: Displayed when 4 evoked responses aren't available.
TOF-C = No. of Responses / 4

NMT Numerical Result
TOF-R: 0 - 150%
TOF-C: 0/4 - 3/4

Depth of Block
Recovered - Deep

NMT Mode Control
TOF Mode: Active

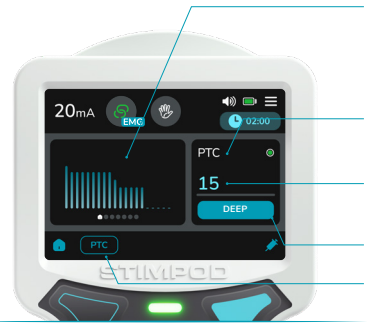
The TOF stimulation pattern consists of four square stimulation pulses, each with a pulse width of 200 microseconds, separated 500 milliseconds apart from each other.

Selecting TOF Mode:
- Ensure that an NMT Monitorig Cable (AMG/EMG) is connected to the STIMPOD.
- Tap on the Stimulation Mode Control icon and select TOF Mode on the popup screen.

Real-Time Patient Data Displayed:
- The TOF Mode will default to the screen layout as illustrated above. The magnitude of the evoked response for each stimulation pulse in a TOF stimulation is represented by a rectangular bar and is displayed in the Waveform Window.
- If an evoked response is obtained for each of the four stimulation pulses the TOF Ratio (TOF-R), expressed as the magnitude of the 4th response (T4) relative to the 1st response (T1), shall be displayed in the Numerical Results Window as a percentage value.
- If an evoked response is not obtained for each of the four stimulation pulses the TOF Count (TOF-C), expressed as the number of available responses, shall be displayed in the Numerical Results Window as a count value out of four.

Waveforms:
- If an EMG Monitoring Cable is in use, the measured CMAP response waveforms can be viewed by swiping left or right over the waveform carousel.
- The first position in the carousel provides a composite view of the CMAP waveform for all of the measured responses.
- The remaining positions in the carousel provide a view of the available CMAP response waveforms up to a maximum of four,starting with T1.

3.18 I Post Tetanic Count (PTC)



Evoked Response & Waveform Display Window
Default View: Evoked Response Magnitude for each stimulation pulse.

NMT Result Type Indicator
PTC: Displayed when evoked responses are available.
PTC = No. of Responses out of a maximum of 20.

NMT Numerical Result
PTC: 0 - 20.

Depth of Block
Moderate - Profound

NMT Mode Control
PTC Mode: Active

The PTC stimulation pattern consists of a Tetanus stimulation for 5 seconds at 50Hz followed by a 3 second delay and then 20 single pulses at 1Hz.

Selecting PTC Mode:
- Ensure that an NMT Monitorig Cable (AMG/EMG) is connected to the STIMPOD.
- Tap on the Stimulation Mode Control icon and select PTC Mode on the popup screen.

Real-Time Patient Data Displayed:
- The PTC Mode will default to the screen layout as illustrated above. The magnitude of the evoked response for each of the 1Hz stimulation pulses is represented by a rectangular bar and is displayed in the Waveform Window.
- The Post Tetanic Count (PTC), expressed as the number of available responses, shall be displayed in the Numerical Results Window as a count value.

Waveforms:
- If an EMG Monitoring Cable is in use, the measured CMAP response waveforms can be viewed by swiping left or right over the waveform carousel.
- The first position in the carousel provides a composite view of the CMAP waveform for all of the measured responses.
- The remaining positions in the carousel provide a view of the available CMAP response waveforms up to a maximum of four, starting with T1.

3.19 I Supra Maximal Current (SMC)

Current Settings Control
SMC Value: 0 - 80mA.
Changes to the calculated SMC value upon completion of the SMC stimulation pattern.

Evoked Response & Waveform Display Window
Default View: Evoked Response Magnitude for each stimulation pulse of increasing current intensity.

NMT Mode Control
SMC Mode: Active

The SMC stimulation pattern consists of up to 16 square stimulation pulses of increasing current intensity, each with a pulse width of 200 microseconds, separated 1s apart from each other. The current intensity increases in 5-10mA increments from one stimulation pulse to the next, starting at 10mA for the first pulse and ending with a maximum of up to 80mA for the last pulse.

The maximal current value is derived from the evoked response obtained for each stimulation pulse and then a further 5mA is added to it to get the supramaximal current value. If a valid maximal current value cannot be determined then a default value of 60mA is adopted for the supramaximal current.

Note: The maximum current setting is limited to 40mA when NMT Monitoring of the facial nerve is performed.

Selecting SMC Mode:
- Ensure that an NMT Monitorig Cable (AMG/EMG) is connected to the STIMPOD.
- Tap on the Stimulation Mode Control icon and select SMC Mode on the popup screen.

Real-Time Patient Data Displayed:
The SMC Mode will default to the screen layout as illustrated above where the magnitude of the evoked response for each stimulation pulse in a SMC stimulation is represented by a rectangular bar and is displayed in the Waveform Window.

3.20 I Twitch (TWI)

Evoked Response & Waveform Display Window
No evoked response waveform available.

The TWI stimulation pattern consists of a continuous train of square stimulation pulses, each with a pulse width of 200 microseconds, and is provided at a frequency of 1Hz, 2Hz or 5Hz.

Selecting TWI Mode:
- Ensure that an NMT Monitorig Cable (AMG/EMG) is connected to the STIMPOD.
- Tap on the Stimulation Mode Control icon and select TWI Mode on the popup screen.

Real-Time Patient Data Displayed:
- A TWI stimulation is started by pressing the play/pause key on the keypad and will continue to stimulate until it is stopped by pressing the play/pause key again.
- Evoked responses are not measured in the TWI stimulation mode, therefore, no waveforms are avaialble for display.

3.21 | Tetanus (TET)

Evoked Response & Waveform Display Window
No evoked response waveform available.

The TET stimulation pattern consists of a continuous train of square stimulation pulses, each with a pulse width of 200 microseconds, and is provided at a frequency of 50Hz or 100Hz.

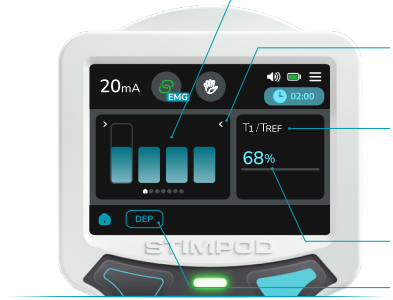
Selecting TET Mode:

- Ensure that an NMT Monitorig Cable (AMG/EMG) is connected to the STIMPOD.
- Tap on the Stimulation Mode Control icon and select TET Mode on the popup screen.

Real-Time Patient Data Displayed:

- A TET stimulation is started by pressing the play/pause key on the keypad and will continue to stimulate until it is stopped by pressing the play/pause key again.
- Evoked responses are not measured in the TET stimulation mode, therefore, no waveforms are avaialble for display.

3.22 | Depolarising Muscle Relaxant Monitoring (DEP)



Evoked Response & Waveform Display Window
Default View: Evoked Response Magnitude for each stimulation pulse.

Reference Level Indicator
Indicates Magnitude of measured reference value.

NMT Result Type Indicator
$T1/T_{REF}$: Displayed when all 4 evoked responses are available.
DEP Ratio = (T1/TreF)×100 %
***Note:** T_{REF} refers to the maximal response obtained during an SMC stimulation performed prior to an NMBA being given.

NMT Numerical Result
DEP Ratio: 0 - 100%

NMT Mode Control
DEP Mode: Active

The DEP mode makes use of the standard TOF stimulation pattern, without alteration, to monitor depolarising muscle relaxants.

Selecting DEP Mode:

- Ensure that an NMT Monitorig Cable (AMG/EMG) is connected to the STIMPOD.
- Tap on the Stimulation Mode Control icon and select DEP Mode on the popup screen.

Real-Time Patient Data Displayed:

- An SMC stimulation pattern shall commence immediately after the DEP mode is selected - this should be performed before an NMBA is given to the patient.
- The response magnitude measured at the supramaximal current setting shall be used as a reference value (TREF) to calculate the TOF Ratio. The TOF Ratio in this case is expressed as the magnitude of the 1st response (T1) relative to the reference value (TREF), and shall be displayed in the Numerical Results Window as a percentage value.

Waveforms:

- If an EMG Monitoring Cable is in use, the measured CMAP response waveforms can be viewed by swiping left or right over the waveform carousel.
- The first position in the carousel provides a composite view of the CMAP waveform for all of the measured responses.
- The remaining positions in the carousel provide a view of the CMAP response waveform of each measured response starting with T1.

3.23 I Double Burst Mode (DB)

Evoked Response & Waveform Display Window
Default View: Evoked Response Magnitude for each stimulation pulse.

NMT Result Type Indicator
DB-R: Displayed when 2 evoked responses are available.
DB-R = (T2/T1)×100%

NMT Numerical Result
DB-R: 0 - 100%.

NMT Mode Control
DB Mode: Active

The DB Stimulation pattern consist of two bursts separated 750ms apart from one another. Each burst consists of three square stimulation pulses, each with a pulse width of 200 microseconds, separated 20 milliseconds apart from one another.

Selecting DB Mode:

- Ensure that an NMT Monitorig Cable (AMG/EMG) is connected to the STIMPOD.
- Tap on the Stimulation Mode Control icon and select DB Mode on the popup screen.

Real-Time Patient Data Displayed:

- The DB Mode will default to the screen layout as illustrated above where the magnitude of the evoked response for each burst in a DB stimulation is represented by a rectangular bar and is displayed in the Waveform Window.
- If an evoked response is obtained for both stimulation bursts the DB Ratio (DB-R), expressed as the magnitude of the 2nd response (T2) relative to the 1st response (T1), shall be displayed in the Numerical Results Window as a percentage value.

Waveforms:

- If an EMG Monitoring Cable is in use, the measured CMAP response waveforms can be viewed by swiping left or right over the waveform carousel.
- The first position in the carousel provides a composite view of the CMAP waveform for all of the measured responses.
- The remaining positions in the carousel provide a view of the CMAP response waveform of each measured response starting with T1.

4 | Setting Up
Device Defaults

Menu Settings
The menu provides the user with the means to preset commonly used stimulation settings that do not necessarily change often during use, access and view recorded case data, change device and user information and gain access to additional instructional data.

4.1 | Accessing the Menu Settings

Tap on the menu control icon (☰) located at the top right hand side of the display screen, in any of the main stimulation modes, to open up the main menu.

Default Stimulation Settings
Tap to access and change default NMT settings (with NMT Cable connected) or MAP/LOC Stimulation Settings (with MAP/LOC Cable Connected).

Recorded NMT Case Files
Tap to access and view recorded NMT case files.

User Information
Tap to access and change user specific information and settings.

Xavant University
Tap to access scannable QRCode link to Xavant University.

4.2 | Default Stimulation Settings

4.2.1 NMT Settings
NMT settings are only accessible when either of the two NMT Monitoring cables are plugged into the STIMPOD NMS450X+. Tap on the default stimulation settings icon to open up the NMT sub-menu.

Refractory Timer Settings

Tap on the Refractory Timers menu item to preset the default refractory timer setting for the TOF, DB and PTC stimulation patterns.

Factory Defaults:
TOF: 15s, DB: 1min, PTC: 2 mins

- Swipe up or down to view the setting controls for each of the available stimulation patterns.
- Tap on the left arrow icon for any given stimulation pattern to decrease the refractory time, or on the right arrow icon to increase the refractory time.
- Tap on the up arrow icon to return to the NMT Settings sub menu.

Repeat Timer Settings

Tap on the Repeat Timers menu item to preset the default repeat timer setting for the TOF, DB and PTC stimulation patterns.

Factory Defaults:
TOF: 15s, DB: 1min, PTC: 2 mins

- Swipe up or down to view the setting controls for each of the available stimulation patterns.
- Tap on the left arrow icon for any given stimulation patterns to decrease the repeat time, or on the right arrow icon to increase the repeat time.
- Tap on the up arrow icon to return to the NMT Settings sub menu.

Auto Timer Settings

Tap on the Auto Timers menu item to preset the default repeat timer setting that will be observed for each of the six depth of block states that can occur in the AUTO stimulation mode.

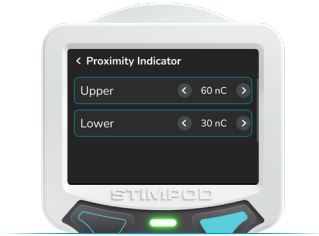
Factory Defaults:
Recovered: 15s,
Minimal: 15s,
Shallow: 15s,
Moderate: 15s,
Deep: 5 Mins,
Profound: 5 mins

- Swipe up or down to view the setting controls for each of the available depth of block states.
- Tap on the left arrow icon for any given depth of block state to decrease the repeat time, or on the right arrow icon to increase the repeat time.
- Tap on the up arrow icon to return to the NMT Settings sub menu.

4.2.2 MAP/LOC Settings

MAP/LOC settings are only accessible when the MAP/LOC stimulation cable is plugged into the STIMPOD NMS450X+.
Tap on the default stimulation settings icon to open up the MAP/LOC sub-menu and preset the proximity indicator.

Factory Defaults:
Upper Limit: 60nC, Lower Limit: 30nC



- Tap on the left arrow icon for the upper or lower limit setting to decrease the charge limit, or on the right arrow icon to increase the charge limit.
- Tap on the up proximity indicator to return to the NMT Settings sub menu.

4.2.3 Recorded NMT Case Files

Tap on the Recorded Case Files icon on the main menu to access and view recorded NMT Data.

Page Control
Indicates current data page - (8 case files are accessible on each date page).
Tap Left arrow or right arrow to backtrack or advance to a required data page.

Delete Control
Tap to delete “all” case files from memory.

Case Files
Tap on a case file to access and view the stored data for the case.

Depth of Block Indicator
Indicates Depth of Block at end of recording.

Duration Indicator
Indicates duration of the case.

File Identifier
Indicates Case File ID.

- The case files stored in memory are organised on the display in data pages, where up to 8 case files are listed on a data page.
- Tap on the left and right arrows of the page control to navigate between data pages, and swipe up or down to access and view all the case files available on a data page.

Viewing Case Files

Tap on a case file for a graphical view of the recorded case data.

File Identifier

Indicates Case File ID.

Segment Control

A full case file is displayed in 15 min segments at a time. Tap on left arrow icon to go back to previous 15 min segment of case. Tap on Right arrow icon to advance to next 15 min segment of case.

Segment Indicator

Indicates current 15 min segment of case out of the total number of available 15 min segments.

Segment End Time

Indicates end time of current segment (0 - 15 min).

Segment Start Time

Indicates start time of current segment (0 - 15 min).

- A full case is displayed on the screen in segments of up to 15 minutes at a time. The relative start and end times of the segment currently displayed on the screen is indicated just below the graph area.
- Tap on the left and right arrow icons to view the previous or next 15 minute segment of the currently selected case.
- Tap on the file identifier to return to the list of Recorded Case files.

Downloading Case Files

The full complement of case files can be downloaded from the STIMPOD NMS450X+ to an external computing device through the use of a Xavant manufactured data cable. Instructions for downloading the case files are provided with the data cable.

Deleting Case Files

The full complement of recorded case files can be deleted from the internal memory of the STIMPOD NMS450X+ by tapping on the delete control (trash can icon) displayed together with the list of Recorded Case files.

⚠ Caution:

A confirmation message will be raised on the display screen before the case files are deleted, but once confirmed the data will be permanently wipe and will not be recoverable

4.2.4 | User Information

Tap on the User Information icon on the main menu to access, view and change user related information recorded by the STIMPOD NMS450X+.

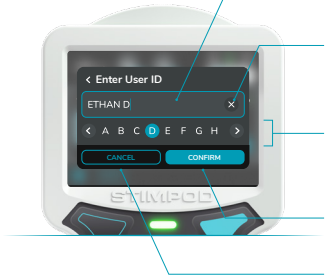
Language Settings

Tap on the left and right arrow icons associated with the language menu item to navigate through all of the languages supported by the STIMPOD NMS450X+.

The device will automatically adopt the displayed language as the language of choice - no further action is required. All warning and information messages, menu text and popup text will henceforth be displayed in the language of choice during normal use of the device.

User ID Settings

Tap on the User ID menu item to access and preset a user ID of choice.



User ID Text
Active alphanumeric text string being entered for the User ID.

Backspace Control
Tap on the back space icon to remove the last character from the User ID text.

Character Set
Tap on left and right arrow to navigate through available alphanumeric characters. Tap on the character highlighted in blue to append it to the User ID text.

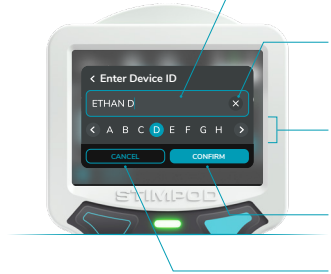
Confirm Button
Tap to save the User ID Text and Exit.

Cancel Button
Tap to discard any changes and Exit.

- Construct a User ID text string by selecting alphanumeric characters from the character set.
- Tap on the left and right arrows to navigate through the alphanumeric character set and then tap on of the character highlighted in blue to append it to the User ID text.
- Tap on the backspace icon to remove the last character from the User ID text.
- Tap the Enter button to save the User ID and exit, or alternatively tap on the cancel button to discard any changes and exit.

Device ID Settings

Tap on the Device ID menu item to access and preset a Device ID of choice.



Device ID Text
Active alphanumeric text string being entered for the Device ID.

Backspace Control
Tap on the back space icon to remove the last character from the Device ID text.

Character Set
Tap on left and right arrow to navigate through available alphanumeric characters. Tap on the character highlighted in blue to append it to the Device ID text.

Confirm Button
Tap to save the Device ID Text and Exit.

Cancel Button
Tap to discard any changes and Exit.

- Construct a Device ID text string by selecting alphanumeric characters from the character set.
- Tap on the left and right arrows to navigate through the alphanumeric character set and then tap on the character highlighted in blue to append it to the Device ID text.
- Tap on the backspace icon to remove the last character from the Device ID text.
- Tap the Enter button to save the Device ID and exit, or alternatively tap on the cancel button to discard any changes and exit.

5 | Technical Notes

5.1 | Performance Test

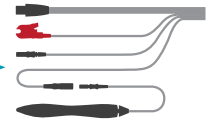
Before operating and using the device a performance test must be carried out at the site of use. The performance test described below is in compliance with the German § 5 MPBetreibV directive.

- Insert the batteries and switch on the device.
  The following screen should appear on the display.

Followed by

5.1.1 | Nerve Locating Mode

- Insert the Nerve Mapping/Nerve Locating Cable.
  The following screen should appear on the display.

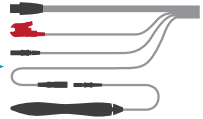


- The LED should flash RED and no audible feedback should be heard.

- Short-circuit the needle connector and the ECG connector.
  The following screen should appear on the display.

- The LED should flash GREEN and if sound is enabled in the menu a 'beep' should be heard each time a stimulus is delivered.
- Stimulus should occur at the set frequency. (1, 2 or 5 Hz).
- Using the scroll wheel or function keys, slowly increase the current to 0.5mA.
- Check that the stimulation waveform displayed in the waveform display window is square as shown below.

5.1.2 | Combined Nerve Mapping/Nerve Locating Mode

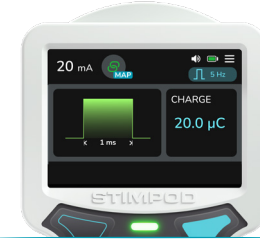


- Insert the Nerve Mapping/Nerve Locating Cable.
- Short-circuit the Nerve Mapping probe and the ECG connector for a short time and then separate them again.
  The following screen should appear on the display.

- The LED should flash RED and no audible feedback should be heard.

- Short-circuit the Nerve Mapping probe and the ECG connector.
  The following screen should appear on the display.

- The LED should flash GREEN and if sound is enabled in the menu a 'beep' should be heard each time a stimulus is delivered.
- Stimulus should occur at the set frequency. (1,2 or 5 Hz).
- Using the scroll wheel or function keys, slowly increase the current to 20mA.
- Check that the stimulation waveform displayed in the waveform display window is square as shown below.



In order to test the Nerve Locating connection and device functionality follow the instructions in 5.1.1.

5.1.3 | NMT Monitoring Mode (AMG)

- Insert the NMT Monitoring Cable (AMG).
  The following screen should appear on the display.

- Ensure that the device is in TOF mode.
- The TOF indicator may or may not be displayed in the results window.
- Short-circuit the red and black electrode connectors.

- Use the scroll wheel or touch slider, to increase the current to 80mA.
- Press the play/pause button while shaking the accelerometer.

The NMS450X+ should respond as follows:

- The LED should flash GREEN in accordance with the four stimulations.
- Each stimulation should be accompanied by an audible ‘beep’.
- In the graph display window four bars of different heights should indicate that the accelerometer detected movement.

- Separate the red and black electrode connectors to cause an open circuit between them.
  The following screen should appear on the display.

- Press the play/pause button.
- The LED should not flash GREEN.
- No audible feedback should be heard.

5.1.4 | NMT Monitoring Mode (EMG)

- Insert the NMT Monitoring Cable (EMG).
  The following screen should appear on the display.

- Ensure that the device is in TOF mode.
- The TOF indicator may or may not be displayed on the results window.
- Attach an EMG electrode and short circuit the stimulation and sense pads.

- Use the scroll wheel or touch slider, to increase the current to 80mA.
- Press the play/pause button.

The NMS450X+ should respond as follows:

- The LED should flash green and if sound is enabled in the menu a ‘beep’ should be heard each time a stimulus is delivered.
- In waveform display window no bars should be displayed.

- Separate the sense pads or stimulation pads to create an open circuit.
  The following screen should appear on the display.

- Press the play/pause button.
- The LED should not flash GREEN.
- No audible feedback should be heard

- If the STIMPOD malfunctions in any one of these performance tests, it should be checked by the relevant technical department in accordance with the test instructions in the Technical Service Manual.
- Equipment may only be repaired by the manufacturer or by an organisation expressly authorised by the manufacturer.
- Equipment does not require regular calibration.

5.2 | Applied Part

The parts that are intended to come in contact with patients during normal clinical operation are the AMG electrode, EMG electrode, and patient cable connecting the STIMPOD device to the electrode is considered as applied part. The Smart Data Cable accessories that facilitate connection to external monitors are classified as applied parts.

5.3 | Technical Specifications

Stimulation Settings

Stimulus	NMT Mode	Nerve Mapping Mode	Nerve Locating Mode
Stimulus Type	Current Controlled	Current Controlled	Current Controlled
Stimulus Waveform	Monophasic Square Wave	Monophasic Square Wave	Monophasic Square Wave
Stimulus Pulse Width	200µs ± 5%	50µs, 100µs, 200µs, 300µs, 500µs, 1ms ± 5%	50µs, 100µs, 200µs, 300µs, 500µs, 1ms ± 5%
Stimulus Voltage	$400V_{max}$	$400V_{max}$	$100V_{max}$
Stimulus Current	0-80mA ± 5%	0-20mA ± 5%	0-5mA ± 5%
Stimulus Frequency	1Hz, 2Hz, 5Hz, 50Hz, 100Hz ± 5%	1Hz, 2Hz, 5Hz ± 5%	1Hz, 2Hz, 5Hz ± 5%
Load Impedance	0 kΩ - 5 kΩ	0 kΩ - 20 kΩ	0 kΩ - 20 kΩ
Operational Modes	AUTO, TOF, PTC, SMC, DEP, ST, DB, TET	-	-

Power Supply

Source	Type	Form Factor	Length	Rating	Electrical Interface/s
Removable Battery	Rechargeable INR Lithium battery with short-circuit and over-voltage protection	21700	75.5mm (nom)	3.6v, 5000mAh	Internal 5V, 2A Charger - USB Interface External 5V, 2A Desktop Charger 5 hours 30 mins to full charge at $1.3A_{max}$

* *Refer to Section "Battery Charging and Replacement" for important instructions related to battery.*

Physical Specifications

Display	Dimensions
3.5" 24 bit Colour TFT LCD Display with Capacitive Touch Screen	174mm (L) x 90mm (W) x 35mm (H)
Weight (Device Without Battery)	**Weight (Device With Battery)**
195g	265g
Operating Temperature	**Storage & Transport Temperature**
10-40 °C	0 - 50 °C
Operating Humidity	**Storage & Transport Humidity**
90% RH	90% RH
Operating Atmospheric Pressure	**Storage & Transport Atmospheric Pressure**
80-106 kPa	80-106 kPa

Power Consumption

NMT Mode (AMG)		NMT Mode (EMG)		MAP Mode / LOC Mode	
Average Power	Continuous Use	Average Power	Continuous Use	Average Power	Continuous Use
460mW @130mA	Up to 35 Hours	520mW @150mA	Up to 32 Hours	426mW @120mA	Up to 38 Hours

* *The maximum continuous use hours were determined for the recommended default display intensity - Increased display intensity settings shall result in a reduction of the continuous use hours.*

** *The above conditions are suitable for a battery in good condition.*

5.4 | Requirements for Other Equipment Connected to The Device

Other equipment intended for connection to STIMPOD's signal or connector ports shall comply with IEC standard series applicable for medical electrical equipment. The user shall bear the overall responsibility for the connected system. Contact Xavant's authorised service personnel for any technical support.

5.5 I Cleaning and Disinfecting STIMPOD NMS450X+

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.

⚠ Cautions:

- Soap and water should only be applied with a damp cloth - under no circumstances should the STIMPOD or any of its parts or accessories come into direct contact with, be immersed in, or filled with liquid.
- Do not place the STIMPOD or any of its parts or accessories inside an autoclave.
- The STIMPOD and its parts and accessories are non-sterile devices and must not be sterilized.

Disinfecting:

- Any commercially available methanol-free disinfectant in an ethyl alcohol base can be used for disinfection.
- The surfaces of the STIMPOD 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:
  - MeliseptolR fluid and tissues from the manufacturer B. Braun.
  - MikrozidR AF from the manufacturer Schulke.
  - 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 link free cloth moistened in water to wipe of the traces of the disinfectant.

⚠ Caution:

- The STIMPOD cable (electrode and/or sensor) 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.

5.6 I Battery Information, Periodical Checks and Maintenance:

- Always inspect the battery charge level prior to use to ensure battery is suffciently charged for the duration of its intended use.
- It is recommended to remove the battery if the STIMPOD is likely not in use for extended period of time.
- The expected lifetime of the battery is 500 cycles (charging and discharging is 1 cycle) and generally degrades with usage. If the battery has degraded beyond its useful service life, consider replacing with manufacturer recommended battery only.
- The user and/or hospital technician may replace the battery in the STIMPOD by following the battery replacement instructions in a safe manner.

5.7 I Routine 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 charging 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.

5.8 I Storage Considerations:

Batteries intended for long term storage (i.e. greater than 6 months) should be charged/discharged to ~60% of the battery capacity prior to storage. Additionally, the battery should be checked every 12 months and recharged as needed to maintain the ~60% charge level. This practice will ensure maximum battery life.

5.9 I Battery Charging and Replacement

- The battery can be charged internally only when the STIMPOD is not connected to patient i.e., the STIMPOD cannot be used on patient simultaneously while charging.
- The battery can be removed from the STIMPOD unit and charged externally using the external charging adapter provided by the manufacturer.
- Alternatively, the battery can be charged while in the STIMPOD through X Link only if the patient is disconnected. (applicable only for v10.6.11 or higher).
- In event of malfunction during charging, disconnect the charging cable from the device to stop charging. Ensure that the connection to mains is easily accessible.
- Always use XT-45200 Battery provided by Xavant, as a replacement when required.
- Always use the Adapter and External Charger provided by Xavant to charge the battery.

5.9.1 Battery Replacement

- Ensure the device is turned off and disconnected from external battery charger before battery removal.
- Access the battery compartment at the rear side of the device.
- Press and slide down to remove the battery compartment cover as illustrated *(Image 01).*
- Carefully remove the battery from the compartment *(Image 02).*
- Place the new battery into the compartment, aligning it to the correct +/- polarity markings provided on the battery orientation label inside the battery compartment *(Image 03).*
- Slide the battery cover into position along the guide rails and press gently until it clicks into place *(Image 04).*
- Turn on the device and check to ensure proper operation.

Image 01

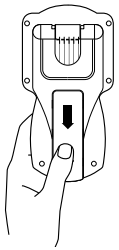


Image 02

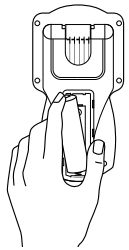


Image 03

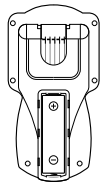
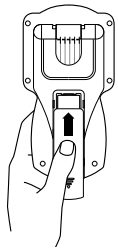


Image 04



5.10 I Product Lifetime

The lifetime of the STIMPOD monitor is 10 years and its accessories have a lifetime of 5 years.

5.11 I Side Effects

Some known side effects that could occur from use of STIMPOD and its patient sensor electrodes as follows:

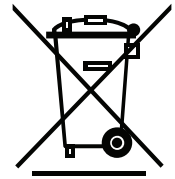
- Develop allergic skin reactions to the clinical adhesive.
- Stimulation using higher maximum current levels may induce pain for patients recovered from anesthetized state.
- Patients who are sensitive may experience superficial skin burns or irritation where electrodes are placed on the skin.
- Skin irritation may occur for some patients if electrodes are not fitted properly to the skin surface.

5.12 I Cybersecurity Controls and Data Protection

- The STIMPOD NMT monitor can transmit data over the SDC and/or X-Link , and does not include any confidential or protected patient health information. Note : The STIMPOD itself is not a networked device and does not transmit any information.
- The monitor cannot be controlled directly or indirectly via SDC or X Link connections.
- Always ensure the external device(s) connected to STIMPOD are connected in a “trusted network” for secure data transmission and to avoid any unauthorized data access.

Note: Only authorised personnel should access or connect to the device. User accounts and access credentials should be managed according to the institution IT policies.

5.13 I Disposal of Waste Electrical and Electronic Equipment (WEEE)



- 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.

5.14 I Guidance and Manufacturers Declaration

Guidance and Manufacturers Declaration – Electromagnetic Emissions– for All Equipment and Systems		
The STIMPOD NMS450X+ is intended for use in electromagnetic environment specified below. The customer or user of the STIMPOD NMS450X+ 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 STIMPOD NMS450X+ must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. The STIMPOD NMS450X+ 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 STIMPOD NMS450X+ or shielding the location.

Guidance and Manufacturers Declaration – Electromagnetic Immunity- for All Equipment and Systems			
The STIMPOD NMS450X+ is intended for use in the electromagnetic environment specified below. The customer or the user of the STIMPOD NMS450X+ 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	± 6 kV contact ± 15 kV air	± 6 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 STIMPOD NMS450X+ is intended for use in the electromagnetic environment specified below. The customer or the user of the STIMPOD NMS450X+ 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 STIMPOD NMS450X+, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** $d = 1.2\sqrt{P}$ 80 MHz - 800 MHz $d = 2.3\sqrt{P}$ 800 MHz - 2.5 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.  Interference may occur in the vicinity of equipment marked with this symbol.
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).	

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 STIMPOD NMS450X+ is used exceeds the applicable RF compliance level above, the STIMPOD NMS450X+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the STIMPOD NMS450X+.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the STIMPOD NMS450X+

The STIMPOD NMS450X+ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the STIMPOD NMS450X+ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the STIMPOD NMS450X+ 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 STIMPOD NMS450X+ is intended for use in the electromagnetic environment specified below. The customer or the user of the STIMPOD NMS450X+ 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.

6 | Products & Accessories

Products & Accessories	Product Code
STIMPOD NMS450X+	XT-45030
Nerve Locating/Mapping Cable	XT-41014
NMT Monitoring Cable AMG (1.8m)	XT-45025
NMT Monitoring Cable AMG (3.0m)	XT-45025B
NMT Monitoring Cable EMG (1.8m)	XT-45003
NMT Monitoring Cable EMG (3.5m)	XT-45003A
NMT Electrode (Pack of 10)	XT-45008
EMG Electrode Large (Pack of 1)	XT-45009L
EMG Electrode Small (Pack of 1)	XT-45009S
Accelerometer Strap (Pack of 5)	XT-45007
Accelerometer Strap XL (Pack of 5)	XT-45007A

Products & Accessories	Product Code
Smart Data Cable NMShow - USB	XT-45100A-NMS
Smart Data Cable NMShow - RS232	XT-45100C-NMS
Smart Data Cable Philips - RS232	XT-45100C-PHI
Lithium-Ion Battery	XT-45200
Power Adapter - Australia	XT-45201-AU
Power Adapter - Europe	XT-45201-EU
Power Adapter - United States	XT-45201-US
Power Adapter - United Kingdom	XT-45201-UK
Charging Cable	XT-45202
External Charger	XT-45203
X-Link	XT-45300

6.1 I Inside the Carry Case

- XT-45030 NMS450X+ Stimpod Monitor.
- XT-45202 Charging Cable.
- XT-45201-** Power Adapter.
- XT-45200 Rechargeable Li-ion Battery.

Note:
Refers to the Type of Power Adapter applicable to the jurisdiction.

6.2 I Accompanied Documents

- Instructions for Use (Outside of US).
- Quick Start Guide.

6.3 I AMG Monitoring Accessories

- XT-45025/XT-45025B NMT Monitoring AMG Cable (1.8m/3.0m).
- XT-45008 NMT Electrode (Pack of 10).
- XT-45007 Accelerometer Strap.

6.4 I EMG Monitoring Accessories

- XT-45003/XT-45003A NMT Monitoring EMG Cable (1.8m/3.5m).
- XT-45009L/XT-45009S EMG Electrode (Large/Small).

6.5 I Nerve Map/Loc Accessory

- XT-41014 Nerve Mapping/Locating Cable.

6.6 I Optional Accessories

- XT-45007A Accelerometer Strap XL.
- XT-41017 STIMPOD Infinity Mount.
- XT-45100A-NMS Smart Data Cable NMShow - USB.
- XT-45100C-NMS Smart Data Cable NMShow – RS232.
- XT-45100C-PHI Smart Data Cable Philips – RS232.
- XT-45300 X-Link.

Note:
Always clean and disinfect the device and accessories prior usage.

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 : customercare@xavant.com