

THE NEUROSIGN® V4

INTRAOPERATIVE NERVE MONITOR

PRESERVING NERVE INTEGRITY



 **NEUROSIGN® V4**

User Manual

NOP08-EN-10
March 2021

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2797






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Welcome to the Neurosign® V4 Intraoperative Nerve Monitor



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Preface

The Neurosign® V4 Intraoperative Nerve Monitor (referred to as 'nerve monitor') is a Neurosign® product and belongs to the Neurosign® division of The Magstim Company Limited.

This user manual has been written to provide information on the configuration, operation and maintenance of the nerve monitor

The Neurosign® V4 Assembly Guide (NOP18-EN) and Reference Guide (NOP19-EN) are also available for reference.

It is important to ensure that the most up-to-date documents are used as reference materials. Documents are available from Neurosignsurgical.com or on request from your local Neurosign® representative. See page ii for contact details.



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Devices Covered

This user manual is applicable to the following devices:

Neurosign® V4 Intraoperative Nerve Monitor
(Referred to as 'nerve monitor') - P/N: 4230-00

Accessories:

Neurosign® V4 Stimulator Pod - P/N: 4440-00

Neurosign® V4 Pre-amplifier - 4-Channel - P/N: 4444-00

Neurosign® V4 Pre-amplifier - 8-Channel - P/N: 4448-00

Neurosign® V4 Mute Sensor - P/N: 4225-00

Note: Disposables that are compatible are listed in "2.4 Disposables" on page 22. Full documentation regarding disposables is provided along with the item/s. Alternatively documentation can be obtained on request from your Neurosign® representative.



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Product Guarantee

The Magstim Company Ltd. guarantees the effectiveness of both materials and workmanship for a period of two years from the date of shipment for the following products:

Neurosign® V4 Intraoperative Nerve Monitor	- P/N: 4230-00
Neurosign® V4 Stimulator Pod	- P/N: 4440-00
Neurosign® V4 Pre-amplifier - 4-Channel	- P/N: 4444-00
Neurosign® V4 Pre-amplifier - 8-Channel	- P/N: 4448-00
Neurosign® V4 Mute Sensor	- P/N: 4225-00

The Magstim Company Ltd. reserves the right to perform guarantee services in its factory, at an authorised repair station, or at the customer's installation at the discretion of the company.

The Magstim Company Ltd. guarantees to repair or replace defective equipment or parts, free of charge within the guarantee period, provided that the said defects occur during normal use. Replacement will be only at the company's discretion where a repair is not possible and/or not feasible.

Disposables such as batteries, electrodes and stimulating probes are not covered under this guarantee.

Claims for damages during shipment must be filed promptly with the transportation company. All correspondence concerning the equipment must specify the model name and/or number, as well as the serial number, exactly as they appear on the equipment invoice/unit.

Improper use, mishandling, tampering with, or operation of the equipment without following operating instructions will void this guarantee and release The Magstim Company Ltd. from any further obligations under this guarantee.

The Magstim Company Ltd. will accept responsibility for effects on safety, reliability and performance of the equipment provided:

- Any modifications, repairs or servicing of the products are carried out by The Magstim Company Ltd. or persons authorised by the company;
- The electrical installation of the relevant room complies with local regulations and;
- The equipment is used in accordance with the User Manual.

The Magstim Company Ltd. guarantees to support the products stated above for a period of seven years from date of shipment and where the terms of this guarantee have been met. Servicing and replacement parts will be available within this time.

The Magstim Company Ltd. cannot guarantee that spare parts will be available after this time. Please see "6.4 Servicing & Device Lifetime" on page 77 for more information.

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SECTION 1

PRODUCT OVERVIEW

1.1 Product Description

The Neurosign® V4 Intraoperative Nerve Monitor is a multi-channel touch screen nerve monitor designed for use in ENT surgery and neurosurgery.

Using Neurosign® needle or surface electrodes connected to the pre-amplifier, the nerve monitor detects EMG signal within muscles caused by the contraction of the muscle due to mechanical or electrical stimulation of the nerve controlling it. The nerve monitor then amplifies the EMG data into an audible signal and displays the data as a waveform on the active monitoring screen (page 43).

The nerve monitor allows for substantial personalisation of its functions which can be saved in personalised surgeon profiles with customised procedure settings. All functions and settings are controlled via the touch screen, except for the three dedicated control dials located below the screen for the Master Volume, Stimulator 1 and Stimulator 2 adjustments.

A connection for up to two stimulating probes is provided via the stimulator pod so that suspect tissue or a nerve, may be directly stimulated during the surgery using a Neurosign® stimulating probe.

The nerve monitor has a number of self-checking routines to ensure that the unit is working reliably. In the event of failure the unit will alert the operating room staff and prevent further use.



1.2 Indications & Contraindications

a. Intended Use

The Neurosign® V4 Intraoperative Nerve Monitor is intended for locating and identifying cranial and peripheral motor and mixed motor-sensory nerves during surgery, including spinal nerve roots.

b. Indications For Use

Indications for 4 channel intraoperative nerve monitoring include, Intracranial surgeries, Extracranial surgeries (e.g. parotidectomy), Intratemporal surgeries (e.g. mastoidectomy), Extratemporal surgeries, Neck surgeries (e.g. thyroidectomy).

Indications for 8 channel intraoperative nerve monitoring include, Intracranial surgeries, Extracranial surgeries (e.g. parotidectomy), Intratemporal surgeries (e.g. mastoidectomy), Extratemporal surgeries, Neck surgeries (e.g. thyroidectomy), Spinal surgeries (e.g. tethered cord, degenerative treatments, pedicle screw procedures, cauda equina, fusion cages, rhizotomy, and open/percutaneous lumbar procedures), Surgeries to the upper and lower extremities (e.g. tethered cord, pedicle screw procedures, cauda equina).

c. Contraindications

The nerve monitor is contraindicated for use with neuromuscular blocking agents that will significantly reduce, if not completely eliminate, EMG responses to electrical or mechanical nerve stimulation.

The nerve monitor requires the patient to have a relevant pre-operative functioning nerve in order to detect the relevant EMG responses.

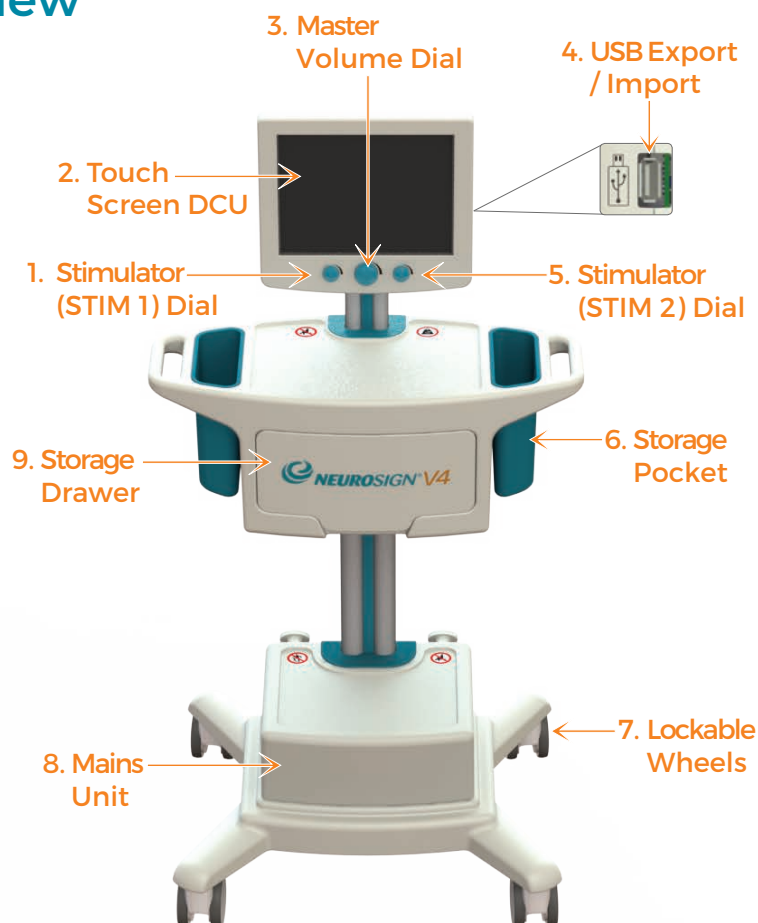
d. Training

The nerve monitor is intended to be used with the minimum of training. However it is assumed that those interacting with the unit are qualified to the minimum standard to be present in the operating theatre during surgery and are overseen by a qualified surgeon.

The nerve monitor should only be used by those who have fully read and understood this user manual, in conjunction with training provided by a certified Neurosign® trainer to ensure proper understanding of the product, disposables and the associated protocols.

Please contact The Magstim Company Ltd. to arrange training. Contact details can be found on page ii.

1.3 Front View



1. Stimulator (STIM 1) Dial

This controls the current/voltage for the primary stimulating probe/s

2. Touch Screen DCU

The majority of the functions are selected via the touch screen DCU (Display Control Unit).

3. Master Volume Dial

Rotate the dial clockwise to increase the volume, anticlockwise to decrease the volume. Press and hold for 2 seconds to mute the EMG audio.

4. USB Export/Import

The USB memory stick connection for import/export, provided with a rubber cover. See page 24 for more information.

5. Stimulator (STIM 2) Dial

Not currently available. For more information contact the product enquiries team (page ii).

6. Storage Pockets

The nerve monitor houses a 'pocket' on either side of the unit to safely store the pre-amplifier and the stimulator pod. The 'pockets' are fully removable to facilitate cleaning.

7. Lockable Wheels

The wheels allow the nerve monitor to be moved around i.e. between theatre's. To lock the wheels, press down on the tab for each wheel.

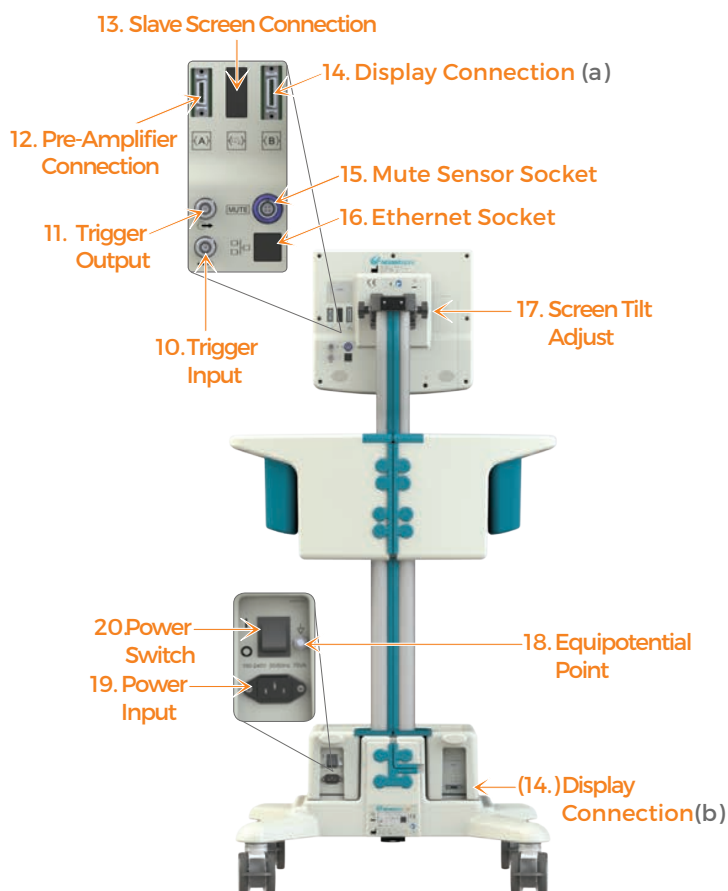
8. Mains Unit

The mains unit houses the power supply and speaker.

9. Storage Drawer

The storage drawer is designed to accommodate and store the disposables.

1.4 Rear View



10. Trigger Input

Connect an external stimulator trigger to this connector. This requires a TTL 5V pulse.

11. Trigger Output

The output is a TTL 5V signal at the same frequency as the stimulator.

12. Pre-Amplifier Connection

Connection socket for the pre-amplifier lead.

13. Slave Screen Connection

For more information contact the product enquiries team (page ii).

14. Display Connection

(a) Touch Screen DCU

(b) Mains unit

The connection between the touch screen DCU and the mains unit via the UI cable.

15. Mute Sensor Socket

Connection socket for the mute sensor lead.

16. Ethernet Socket

For more information contact the product enquiries team (page ii).

17. Screen Tilt Adjust

See "4.3 Adjusting The Screen Tilt" on page 41 for information.

18. Equipotential Point

See "a. Electrical Testing" on page 77

19. Power Input

Connection socket for the AC mains power lead provided with the nerve monitor.

20. Power Switch

The switch to turn the nerve monitor ON and OFF.

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SECTION 2

ACCESSORIES

2.1 Pre-Amplifier

The pre-amplifier collects the EMG signals from the electrodes and amplifies them for processing and display.

The pre-amplifier is available in a 4-Channel or 8-Channel variant.

21. Mounting Clip

A mounting clip is located on the side of the pod so that it can be attached to the side rail of the operating table.

22. Electrode Channels 1 - 4.

The corresponding sockets for channel one (blue), channel two (red), channel three (violet) and channel four (orange).

23. Reference Electrode Channel.

The corresponding sockets for the reference electrode channel (green).

24. Electrode Channels 5 - 8.

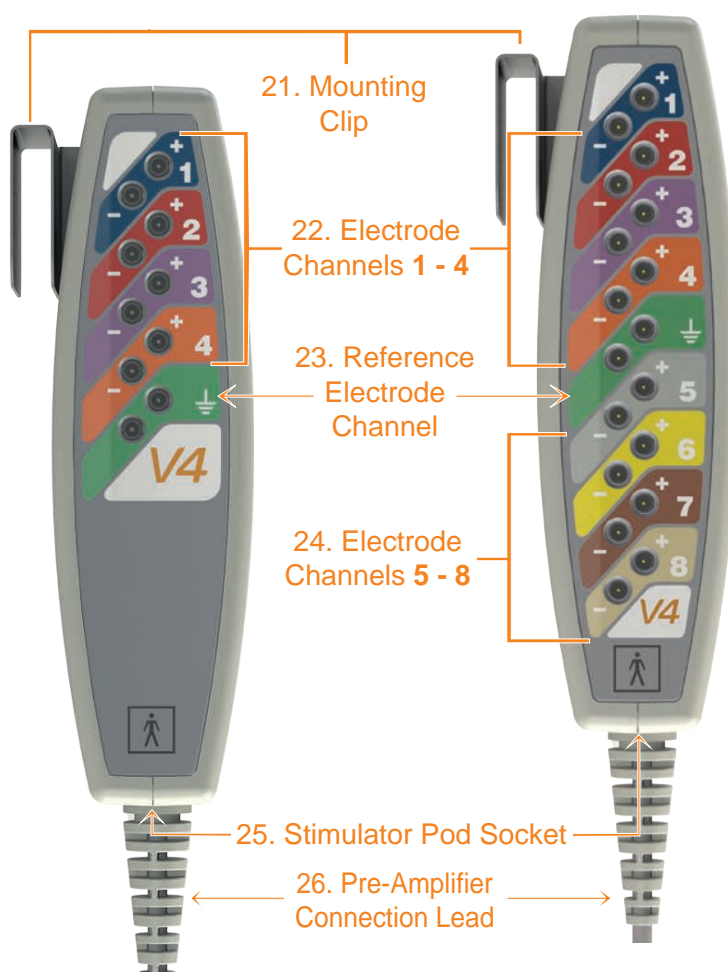
The corresponding sockets for channel five (grey), channel six (yellow), channel seven (brown) and channel eight (cream). These are unique to the 8-Channel pre-amplifier.

25. Stimulator Pod Socket. (S)

Plug the stimulator pod connection lead into here (see page 21).

26. Pre-Amplifier Connection Lead.

Connect the other end of this lead to the corresponding socket on the rear of the touch screen DCU (see page 17).



2.2 Stimulator Pod

The stimulator pod serves as a connection point for the stimulating probes and allows for two stimulating probes to be connected simultaneously. This can be useful when both precise and wide-field stimulation is required. The stimulator pod also serves to reduce the length of cable attached to the stimulating probes, making them easier to handle.

27. Mounting Clip

A mounting clip is located on the side of the stimulator pod so that it can be attached to the side rail of the operating table.

28. Primary Stimulator Sockets

The primary stimulating probes should be connected into the corresponding coloured sockets.


29. Stimulator Pod Socket

The stimulator pod connection lead should be attached to the pre-amplifier socket (see page 20).



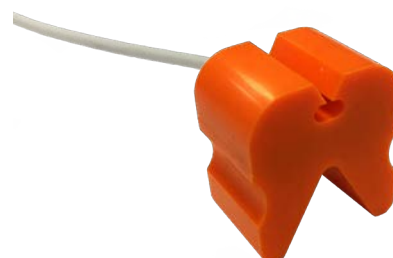
2.3 Mute Sensor

In order to eliminate the effect of electrocautery noise on the nerve monitor, a mute sensor (right) may be connected to the mute sensor socket (see page 17).

When a mute sensor is connected and the mute function is active, the screen will display  and all EMG audio will be muted.

If monopolar electrocautery is used the mute sensor should be attached to the active lead of the electrocautery machine. If only bipolar electrocautery is used, the mute sensor is not necessary. Do not connect the mute sensor if it is not to be used.

Note: Do not connect the mute sensor to the nerve monitor without attaching the clamp to the electrocautery cable or spurious muting of the nerve monitor may occur.



2.4 Disposables

A range of stimulating probes, instruments and electrodes are available for use with the Neurosign® V4 Intraoperative Nerve Monitor. A brief overview of the available disposables is provided. Contact your local Neurosign® representative for more information.

Only Neurosign® branded disposables purchased from a Neurosign® representative should be used with the Neurosign® V4 Intraoperative Nerve Monitor.

The use of the correct disposables is essential to the functioning of the nerve monitor. The Magstim Company Ltd. cannot guarantee the performance of the device unless the compatible disposables and accessories are used.

Sub-Dermal EMG Electrodes

Part number	Description	Box of;
4469-00	2-Channel Electrode Set	10
4470-00	4-Channel Electrode Set	10
4472-00	8-Channel Electrode Set	5
1705-00	Reference Electrode	20

Surface Electrodes

Part number	Description	Box of;
4200-00	Lantern Laryngeal Electrode - 8-9mm * includes Laryngeal Cable - 4203-00	10
4201-00	Lantern Laryngeal Electrode - 6-7mm * includes Laryngeal Cable - 4203-00	10
4203-NM	Laryngeal Electrode Cable *for use with Laryngeal Electrodes - 4200/4201/4202	1

Stimulating probes

Part number	Description	Box of;
3600-00	Concentric Probe	10
3601-00	Bipolar Probe	10
3604-00	Precision Bipolar Probe	10
3602-00	Monopolar Probe *requires the use of a return electrode	10
3605-00	Tapered Monopolar Probe *requires the use of a return electrode	10
4015-00	XL Monopolar Probe *requires the use of a return electrode	1
3603-00	Pedicle Screw Probe, 3mm Ball, *requires the use of a return electrode	10


Part number	Description	Box of;
4008-00	Pedicle Screw Probe - 2.3mm Ball *requires the use of a return electrode	10
4006-00	XL Pedicle Screw Probe, 3mm Ball *requires the use of a return electrode	1
4056-00	XL Pedicle Screw Probe, 3mm Ball *requires the use of a return electrode	10

Stimulating Instruments

Part number	Description	Box of;
4003-00	Triple Hook Paediatric Probe	1
4009-00	Double Hook Paediatric Electrode	1
4012-00	Ring Dissector *requires the use of a return electrode	1
4013-00	Stimulating Dissectors *requires the use of a return electrode	10
4016-00	Curved Needle *requires the use of a return electrode	1
4017-00	Elevator *requires the use of a return electrode	1

2.5 Connections

a. USB

The external USB port is located on the right-hand side of the touch screen DCU housing (see page 16), under a rubber cover labelled . The nerve monitor is compatible with a basic USB 2.0 memory stick (available separately).

The USB cover should remain in place when the port is not in use to provide protection to the USB port.

For more information on exporting files see "d. Exporting Reports" on page 59 and "d. Transferring Profiles" on page 53.

Note: Only a basic USB 2.0 memory stick is compatible with the nerve monitor. Do not attempt to connect any other devices - the USB ports are protected and will not support unauthorised devices. Attempting to connect an unauthorised device may result in damage to the device or the nerve monitor.

b. Keyboard

The nerve monitor has a built in touch screen keyboard.

c. Bluetooth

Warning: Bluetooth export is not intended to be used when monitoring mode is active.

The nerve monitor is capable of pairing via Bluetooth in order to wirelessly export files. To connect to a device please see "c. Bluetooth Setup" on page 63.

For more information on exporting files see "d. Exporting Reports" on page 59 and "d. Transferring Profiles" on page 53.



SECTION 3

WARNINGS & SYMBOLS

3.1 Warnings & Precautions



Failure to heed the following warnings and precautions may cause damage to the equipment and render the equipment unusable or dangerously unsafe.



The Neurosign® V4 Intraoperative Nerve Monitor is designed for use during surgical procedures and must only be used by trained personnel who have carefully studied this User Manual.

- **Electromagnetic compatibility (EMC):** This Neurosign V4 complies with IEC 60601-1-1:2014, Edition 4.0 (Conducted and radiated emissions comply with CISPR 11 Group 2 Class A limits and immune to the Professional Healthcare Environment).

The Neurosign V4 also complies with IEC 60601-2-40:2016 regarding compatibility for use alongside HF Surgical Equipment.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Neurosign V4, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Please be aware: It is not possible to test all sources of RF interference. Consequently, if you experience any unexpected operation from the Neurosign® V4, isolate the device from any surrounding portable and mobile radio frequency communications equipment. If incorrect operation continues, please contact Magstim using the contact details on page ii.

- Excepting those stated in "6.3 User Maintenance & Calibration" on page 76, no user-serviceable parts are found within the Neurosign® V4 Intraoperative Nerve Monitor. Please refer to **page 75** for proper Care and Maintenance information.
- Opening the case presents a serious threat of electric shock and immediate risk to the user.

- Any attempt to remove the security screws will invalidate the product guarantee.
- No unauthorised modifications may be made to the nerve monitor or any of its associated accessories.
- CLASS I: Equipment must only be connected to an AC mains supply with protective earth. Connection should only be made with the power lead provided with the equipment.
- This device is designed as an aid to surgeons in the identification and monitoring of nerves at risk of injury during surgery. It is not a replacement for surgical experience.
- Do not use this equipment in the presence of flammable anaesthetic mixtures.
- Handle with care. Dropping this device or any accessories may cause physical damage and affect performance.
- Ensure that the mains plug and socket are readily accessible to provide isolation from the supply mains if necessary.
- Do not permit liquid close to the ventilation slots in the bottom of the casing.
- Do not insert objects into connector housings, holes or slots in the casing for cleaning purposes, as this may cause damage.
- In the event of hardware failure or software corruption the nerve monitor is designed to fail in a safe state. In this state the stimulator and EMG audio channels are disabled.
- Do not connect the mute sensor to the nerve monitor without attaching the clamp to the electrocautery cable or spurious muting of the nerve monitor may occur.
- When a mute sensor is connected and active, the stimulator current confirm will not be reported.
- High levels of radio frequency (RF) may interfere with the operation of the mute sensor if the device is not connected to the electrocautery cable.
- Care should be taken to avoid the tip of the stimulating probe coming into contact with that of the electrocautery probe, this will cause damage to the internal circuitry of the nerve monitor.
- The use of this device other than as described will reduce the level of protection provided by the equipment. If it is deemed necessary to use the device in any way other than as stated in this document it is strongly advised to contact The Magstim Company Ltd. for advice before use.
- During use, the nerve monitor will have a number of leads/cables connected. Therefore, care should be exercised with lead/cable placement to avoid a tripping hazard.

- Under extreme conditions it may be possible that the mute sensor, pre-amplifier or the stimulator pod are affected by RF. In this case, the offending piece of equipment should be identified and replaced. Alternatively, an improvement may be achieved by moving the pre-amplifier, stimulating pod, associated cables, or changing the position of the mute sensor.
- Incorrect needle placement or faulty electro-surgical equipment has the potential to cause burns at the point of contact between the needle electrodes and tissue. It is therefore strongly recommended that instructions are strictly adhered to, and that the equipment is regularly checked and serviced.
- The possible risk of burns caused by interaction between the electrosurgical machine and the monitor should be a factor in balancing the risks associated with the surgery.
- In order to reduce possible induced current in needle electrode leads (caused by stray RF emitted by the electro-surgical unit), the electrode leads should be kept as far as possible from the electro-surgical unit.
- Cables from the electro-surgical unit, both active and return, should also be kept as far as possible from the electrode leads.
- Patients with active medical devices, such as pacemakers or cochlear implants, should not be stimulated using the stimulating probe without due consideration being given to the risks involved. Current must not pass across the heart or the implanted device. The use of bipolar probes will greatly reduce any possible current spread. If used, keep the current to the minimum needed to stimulate the nerve.
- Leads or equipment which do not comply with IEC 60601-1 should not be connected to the nerve monitor (and accessories), or plugged into the connection sockets.
- Only the supplied AC power lead should be connected to the nerve monitor. If required, replacement/s can be obtained via the sales department.
- The nerve monitor must not be used in the vicinity of objects sensitive to magnetic fields.
- Neurosign® stimulating probes have been specifically designed to limit the current density at the tips. Do not use non-Neurosign® devices as these may not comply with the current density limits.
- Wireless/Bluetooth export is not intended to be used when monitoring mode is active
- It is the responsibility of the user to identify, analyse, evaluate and control potential risks every time a device is connected or disconnected.



DO NOT step on the device.



DO NOT sit on the device.



The maximum load permitted on the device is 1.5kg and should not be exceeded.

3.2 Device symbols key

The following symbols can be physically found on the device.



Consult user manual.



Consult accompanying documentation before using this device. User manual NOP08-EN and assembly guide NOP18-EN.



CE mark - the manufacturer's declaration that the product meets the requirements of the applicable CE mark EC directives.



Manufacturer - see page ii for contact details.



Product serial number



Product reference number



Date of manufacture



DO NOT dispose in general waste. Please contact the Magstim Company Ltd. for advise on disposal in compliance with the appropriate environmental regulations.



RX only: "Rx only" is in accordance with US law, only.



DO NOT step.



DO NOT sit.



Maximum load permitted.



Pre-amplifier to touch screen DCU connection - see page 17.



Display connection (touch screen DCU to mains unit) - see page 17.



Slave screen connection - For more information contact product enquiries (see page ii).



Trigger output socket - see page 17.



Trigger input socket - see page 17.



Mute sensor socket - see page 17.



Ethernet socket - see page 17.



Stimulator pod to pre-amplifier connection - see page 20.





























USB socket - see page 24

3.3 Touch screen symbols Key

The following symbols can be found within the touch screen user interface. This section is intended as a glossary of icons only. More information can be found in the relevant section of the manual.












i. General

	WARNING/ERROR i.e. incorrect password		ALARM page 66
	INFORMATION PROMPT		OFFLINE pre-amplifier not detected, see page 71
	RESTORE LAST SESSION page 41		PROCEDURE NOT AVAILABLE see page 54
	NEXT/ PROCEED		USB IMPORT page 24
	BACK/ PREVIOUS		USB EXPORT page 24
	ACCEPT		SAVE
	CANCEL		EXPAND page 57
	EDIT		BLUETOOTH page 24
	SYSTEM RESTART - This indicates the system is restarting		MANAGE PROFILES page 48
	SOUND MUTED		MANAGE REPORTS page 57
	VOLUME		SETTINGS page 61
	EMG AUDIO DISABLED page 40		SECURED page 48
	DELETE RECORD/ PROFILE		DATE

	TIME		DATE OF MANUFACTURE page 83
	SERIAL NUMBER page 83		TRANSMITTING WIRELESSLY (Bluetooth)
	REFERENCE NUMBER page 83		TRANSMITTING TO USB









ii. Settings











See "4.11 Settings" on page 61 for more information

	SET TIME AND DATE		SYSTEM SETTINGS
	SET TIME ZONE		LANGUAGE SELECTION
	KEYBOARD SETUP		SYSTEM DETAILS
	BLUETOOTH DISCOVERY		SERVICE PANEL
	PAIR WITH BLUETOOTH DEVICE		SERVICE CONTACT
	REMOVE BLUETOOTH PAIRING		

iii. Customising








See "c. Procedure Settings" on page 49 for more information

	CHANNEL LABEL		CONSTANT CURRENT
	ADD CHANNEL LABEL		TRIGGER MODE
	DUPLICATE PROCEDURE SETUP		TRIGGER FREQUENCY
	CONSTANT VOLTAGE		PULSE WIDTH

	NOTCH FILTER		TIMEBASE SCALE
	WAVEFORM SETTINGS		CHANNEL ON/OFF
	WAVEFORM THRESHOLD		ARTEFACT REJECTION FILTER
	STIMULATION ARTEFACT REJECTION (SAR) FILTER		EDIT FIELD
	WAVEFORM SCALE		ENTER TEXT

iv. Keyboard Symbols

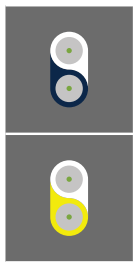
The following symbols are found on the 'on-screen' keyboard.

	SPECIAL CHARACTERS		CAPS LOCK ENABLED
	ENTER/RETURN/NEW LINE		SPACE BAR
	SHIFT ENABLED		DELETE/BACKSPACE
	SHIFT DISABLED		

v. Monitoring

See "f. Monitoring Menu" on page 44 for more information

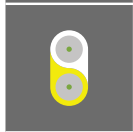
	HOME		IMPEDANCE CHECK
	SCREEN CAPTURE		START PROCEDURE MONITORING
	LATENCY CURSORS		END PROCEDURE MONITORING



PRIMARY STIMULATOR



PROCEDURE SETTINGS



SECONDARY STIMULATOR



AUDIO SQUELCH

vi. Reporting

See "d. Exporting Reports" on page 59 for more information



ATTACH/DETACH EVENT TO
EXPORT



EXPORT AS .BMP



EXPORT AS .PDF



EXPORT AS .CSV



SECTION 4

INSTRUCTIONS FOR USE



For correct assembly please refer to the Neurosign® V4 Assembly Guide (NOP18-EN). Additional copies are available at neurosignsurgical.com, or from your Neurosign representative (see page ii).



Important: Before use please make sure you have read and understood "3.1 Warnings & Precautions" on page 26!

Before use the equipment and accessories should be checked for any damage or tampering as below:

- Check the cables for splits/cracks
- Check the pre-amplifier and stimulator pod for cracks in the case and for any signs of tampering

If the equipment is found to be damaged or faulty cease to use immediately and contact Magstim to arrange a repair or replacement.

4.1 System Configuration

The following will take you step-by-step through the software configuration. There is no need to connect the pre-amplifier or stimulator pod at this stage.

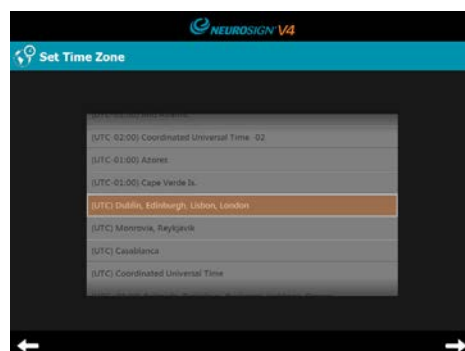
Ensure the device is correctly assembled as per the Neurosign® V4 Assembly Guide.

Ensure the power cable is connected and set the power switch to ON (I) (See page 38). Once the system has initialized you will be taken through the system configuration detailed.

Press the relevant flag to set the required language.

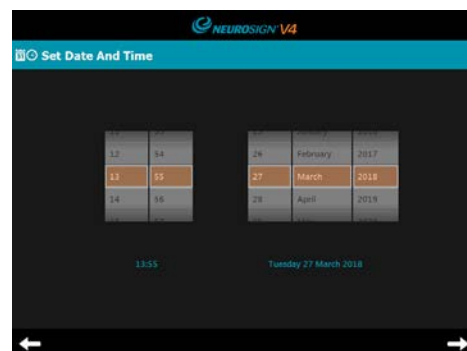


Scroll up or down to select your time zone.
Press → to continue (or ← to go back).



Scroll up or down to set the correct time and date.
Press → to continue (or ← to go back).

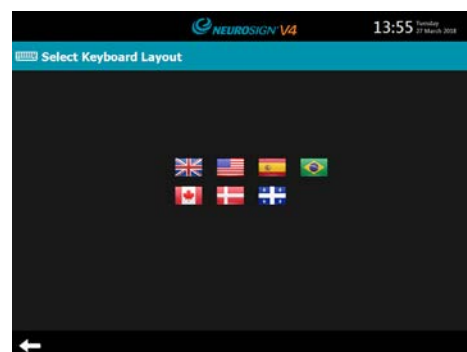
Note: it is important to set these correctly as any captured waveforms will be automatically time and date stamped.



Press the flag to choose the appropriate keyboard layout.



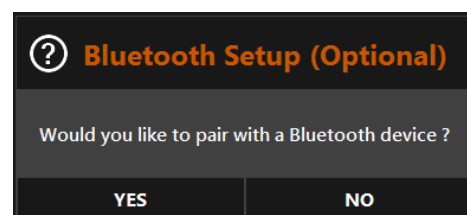
Note: this will affect both the touch screen and external keyboard (if used).



A pop-up box will now appear asking "Would you like to pair with a Bluetooth device?"

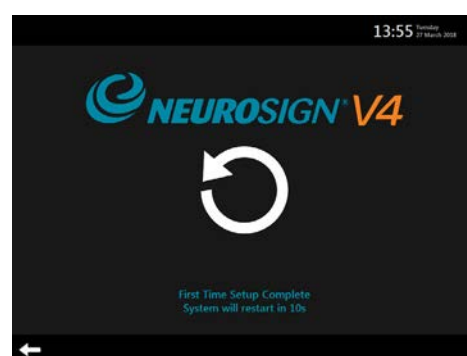
Refer to "c. Bluetooth Setup" on page 63 for information on Bluetooth pairing.

If you press NO, this can be setup at a later time.




Once configuration is complete the following screen will be displayed.

The system will then automatically restart and store the configuration settings. On restart, the monitor will automatically run a connection and audio test (see "b. Connection & Audio Test" on page 40).



The nerve monitor is now ready for use and will present the home screen. Please familiarise yourself with the operating instructions on the following pages before use.

These settings can be changed at any time by selecting  from the home screen. Please see page 61 for more information on the settings menu.

4.2 Connection & Disconnection

Note: Ensure the AC mains lead is connected to the power input socket (19, page 39 before use but do not switch the unit on yet.

First, clean and/or protect all equipment according to hospital procedure (see page 76 for information on cleaning and sterilising).

a. Connection

Once the patient is anaesthetised, the electrodes may be inserted into the relevant locations on the patient.

Plug the electrodes into the corresponding sockets on the pre-amplifier (22, or 22 & 24, right).

Plug the green reference electrode/s into either green socket (23, right).

Plug the pre-amplifier lead (25, right) into the correct socket on the rear of the screen **[A]** (12, page 39).

Attach the pre-amplifier to the side rail of the operating table using the mounting clip.

Plug one end of the stimulator pod lead into the socket on the stimulator pod (29, right) and connect the other end to the socket on the pre-amplifier **[S]** (25, right).

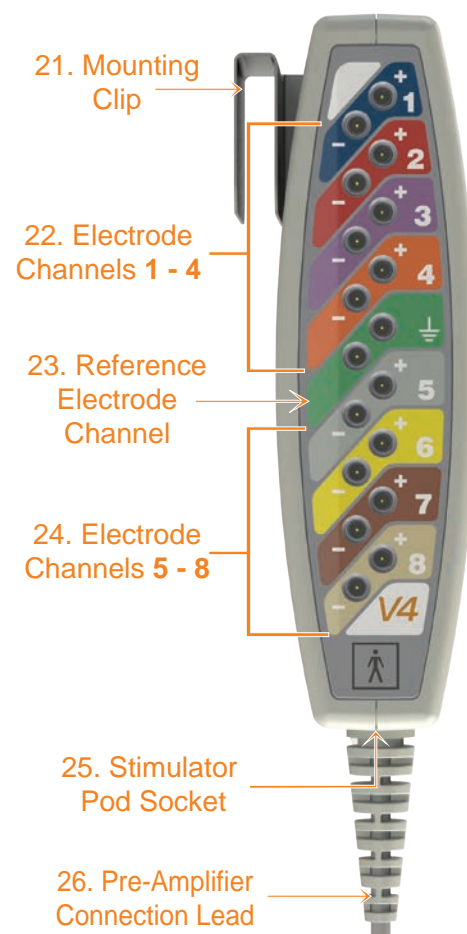
Attach the stimulator pod to the side rail of the operating table (away from the surgical zone) using the mounting clip.

Set the power switch to ON (I) (20, page 39), The monitor will run a connection and audio test (see "b. Connection & Audio Test" on page 40).

Note: It is advised not to drape the patient until after the electrode impedance check.

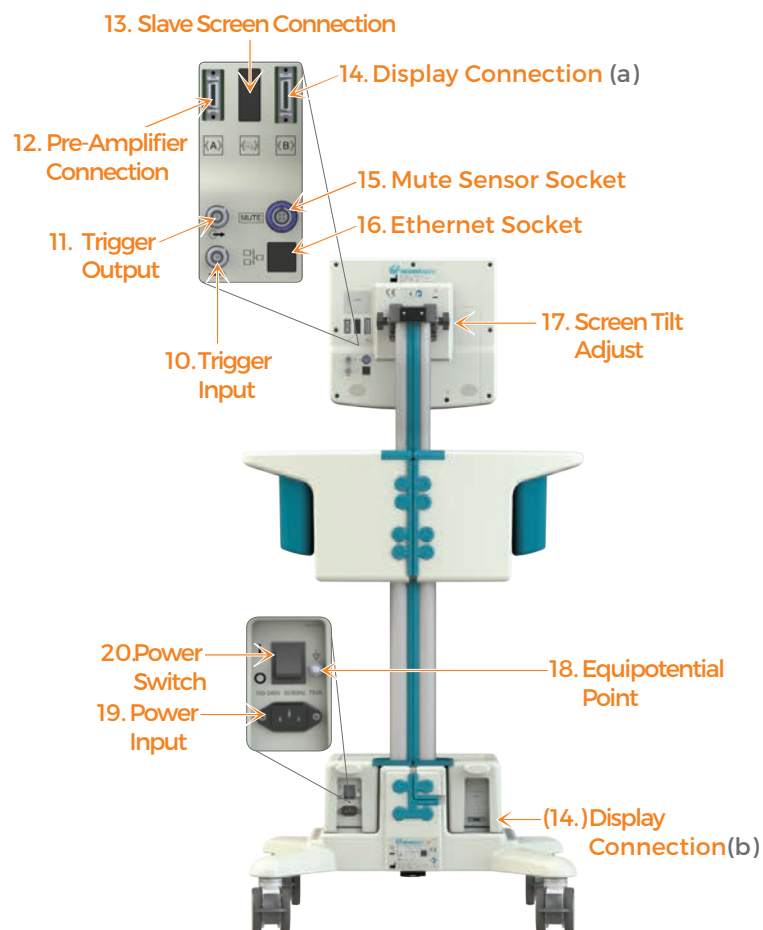
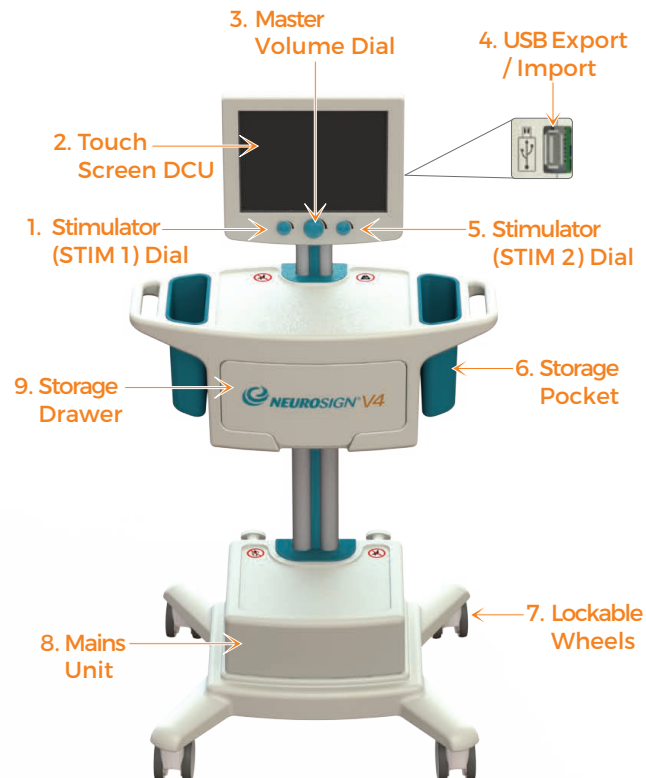
If used, attach the mute sensor to the electrosurgical unit's monopolar pencil lead and plug the mute sensor into the mute sensor socket **[MUTE]** (15, Page 39).

Note: It is advised that you do not connect the stimulating probe/s until required.



8-Channel variant shown





b. Connection & Audio Test

Following connection (page 38) and having set the power switch to ON (I) (20, page 39), the nerve monitor will perform a pre-amplifier and stimulator pod connection test and an audio test as well as a full system function test.

An audible beep will sound to confirm the test.

Once communication with the pre-amplifier and stimulator pod are established, the 'home screen' will appear on the touch screen DCU (page 41).

i. Test failure

If the pre-amplifier fails the connection and audio test during electrocautery use, please disconnect the mute sensor from the rear of the DCU and re-try the test. After the test is complete, an audible beep will sound and the 'home screen' will appear as described above. The mute sensor can then be re-connected to the rear of the DCU (page 17).

If one component fails testing, the option is given to proceed with that component disabled e.g. If the pre-amplifier fails the connection test, a prompt will ask 'Do you wish to proceed with monitoring disabled?'

Note: If audio is disabled following audio test failure; no EMG audio will be output and the following icon will display in place of the master volume:



c. Disconnection

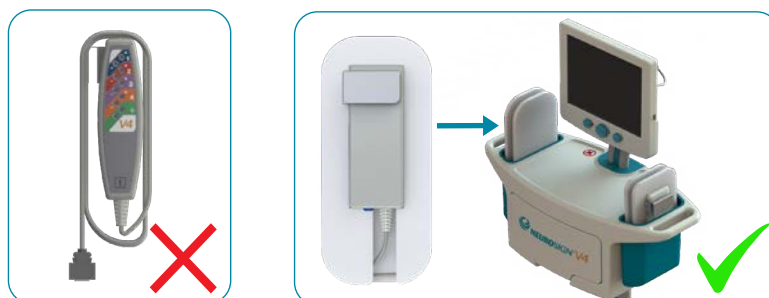
Note: If applicable, ensure that the monitoring session has been stopped and the patient report completed before disconnection, or any data for that session will be lost.

At the end of the operation, once monitoring has been stopped; set the power switch to OFF (O) (20, page 39). If necessary, disconnect the AC mains lead and wrap around the 2 lugs at the rear of the base unit for storage.

Remove and dispose of any disposables used (such as electrodes and probes) and clean and/or disinfect the nerve monitor and accessories if necessary (see page 76).

Disconnect the pre-amplifier and stimulator pod and store in the storage pockets of the nerve monitor, using the storage aids provided as illustrated below. Do not wrap the cable around the pod as doing so may cause damage to the cable.

Note: Once powered down, you must wait a minimum of 30 seconds before starting the system up again to allow the nerve monitor to restart correctly.



4.3 Adjusting The Screen Tilt

The angle of the screen may be adjusted by loosening the screen tilt wheels on the either side of the rear of the screen (right). Re-tighten the wheels to secure your desired angle.



4.4 Home Screen

Ensure you have correctly connected the device and that the device is switched on (see "4.2 Connection & Disconnection" on page 38).

Once the system is fully initialized the home screen (below) will be displayed.

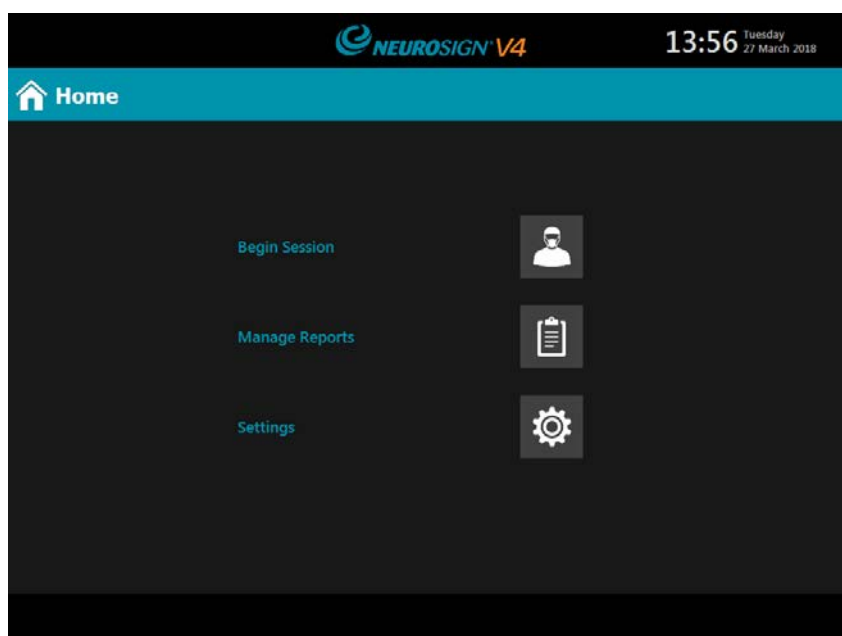


Figure 4.1. Home screen

In subsequent uses, the option is given to restore the last session (below), with a description of the profile and procedure used.

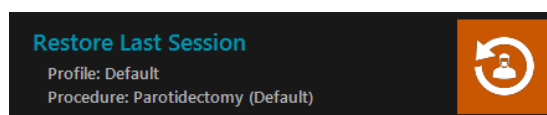


Figure 4.2. Restore last session

Selecting this will re-load the same procedural setup used before the nerve monitor was switched off. If this was a personalised procedural setup, the surgeon profile password will be required. This is only available if the connected pre-amplifier can support the last procedure performed.


Note: The 'restore last session' function will restore the procedural setup only and not the patient details, report or event logs. A new patient report must be created with each use.

4.5 Quick Start Session (default)



Patient Reports

Patient reports are not available in the default profile. In order to save patient reports a surgeon profile must be created (see "a. Profile Management" on page 48).

A surgeon profile will also allow custom procedure settings to be saved.

- On the **Home screen**, select 
- Select **Default** and press ➡
- Select a surgical procedure and press ➡
- Press Ω to perform the **electrode impedance** check

(See "j. Impedance Check" on page 47)

- The patient can now be draped.
- Press  to begin monitoring
- Press  to end monitoring

Note: In default mode, procedure settings can be altered via the monitoring menu (page 44) but the setting cannot be saved.

4.6. In Surgery

The active monitoring screen is displayed when monitoring is active (i.e. during a surgical procedure). The screen will be automatically adapted to accommodate the channels used. The 4-channel monitoring screen is shown below.

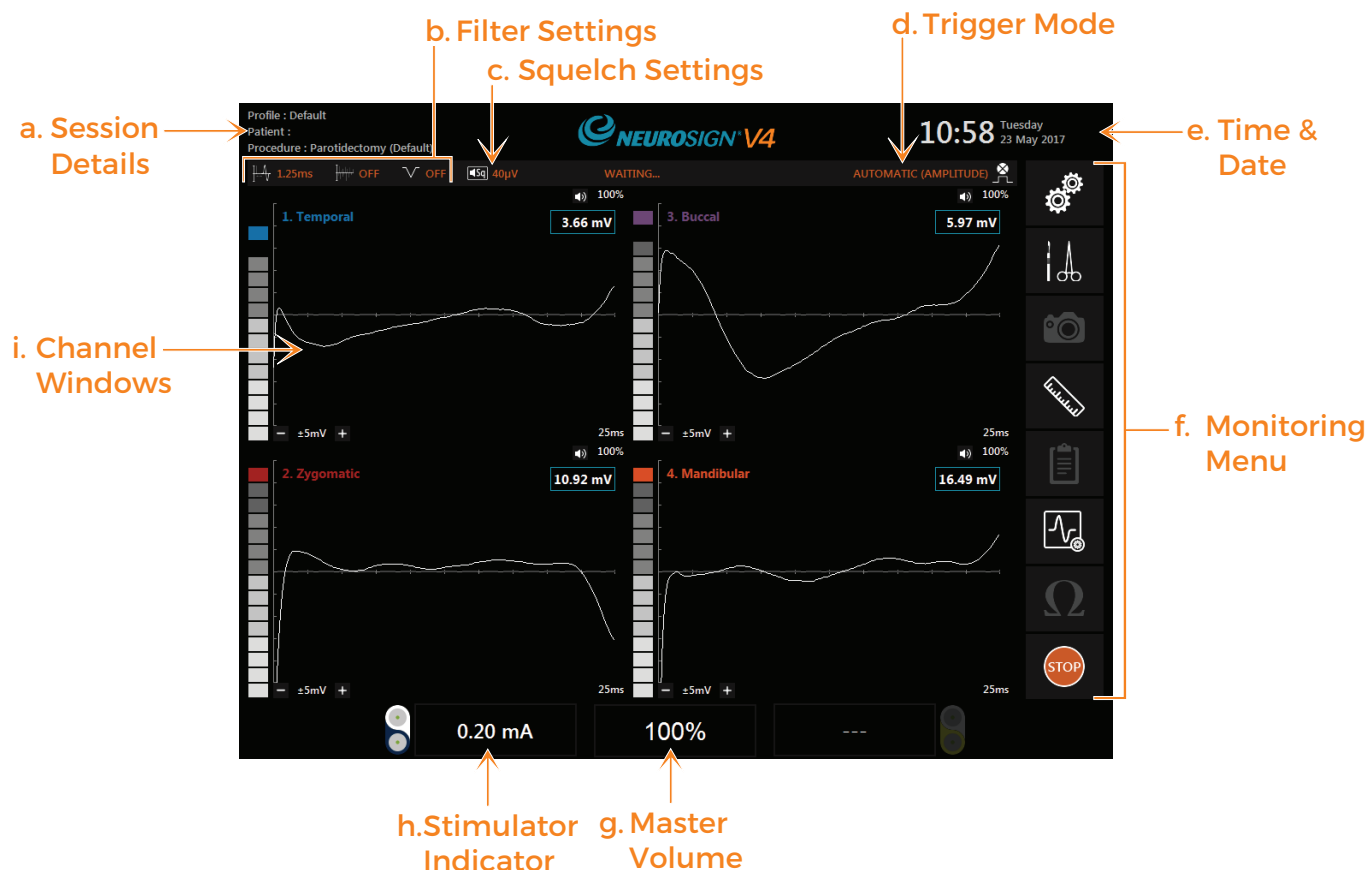





Figure 4.3. Active monitoring screen - 4-Channel Procedure

a. Session Details

The surgeon profile, patient name and procedure setup name are displayed in the top left-hand corner.

b. Filter Settings

This shows the current settings for:

 Artefact rejection,  Stimulator Artefact Rejection (SAR),  Notch filter. For more information see "iv. Filter settings tab" on page 52.

c. Squelch Settings

This shows the current squelch settings. For more information see "i. Squelch" on page 63.

d. Trigger Mode











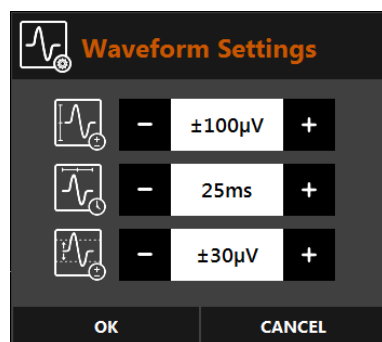
This shows the current trigger mode setting. For more information see "iii. Waveform setting tab." on page 51.




e. Time & Date

The current time and date are displayed in the top right-hand corner.

f. Monitoring Menu

The monitoring menu can be found on the right of the monitoring screen,

	HOME	Press to return to the home screen (available when monitoring is not active).
	SYSTEM SETTINGS	When monitoring is active, this is shown in place of the home button and will give the option to change the system settings (see page 62).
	PROCEDURE SETTINGS	Access to the procedure settings menu (see "b. Custom Procedure" on page 49 for more information).
	SCREEN CAPTURE	Press this at any point in the procedure to perform a screen capture of the waveforms and latency cursors, if shown. This will be automatically saved. Events must be captured and annotated whilst monitoring is active. Not available in default mode, see page 42
	LATENCY CURSORS	Show or hide the latency cursors. Latency cursors can be dragged to any point on a waveform, the values at that point will be shown at the top of the channel window.
	PROCEDURE REPORT	View the current procedure report, including the patient details, events / screen captures and the procedure details. The option is provided to add notes to the procedure or screen capture. Notes must be added/edited at this stage, as reports viewed later are read-only. See "a. Creating Reports" on page 56. Not available in default mode, see page 42
	WAVEFORM SETTINGS	<p>This displays the Waveform settings window (below).</p> <div data-bbox="520 1671 906 1912">  Waveform scale  Timebase scale  Waveform threshold </div> <div data-bbox="983 1581 1366 1921">  </div> <p>For more information see "iii. Waveform setting tab." on page 51</p>

	IMPEDANCE CHECK	See "j. Impedance Check" on page 47.
	START	Press to begin monitoring the procedure.
	STOP	Press to end monitoring the surgery.

g. Master Volume

The master volume level is shown at the bottom of the screen, in the centre. You can adjust the master volume using the master volume dial (3, page 16) found below the master volume display.

i. Mute

To mute all channels, press and hold the master volume control for 2 seconds. The master volume display will then show the following:



To un-mute all channels, either press and hold the master volume control for 2 seconds, or rotate the dial to increase the volume.

h. Stimulator Indicator

The stimulator current/voltage is displayed at the bottom left of the screen. Adjust the stimulator current/voltage using the left stimulator dial (1, page 16).

i. Stimulator confirmation

When the stimulating probe is used, the stimulator indicator will change to green (as below) and a warble tone will sound to confirm that the set current/voltage has been applied. This shows that the probe is working correctly and that the set stimulus has been applied.



During a continuous stimulation period greater than 1 second, a single warble tone will sound. The maximum rate at which warble tones will sound is twice per second.

If the stimulator indicator does not change colour the probe has not delivered the required stimulus.

The stimulus must flow through both the probe and tissue for the indicator to confirm. If the tissue is dry and the stimulus is set at a high level, the actual current/voltage flowing may be less than the stimulus set and as a result the indicator will not confirm. For more information on possible causes see "Trouble shooting" on page 65.

Note: When a mute sensor is connected and active, the stimulator confirmation will not be reported.

i. Channel Windows

There is a window for each active channel.

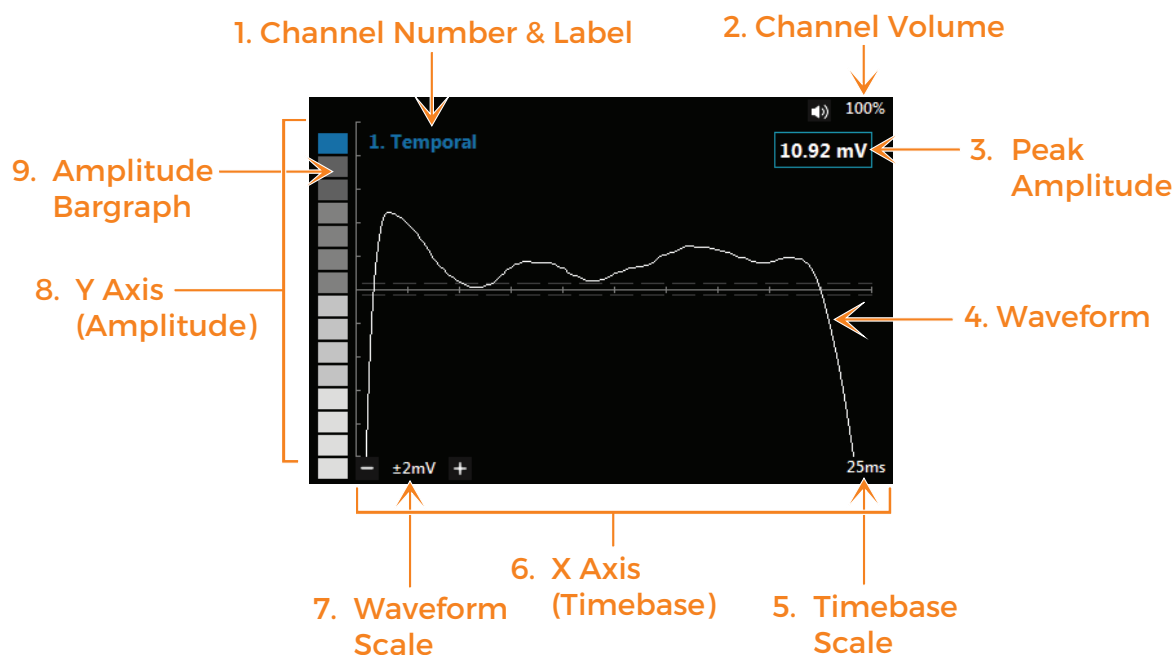


Figure 4.4. Single Channel Window

1. Channel Number & Label

The channel number and label are shown in the top left of each channel window.

2. Channel Volume

The channel volume (%) is shown in the top right of each channel window. You can change the individual channel volume by pressing here.

If set to 0%,  will be displayed to indicate the channel is muted.

3. Peak Amplitude



The peak amplitude of the displayed waveform.

4. Waveform

The displayed signal which has exceeded the waveform threshold.

5. Timebase Scale

This sets the scale of time currently displayed on the screen (X axis).

To adjust the scale press  in the monitoring menu, then press + or - to adjust the timebase scale .

6. X Axis (Timebase)

The timebase is shown along the X axis. The set timebase can be seen on the timebase scale (5)

7. Waveform Scale

The set waveform (amplitude) scale. This scale alters the sensitivity of the waveform display. Increasing the scale reduces the visible amplitude of the waveform.

Press the + or - to adjust the scale.

8. Y Axis (Amplitude)

The Y axis shows the amplitude. The set amplitude can be seen on the waveform scale (7)

9. Amplitude Bargraph

A bargraph representation of the amplitude. The top (coloured) segment remains lit for a period of time which can be defined in "b. System Settings" on page 62.

j. Impedance Check

Once the electrodes have been connected and the procedure is setup, the impedance can be checked before the procedure begins;

- From the Monitoring menu (page 44), Press Ω ,
- An indicator will show to the left of each channel window as can be seen below.

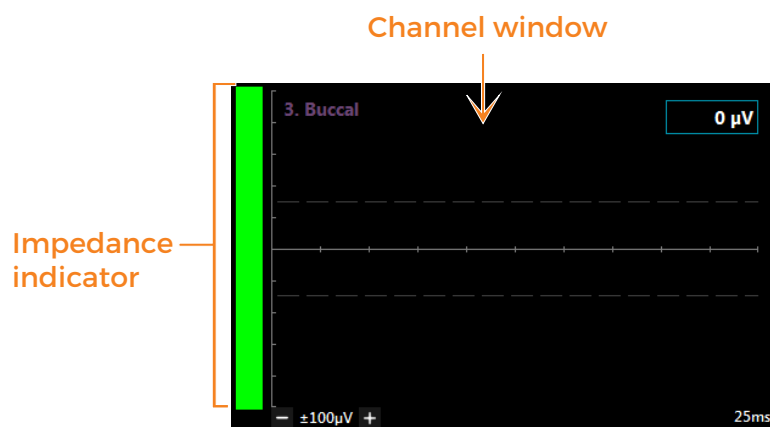






Figure 4.5. Channel Window - Impedance Check


-  Green indicates the impedance is good.
-  Amber indicates the impedance is adequate, but not ideal.
-  Red indicates the impedance is poor.

- A good impedance level should always be expected. If impedance is not good, check the electrodes and reposition until the indicator shows green.
- Once you have checked the impedance, press  to begin monitoring.

4.7 Advanced Features


a. Profile Management



From the home screen press  to access the profile management screen. This menu provides the following options to manage the surgeon profiles;

i. New surgeon profile



- Press 
- Enter a name for the profile.
- Enter a unique password for the profile.

The password must contain a minimum of 6 characters.



- Once complete press .

Note: Due to patient data protection, **passwords are non-recoverable**. Service representatives are not able to recover profiles or the patient data associated with them. Unfortunately if a password is forgotten, that profile will be inaccessible and a new profile should be created.

ii. Edit profile

- Select a profile




- Press 
- Enter the profile's password.
- Once changes are complete, press .

iii. Delete profile




Once a profile is deleted it cannot be recovered!

Note: Deleting a surgeon profile will also permanently remove all patient data associated with that profile. Reports **must** be exported before deleting the profile, see "d. Exporting Reports" on page 59.

- Select a profile and press  to delete the profile from the system.
- Enter the profile password.
- Press 'YES' when prompted to **permanently** delete the profile and any associated records.

b. Custom Procedure

Select or create a surgeon profile (see "a. Profile Management"). The procedure management screen will then be displayed.

- Select a default procedure setup and press  to duplicate that procedure. Type in a name for this new procedure setup and press OK.
- This new procedure setup can now be edited by pressing .
- To edit an existing procedure setup select the procedure and press  (a default procedure setup cannot be edited and should be duplicated first).

Note: Procedures shown with the symbol  are not supported by the connected pre-amplifier, see page 54.

The procedure settings menu will now be displayed (See c. Procedure settings).

c. Procedure Settings

i. Channel settings tab

- Toggle each channel ON (✓) or OFF (✗).
- Select a label for each channel by pressing ← and → to scroll through the alphabetical list. Default nerve branch labels are built into the software.

• New label

Note: Once a label is created it cannot be removed.

- Press  to create a custom label for the channel.

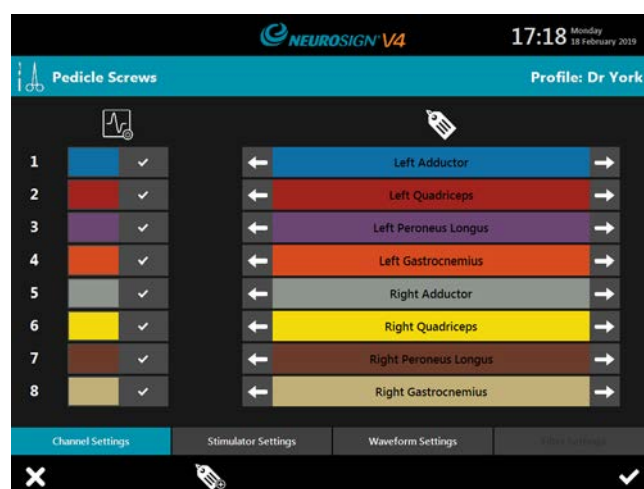






Figure 4.6. Channel settingstab - 8-Channel Procedure.

- Type in a channel label and press 'OK'.
- This new channel label can now be found by scrolling through the alphabetical list.
- Once the channels are labelled press , then select the next tab.
- Press  at anytime to finish making changes and proceed straight to monitoring.

ii. Stimulator settings tab

• Stimulator mode

-  Constant current
-  Constant voltage

- **Initial** - Set the starting stimulation current for the procedure.
- **Maximum** - Set the maximum stimulation current for the procedure.

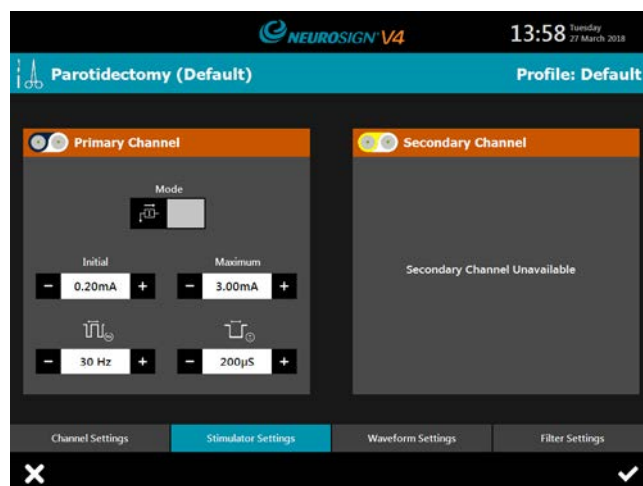


Figure 4.7. Stimulator settings tab

For safety reasons, default procedures have built-in maximum values that cannot be exceeded.



- **Trigger frequency**  - Set to either 30Hz or 3Hz.
- **Pulse Width**  - Default 200µs.

This should not be adjusted unless the consequences are clearly understood. The pulse width will always default back to 200µs.

It is advised that you contact the Magstim Company Ltd. for further information before changing the pulse width.

• Secondary channel

Not currently available. Contact the product enquiries team for more information.

- Once the required changes are made, press , then select the next tab.
- Press  at anytime to finish making changes and proceed straight to monitoring.

iii. Waveform setting tab.

• Display settings

The following procedure values can be adjusted:



Waveform scale - Adjust the size of the amplitude signal displayed on the screen (y axis).



Timebase scale - Adjust the amount of time displayed on the screen (x axis).



Waveform threshold - Set by default to 30 μ V.

Any waveform data below this setting will not be displayed. Increase this setting to reduce the amount of data displayed. Audio signals are not affected.

• Trigger Mode Settings

There are 5 trigger modes available;

Amplitude - The waveform screen is triggered by the amplitude of the signal. Any signal over the waveform threshold value (default 30 μ V) will be displayed on the screen. As the waveform screen is triggered by the amplitude, any electrically stimulated response may appear anywhere within the channel window, if the amplitude of the signal is greater than the set threshold value.

Stimulator - The waveform screen will trigger on the first confirmed stimulator pulse (see "i. Stimulator confirmation" on page 45) which is followed by a signal over the waveform threshold value (default 30 μ V). This means that when using a stimulating probe, the latency of the waveform can be captured and measured.

Automatic - This is the default trigger setting. When the stimulator is not being used the automatic setting acts like the amplitude trigger. If the stimulating probe is used, the automatic setting acts like the stimulator trigger.

Free run - The signal is displayed continuously, with no triggers. This can be useful to see repetitive artefacts or signals.

External - Select this option when an external stimulator is required to be used (e.g. a cortical electrical stimulator). The waveform screen will trigger on the first confirmed external stimulator pulse which is followed by a signal over the waveform threshold value (default 30 μ V).

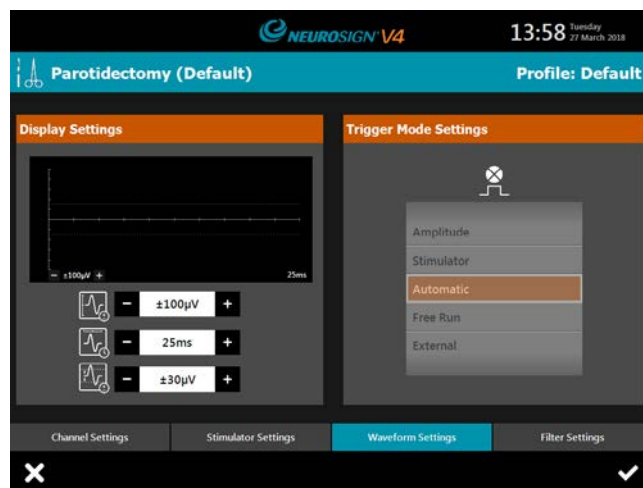





Figure 4.8. Waveform settings tab

- Once the required changes are made, press , then select the next tab.
- Press  at any time to finish making changes and proceed straight to monitoring.

iv. Filter settings tab

Note: This tab cannot be accessed from the main menu and can only be accessed via the monitoring menu (see page 44).

To access the tab:

- From the monitoring menu, press .
- Select the filter settings tab

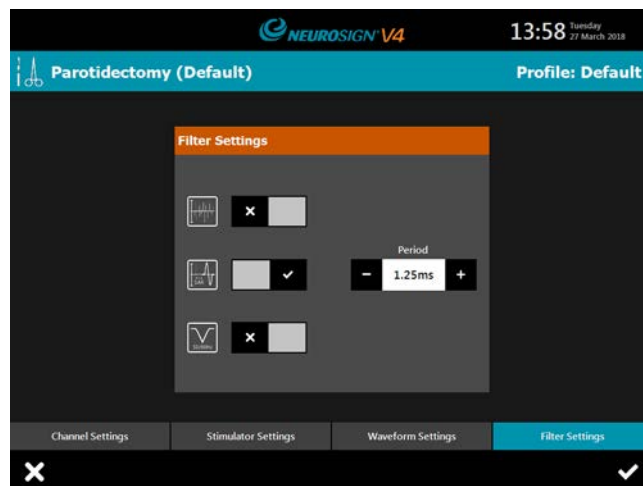


Figure 4.9. Filter settings tab



Artefact rejection filter

This feature eliminates the artefacts generated by metal instruments touching.

- Toggle the artefact rejection filter ON (✓) or OFF (✗),
- Adjust the sensitivity using the (-) or (+).



Stimulator Artefact Rejection (SAR) filter

The SAR filter removes the stimulus 'click' wherever the stimulating probe is touched.

- Toggle the SAR filter ON (✓) or OFF (✗),
- Modify the SAR period using (-) or (+)

The default is 1.25ms - that is, the audio path is disabled for 1.25ms from the time of stimulation. Unless there is an audible clicking noise when the probe is touched to tissue, do not alter this setting.

Note: If the value is increased, the time should always be less than the latency of the recorded signal, otherwise the audio element of the signal will be lost. For example, the recurrent laryngeal nerve has a latency of about 3ms when stimulated in the neck; so do not increase the SAR filter to more than 2.8ms.



Notch filter




- Toggle the notch filter ON (✓) or OFF (✗).

Enable the notch filter to remove mains power interference. The nerve monitor will automatically adjust to the mains supply frequency of the country. Be aware that the filter will also remove EMG signal frequencies centred around the same frequency (50 or 60Hz), therefore some EMG data may be lost, but this may be preferable to any mains-borne noise.




d. Transferring Profiles

If more than one Neurosign® V4 Intraoperative Nerve Monitor is used, the relevant profiles can be copied between machines using USB memory stick (see "a. USB" on page 24).

To export a profile:

- Insert the USB memory stick into the USB socket (4, page 16)
- On the home screen, select .
- Select .
- Select the profile to be copied onto the USB memory stick.
- Once the exporting icon  has gone, the USB memory stick may be removed.

To import a profile;


- Insert the USB memory stick containing the required profile into the USB socket.
- On the home screen, select .
- Select .
- Select the desired profile from the list of profiles stored on the USB memory stick.
- Once the importing icon  has gone, the USB memory stick may be removed.

4.8 Reconfiguring Channels

a. Reconfiguring Channels Mid-Surgery

In some cases it may necessary to reconfigure the procedure channels mid-surgery. The process for this is described below.




To re-configure the channels mid-surgery:

- From the monitoring menu, press .
- Select the Channel Setting tab.
- Refer to "c. Procedure Settings" on page 49 to reconfigure you channels.

b. Configuring an 8-channel Procedure For a 4-channel Pre-Amplifier

This functionality may be used when you wish to configure an 8-channel procedure before surgery, which is not supported by the connected 4-channel pre-amplifier as standard.

Note: In cases where the monitoring is active, follow the instructions in section 4.9.

- Select or create a surgeon profile (see "a. Profile Management"). The procedure management screen will then be displayed.
- Toggle 'Include Unsupported Procedures' ON (✓) at the top of the screen.
- Unsupported procedures can now be seen with the  symbol.
- Select the desired procedure and press  to duplicate that procedure. Type in a name for this new procedure setup and press OK.
- This new procedure setup can now be edited by pressing .
- To configure the new procedure for use with the connected pre-amplifier, refer to "c. Procedure Settings" on page 49 to reconfigure your channels.

4.9 Pre-Amplifier Replacement

To change the pre-amplifier mid-surgery do not press stop to end monitoring. If the pre-amplifier is changed mid-surgery to a higher capacity (i.e. 4 to 8) transfer the electrodes to the corresponding sockets, the channels do not have to be reconfigured.

If the pre-amplifier is changed mid-surgery to a lower capacity (i.e. 8 to 4) the screen below will be shown:

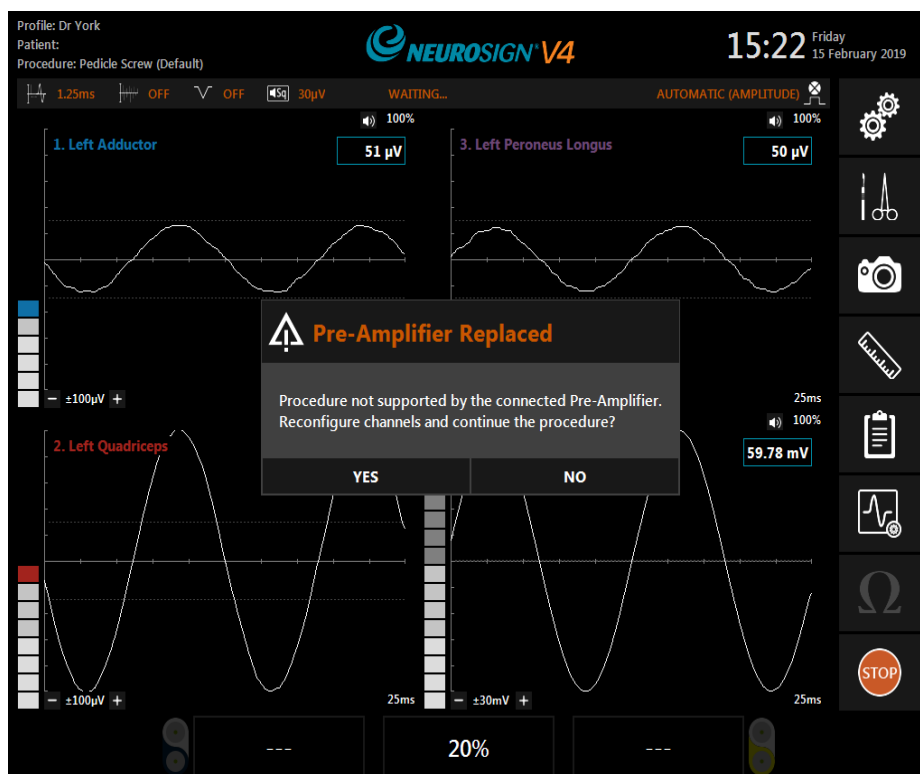


Figure 4.10. Monitoring - Pre-Amplifier Replaced


- In this case it is not necessary to match the channel colours. Instead connect the required electrodes into any available channel on the pre-amplifier. The reference electrode/s (green) must be transferred to the reference electrode channel.
- Connect the pre-amplifier and press 'YES' to reconfigure the channels from the channel settings tab (see "c. Procedure Settings" on page 49 to reconfigure your channels). Do not stop monitoring.
- Press 'NO' to end the procedure and exit the monitoring screen.

4.10 Patient Reports

a. Creating Reports

Note: Patient reports are not available in the default profile. In order to save patient reports a surgeon profile must be created (see "a. Profile Management" on page 48).


Reports can only be created from the active monitoring screen.

- From the monitoring screen, press  to begin monitoring
- Press 'YES' when prompted to create a patient report.

If 'NO' is selected, the user will be prompted again when the monitoring session is ended.

- Press  to enter the Patient Name, Date of Birth, and Patient ID.

Note: in order to save and access surgery reports, the patient details **must** be entered.

- A procedure summary can now be added in the procedure summary box (e.g. Exploration of right ear for cholesteatoma).
- Press  to save the settings.

b. Events/Screen Captures

Note: Events must be captured and annotated before the monitoring screen is exited. Once the monitoring screen is exited the report cannot be changed, annotated or added to.


• Capture a time-stamped event


- From the monitoring menu, press .

This will take a screen capture of the waveforms and any active latency cursors shown which will be saved to the patient report. Notes must be added before monitoring is stopped.

• Add notes

See "i. Procedural report screen" on page 58 for an explanation of the report screen






- From the monitoring menu, press .
- Under event selection, select the desired event to annotate.

- Press the event note box.
- Enter the desired notes.
- Pressing the event note box again to exit.
- Once the required changes are made, press  to exit the report screen.


c. Manage Reports

View previously recorded procedure reports via the Procedural report screen ("Figure 4.11. Procedural report screen" on page 58).

Reports can only be edited before the monitoring session is exited by pressing  from the monitoring menu. Reports accessed from the report management screen are **read only**. To access the report management screen;

- From the home screen press 
- Scroll up or down under the Surgeon , Procedure , date  and time  fields to select the required surgical report.
- A preview of the procedure information is displayed at the bottom of the screen.

Note: Patient information will be hidden until the profile password is entered. To preview patient information, press on the procedure information box. When prompted, enter the password and press 'OK'.

- Press the  to view the report,
- Enter the profile password (if not already entered) and press OK.

i. Procedural report screen

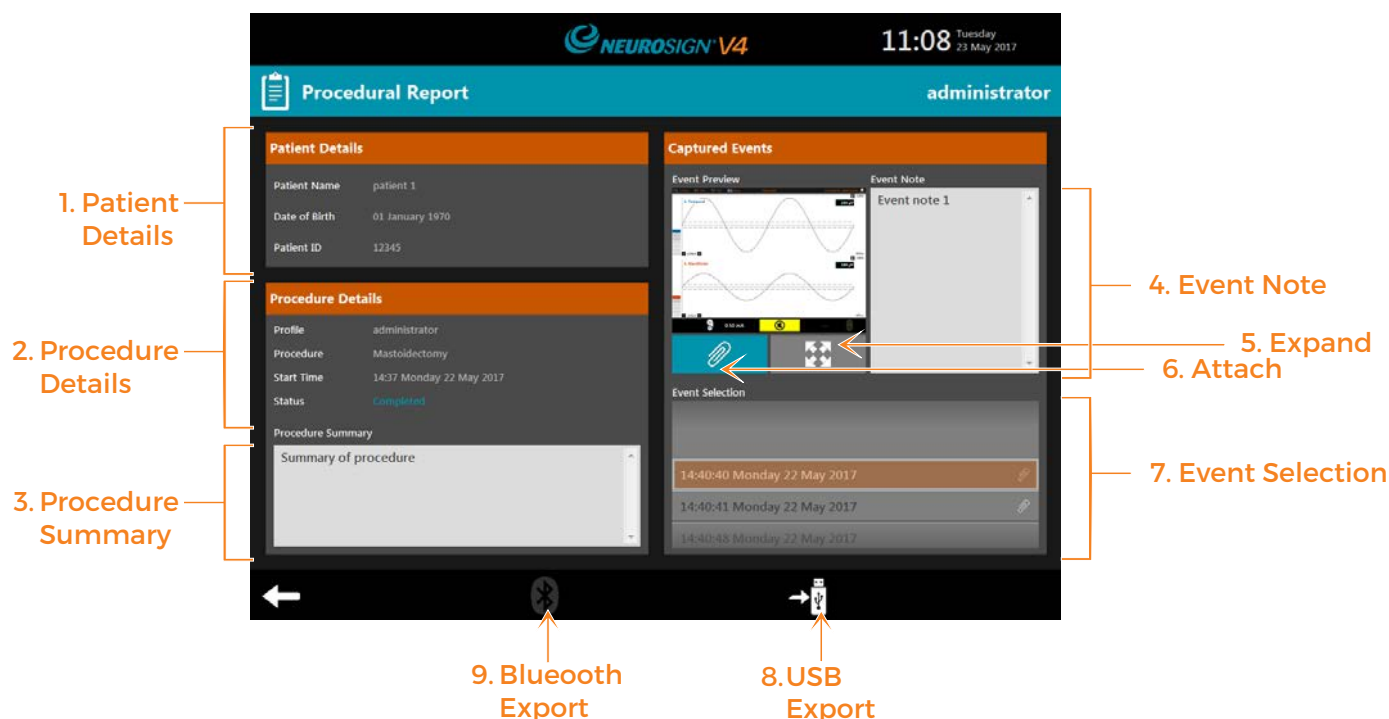


Figure 4.11. Procedural report screen

1. Patient Details

View the patient's name, date of birth and ID number.

2. Procedure Details

Review the procedure details.

3. Procedure Summary

This is where the procedure summary will appear if entered during monitoring.

4. Event Note


The event note for the selected event if entered during monitoring.

5. Expand

See the selected event in a larger view.

6. Attach

Attach the selected event to the patient report for exporting.

Only attached events will be exported along with the report. Attached events show  next to them.

7. Event Selection

Choose from the list of captured events to view, add notes and attach events.

8. USB Export

See "d. Exporting Reports" on page 59. If no USB memory stick is found this icon will be greyed out,




9. Bluetooth Export

See "d. Exporting Reports" on page 59. If no paired Bluetooth devices are found this icon will be greyed out (as shown).






d. Exporting Reports

Reports can be exported in order to archive, view or print from another device.

Captured events must be attached to procedure report before exporting. Only attached events will be exported with the procedure report.

- From the Home screen, or monitoring menu, press 
- Select the desired report (if accessed from the home screen),
- Press  to attach the selected event to the report (attached events show  next to them).
- Choose to **i. USB Export** or **ii. Wireless Export** your report below.



i. USB export (see "a. USB" on page 24).

- Insert the USB memory stick into the USB port ([4](#), page 16)
- Press  to export to the USB memory stick.
- Select the required file type:   
- Once the importing icon  has gone, the USB memory stick may be removed.

ii. Wireless export

Warning: Wireless export is not intended to be used when monitoring mode is active.



Note: Wireless export is only available to devices already paired with the nerve monitor. For information on Bluetooth pairing, see "c. Bluetooth Setup" on page 63

- Press .
- Select the desired device from the list
- Press 'OK' to begin the export.
- Check the device for prompts to accept or receive the file (for exact information on receiving Bluetooth files refer to the device documentation).
- Once the exporting icon  has gone, the transfer is complete.

Note: Reports will be encrypted using the surgeon profile password. In order to view the report on the external device, enter the password. If exported as a .pdf, a .pdf viewer is required on the device in order to view the file. For details on exporting a .csv report (tab delimited data), contact product enquiries (page ii).

e. Storage Management

i. Checking storage availability

- From the home screen, press .
- Press .






The system details screen will then be displayed.

Information on available storage (%) can be found under 'Display Unit' (top left), titled 'User Storage Free'.


Low memory: If the user storage is low, surplus reports must be exported to external memory for archiving, see page 59. Once exported the reports can be deleted from the system to increase the available memory (see below).

Note: Whilst it is expected that the internal memory can store in excess of 100,000 events, it is advised that periodic exporting of patient records be carried out at least once a year to protect from accidental data loss.

ii. Deleting reports

- From the home screen press .
- Scroll up or down the Surgeon , Procedure , date  and time  to select the required surgical report.
- A preview of the procedure information is shown at the bottom of the screen.




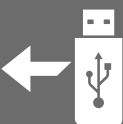
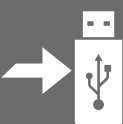



Note: patient information will be hidden until the profile password is entered. To preview patient information, press on the procedure information box. When prompted, enter the password and press 'OK'.

- Press  to **permanently** delete the file, a confirmation dialogue box will be displayed; Press 'YES' to delete the file, or 'NO' to cancel.
- Enter the profile password (if not already entered) and press OK.

Note: To avoid data loss files must be exported before deleting. Once deleted files cannot be recovered. Please check the hospital policy for procedures on archiving and deleting patient data before deleting patient records.

4.11 Settings

- From the home screen, press 



	Regional settings - (see "a. Regional Settings" on page 62).
	System settings - (see "b. System Settings" on page 62).
	Bluetooth setup - (see "c. Bluetooth Setup" on page 63).
	USB profile import (see "d. Transferring Profiles" on page 53).
	USB profile export (see "d. Transferring Profiles" on page 53).
	System details - access the unique device details including system serial numbers and software versions.
	Service panel - for use by authorised service personnel ONLY.
	Service contact - This provides the service contact details

a. Regional Settings



Language settings - Press the relevant flag to set the language.



Date and time settings - Scroll up or down to set the correct time and date. Press  to save you settings or  to cancel.



Time zone settings - Scroll up or down to select your time zone.

Press  to save you settings or  to cancel.



Keyboard setup - press the flag to choose the keyboard layout.



b. System Settings

- Screen brightness, 0-100 (%)
- System volume, 10-100 (%) - Set the maximum volume for the system tones (i.e. keyboard tones, stimulator confirmation) - this does not affect the EMG audio volume.
- Alarm volume, 10-100 (%) - Set the maximum volume for the system alarms - this does not affect the EMG audio volume.
- Bargraph peak hold (500ms-2s) - the amount of time that the bargraph peak will be held for.
- Squelch threshold (off, 10-250 μ V) - see "i. Squelch".
- Squelch volume, 10-90 (%) - see "i. Squelch".

i. Squelch

The squelch feature is designed to reduce the level of unwanted EMG noise, so that the required signals are heard more clearly.

The squelch threshold is the threshold at which the 'squelch' feature is enabled. Any signal below the squelch threshold level will emit at the squelch volume level (below).

The squelch volume is the volume level that any signal below the squelch threshold level will be emitted at.

For example if the threshold is set to 10 μV and the squelch volume at 10, but the master volume dial is set to 100% - any signal below 10 μV will be reduced to 10% volume but any signal above 10 μV will emit at 100% volume.






c. Bluetooth Setup

The nerve monitor is capable of pairing to certain devices via Bluetooth, creating a two-node IT-network, to allow reports to be exported wirelessly. This type of connection could result in unforeseen risks. It is the responsibility of the user to identify, analyse, evaluate and control potential risks every time a device is connected or disconnected.

To export a file using Bluetooth see "d. Exporting Reports" on page 59.





i. Bluetooth pairing

To connect to a Bluetooth device:

- From the home screen, Press .
- Press .
- Ensure that the receiving device has Bluetooth enabled.
- Press  to search for devices.
- Once found, select the device from the list.
- Press  to pair with the device.
- Press  to confirm pairing.

Note: If the device is not found, check that the device is set to 'discoverable' and retry the search. To check that your device is compatible see "iii. Compatible devices" on page 64.

ii. Remove a paired device;

- From the home screen, Press .
- Press .
- Select the device you wish to remove from the list.
- Press   to remove the pairing with this device.
- Press 'OK' to confirm the device is to be removed.

This device will no longer be available for exporting files.

iii. Compatible devices

If exported as a .pdf, a .pdf viewer is required on the device in order to view the file.

The Bluetooth capability of the nerve monitor is currently only available for the following devices:

Desktop or laptop using MS Windows XP, 7, 8, 10, or IOS X

Android / Windows tablet

Android / Windows smartphone

Note: Unfortunately due to software implementation, Apple smartphones and tablets as well as kindle tablets do not currently support the Bluetooth feature of the nerve monitor.



SECTION 5

TROUBLE SHOOTING

5.1 Alarm Overview

The nerve monitor has an intelligent alarm system to determine when to raise an alarm and to keep track of active alarms. There are alarm priority levels, medium and low. There are no high priority alarms. In the event of an alarm, a banner will be displayed across the top of the screen, along with details of the alarm and a tone will sound. The alarm volume is linked to the system volume (see "b. System Settings" on page 62).

In the event of multiple alarms the following logic will be applied:

1. Lower priority alarms will be replaced if a higher priority alarm is reported.
2. Lower priority alarms will not be reported until the higher priority alarm has been acknowledged or cleared.
3. Multiple alarms of the same priority will be cycled through, with each alarm being reported.

Further information on each alarm priority is shown below. More detailed information on specific errors and alarms can be found in "5.3 System Alarms & Messages" on page 67.



Alarm details, Example Instruction



Medium priority alarms display a yellow banner. They may indicate a fault, or provide information needing attention (e.g. If an electrode is disconnected).

Follow the instructions provided in the banner to clear the alarm. If a tick is displayed within the banner (see above), the alarm may be acknowledged by pressing on the tick.



Alarm details, Example Instruction



Low priority alarms display a cyan banner. They provide information the user should be aware of (e.g. If the system is running low on storage space).

Follow the instructions provided in the banner to clear the alarm. If a tick is displayed within the banner (see above), the alarm may be acknowledged by pressing on the tick.


5.2 Non-Recoverable Error

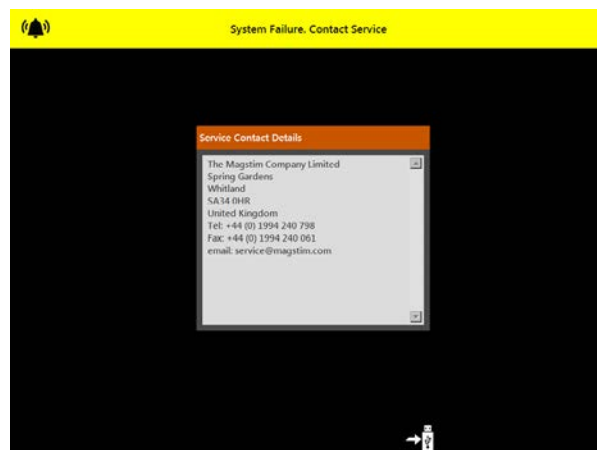
The non-recoverable screen (right) is displayed when the system detects an error/failure condition that impacts the essential performance of the system.

If this screen is displayed during the use of electrocautery, the error condition may be recoverable by switching the nerve monitor off using the mains power switch on the rear of the base, waiting 30 seconds and switching the nerve monitor back on.

If the error persists, this is a non-recoverable error and you must contact the service provider to arrange for a repair.



The alarm banner displays the type of fault detected and the service contact details are displayed on the screen. In order to export the fault details insert a USB memory stick into the external

USB port (right) and press . This information can then be sent to the relevant service provider for further evaluation.















5.3 System Alarms & Messages

Note: DO NOT switch the nerve monitor off & on to clear an error message, unless instructed to do so in the following table:

Banner	Message	Action
	'Check Electrode Connection'	<p>Check the electrode's connection to the patient. Re-insert or replace the electrode if necessary.</p> <p>Check that the electrode lead is correctly connected in the pre-amplifier socket.</p> <p>This alarm may be shown briefly during the use of electrocautery, if the problem persists contact your service provider. Contact details can be found on page ii.</p>
	'Impedance Too Low. Reduce Primary Output Voltage'	<p>Ensure that the stimulating probe is not in contact with a metallic object.</p> <p>Reduce the stimulating voltage by rotating the left stimulator (STIM1) dial clockwise.</p> <p>If the problem persists contact your service provider. Contact details can be found on page ii.</p>

Banner	Message	Action
	' Pre-Amplifier Error. Disconnect and Reconnect'	<p>Disconnect the pre-amplifier lead from the pre-amplifier connection socket on the rear of the screen.</p> <p>Reconnect the pre-amplifier, if after a few minutes the error remains contact your service provider. Contact details can be found on page ii.</p>
	' Stimulator Pod Error. Disconnect and Reconnect'	<p>Disconnect the stimulator-pod lead from the pre-amplifier.</p> <p>Reconnect the stimulator-pod, if after a few minutes the error remains contact your service provider. Contact details can be found on page ii.</p>
	' Stimulator Pod Failure. Disconnect and Contact Service'	<p>Disconnect the stimulator-pod lead from the pre-amplifier and contact your service provider. Contact details can be found on page ii.</p>
	' System Audio Error'	<p>If necessary, you can continue with audio disabled by pressing 'YES' when prompted. See "b. Connection & Audio Test" on page 40 for more information.</p> <p>Alternatively, switch the nerve monitor off using the mains power switch on the rear of the base, wait 30 seconds and switch the nerve monitor back on.</p> <p>Wait for the nerve monitor to perform the connection & audio test. If the error returns contact your service provider. Contact details can be found on page ii.</p>
	' System Error. Cycle System Power'	<p>Switch the nerve monitor off using the mains power switch on the rear of the base, wait 30 seconds and switch the nerve monitor back on.</p> <p>Wait for the nerve monitor to perform the connection & audio test. If the error returns contact your service provider. Contact details can be found on page ii.</p>
	' System Failure. Contact Service'	<p>Contact your service provider. Contact details can be found on page ii.</p> <p>See "5.2 Non-Recoverable Error" on page 67.</p>

Banner	Message	Action
	' System Storage Critical'	<p>Contact your service provider to relieve the system memory log.</p> <p>Contact details can be found on page ii.</p>
	' Connection to Pre-Amplifier Lost'	<p>Disconnect the pre-amplifier lead from the pre-amplifier connection socket on the rear of the screen.</p> <p>Reconnect the pre-amplifier, if the error remains contact your service provider. Contact details can be found on page ii.</p>
	' Connection to Stimulator Pod Lost'	<p>Disconnect the stimulator-pod lead from the pre-amplifier.</p> <p>Reconnect the stimulator-pod, if the error remains contact your service provider. Contact details can be found on page ii.</p>
	' Battery Voltage Low'	<p>Contact your service provider to replace the internal battery. Contact details can be found on page ii.</p>
	EMG Audio is Muted	<p>Un-mute the audio by rotating the master volume dial clockwise, or briefly pressing the dial in.</p>
	' Pre-Amplifier Failure. Disconnect and Contact Service'	<p>Disconnect the pre-amplifier lead from the pre-amplifier connection socket on the rear of the screen and contact your service provider. Contact details can be found on page ii.</p>
	' Report Storage Critical'	<p>The user report storage is full.</p> <p>See "e. Storage Management" on page 60 for details on how to relieve the user storage.</p>


Banner	Message	Action
	' Stimulator Pod Error. Disconnect and Reconnect'	<p>Disconnect the stimulator-pod lead from the pre-amplifier.</p> <p>Reconnect the stimulator-pod, if the error remains contact your service provider. Contact details can be found on page ii.</p>
	' System Error. Cycle System Power'	<p>Switch the nerve monitor off using the mains power switch on the rear of the base, wait 30 seconds and switch the nerve monitor back on.</p> <p>Wait for the nerve monitor to perform the connection & audio test. If the error returns contact your service provider. Contact details can be found on page ii.</p>
	' System Failure. Contact Service'	<p>Contact your service provider. Contact details can be found on page ii.</p> <p>See "5.2 Non-Recoverable Error" on page 67.</p>
	'Report Storage Low'	<p>The user report storage is running low.</p> <p>See "e. Storage Management" on page 60 for details on how to relieve the user storage.</p>
	' System Storage Low'	<p>Contact your service provider to relieve the system memory log.</p> <p>Contact details can be found on page ii.</p>

5.4 Troubleshooting (Physical)

Note: DO NOT switch the nerve monitor off & on to clear an error, unless instructed to do so in the following table:

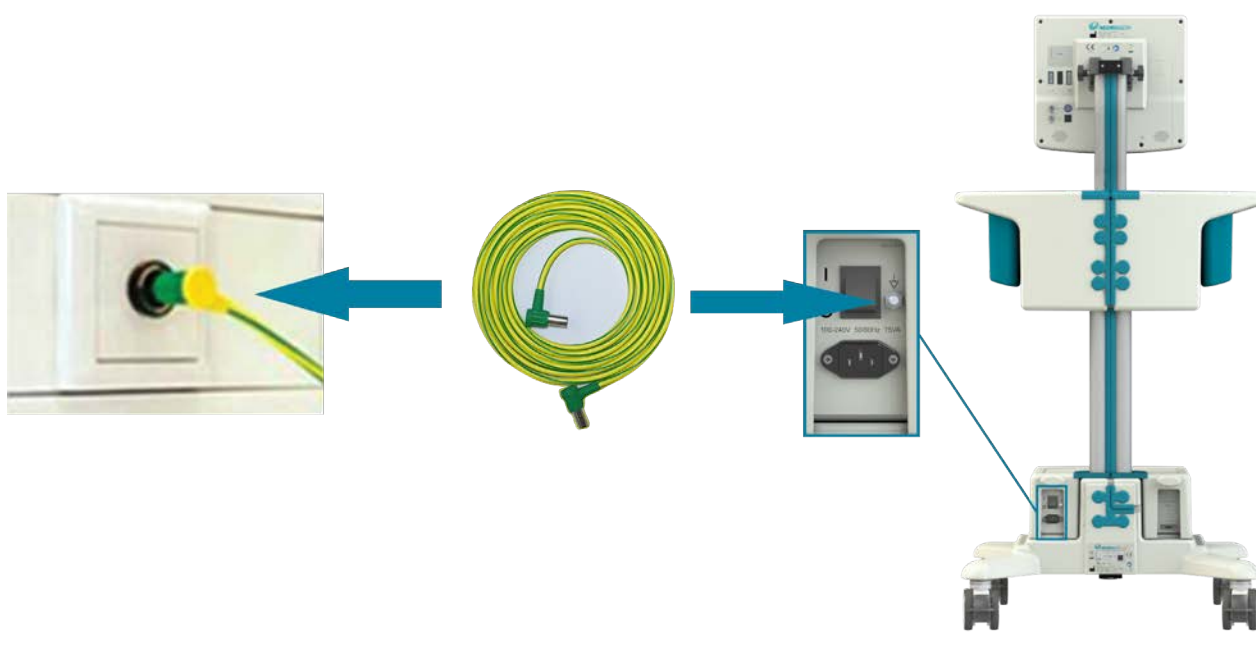
Problem	Cause	Action
Pre-amplifier audio connection test fails during the use of electrocautery	The use of electrocautery during the pre-amplifier audio connection test	Refer to "i. Test failure" on page 40.
Signs of external electrical interference	External electrical interference	Connect the Earthing Cable to the equipotential point. See "5.5 Neurosign V4 Earthing Cable" on page 73.
Blank screen	Lack of power	Check the power lead is correctly installed in the power input socket on the rear of the base and that the power switch and mains plug switch are on.
	Display connection cable is not properly connected.	Check the cable is properly connected and secured at both ends (see "1.4 Rear View" on page 17). If the problem persists please contact your service provider (page ii).
Touch screen not responding correctly.	The touch screen needs recalibrating.	Refer to "6.3 User Maintenance & Calibration" on page 76. If the problem persists please contact your service provider (page ii).
Touch screen not responding at all.	DCU failure	Contact your service provider (page ii).
The stimulating probe fails to stimulate and the current confirm does not light. - see "i. Stimulator confirmation" on page 45	Stimulator fail	Check probe is properly connected to the primary stimulator connection (STIM 1). Replace probe. If the problem persists please contact your service provider (page ii).

Problem	Cause	Action
The stimulating probe fails to stimulate, but the current confirm does light. - see "i. Stimulator confirmation" on page 45	Stimulator fail	<p>Check current level is adequate.</p> <p>Check stimulator pod connection.</p> <p>If the problem persists please contact your service provider (page ii).</p>
Pre-Amplifier Replaced	The pre-amplifier has been replaced mid-surgery for one of a lower capacity.	See "4.8 Reconfiguring Channels" on page 54.
Silence/ Lack of sound.	Sound is muted	<p>Increase the main volume by rotating the master volume dial clockwise.</p> <p>Check the individual channel volume is not muted or too low by looking for the channel volume in the top right of each channel window (see page 46). Press the channel volume and use the slider to increase.</p>
	<p>Silence when stimulating; the device has not detected any voltage in the muscle, the muscle has not contracted.</p> <p>The muscle may not contract for a variety of reasons; the nerve may not be stimulated, the nerve may be damaged or transected, or any neuromuscular block may be too deep.</p>	The surgeon in charge should decide whether or not to proceed with the procedure taking the possible causes into consideration.
	Monitor failure.	If you feel the silence is an indication of a monitoring failure please contact your service provider (page ii).
Waveforms are too large and cannot be clearly seen.	Amplitude scale is set too low.	Increase amplitude scale (see "i. Channel Windows" on page 46).
Waveforms appear and immediately disappear	Waveform threshold is set too low.	Increase the waveform threshold (see "i. Channel Windows" on page 46).

Problem	Cause	Action
<p>Pre-amplifier offline/ lost connection</p> 	<p>The pre-amplifier is either not connected, or there is a problem with the connection.</p>	<p>If you are not currently monitoring you can continue with monitoring disabled by pressing 'YES' when prompted.</p> <p>Alternatively, disconnect the pre-amplifier lead from the pre-amplifier connection socket on the rear of the screen.</p> <p>Reconnect the pre-amplifier, if the error remains contact your service provider. Contact details can be found on page ii.</p>

5.5 Neurosign V4 Earthing Cable

In cases of electrical interference, the earthing cable (PN: 210230) should be fitted to the Neurosign V4 equipotential point, found near the power switch, and to the hospital equipotential wall socket (POAG socket) as below.



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SECTION 6

CARE & MAINTENANCE

6.1 Cleaning & Disinfecting

The nerve monitor and accessories (excluding disposables) are not designed to come into direct contact with the patient. As the nerve monitor cannot be autoclaved or soaked, care should be taken to avoid contamination with bodily fluids.

The nerve monitor, pre-amplifier, stimulator pod and mute sensor, may be wiped cleaned in accordance with hospital protocol (The Magstim Company Ltd. recommends that a lint free cloth moistened with 70% isopropyl alcohol should be used). Care must be taken to ensure the equipment is not soaked and has dried thoroughly before use. The side storage pockets (6, page 16) are entirely removable to allow for easier cleaning. Do not clean or wipe the touch screen with anything abrasive as it will cause permanent damage.

The reference guide sheets may be wiped clean using an isopropyl-moistened cloth but should not be soaked for any length of time.

Disposables such as probes and electrodes are sterile and single use and should be disposed of after use, in accordance with the policy of your facility.

6.2 Storage & Environment

In order to avoid possible damage to, or failure of, the nerve monitor and accessories, the equipment should be kept within the following ranges:

Operational ranges:

Ambient temperature:	5°C to 40°C
Relative humidity:	10% to 80% (non-condensing)
Atmospheric pressure:	70kPa to 106kPa

Transport and storage ranges:

Ambient temperature:	-19°C to 60°C
Relative humidity:	10% to 80% (non-condensing)
Atmospheric pressure :	50kPa to 106kPa

Note: following transportation or storage outside of the operational ranges, allow the unit to acclimatise for a minimum of 3 hours prior to the application of electrical power.

6.3 User Maintenance & Calibration

a. Touch Screen Calibration

Should the touch screen appear not to accurately respond when pressing an area of the screen, it may need to be re-calibrated.

From the home screen, press and hold both the left and right control dials below the screen; after a few seconds the screen will change and a target mark will appear on the screen.

Press and hold the target marks as prompted, until prompted to either accept or cancel the changes.

b. Damage Inspection

Before use the equipment and accessories should be checked for any damage or tampering as described below:

- Check the cables for splits/cracks
- Check the pre-amplifier and stimulator pod for cracks in the case and for any signs of tampering

If the equipment is found to be damaged or faulty discontinue use immediately and contact your local Neurosign® representative to arrange for a repair or replacement.

c. Storage Management

See "e. Storage Management" on page 60 for information on storage management,

d. Battery Voltage

The battery voltage can be found on the system details screen.

To access the system details screen;

- From the 'home' screen, press  and then press 
- The battery voltage can be found under 'Display Unit' (top left).

6.4 Servicing & Device Lifetime

a. Electrical Testing

The nerve monitor and associated accessories must be tested annually for electrical safety in accordance with local regulation or hospital policy. There is an equipotential point fitted near the power switch which may be used for electrical safety testing, or connected to a theatre equipotential earthing system.

Note: Once powered down, you must wait a minimum of 30 seconds before starting the system up again to allow the nerve monitor to restart correctly.

b. Servicing

All servicing and repair work must be carried out by The Magstim Company Ltd. or an authorised service personnel designated by the company, Service provider contact details can be found on page ii.

Excepting of those stated in "6.3 User Maintenance & Calibration" on page 76, no user-serviceable parts are found within the Neurosign® V4 Intraoperative Nerve Monitor. Opening the case presents a serious threat of electric shock and immediate risk to the user. Any attempt to remove the security screws will invalidate the product guarantee.

Performance verification should be carried out by service personnel annually, once the guarantee period has expired.

A service manual is available on request for those who have undergone service training on the equipment and to suitably authorised personnel.

Patient data protection and equipment returns.

Due to patient data protection, patient data must be removed prior to return to Magstim®. For details on how to remove the internal SD card, refer to the service manual or contact your service provider / the Neurosign® service department. Contact details can be found on page ii.

If patient data is not removed prior to shipping, the equipment will be returned untouched at the expense of the customer. You will be advised to remove the SD card and then re-ship the equipment.

c. Device Lifetime

The device lifetime/s of the Neurosign® V4 Intraoperative Nerve Monitor and associated accessories are defined as 5 years from the date of shipment, provided electrical safety testing and performance verification are performed as specified.

Spare parts and repairs will be available for 7 years after the last date of sale. Spare parts cannot be guaranteed after this time.

Please contact the Magstim Company Ltd for information on spare parts availability after the expiration of the device lifetime. The company reserves the right to refuse to service or repair equipment outside of the product's lifetime if the general state of the equipment would make repair or servicing uneconomic.

6.5 Packaging & Transportation

If, for any reason, it is necessary to return the nerve monitor or accessories, care should be taken to ensure that the equipment is adequately packaged to prevent damage in transit. Ideally the equipment should be returned in the original packaging. If this, or an adequate replacement is not available, replacement shipping cartons can be obtained from The Magstim Company Ltd.

All equipment must be completely disconnected before shipping. Failure to do so will likely to result in damage in transit.

Note: When returning the nerve monitor or accessories, a decontamination certificate must be included with the equipment and the SD card must be removed (see **Patient data protection and equipment returns** above).

Contaminated items should not be returned to the company without prior agreement. The company reserves the right to safely dispose of any contaminated item and charge the customer for any associated disposal costs, in addition to the supply of new components or accessories.

6.6 Decommissioning



Electrical and electronic waste should not be disposed of in general waste. Consult your local environmental regulations or contact the Magstim Company Ltd. for advice on appropriate disposal.

Note: In order to comply with patient data protection. All patient data should be removed prior to disposal.



SECTION 7

TECHNICAL INFORMATION

7.1 Safety Specification

The Neurosign® V4 Intraoperative Nerve Monitor and its accessories comply with safety standard IEC 60601-1.

a. Classification, protection against electrical shock

With reference to safety standard IEC 60601-1 the nerve monitor and its accessories are classified as:

CLASS I

Equipment must only be connected to supply mains with protective earth. Connection should only be made with the power lead provided with the equipment



Type BF

Applied Parts: stimulating probes, stimulator pod, electrodes and pre-amplifier circuits are electrically isolated from the other parts of the equipment and meet Type BF leakage current limits.

Continuous Mode Of Operation

b. Connection of further equipment

Only equipment that meets the relevant IEC standards and is configured in compliance with IEC 60601-1, should be connected to the nerve monitor.

c. Degree of protection provided by enclosure

The nerve monitor and its accessories are classified as IPX0 (Not Protected), as specialised protection provided against the ingress of liquids is not required.

d. Flammable and combustive environments

The Neurosign® V4 Intraoperative Nerve Monitor and its accessories are not protected from, and should not be used in, the following environments (safety standard IEC 60601-1):

- Flammable anaesthetic mixtures with air, oxygen or nitrous oxide.
- Oxygen rich environments

7.2 Technical Specification

a. Main unit

Screen	15" Colour LCD, 1024 x 768 pixels
Display	
Bar graph range	30µV – 30mV peak to peak
Bar graph resolution	16 segments, logarithmic
Waveform amplitude ranges	±25µV, ±50µV, ±100µV (default) , ±200µV, ±500µV, ±1mV, ±2.0mV, ±5mV, ±10mV, ±20mV, ±30mV

Accuracy	2% of FSD
Waveform time base ranges	12.5ms, 25ms (default) , 50ms, 100ms, 500ms, 1s, 5s, 10s
Accuracy	2% 12.5ms-1s; 5% 5s; 10% 10s.
Time base cursor accuracy	2%
Software	See "7.4. System Details" on page 83
Rotary actuators	3:
Left dial	- Primary stimulator stimulation setting (STIM1)
Right dial	- Secondary stimulator stimulation setting (STIM2)
Centre dial	- EMG response audio volume (Master Volume)
External connections	EMG Amplifier Module (Pre-amplifier) Trigger In Trigger Out – Open Drain Mute sensor USB
EMG Audio	8.4W rms (95dBa @ 1m)

b. Stimulator pod

Primary Stimulator

Operational mode	Constant Current or Constant Voltage
Current ranges	10µA – 10mA, in steps dependent on procedure.
Accuracy	±5%, into 1kΩ load
Voltage	10mV – 10V, in steps dependent on procedure.
Accuracy	±5%, into 1kΩ load
Voltage/current confirm	≥ 85% of set point
Stimulating pulse	Square wave negative going
Width	100µs, 200µs (default), 300µs, 400µs, 500µs
Repetition frequency	3Hz, 30Hz
Probe connections	2

Secondary stimulator

Not currently available - contact the product enquiries team (page ii) for more information.

c. Pre-amplifier

Monitoring channels	Max. 4 (4-Channel Pre-amplifier) Max. 8 (8-Channel Pre-amplifier)
Signal input range	$\pm 5\mu\text{V}$ to $\pm 40\text{mV}$
Common mode rejection ratio	> 90dB (@ 50/60Hz)
Bandwidth	10Hz – 1kHz (-3dB points)
Noise	<20 μV rms (Input referred)
Notch filter	50Hz, 60Hz, off



7.3 General Specification

Power	100V-230V ~50/60Hz; 75VA
Dimensions	790mm wide, 400mm deep, 1600mm high
Weight	24Kg
Maximum load permitted	1.5kg
Total maximum weight	25.5kg
Environmental conditions:	
Operational ranges:	
Ambient temperature:	5°C to 40°C
Relative humidity:	10% to 80% (non-condensing)
Atmospheric pressure:	70kPa to 106kPa
Transport and storage ranges:	
Ambient temperature:	-19°C to 60°C
Relative humidity:	10% to 80% (non-condensing)
Atmospheric pressure :	50kPa to 106kPa

7.4. System Details

The system details screen provides access to all data about the system including the serial numbers, software versions, available storage and battery voltage.

To access the system details screen;

- From the home screen, Press .
- Press .
- The system details screen will be displayed (below).

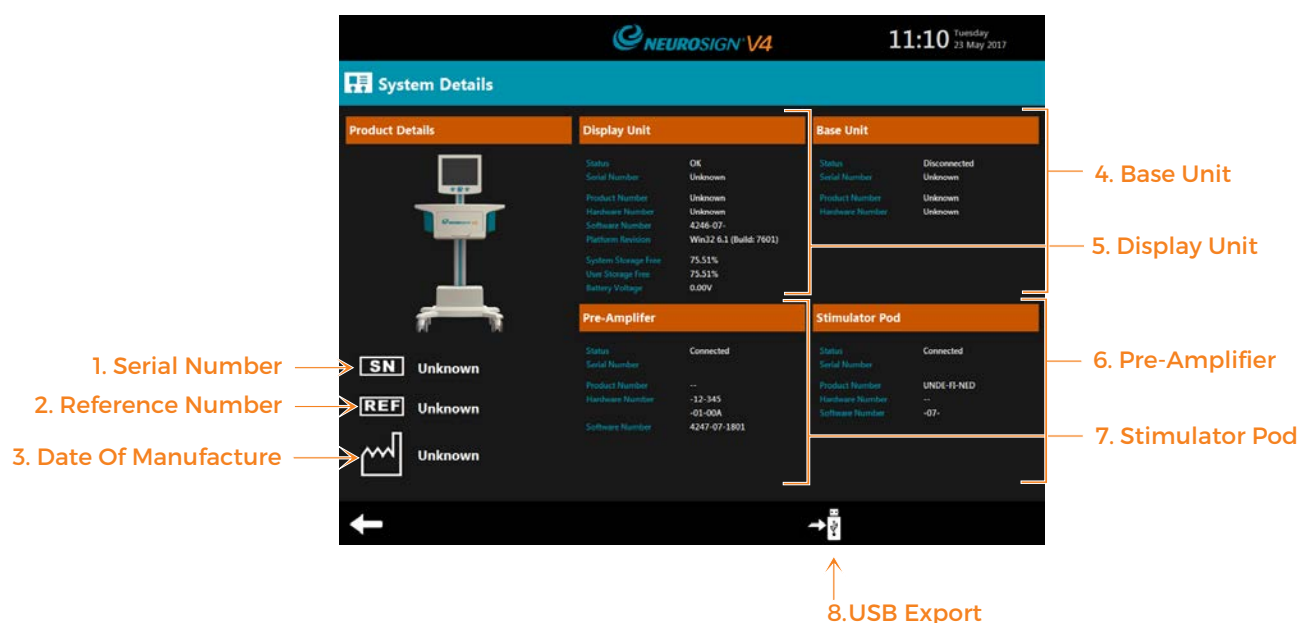


Figure 7.1: System details screen

1. Serial Number

The product serial number.

2. Reference Number

The product reference number.

3. Date Of Manufacture

The date this product was manufactured.

4. Base Unit

The details for the product trolley base (e.g.. status, serial number).

5. Display Unit

The details for the touch screen DCU (e.g.. status, serial number).

6. Pre-amplifier



The details for the Pre-amplifier connected (e.g.. status, serial number).

7. Stimulator Pod

The details for the Stimulator Pod connected (e.g.. status, serial number).

8. USB Export

Export the displayed system details for evaluation:

- Insert the USB memory stick into the USB socket (4, page 16),
- Select ,
- Once the exporting icon  has gone, the USB memory stick may be removed.

7.5 Glossary Of Terms

As an aid to the user, an alphabetical glossary of definitions used in this manual has been compiled that is considered to be beneficial to the user. These terms are written in the context of this manual and may not be absolute.

TERM	DEFINITION
Amplitude	The maximum absolute value reached by a voltage or current waveform - in this context, EMG (see below).
Artefact	Something observed in a scientific investigation or experiment that is not naturally present but occurs as a result of the preparative or investigative procedure
Electro surgical	Surgery performed with electrical devices. The surgical use of high-frequency electric current for cutting or destroying tissue (as in cauterization) - see Electrocautery.
Electrocautery	The cauterization of tissue by means of directing a high-frequency current through a local area of tissue.
Electrode	A conductor through which electricity enters or leaves an object, substance, or region.
EMG	Electromyography (EMG), the electrical activity of muscles.
Monopolar pencil	A form of Electro Surgical Unit (ESU) - see 'Electro Surgical'.
Neurosurgery	Surgery performed on the nervous system, particularly the brain and spinal cord.
Radio Frequency (RF)	Any frequency within the electromagnetic spectrum associated with radio wave propagation.
Stimulating probe	The probe used to stimulate nerve or tissue.
Surgeon profile	The personal profile set up for each surgeon. This saves all of the surgeons settings and preferences for quick access.
Unmyelinated nerve	The unmyelinated nerve pertains to any of the nerve cells without myelin sheath (a sheath involved in the rapid conduction of action potential). Compared to myelinated nerves, unmyelinated nerve cells are slower in conducting impulses.
Waveform	A curve showing the shape of a wave at a given time - in this context used to illustrate the EMG signal.

7.6 Document Version/s

Current editions

Document	Description	Language
NOP08-EN	Neurosign® V4 User Manual	English (UK)
NOP08-US	Neurosign® V4 User Manual (US Variant)	English (US)
NOP08-PTbr	Manual do usuário do Neurosign®V4	Português (Brasil)
NOP08-ES	Manual del usuario de Neurosign® V4	Español
NOP08-FRca	Manuel d'utilisation Neurosign® V4	Français (Canadien)

Supporting documents

Document	Description	Language
NOP18-EN	Neurosign® V4 Assembly Guide	English (UK)
NOP19-EN	Neurosign® V4 Reference Guide	English (UK)
NOP20-EN	Neurosign® V4 Service Manual	English (UK)



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