THE NEUROSIGN V4

INTRAOPERATIVE NERVE MONITOR

PRESERVING NERVE INTEGRITY

NEUROSIGN® V4

CE
2797

Service Manual

NOP20-EN-03
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magstim®

Company details

Neurosign®

The Magstim Company Limited
Spring Gardens, Whitland,
Carmarthenshire, SA34 0HR

Website: http://www.neurosignsurgical.com

Product Enquiries

Telephone: +44 (0)1994 240798
Fax: +44 (0)1994 240061
E-mail: info@neurosignsurgical.com

Servicing Enquiries

Telephone: +44 (0)1994 242900
E-mail: service@neurosignsurgical.com

Sales Enquiries

Telephone: +44 (0)1994 241111
Fax: +44 (0)1994 242917
E-mail: sales@neurosignsurgical.com

Authorised Representative in the European Community:

Technomed Europe EC REP
Amerikalaan 71, 6199 AE Maastricht-Airport,
The Netherlands

Tel: +31 43 408 68 68

Preface

The Neurosign® V4 Intraoperative Nerve Monitor is a Neurosign Surgical product which belongs to the Neurosign® division of the Magstim Company Limited.

This service manual has been written to provide information on how to service and maintain the Neurosign® V4 Intraoperative Nerve Monitor.

!Note: Any modifications, repairs or servicing of the products, named in this manual or otherwise, not carried out by The Magstim Company Limited or persons authorised by the company will invalidate the product guarantee.

Within the guarantee period you are advised to contact the Magstim service department for any servicing or repairs. Contact details can be found on page ii.

For more information on the product guarantee see page 9.

Tools required

The following tools may be required in order to assemble, disassemble and service the Neurosign® V4 Intraoperative Nerve Monitor.

Pozi drive No. 1

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Contents

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Devices covered

This service 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: Full information regarding consumables such as stimulating probes and electrodes are not included in this document. Documentation regarding consumables 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 Limited 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 "4.4 Servicing & Device Lifetime" on page 31 for more information.

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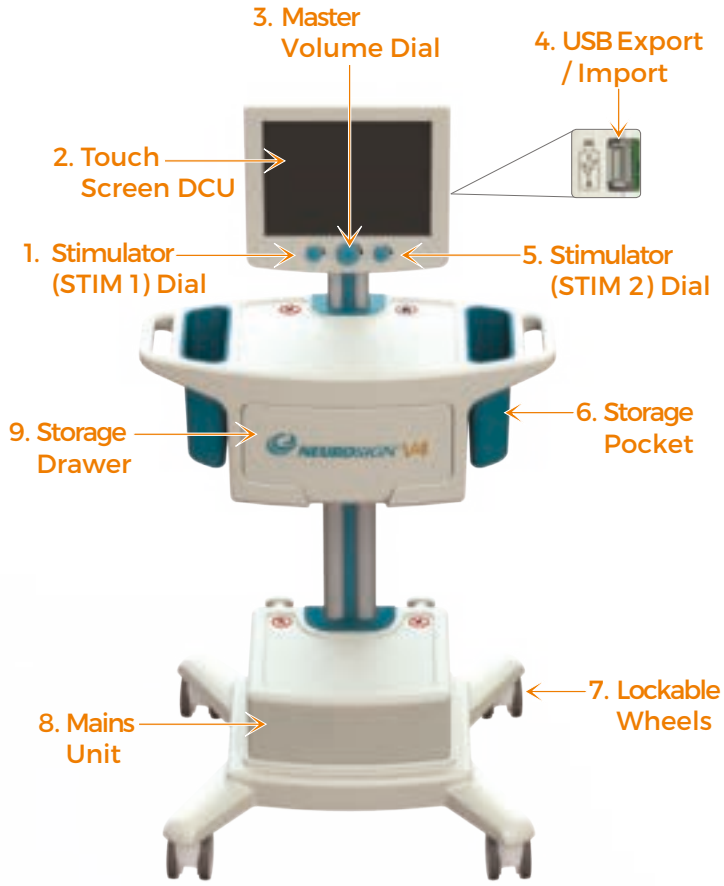
SECTION 1

PRODUCT OVERVIEW

1.1 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

5. Stimulator (STIM 2) Dial
Not currently available. For more information contact the product enquiries team (page ii).

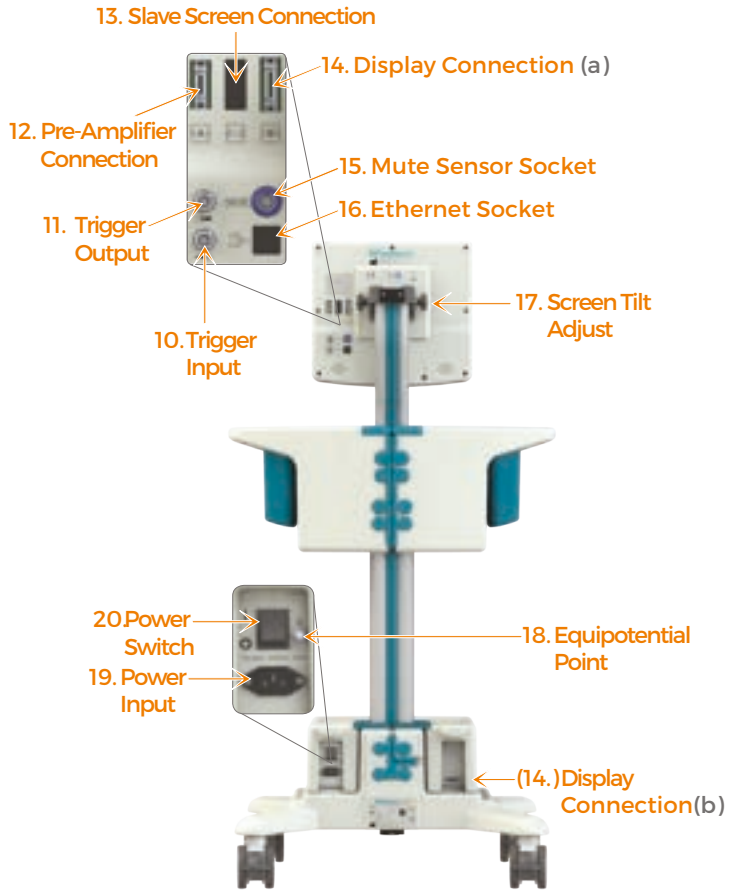
6. Storage Pockets
The nerve monitor houses a 'pocket' on either side of the unit to safely store the pre-amplifier and the stimulator pod. The 'pockets' are fully removable to facilitate cleaning.

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.

1.2 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

Refer to the operating manual for information.

18. Equipotential Point

See "a. Electrical Testing" on page 31

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.

1.3 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.

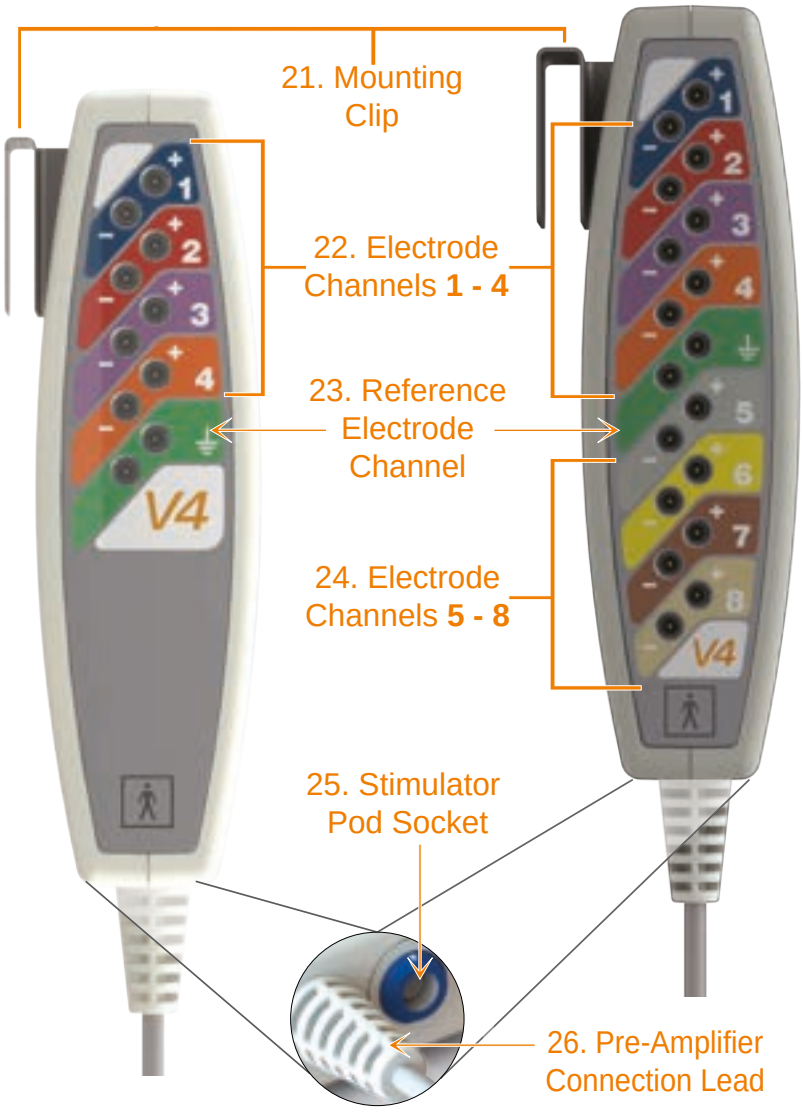
22. Electrode Channels 1 - 4.
The corresponding sockets for channel one (blue), channel two (red), channel three (violet) and channel four (orange).

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.

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 13).



1.4 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 14).

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SECTION 2

WARNINGS & SYMBOLS

2.1 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 "4.3 User Maintenance & Calibration" on page 30, no user-serviceable parts are found within the Neurosign® V4 Intraoperative Nerve Monitor. Please refer to **page 30** 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 securing 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.

2.2 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.

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

DO NOT step.

DO NOT sit.

Maximum load permitted.

Pre-amplifier to touch screen DCU connection - see page 13.

Display connection (touch screen DCU to mains unit) - see page 13.

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

Trigger output socket - see page 13.

Trigger input socket - see page 13.

Mute sensor socket - see page 13.

Ethernet socket - see page 13.

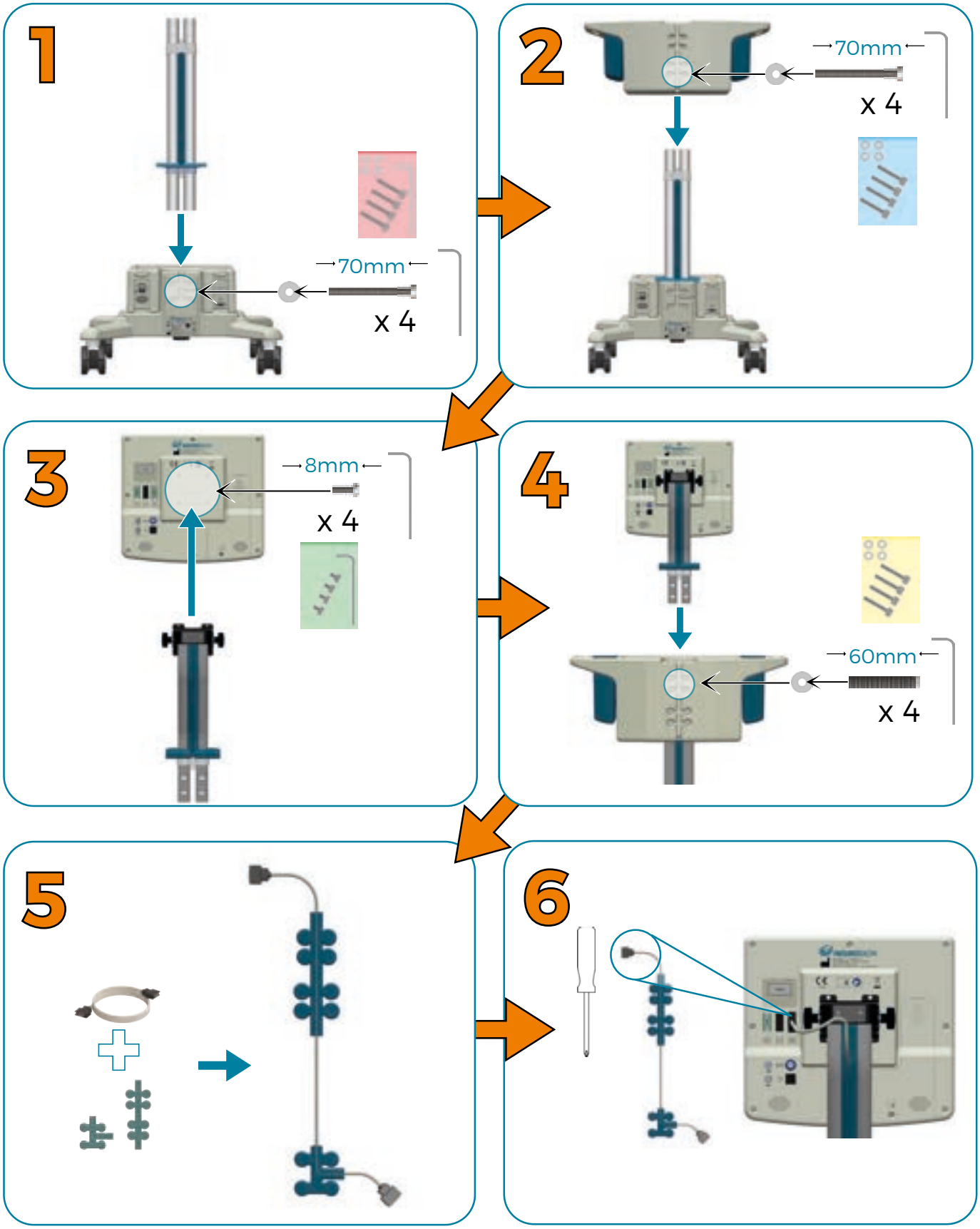
Stimulator pod to pre-amplifier connection - see page 15.

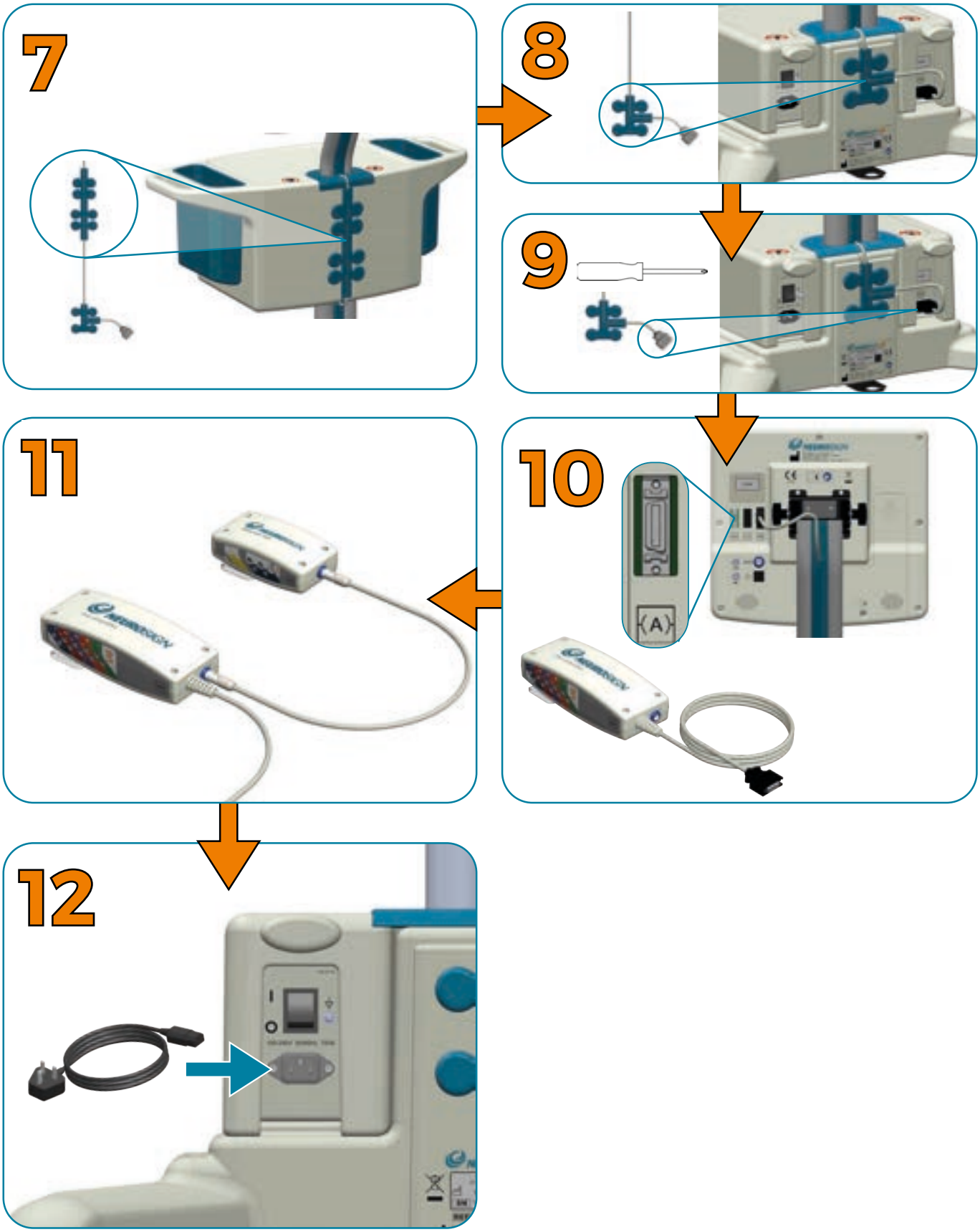
USB socket - see page 12.

SECTION 3

ASSEMBLY & DISASSEMBLY

3.1 Assembly

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(A)
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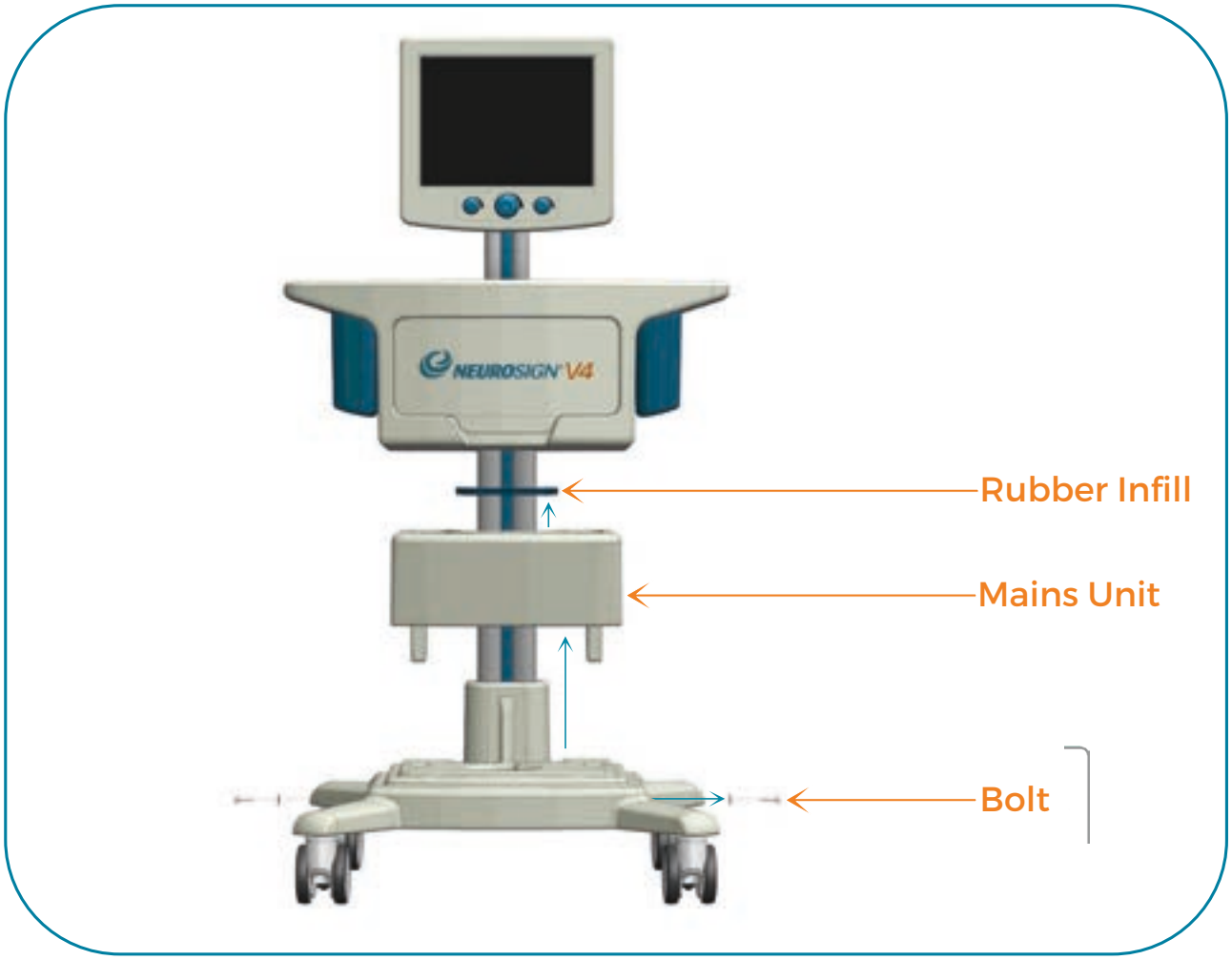
3.2 Disassembly

a. Mains unit removal

- Ensure that the nerve monitor is turned off. Remove the AC mains power lead from the power input socket (**right**).
- Remove the two bolts on either side of the mains unit (**below**), using a 5 mm allen key (supplied with the nerve monitor).
- Slide the rubber infill upwards.
- Lift the mains unit upwards.
- The mains unit can now be pulled away from the nerve monitor and removed.



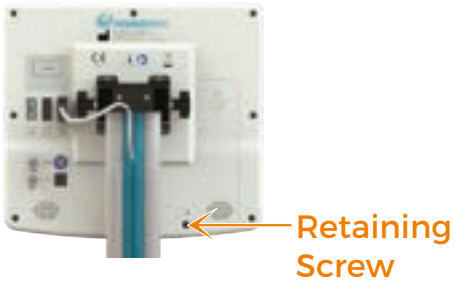
Note: To re-attach the mains unit, the process should be reversed, ensure that the original bolts are replaced and sufficiently tightened.

b. Touch screen DCU removal

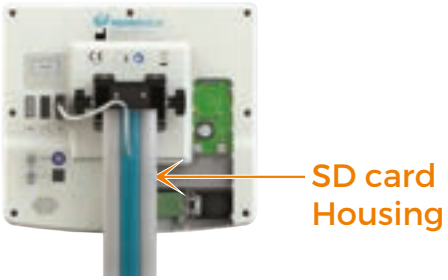
The SD card must be removed prior to returning the touch screen DCU for service or repair in order to comply with data protection requirements

If the SD card 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 re-ship the equipment. The SD Card should be securely stored to protect patient data. Do not send the SD card with the equipment.

i. SD card removal



- Remove the retaining screw from the rear panel of the touch screen DCU (**right**).
- Remove rear panel by sliding downwards (indicated by an arrow).
- Gently push the SD card in to release the SD card from its housing beneath the rear panel (**right**). The SD card can now be removed.

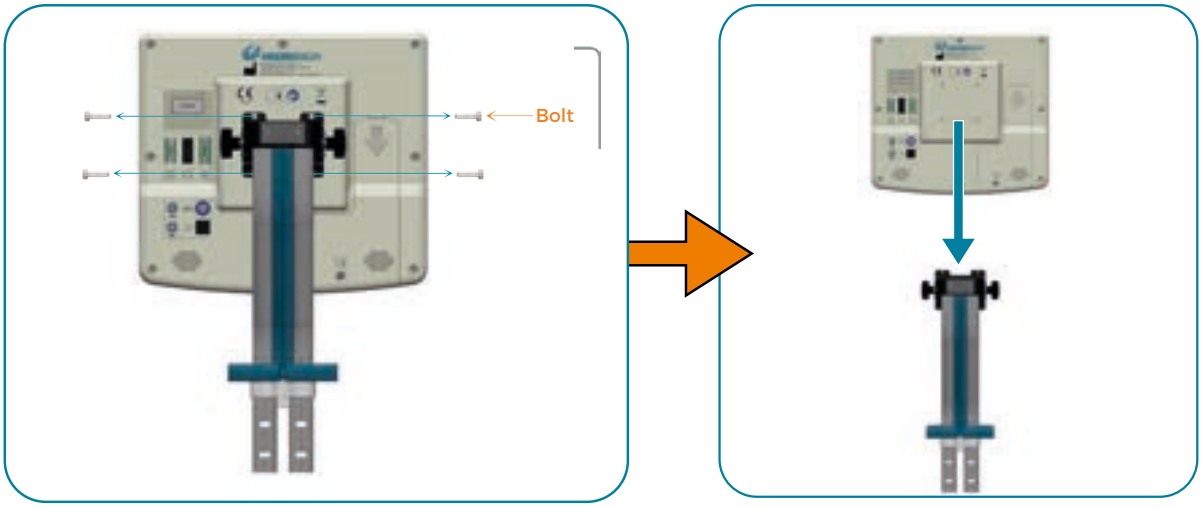


- Replace the rear panel and secure with the retaining screw.

ii. Touch screen DCU removal

!Note: to avoid damage, the touch screen DCU should be supported before the screws are removed.

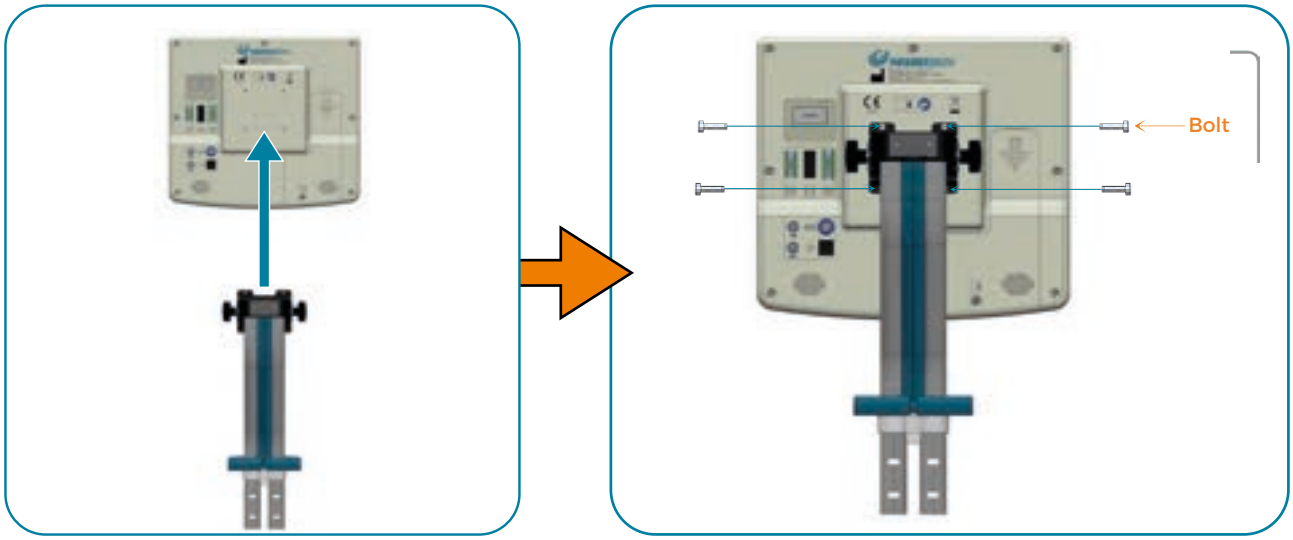
- Disconnect all cables from the touch screen DCU.
- Remove the four bolts from the upper spine bracket (**below**) using a 3 mm allen key.
- Lift the touch screen DCU away from the upper spine



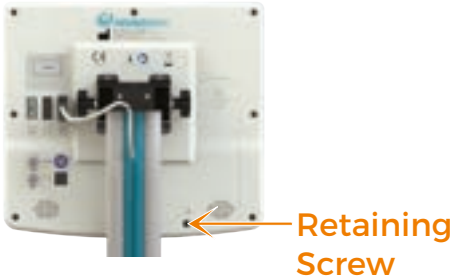
iii. Touch screen DCU and SD card replacement

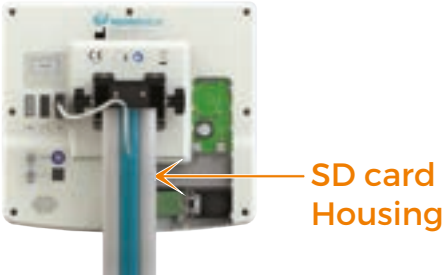
Upon return of the touch screen DCU;

- Re-attach the touch screen DCU to the upper spine using the original screws (**below**).



- Remove the retaining screw from the rear panel of the touch screen DCU (**right**).
- Remove rear panel by sliding downwards (indicated by an arrow).
- Return the SD card into its housing (**right**). A click will be heard when the SD card is in place.





!Note: The SD card can only be inserted in one orientation. Do not apply force or damage may occur.

- Replace the rear panel and secure with the retaining screw.
- Connect the UI cable to the touch screen DCU and the mains unit, (**14** (a) → **14** (b), page 13).
- Connect the AC mains power lead to the power input socket (**19**, page 13).
- Set the power switch to ON (I) (**20**, page 13).
- Verify the system powers up correctly and that the patient data is restored.

Note: If language selection flags are displayed on start-up, the system configuration must be completed. Refer to the user manual, "4.1 System Configuration" for more information.

SECTION 4

CARE & MAINTENANCE

4.1 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 wipe 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 12) 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.

4.2 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.

4.3 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

Refer to the user manual 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 
- Press 
- The battery voltage can be found under 'Display Unit' (top left).

4.4 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.

b. Servicing

Excepting of those stated in the user manual, 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 securing screws will invalidate the product guarantee.

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

Authorised service personnel should refer to "Servicing" on page 33.

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.

4.5 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.

4.6 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 advise on appropriate disposal.

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

SECTION 5

SERVICING

5.1 Testing Requirements

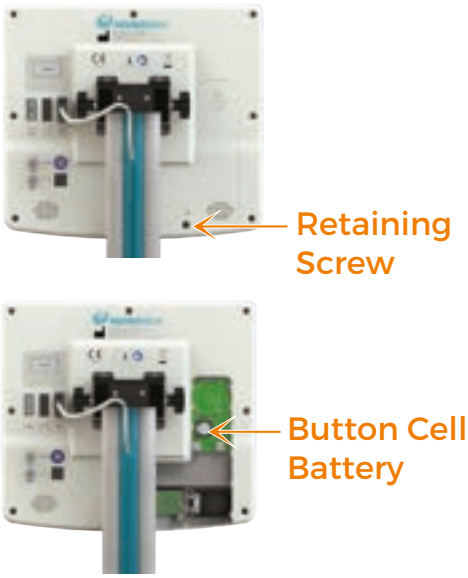
On start-up the nerve monitor will automatically run a connection and audio test. Refer to the user manual for more information.

The nerve monitor must undergo annual electrical safety testing in accordance with the hospital policy, as well as annual performance verification, once the gurantee period has expired. More information can be found in "4.4 Servicing & Device Lifetime" on page 31.

5.2 Battery Replacement

Note: Before removing the retaining screws, ensure that the nerve monitor is switched off and disconnected from the AC mains supply.

- Remove the retaining screw from the rear panel of the touch screen DCU (**right**).
- Remove rear panel by sliding downwards (indicated by an arrow).
- Remove the button cell battery from the retaining clip (**right**) and dispose of appropriately.
- Insert the new button cell battery ensuring the positive (+) is facing outward.
- Replace the rear panel and secure with retaining screw.



- Connect the AC mains power lead to the power input socket (**19**, page 13).
- Set the power switch to ON (I) (**20**, page 13).

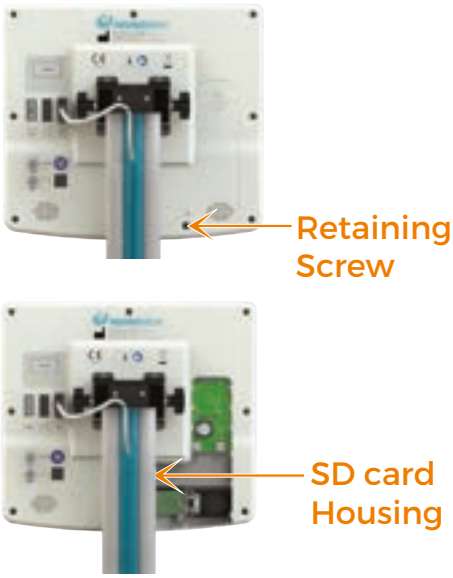
Note: If language selection flags are displayed on start-up, the system configuration must be completed. Refer to the user manual, "4.1 System Configuration" for more information.

5.3 Software Upgrade

a. Touch screen DCU

Note: Before removing the retaining screws ensure that the nerve monitor is switched off and disconnected from the AC mains supply.

Note: For information on how to obtain software please contact the Service department (page ii).



- Remove the retaining screw from the rear panel of the touch screen DCU (**right**).
- Remove rear panel by sliding downwards (indicated by an arrow).
- Gently push the SD card in to release the SD card from its housing (**right**). The SD card can now be removed.
- Using a suitable SD card reader, connect the SD card to a PC/laptop.
- Install the software upgrade onto the SD card.
- Return the SD card into its housing at the rear of the touch screen DCU. A click will be heard when the SD card is in place.

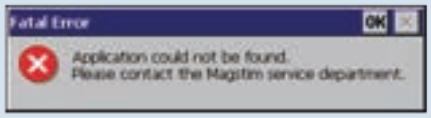
  !Note: The SD card can only be inserted in one orientation. Do not apply force or damage may occur.

- Replace the rear panel and secure with the retaining screw.
- Connect the AC mains power lead to the power input socket (**19**, page 13).
- Set the power switch to ON (I) (**20**, page 13).

Note: If language selection flags are displayed on start-up, the system configuration must be completed. Refer to the user manual, "4.1 System Configuration" for more information.

- On the home screen, press 
- Press 
- Verify software version displayed corresponds with the software upgrade version.

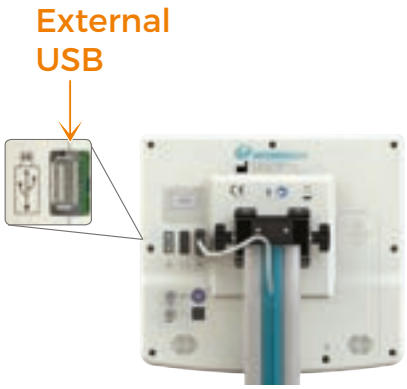
i. Touch screen DCU update troubleshooting

Problem	Solution
After software update, the system does not boot or is stuck showing the splash screen (below). 	Remove the SD card from the nerve monitor and using a suitable SD card reader, connect the SD card to a PC/laptop. Navigate to the SD card and confirm that the file "4503-62.BIN" is present in the root directory of the SD card. If the file is named "4503-62-Vn.n" (where 'n.n' represents the software version of the update being applied) rename the file to "4503-62.BIN". If the file is not present on the SD card, re-install the software update on to the SD card and retry the update.
Message box "Application is corrupted" is displayed during start up (below). 	Remove the SD card from the nerve monitor and using a suitable SD card reader, connect the SD card to a PC/laptop. Navigate to the SD card and delete the file "4246-62-Vn.n" (where 'n.n' represents the software version of the update being applied). Re-install the software update on to the SD card and retry the update.
Message box "Application could not be found" is displayed during start up (below). 	Remove the SD card from the DCU and using a suitable SD card reader, connect the SD card to a PC/laptop. Re-install the software update on to the SD card using the files provided to you. Confirm the file "4246-62-Vn.n) is present in the root directory of the SD card (where 'n.n' represents the software version of the update being applied) and retry the update.

b. Pre-amplifier

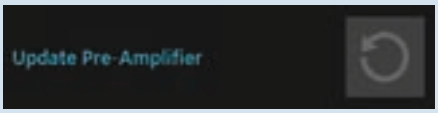
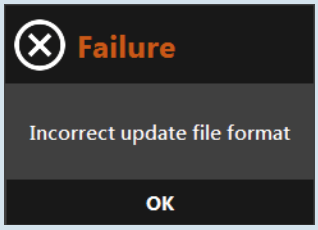
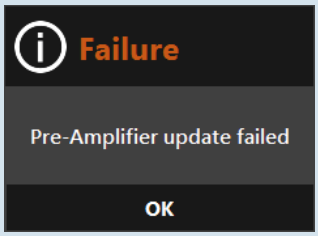
!Note: For information on how to obtain software please contact the Service department (page ii).

- Install the software onto a blank, basic USB 2.0 memory stick.
- Connect the pre-amplifier lead to the nerve monitor, (**26 → 12**, page 13 & 14).
- Set the power switch to ON (I) (**20**, page 13).
- From the home screen, press ⚙,
- Press 🔧, enter code **1478963** and press ✔.
- The system update screen will now be displayed.
- Insert the USB memory stick into the external USB socket (**right**).
- Select "**4247-62-Vn.n-DCU.BIN**" - Where 'n.n' represents the software version.
- Press ↻ next to "Update pre-amplifier".



- A progress bar and a label containing the message “retrieving page sizes” will be displayed. The displayed message will then change to "programming flash".
- On completion a message box should display "Pre-Amplifier updated successfully". If not refer to page 38.
- Press **OK**.
- From the home screen, press ⚙,
- Press 🖥,
- Verify pre-amplifier software version displayed corresponds with the software upgrade version.

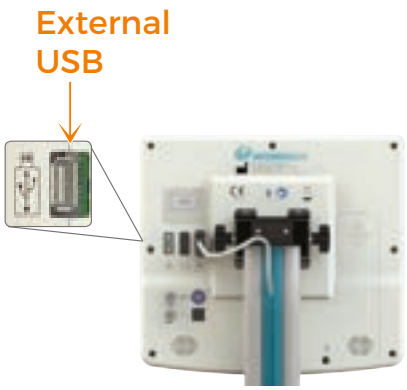
i. Pre-amplifier update troubleshooting

Problem	Solution
The 'Update Pre-Amplifier' option is not selectable/faded out (below). 	Ensure the pre-amplifier is correctly connected (see "b. Pre-amplifier" on page 37).
Message box "Incorrect update file format" is displayed (below). 	Ensure the correct file is selected. The file should be named "4247-62-Vn.n-DCU.bin", where n.n represents the software version of the update being applied. If the correct file was chosen and the problem persists, remove the USB memory stick from nerve monitor and connect the USB memory stick to a PC/laptop. Navigate to the USB memory stick and re-copy the update file to the USB memory stick (overwriting the existing file) and retry the update.
Message box "Pre-Amplifier update failed" is displayed (below). 	Ensure the pre-amplifier is correctly connected (see "b. Pre-amplifier" on page 37) and retry the update.

c. Stimulator Pod

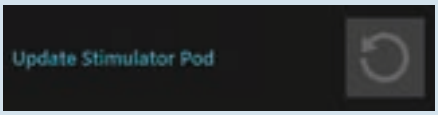
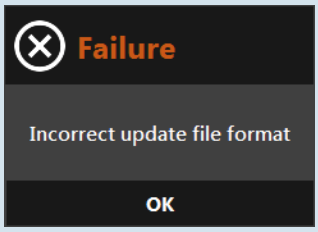
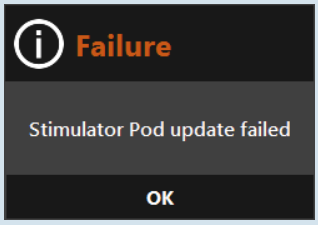
!Note: For information on how to obtain software please contact the Service department (page ii).

- Install the software onto a blank, basic USB 2.0 memory stick.
- Connect the stimulator pod lead to the pre-amplifier, (**29 → 25**, page 14 & 15).
- Connect the pre-amplifier lead to the nerve monitor, (**26 → 12**, page 13 & 14).
- Set the power switch to ON (I) (**20**, page 13).
- From the home screen, press ⚙,
- Press 🔧, enter code **1478963** and press ✔.
- The system update screen will now be displayed.
- Insert the USB stick into the external USB socket (**right**).
- Select "**4247-62-Vn.n.BIN**" - Where 'n.n' represents the software version.
- Press ↻ next to "Update Stimulator Pod".
- A progress bar and a label containing the message “retrieving page sizes” will be displayed. The displayed message will then change to "programming flash".



- On completion a message box should display "Stimulator Pod updated successfully". If not refer to page 40.
- Press **OK**.
- From the home screen, press ⚙,
- Press 🖥,
- Verify stimulator pod software version displayed corresponds with the software upgrade version.

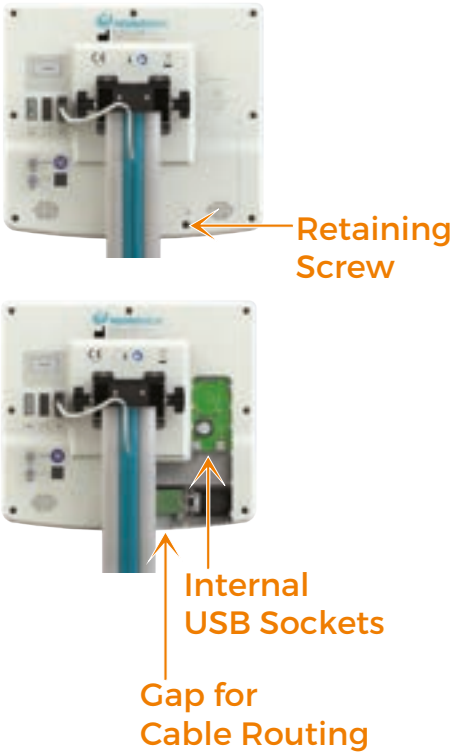
i. Stimulator pod update troubleshooting

Problem	Solution
The 'Update Stimulator Pod' option is not selectable/faded out (below). 	Ensure the stimulator pod and pre-amplifier are correctly connected (see "c. Stimulator Pod" on page 39).
Message box "Incorrect update file format" is displayed (below). 	Ensure the correct file is selected. The file should be named "4248-62-Vn.n.bin", where n.n represents the software version of the update being applied. If the correct file was chosen and the problem persists, remove the USB memory stick from nerve monitor and connect the USB memory stick to a PC/laptop. Navigate to the USB memory stick and re-copy the update file to the USB memory stick (overwriting the existing file) and retry the update.
Message box "Pre-Amplifier update failed" is displayed (below). 	Ensure the stimulator pod and pre-amplifier are correctly connected (see "c. Stimulator Pod" on page 39) and retry the update.

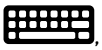
5.4 Keyboard Installation

Note: Before removing the retaining screws ensure that the nerve monitor is switched off and disconnected from the AC mains supply.

- Remove the retaining screw from the rear panel of the touch screen DCU (**right**).
- Remove rear panel by sliding downwards (indicated by an arrow).
- Insert the keyboard USB connector into any internal USB socket.
- Route the cable through the gap provided at the bottom of the monitor case (**right**).
- Replace rear panel and secure with the retaining screw.
- Set the power switch to ON (I) (**20**, page 13).



To set the Keyboard language;

- From the home screen, press  ,
- Press  ,
- Press  ,
- Select the relevant flag for the required language.

5.5 Device Schematics & Drawings

If device schematics or drawings are required please contact the service department.

Servicing Enquiries

Telephone: **+44 (0)1994 242900**
E-mail: **service@neurosignsurgical.com**

SECTION 6

TECHNICAL INFORMATION

6.1 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. EMC
The nerve monitor and its accessories comply with the requirements of EMC Standard EN 60601-1-2. Refer to the user manual for more information.

Note: To avoid problems with EMC interference, the nerve monitor should not be used in the vicinity of any equipment that does not comply with EMC Safety Standard EN 60601-1-2, including mobile phones. Any interface cable which connects the nerve monitor to an external piece of equipment not supplied by the The Magstim Company Ltd. must be no more than 4m in length.

c. 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.

d. 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.

e. 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

6.2 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 "6.4. System Details" on page 47
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	4
Signal input range	±5µV to ±40mV
Common mode rejection ratio	> 90dB (@ 50/60Hz)
Bandwidth	10Hz – 1kHz (-3dB points)
Noise	<20µV rms (Input referred)
Notch filter	50Hz, 60Hz, off

6.3 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

6.4. 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).

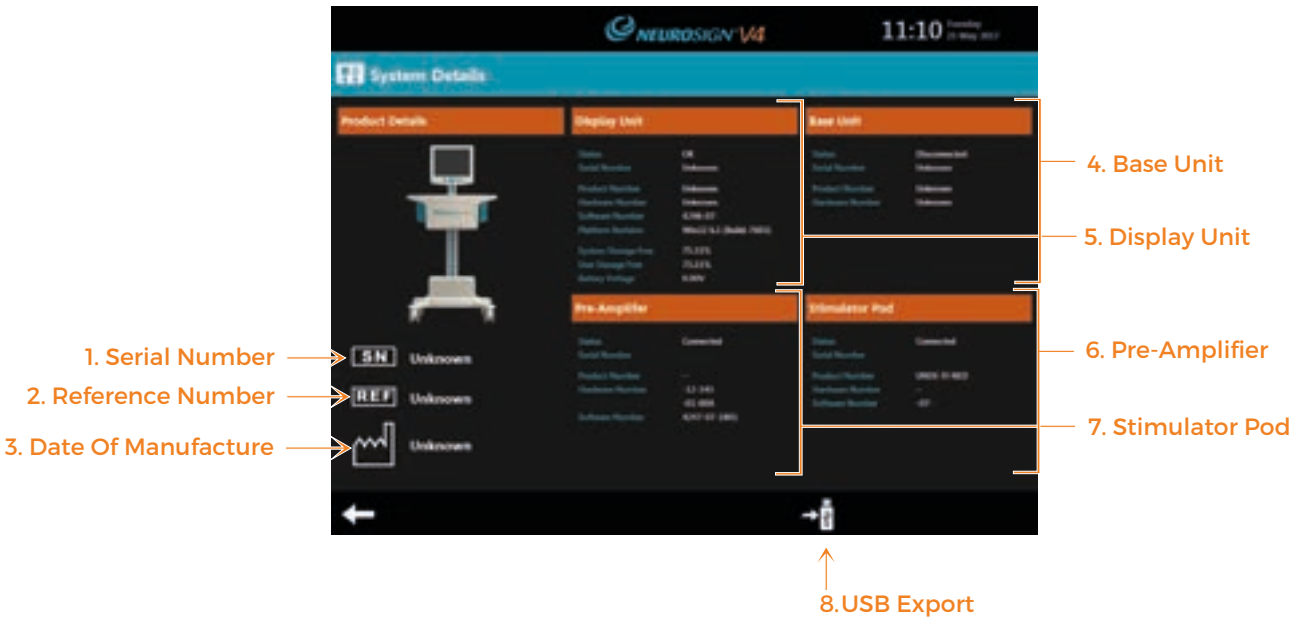


Figure 7.1: System details screen

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 (eg. status, serial number).

5. Display Unit
The details for the touch screen DCU (eg. status, serial number).

6. Pre-amplifier
The details for the Pre-amplifier connected (eg. status, serial number).

7. Stimulator Pod
The details for the Stimulator Pod connected (eg. status, serial number).

8. USB Export
Export the displayed system details for evaluation:

- Insert the USB memory stick into the USB socket (**4,** page 12),
- Select ,
- Once the exporting icon has gone, the USB memory stick may be removed.

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Document Version/s

Current editions

Document	Description	Language
NOP20-EN-02	Neurosign® V4 Service Manual	English (UK)

Supporting documents

Document	Description	Language
NOP08-EN	Neurosign® V4 User Manual	English (UK)
NOP18-EN	Neurosign® V4 Assembly Guide	English (UK)
NOP19-EN	Neurosign® V4 Reference Guide	English (UK)

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