Natus Neurology Incorporated UltraPro S100 User Guide

September 13, 2018

Part Number: 269-653300 Rev 05

UltraPro S100

Indications for use statement

The UltraPro S100 is intended for the acquisition, display, analysis, storage, reporting, and management of electrophysiological information from the human nervous and muscular systems including Nerve Conduction (NCS), Electromyography (EMG), and Autonomic Responses.

The UltraPro S100 may be used to determine autonomic responses to physiologic stimuli by measuring the change in electrical resistance between two electrodes (Galvanic Skin Response and Sympathetic Skin Response). Autonomic testing also includes assessment of RR Interval variability. The UltraPro S100 is used to detect the physiologic function of the nervous system and to support the diagnosis of neuromuscular disease or condition.

The listed modalities do include overlap in functionality. In general,

- Nerve Conduction Studies measure the electrical responses of the nerve.
- Electromyography measures the electrical activity of the muscle.
- Evoked Potentials (EP) includes Visual Evoked Potentials (VEP), Auditory Evoked Potentials (AEP), and Somatosensory Evoked Potentials (SEP).

The UltraPro S100 is intended to be used by a qualified healthcare provider.

Specification and accuracy information

Please see the system Specification sheet 169-443700.

Contact information

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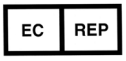
CE mark

CE 0086 Compliant to Medical Device Directive 93\42\EEC

Labels and symbols

The following labels and symbols may be affixed to the **UltraPro S100** system:

	**When applied on device:** Attention: Consult Accompanying Documentation (ISO 7000-0434A) **When used in documentation:** Caution, Warning or Precaution follows.
	Consult Operating Instructions. Failure to follow operating instructions could place the patient or operator at risk (ISO 7010 M002). Image on blue background.
	Consult Operating Instructions. (ISO 7000-1641)
	European Authorized Representative
	Manufacturer
	Disposal at end of operating life instructions. When the equipment comes to the end of its operating life, it should be disposed of in accordance with local waste regulation authority, which is typically within the local government office.
CE 0086	CE Mark and Notified Body (Compliant to Medical Device Directive 93/42/EEC)
	Type BF equipment.
RX Only	**CAUTION:** USA Federal law restricts this device to sale or on the order of a licensed medical practitioner.

Read the safety reference guide

Please read thoroughly the *Additional Information and Safety Notes for Assorted Nicolet Brand Products Reference Guide* included on a CD included with your system, paying special attention to the **Safety information** before applying power to and using your system.

Electromagnetic Compatibility (EMC)

WARNING Please refer to the *Electromagnetic Compatibility* section of this manual.

Safety summary

In this manual, two labels identify potentially dangerous or destructive conditions and procedures:

WARNING

The **WARNING** label identifies conditions or practices that may present danger to the patient and/or user.

CAUTION

The **CAUTION** label identifies conditions or practices that could result in damage to the equipment.

NOTE: Notes help you identify areas of possible confusion and avoid potential problems during system operation.

WARNING

Do NOT use outside of the published specification ranges. Use of device outside of the specified ranges may result in inaccurate results.

CAUTION **Aliasing of the displayed data can occur if the time base and the data displayed are not appropriate for the data acquired. Example, if the time base of a response normally displayed at 10 milliseconds is displayed at a time base of 1 second the data will be decimated and aliasing will occur. Remember to adjust the time base to be appropriate for the type of signal being acquired. Slow (long responses) should be displayed with a long time base, short (fast responses) should be displayed at a short time base.**

WARNING **Prolonged electrical stimulation can cause a patient burn.**

Table 1 describes the minimum size of the stimulus electrode needed to not exceed 0.25 W/cm^2 to guard against the possibility of causing a burn due to excessive densities at the site of prolonged stimulation.

Resistance (Ohms)	Max Current Used (mA)	Stim Duration (us)	Rate (Hz)	Surface area (cm2)	Required Diameter of disc (mm)
2000	25	100	2	0.001	0.356824974
2000	25	100	5	0.0025	0.564189822
2000	50	100	2	0.004	0.713649948
2000	50	100	5	0.01	1.128379644
4000	25	100	2	0.002	0.504626718
4000	25	100	5	0.005	0.797884898
4000	50	100	2	0.008	1.009253435
4000	50	100	5	0.02	1.595769796
2000	25	200	2	0.002	0.504626718
2000	25	200	5	0.005	0.797884898
2000	100	1000	100	8	31.91539591
4000	100	1000	100	16	45.13518575

Table 1

Legend for Table 1

Resistance is the impedance of the stimulus electrodes in ohms.

Max Current Used is the maximum stimulus intensity you plan on using in milliamperes (mA).

Stim Duration is in microseconds (us).

Rate is the maximum rate of stimulus you plan on using.

Surface area is the miniumum surface area of the stimulus electrodes that should be used.

Required diameter of disc is the minimum diameter of a round disc electrode that should be used.

The diameter of disk = 20 * square root(surface area/3.14159) millimeters (mm)

Maintenance

Inspecting the system

Routinely check the instrument for exterior damage.

Follow your medical facilities safety guidelines.

Decontamination

Decontamination that can be performed by the operator is limited to cleaning and disinfecting the device. Any maintenance inside the device must be performed by qualified service personnel only.

Cleaning instructions

Regular cleaning maintenance should be performed according to frequency of use of the device. Always observe your local hygiene authority's guidelines, and the following points below:

- Disconnect the mains power before cleaning the equipment.
- Clean the equipment surfaces with a clean, slightly damp cloth with a mild detergent (e.g., Wet Wipes®), and wipe it dry.
- Make sure that no liquids enter the device at push buttons and other openings in the enclosure.

CAUTION Do not use cleaning detergents, or cleaning agents based on solvent, silicon-based, abrasive and/or flammable substances.

Disinfection procedure

When disinfecting the equipment, if required, surgical spirit (70%), a Chlorine (1000ppm), or ethanol (70%) detergent may be used. Carefully follow the disinfectant manufacturer's instructions for use, and the steps under the Cleaning Instructions section above.

Preventative maintenance

Safety checks

The following safety checks should be conducted by qualified personnel only at least once a year and in the event of repair:

1. Inspection for visible damage to device.
2. Inspection of mains cord and connecting cables.
3. Check of electrode cables and patient connections.
4. Measurement of insulation resistance.
5. Measurement of leakage currents.
6. Measurement of resistance of protective earth conductor.
7. Measurement of resistance of protectively earthed enclosure and cart parts.

Safety

WARNING Any interruption of the protective earth conductor inside or outside of the device or disconnection of the protective/functional earth connector is likely to make the device dangerous. Intentional interruption is prohibited. The protective earth / ground conductor should be checked regularly.

Adhere to the following recommendations for safe operation of the device:

- When connecting medical equipment being supplied from an outlet located in a non-medically used room, or when connecting non-medical electrical equipment to this device, pay attention to the requirements of IEC 60601-1 (IEC 60601-1-1), Safety Requirements for medical electrical systems, cf. the text on IEC 60601-1 (IEC 60601-1-1), further below in this section.
- When the device is connected to its mains supply, connectors may be live, and any opening of covers or removal of parts possible only with the aid of a tool is likely to expose live parts.
- The device must be disconnected from all voltage sources before being opened for any adjustment, replacement, maintenance or repair.
- Service must be referred to Natus Neurology Incorporated authorized service personnel, except for such works described in this manual as being performed by the operator.
- Make sure that only fuses with the required rated current and of the specified type are used for replacement. The use of makeshift fuses and the short-circuiting of fuse holders are prohibited.
- Where more than one piece of equipment is connected to the patient, attention must be paid to the summation of patient leakage currents.
- Whenever it is likely that the protection has been impaired, the device shall be made inoperative and be secured against any unintended operation.

Call qualified service personnel to conduct at least a functional test and a safety check that should include the following:

- Insulation test.
- Ground continuity test.
- Leakage current test, according to IEC 60601-1.

The protection is likely to be impaired if, for example, the device:

- Shows visible damage.
- Fails to perform the intended function(s).
- Has been subject to severe transport stresses.

Recycling / disposal

Many local laws and regulations consider electric equipment-related waste as hazardous or requiring special procedures to recycle or dispose of. This includes batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. Follow all of your respective local laws and regulations for the proper disposal of batteries and any other parts of your system, such as monitors, UltraPro S100 amplifiers, keyboards, electrodes.

Refer to your **Natus Neurology Incorporated** service representative for recommended instructions and addresses for proper return or disposal of electronic wastes relating to Nicolet Brand products in Europe and other localities.

The contact information for the WEEE - In Europe

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Copyright

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Table of contents

Introduction 1-1

System Overview 2-1

Patient Information 3-1

Performing an Exam 4-1

Backup and Restore Data 5-1

Electromagnetic Compatibility (EMC) 6-1

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1 Introduction

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Technical description

Your UltraPro S100 allows you to perform a wide range of Nerve Conduction Studies (NCS), Electromyography (EMG), and Autonomic Studies. Separate software programs and optional accessories let you customize your UltraPro S100 to meet your specific clinical needs.

Installation and servicing instructions

Device continuity maintenance and installation test

WARNING During installation, assembly and operation, some protective ground connection points are susceptible to becoming electrically detached or not properly connected. This can pose a safety hazard to both the user and patient.

It is recommended/required that you perform regular electrical continuity tests from exposed conductive materials on the medical system to the protective ground on the medical system. Regular testing will help ensure that proper protective grounding is maintained. This test should always be performed after installation and maintenance. Additionally, this test should be performed on a regular maintenance basis.

UltraPro S100 amplifier and system essential performance

The UltraPro S100 amplifier and system is designed to function under a wide range of environmental conditions without any compromise in performance specifications.

In the event that an environmental artifact (e.g. ESD, line voltage fluctuations, etc.) is of sufficient intensity and/or duration to adversely affect system performance, the system is designed to detect this condition and send a message notifying the operator that an adverse event has occurred. Once the operator has cleared this message, the system will indicate that acquisition can resume with the settings restored to the previous state.

If this type of condition causes persistent messages, please contact your local service representative.

Protective and equipment classifications

1. This system is intended for continuous operation and has an IEC 60601-1 protective classification of Class I, Type BF applied parts, ordinary equipment, not suitable for use in the presence of flammable anesthetics.
2. The MDD equipment classification is IIb.

Intended operator

The UltraPro S100 is intended to be used by a qualified healthcare provider.

Using this guide

This guide provides the basic information needed to operate your UltraPro S100. It includes instructions for creating patient files, working with studies and exams and for performing simple studies.

Your system includes a computer on which the UltraPro S100 software program is installed.

About the system

UltraPro S100 systems feature a dedicated control panel, color-coded multifunction softkeys and easy-to-use Windows-based interfaces to simplify operation.

The UltraPro S100 cart accommodates all system components and provides large, convenient storage for your supplies.

Innovative software features and an intuitive interface simplify operation. The Study feature allows you to create a list of assorted protocols and select them sequentially using a single button press. This allows for faster testing using standard protocols.

Ancillary accessories

To facilitate the acquisition of electrophysiological information using the Natus Neurology Incorporated system, there are ancillary accessories that must be used. These accessories include surface electrodes and needle electrodes that are not included with the Natus Neurology Incorporated system. In an effort to ensure proper use of the system; descriptions, recommendations and or specifications are provided for these ancillary accessories that are deemed compatible with the Natus Neurology Incorporated system.

It is recommended that the surface electrodes selected are those that have been cleared or approved for nerve conduction and or evoked potential studies. Either disposable or reusable surface electrodes may be used. The size of the electrode should be appropriately selected for the test being conducted. Reusable surface electrodes are made of metal and are typically fabricated from platinum, gold or silver. Metallic reusable electrodes must be cleaned and or conditioned for reuse according to instructions provided by the manufacturer of those electrodes. All surface electrodes used should have a protective pin connector that complies with DIN 42 802 standard. This nonproprietary pin connector is an industry standard for EMG systems.

Disposable and reusable needle electrodes may be used. Needle electrodes are fabricated from a variety of materials. It is recommended that the needle electrodes selected are those that have been cleared or approved for electromyography applications. Use a length and gauge appropriate for the test being conducted. The connector is a circular 5 pin DIN connector. This nonproprietary pin connector is an industry standard for EMG systems. The pin configuration for this connector is as follows: **pin 1** is active, **pin 2** is reference, **pin 3** is driven shield and **pins 4** and **5** are patient ground.

Cleaning

All external parts of the assembly can be wiped down with the following:

CAUTION **Chemical contact will be limited to chemicals specified below to clean the assembly only. Other chemicals may or may not affect the device, but do not fall under tested chemicals for the assembly.**

- Water
- Isopropyl Alcohol (70-90% concentration in water)
- PDI SaniClothPlus #Q89702
- HB Quat (3M)
- Mild soap solution such as Basis, Cetaphil, Dove in water solution
- Ethyl alcohol (70-90% concentration)
- A solution of 1 part household bleach (5-6% concentrate sodium hypocholorite) and 50 parts water.

Connecting the system components

Please refer to the UltraPro S100 Installation Guide for cabling instructions.

Entering commands

You enter commands, text or values and select functions by pressing a key on the control panel or by typing a series of keys on the keyboard. If you have a pointing device, such as a mouse or track ball, you perform these functions by pointing and clicking on an item in the Function key area.

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2 System Overview

This chapter introduces you to the basic hardware and software controls used to operate your UltraPro S100 system.

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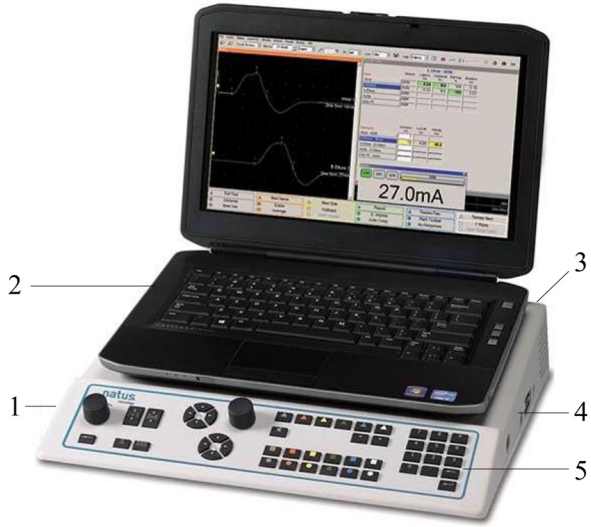
UltraPro S100 base unit



1	**Base Unit**	**4**	**Side Panel**
2	**Computer**	**5**	**Control Panel**
3	**Rear Panel**		

UltraPro S100 system interface

Before operating the device, the system parts need to be connected:

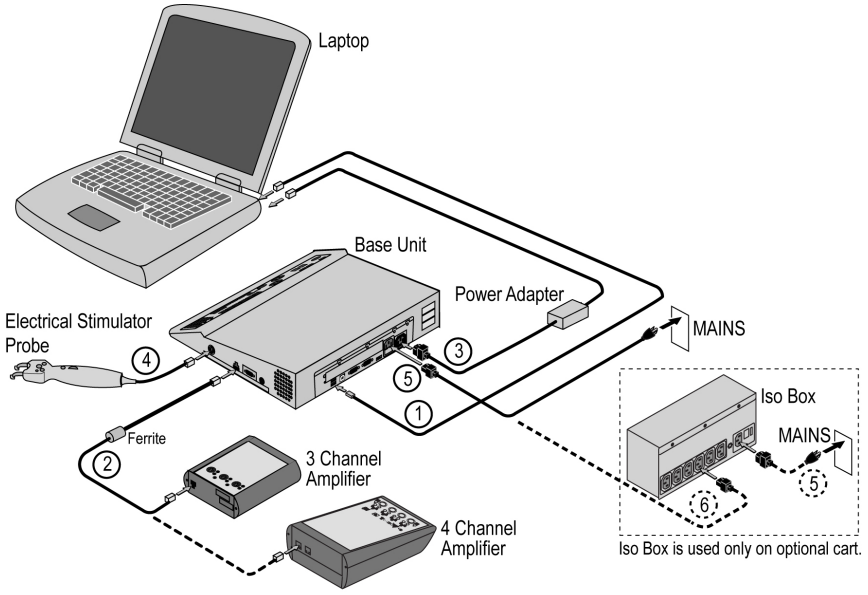
1. Connect all the signal interface cables (USB / HS-Link) as shown in the following illustration.
2. Connect all the power interface cables, except the power cord until step 3.
3. Connect the power cord to the wall outlet.

CAUTION **Use only optional devices specified by Natus Neurology Incorporated in order to comply with IEC 60601-1 (IEC 60601-1-1).**

CAUTION **Always use shielded power line cables from Natus Neurology Incorporated to avoid hum line interference, especially near the patient or the amplifier.**

NOTE: Make sure the device connected to the wall power outlet is positioned in such a way to allow easy disconnection from the mains, if needed.

NOTE: Unplugging the power line cable from the mains input on the Base Unit or Cart disconnects the mains power of the complete UltraPro S100 system.

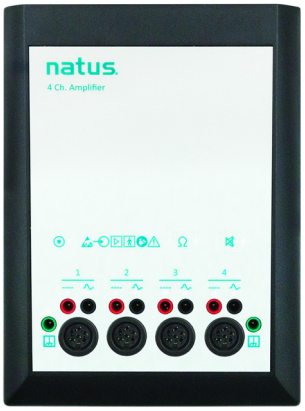


Component styles may vary from those shown.

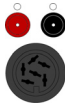
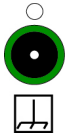
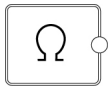
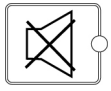
Cable connections

Item	Description
1	USB 2.0 Cable (2M)
2	High-Speed Link Cable (Proprietary)
3	Power Adaptor IEC Cable (1ft)
4a	Advanced Stimulus Probe
4b	Comfort Probe RS10 (Optional, not diagrammed)
5	Hospital Grade Power Cable, Shielded
6	Power Jumper Cable IEC (2M)

UltraPro S100 amplifier module - 3 and 4 channels

	
UltraPro S100 3 Channel Amplifier	**UltraPro S100 4 Channel Amplifier**

Front Panel	
 **3 Channel Amplifier**  **4Channel Amplifier**	**Amplifier Input (Isolated)** All amplifier input connectors are electronically isolated.
 **3 and 4 Channel Amplifier**	**Electrostatic Sensitive Amplifier Input Connectors** **CAUTION** Do not touch the Amplifier input connectors because it may damage the amplifier or affect its performance.
 **3 and 4 Channel Amplifier**	**Active Electrode - Black** The Active electrode corresponds to the black input connector.
 3 and 4 Channel Amplifier	**Reference Electrode - Red** The Reference electrode corresponds to the red input connector.
 **4 Channel Amplifier**	**On LED**

Front Panel	
 **3 Channel Amplifier**  **4 Channel Amplifier**	**Amplifier Input Connectors (1-3) / (1-4)** The amplifier input connectors feature both a DIN-type socket and a pair of 1.5mm touch-proof connectors.
 **3 Channel Amplifier**  **4 Channel Amplifier**	**Patient Ground Connectors** Connect the patient's ground electrodes to the green connectors. **WARNING** Do not connect the 'patient ground' to the protective earth connection on the Isolating Transformer Unit, or to any other 'ground' connects, as the electrode inputs are galvanically isolated.
 **4 Channel Amplifier**	**Impedance Test Button**
 **4 Channel Amplifier**	**Mute Button**

3 Channel Side Panel / 4 Channel Rear Panel	
LINK **3 and 4 Channel Amplifier**	**HS Link Input Connector - Main Unit - Side Panel / Rear Panel** **WARNING** Due to risk of electric shock, the operator and/or patient must not directly or indirectly touch the metal shield on the LINK cable attached to the rear of the amplifier.

Current stimulator

Safety information

Stimulator

WARNING When operating the current stimulator, be careful not to expose patients to high currents. Before connecting or disconnecting the stimulus electrode, always “reset” the stimulator.

WARNING Simultaneous connection of a patient to HF surgical equipment may result in burns at the site of the electrical stimulus, or recording electrodes and possible damage to the electrical stimulator, or the electrode input amplifiers. Operation in close proximity (e.g., 1m) to short wave, or microwave therapy equipment may produce instability in the electrical stimulator output.

WARNING Dangerous physiological effects! The current stimulator may give off dangerous currents and voltage.

CAUTION Avoid electrical stimulation for an extended period of time.

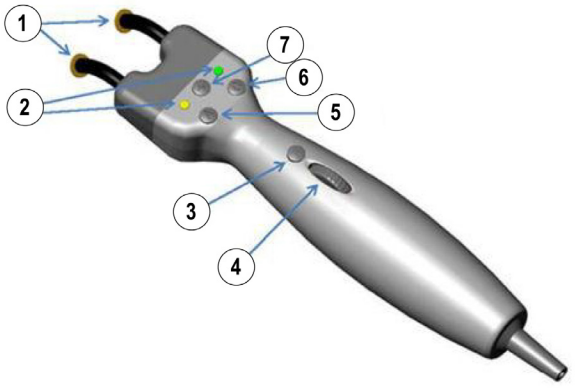
Stimulus electrodes

WARNING When using needle electrodes for recording or stimulation, either use pre-sterilized, single-use needle electrodes, or thoroughly sterilize multiuse needle electrodes.

CAUTION Avoid accidental contact between connected, but unapplied electrodes and other conductive parts; including those connected to protective earth.

Note: For cleaning reusable surface electrodes, refer to their accompanying instructions for use.

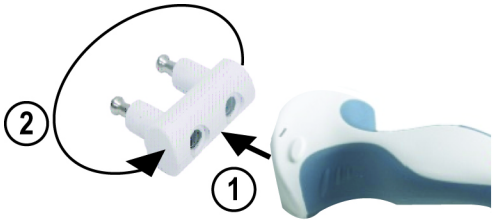
Stimulus probe



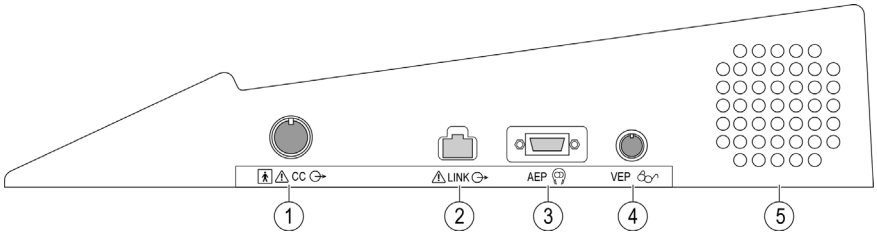
1	**Output Electrode Pins** For direct stimulus on the skin, see the description of the stimulus electrodes in this section.
2	**Polarity and Stimulus Indicators** The stimulus cathode is indicated by a constant green light (LED). During stimulus, the other LED indicator will flash yellow – once for single stimulus and intermittently for repetitive stimulus. Note that if the stimulator is not enabled, no LEDs will light.
3	**Single Stimulus Button** Momentarily press the button on the handle. **Repetitive Stimulus Button** Press and hold down the button on the handle for at least 1 second.
4	**Stimulus Intensity Control Wheel** To increase or decrease the current intensity, rotate the wheel. Alternatively, you can also use the mouse wheel or the Stimulus Intensity control knob on the control panel. **Reset** To reset the intensity to its zero level, press the **Reset Stimulus Intensity** key on the control panel.
5	**Button A** **Next Site Button – Active in Motor and Sensory Nerve testing** Momentarily press the button on the handle.
6	**Button C** **Next Study Exam** Active in all tests. Momentarily press the button on the handle.
7	**Polarity Button** Press the button to change polarity.

Changing polarity on the Comfort Probe RS10

1. Pull the Probe Head straight out from the Comfort Probe RS10.
2. Rotate the Probe Head 180 degrees.
3. Insert the Probe Head back into the Comfort Probe RS10.

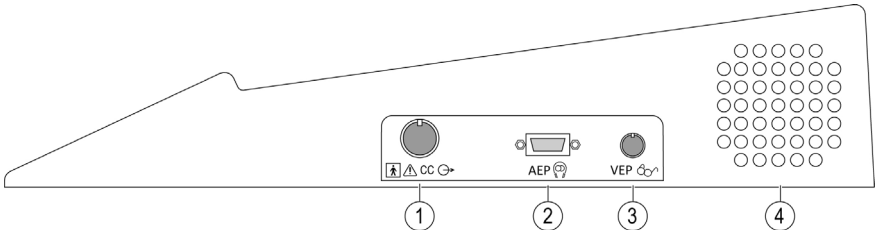


UltraPro S100 Base - Version #1 side panel



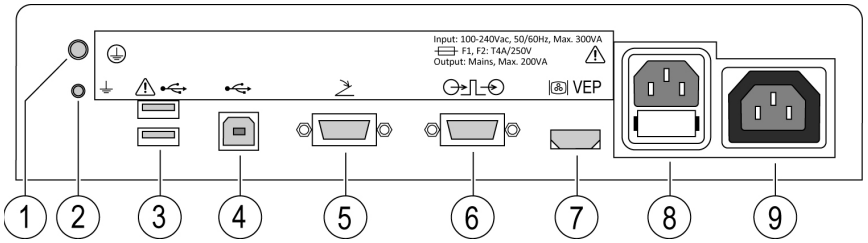
1	CC	**Stimulator Output (isolated)** The stimulator output connectors are electronically isolated. **Stimulator Output Socket (isolated)** For connection of stimulus electrodes with DIN plugs. Support for the active stimulus probe.
2	LINK	**HS Link Output Connector** Amplifier Connection **Cat5 with built-in EMI Suppression** Proprietary Cable
3	AEP	**Auditory Transducer Connection**
4	VEP	**LED Goggles Transducer Connection**
5		**EMG Speaker**

UltraPro S100 Base - Version #2 side panel



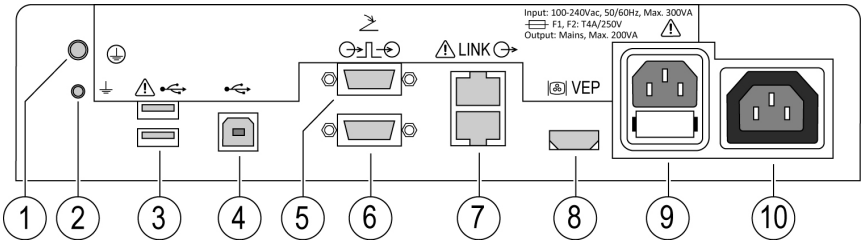
1	CC	**Stimulator Output (isolated)** The stimulator output connectors are electronically isolated. **Stimulator Output Socket (isolated)** For connection of stimulus electrodes with DIN plugs. Support for the active stimulus probe.
2	AEP	**Auditory Transducer Connection**
3	VEP	**LED Goggles Transducer Connection**
4		**EMG Speaker**

UltraPro S100 Base - Version #1 rear panel



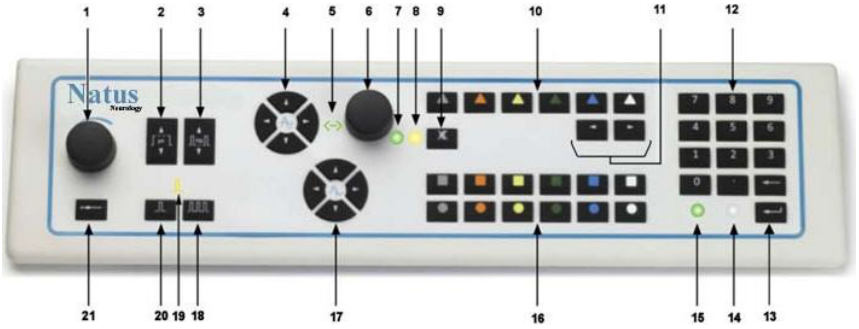
1		**Protective Earth**
2		**Functional Earth** To be used for suppression of noise.
3		**Dual USB Connectors – Type A** Limited power available. Only used for footswitch and memory stick.
4		**USB Connector – Type B** For computer interface.
5		**Footswitch Connector**
6		**Trigger Input / Output Connector**
7	VEP	**Visual Transducer Connector**
8		**Power Inlet** Input: 100-240Vac, 50/60Hz, Max. 300VA **Fuses** F1, F2 : T4A/250V
9		**Power Outlet (only for computer when not used with the Isolating Transformer)** Output: Mains 100 - 240VAC Max.200VA

UltraPro S100 Base - Version #2 rear panel



1		**Protective Earth**
2		**Functional Earth** To be used for suppression of noise.
3		**Dual USB Connectors – Type A** Limited power available. Only used for footswitch and memory stick.
4		**USB Connector – Type B** For computer interface.
5		**Footswitch Connector**
6		**Trigger Input / Output Connector**
7	LINK	**HS Link Output Connector** Amplifier Connection **Cat5 with built-in EMI Suppression** Proprietary Cable
8	VEP	**Visual Transducer Connector**
9		**Power Inlet** Input: 100-240Vac, 50/60Hz, Max. 300VA **Fuses** F1, F2 : T4A/250V
10		**Power Outlet (only for computer when not used with the Isolating Transformer)** Output: Mains 100 - 240VAC Max.200VA

Control Panel – front view



1	Stimulus Intensity Control Knob
2	Stimulus Duration Control Key
3	Stimulus Repetition Rate Control Key
4	Arrow Keys (Marker Navigation Control Keys)
5	Cursor Mode Indicator
6	Selection Knob
7	Volume Indicator
8	Audio Mute Indicator
9	Audio Mute Key
10	Screen Navigation Keys
11	Audio Keys
12	Numeric Keypad
13	Enter Key
14	Standby Indicator
15	Power ON Indicator
16	Function Keys
17	Display Keys
18	Recurrent Stimulus Key
19	Stimulus Indicator
20	Single Stimulus Key
21	Reset Stimulus to 0

Control functions

Power On/Standby indicators

	**Power On**
	**Stand By**

Screen navigation / software functions

	**Screen Navigation Keys – Color Coded** The Software Screen Navigation keys allow you to navigate through the application tabs. The 6 Software Navigation keys' colors and functions correspond to the Software Screen Navigation buttons on the application.
 	**Function Keys – Color Coded** The Software Function keys allow you to control the different software functions on the application. The 12 Software Function keys' colors and functions correspond to the Software Function buttons on the application.

Display Keys

	**The Right and Left control keys allow you to modify the sweep speed.** • The Right key increases the sweep speed. • The Left key decreases the sweep speed. **The Up and Down control keys allow you to modify the level of sensitivity.** • The Up key increases the sensitivity level. • The Down key decreases the sensitivity level.

Stimulus

	**Stimulus Indicator** The stimulus indicator yellow light (LED) blinks once for Single Stimulus, and intermittently for Repetitive Stimulus.
	**Single Stimulus Key** When the Single Stimulus key is pressed, a single stimulus is presented and the indicator blinks once. The Single Stimulus key can also be used to stop Repetitive Stimulus.
	**Repetitive Stimulus Key** When the Repetitive Stimulus key is pressed, repetitive stimulus is presented and the indicator blinks intermittently. To stop repetitive stimulus, press either the same Repetitive Stimulus key or the Single Stimulus key.

Stimulus Intensity / Duration / Repetition Rate

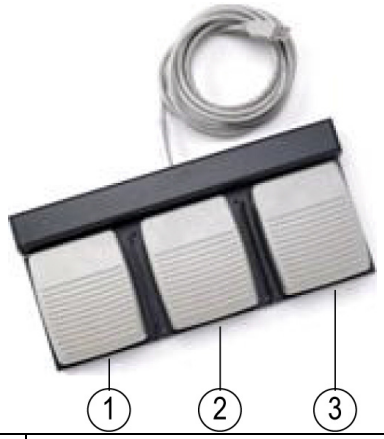
	**Stimulus Intensity Control Knob** The Stimulus Intensity control knob allows you to adjust the intensity of the stimulus released. Rotate the control knob to the right to increase the stimulus intensity. Rotate the control knob to the left to diminish the stimulus intensity.
	**Reset Stimulus Intensity Key** Press the Reset Stimulus Intensity key to reset the stimulus intensity to its base level. **WARNING** When operating the current stimulators, be careful not to expose the patient to high currents. Before connecting or disconnecting the stimulus electrode, always reset the stimulator.
	**Stimulus Duration Control Keys** The Stimulus Duration Up and Down control keys allow you to increase / decrease the duration of the stimulus. The Up key Increases the stimulus duration. The Down key decreases the stimulus duration.
	**Stimulus Repetition Rate Control Keys** The Stimulus Repetition Rate Up and Down control keys increase and decrease the stimulus repetition rate. The Up key increases the stimulus repetition rate. The Down key decreases the stimulus repetition rate.

Audio / Volume / Cursor Mode / Trace / Marker / Trigger

	**Audio Keys** The Left and Right arrow keys are used to decrease/increase the audio volume.
	**Audio Mute Key / Indicator** Press the Loudspeaker Mute key to switch between the On and Off function. The yellow light (LED) indicates the loudspeaker is muted. To adjust the volume, see the Marker Control wheel function below.
	**Selection Knob** Rotate the wheel to move the traces / markers or the trigger cursor. Press the wheel to cycle through the markers on the active trace.
	**Cursor Mode Indicator** The green light (LED) indicator is on when the cursor mode is enabled. When enabled, it allows you to move the Trace / Marker or the trigger cursor with the use of the Marker Control wheel – see the Marker Control wheel function above.
	**Trace / Marker / Trigger Control Keys** In Motor and Sensory; F-Wave; and H-Reflex Applications: The Up and Down control keys select the active trace. The Left and Right control keys select the active cursor. **In EMG Application:** The Up and Down control keys move the trigger cursor in small steps. The Left and Right control keys move the trigger cursor to the left and to the right.

Footswitch with 3 pedals (option)

Footswitch is available as a triple pedal model (1, 2 and 3 features) with USB interface.



	IPX1	Degree of protection against harmful ingress of water
1		User Programmable
2		Next Site (User definable)
3		Start/Stop Stimulus (User definable)

Powering the system

1. Ensure that all the components are connected properly in accordance to what's explained earlier in this chapter then follow these steps.
2. Connect the power cord into the wall outlet.
3. The Windows login screen appears. Click on the correct **user icon** and type in your **password**(if you have a password).

Note: Your logon ID and password may vary.

Shutting down the system

Follow these procedures for a proper shutdown of your system to prevent damages to the unit.

1. Click on **Start > Shutdown** on the lower left hand of your computer screen.
2. Disconnect the power cable from the wall outlet once the system is off.

Synergy/ Viking Software - Warning and Error Codes

In the Synergy/ Viking Application, errors and other informational messages are designed to be self-explanatory.

However, additional information and suggested user actions are provided in document 022210 found on the User Guide disk 482-651400.

UltraPro S100 acquisition software installation

Follow these procedures to install and license your UltraPro S100 software if it has not been installed and licensed or if you are doing new software installation.

1. Acquisition software installation

1. Insert the Synergy/Viking EMG installation CD into the CD drive. The setup program should start up automatically.
2. Click **Next**.
3. Check **Accept license agreement** and click **Next**.
4. Check **Acquisition System** and click **Next**.
5. Enter the **system serial number** from the supplied licensing form and click **Next**.
6. Click **Next** to accept default application program destination.
7. Click **Next** to begin installation.
8. Click **Install** to install the device driver.
9. Click **Install this driver anyway**.
10. Click **Next** to finish the installation.
11. Click **OK** to reboot the PC.
12. The UltraPro S100 software installation is complete.

2. Create and apply UltraPro S100 software license

1. For creating and applying the UltraPro S100 License, refer to the *UltraPro S100 License Letter*.

Technical specifications

For technical specifications, refer to the UltraPro S100 section in the Technical Specifications Sheet.

3 Patient Information

This chapter explains how to use the Patient Information feature used for working with your patient exam files.

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The Patients screen

Patient Information has sections where you enter specific data about the patient, such as the Patient ID, Gender, Birth Date, and Patient Name as well as physician information, summary and conclusions.

Entering a new patient

1. Click **New Patient** to prepare the system for the new patient. If there is any unsaved data, you will be asked to save or discard it. The patient demographic area is cleared.
2. Enter the patient demographic data and the visit information.

   You must enter the required fields at a minimum. Once the required fields are entered, the full patient demographics will be available.

   The highlighted field indicates the location on the screen where the text will be entered. Press <**Enter**> or <**Tab**> to advance to the next line in the form. Press <**Shift Tab**> to move the blinking cursor to the previous line. The patient data should be entered before beginning any test procedures.
3. Enter the name, date of birth, etc. as needed.
4. The patient's name, ID, etc. are displayed on the left side of the screen.
5. If desired, to complete the remaining information fields, place the cursor in the desired field and type the information. Press the **Tab** key to advance the cursor to the next field.
6. Click **Save** to save the patient data to the hard disc.
7. Click **Begin Testing** to start testing or to enter visit details.
8. Visit information can be added by pressing the **Visit Details** button.

Selecting / editing patient information

1. Click the **Patient List** function key in the main UltraPro S100 screen to list all the patients in the Patient Database or use the **Search** utility to find a patient.
2. Use the vertical scroll bar or up/down arrow keys to scroll down the fields to the patient you want. To load the patient, either double-click on the **patient** or highlight the patient and click **Load Patient**. The current patient information is displayed on the left side of the screen.
3. Edit the patient information as necessary.
4. Make changes to the current patient information by retyping the information that needs to be updated. The basic Current Patient Information is applied to all reports. However, Visit Information is unique to each visit.
5. To change visit details, select **Restart Visit**.
6. Select **Visit Details**.
7. When finished with Visit Information, click **Done**. You will be prompted to save changes.

   If only updating Current Patient Information, click **Save** when completed.

Note: Loading a patient replaces the current patient and you may be prompted to save the current patient before you can proceed.

Starting a new visit

1. Click the **Patient List** function key in the main UltraPro S100 screen to list all the patients in the Patient Database or use the **Search** utility to find a patient.
2. Use the vertical scroll bar or up/down arrow keys to scroll down the fields to the patient you want. To load the patient, either double-click on the **patient** or highlight the patient and click **Load Patient**.

Note: Loading a patient replaces the current patient and you may be prompted to save the current patient before you can proceed.

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3. Click **New Visit**.

Recalling a patient for testing

1. Click the **Patient List** function key in the main UltraPro S100 screen to list the patients in the Patient Database or use the **Search** utility to find a patient.
2. Load the patient. The patient's information is displayed on the left.
3. Make any needed changes to the Visit Information. When finished, click **Done**. You will be prompted to save changes.
4. The test menu is displayed automatically on the right. Find and select the desired test to start testing.
5. If you need to add testing to an existing visit.
   a. Click the **Patient List** function in the main UltraPro S100 screen. Patients are listed on the right.
   b. Find your patient and highlight the name.
   c. Click **Catalog** to display all the visits for this patient.
   d. Search by date to find the visit to be appended and highlight the date.
   e. Click **Restart**. Additional testing will be assigned to this visit.

Recalling an exam for review

1. To review waveform data.
   a. Click the **Patient List** button to display all patients on the right side of the screen.
   b. Locate the patient either by scrolling through the list or using the Search function and highlight the patient.
2. Click **the Catalog** button to display all visits and data for this patient on the right side of the screen display.
   a. Find the correct visit and, if necessary, click the "+" in front of the folder to expand it.
   b. Double-click the waveform data name (Median APB, Ulnar FDI, etc.). Changes to the data can be made such as moving the markers.
3. To save changes.
   a. Click **Exit Test** to return to the patient information screen.
   b. Click the **Report** button to regenerate/recompile the report.
4. Click **End Visit** to save your changes and exit this patient.

Note: Notice that a "+" or "-" sign appears before each section title. As in Windows, click on the "+" to open a closed folder or section or click on the "-" to close a section.

Deleting exams from a patient file

1. Click the **Patient List** button to display all patients in the pane to the right.
2. Highlight the desired patient.
3. Click the **Catalog** button to display the visits and data files for this patient. Find and highlight either the waveform file or visit depending on what you'd like to eliminate.
4. From the menu bar, click **File** > **Delete Test** to delete a specific waveform file or click **File** > **Delete Visit** to delete all data for a specific date. In either case, you are prompted to confirm the deletion.

Deleting a patient

1. Highlight the **patient** you want to delete in the **Patient List**.
2. Select **File > Delete Patient**. You will be prompted to confirm the deletion.

4 Performing an Exam

This chapter provides general instructions for performing a study or exam, using a motor nerve conduction study for the example. You can apply these basic steps to perform most of the exams available on the UltraPro S100 program.

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Setting up the system

Make sure the components are properly connected to your system.

CAUTION Do not turn on any system power until all cable connections have been connected properly and verified.

For information about system components, please see *Chapter 2* in this guide.

You will also need the appropriate application software installed on your system.

Getting started

When you switch on the main power, the system may display the Windows Logon screen.

After you log on to the system:

1. Double-click the **Viking** or **Synergy** icon on the desktop and then log in.
2. Enter the patient's demographic information.

Using UltraPro S100, Study Menu vs Test Menu

There are two basic approaches to selecting exams for testing: **Test Menu** or **Study Menu**. Each is discussed in greater detail below.

Test menu 

With Test Menu, exams are grouped by type; motor, sensory, F-Waves, etc. When you start an exam, on the waveform screen, you can change to a different exam by double-clicking the **Test Folder** and then from a Select Protocol dialog, choose the specific **exam** and **side**.

Study menu 

In Study Menu, exams are typically grouped based on diagnosis, patient complaint, or some other custom setup. When performing a study, while in the waveform screen, you can select your next exam from the Study Exam in the lower right center of the screen, which is independent of exam type. When done in this fashion, there is no dialog box. A study can contain motor, sensory, F-Wave, H-Reflex, needle EMG, etc.

Testing using Study menu

1. From Study Menu, double-click the **exam** to enter the waveform screen.

   Select/change to left or right side by clicking the **Reverse**  icon.
2. Perform the exam.
3. Press or cick the **Next Study Exam** function key.
4. Continue with testing until completed.

Testing using Test menu

1. From Test Menu, select the **test type** you want from the appropriate folder.
2. From the waveform screen, the **Select protocol** dialog box appears. Choose the protocol and side that you want to use for this exam and click **OK**.
3. Proceed with testing.
4. When this test is completed, while still in the waveform screen, press or click the **New Nerve** navigation key (if performing a nerve of the same type) or **Exit Test** (if the nerve is from another folder).
5. Perform the exam.
6. Continue with testing until completed.

Patient to report in seven steps

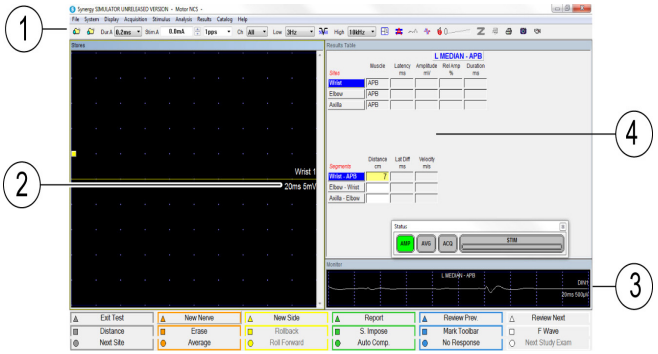
The typical procedure for performing an exam is as follows:

1. Click **New Patient** (or **End Visit** if prior patient's exam is not ended).
2. Enter the Current Patient Information.
3. Click **Save**.
4. Acquire the exams.
5. Look at Report.
6. Return to Test Menu/Study Menu.
7. Click **End Visit** prior to starting next patient.

Example Motor Nerve Conduction Study

Position and secure the electrodes to your patient according to your conventions for the type of test you are performing.

About the waveform screen



1	The filter and/or stimulator settings are indicated on the tool bar.
2	The trace labels and settings are indicated to the right of the waveform.
3	The monitor trace displays the incoming signal to assess noise and interference.
4	The results table. Measured values from cursor placements are shown here.

Select the exam

From the function keys or the Test/Study Menu, select the exam you want to use.

Select a protocol (only if using Test Menu)

1. Use the mouse to select the nerve and tested side.
2. Press **Enter** to accept the selection.
3. If you do not find the desired protocol, select **General Nerve**.
4. When testing is completed, the nerve and site labels can be changed. Left click the site to highlight it, then right-click and select **Edit Segment**.

Motor NCS electrode placement

- The active recording electrode is placed over the endplate zone of a muscle innervated by the tested nerve.
- The reference electrode is placed nearby in an electrically "quiet" area.
- The ground electrode is usually placed between the stimulating and recording electrodes.
- Using electrolytic gel between the skin and recording electrode improves the "electrical contact" and reduces noise.
- Excessive noise may require abrading the skin to lower impedances.

Note: The recording electrode is placed on a muscle, even though the interest is in the conduction along the nerve.

The nerve is stimulated using surface electrodes at two or more sites where the nerve is located superficially. The stimulator is commonly oriented so that the cathode of the stimulator faces the active recording electrode.

Sensory NCS electrode placement

1. Surface disk or ring electrodes are placed over the skin where the tested nerve is located superficially.
2. The nerve is stimulated at sites where it is located superficially.

   The cathode of the stimulator is oriented towards the active recording electrode.

Acquire the data

Data is acquired by the instrument, displayed on-screen, and marked and saved automatically. The waveforms along with the measured values are then transferred to a Report.

1. Set the stimulus intensity to **0**.
2. Position the stimulator at the appropriate site.
3. Press the **Single Stimulus** key on the Control Panel (or footswitch or the **Acquire** button above the wheel on the stimulator probe) to stimulate and acquire responses.
4. Use the **Stimulus Intensity** control knob or the **Intensity** wheel on the stimulator probe to gradually increase the intensity of the electrical stimulus until the response is maximal.
5. If using continuous stimulation, press the **Repetitive** key on the Control Panel or press and hold briefly the **Acquire** button on the stimulator probe. When an acceptable response is observed, press either button again to stop stimulation.
6. To average, press the **Average** function key on the Control Panel. The averager is then enabled. Press the **Repetitive** key on the Control Panel to acquire the defined number of sweeps.
7. To advance to the next stimulus site, press the **Next Site** down arrow from the Navigation keys or the **A** button on the probe.
8. Follow the same procedure to obtain a response for each required site.

Marking data

1. Markers are placed automatically as the responses are acquired.
2. To adjust the markers, click the desired marker and drag it to its new location or use the Marker knob to move the Red marker; push the Marker knob to advance to the next marker.
3. To manually position latency or amplitude markers, select **Mark Toolbar** from the Function keys.
4. From the toolbar that appears, you can Clear, Clear All, Hide, Show, Fast Mark or place individual markers.
5. If using the UltraPro S100 Control Panel, press the **Marker Control Wheel** to activate/advance through the markers. Turning the wheel allows you to position the active marker (Red) appropriately

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Note: To remove a marker, use the **Mark Toolbar** in the function keys. Click the undesired marker on the waveform, it turns red. Then select **Clear** from the Mark Toolbar.

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6. To repeat on additional traces, use the Up/down Cursor keys to activate the correct trace and repeat the previous steps.

Resetting the markers

If you have repositioned markers that have been placed automatically by the system, you can return those markers to their original positions by pressing **Analysis** > **Reanalyse** in the menu bar.

Erasing data

1. Click the waveform to highlight it.
2. Right-click the waveform.
3. Select **Erase**. Data is removed from the trace and results are cleared from the Results Table.
4. To undo the erase, right-click the waveform and select **Unerase**. If unerasing, it needs to be done immediately.

Deleting data

1. Click the waveform to highlight it.
2. Click the **Erase** function key.
3. The data, trace and site are deleted from the trace area and Results Table.

   IMPORTANT: There is no undo.

Superimposing traces

1. Click on the **Superimpose** function key;. All waveforms for a given channel are superimposed.

   The superimposed traces are displayed in the center of the screen.
2. Click the **Superimpose** function key again to return the traces to their original positions.

Calculate the velocity

- Distances may be entered after each site has been acquired, or all distances may be entered after all sites have been acquired.
- Enter distances in **cm** to one decimal place (e.g., 23.5cm / 235mm)
- The distance entered will be displayed in the Results Table in the corresponding Distance field.
- Press **Enter** to accept the distance and to calculate the conduction velocity.

Note: You can enter Default Distances using the protocol table. Conduction Velocities will then be calculated automatically.

Trace analysis and display

You can use the full screen to examine your traces.

1. Select **Display > Full Trace Area ON** or double-click the Header bar.

Displaying large Results Tables

Results can be seen on screen immediately, as you acquire data. If columns on the table are not in view, either scroll the table or select **Results** > **Full Results** from the menu bar to see full tables and graphs. or double-click the Header bar.

Graphs

Up to two graphs can be displayed on the test screen. Up to six graphs can be displayed in the full screen RESULTS view.

1. Select **Results > Graph Options** to choose the results you want to view.

Acquiring EMG

1. To acquire free running EMG using the Test Menu, select or press **Needle EMG** from the function keys on the control panel or double-click the **Needle EMG** folder in the Test Menu.
2. The waveform screen appears with the EMG Summary Selection dialog in the center. Select your **muscle** and **side** and click **Acquire**.
3. The Monitor portion of the display begins displaying EMG. There is no sound initially. To enable sound, just unmute  the speakers.
4. When you are finished with the first muscle, press or click **New Muscle** from the function keys. The EMG Summary Selection dialog appears again. Select your **muscle** and **side** and click **Acquire**.
5. EMG is displayed in the Monitor portion of the waveform screen. Again, unmute the speaker.
6. Continue with this process until all muscles have been tested.

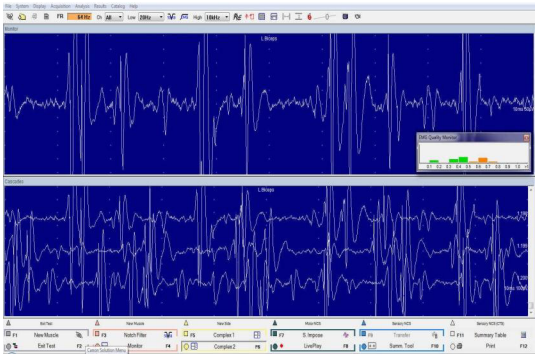
Scoring muscles

1. When muscle testing is completed, press or click **Summary Table** from the function keys. The EMG Summary Table is displayed showing all muscles that were tested.
2. By default, all muscles are scored as “N” or “None”. In the lower half of this summary table, you can change the scoring by highlighting the muscle in question and then rescoring the various categories from the lower half of this dialog as appropriate.

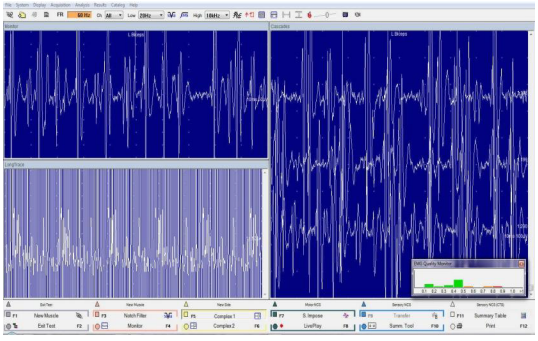
EMG screen displays

There are two basic EMG displays available from the function keys: Complex 1 or Complex 2.

Complex 2 displays a full-screen of Monitor EMG and Cascades.



Complex 1 displays a quadrant of Monitor EMG, a quadrant of Long Trace EMG and a half screen of Cascades.



In both cases, if you wish to acquire either Cascades or Long Trace EMG, you must press or select **Acquire** from the function keys. If Acquire is used, the sound is activated automatically.

The Summary Table can be used with either Complex 1 or 2 as described above.

Storing data

Data is stored automatically as you advance to the next trace.

Adding a screen shot to a report

1. Press **Transfer** to move the current screen display to the report.

5 Backup and Restore Data

This chapter provides some instructions on backing up and restoring patients and settings.

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Backing up files

Backing up data is easily done via the menu bar above the Patient Information screen. The data can be copied to the media of your choice: CDR, DVD-R, flash drive, external hard drive, etc. Backed up data will appear as .mps files which can then also be restored to your patient database through the "Load Patient from File" function.

1. From the Home Page screen, click **Patient List** to display all patients on the right side of the screen.
2. Find the patient to be backed up and highlight the **name**. All visits for this patient are included in the backup.
3. From the menu bar at the top of the screen, click **File** > **Export Patient(s) to File**.
4. Find the back up device via the **Save In** cell at the top of this dialog. Name the file and click **Save**. A progress window appears while the data is copied to your media. When completed, confirmation of a successful back up is displayed.
5. The patient will then need to be deleted manually from the system if desired. With the Patient Name highlited, click File Delete Patient.

Restoring files

Restoring patient data back to the local hard drive is similar to the back up process.

1. Ensure the backup media is connected to the system.
2. From the Home Page screen, click **Patient List** to display all patients on the right side of the screen display.
3. In the menu bar near the top, click **File** > **Import Patient(s) from File**. A dialog appears where you can locate your back up device.
4. Once the back up device has been located, search for the patients by looking for **.mps** files. It may be helpful to sort the files by **Type** to group all .mps files together to make it easier to find the patient(s) in question.
5. Highlight the patient's file on the backup device and click **Open**. A confirmation dialog appears. If the information in this dialog is correct, click **Load**. The patient reappears in the Patient List.

6 Electromagnetic Compatibility (EMC)

This chapter provides EMC information for the UltraPro S100.

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List of UltraPro S100 items; additional and optional parts

List of all modules, cables and accessories with which the manufacturer of the UltraPro S100 claims compliance. The customer or the user of the UltraPro S100 should assure that it is used with these parts.

Part Number	Type	Guidance
9033G070- *	UltraPro S100 Main Unit	-
9006A220- *	Mains cable, USA	Shielded, earth connection and maximum cable length of 3 m.
Generic	Power interface cable (printer)	Cable length 1 m
Generic	Power interface cable (display)	Cable length 1.5 m
Generic	Power interface cable (PC)	Cable length 1 m
Generic	Power interface cable (laptop)	Cable length 1.2 – 1.8 m
9080K0541 + 9080K0522	HS link patch cable (Main Unit – Ampifier)	Cable length 2.0 m
Generic	USB cable (PC - Front End)	Cable length 1 m
Generic	Video signal cable (digital RGB)	Maximum cable length 1.7 m
Generic	Printer signal cable	Maximum cable length 1.7 m
Generic	Electrode and stimulation cables	Shielded. Maximum cable length 2 m
Generic	Stimulation, grounding and recording electrodes	Shielded or unshielded. Maximum cable length 1.2 m
Generic	PC (Laptop/Desktop)	-
Generic	Mouse	Maximum cable length 2 m (partly internal)
Generic	Keyboard	Maximum cable length 2 m (partly internal)
Generic	Monitor 22” wide	-
9031D040- * 9031D041- *	Isolating transformer 115V Isolating transformer 230V	-
515-016300	Passive stim. handgrip (RS10)	Cable length 2.5 m
9031E015- *	Active stim. handgrip	Cable length 2.5 m
9033C073- *	3 ch. amplifier box	
9031E017- *	Advanced stim handgrip	Cable length 2.5 m
9031E027- *	Tubal ear inserts	Cable length 5 m
9031E025- *	Headset	Cable length 5 m
9031E026- *	Screened headset	Cable length 5 m
9031E028- *	Bone conductor	Cable length 5 m
222-510800	Footswitch, 3 key (USB)	Cable length 5 m
9031E040- *	Tendon hammer	Cable length 1.8 m
9033B033- *	Handheld switch cable	Cable length 1.8 m

Part Number	Type	Guidance
9031C073 *	3 channel amplifier box	-
9031C0742 *	4 channel amplifier box	
9031F112	VEP Monitor	Cable length 5 m
Generic	Color printer	-
Generic	Laser printer	-
9031E022 *	Goggles	Cable length 2.9 m

* Components, items, with high integrity characteristics.

WARNING **The use of accessories and cables other than those validated by Natus Neurology Incorporated may result in increased emissions, or decreased immunity of the equipment.**

Pins on connectors identified with this  ESD warning symbol should not be touched and connections should not be made to these connectors unless ESD precautionary procedures are used.

Precautionary procedures include:
- Methods to prevent build-up of electrostatic charge (e.g., air conditioning, humidification, conductive floor coverings, non-synthetic clothing);
- Discharging one's body to the frame of the EQUIPMENT or SYSTEM or to earth or a large metal object;
- Bonding oneself by means of a wrist strap to the EQUIPMENT or SYSTEM or to earth.

Staff that could touch connectors identified with the ESD warning symbol should receive this explanation and training. This includes clinical/biomedical engineering and health care staff.

ESD training should include an introduction to the physics of electrostatic charge, the voltage levels that can occur in normal practice and the damage that can be done to electronic components if they are touched by an OPERATOR who is electrostatically charged. Further, an explanation should be given of methods to prevent build-up of electrostatic charge, and how and why to discharge one's body to earth or to the frame of the EQUIPMENT or SYSTEM, or bond oneself by means of a wrist strap to the EQUIPMENT or SYSTEM or to earth prior to making a connection.

Table 1 - Electromagnetic emissions

Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions **CISPR 11**	Group 1	The Nicolet UltraPro S100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic environment.
RF emissions **CISPR 11**	Class A	The Nicolet UltraPro S100 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **WARNING** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment or shielding the location.
Harmonic emissions **IEC 61000-3-2**	Class A	
Voltage fluctuations/flicker emissions **IEC 61000-3-3**	Complies	

Table 4 - Immunity Test Levels - Enclosure Port

Phenomenon	Basic EMC Standard or Test Method	Immunity Test Levels - Professional Healthcare Facility Environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM Fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz
Proximity Fields from RF Wireless Communications Equipment	IEC 61000-4-3	See “Table 9 - Enclosure Port Immunity to RF Wireless Communications Equipment” below
Rated Power Frequency Magnetic Fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 5 – Immunity Test Levels – Input A.C. Power Port

Phenomenon	Basic EMC Standard	Immunity Test Levels - Professional Healthcare Facility Environment
Electrical Fast Transients / Bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges **Line-to-line (Differential Mode)**	IEC 61000-4-5	± 0,5 kV, ± 1 kV
Surges **Line-to-ground (Common Mode)**	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV
Conducted Disturbances Induced by RF Fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz
Voltage Dips	IEC 61000-4-11	100% dip; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 100% dip; 1 cycle and 30% dip; 25 cycles (50Hz) Single phase: at 0°
Voltage Interruptions	IEC 61000-4-11	100% dip; 250 cycles (50Hz) /300 cycles (60 Hz)

Table 7 – Patient Coupling Port

Phenomenon	Basic EMC Standard or Test Method	Immunity Test Levels - Professional Healthcare Facility Environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Conducted Disturbances Induced by RF Fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz

Table 8 – Immunity Test Levels - Signal Input / Output Parts Port

Phenomenon	Basic EMC Standard	Immunity Test Levels - Professional Healthcare Facility Environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Electrical Fast Transients/Bursts	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency
Surges Line-to-Ground (Common Mode)	IEC 61000-4-5	± 2 kV
Conducted Disturbances Induced by RF Fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz

Table 9 - Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
870						
930						
1,720	1,700 – 1,990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 2 UMTS	Pulse modulation 217 Hz	2	0,3	28
1,845						
1,970						
2,450	2,400 – 2,570	990Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5,240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5,500						
5,785						

Notes

The Nicolet UltraPro S100 system is designed to function under a wide range of environmental conditions without compromise to Safety or Essential Performance.

In the event that an environmental artifact (e.g. ESD, line voltage fluctuations, etc.) is of sufficient intensity and/or duration to possibly affect the system performance, the system is designed to enter a fail-safe mode and temporarily discontinue operation. If this should occur, a message will display notifying the operator that such an event has occurred. Once the operator has cleared this message, the system will typically reinitialize and indicate that acquisition can resume with the settings restored to the previous state (other than Stimulation – which must be manually reset/started).

In severe cases, such as if the Voltage fluctuation dips below 100v for an extended period, the unit may need to be rebooted to recover.

If this type of condition causes persistent issues, please contact your local service representative.

Essential Performance and Criteria for Ultrapro S100 Compliance, related to immunity testing:

Performance criteria according to corresponding standard were applied during immunity test as follows.

General essential performance criteria

The UltraPro S100 shall not become dangerous or unsafe as a result of application of tests.

In normal operation mode, essential performance is defined as follows:

The displayed waveform may contain electrical artifacts presented during the susceptibility testing, but should continue to update display while operating expect while in “fail safe “mode.

Communication in between the base unit, amplifier and host PC may be lost during immunity testing as long as user can recover by re-powering the system and/or re start the application software.

These deviations of operation are considered acceptable as this has been determined to not pose an unacceptable risk to patients.

Compliance for the Electrical, VEP, and AEP stimulator

The Electrical stimulation is monitored by measuring during all tests while operating In CC mode, during immunity test Stimulation is actively stimulating or switches to safe mode = 0mA and stop pulsing. Before and after immunity test pulse max deviation remains within 10%.

Visual Stimulation mode will be active and LED goggles will be active and visually monitored.

Auditory Stimulation will be active and the headphone will be monitored to ensure consistent functionality. Stimulation will continue to function throughout the immunity testing, except when fail safe condition occurs and the stimulation is stopped.

Compliance for the amplifier

The amplifier curves can be disturbed during testing, but must return to baseline after test completion. During Fast Transients and ESD, much higher disturbances are allowed and immunity level shall not be noted. Before and after immunity test Amplifier curves disturbance should be, max 5µVpp.

Compliance for intended operation

Ultrapro S100 shall remain safe and be restorable in case of cessation or interruption of any intended operation during immunity tests. Disturbance of display, re-connection of PC USB keyboard and USB mouse or loss of USB connection to Main Unit does not constitute noncompliance

Compliance to no damage allowed

Ultrapro S100 Start-up test performs without unexpected errors.

Compliance for not losing stored patient data

No change allowed. Check normal program start up before and after immunity test are completed, to confirm test loads properly ensuring safe storing of data.

Compliance to not burning

No fire or smoke are allowed during all immunity tests observe that the system is free of fire or smoke from burned or overheated components.

The Essential Performance is verified after the tests.

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