



USER GUIDE

INSTRUCTIONS FOR SETUP AND USE

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Sierra Summit User Guide

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Disclaimer

Clinical conclusions and decisions based on the use of this product are the responsibility of the user. The manual provides an operational summary for the Sierra Summit system. It does not provide clinical training. It is assumed that the user has adequate clinical training to perform electrodiagnostic procedures.

This document may contain technical inaccuracies or typographical errors. Changes are periodically made to the information herein; these changes will be incorporated in future revisions of this document. Features and specifications are subject to change without notice.

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User Guide Intent

This device is intended for qualified users only. Refer to your institution's policy regarding particular training and qualifications required to operate this equipment.

This manual is intended as a basic guide to installing and operating your Cadwell Sierra Summit. Please refer to the following information sources for more detailed information on operating and servicing your Sierra Summit.

- 190272-620 Sierra Summit Operator's Manual
- 369043-620 Sierra Summit Help File - Available with installed Sierra Summit application.
- 100850-621 Sierra Summit Technical Manual
- 190272-931 Sierra Summit Specifications

- 369043-934-WN10 Sierra Summit Installation Instructions - Windows 10 & 11
- 369043-810 Sierra Summit Release Notes - Version 4.0
- 369043--630-WN10 Configuring Windows 10 for Sierra Summit

Overview

The **Cadwell Sierra Summit™** is a complete electromyography and evoked potential system with up to 12 channels of data acquisition.

The Summit can be configured in a **portable** or **desktop** version. The portable version comes with a laptop computer and soft-sided carrying case for greater mobility.

The desktop version comes with a tower or mini-tower PC and an LCD monitor.

Both a lightweight and hospital-grade cart are available.

The Sierra Summit basic system includes a digital amplifier with EMG, Quantitative EMG (Multi-MUP and Interference Pattern), NCS, RNS, Blink Reflex, SSR, RR Interval, Somatosensory Evoked Potentials, and Report Generation using Microsoft Word.

Optional capabilities include Single Fiber EMG, Stimulated Single Fiber EMG, Macro EMG, Auditory Evoked Potential, Visual Evoked Potential, P300 Cognitive Evoked Potential, and Motor Unit Number Estimation.

Intended Use and Precautions

Intended Use:

Cadwell Sierra Summit is indicated for acquisition, display, storage, transmission, analysis, and reporting of electrophysiological and environmental data including Electromyography (EMG), Nerve Conduction Studies (NCS), Evoked Potentials (EP), and Autonomic Responses (RR Interval Variability). The Cadwell Sierra Summit is used to detect the physiologic function of the nervous system, and to support the diagnosis of neuromuscular diseases or conditions.

The listed modalities do include overlap in functionality. In general, Nerve Conduction Studies measure the electrical responses of the peripheral nerve; Electromyography measures the electrical activity of the muscle, and Evoked Potentials measure the electrical activity from the central nervous system. The interface for third-party non-invasive imaging display and control is used to visualize the morphology and location of nerves and muscles, and serves as an aid in confirming the results of the aforementioned modalities.

Cadwell Sierra Summit is indicated for use by qualified medical practitioners. This device does not provide any diagnostic conclusion about the patient's condition to the user.

Common applications include:

- Measurement of sensory and motor conduction latencies and velocities including those of the peripheral nerves, spinal cord, and central nervous system.
- Related measurements that are also indicated include F-wave, H-reflex and Blink response tests, and repetitive stimulation studies.
- Measurement of evoked potential amplitudes and latencies generated by electrical, auditory, and visual stimulators.
- Evaluation of muscle and nerve integrity by needle electromyographic examination.
- Evaluation of nerve, spinal cord, and cortical functionality and integrity.

Precautions:

There are applications in which the benefits of the test should be weighed against possible adverse effects. This is a judgment best left to a skilled clinician familiar with the characteristics of the device. These applications include:

- Use in the presence of cardiac pacemakers or other implanted electronic devices,
- Pregnancy
- Use on anesthetized or comatose patients
- Use on patients with absent or reduced pain sensation
- Use on neonates and very young children or patients otherwise unable to communicate in the event of prolonged or high intensity stimulation.



CAUTION: Federal law restricts this device to sale by or on the order of a physician or qualified medical practitioner.

Application Specification

Per IEC 62366

Medical Purpose

Sierra Summit and Sierra Ascent are electroneurodiagnostic medical devices which measure and display the electrical signals generated by peripheral nerve, muscle and central nervous system. They acquire the data necessary to perform - electromyography (EMG), nerve conduction velocity (NCV, F wave, and H reflex), evoked potentials (EP, brainstem, visual, somatosensory), electronystagmography (ENG), and repetitive nerve stimulation (RNS) testing. They are intended for use only during the duration of the procedure.

The Sierra Summit/Ascent system is intended to be used by personnel trained to perform the intended tests. The system is used primarily in a clinical setting to diagnose neurological disease (peripheral nerve disorders, muscle disorders, central nervous system disorders).

Patient Population

- a) Age: newborn to geriatric
- b) Weight: >2.5 kg
- c) Health: not relevant
- d) Nationality: multiple
- e) Patient State: not relevant, the patient is not the operator.

- f) Patient Condition: awake, sedated, or asleep.

Part of the body or type of tissue applied to or interacted with

- a) Measurement Site:
- skin over peripheral nerves and muscles
 - scalp overlying the somatosensory or motor cortex
 - intramuscular (needle EMG)
- b) Stimulation Site:
- skin over peripheral nerves and muscles
- c) Condition:
- intact skin within and around electrode site

Intended User

- a) Education and Training
- Physician or technician who has had special training in the diagnosis and treatment of neurological and neuromuscular diseases. The patient is not the user of the device.
 - No maximum
- b) Knowledge
- Minimum
 - anatomy
 - pathology of muscle and nerve
 - neuromuscular physiology
 - electrophysiology, including instrumentation, quantification, and statistical analysis
 - No maximum
- c) Language Understanding
- English for user manuals, setup guides, etc.
- d) Experience
- Minimum
 - Clinical aspects of neurological and musculoskeletal conditions with particular emphasis on diagnosis and treatment of neuromuscular diseases as they pertain to clinical electrodiagnostic medicine.
 - No maximum
- e) Permissible Impairments
- mild reading vision impairment or vision corrected to log MAR 0.2 (6/10 or 20/32)
 - one arm/hand capable of guiding and holding mouse, needle, or stimulator
 - impaired by 40% resulting in 60% of normal hearing at 500 Hz to 2 kHz

Application

- a) Environment
- General
 - intended for professional use, not intended for home use
 - hospital or physician's office
 - indoor use only
 - not for use in shower, bath tub, or sink
 - Conditions of visibility
 - ambient luminance range: 100 lux to 1500 lux
 - viewing distance: 20 to 100 cm
 - viewing angle: normal to the display +/- 45 degrees

- Physical:
 - temperature range: 10 C to 40 C
 - relative humidity range: 20 to 95%, non-condensing
 - ambient pressure range: 700 hPa to 1060 hPa
 - voltage input: 100-240 VAC, 50-60 Hz, 180 VA
- b) Frequency of Use:
 - once a day up to 10 times a day
- c) Mobility:
 - for use on stationary table or cart
 - should not be used during transport

Setup Instructions

Unpacking the System

As you unpack, please carefully check to make sure the contents of the shipping box match the packing slip. Do not discard the shipping boxes or packing material until all items on the packing list are accounted for.

Note: DO NOT discard any boxes or packing material until all items on the packing list are accounted for.

List of Standard Items

You should receive the following as standard items:

- Sierra Summit Base Unit with detachable power cord.
- Backup Sierra Summit installation software media (DVD or USB).
- Either a 1-2 Channel or 3-12 Channel Amplifier.
- One (1) StimTroller Plus handheld electrical stimulator.
- One (1) USB-A to USB-B cable, to connect the base unit to the PC.
- If ordered, a Laptop or Desktop computer with AC adapter and/or AC power cord.

Optional Items

You may receive one or more of the following optional items:

- 2nd StimTroller Plus
- Headphones, Insert Earphones, or Bone Transducer
- LCD Checkerboard Monitor and Cable
- VEP Calibration Sensor and Cable
- Instrument cart with instructions, grounding cable and screw, and any accessories such as a retractable arm, amplifier bracket, or printer tray
- Printer with cables and instructions
- External keyboard
- External mouse
- Temperature Probe

- Reflex Hammer
- Diagnostic Test Fixtures
- USB Footswitch
- Soft-sided carry case
- Ultrasound scanner, transducer (probe), and USB interface cable
- Isolation Transformer or UPS

Cadwell supplied Computer

If you purchased your computer from Cadwell, all necessary Windows and Sierra Summit software is already installed on your computer from the Cadwell factory. There is no need for you to install any software. Please put the installation media (DVD or USB) that came with your system in a safe place. The installation media is included as a backup copy only. Laptop computers may require you to make your own backup DVD for the computer.

Non-Cadwell supplied Computer

If you purchased your computer from a source other than Cadwell, you must install Microsoft Word and configure Microsoft Windows prior to installing and activating the Sierra Summit software. Follow the instructions in these applicable documents:

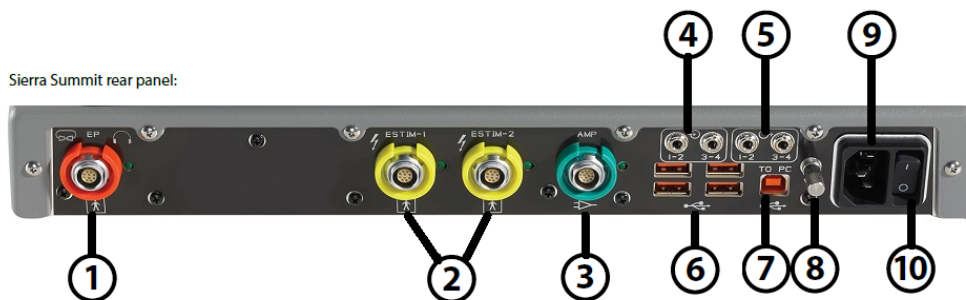
- 369043-630-WN10 Configuring Windows 10/11 for Sierra Summit.pdf
- 369043-934 Sierra Summit Installation Instructions.pdf
- 100850-623 Summit System Configuration.pdf

Note: the above documents are available on the software installation media.

Back Panel Connections

The following connections correlate with the peripheral device connection indicated in the image of the Sierra Summit base below.

1. Evoked potential stimulator (headphones, inserts, bone transducer, LED goggles)
2. StimTroller Plus™ connections
3. Amplifier Input
4. Trigger Input connections
5. Trigger Output connections
6. High speed USB hub (footswitch, printer, VEP calibration sensor, ultrasound scanner). Devices connected to these ports must be compliant with IEC 60601-1, or IEC 60950-1, or IEC 62368-1
7. High speed USB connection to PC
8. Terminal for the connection of a Potential Equalization Conductor
9. Appliance Inlet
10. Power on/off switch



Status Indicator Lights

- Solid green to indicate internal circuit board is operational.

Power Status

- Summit and Cadwell logos on base unit backlit in ice-blue color.

The connectors on the Sierra Summit come standard with durable, color-coded, quick connect fasteners.

Connectors are labeled using text and graphics to indicate the peripheral devices that connect to each port.

Please refer to the Peripheral Device Connection section for instructions about where each peripheral device connects.



EP: Optional connection for Auditory Headphones, Insert Earphones, Bone Transducer, and LED Goggles.



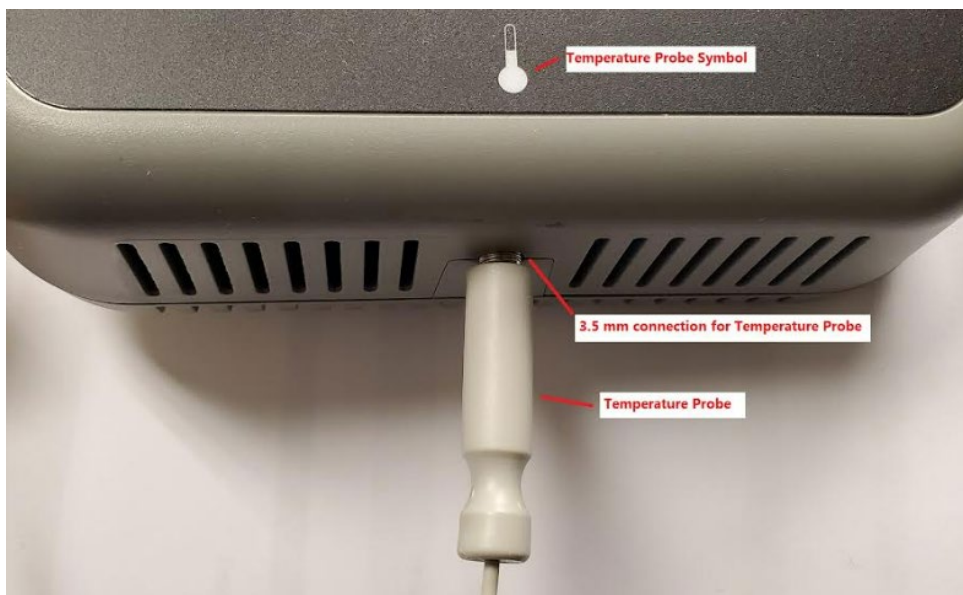
ESTIM-1: Connection for Electrical Stimulator Handle #1.

ESTIM-2: Optional connection for Electrical Stimulator Handle #2.



Amplifier: Connection for the digital amplifier.

Amplifier Connections



Temperature Probe: Connection for optional Temperature Probe.



Trigger Input 1-2: Connection for Trigger Input signals #1 and #2.

Trigger Input 3-4: Connection for Trigger Input signals #3 and #4.



Trigger Output 1-2: Connection for Trigger Output signals #1 and #2.

Trigger Output 3-4: Connection for Trigger Output signals #3 and #4.



USB HUB: 4-port USB Hub. Suitable for printer, footswitch, mouse, or ultrasound scanner.



The base unit must be powered ON in order for this hub to be functional.



TO PC: High speed USB connection to Laptop or Desktop PC.



Equipotentiality: Terminal for the connection of a Potential Equalization Conductor (e.g., Cart Potential Equalization Conductor).



POWER: Connection for hospital-grade power cord and I/O switch. 100-240Vac, 50-60Hz, 180VA.

Turning Equipment On and Off

Note: Do not turn the Sierra Summit instrument base on or off while a patient is connected.

To turn the equipment On:

1. Connect the amplifier, stimulators, and other accessories to the Sierra Summit base unit (if not already connected).
2. Turn equipment on in the following order.
 - Computer
 - Monitor (if desktop computer)
 - Summit base unit.

To turn equipment Off:

1. Close the Sierra Summit program and any other programs that are running on the computer.
2. Turn off the Sierra Summit base unit.
3. On the Windows taskbar, click on the Start icon, and then select Shutdown.
4. Turn off the Monitor (if desktop computer).
5. You do not need to disconnect the amplifier, stimulators, or accessories. You may leave them connected.

Opening and Closing Sierra Summit Software

To Start the Sierra Summit program:

Start the Sierra Summit program on your computer in one of the following ways:

- Double-click the Sierra Summit icon on the Windows desktop, or
- Click the Windows Start button, select All Programs, Cadwell, and then Sierra Summit.

Note: If you receive a Communication Error message:

Close the Sierra Summit program and make sure the Sierra Summit base unit is turned On, and that the USB cable is attached securely between the computer and the Sierra Summit base unit. Then, restart the Sierra Summit program.

Note: The default user is Admin and the default password is "admin". See the Help Topics for information on creating and editing users.

To Close the Sierra Summit program:

- Click on the File menu and select Exit Sierra Summit, or
- Click on the red X in the upper right-hand corner of the screen.

Verification and Basic Operation

Summit Setup Verification

This procedure is used to verify that the Sierra Summit system has been setup correctly and that NCV clinical data can be acquired, saved, and printed. The person performing this procedure should have a basic knowledge of nerve conduction testing.

Turning Equipment On

1. Connect the amplifier, stimulators, and other accessories (if not already connected). Refer to the Sierra Summit Setup Instructions for a description of the connections.
2. Turn equipment on in the following order:
 - Computer
 - Monitor (if desktop computer)
 - Sierra Summit base unit
 - Printer



If you are using the isolation transformer and cart power switches, you will need to turn on the cart power switch and then the computer.

Starting the Sierra Summit Program

Start the Sierra Summit software on your computer in one of the following ways:

- Double-click the Sierra Summit icon on the Windows desktop.
- Click the Windows Start button, select All Programs, Cadwell, Summit, and then Sierra Summit.



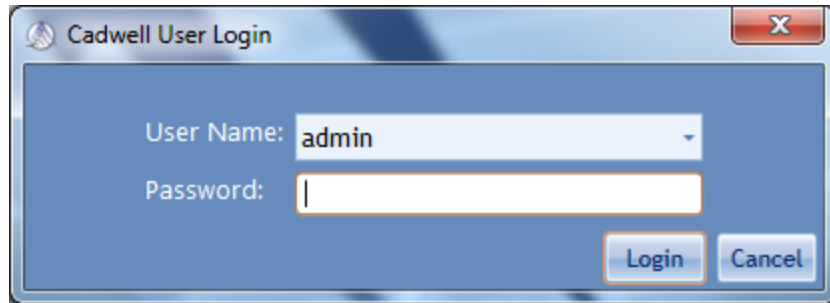
If you receive a Communication Error message.

Close the Sierra Summit program and make sure the Sierra Summit base unit is turned On, and that the USB cable is attached securely between the computer and the Sierra Summit base unit. Then, restart the Sierra Summit program.

Login Window

After launching the Sierra Summit program the **Cadwell User Login** window will be displayed. You will need to select a user name from the drop-down list and then enter the appropriate password.

If no users have been created, select the **Admin** user and enter the password **admin**.



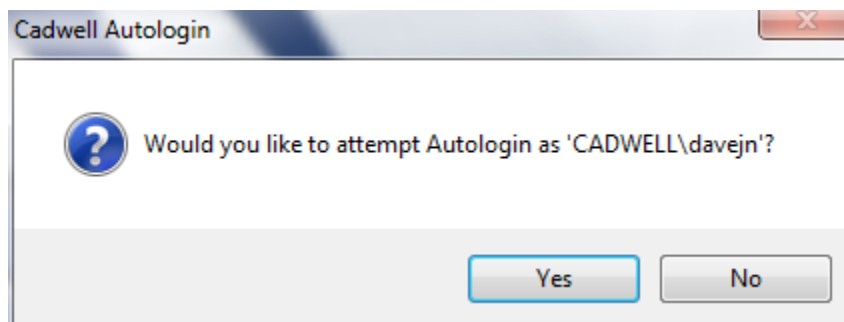
User Login window



For improved security, you should change the password of the Admin account. The Admin account cannot be deleted.

Domain User Accounts:

If you are an Active Directory (Domain) user, the program will automatically ask you if you want to log in using your domain credentials.



Domain User login

Starting a New Study and entering Patient Information

To start a New Exam and enter Patient Information use one of the following methods.

- Press **F1 - New Patient**.
- Select **New Patient** from the **File** menu.

All of these methods will display the following Patient Information Window.

Patient Information

Last Name: First Name: M.I.: Height: cm Inches:

Patient ID: Birth Date: Gender: Male Weight: lbs. BMI:

Exam Information

Test Date: 2/ 4/2019 Test Time: 1:11:26 PM Facility: Room:

Physician: Referring Physician: Technician:

Custom Information

Patient Complaints: [Complaints](#)

Medications: [Medications](#)

Report Header

ReportHeader.doc

F1 - Load Patient Info F2 - Save Patient & Close F3 - New Study F4 - Cancel

Patient Information window

A blinking cursor will automatically be displayed in the Last Name field. You can use the tab key, mouse, or Knob #1 on the Sierra Summit base unit to move from field to field.



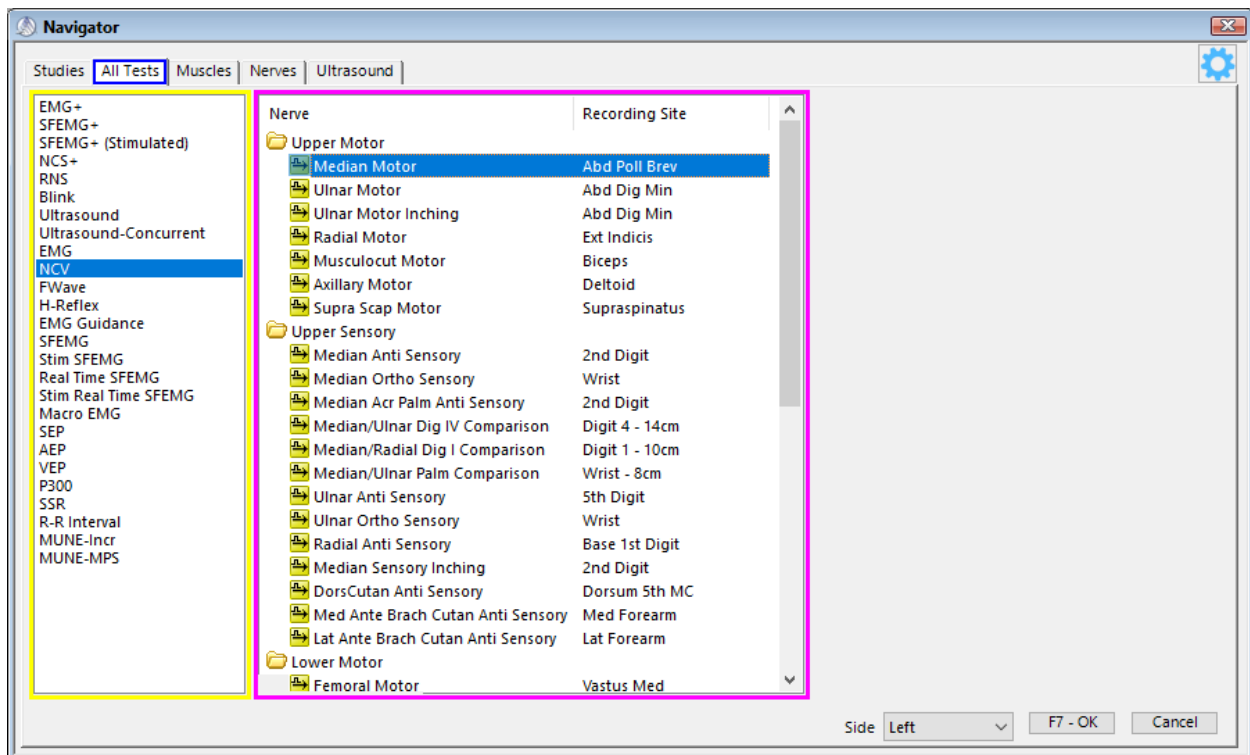
At a minimum, you should enter a Last Name and First Name, this is what the Sierra Summit program uses to create the patient's data file.

The **Test Date** and **Test Time** will automatically be entered for you, and can be modified if needed.

Selecting the NCV Test Protocol

Select the NCV Test

Click the **F3 - New Study** button. The patient information will be saved and the **Navigator window** will be automatically displayed. Select the **NCV** test protocol from the **All Tests tab**. A nerve list will be displayed allowing you to pick the nerve or nerves that you will be testing on the patient.



Navigator window.

1. Select the **Median Motor** nerve.
2. Change the **Side** field to **Left**.
3. Click **F7-OK**. The Median Motor nerve conduction test will be displayed.

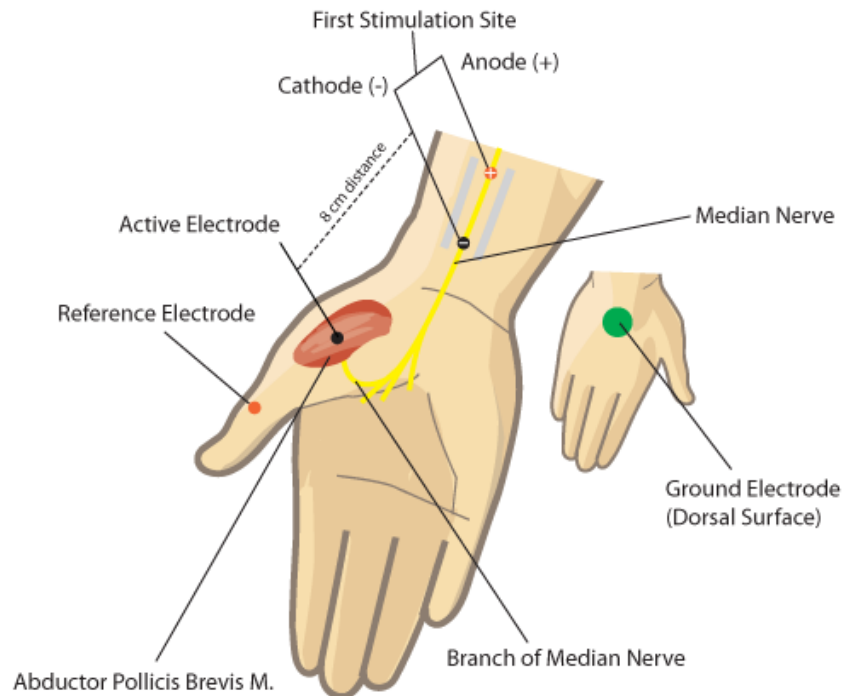
Follow these steps for performing a routine Median Motor nerve conduction study.

1. Electrode Placement

Attach the electrodes to the patient as shown in the following diagram.

NCV

Median Motor
Recording Setup and Distal
Stimulation Site



Parameters:

Gain = 2000 - 5000 $\mu\text{V}/\text{Div}$

Hicut = 10k Hz

Locut = 10 Hz

Sweep Speed = 2 - 5.0 ms/Div



Median Motor Recording Setup and Wrist Stimulation

2. Stimulate at the Wrist

Position the stimulator over the median nerve at the wrist. The Cathode (-) terminal of the stimulator should be closest to the recording electrodes (see previous diagram). The Cathode is indicated by the Green LED on the stimulator handle.

Increase the stimulus intensity level by turning the **wheel** on the electrical stimulator handle. The **intensity level** (in milliamps) is displayed on the screen in a small pop-up window and also in the Stimulator section. Once you have reached an appropriate

starting intensity apply the stimulator to the patient and deliver the stimulus by pressing the **Stim button** on the electrical stimulator handle. The stimulator light, located next to the intensity level on the Screen, will flash Green and the patient's response will be displayed.



The **Knob #1 (Intensity/Single)** on the Sierra Summit base unit can also be used to adjust stimulus intensity and deliver a single stimulus.

Continue to increase the intensity level and stimulate until a supra-maximal response is acquired. If the response is large and "clips" at the top or bottom, decrease the amplifier sensitivity by adjusting the Gain setting. For example, change gain from 2k to 5k and re-stimulate. Gain can be adjusted easily by using **Knob #3 (Gain /Sweep)** on the Sierra Summit base unit.

3. If necessary, Adjust Auto Cursors

Auto Cursors are placed on the response as soon as it is displayed. The cursors are **Onset (O)**, **Peak (P)**, **Trough (T)** and **Recovery (R)**. The configuration of the Site and Segment tables determines which of the four cursors are placed on the trace. The positions of these cursors can be adjusted by performing one of the following actions;

- By using **Knob #2 (Sel Cursor / Move Cursor)** on the Sierra Summit base unit.
- By clicking on them with the **left mouse button** and dragging them to their new position.

For the correct placement of the auto-cursors the response must meet or exceed certain amplitude and slope criteria. When these criteria are not met the cursors will be placed on the response in the following pattern.



Pattern of auto-cursor placement when amplitude criteria is not met.

4. Store the Responses

To store the response and advance to the next stimulation site, perform one of the following actions:

- Press the **Store button** on the **Electrical Stimulator handle**.
- Press the **Store key** on the **Sierra Summit base unit**.
- Press the **Footswitch** pedal.

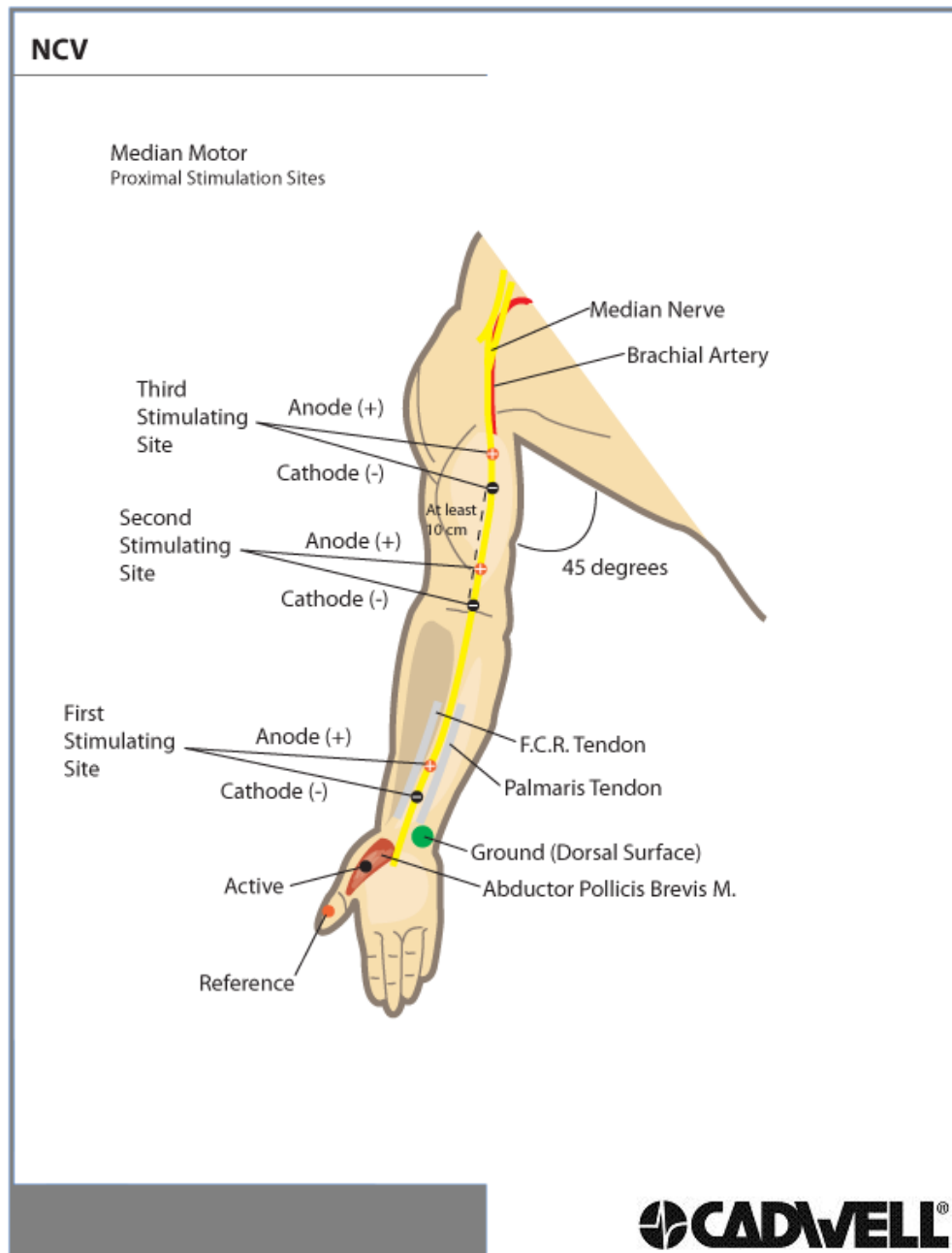
When the response is stored the color of the trace changes from **white to purple** and the next row in the Site table (Elbow) is automatically highlighted.



If the nerve has only one stimulation site, it is not necessary to store the response. The Sierra Summit will automatically keep the trace when you change nerves or test protocols.

5. Stimulate and Store the Elbow Site

Move the stimulator to the elbow stimulus site. Stimulate and store the response. Refer to the following diagram for the correct stimulation site.

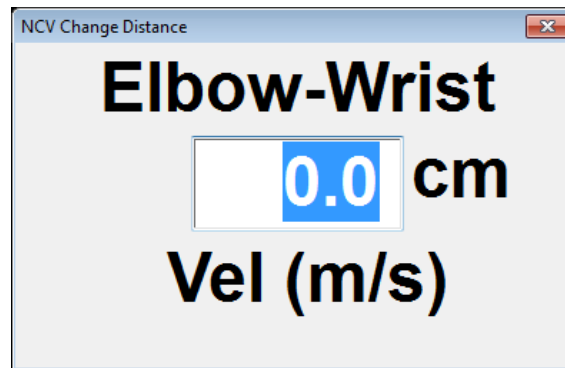


Median Motor - Elbow (second stimulation site)

6. Enter Distance to calculate Velocity

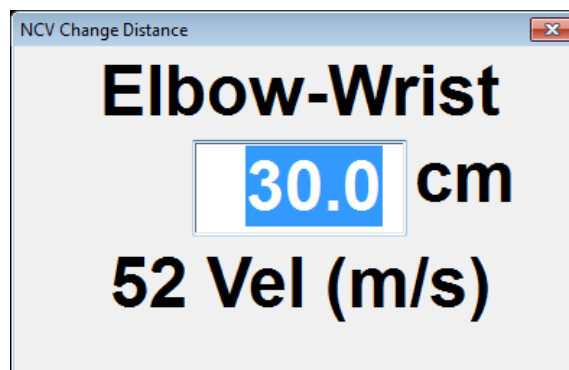
Measure the distances between the Wrist and the Elbow stimulation sites (from cathode to cathode) and enter the value (in centimeters) into the segment table. There are **two ways** to enter the distance.

- Press the **F1 - Distance key** on the **Sierra Summit base unit** or **click** on the appropriate distance field with the **mouse**. The distance field will become activated and a small pop-up window is displayed showing the segment name and a place for the distance measurement, type the distance value and then press the **Enter key**. *You can also press the Distance key a second time instead of pressing the Enter key.*



Distance pop-up window.

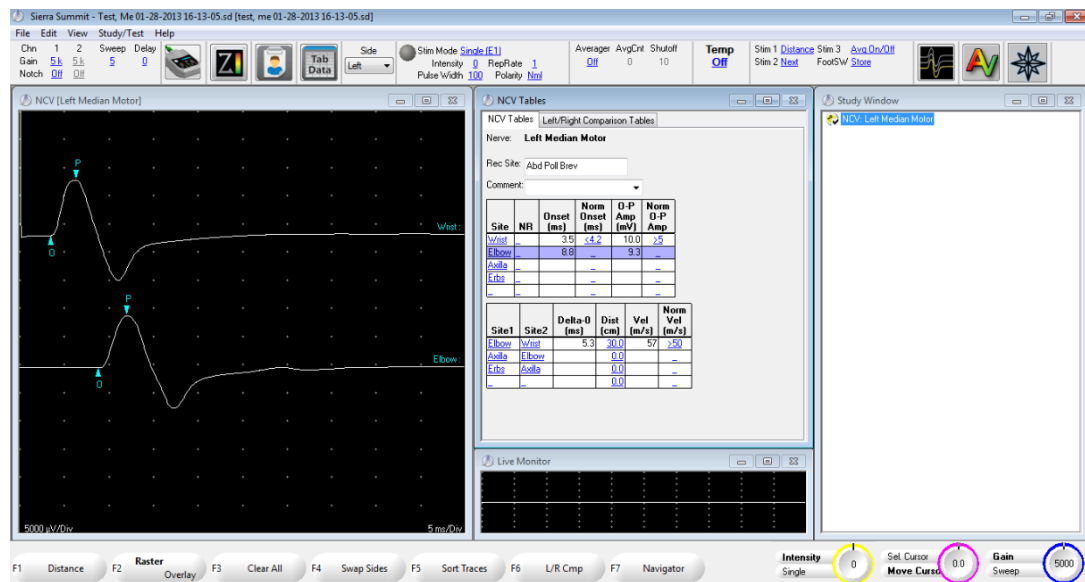
- Press **Programmable button #1** on the **Electrical Stimulator handle**. A small pop-up window is displayed showing the segment name, distance value, and velocity. Now, **turn the wheel on the stimulator handle to increase or decrease the distance value in 0.5 cm increments**. When the correct distance value is reached, press **Programmable button #1** a second time or press the **Enter key**.



Distance pop-up window.

7. Verify Responses

Your screen and the recorded responses should be similar in appearance to those shown in the following example.



Median Motor study with Wrist and Elbow responses

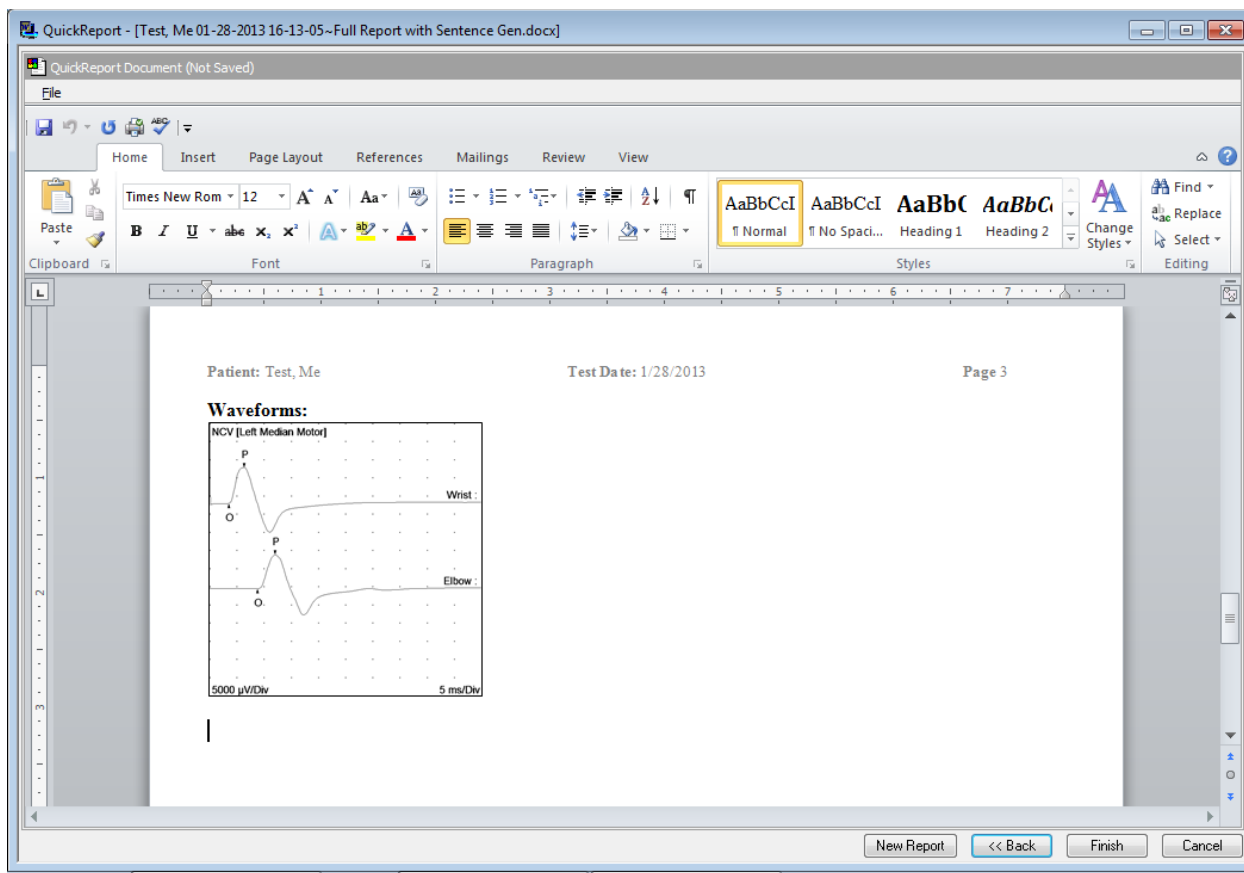
Generate a Report

The Sierra Summit uses a separate program for report generation, this program is called **QuickReport**.



QuickReport is a Microsoft Word™ based application and includes such Word features as spell check, grammar check, table formatting, and graphics support.

1. Press the **Favorite** key on the Sierra Summit base unit.
2. QuickReport will launch and begin to generate the report.
3. When the report is ready the Microsoft Word screen will be displayed.



QuickReport / Microsoft Word screen.

To Print the Report

- Click on the Printer icon  at the top of the screen. The report will be sent to your default printer.

To Save the Report and close QuickReport

- Click the Finish button; you will be prompted to save the report.
- Answer Yes, to the confirmation message. The report is saved to the user's Data directory with the filename of "lastname, firstname, date, time~template name.doc" .
- QuickReport is closed and you are returned to the median motor test screen.



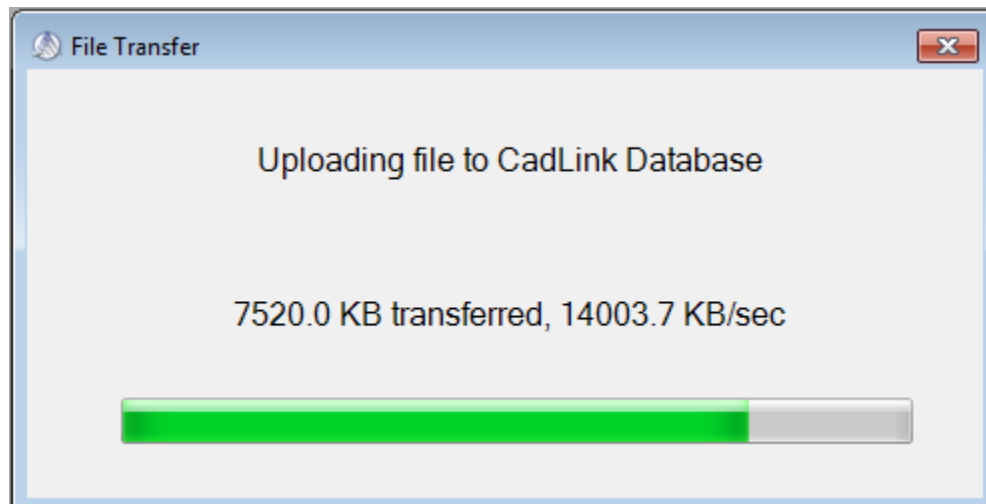
To get a simple printout of the current test screen, select Print Screen from the Sierra Summit File menu.

Moving the Exam to the CadLink Database

Once the patient exam has been closed it can be uploaded to the CadLink database, or it can be kept in the user's local data folder. This is determined by the option that has been selected in the Network Setup window.

Automatic (without user confirmation):

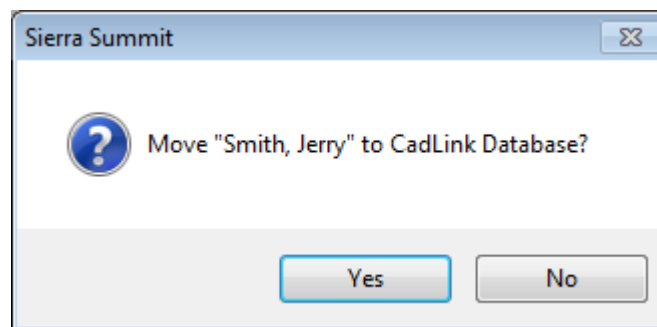
If this option is selected, the patient's exam and all report documents are automatically moved to the CadLink database as soon as the exam is closed.



File Transfer window

Automatic (with user confirmation):

If this option is selected, the program will prompt the user to move the patient's exam and report documents to the CadLink database. Click the **Yes** button to move the files, click the **No** button to keep the files in the user's local data folder. *The Move-to-Database tool can be used at a later time to move the local files into the CadLink database.*



Confirm upload to database

Closing the Sierra Summit Program

To close the Sierra Summit Program.

- Click on the **File menu** and select **Exit Sierra Summit**.
- or,
- Click on the **red X**  in the upper right hand corner of the screen.

Ultrasound Setup Verification – NMUS1

Product availability may vary between different countries and markets. Please contact Cadwell for additional information.

Hardware Setup

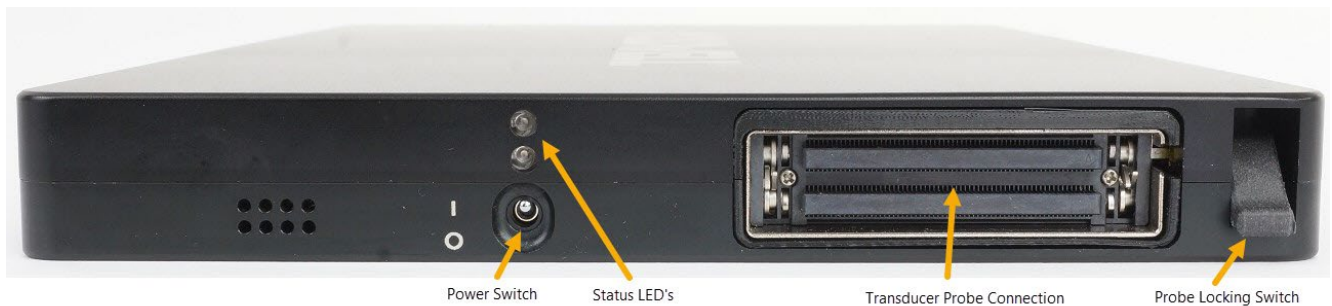
NMUS1 Front:



NMUS1 Back:



NMUS1 Right Side:



Connections:

Thunderbolt Cable - connect one end of a Thunderbolt 3 or 4 compatible cable to either one of the TB3 connections on the back of the NMUS1, connect the other end of the cable to a compatible Thunderbolt port on the PC or Laptop computer.

Transducer Probe - connect the L14-4 Linear, HL18-4 Linear Hockey Stick, or the C5-2 Curvilinear transducer probe to the Transducer Probe Connection on the right side of the NMUS1. Flip the probe locking switch to the up position to lock the probe in place.

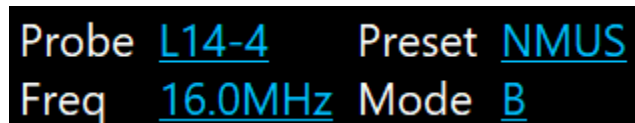
Power - connect the 12V DC power supply cable to the power input on the back of the NMUS1.

Trigger In / Out - these connections are for future development and are not used at this time.

Ultrasound Software Verification – NMUS+

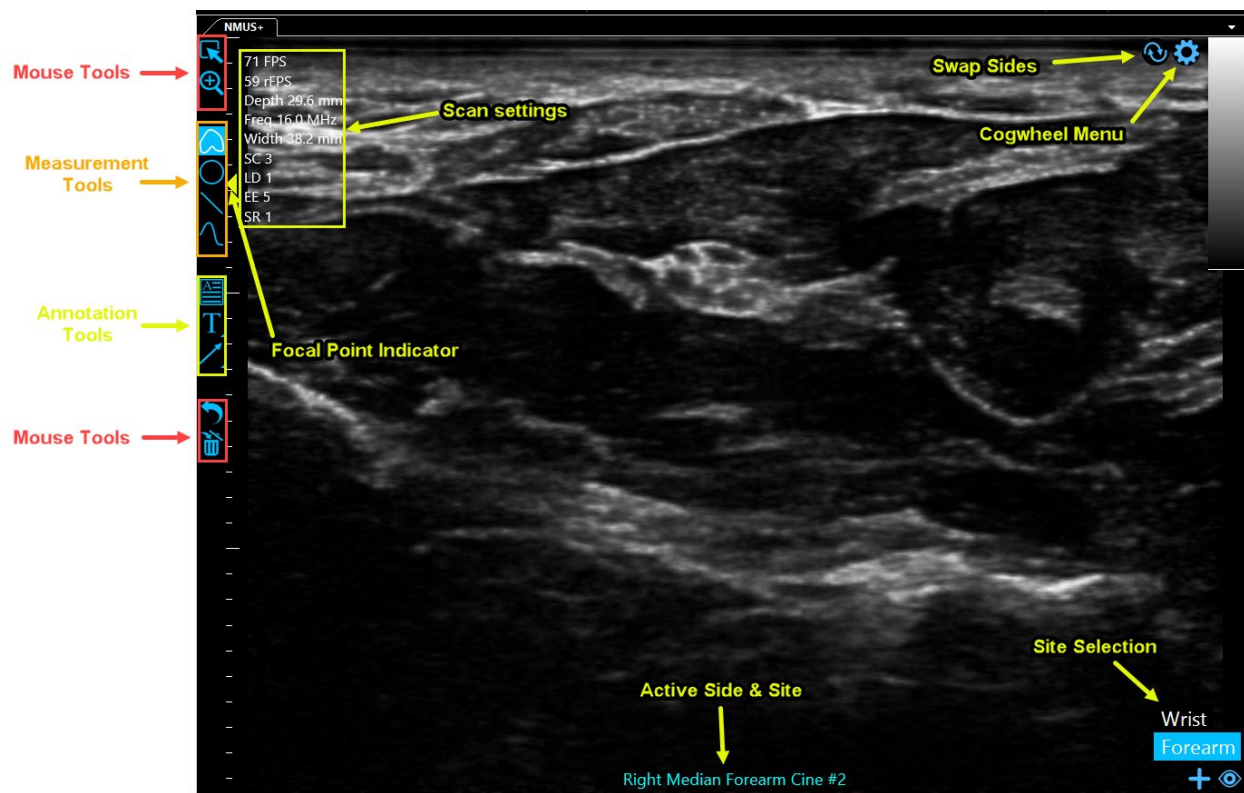
Routine Scanning and Measurements:

1. On the Home Page, press the **F1-New Patient** function key or select a new patient from the appointments tab or patient list.
2. Enter or add patient info and exam info and then press the **F3-New Study** function key.
3. Select the **NMUS+ Tab** and select one or more anatomy to scan from the Nerves, Muscles and Structures lists, select Side and **click OK**.
4. Ensure the correct anatomy is selected in the Study Window and select a Site in the image window if one is available. Image will be automatically annotated based on the selected anatomy and site.
5. Select desired **scanning mode from drop down** window in the top tool bar or using the Functions keys on the base unit.
6. Adjust image settings or select a **preset from the drop down** at the top of the screen. Image settings can be adjusted with base unit controls or by pressing the **F5-Settings function key** to open the Settings window.



Probe L14-4 Preset NMUS
Freq 16.0MHz Mode B

7. Scan the structure of interest, push **Run/Stop** to freeze then use the **Yellow Knob** to review through the Cine buffer to find an image of interest.
8. Place measurements and annotations using the **mouse tools on the left side of the image**.



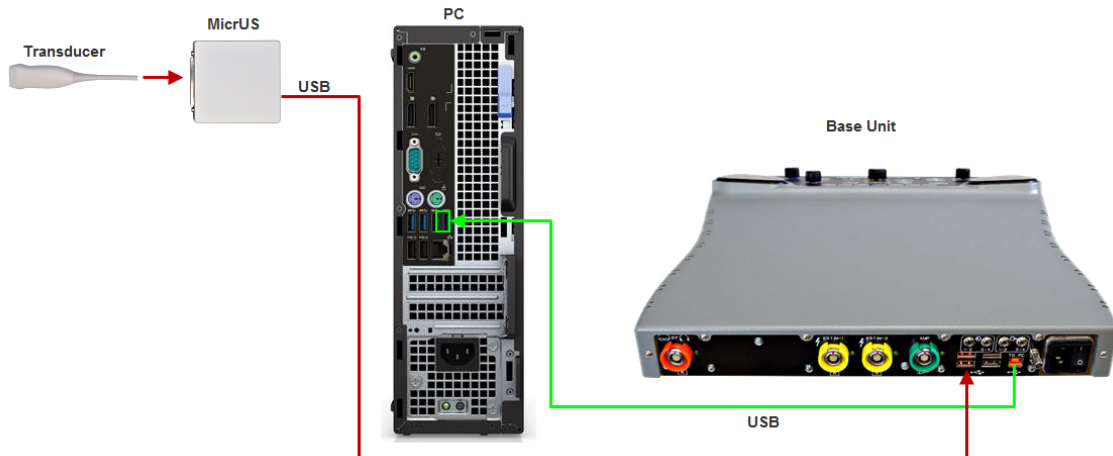
NMUS+ Image window.

9. Ensure that you have selected the correct anatomy, site and side then save image using the **F3-Save Image** function key or by pressing the **Store button**. Store will advance to next site if one is available and start the scanner after the image is saved. Save Image button will not advance to the next site and will keep the current cine available so other frames can be reviewed or saved. Multiple images can be stored per anatomy and site selection. If “Auto-save Annotated Images” is enabled in the cogwheel than images will be automatically saved when the first annotation is placed.
10. To save the Cine click **F4-Save Cine** function key or select the [Save Cine] icon next to the Cine buffer display. Cine will be automatically annotated based on the selected anatomy/site. Additional annotations can be added to the Cine by selecting the saved Cine in the Study Window, then use the **Annotation Tools** in the image window. Multiple cine can be stored for each anatomy and site selection.
11. If an image or cine is saved to the wrong anatomy click and drag the item to the correct anatomy in the study window and release the mouse button. If the new anatomy has sites a pop-up window will appear so the correct site may be selected. The selected item will then be moved to the correct anatomy, image and results will be relabeled accordingly.
12. Close the patient study by clicking on the **Home icon** at the top of the screen. The study will be closed and uploaded to the CadLink database.

Ultrasound Setup Verification – SmartUs or MicrUs

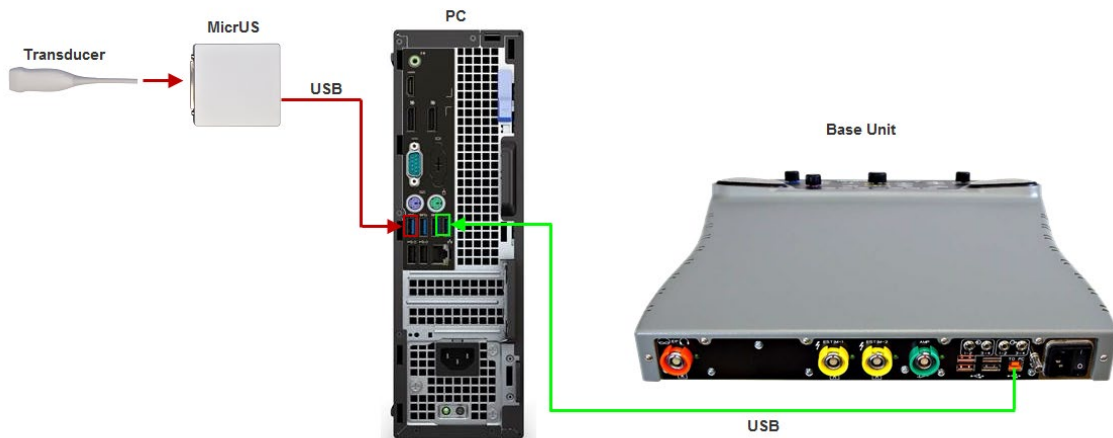
Hardware Setup

MicrUS connected to Summit Base Unit: (Option 1)



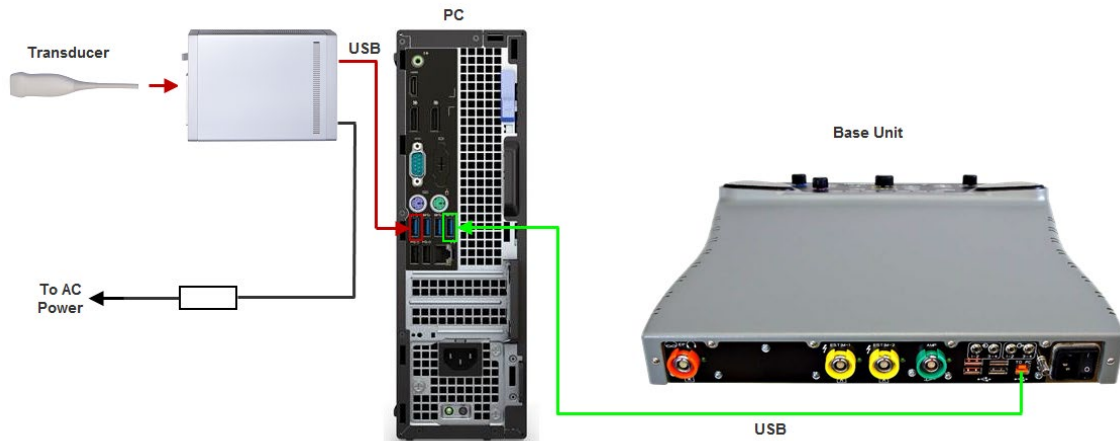
1. Connect the Transducer to the front of the MicrUS.
2. Connect the USB cable from the MicrUS to an available USB port on the Summit Base Unit.
3. Connect the Summit Base Unit to an available USB port on the PC or Laptop computer.

MicrUS connected to the PC or Laptop: (Option 2)



1. Connect the Transducer to the front of the MicrUS.
2. Connect the USB cable from the MicrUS to an available USB port on the PC or Laptop.
3. Connect the Summit Base Unit to an available USB port on the PC or Laptop.

SmartUS Connections:



1. Connect the Transducer to the front of the SmartUS. Lock the transducer in place by pressing down on the locking switch.
2. Connect the USB cable from the SmartUS to an available USB port on the PC or Laptop (*connecting the SmartUS to the Summit Base Unit is not advised*).
3. Connect the Power Cable from the SmartUS to an available AC outlet.
4. Connect the Summit Base Unit to an available USB port on the PC or Laptop.

Ultrasound Software Verification – SmartUs or MicrUs

Select the Ultrasound Test:

- **If a Study has already been selected**, simply click on the ultrasound site name (i.e., Median - Wrist) within the Study window.
- **If a Study has not been selected, or you don't want to use a Study**. Select the individual Ultrasound test protocol from the **Navigator window**, a ultrasound site list will be displayed allowing you to pick the anatomical site you will be scanning on the patient.

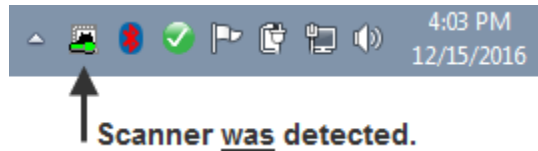
Once the anatomical site has been selected. Follow these steps for performing routine Ultrasound scanning:

1. Verify that the Scanner and Transducer are detected.

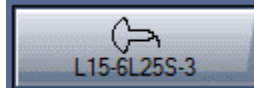
If the scanner (MicrUS or SmartUS) is not detected by the software you will see the following icon in the system tray.



In this case, check the USB cable connections between the scanner and the computer. When the scanner is detected you will see the following icon.

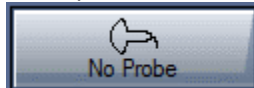


The transducer probe should automatically be detected by the system, to verify this look in the upper left corner of the ultrasound window, you should see the name of the probe here.



The 15 MHz transducer probe is connected.

If the probe was not detected, the following will be displayed:

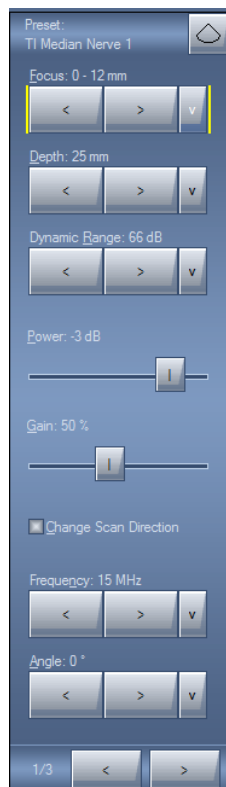


No transducer connected.

Disconnect the probe and then reconnect to the ultrasound scanner (MicrUS or SmartUS).

2. Verify that the correct scanning presets have been loaded. Shown on the left side of the ultrasound window.

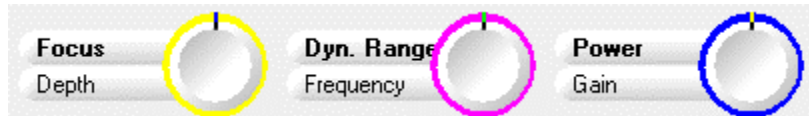
The scanning presets (parameters) are shown in the control panel on the left hand side of the ultrasound window.



To change these settings use one of the following methods:

- **Summit Base Unit Knobs**

The three knobs on the Summit base unit can be used to adjust the **Focus**, **Depth**, **Dynamic Range**, **Frequency**, **Power**, and **Gain**.



- **Mouse**

Move the mouse over the control of interest and use the Left or Right arrow buttons to adjust the setting, or simply turn the mouse wheel while hovering over the setting of interest.

3. Begin Scanning.

Position the transducer (probe) and begin scanning. If needed, adjust the presets as described above to optimize the image.



Be sure to use adequate ultrasound gel at the scanning site.

4. Freeze the Image.

To freeze the image on the screen do one of the following:

- Press the **Run/Stop button** on the Summit base unit.
- **Right-click the mouse** over the image.
- Press the **Spacebar** on the PC's keyboard.

When the image is frozen (scanning paused), the diamond shaped icon in the upper left hand

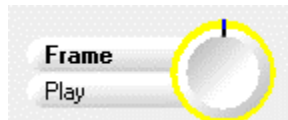
corner of the image will change from  to .

5. Review through the captured frames (optional).

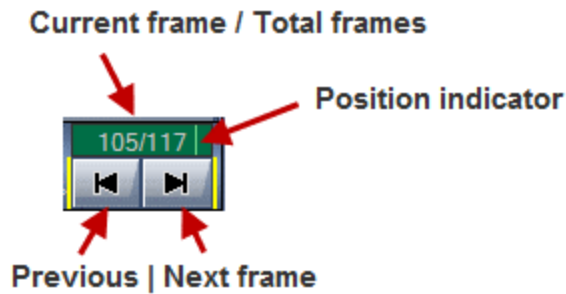
Once scanning is paused, you have the ability to review through previously captured frames. The number of frames will vary depending on the amount of memory allocated to the **Cine buffer** in the Echo Wave II software.

To review previous frames, do one of the following:

- **Turn Knob #1 (Frame / Play)** to go back and forth in the buffer. Press the knob to playback the Cine buffer frame by frame.



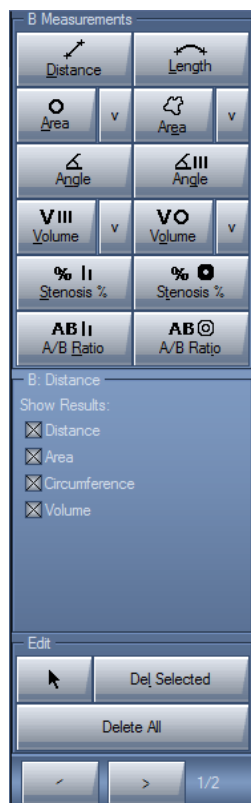
- Use the **mouse** to move the current position indicator in the Cine buffer. This is shown in the lower right hand corner of the ultrasound screen.



Or, click on the **Previous / Next** frame buttons.

6. Measure important structures (optional).

Measurements such as distance or area can be performed by using the **Measurements control panel** on the right side of the ultrasound window.



Please refer to the Echo Wave II User Manual (page 92) for detailed instructions on using the measurement tools.

7. Annotate (label) the image (optional).

Annotations or labels can be added to the image by using the **Annotations control panel**. This panel is normally hidden from view and will appear when you hover the mouse over the right hand edge of the Measurements control panel.



Annotation control panel (green box) and example image with cross-sectional area measurement and label.



Please refer to the Echo Wave II User Manual (page 140) for detailed instructions on using the annotation tools.

8. Store the Image.

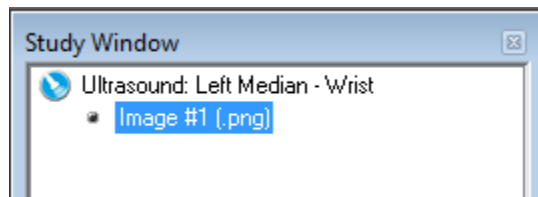
To Store the current image for later review or inclusion in a report, do one of the following:

- Press the **Store key** on the Summit base unit.
- Click on the **Image Quick Save button** at the bottom of the ultrasound window.



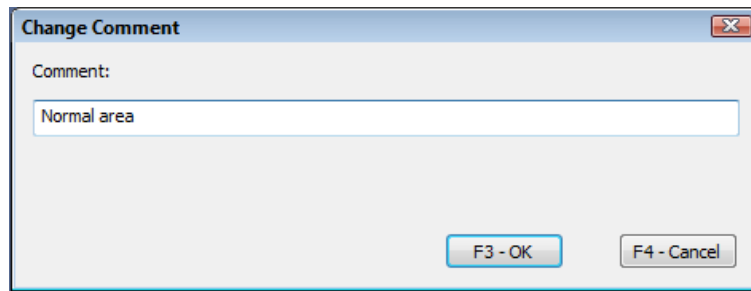
- Press the **number 9 key** on the computer keyboard.

Once the image has been stored you will see an image node appear in the Study window for the current body site.

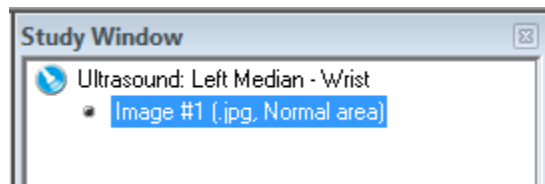


9. Add a comment to the stored image node (optional).

An optional comment can be added to the stored image node in the Study window. To do this **right-click over the image node** and select "**Change Comment**" from the context menu. Enter your comment and click OK.



The comment will now be shown next to the image node in the Study window.



10. Return to Scanning mode.

Return to scanning mode by performing one of the following:

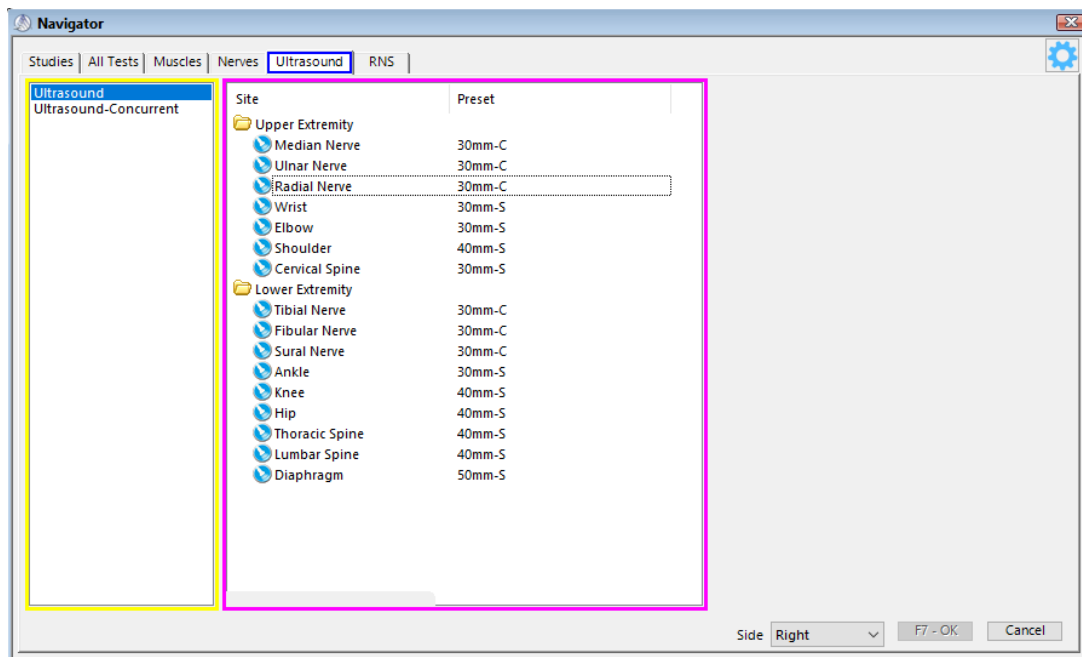
- Press the **Run/Stop button** on the Summit base unit.
- **Right-click the mouse** over the image.
- Press the **Spacebar** on the PC's keyboard.

When scanning resumes, the diamond shaped icon in the upper left hand corner of the image will

change from  to .

11. Select a different Body Site (optional).

To select a different body site, press the **F7 (Navigator)** function key on the Summit base unit. The **Navigator** window will be displayed.



Select a new site from the list, then confirm the side setting at the bottom of the window. Click **F7-OK** to add it to the Study window.

12. Close the Study.



Close the patient study by clicking on the **Home icon** at the top of the screen. The study will be closed and uploaded to the CadLink database.

For detailed descriptions of the available ultrasound controls and measurement tools, please refer to the ultrasound manual that was delivered with the ultrasound hardware.

EMG+ Operation

Select the EMG+ Test:

- **If a Study has already been selected**, simply click on an EMG+ muscle name (i.e., Right Deltoid) within the Study window. Notice that as soon as any muscle is selected within the EMG test protocol, all the muscles are automatically added to the muscle score table.
- **If a Study has not been selected, or you don't want to use a Study**. Select the individual EMG+ test protocol from the **Navigator window**, a muscle list will be displayed allowing you to pick the muscle or muscles that you will be testing on the patient. Notice that as soon as any muscle is selected, it is displayed within the Study window and is automatically added to the muscle score table.

Once the muscle has been selected. Follow these steps for performing routine EMG+ data acquisition:

1. Choose the Acquisition Mode

The EMG+ protocol has four acquisition modes. **Spontaneous, Volitional, Auto MUP**, and **IPA**. Detailed information on each mode is presented in the following help topics.

Spontaneous Mode

Volitional Mode
Auto MUP Mode
IPA Mode

2. Verify the Side

Make sure the appropriate side, **Right** or **Left**, is selected.

3. Insert the Needle Electrode

4. Adjust Volume

Increase or decrease the volume of the Sierra Summits's internal speakers by using the **Volume Knob** on the left hand side of the base unit.

5. Adjust Gain & Sweep

During EMG+ data acquisition you can easily adjust the Gain and Sweep Speed by using **Knob #3 (Gain / Sweep)** on the Sierra Summit base unit. Simply turn the knob to adjust the gain, to change the sweep speed, press the knob first to toggle it to the sweep mode, then turn to change the sweep speed.

You can also use the mouse to change these settings within each window by clicking on the right or left side of the Gain or Sweep label.

6. Enable and Adjust the Trigger (optional)

Refer to the Live EMG Window help topic for a review of the trigger & delay operation.

7. Stop Data Acquisition and Review (optional)

To stop data acquisition perform one of the following actions;

- Press the **Run/Stop key** on the **Sierra Summit base unit**.
- Press the **Footswitch** pedal.
- Click on the **Stop button** in the **Control Toolbar**.

The operations that can be performed in review mode depend on the selected acquisition mode and the types of windows that are displayed in the View. For a description of each window type, and the functions that they support, please refer to the following help topics.

Live EMG
Spontaneous Triggered
All Triggered Traces
Average MUP
Auto MUP
MUP Overview
Results
Histograms
Amplitude vs. Duration Plot
Stability
IP Cloud Plots
Muscle Scoring Table
Study List

8. Return to Data Acquisition Mode

Perform one of the following actions to resume data acquisition;

- Press the **Run/Stop key** on the **Sierra Summit base unit**.
- Click the **Run button** in the **EMG Controls** window.

The Run # will increment.

9. Modify Muscle Scoring

With the **Automatic Muscle Scoring** feature enabled, as soon as a muscle is selected in the Study window, or added to the Study window using the **F7 (Muscle List)** function key, it is automatically added to the **Muscle Scoring Table** and is scored as normal.

To change the muscle scoring for a muscle:

- Turn **Knob #2 (Score Table / Modify)** until the highlight is over the scoring field that you want to change, press the knob to pop up a list of choices, turn the knob to highlight one of the choices and press again to select it.
- Using the **left mouse button**, click on the scoring field that you want to change. From the pop up list of choices click again to make a selection.

Side	Muscle	Nerve	Root	Ins Act	Fibs	Psw	Amp	Dur	Poly	Recrt	Int Pat	Comment
Right	Abd Poll Brev	Median	C8-T1	Incr	2+	1+	Nml	Nml	Q	Nml	Nml	-
Right	ABD Dig Min	Ulnar	C8-T1	Nml	Nml	Nml	Nml	Nml	Q	Nml	Nml	-
Right	1stDorInt	Ulnar	C8-T1	Nml	Nml	Nml	Nml	Nml	Q	Nml	Nml	-
Right	FlexCarRad	Median	C6-7	Nml	Nml	Nml	Nml	Nml	Q	Nml	Nml	-
Right	FlexCarpiUln	Ulnar	C8,T1	Nml	Nml	Nml	Nml	Nml	Q	Nml	Nml	-
Right	ExtDigCom	Radial (Post Int)	C7-8	Nml	Nml	Nml	Nml	Nml	Q	Nml	Nml	-
Right	Biceps	Musculocut	C5-6	Nml	Nml	Nml	Nml	Nml	Q	Nml	Nml	-
Right	Triceps	Radial	C6-7-8	Nml	Nml	Nml	Nml	Nml	Q	Nml	Nml	-
Right	Deltoid	Axillary	C5-6	Nml	Nml	Nml	Nml	Nml	Q	Nml	Nml	-

Muscle Scoring Table



If your view layout has the Muscle Scoring Table hidden, simply turn **Knob #2 (Score Table**



/ Modify) or click on the **Muscle Scoring Table icon** in the upper toolbar.



Depending on your preferences in System Setup, abnormal values can be flagged with a red background color, as bold text, as bold text with an asterisk, or as bold text & background color red.

10. Select Next Muscle

Select the next muscle in the Study window. If the muscle you want to examine is not displayed within the Study window, press **F7 (Navigator)** and select the muscle from the list.

Move the Needle Electrode to the new muscle and repeat the above steps as necessary.



It is a good idea to mute the Volume when moving the needle electrode to a new location. To mute, **press the Volume knob**.

SFEMG+ Operation

The **SFEMG+** test protocol allows for the analysis of jitter during data acquisition. Analysis is based on the peak latency rather than on a rising or falling edge passing through an analysis marker. Up to 4 peaks (not including the triggering peak) can be analyzed simultaneously. SFEMG+ streamlines workflow and allows for complete offline editing and reanalysis of the Live SFEMG+ Buffer.

Select the SFEMG+ Test:

- If a **Study has already been selected**, simply click on a SFEMG+ muscle name (i.e., Right Biceps) within the Study window.

- **If a Study has not been selected, or you don't want to use a Study.** Select the SFEMG+ test protocol from the **Navigator window**, a muscle list will be displayed allowing you to pick the muscle or muscles that you will be testing on the patient. Notice that when a muscle is selected, it is displayed within the Study window.

Once the muscle has been selected. Follow these steps for performing routine SFEMG+ data acquisition and analysis:

1. Verify Amplifier Settings

Check the **Gain, Hicut, Locut, and Sweep Speed** settings and make sure they are appropriate.

Typical Settings for SFEMG+

Gain = 100 μ V/Div

Hicut = 10k Hz

Locut = 500 Hz (1 kHz for Concentric needle)

Sweep Speed = Live SFEMG window (10 ms/Div) and Triggered Traces window (0.5 ms/Div)

2. Verify the Side

Make sure the appropriate side, **Right** or **Left**, is selected.

3. Insert the Single Fiber or Concentric Needle Electrode.

4. Adjust the Gain and Sweep Speed as necessary.

During SFEMG+ data acquisition you can easily adjust the Gain and Sweep Speed by using **Knob #3 (Gain / Sweep)** on the Sierra Summit base unit. Simply turn the knob to adjust the gain, to change the sweep speed, press the knob first to toggle it to the sweep mode, then turn to change the sweep speed.

You can also use the mouse to change these settings within each window by clicking on the right or left side of the Gain or Sweep label.

5. Adjust the Volume

Increase or decrease the Sierra Summit's internal speaker volume by using the **Volume knob** on the left hand side of the base unit.

6. Adjust Trigger Level & Delay

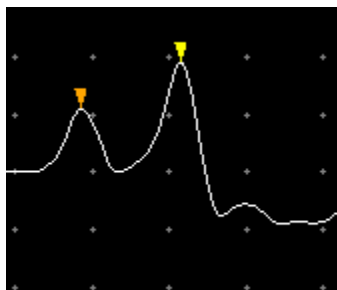
Knob #1 (Trig Level /Trig Del) defaults to the **Trig Level** mode, turn this knob to move the position of the trigger level (dotted line within Live SFEMG window) up or down. Each time a single fiber potential crosses the trigger level the sweep is added to the capture buffer and the Triggered Traces and Peak Plot windows are updated. Press the knob to activate **Trig Del** mode then turn to move the delay point left or right in one division increments. Changing the delay point allows you to see more or less data after the triggering potential.



The **mouse** can also be used to move the **Trigger Level/Delay** indicator within the Triggered Traces window.

7. Acquire Single Fiber Potentials

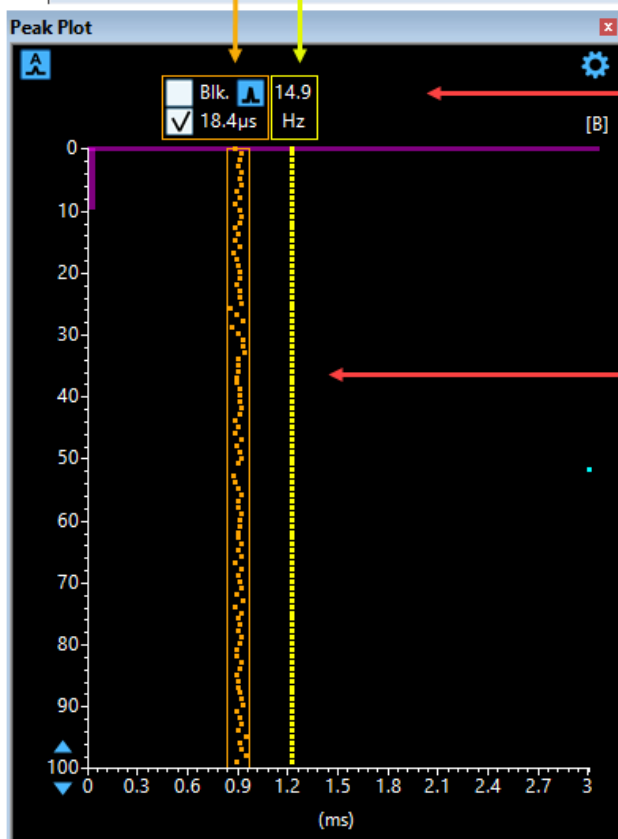
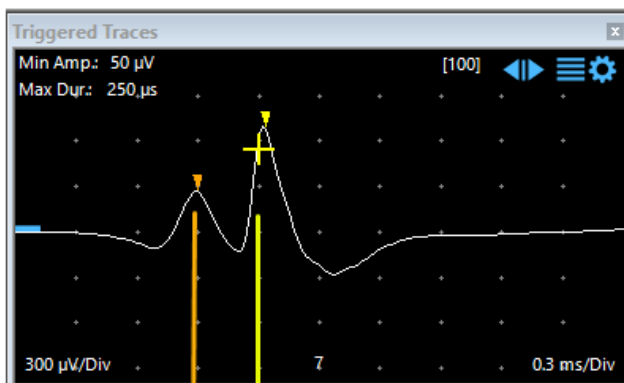
Once the appropriate single fiber signal is located and the Trigger and Delay positions have been adjusted, acquire potentials until the Peak Plot window makes one complete cycle (one cycle represents 100 captured traces). The number of traces is also shown in the top-right of the Triggered Traces window.



Valid peaks are indicated with a colored triangle.



Trigger level is indicated by a horizontal cursor.



Peak Tag Area.

Note that the data is color-coded to match the corresponding peak cursors.

Peak Latency Plot Area.

This example represents 100 discharges.

Triggered Traces and Peak Plot windows during a recording.

8. Stop Data Acquisition

Press the **Run/Stop** key on the Sierra Summit base unit to stop data acquisition. This will change the display to the **Review** mode.

Peak Plot window:

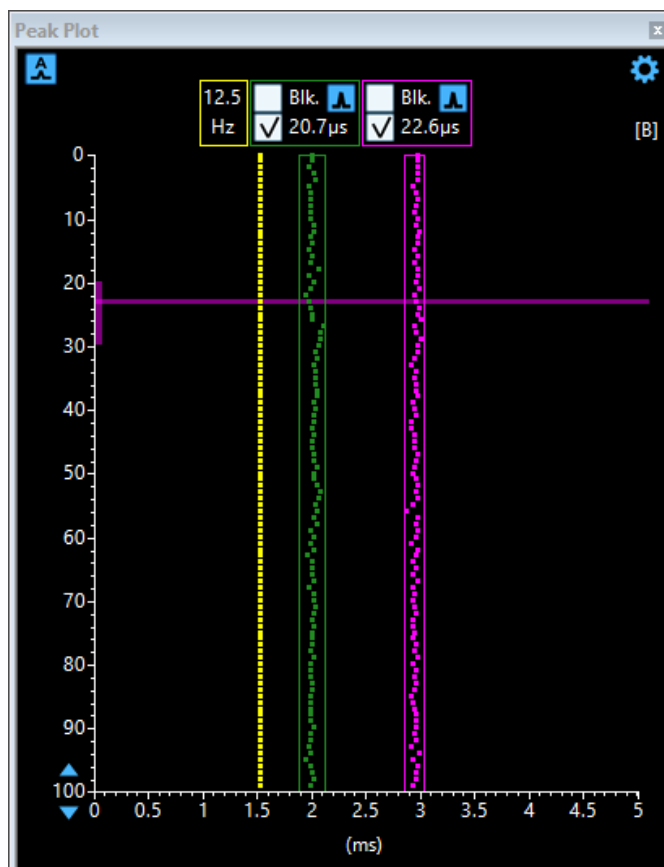
In review mode, the Peak Plot window displays the **firing frequency (Hz)** of the reference (trigger) peak and the real-time jitter measurement for the other peaks in the recording. These values are shown in color coded boxes.

By default, the **Jitter (uS)** box is checked for each detected peak. If you do not wish to keep the data for a particular peak (potential pair) you can remove the check mark which will remove the corresponding data from the Results Table.

If a check mark appears in the **Block (Blk.)** box this indicates that the jitter for the potential pair is outside normal reference limits and that the program has detected one or more blocks for that pair.

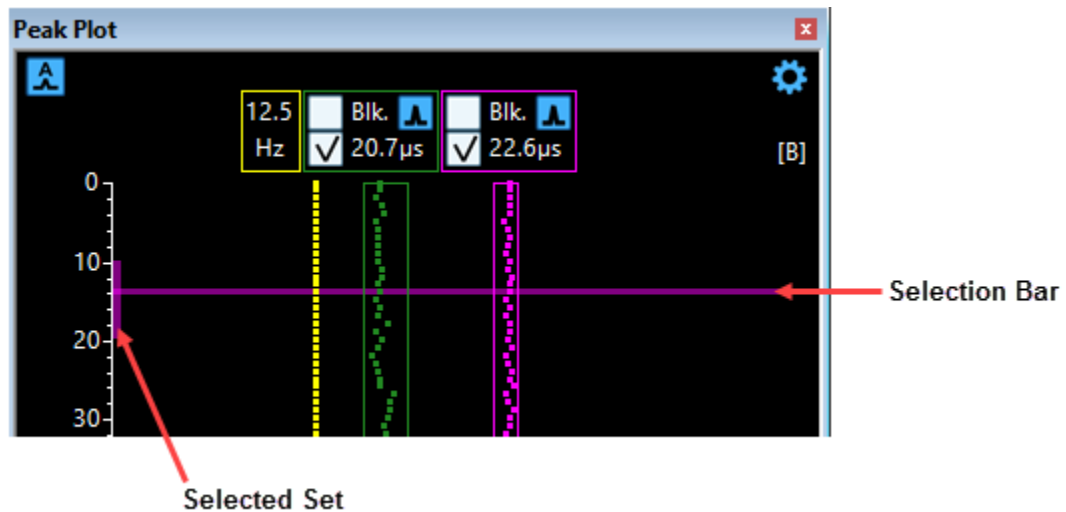


If the jitter value is normal for the individual potential pair, the **Block (Blk.)** box will not be automatically checked by the program as this is probably due to artifact in the data. Blocking does not occur when the jitter is normal.

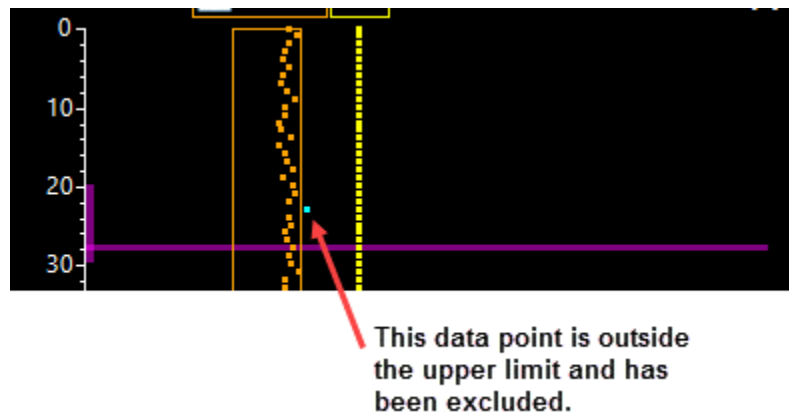


The currently selected trace, which appears at the top of the Triggered Traces window, is shown by a horizontal bar in the plot. To select a different trace;

- Turn **Knob #1 (Sel. Trace / Exclude)** on the Summit base unit.
- Click and drag the bar up/down using the left mouse.
- Click on any data point in the plot.
- Click on a trace in the Triggered Traces or All Traces windows.

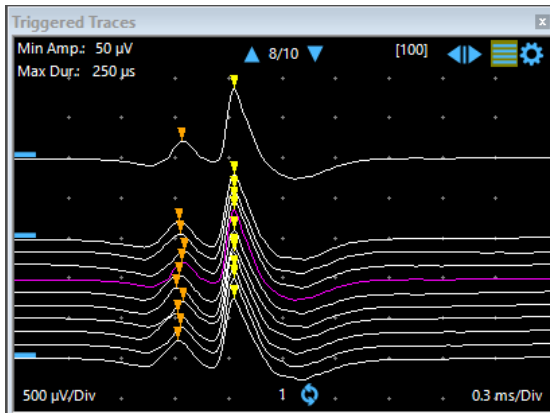


Vertical lines are drawn on either side of the data points to indicate the standard deviation limits for the peak latency. The standard deviation limit is specified in the cogwheel menu of the Triggered Traces window. The default setting is +/- 4 standard deviations, meaning that a peak latency must be within 4 standard deviations of the mean latency of that peak to be considered valid. Should a data point fall outside these limits, it will be automatically excluded from the analysis and is indicated by the **excluded color**. The width of these markers can be manually adjusted with the mouse.

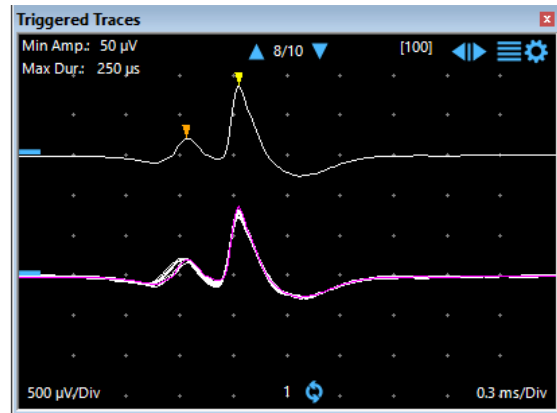


Triggered Traces window:

In review mode the Triggered Traces window is synchronized with the Peak Plot window. The currently selected trace in the Peak Plot window is shown in the factory default **purple color** in the raster or overlay stack and is also shown offset at the top of the window.



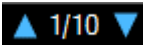
Review Mode - raster enabled.



Review Mode - raster disabled.

To select another trace, do one of the following;

- Left click the mouse on another trace in the raster or overlay stack.
- Turn **Knob #1 (Sel. Trace / Exclude)** on the Summit base unit, this will move the selected trace indicator in the Peak Plot window.
- Left click the mouse on another data point in the **Peak Plot** window.

Use the **Next / Previous** icons  to advance or return to the previously displayed set of traces. The number of traces in a set is specified in the cogwheel menu. **Knob #2 (Sel. Set)** on the Summit base unit can also be used for this purpose.

Detected peaks are shown with colored triangular cursors on the topmost (selected) trace and on all traces in the raster stack. The peak cursors are hidden in the overlay view.

If a peak was not detected, or lies outside the Frequency or SD criteria, the trace will be shown in the factory default **red color**, indicating that a block occurred (if the jitter value is abnormal), or a technical artifact occurred (if the jitter value is normal).

Blocked traces (due to artifact with a normal jitter value) can automatically be excluded from analysis via a setting in the **Peak Plot** window's cogwheel icon.

9. Manually Reject Traces

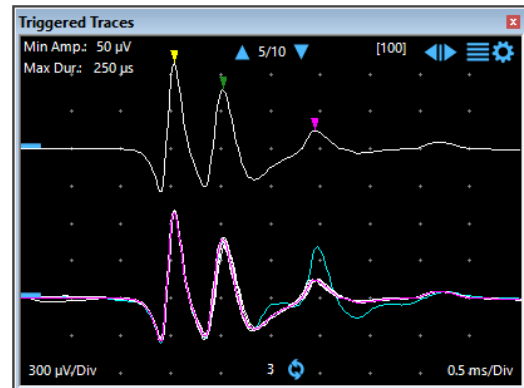
Traces can be manually excluded from the analysis by one of the following methods:

- **Triggered Traces window - Raster On:**

In the raster mode, move the mouse over the trace you want to exclude, the trace will change to **light green color**, now right-click the mouse to exclude it. Once the trace has been excluded it will be displayed in the default **cyan color** and will be removed from the All Traces window.

- **Triggered Traces window - Raster Off:**

In the overlay mode, use the mouse to draw an exclude box around a portion of the trace(s) you want to exclude. When you release the mouse button those traces that pass within the box will be excluded and will be shown in the default **cyan color**.

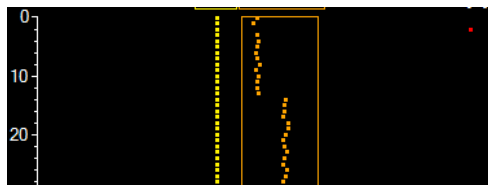


- **Using Knob #1**

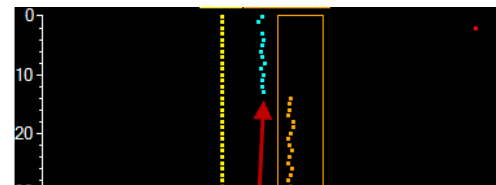
Turn **Knob #1 (Sel. Trace / Exclude)** on the Summit base unit, this will move the selected trace indicator in the Peak Plot window and the corresponding traces will be shown at the top of the Triggered Traces window. Press the knob to exclude the trace.

- **Adjust the Latency Deviation Markers in the Peak Plot window**

The peak latency standard deviation limits can be manually adjusted to exclude or include data points. Simply click and drag the indicator lines left or right.



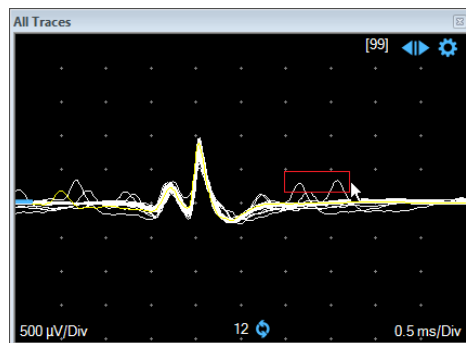
Drag this marker to the right to exclude data points.



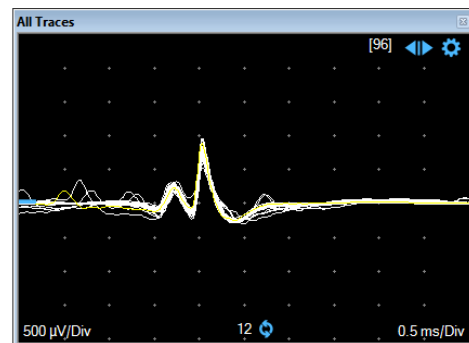
Data points outside the box are now automatically excluded.

- **Using the All Traces window**

Use the mouse to draw an exclude box around a portion of the trace(s) you want to exclude. When you release the mouse button those traces that pass within the box will be excluded and will be removed from the All Traces window.



Use left mouse button to draw an exclude box.



When you release the mouse button, those traces lying within the box will be excluded.

To Reset and Reanalyze Traces:

Click the reanalyze icon  to automatically include all previously excluded traces.

10. (Optional) Manually record a Potential Pair

Use the **Normal**, **Jitter**, or **Block** buttons within the **Manual Results** window to manually record a potential pair that is not detected by the automatic peak detection algorithm.



These values are automatically included in the **Potential Pairs**, **Normal Pairs**, **Increased Jitter**, and **Blocks** summary calculations at the bottom of the Results Table.

11. Review the Numerical Data

The **Results Table** records the analysis results for each run and calculates the mean and standard deviation values.

Run	Samples	Blocks	IPI [μs]	Jitter [μs]	Jitter Norm [μs]	MCD [μs]	MSD [μs]	Freq [Hz]
1.1	96	No	393	18.0	<53.0	20.2	18.0	12.8
2.1	41	No	388	26.3		26.4	26.3	13.2
3.1	100	No	391	19.1		21.8	19.1	11.9
4.1	100	No	480	22.2		22.2	31.8	12.8
4.2	100	No	1420	22.8		22.8	23.6	12.8
5.1	81	Yes	1831	142		142	165	16.8
Mean			817	41.7	<36.0	42.6	47.4	13.5
SD			641	49.2		48.7	58.0	1.91
Potential Pairs: 6 Increased Jitter: 16.7 % Normal Pairs: 83.3 % Jitter: 41.7 Blocks: 16.7 % Fiber Density: -								

Results Table - Run #4 is selected.

Table Columns:

Run – indicates the run #. If a run contains more than one analyzed potential pair, it is indicated by .2, .3, .4.

Samples - the total number of discharges (traces) analyzed for the run.

Blocks – a value of "Yes" indicates blocking occurred.

IPI – displays the mean Inter-Potential Interval in microseconds (us).

Jitter – displays the lowest value of either the MCD or MSD in microseconds (us).

Jitter Norm – the value shown in the first row of the table is the jitter norm for individual potential pairs. The value in the mean row of the table is the overall jitter norm for the muscle.

MCD – the jitter as calculated by using the Mean Consecutive Difference for the run.

MSD – the jitter as calculated by using the Mean Sorted Consecutive Difference for the run.

Freq. – displays the mean firing frequency of the triggering potential in hertz (Hz).

Summary Data:

Potential Pairs: - displays the total number of potential pairs (automatic & manually entered) that have been recorded.

Increased Jitter: - indicates the percentage of runs with increased jitter for individual potential pairs.

Normal Pairs: - indicates the percentage of runs with normal jitter for individual potential pairs.

Jitter: - displays the mean jitter value for the muscle.

Blocks: – indicates the percentage of runs with blocking potentials.

Fiber Density - displays the fiber density value from the Fiber Density window.

12. Acquire additional Runs.

Press the **Run/Stop** key to return to **Acquisition mode** and repeat **steps 6 through 11** to acquire additional runs. Typically 20 potential pairs should be collected for the muscle.

13. Select Next Muscle (optional)

From Acquisition mode, press the **Next** button on the base unit to highlight the next muscle in the Study window. If the muscle you want to examine is not displayed within the Study window, press **F7 (Navigator)** and select the next SFEMG+ muscle from the list.

Move the Single Fiber or Concentric Needle Electrode to the new muscle and repeat the above steps as necessary.



It is a good idea to turn Off the amplifier or turn down the Volume when moving the needle electrode to a new location.

NCS+ Operation

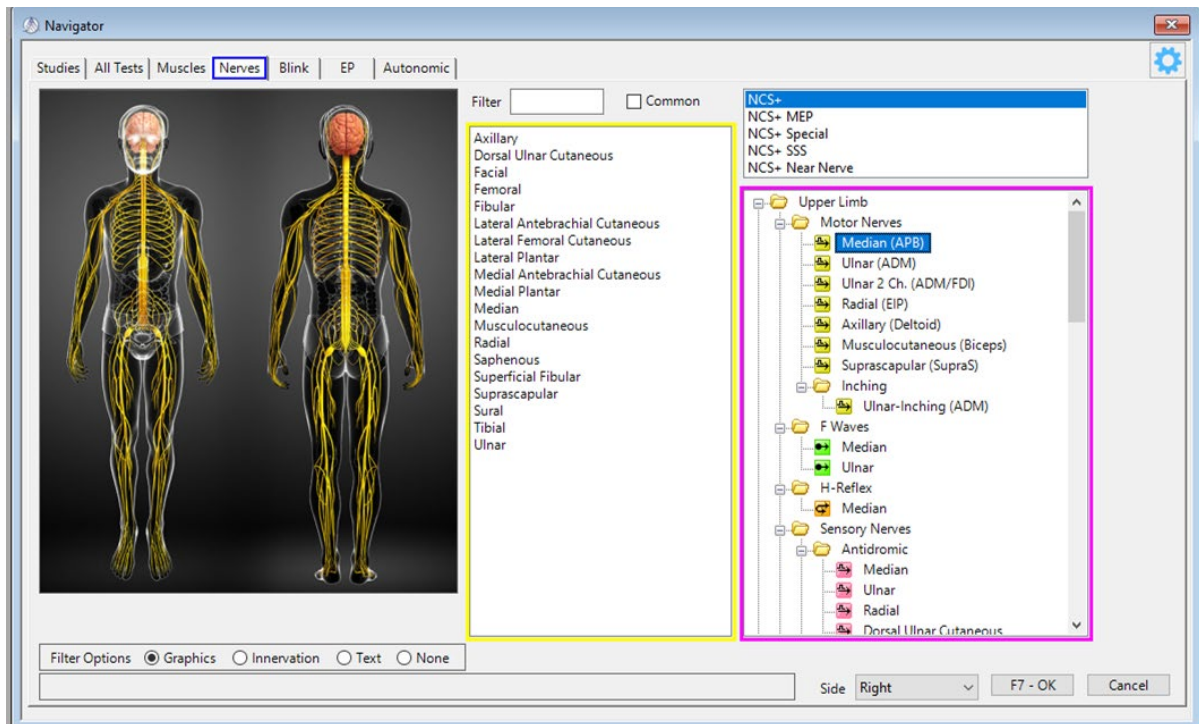
Select the NCS+ Test:

1. On the **Home Page**, press the **F1-New Patient** function key.
2. **Enter Patient data** and then press the **F3-New Study** function key.



Ensure patient's gender, birth date, height and BMI are inserted correctly if included as part of used reference limits.

3. Select the **NCS+ (Nerves)** tab and a **NCS+ Test Protocol** in the **Navigator**.
4. **Select a Test or Nerve and Side** and click **OK**.



Navigator window.

5. Verify Amplifier Settings

Check the **Gain**, **Hicut**, **Locut**, and **Sweep Speed** settings and make sure they are appropriate for the nerve being tested.

Typical Settings

	Gain	Hicut (Hz)	Locut (Hz)	Sweep Speed (ms/Div)
Motor Nerves	2 to 5 mV/Div	10k	20	3-5
Sensory Nerves	10 to 20 uV/Div	3k	20	1-2
F Wave	5 mV/Div, 500 uV/Div	10k	20	5
H-Reflex	500 uV/Div	10k	20	5

6. Electrode Placement

Attach the electrodes.

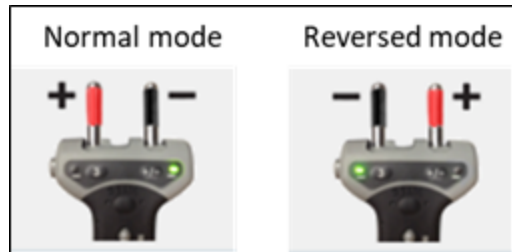
7. Check Stimulator Polarity

For **Motor**, **Sensory** and **F Wave** recordings, the **Cathode (-)**, indicated by a green LED, should be oriented towards the active **recording electrode**.

For **H-Reflex** recordings, the **Cathode (-)**, indicated by a green LED, should be oriented **towards the spinal cord**.

To change polarity, click on the  icon in the toolbar or press the **(+/-)** button on the StimTroller.

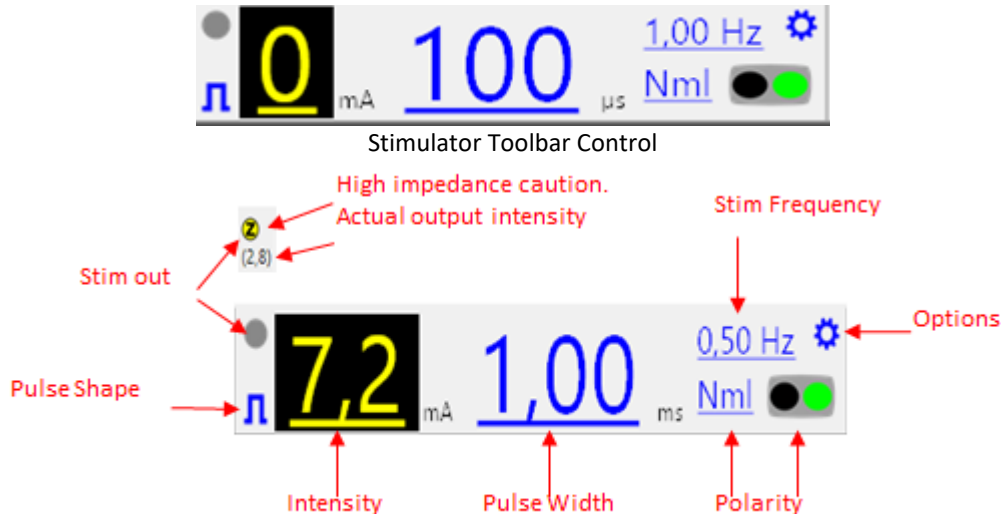
In the **Normal mode**, the polarity field on the screen will indicate **Nml**. In the **Reversed mode**, the polarity field on the screen will indicate **Rev**.



8. Stimulate the first Site

Increase the stimulus intensity level by turning the **wheel** on the StimTroller or the **yellow knob** on the Summit base unit. The **intensity level** (in mA) is displayed on the screen in the **Stimulator Toolbar Control**. Stimulate by pressing the **Stim button** on the StimTroller or by **pressing the yellow knob**. The stimulator light, located next to the intensity level on the screen, will flash yellow and the patient's response will be displayed.

Continue to increase the intensity level and stimulate until a slightly higher (supra-maximal) intensity level than necessary for a maximal response is reached.



The **pulse width** (duration) can be adjusted using the **PW up** and **PW down** arrow keys on the base unit. The displayed units can be either microseconds (us) or milliseconds (ms).



Repetitive stimulation can be delivered by pressing the **Run/Stop button** on the base unit, or by holding down the **StimTroller's Stim button** for 2 seconds.

Gain and sweep speed can be adjusted using the Blue Knob on the Sierra base unit or with the mouse wheel.

9. Motor / Sensory: Select the best response

All recorded traces are automatically saved. Press function key **F4-History** or click on the **active**

Site's History icon or or to show all recorded traces. Click on the best trace to select it. Press **F4-History** again, or click on the history icon to close the trace history. Only the last selected trace will be used as the result.

For motor responses, if the **F1-Hold M-Max** function key is activated, the response with highest amplitude is automatically selected.

10. Sensory: Start Averager

To start averaging, press the **AVG** button on the base unit, or the **Site's averager icon** . Record until a noise free baseline is obtained.

11. F Wave: Record all Responses

Continue to stimulate with supra-maximal stimulus intensity and record typically 20 responses.

12. H-Reflex: Record all Responses

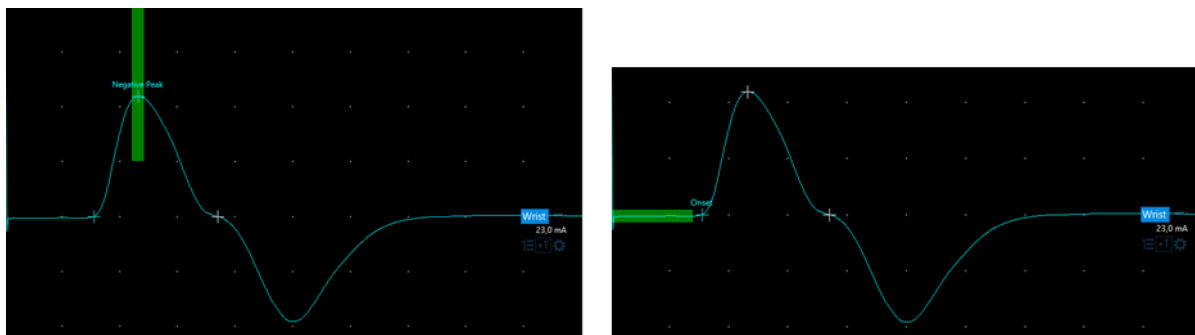
Continue to record the H-Reflex responses, with slightly increasing stimulus intensity between each stimulation.

13. Adjust Markers

All Markers are automatically placed on the response as soon as it is displayed. The parameter selection in the Site and Segment tables determines which of the markers are placed on the trace. The marker positions can be adjusted by performing one of the following actions:

- By using the **purple knob** on the base unit. **Press to select** next marker and **turn it to change** its position. The currently selected marker is highlighted.
- By left-click on the marker, hold down and drag it to a new position.

If normal reference limits are inserted, the normal latency and amplitude ranges are indicated graphically by highlighted rectangles during marker adjustment or when the mouse pointer is hovering above a marker or a result in the Result tables.



Example showing normal amplitude and prolonged latency.

To **remove a marker**, click and drag it outside the trace window on the right-hand side.

To **set a missing marker**, click on the response (trace) to place the marker.

To indicate a **missing response**, perform one of the following actions:

- Press the **F3-No Response** function key.
- Click and drag the left most marker outside the trace window on the right-hand side. This will remove all markers from the trace.

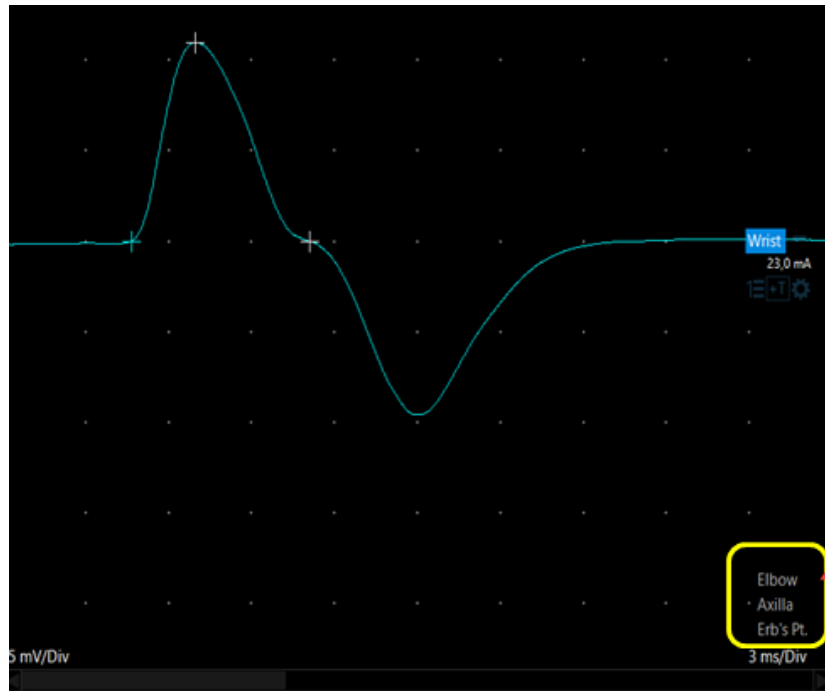


Responses without markers will be indicated in the Site and Segment table and no numerical results shown.

14. Next Site

To select Next Site, perform one of the following actions:

- Press the **Store button** on the **base unit**.
- Press the **Store button** on the **StimTroller**.
- Click on the **Site name** in the lower right corner in the Trace window.



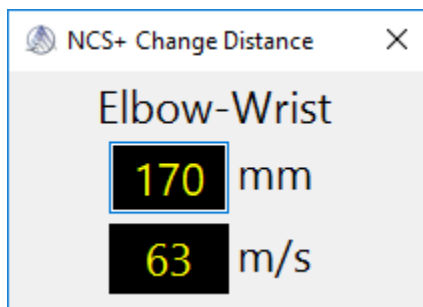
15. Continue to stimulate and store sites on the nerve

16. Enter Distance

Verify that the correct distance field is selected in the Segment table. If not, left-click on the distance field or press Enter until the appropriate field is highlighted.

Perform one of the following actions to insert a distance:

- Type the distance using the PC keyboard.
- If Distance is programmed to one of the StimTroller buttons, press the programmable StimTroller button (1, 2 or 3) and use the StimTroller wheel to change distance, or type the distance. Press the same StimTroller button again or press **Enter** to accept the distance value. The distance and conduction velocity is shown in a window while adjusting the distance with the StimTroller wheel.



17. Results

Site and Segment results are shown in the result tables. Displayed parameters are selected in the Test Setup – Test Type. If normal reference limits are available, results will be indicated as abnormal (red by default) or normal (green by default).

Results

Tables L/R Compare Notepad Graphs

Motor Sites

Site	Latency		Amplitude		Min F-Lat		Comment
	(ms)	Norm	(mV)	Norm	(ms)	Norm	
Left Median (APB)							
Wrist	4.3	< 4.2	9.8	> 5.0	30.8	24.5...33.7	
Elbow	9.4	-	9.3	-			

Motor Segments

Segment	Delta-O	Distance	CV	
	(ms)	(cm)	(m/s)	Norm
Left Median (APB)				
Elbow-Wrist	5.1	26	51	> 50

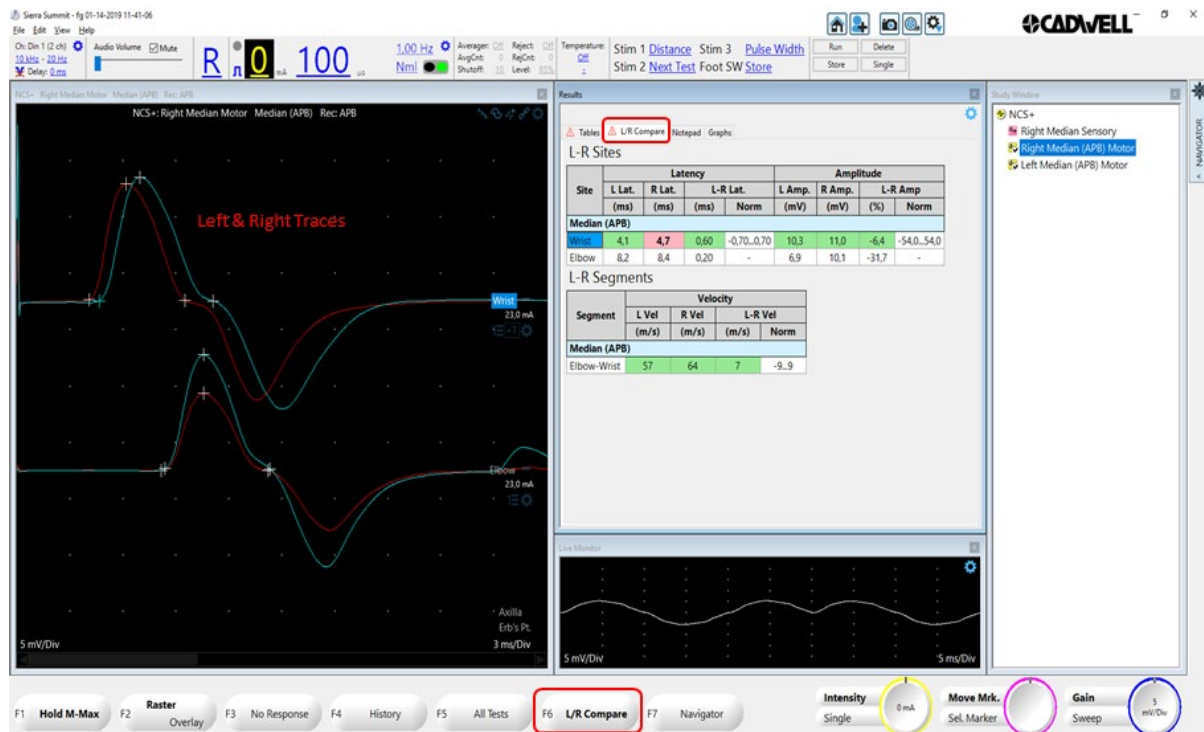
Site and Segment results.

18. Compare Left and Right side (optional)

Press the **F6-L/R Compare** function key or the **L/R Compare** tab in the Result Table window, to overlay Left and Right traces, and show Left/Right comparison tables.

Markers can be adjusted and new recordings can be obtained in L/R Compare mode.

Press the **F6-L/R Compare** function key again, or the **Tables** tab in the Results window, to exit the Left/Right compare mode and only show traces and results for active side.



L/R Compare Mode.

19. Next Test/Nerve

Open the **Navigator** window and select a new Test/Nerve, or select a test in the **Study Window**. The Navigator can be opened in the following ways:

- Press the **F7-Navigator** function key.
- Click on the vertical **Navigator tab** on the right hand side of the screen.
- Click on the **Navigator icon** in the toolbar.



20. Review (optional)

All recorded and planned Tests/Nerves are listed in the **Study Window**. Tests containing recordings are indicated with a **check mark**. Click on any Test with a check mark to review traces and results.

21. All Tests (optional)

Press the **F5-All Tests** function key to see all recorded nerves and results for this patient. Markers can be adjusted and new recordings can be obtained in **All Tests** mode.

RNS Operation

Select the RNS Test:

- If a **Study has already been selected**, simply click on the RNS muscle name within the Study window to select the test.
- If a **Study has not been selected, or you don't want to use a Study**. Select the RNS test protocol from the **Navigator window**, a muscle list will be displayed allowing you to pick the muscle or muscles that you will be testing on the patient.

Once the muscle has been selected. Follow these steps for performing RNS data acquisition:

1. Verify Amplifier Settings

Check the **Gain**, **Hicut**, **Locut**, and **Sweep Speed** settings and make sure they are appropriate for the test being performed. RNS typically uses the same settings as a motor NCV.

2. Verify Side Setting

Make sure the appropriate side, **Right** or **Left**, is selected.

3. Electrode Placement

Attach the electrodes to the patient.

Active 1 Input: Belly of the muscle.

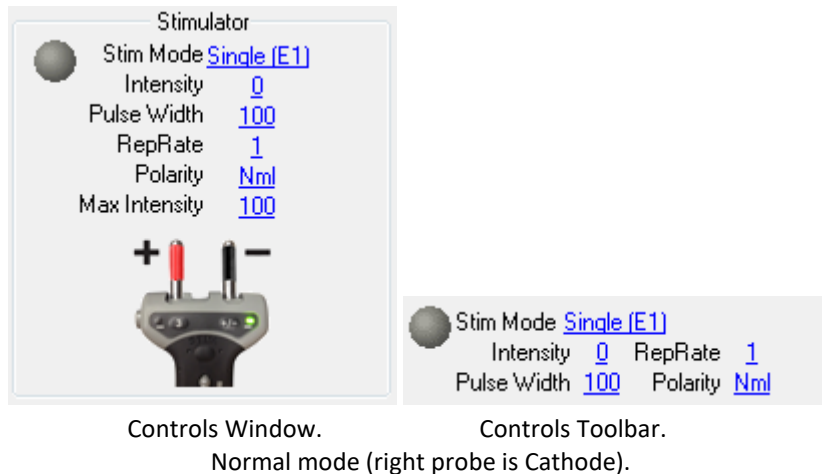
Reference 1 Input: Tendon of the muscle.

Ground Electrode: On stimulated limb or forehead.

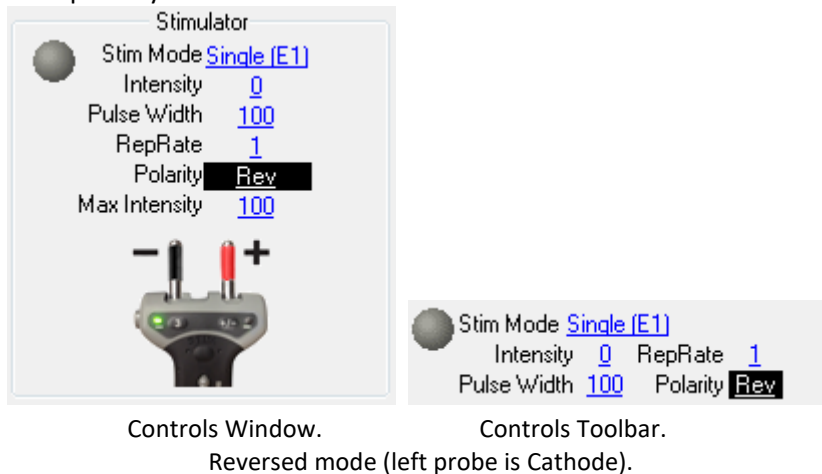
4. Check Stimulator Polarity

For RNS Studies, the **Cathode (-)** should be oriented **closest to the recording electrodes**.

The Cathode (i.e., the negative stimulus probe) can be selected by pressing the **Reverse Polarity (+/-)** button on the electrical stimulator handle. A **green LED** indicates the probe that is the Cathode. Clicking on the **Polarity field** in the **RNS Controls window** or **Controls Toolbar** can also reverse the stimulator polarity. The default (i.e., normal) mode has the right-side probe as the Cathode (if holding the stimulator with the Stim button facing you and the probes up); the reversed state will make the left-side probe the Cathode. The image of the stimulator on the screen updates to indicate the selected polarity as well. In the Normal mode, the electrical stimulator image on the screen will show the Right-side probe as the cathode (-). The polarity field on the screen will indicate **Nml**.



In the Reversed mode, the electrical stimulator image on the screen will show the Left-side probe as the cathode (-). The polarity field on the screen will indicate **Rev**.



5. Check the RNS Table

The RNS test protocol supports a pre-programmed stimulus train table. This table controls the number of stimuli presented in each train, the repetition rate for the stimuli, the amount of time to pause before proceeding to the next stimulus train, and it also provides a convenient way to label each stimulus train.

The program allows for either manual or automatic delivery of the stimulus train table.

RNS Table											
RNS Tables All Trace Table											
Trial #	Label	Amp 1 (mV) O-P	Amp 5 (mV) O-P	Amp % Dif	Area 1 (mV·ms)	Area 5 (mV·ms)	Area % Dif	Rep Rate	Train Length	Pause Time (min:sec)	Comments
Act:	Baseline							3.00	10	00:30	—
2	Post Exercise							3.00	10	01:00	—
3	1 min Post							3.00	10	01:00	—
4	2 min Post							3.00	10	01:00	—
5	3 min Post							3.00	10	00:00	—

RNS Table.

If your stimulus train table is undefined, select **Current Test** from the **Edit** menu. Fill in the **Sequencer Setup** table in the lower left corner of the setup window, then click **OK**.

6. Check the General and Stimulator Settings

General Settings

Mode: Choices are **Train** or **Single**.

- **Train** - When the **Stim** button on the handheld stimulator or the **Run/Stop** button is pressed, a train of stimuli, corresponding to the highlighted row in the RNS Table, will be delivered.
- **Single** - When the **Stim** button on the hand held stimulator or **Knob #1** is pressed, a single stimulus will be delivered. This mode is useful for determining supramaximal stimulation prior to delivering a train of stimuli.

Train #: The total number of stimuli that will be delivered to the patient when the program is set to the Train mode. The typical setting is four to eight. The maximum setting is 500. This value is updated from the RNS Table.

Spread: This is the distance (in horizontal divisions) that will separate the individual traces within the train. If this value is set to zero, the traces will be superimposed upon one another.

Response 1: Select the first response in the train that will be analyzed for amplitude and area measurements. Typically this is always set to number 1.

Response 2: Select the second response in the train that will be analyzed for amplitude and area measurements. In addition, the percentage difference between this response and the trace selected for Response 1 will be computed. This is typically set to number 4 or 5.

Auto Seq: Allows for either manual or automatic sequencing through the RNS Table. When set to **On**, the program will automatically deliver the trains specified in the RNS table (automatically pausing for the specified time after each train). When set to **Off**, the user must manually start each train after the appropriate pause time, by pressing the Run/Stop key for each train.

Stimulator Settings

Pulse Width: Set the electrical stimulus pulse width, also known as pulse duration, in microseconds (*usec*) or milliseconds (*msec*).

Rep Rate: Set the repetitive stimulus rate, in pulses per second (Hz). This is typically set to 2 or 3 Hz. This setting only applies when delivering repetitive (i.e., Train) stimulation, it does not apply during manual Single stimulus delivery.

7. Check Recording Setup

Press the **F1 (Train/Single)** function key to select **Single** mode. Increase the stimulus intensity level by turning the **wheel** on the electrical stimulator handle. The **intensity level** (in milliamps)

is displayed on the screen in a small pop-up window and also in the Stimulator controls section. Once you have reached an appropriate starting intensity apply the stimulator to the patient and deliver the stimulus by pressing the **Stim button** on the electrical stimulator handle. The stimulator light, located next to the intensity level on the Screen, will flash Yellow and the patient's response will be displayed.



The **Knob #1 (Intensity / Single)** on the Sierra Summit base unit or the **Single button** within the on-screen RNS Controls window can also be used to deliver a single stimulus. Intensity can also be adjusted using **Knob #1 (Intensity / Single)** on the base unit. Continue to increase the intensity level and stimulate until a supra-maximal response is acquired. If the response is large and "clips" at the top or bottom, decrease the amplifier sensitivity by adjusting the Gain setting. For example, change gain from 2k to 5k and re-stimulate. Gain can be adjusted easily by using **Knob #3 (Gain /Sweep)** on the Summit base unit.

8. Deliver Stimulus Trains

Press the **F1 (Train/Single)** function key to select **Train** mode. Follow the instructions below for either Manual or Automatic Stimulus Train delivery.

Manual Stimulus Train Delivery:

Press the **Stim button** on the electrical stimulator handle. A train of stimuli will be delivered to the patient and a trace will be displayed for each stimulus within the train. The traces are stacked in a horizontal fashion (see Spread setting above).

After the Train is completed the program will automatically store the train and it will be displayed in a "purple" color.



The **Run/Stop key** on the Sierra Summit base unit or the **Run button** within the on-screen RNS Controls window can also be used to deliver a train of stimuli.

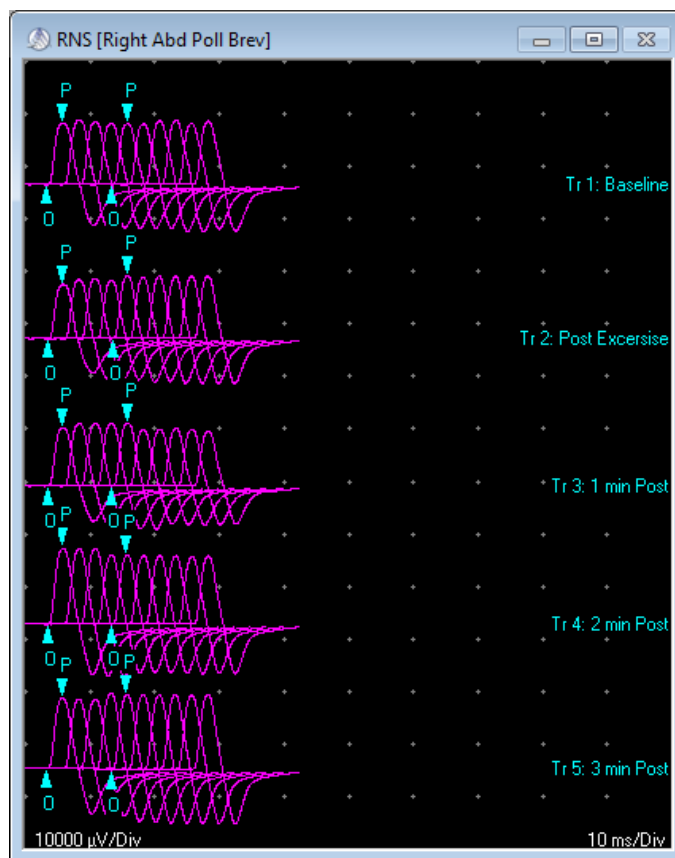
After a train is automatically stored, a timer is started. The timer is displayed just below the side field in the RNS Controls window or at the top of the screen in the Controls Toolbar.

Use the timer to measure the time elapsed while the patient exercises the muscle or the time elapsed between successive stimulus trains. Typically, the patient will exercise the muscle for 30 seconds after the first train is delivered then another train will be delivered immediately after completion of exercise. Additional trains are then typically delivered at 1 minute intervals after this.

Press the **Run/Stop** key again to deliver the second stimulus train. Proceed in this fashion until all stimulus trains have been acquired.



The timer automatically resets to zero after each train is stored. You can also manually reset the timer to zero by pressing the **F2 (Reset Timer)** function key on the Sierra Summit base unit.



Example RNS Traces

Automatic Stimulus Train Delivery:

Change the **Auto Seq.** control from **Off** to **On (F5 key)**. The first row in the RNS Table will be automatically highlighted.

Press the **Stim button** on the electrical stimulator handle. A train of stimuli will be delivered to the patient and a trace will be displayed for each stimulus within the train. The traces are stacked in a horizontal fashion (see Spread setting above).

After the Train is completed the program will automatically store the train and it will be displayed in a "purple" color. At this point the timer is started. The timer is displayed just below the side field in the RNS Controls window or at the top of the screen in the Controls Toolbar.

Once the timer reaches the preprogrammed pause time for the stimulus train, the program will automatically deliver the next stimulus train in the RNS Table.

Stimulation will continue in this manner until the last stimulus train is delivered.



You can stop the automatic sequencer at any time by changing the **Auto Seq.** control from **On** to **Off (F5 key)**.

9. Adjust Cursors (optional)

Onset (O) and **Peak (P)** cursors are automatically placed on the selected responses (see Response 1 and Response 2 settings above) as each train is acquired. The amplitude (onset to peak) and area (negative peak) of each response is calculated and displayed in the RNS table window.

The positions of these cursors can be adjusted by performing one of the following actions;

- By using **Knob #2 (Sel Cursor / Move Cursor)**.
- By clicking on them with the **left mouse button** and dragging them to their new position.

The difference for both amplitude and area, between the two marked responses, is also automatically calculated and is displayed as a percentage (%). The equation used for this calculation is as follows;

$$D = (VR2 - VR1) / VR1 \times 100\%$$

Where D = decrement or increment

V = value (amplitude or area)

R1 = response 1

R2 = response 2

A decrement is displayed as a negative number, typically more than a **-10%** decrement is considered abnormal. An increment is displayed as a positive number.



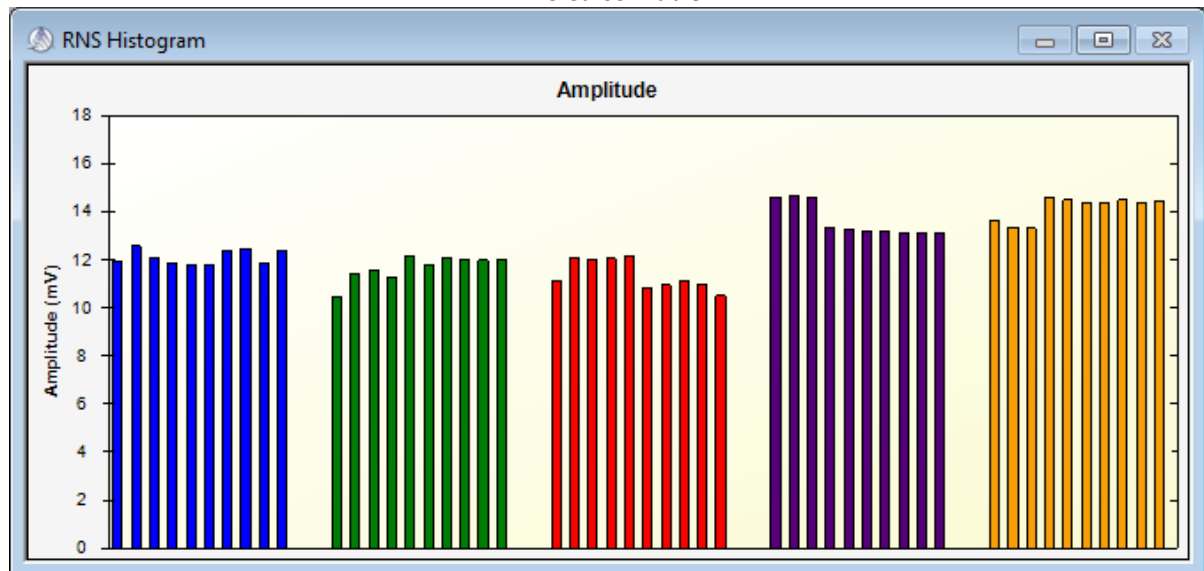
Peak-to-Trough amplitude measurements can also be selected in the RNS protocol's test setup window. In this case, **Peak (P)** and **Trough (T)** cursors will be automatically placed on the responses.



Use the **Comments** field in the RNS table to enter a notation for the train.

RNS Table											
RNS Tables All Trace Table											
Trial #	Label	Amp 1 (mV) O-P	Amp 5 (mV) O-P	Amp % Dif	Area 1 (mV·ms)	Area 5 (mV·ms)	Area % Dif	Rep Rate	Train Length	Pause Time (min:sec)	Comments
Tr 1	Baseline	11.93	11.78	-1.2	34.91	32.56	-6.7	3.00	10	00:30	—
Tr 2	Post Exercise	10.47	12.14	15.9	28.44	30.23	6.3	3.00	10	01:00	—
Tr 3	1 min Post	11.15	12.16	9.0	31.00	32.49	4.8	3.00	10	01:00	—
Tr 4	2 min Post	14.62	13.29	-9.1	39.62	34.34	-13.3	3.00	10	01:00	—
Tr 5	3 min Post	13.63	14.49	6.3	36.72	38.09	3.7	3.00	10	00:00	—

RNS Cursor Table



RNS Histogram Window

Blink Reflex Operation

Select the Blink Test:

- If a Study has already been selected, simply click on the Blink test protocol within the Study window to highlight the test.
- If a Study has not been selected, or you don't want to use a Study. Select the Blink test protocol from the Navigator window.

Once the test has been selected. Follow these steps for performing Blink data acquisition:

1. Verify Amplifier Settings

Check the **Gain**, **Hicut**, **Locut**, and **Sweep Speed** settings and make sure they are appropriate for the test being performed.

Typical Blink Settings

Gain = 200 μ V/Div

Hicut = 5k Hz

Locut = 10 Hz

Sweep Speed = 10.0 ms/Div

2. Electrode Placement

Attach the electrodes to the patient.



Connect the electrode leads from the patient's **left** side to the **Channel 1 inputs** on the amplifier, and connect the electrode leads from the patient's **right** side to the **Channel 2 inputs**. Electrodes must be connected to the amplifier in this configuration to ensure proper display of test data.

Active 1 Input: Belly of the Left orbicularis oculi muscle below the eye.

Reference 1 Input: Left side of nose.

Active 2 Input: Belly of the Right orbicularis oculi muscle below the eye.

Reference 2 Input: Right side of nose.

Ground Electrode: Forehead or cheek.

3. Select Side of Stimulation

Select the side, **Left** or **Right**, that will be stimulated first.

In **Horizontal Split** mode, trials collected during left-side stimulation are displayed in the top half of the screen with the response recorded on the ipsilateral side (e.g., Ch1 : L) positioned above the response recorded on the contralateral side (Ch2 : L).

Responses collected during right side stimulation display in the bottom half of the screen.

Eliminating the need to change electrodes at the amplifier, the Sierra Summit automatically inverts the order in which trials collected during right side stimulation are displayed so that the ipsilateral response (Ch2 : R) appears above the contralateral response (Ch1 : R).



Right click over the trace area and select **Vertical Split** if you want the responses to Left side stimulation displayed on the Left side of the screen and the responses to Right side stimulation displayed on the right side of the screen.

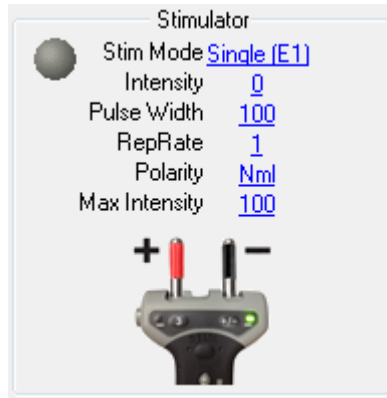
4. Check Stimulator Polarity

For Blink Reflex Studies, the **Cathode (-)** should be oriented **closest to the recording electrodes**.

The Cathode (i.e., the negative stimulus probe) can be selected by pressing the **Reverse Polarity (+/-)** button on the electrical stimulator handle. A **green LED** indicates the probe that is the Cathode.

Clicking on the **Polarity field** in the **Blink Controls window** or **Controls Toolbar** can also reverse the stimulator polarity. The default (i.e., normal) mode has the right-side probe as the Cathode (if holding the stimulator with the Stim button facing you and the probes up); the reversed state will make the left-side probe the Cathode. The image of the stimulator on the screen updates to indicate the selected polarity as well.

In the Normal mode, the electrical stimulator image on the screen will show the Right-side probe as the cathode (-). The polarity field on the screen will indicate **Nml**.



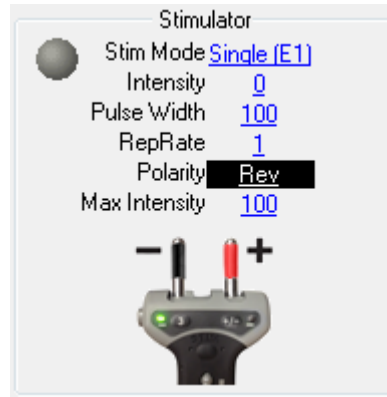
Controls Window.



Controls Toolbar.

Normal mode (right probe is Cathode).

In the Reversed mode, the electrical stimulator image on the screen will show the Left-side probe as the cathode (-). The polarity field on the screen will indicate **Rev**.



Controls Window.



Controls Toolbar.

Reversed mode (left probe is Cathode).

5. Stimulate

Increase the stimulus intensity level by turning the **wheel** on the electrical stimulator handle. The **intensity level** (in milliamps) is displayed on the screen in a small pop-up window and also in the Stimulator section. Once you have reached an appropriate starting intensity apply the stimulator to the patient's supra-orbital nerve and deliver the stimulus by pressing the **Stim button** on the electrical stimulator handle. The stimulator light, located next to the intensity level on the Screen, will flash Yellow and the patient's response will be displayed.



Knob #1 (Intensity/Single) on the Sierra Summit base unit can also be used to adjust stimulus intensity and to deliver a single stimulus. Turn this knob to adjust the stimulus intensity, and press

the knob to deliver a single stimulus to the patient. The pulse width (duration) can be adjusted using the **PW up** and **PW down** arrow keys on the base unit.

6. Store the Response

To store the response, perform one of the following actions;

- Press the **Store button** on the **electrical stimulator handle**.
- Press the **Store key** on the **Sierra Summit base unit**.
- Press the **Footswitch** pedal.
- Click the **Store button** in the **Blink Controls** window.

When the response is stored the color of the trace changes from **white to purple**

7. Repeat Stimulation & Store additional responses

Generally, two trials are acquired per side.

8. Place Auto Cursors

To place the **R1**, **R2i**, and **R2c** cursors on the traces, follow one of these procedures:

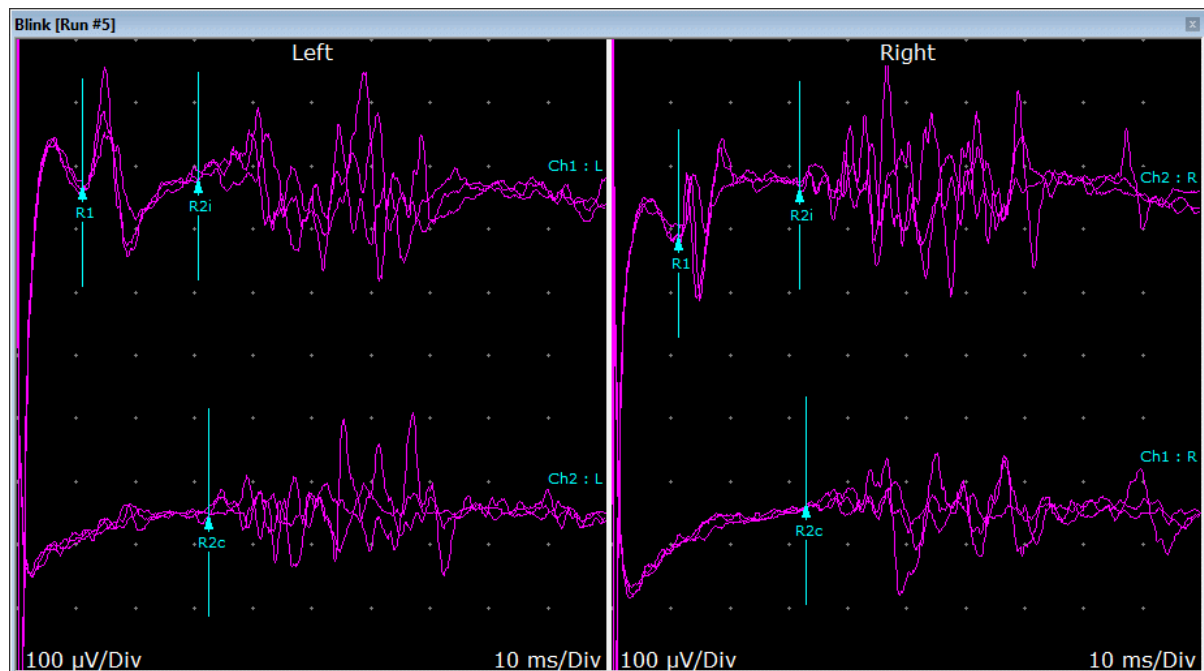
- **Using the Mouse** - simply **left-click on a trial to select it**, the trial will be displayed in yellow. Now, **right-click** the mouse and select **Auto Place Cursors** from the context menu. Cursors will be placed on the selected trial and the latency values derived from the cursors will be displayed in the **Blink Table** window.
- **Using the Mouse and the F5 (Auto Cursors) function key** - simply **left-click on a trial to select it**, the trial will be displayed in yellow. Now, press the **F5** key. Cursors will be placed on the selected trial and the latency values derived from the cursors will be displayed in the **Blink Table** window.

To Adjust the positions of the Cursors:

- Simply **click** on the Cursor you want to move with the left mouse button **and drag** the cursor along the trace to its new location.

9. Change the Side and Repeat steps 4 - 8.

Selecting a different side automatically stores the currently active (white) traces.



Blink Example - screen split vertically.



The program will automatically calculate the R2i-R2c difference for each side. It will also calculate the Left minus Right differences for R1, R2i, R2c, and R2i-R2c.

Blink Table					
Trial	NR	R1 (ms)	R2i (ms)	R2c (ms)	R2i-R2c (ms)
Norm		<13	<40	<41	
Trial2 - R		11.4	31.9	33.0	1.10
Trial6 - L		11.3	30.8	32.5	1.70
L-R Norm		<1.2			
L-R		0.2	1.1	0.5	0.60

Blink Cursor Table

SEP Operation

Select the SEP Test:

- If a Study has already been selected, simply click on the SEP test protocol within the Study window to highlight the test.
- If a Study has not been selected, or you don't want to use a Study. Select the SEP test protocol from the Navigator window.

Once the SEP test has been selected. Follow these steps for performing data acquisition:

1. Apply electrodes to the patient and connect to amplifier

Determine the number of channels that will be recorded and the electrodes that will be required for each channel. Apply the recording electrodes and ground electrode to the patient and connect to the Sierra Summit amplifier.



With the 2 Channel Amplifier, if the same electrode is used as the reference in each channel, use a **Reference Jumper** to connect this electrode into both reference (+) inputs on the amplifier.

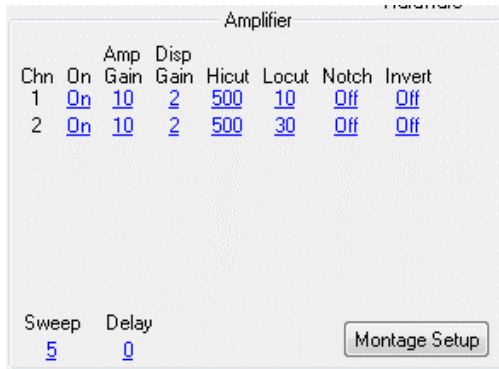
2. Verify Amplifier Settings

Check the **Gain**, **Hicut**, **Locut**, and **Sweep Speed** settings and make sure they are appropriate for the selected SEP test.

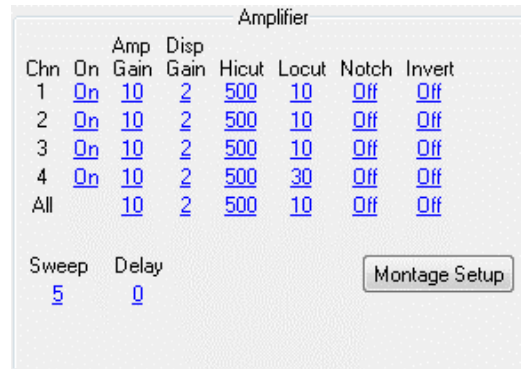
Typical Settings

	Gain (uV/Div)	Hicut (Hz)	Locut (Hz)	Sweep Speed (ms/Div)
Upper Limb SEP	1 to 5	3k to 500	10	5.0
Lower Limb SEP	1 to 5	3k to 500	10	10.0

The **Notch** filter is typically not used during SEP recordings and should remain **OFF**.



2 Channel Median SEP default Amplifier Settings.



4 Channel Median SEP default Amplifier Settings.



For the 3-12 channel amplifier, click the **Montage Setup** button and verify that the appropriate montage has been programmed for this test protocol. For more information about configuring the montage, see the help topic Montage Setup.

3. Check Impedances

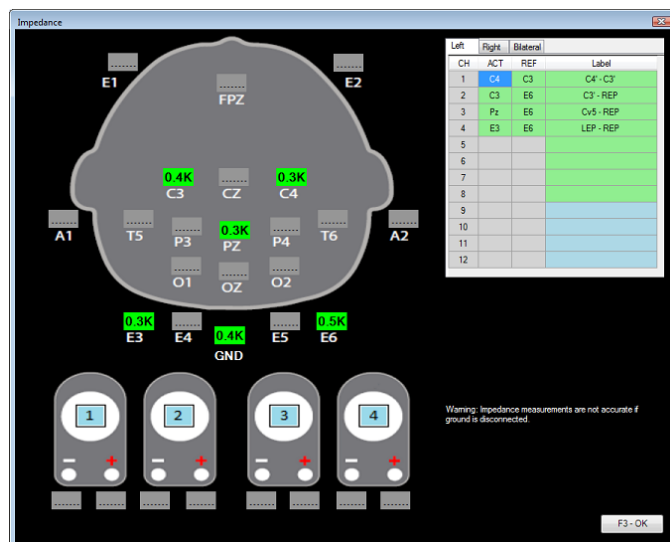
Click on the **Impedance Icon** in the Toolbar Controls at the top of the screen. The impedance window displays a picture of the front of the amplifier.



Impedance Icon



2 Channel Impedance window.



3-12 Channel Impedance window.

2 Channel Amplifier:

The impedance values for the **Active** (-) and **Reference** (+) inputs are displayed for each channel as well as the **Ground** electrode.

If a Channel is turned Off, no impedance values will be calculated for either the active or reference inputs and the word "Off" is displayed over the inputs of that channel.

Impedances less than 5k Ohms (kilo-ohms) are displayed in green. Values between 5.1 and 20 are displayed in yellow. Values greater than 20 are displayed in red. The maximum impedance value is 100k.

3-12 Channel Amplifier:

The impedance values for the **Active** (-) and **Reference** (+) inputs that are utilized in the current montage are displayed as well as the **Ground** electrode.

If an input is not used, no impedance value will be calculated and the label "....." is displayed for that input.

Impedances less than 5k Ohms (kilo-ohms) are displayed in green. Values between 5.1 and 20 are displayed in yellow. Values greater than 20 are displayed in red. The maximum impedance value is 50k for the head pattern inputs, and is 100k for the four EMG channels.

The Montage is displayed to the right of the impedance display, this is for reference purposes only.

To close the impedance window, click the **F3-OK** button.



When performing evoked potential studies all impedances should be **less than 5k Ohms**.

4. Select Side of Stimulation

Make sure the appropriate side, **Right** or **Left**, is selected.

5. Check Stimulator Settings and Polarity

Apply the stimulating electrodes (bar electrode or individual electrodes) to the patient. Connect the stimulating electrodes to the end of the hand-held electrical stimulator (remove the probe tips from the end of the stimulator). The **proximal** stimulating electrode should be connected to the **Cathode** (-) and the **distal** stimulating electrode should be connected to the **Anode** (+).

Stim Mode: Click here to open the **Electrical Stim Controls** window. For more information, see the help topic Advanced Stimulation Settings.

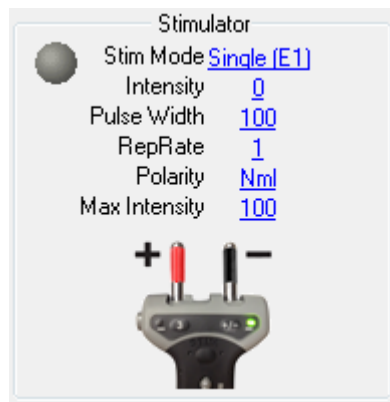
Intensity - start at zero milliamps and after data acquisition is started increase slowly until a visible muscle twitch is seen.

Pulse Width - typically set to 100 or 200 microseconds.

Rep Rate - typically between 2 to 5 Hz and not directly divisible into 60 (e.g., 2.11, 2.66, 4.77).

Polarity - set to **Normal (Nml)** mode. The green LED indicates the Cathode (-).

Max Intensity - sets the maximum intensity level in milliamps. Possible selections are 10, 20, 30, 40, 50, 60, 70, 80, 90, and 100 milliamps.



Controls Window.



Controls Toolbar.

SEP Stimulator Controls

6. Verify Averager Settings

Shutoff - This is the number of responses that will be averaged together to produce the final results. When the shutoff count is reached stimulation will stop.

Reject On / Off - When this feature is turned **On** the program will monitor the **Live** un-averaged data and will not include (i.e., will reject) high amplitude artifacts from the running average. During data acquisition the percentage (%) of stimuli/sweeps that have been rejected from the total delivered will be displayed on the screen.

Level - This is the reject sensitivity level, it is shown as a **percentage of full amplifier scale**. Choices are 30 to 100 % in increments of 5. 100% equals full scale, smaller numbers will make the reject more sensitive.

Averager	AvgCnt	Shutoff	Reject	%	Level
On	0	200	On	0%	95

Example SEP Averager settings.



Reject is based on the **Live** un-averaged data and the **Amp Gain** setting. Every channel has 5 divisions above and below its initial baseline. So, if the Amp Gain is set to 10 uV/Div this means that the Live trace has an amplitude window of 100 microvolts (10 vertical divisions times 10 uV/Div) with 50 uV above the baseline and 50 uV below the baseline. If the reject level is set to 100% (i.e., full scale), then the amplitude of the live data must be below +/- 50 uV to be included in the running average. Should it exceed +/- 50 uV the trace will be rejected from the running average. If the reject level is set to 50% (i.e., half of full scale), then the amplitude of the Live data can't exceed +/- 25 uV (2.5 divisions above or below the baseline) or it will be rejected from the running average. The lower the reject level setting the more sensitive the program will be in rejecting large artifacts.



You can check the **Amp Gain** setting by pressing the **F1 (Avg / Live)** function key to switch to the **Live** mode. Press the function key again to return to the **Avg** mode and view the **Display Gain** setting.

7. Acquire Responses

A. Start Data Acquisition.

Press the **Run/Stop key** to start stimulus delivery and data acquisition. **Slowly turn up the stimulus intensity level** until a visible muscle twitch is observed. The average count (**AvgCnt**) should start to increment and the traces will begin to take shape.

Adjust the vertical size of the all traces by turning **Knob #3 (Gain)**. To adjust the gain of an individual trace, change the corresponding gain setting in the Toolbar Controls.

Press the **F3 (Smooth)** function key during acquisition to remove high frequency noise from the active (white) traces.

B. Store the first trial.

When the Shutoff count is reached, stimulation will stop automatically. Press the **Store key** to store the active (white) traces. A copy of the active traces will appear on the screen and are displayed in a purple color. The average count will be reset to zero.



The **Store key** can be pressed before the Shutoff count is reached. This will cause the currently active traces to be stored, the average count will be reset to zero, and stimulation will continue automatically on a new set of traces.

C. Acquire a second Trial

Press the **Run/Stop key** to start stimulus delivery and data acquisition again. Generally, two trials should always be acquired when performing evoked potentials to show replication of the traces.

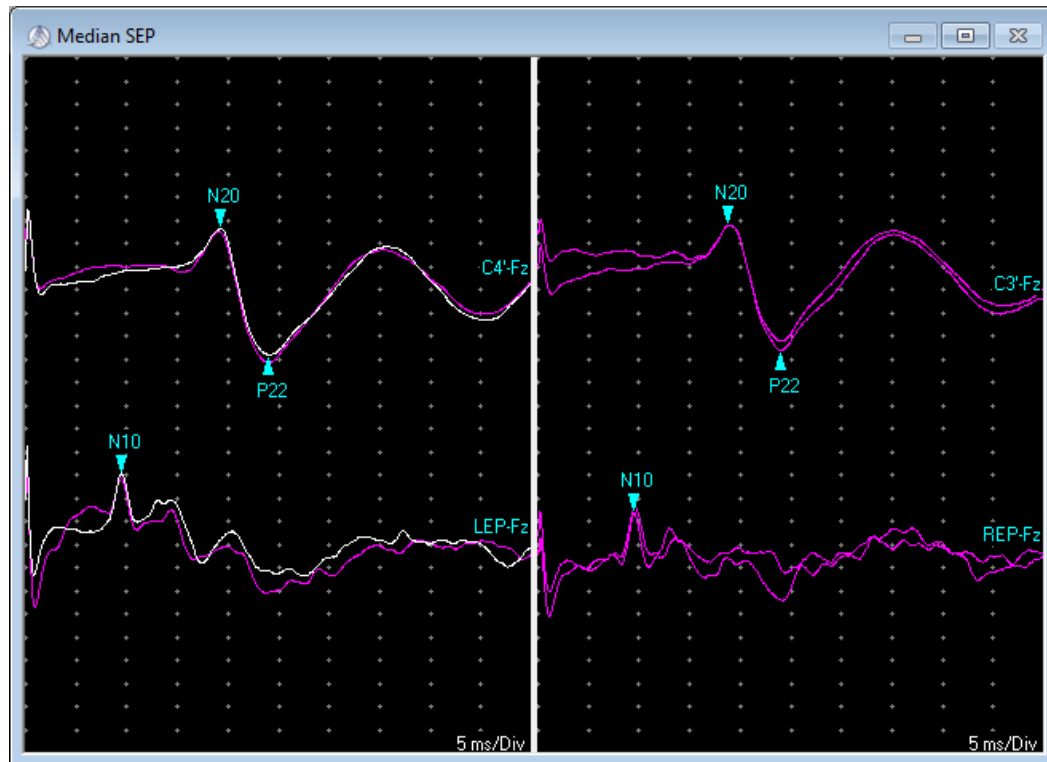
D. Store second trial.

After the Shutoff count is reached for the second trial, press the **Store key** to store the active (white) traces.

E. Change Side of Stimulation.

To acquire traces for the opposite side, change the **Side** setting in the Toolbar Controls. If you are using the Split Screen feature the active (white) traces will automatically move to the opposite side of the Trace window.

F. Repeat steps A - D and collect data for the opposite side.



Example 2 Channel Median SEP, Left and Right.

8. Trace Positioning (optional)

If the position of the traces needs to be adjusted, follow one of these procedures.

- **Using the Mouse** - simply click on the **Trial** you want to move with the left mouse button and drag the trial to its new location. If you want to move an individual **Trace**, not the entire Trial, first right-click the mouse over the Trace window and remove the check mark in front of **Trial Selection Mode**.
- **Using the Trace Position Settings** - right-click the mouse over the Trace window and select **Trace Position Settings** from the pop-up menu. Change the settings for **Start Position**, **Trial Offset**, and **Channel Offset** and click **OK**.

9. Place Auto Cursors

To place Cursors on the important trace features, follow one of these procedures.

- **Using the Mouse** - simply **left-click on a trial to select it**, the trial will be displayed in yellow. Now, **right-click** the mouse and select **Auto Place Cursors** from the pop-up menu. Cursors will be placed on the selected trial and the values (latency, amplitude, etc.) derived from the cursors will be displayed in the **EP Cursor Table** window.
- **Using the Mouse and the F5 (Auto Cursors) function key** - simply **left-click on a trial to select it**, the trial will be displayed in yellow. Now, press the **F5** key. Cursors will be

placed on the selected trial and the values (latency, amplitude, etc.) derived from the cursors will be displayed in the **EP Cursor Table** window.

To Adjust the positions of the Cursors:

- **Using the Mouse** - simply **click** on the Cursor you want to move with the left mouse button **and drag** the cursor along the trace to its new location.

	Trial	N20 (ms)	N10 (ms)	N20-N10 (ms)	N20-P22 (μ V)
Normal Values →	Norm	<22	<12	<10.9	
Results for Right Side →	Trial1 - R	18.9	9.6	9.3	8.75
Results for Left Side →	Trial3 - L	19.1	12.1	7.0	9.17
L - R Normal Values →	L-R Norm	<1.8	<0.7	<0.8	
Calculated L - R Values →	L-R	0.2	2.5	2.3	0.42

Red color indicates abnormal value.

Example Median SEP Cursor Table.



The program will calculate the **left minus right difference values** for each defined measurement after cursors have been placed on **one left** and **one right** side trial.



Depending on your preferences in System Setup, abnormal values can be flagged with a red background color, as bold text, as bold text with an asterisk, or as bold text & background color red.

AEP Operation

Select the AEP  Test:

- If a Study has already been selected, simply click on the AEP test protocol within the Study window to highlight the test.
- If a Study has not been selected, or you don't want to use a Study. Select the AEP test protocol from the Navigator window.

Once the AEP test has been selected. Follow these steps for performing data acquisition:

1. Apply electrodes to the patient and connect to amplifier

Determine the number of channels that will be recorded and the electrodes that will be required for each channel. Apply the recording electrodes and ground electrode to the patient and connect to the Sierra Summit amplifier.



With the 2 Channel Amplifier, if the same electrode is used as the reference in each channel, use a **Reference Jumper** to connect this electrode into both reference (+) inputs on the amplifier.

2. Verify Amplifier Settings

Check the **Gain**, **Hicut**, **Locut**, and **Sweep Speed** settings and make sure they are appropriate for the selected AEP test.

Typical AEP Settings

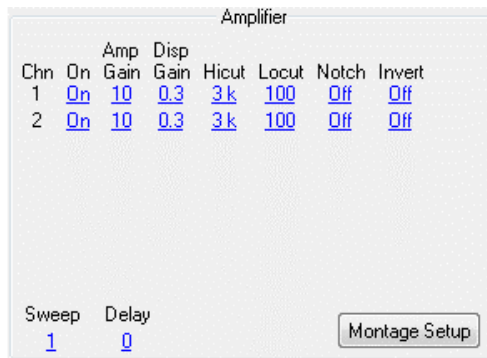
Gain = 0.2 to 0.5 μ V/Div

Hicut = 3k Hz

Locut = 100 Hz

Sweep Speed = 1.0 ms/Div

The **Notch** filter is typically not used during AEP recordings and should remain **OFF**.



AEP Default Settings.



For the 3-12 channel amplifier, click the **Montage Setup** button and verify that the appropriate montage has been programmed for this test protocol. For more information about configuring the montage, see the help topic Montage Setup.

3. Check Impedances

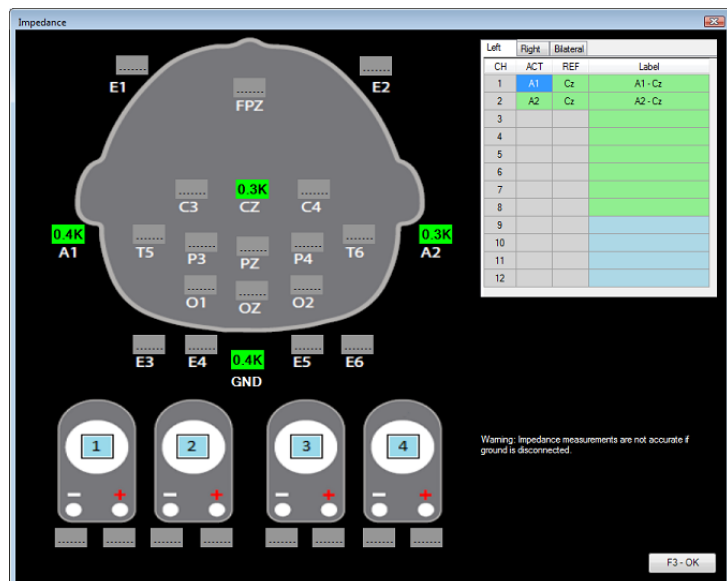
Click on the **Impedance Icon** in the Toolbar Controls at the top of the screen. The impedance window displays a picture of the front of the amplifier.



Impedance Icon



2 Channel Impedance window.



3-12 Channel Impedance window.

2 Channel Amplifier:

The impedance values for the **Active** (-) and **Reference** (+) inputs are displayed for each channel as well as the **Ground** electrode.

If a Channel is turned Off, no impedance values will be calculated for either the active or reference inputs and the word "Off" is displayed over the inputs of that channel. Impedances less than 5k Ohms (kilo-ohms) are displayed in green. Values between 5.1 and 20 are displayed in yellow. Values greater than 20 are displayed in red. The maximum impedance value is 100k.

3-12 Channel Amplifier:

The impedance values for the **Active** (-) and **Reference** (+) inputs that are utilized in the current montage are displayed as well as the **Ground** electrode.

If an input is not used, no impedance value will be calculated and the label "....." is displayed for that input.

Impedances less than 5k Ohms (kilo-ohms) are displayed in green. Values between 5.1 and 20 are displayed in yellow. Values greater than 20 are displayed in red. The maximum impedance value is 50k for the head pattern inputs, and is 100k for the four EMG channels.

The Montage is displayed to the right of the impedance display, this is for reference purposes only.

To close the impedance window, click the **F3- OK** button.



When performing evoked potential studies all impedances should be **less than 5k Ohms**.

4. Select Side of Stimulation

Make sure the appropriate side, **Right** or **Left**, is selected.

5. Check Stimulator Settings

Apply the stimulator (headphones or inserts) to the patient, the red headphone/insert should be placed on the patient's right side, the blue headphone/insert should be placed on the left. Connect the stimulator to the back of the Sierra Summit base unit.

Stimulator		
Mode	Click	nHL
Type	Phones	
Polarity	Rare	
Intensity L-R	70	70
Threshold L-R	0	0
Mask	On	30
RepRate	11.33	
Frequency	1k	
Envelope	None	
DB Incr.	1	
Acoustic Delay	1.00	
Duration	100	

AEP Stimulator Settings - Controls Window

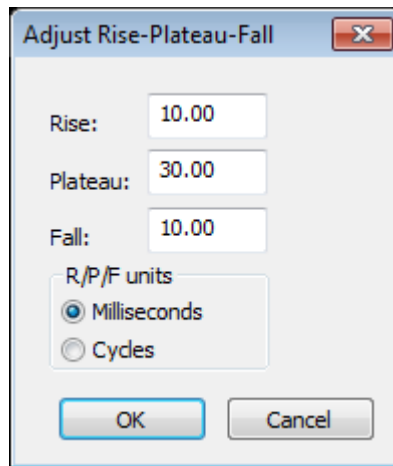
Mode	Click	nHL	Type	Phones	Polarity	Rare	Intensity L-R	70	70	Threshold L-R	0	0	Mask	On	30	RepRate	11.33	Frequency	1k	Duration	100	Env.	None
------	-------	-----	------	--------	----------	------	---------------	----	----	---------------	---	---	------	----	----	---------	-------	-----------	----	----------	-----	------	------

AEP Stimulator Settings - Controls Toolbar

Mode: Click here to select the auditory stimulus type, choose either **Click**, **Tone**, **Pip202**, **Pip212**, **Trigger Out 1-4**, or **Trigger In 1-4**..

- **Click** - this is a broadband click, the default duration is 100 microseconds.
 - **Duration** - when Click is selected a pulse duration setting will be available. Click here to select the duration of the click, the choices are 50, 100, 200, 500, and 1000 microseconds.

- **Tone** - this is a 10-30-10 tone burst stimulus. It has a 10 millisecond rise time, a 30 millisecond plateau, and a 10 millisecond fall time. This stimulus is typically used for long latency auditory evoked potentials.
- **Pip 202 or Pip 212** - these are also tone stimuli but their rise, plateau, and fall times are measured in cycles rather than milliseconds. The 2-0-2 Pip has a 2 cycle rise, 0 cycle plateau, and 2 cycle fall. The 2-1-2 Pip has a 2 cycle rise, 1 cycle plateau, and a 2 cycle fall.
 - **Frequency** - when Tone, Pip202, or Pip212 are selected a Frequency setting will be available. Click here to select the frequency of the tone/pip. The choices are 250, 500, 750, 1000, 2000, 3000, 4000, 6000, and 8000 Hz.
 - **R/P/F** - when Tone, Pip202, or Pip212 are selected the rise, plateau, and fall values are shown here. Click here to change these values.
 -



Change the rise, plateau, and fall values for a Tone or Pip.

- **Envelope** - when Tone, Pip202, or Pip212 are selected a stimulus envelope can be selected here. Choices are None, Linear, Blackman, Hanning, and Gaussian.
- **Trigger Out (1- 4)** - select Trigger Out 1-4 to send a synchronized TTL trigger pulse to another stimulus device. See the AEP Test Setup help topic for more information.
- **Trigger In (1 - 4)** - select Trigger In 1-4 to set the Sierra Summit to trigger the sweep on the positive or negative going edge of an applied external TTL signal. See the AEP Test Setup help topic for more information.

Type: Click here to select the type of stimulus delivery hardware, choose either **Phones**, **Inserts**, or **Bone Transducer**.



When **Inserts** are selected the program will **automatically subtract 1.0 milliseconds** from all latency calculations to compensate for the delay produced by the plastic tubing. This delay value can be modified by clicking on the **Acoustic Delay** value. This value does not shift the displayed trace.

Polarity: Click here to set the stimulus polarity, the choices vary depending on the stimulus type.

- **For Click** - choose either **Rarefaction**, **Condensation**, or **Alternating** polarity.
- **For Tone or Pip** - choose either **Negative**, **Positive**, or **Alternating** polarity.

Intensity L-R: Click here to set the starting stimulus intensity value. The first column is for the left side, the second column is for the right side.

Threshold L-R: Click here to set the starting behavioral threshold value. The first column is for the left side, the second column is for the right side. During data acquisition the Threshold values are added to the Intensity values to produce the stimulus at the headphones/inserts.

Intensity Units: Choose either **nHL** (normalized hearing level) or **SPL** (sound pressure level). When SPL is selected the Threshold settings are disabled.

dB Incr: Click here to change the intensity value scale. The default setting is 1 dB increments, choices are 1, 2, 5 and 10.

Mask: Click here to set the "white" noise masking as either **On** or **Off** and to set the level for the non-stimulated ear. The amount selected is the number of dB's below the Intensity value. This is known as differential masking and allows the intensity of the masking noise to decrease automatically as the intensity of the stimulus is decreased.

Rep Rate: Click here to set the repetitive stimulus rate, in pulses per second (Hz). This setting only applies when delivering repetitive stimulation. It does not apply during manual single stimulus delivery.

6. Determine Behavioral Threshold Levels (optional)

There is one specially designated knob for setting the behavioral threshold levels. **Knob #2 (L or R Thresh / Off)**. To determine the threshold levels follow these steps.

- I. **Select the Side** (Left or Right) that you want to test in the Toolbar Controls.
- II. **Turn Knob #2.** Stimuli will be automatically delivered to the selected ear and the threshold value for that ear will turn "yellow".
- III. **Continue to turn** Knob #2 until the patient can definitely hear the stimulus.
- IV. Now, slowly turn Knob #2 in the reverse direction to **decrease** the threshold level. Keep decreasing the level until the patient signals that they can no longer hear, or can just barely hear, the stimulus.
- V. **Press Knob #2** to stop stimulus delivery and set the threshold value for the that ear.
- VI. **Repeat** the above steps for the other side.



The threshold value is automatically added to the intensity value to obtain the output level for the stimulator. For example, if the left intensity was set to 70 dB and the left threshold was determined to be 12 dB, the actual output intensity from the stimulator would be 82 (70 + 12).

7. Verify Averager Settings

Shutoff - This is the number of responses that will be averaged together to produce the final results. When the shutoff count is reached stimulation will automatically be stopped.

Reject On / Off - When this feature is turned **On** the program will monitor the **Live** un-averaged data and will not include (i.e., will reject) high amplitude artifacts from the running average. During data acquisition the percentage (%) of stimuli/sweeps that have been rejected from the total delivered will be displayed on the screen.

Level - This is the reject sensitivity level, it is shown as a percentage of full amplifier scale. Choices are 30 to 100 % in increments of 5. 100% equals full scale, smaller numbers will make the reject more sensitive.

Averager	AvgCnt	Shutoff	Reject	%	Level
On	0	2000	On	0%	50

AEP Default Averager Settings.



Reject is based on the **Live** un-averaged data and the **Amp Gain** setting. Every channel has 5 divisions above and below its initial baseline. So, if the Amp Gain is set to 10 uV/Div this means that

the Live trace has an amplitude window of 100 microvolts (10 vertical divisions times 10 uV/Div) with 50 uV above the baseline and 50 uV below the baseline. If the reject level is set to 100% (i.e., full scale), then the amplitude of the live data must be below +/- 50 uV to be included in the running average. Should it exceed +/- 50 uV the trace will be rejected from the running average. If the reject level is set to 50% (i.e., half of full scale), then the amplitude of the Live data can't exceed +/- 25 uV (2.5 divisions above or below the baseline) or it will be rejected from the running average. The lower the reject level setting the more sensitive the program will be in rejecting large artifacts.



You can check the **Amp Gain** setting by pressing the **F1 (Avg / Live)** function key to switch to the **Live** mode. Press the function key again to return to the **Avg** mode and view the **Display Gain** setting.

8. Acquire Responses

A. Start Data Acquisition.

Press the **Run/Stop key** to start stimulus delivery and data acquisition. The average count (**AvgCnt**) should start to increment and the traces will begin to take shape.

Adjust the vertical size of the all traces by turning **Knob #3 (Gain)**. To adjust the gain of an individual trace, change the corresponding gain setting in the Toolbar Controls.

Press the **F3 (Smooth)** function key during acquisition to remove high frequency noise from the active (white) traces.

B. Store the first trial.

When the Shutoff count is reached, stimulation will stop automatically. Press the **Store key** to store the active (white) traces. A copy of the active traces will appear on the screen and are displayed in a purple color. The average count will be reset to zero.



The **Store key** can be pressed before the Shutoff count is reached. This will cause the currently active traces to be stored, the average count will be reset to zero, and stimulation will continue automatically on a new set of traces.

C. Acquire a second Trial

Press the **Run/Stop key** to start stimulus delivery and data acquisition again. Generally, two trials should always be acquired when performing evoked potentials to show replication of the traces.

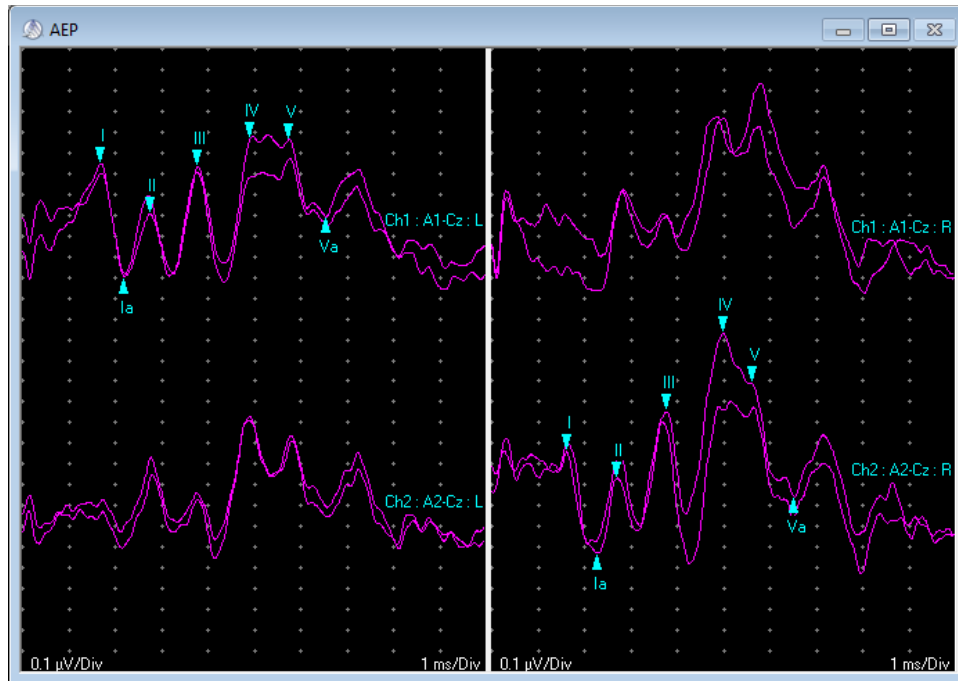
D. Store second trial.

After the Shutoff count is reached for the second trial, press the **Store key** to store the active (white) traces.

E. Change Side of Stimulation.

To acquire traces for the opposite side, change the **Side** setting in the **Toolbar Controls**. If you are using the Split Screen feature the active (white) traces will automatically move to the opposite side of the Trace window.

F. Repeat steps A - D and collect data for the opposite side.



Example 2 Channel AEP, Left and Right.

9. Trace Positioning (optional)

If the position of the traces needs to be adjusted, follow one of these procedures.

- **Using the Mouse** - simply **click on the Trace you want to move with the left mouse button** and drag the trace to its new location.
- **Using the Trace Position Settings** - right-click the mouse over the Trace window and select **Trace Position Settings** from the pop-up menu. Change the settings for **Start Position**, **Trial Offset**, and **Channel Offset** and click **OK**.

10. Place Auto Cursors

To place Cursors on the important trace features, follow one of these procedures.

- **Using the Mouse** - simply **left-click on a trace to select it**, the trace will be displayed in yellow. Now, **right-click** the mouse and select **Auto Place Cursors** from the pop-up menu. Cursors will be placed on the selected trace and the values (latency, amplitude, etc.) derived from the cursors will be displayed in the **EP Cursor Table** window.
- **Using the Mouse and F5 (Auto Cursors) function key** - simply **left-click on a trace to select it**, the trace will be displayed in yellow. Now, press the **F5** key. Cursors will be placed on the selected trace and the values (latency, amplitude, etc.) derived from the cursors will be displayed in the **EP Cursor Table** window.



For information on configuring the Auto Cursors, see the AEP Test Setup help topic.

To Adjust the positions of the Cursors:

- **Using the Mouse** - simply click on the Cursor you want to move with the left mouse button and drag the cursor along the trace to its new location.

Defined Measurements												
	Trace	I (ms)	II (ms)	III (ms)	IV (ms)	V (ms)	I-III (ms)	III-V (ms)	I-V (ms)	V-Va (μ V)	I-Ia (μ V)	V-Va/I-Ia
Normal Values →	Norm	<2.0		<4.5		<6.2	<2.4	<2.3	<4.5			
Results for Right Side →	Ch2 : A2-Cz : R	1.88	2.70	3.78	5.00	5.59	1.90	1.81	3.71	0.55	0.20	2.75
Results for Left Side →	Ch1 : A1-Cz : L	1.69	2.75	3.78	4.92	5.78	2.09	2.00	4.09	0.37	0.55	0.67
L - R Normal Values →	L-R Norm						<0.28	<0.32	<0.33			
Calculated L - R Values →	L-R	0.19	0.05	0.00	0.08	0.19	0.19	0.19	0.38	0.18	0.35	2.08

Red Color indicates abnormal value

AEP cursor table example.



The program will calculate the left minus right difference values for each defined measurement after cursors have been placed on **one left** and **one right** side trace.



Depending on your preferences in System Setup, abnormal values can be flagged with a red background color, as bold text, as bold text with an asterisk, or as bold text & background color red.

VEP Operation

Select the VEP Test:

- If a Study has already been selected, simply click on the VEP test protocol within the Study window to highlight the test.
- If a Study has not been selected, or you don't want to use a Study. Select the VEP test protocol from the Navigator window.



If you are using a LCD Monitor, see the topic VEP Stimulator Setup and refer to the document "190282-933 - Calibration Instructions for LCD Checkerboard Monitor.pdf". LCD monitors have different screen drawing characteristics than CRT monitors, and as such a compensatory delay (or offset) has to be determined and entered into the Sierra Summit program before an LCD monitor can be used. Without this delay value entered into the program the latency of the visual evoked potentials will be greatly prolonged.

Once the VEP test has been selected. Follow these steps for performing data acquisition:

1. Apply electrodes to the patient and connect to amplifier

Determine the number of channels that will be recorded and the electrodes that will be required for each channel. Apply the recording electrodes and ground electrode to the patient and connect to the Sierra Summit amplifier.



With the 2 Channel Amplifier, if the same electrode is used as the reference in each channel, use a **Reference Jumper** to connect this electrode into both reference (+) inputs on the amplifier.

2. Verify Amplifier Settings

Check the **Gain**, **Hicut**, **Locut**, and **Sweep Speed** settings and make sure they are appropriate for the selected VEP test.

Typical VEP Settings

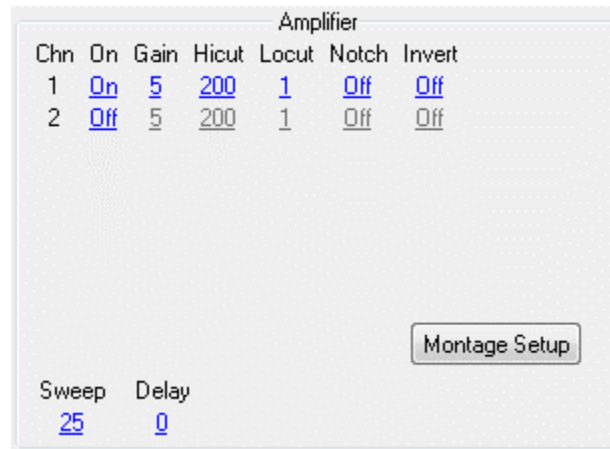
Gain = 5 μ V/Div

Hicut = 200 Hz

Locut = 1 Hz

Sweep Speed = 25 ms/Div

The **Notch** filter is typically not used during VEP recordings and should remain **OFF**.



Default VEP Amplifier Settings.



For the 3-12 channel amplifier, click the **Montage Setup** button and verify that the appropriate montage has been programmed for this test protocol. For more information about configuring the montage, see the help topic Montage Setup.

3. Check Impedances

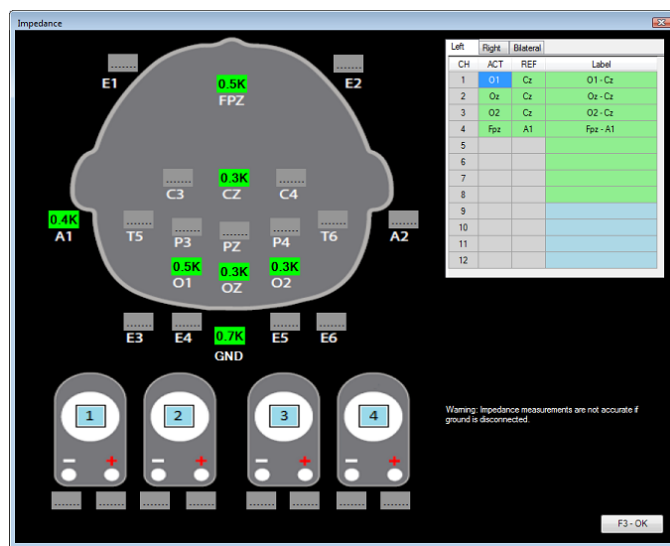
Click on the **Impedance Icon** in the Toolbar Controls at the top of the screen. The impedance window displays a picture of the front of the amplifier.



Impedance Icon



2 Channel Impedance window.



3-12 Channel Impedance window.

2 Channel Amplifier:

The impedance values for the **Active** (-) and **Reference** (+) inputs are displayed for each channel as well as the **Ground** electrode.

If a Channel is turned Off, no impedance values will be calculated for either the active or reference inputs and the word "Off" is displayed over the inputs of that channel.

Impedances less than 5k Ohms (kilo-ohms) are displayed in green. Values between 5.1 and 20 are displayed in yellow. Values greater than 20 are displayed in red. The maximum impedance value is 100k.

3-12 Channel Amplifier:

The impedance values for the **Active** (-) and **Reference** (+) inputs that are utilized in the current montage are displayed as well as the **Ground** electrode.

If an input is not used, no impedance value will be calculated and the label "....." is displayed for that input.

Impedances less than 5k Ohms (kilo-ohms) are displayed in green. Values between 5.1 and 20 are displayed in yellow. Values greater than 20 are displayed in red. The maximum impedance value is 50k for the head pattern inputs, and is 100k for the four EMG channels.

The Montage is displayed to the right of the impedance display, this is for reference purposes only.

To close the impedance window, click the **F3- OK** button.



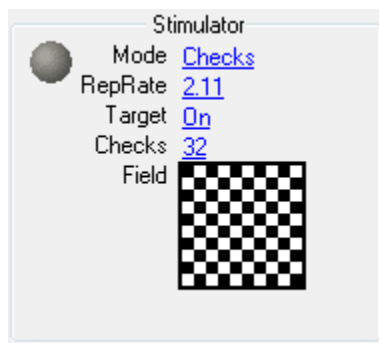
When performing evoked potential studies all impedances should be **less than 5k Ohms**.

4. Select Side of Stimulation

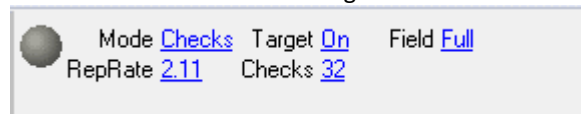
Make sure the appropriate side, **Right** or **Left**, is selected.

5. Checkerboard Stimulus Settings

Connect the VEP Checkerboard Monitor to the external monitor connector on the Laptop or the 2nd monitor port on the PC.. Position the stimulator at the required distance from the patient. Cover the non-stimulated eye. For more information on determining the correct checkerboard distance, see the help topic Determining VEP Checkerboard Distance.



VEP Default Stimulator Settings - Controls Window



VEP Stimulator Settings - Controls Toolbar

Mode: Click here to select the type of visual stimulus. Choices are **Checks**, **Trigger Out 1-4**, or **Trigger In 1-4**.

- **Checks** - selects a reversing black & white checkerboard pattern. When checks are selected as the stimulus type the following additional parameters are available.
 - **Target** - select either On or Off. When turned On a small target is positioned in the center of the LCD monitor, the patient should focus on this target during data acquisition.
 - **Checks** - click here to select the number of checks displayed across a horizontal row. The choices are 1, 2, 4, 8, 16, 32, 64, and 128.
 - **Field** - click in this area to select the field of stimulation. The choices are Full Field, Upper Half, Right Half, Lower Half, Left Half, Left Upper Quarter, Right Upper Quarter, Right Lower Quarter, and Left Lower Quarter.
- **Trigger Out (1- 4)** - select Trigger Out 1-4 to send a synchronized TTL trigger pulse to another stimulus device. See the VEP Test Setup help topic for more information.
- **Trigger In (1 - 4)** - select Trigger In 1-4 to set the Sierra Summit to trigger the sweep on the positive or negative going edge of an applied external TTL signal. See the VEP Test Setup help topic for more information.

Rep Rate: Click here to set the repetitive stimulus rate, in pulses per second (Hz). This setting only applies when delivering repetitive stimulation. It does not apply during manual single stimulus delivery.

6. Verify Averager Settings

Shutoff - This is the number of responses that will be averaged together to produce the final results. When the shutoff count is reached stimulation will automatically be stopped.

Reject On / Off - When this feature is turned **On** the program will monitor the **Live** un-averaged data and will not include (i.e., will reject) high amplitude artifacts from the running average. During data acquisition the percentage (%) of stimuli/sweeps that have been rejected from the total delivered will be displayed on the screen.

Level - This is the reject sensitivity level, it is shown as a percentage of full amplifier scale. Choices are 30 to 100 % in increments of 5. 100% equals full scale, smaller numbers will make the reject more sensitive.

Averager	AvgCnt	Shutoff	Reject	%	Level
On	0	100	On	0%	95

VEP Default Averager Settings.



Reject is based on the **Live** un-averaged data and the **Amp Gain** setting. Every channel has 5 divisions above and below its initial baseline. So, if the Amp Gain is set to 10 uV/Div this means that the Live trace has an amplitude window of 100 microvolts (10 vertical divisions times 10 uV/Div) with 50 uV above the baseline and 50 uV below the baseline. If the reject level is set to 100% (i.e., full scale), then the amplitude of the live data must be below +/- 50 uV to be included in the running average. Should it exceed +/- 50 uV the trace will be rejected from the running average. If the reject level is set to 50% (i.e., half of full scale), then the amplitude of the Live data can't exceed +/- 25 uV (2.5 divisions above or below the baseline) or it will be rejected from the running average. The lower the reject level setting the more sensitive the program will be in rejecting large artifacts.



You can check the **Amp Gain** setting by pressing the **F1 (Avg / Live)** function key to switch to the **Live** mode. Press the function key again to return to the **Avg** mode and view the **Display Gain** setting.

7. Acquire Responses

A. Start Data Acquisition.

Press the **Run/Stop key** to start stimulus delivery and data acquisition. The average count (**AvgCnt**) should start to increment and the traces will begin to take shape.

Adjust the vertical size of the all traces by turning **Knob #3 (Gain)**. To adjust the gain of an individual trace, change the corresponding gain setting in the **Toolbar Controls**.

Press the **F3 (Smooth)** function key during acquisition to remove high frequency noise from the active (white) traces.

B. Store the first trial.

When the Shutoff count is reached, stimulation will stop automatically. Press the **Store key** to store the active (white) traces. A copy of the active traces will appear on the screen and are displayed in a purple color. The average count will be reset to zero.



The **Store key** can be pressed before the Shutoff count is reached. This will cause the currently active traces to be stored, the average count will be reset to zero, and stimulation will continue automatically on a new set of traces.

C. Acquire a second Trial

Press the **Run/Stop key** to start stimulus delivery and data acquisition again. Generally, two trials should always be acquired when performing evoked potentials to show replication of the traces.

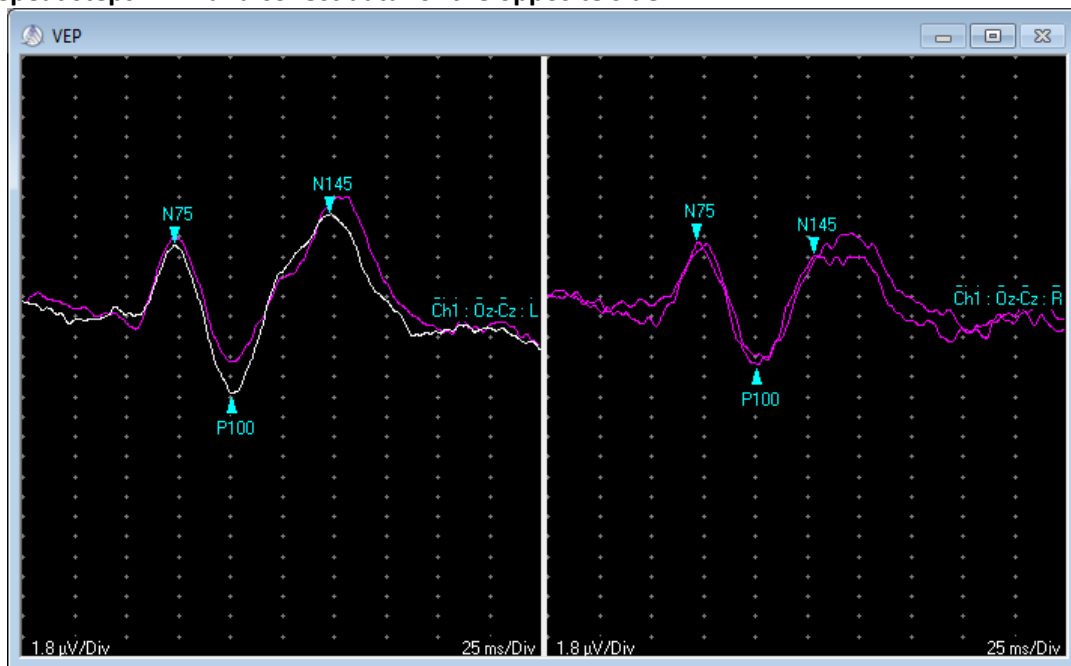
D. Store second trial.

After the Shutoff count is reached for the second trial, press the **Store key** to store the active (white) traces.

E. Change Side of Stimulation.

To acquire traces for the opposite side, change the **Side** setting in the **Toolbar Controls**. If you are using the Split Screen feature the active (white) traces will automatically move to the opposite side of the Trace window.

F. Repeat steps A - D and collect data for the opposite side.



Example VEP, single channel recording, Left & Right.

8. Trace Positioning (optional)

If the position of the traces needs to be adjusted, follow one of these procedures.

- **Using the Mouse** - simply click on the Trace you want to move with the left mouse button and drag the trace to its new location.
- **Using the Trace Position Settings** - right-click the mouse over the Trace window and select **Trace Position Settings** from the pop-up menu. Change the settings for **Start Position**, **Trial Offset**, and **Channel Offset** and click **OK**.

9. Place Auto Cursors

To place Cursors on the important trace features, follow one of these procedures.

- **Using the Mouse** - simply **left-click on a trace to select it**, the trace will be displayed in yellow. Now, **right-click** the mouse and select **Auto Place Cursors** from the pop-up menu. Cursors will be placed on the selected trace and the values (latency, amplitude, etc.) derived from the cursors will be displayed in the **EP Cursor Table** window.
- **Using the Mouse and F5 (Auto Cursors) function key** - simply **left-click on a trace to select it**, the trace will be displayed in yellow. Now, press the **F5** key. Cursors will be placed on the selected trace and the values (latency, amplitude, etc.) derived from the cursors will be displayed in the **EP Cursor Table** window.



For information on configuring the Auto Cursors, see the VEP Test Setup help topic.

To Adjust the positions of the Cursors:

- **Using the Mouse** - simply **click** on the Cursor you want to move with the left mouse button **and drag** the cursor along the trace to its new location.

Defined Measurements						
		Trace	N75 (ms)	P100 (ms)	N145 (ms)	N75-P100 (µV)
Results for Right Side	→	Ch1 : Oz-Cz : R	72.3	101.2	128.9	11.18
Results for Left Side	→	Ch1 : Oz-Cz : L	73.4	102.7	148.0	13.33
Calculated L - R Values	→	L-R	1.1	1.5	19.1	2.15

VEP cursor table example.



The program will calculate the left minus right difference values for each defined measurement after cursors have been placed on **one left** and **one right** side trace.



Depending on your preferences in System Setup, abnormal values can be flagged with a red background color, as bold text, as bold text with an asterisk, or as bold text & background color red.

Operation of other Test Protocols

Basic operating instructions for the following test protocols: **P300**, **EMG Guidance**, **Macro EMG**, **RR Interval**, and **MUNE/MUNIX+** are available in the Summit application's Help Topics.

Release Notes

The Release Notes document (369043-810) contains information on new features and enhancements in the latest version of software. This document can be accessed by selecting the Support Page, and then click on the Reference Documents button.

General Warnings, Precautions, and Contraindications

Warnings

1. Connection of a PATIENT to H.F. surgical equipment and to an ELECTROMYOGRAPH or EVOKED RESPONSE EQUIPMENT may result in burns at the site of the ELECTRICAL STIMULATOR or RECORDING ELECTRODES and possible damage to the ELECTRICAL STIMULATOR or AMPLIFIER.
2. Operation in proximity of short wave or microwave therapy equipment may produce instability in the applied parts.
3. U.S. Federal law restricts this device to sale by or on the order of a physician. Other countries where this product is marketed may have similar restrictions regarding the sale and/or use of this device.
4. Product is intended to be used under the direction and prescription of licensed physician.
5. The Help Topics section provides an operational summary for the Sierra Summit system. It does not provide clinical training.
6. Applied parts (electrodes, sensors, stimulators) connected to a patient connection on the medical device, but not connected to the patient, must be prevented from contacting other conductive parts in order to preserve the patient electrical isolation.
7. For the safety of the user and the patient, always disconnect equipment from the AC power source and from the patient before cleaning.
8. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with a protective earth.
9. Do not modify the Sierra Summit system. Modification of this medical system will render the equipment non-compliant with regulatory requirements and unsafe for use.
10. Do not attempt to service the Sierra Summit system components. There are no user-serviceable parts inside the Sierra Summit system. Service by Cadwell Industries, Inc. or other Cadwell authorized service centers only.
11. To prevent overheating, do not wrap or cover Sierra Summit (Summit base, amplifiers) ventilation slots. Unobstructed slots are required for proper cooling of the system.
12. Portable or Mobile RF communications equipment can affect the functionality of medical electrical equipment. Performance of the Sierra Summit should be observed to verify normal operation in the configuration in which it will be used.
13. Sierra Summit should not be used adjacent to or stacked with any other equipment. If adjacent or stacked use is necessary, performance of the Sierra Summit should be observed to verify normal operation in the configuration in which it will be used.

Contraindications

1. Do not use the system in an MRI environment. MRI systems emit large amounts of electromagnetic energy that can interfere with proper operation of the Sierra Summit.
2. Do not immerse system components in liquid. System does not have protection against liquid or particulate matter ingress. Discontinue use if exposed to liquids.
3. Do not operate the Sierra Summit system in an explosive environment. The system is not designed to operate in this type of environment.
4. Do not operate the Sierra Summit system in an oxygen rich environment. The system is not designed to operate in this type of environment.
5. Do not use the Sierra Summit and a defibrillator simultaneously on a patient. A defibrillator discharge can cause severe damage to the Sierra Summit.
6. Avoid trans-thoracic stimulation. Cardiac arrest and possible death can occur as a result of trans-thoracic stimulation.
7. A patient with an implanted electronic device must not be subjected to electrical stimulation unless a specialist medical opinion has first been obtained. Electrical stimulation may interact with implanted electronic devices and disrupt their operation.

Precautions

- 1) The proper use of this device for its intended purpose can only be assured once all instructions have been read and understood. If there are any questions regarding the operation of the Sierra Summit EMG/EP system, contact Cadwell.
- 2) Current densities for any electrode exceeding 2 mA r.m.s./cm² may require the special attention of the operator. Stimulation exceeding 10 mA rms or current densities greater than 2 mA/cm² may cause burns at the site of the stimulation. Examine the stimulation site prior to delivering additional stimulation.
- 3) Perform system diagnostic test prior to performing a procedure to ensure system is operating properly. Return Summit to Cadwell or a Cadwell authorized service center if system fails diagnostic test.
- 4) Clean and disinfect system and accessories (between uses) to prevent infection. Follow procedure as described in the user guide under Cleaning and Disinfection.
- 5) Use only Cadwell recommended accessories with the Sierra Summit. Use of not recommended accessories can damage the system or render it unsafe. Use of accessories, transducers, and cables other than those specified by Cadwell could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Sierra Summit and result in improper operation.
- 6) Do not connect multiple patients to the Sierra Summit. Results will be incorrect if more than one patient is connected to a single system. System is designed to be used on one patient at a time.
- 7) Do not attempt to sterilize the equipment. The Sierra Summit system is not intended to be sterilized. Attempting sterilization may damage the system.
- 8) Do not connect stimulating devices to the patient while manipulating trigger in, trigger out. Unintended triggers may occur when connecting or disconnecting devices from the Trigger Out or Trigger In connectors.

- 9) Please dispose of equipment in accordance with the regulatory requirements of your country. Packaging materials may be re-used. For the EU, disposal has to take place in conformance with the WEEE directive (2012/91/EU)

Incident Reporting

Any serious incident that occurs in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Transport and Storage Limits

Transport and Storage Limits (ambient conditions)

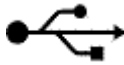
The Sierra Summit system should be stored in a clean, dry place. Handle the system with care.

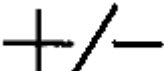
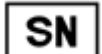
Temperature: Do not expose to temperatures below -20° C (-4° F) or above 65° C (149° F)

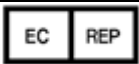
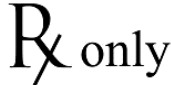
Relative Humidity: Do not expose to relative humidity below 10% or above 95% non-condensing

Atmospheric Pressure: 500 hPa to 1060 hPa

Symbols

Symbol	Title/Meaning	Reference
	Attention, consult accompanying documents.	IEC 348, ISO 15223-1:2021
	Attention, consult accompanying documents.	ISO 7010-M002
	Power ON	IEC 60417-5007
	Power OFF	IEC 60417-5008
	Push to power OFF, push again to power ON	IEC 60417-5010
	Equipotentiality	IEC 60417-5021
	Type BF equipment. Isolated patient connection.	IEC 60417-5333
	Output	IEC 60417-5035
	Input	IEC 60417-5034
	Audio transducer connection.	IEC 60417-5077, Cadwell convention
	LED Goggles connection.	Cadwell convention
	USB symbol	KEMA Medical, ISO 7000-3650

	Amplifier Symbol	Cadwell convention
	Negative polarity (inverting amplifier input)	IEC 60417-5006
	Positive polarity (non-inverting amplifier input)	IEC 60417-5005
	Isolated patient ground input.	Cadwell convention
	Temperature Probe	ISO 7000-0034
	Audible sound is heard when circuit is closed.	Cadwell convention
	Variability, for rotating movement. Turn clockwise to increase.	IEC 60417-1364
	Reverse Polarity	Cadwell convention
	Variability, rotate wheel to increase electrical stimulus intensity	IEC 60417-5004, Cadwell convention
	Reduction of Hazardous Substance Compliant	RoHS
	Listing Mark: EMG/EP equipment with respect to electric shock, fire, and mechanical hazards only in accordance with UL 2601-1 and CAN/CSA C22.2 No 601-1 (XXXXX)	Intertek
	Declaration of compliance with the provisions of Regulation 2017/45 concerning medical devices (applies only to equipment so marked and only in the countries stated on the declaration of conformity for the device). Notified Body Number (0344) DEKRA.	MDR
	Serial number, includes date of manufacture	ISO 15223-1:2021
	Catalogue number (part number)	ISO 15223-1:2021

	European Authorized Representative	ISO 15223-1:2021
	Waste Electrical and Electronic Equipment. Do not throw in standard garbage. Recycle or dispose of equipment according to regulatory requirements of your country.	WEEE
	Manufacturer	EU MD R, ISO 15223-1:2021
	For prescription use only.	Cadwell Convention
	Fragile Medical Equipment Do Not Drop	Cadwell Convention (Device Packaging)
	Humidity Range 10% to 95% Non-Condensing	ISO 7000- 0505, Cadwell Convention (Device Packaging)
	Indicates device is a medical device	EU MDR
	Indicates UDI label	ISO 15223-1:2021
	Swiss Authorized Representative	SwissMedic
	Indicates additional useful information or notes to the user	Cadwell Convention

	TabData	Cadwell Convention
	Favorite	Cadwell Convention
	View	Cadwell Convention

	Store	Cadwell Convention
	Reports	Cadwell Convention
	Delete	Cadwell Convention
	Volume indicator	Cadwell Convention
	Start/Stop data acquisition	Cadwell Convention
	Next	Cadwell Convention
	Average	Cadwell Convention
	Decrease pulse width	Cadwell Convention
	Increase pulse width	Cadwell Convention
	Dangerous voltage	IEC 60417-5036

Date of Manufacture

The year and date of manufacture, format YYYY-MM, can be derived from the device serial number found on the Summit base unit's device label as follows:

190272 | XX | XX | XX | XX | XXX
MM YY

For example, the following serial number equates to date of manufacture **2015-10** (YYYY-MM):

Sierra Summit Base



REF 190272-200

SN 19027201AA1015050

(01)00840067100035

(21)19027201AA1015050

CE
0344

Label 190272-822 rev 0

Electrical Stimulator Characteristics

The Sierra Summit includes one constant-current electrical stimulator, a second electrical stimulator can be added as an option. The output generated can be either monopolar or bipolar (biphasic).

The maximum outputs (which cannot occur simultaneously) are:

400 volts

100 mA

1000 microseconds pulse width

200 pulses per second

Maximum pulse energy with a load resistance of 1 kOhm is 50 mJ (millijoule) per pulse.

Continuous, fast repetition rates and high currents will cause the output voltage to droop as a safety measure, stabilizing at the smaller of the rated r.m.s. wattage or r.m.s. current.

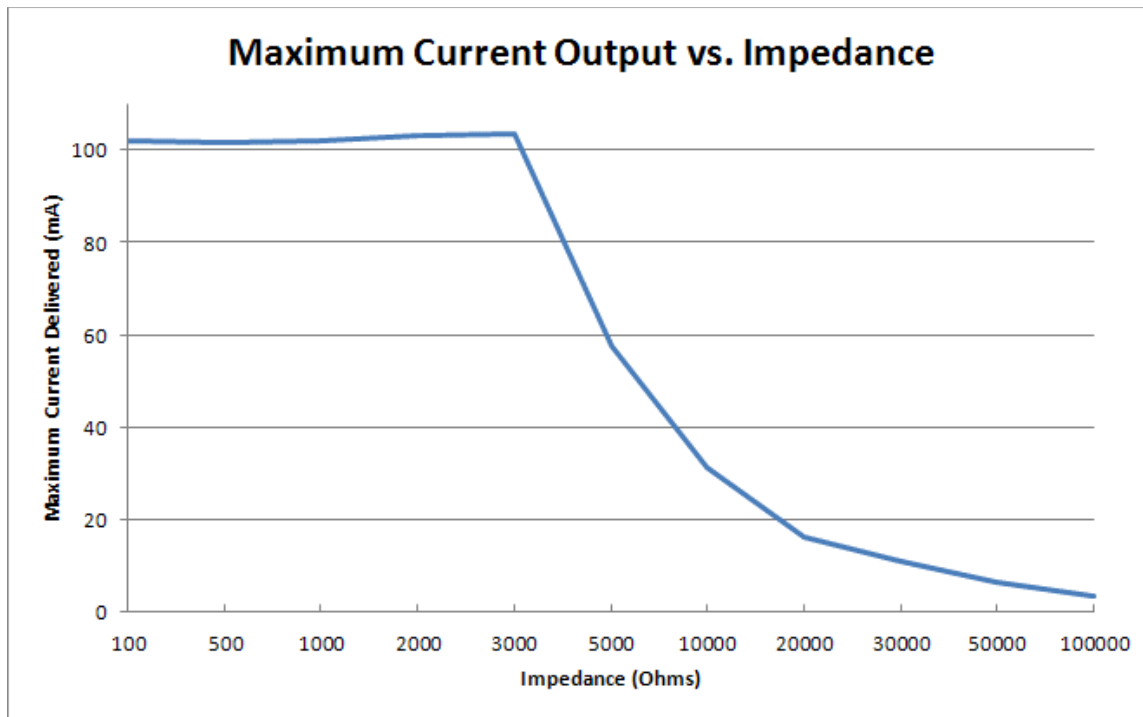
The stimulator contains fault detectors that monitor for current delivered when no stimulus is requested, for current that is higher than requested, and for other conditions. The fault detector will disable the high voltage, and/or clamp the outputs until reset.

The maximum deliverable current for a single stimulus is a function of electrode impedance, and is calculated as:

$$I \text{ (mA)} = 400 \text{ volts} / R \text{ (kOhms)}, \text{ or } R = 400 / I$$

Current	Maximum Resistance
10 mA	40 kOhm
20 mA	20 kOhm
50 mA	8 kOhm
100 mA	4 kOhm

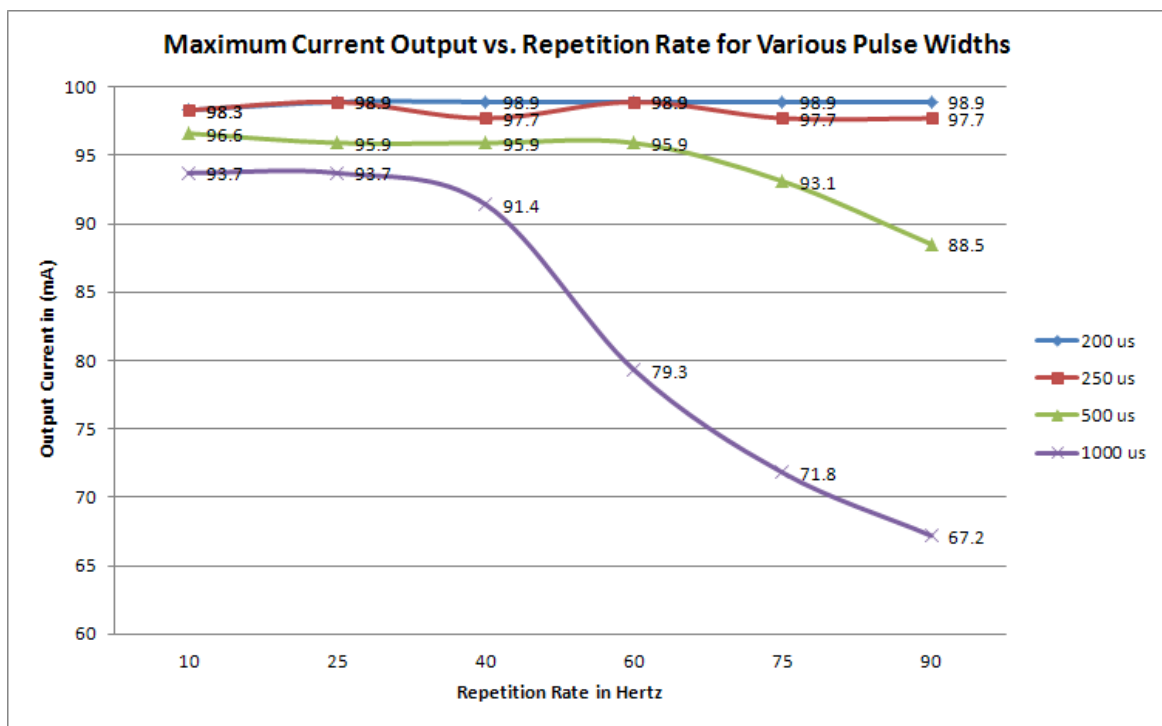
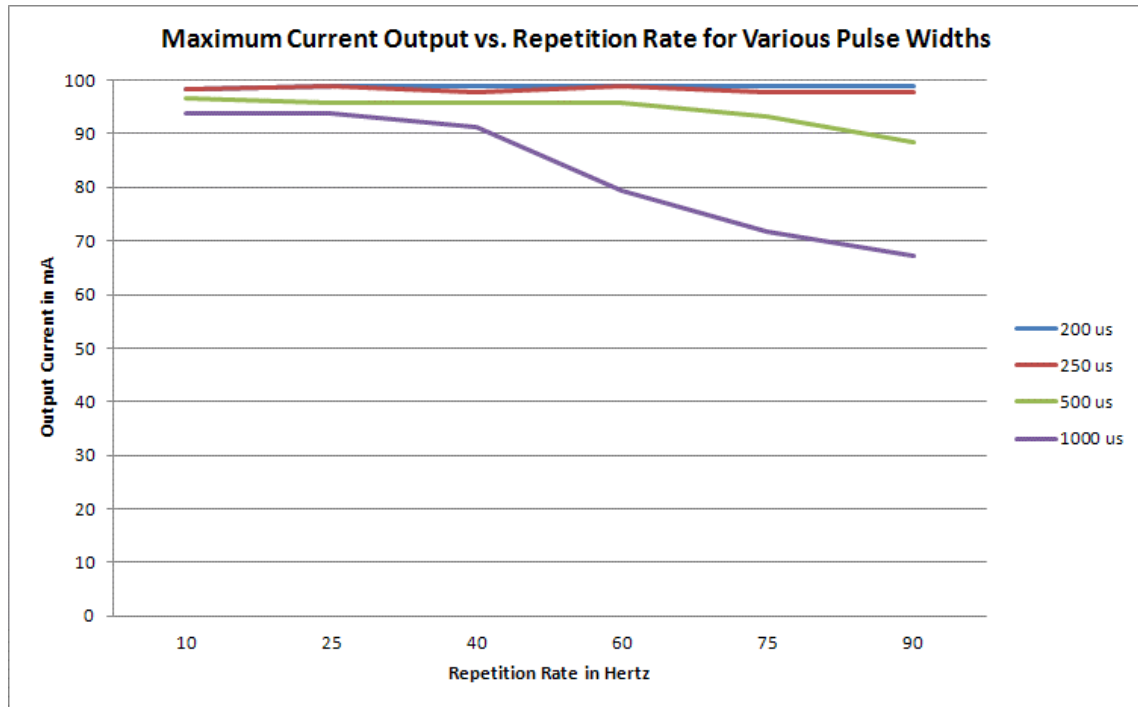
Electrode gel and/or abrasive skin preparation should be applied as needed.



If the specified current cannot be delivered, a “Z” symbol  appears on the screen for approximately 1 second each time the stimulator is fired.



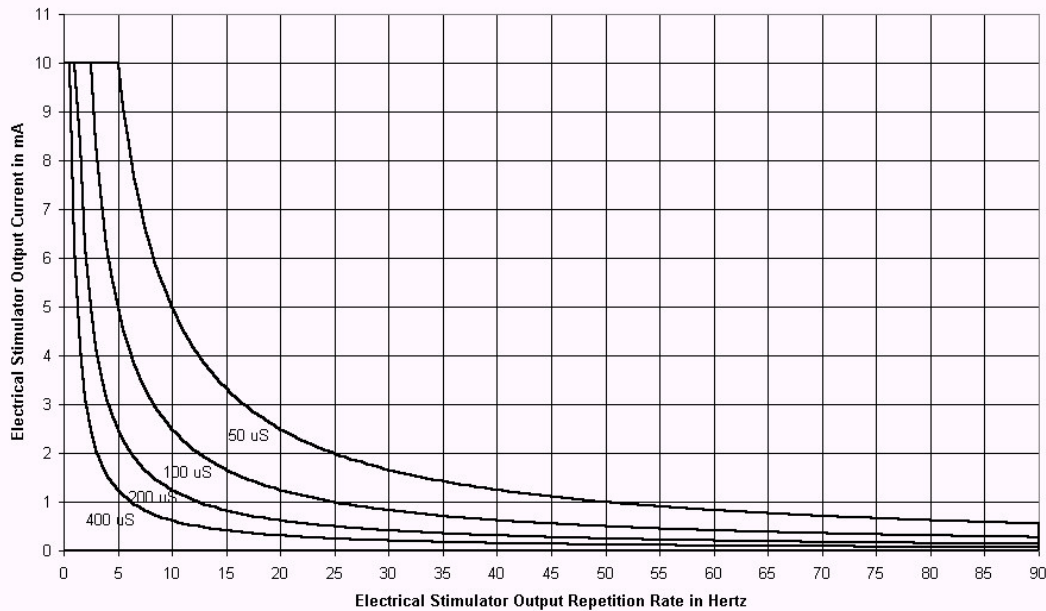
If more current is delivered than was requested, an "Over Current Error" message will be displayed and stimulation will be stopped.



Electrode Current Densities

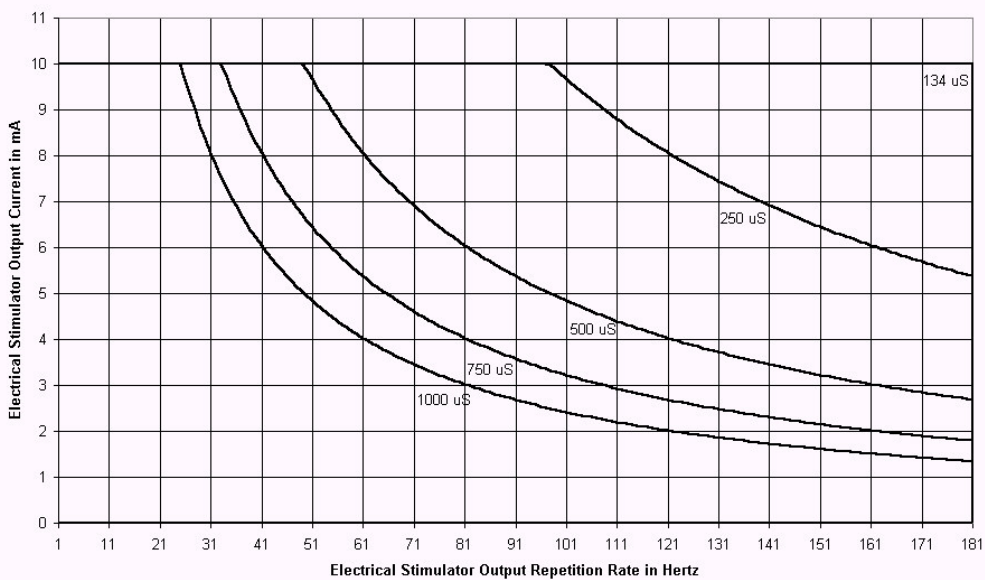
Current Density Graph for EMG Needle

2 mA r.m.s. / sq. cm Operating Area for Insulated 0.25 sq. mm EMG Needle Electrode
202221-000



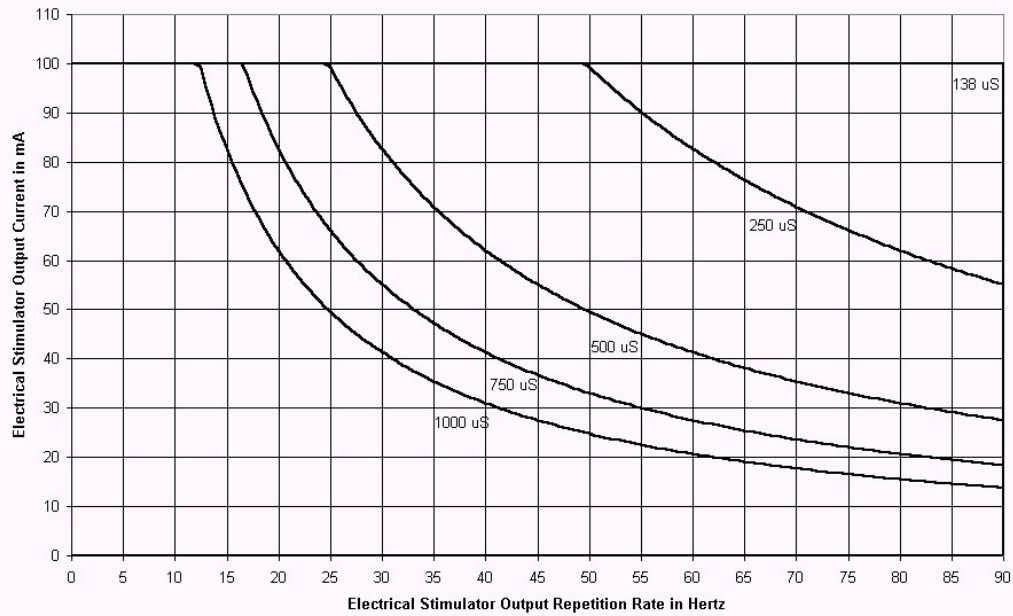
Current Density Graph for EEG Needle

2 mA r.m.s. / sq. cm Operating Area for Bare EEG Needle Electrode (302353-000-040)
at 6mm Insertion Depth



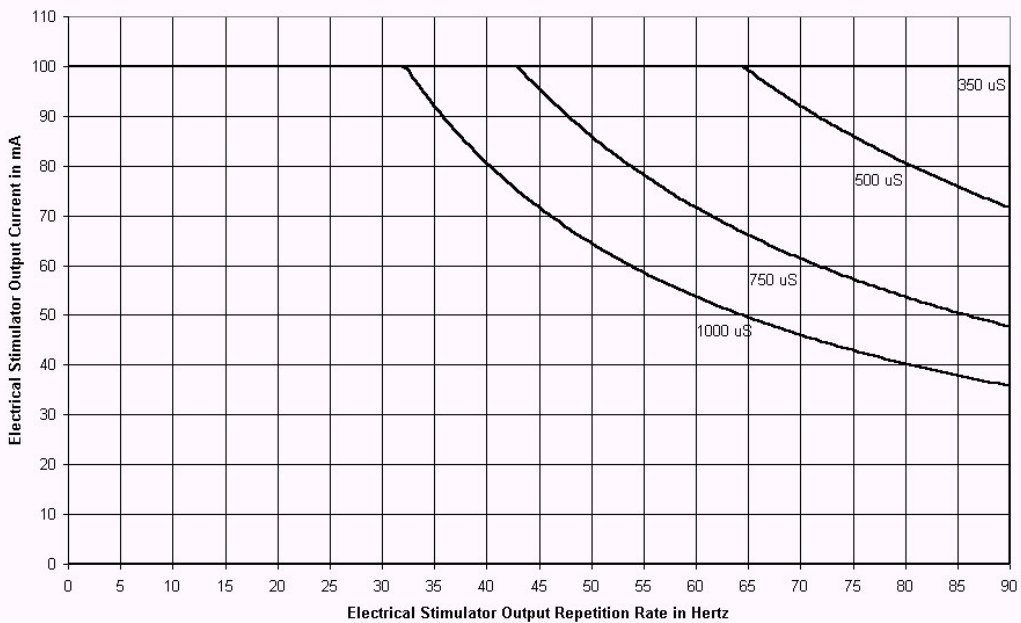
Current Density Graph for Bar Electrode

2 mA r.m.s. / sq. cm Operating Area for Bar Electrodes (302147-000 & 302247-000)



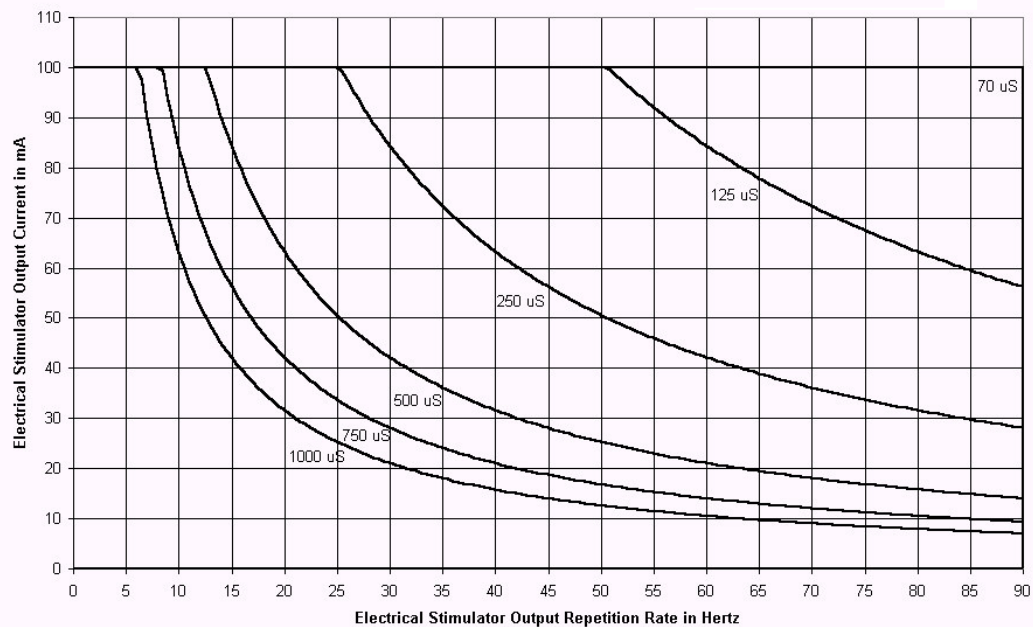
Current Density Graph for Disposable Bar Electrode

2 mA r.m.s. / sq. cm Operating Area for Disposable Bar Electrodes (302287-000)



Current Density Graph for Felt-Pad Bar Electrode

2 mA r.m.s. / sq. cm Operating Area for Felt-pad Bar Electrode (302089-200)



Recommended Stimulating Electrodes

The following Cadwell electrodes (or their equivalent) are recommended for use as stimulating electrodes:

- Cadwell Stainless Steel Electrical Stimulator Probes

- Straight, round head, 6.35 mm diameter. (339073-200)
- Straight, round head, 4.75 mm diameter. (339080-200)
- Straight, pointed tip. (339078-200)
- Felt pad tip. (339079-200)

- Stimulating Needle

- Monopolar EMG, 25 mm, 1.0 inch, 28 gauge. (202221-000)
- Subdermal EEG, 13 mm, 0.5 inch, 27 gauge. (302353-000-040)

- Bar Electrode

- Concave bar. (302247-200)
- Disposable bar (302287-000)
- Disposable felt pad. (302089-200)

- Ring Electrode

- Stainless steel. (302143-200)
- Disposable. (302286-000)

Maintenance

Visually inspect the instrument and its components for damage or wear. Contact Cadwell if you notice damage to the exterior of the instrument, accessories, or cables.

While the Sierra Summit EMG/EP system has been carefully designed and manufactured to be as reliable and durable as possible, regular inspection of the system components can help ensure the long-term trouble-free operation of the system.

Preventive Maintenance

To ensure that your instrument provides optimum performance, Cadwell recommends that you schedule annual preventive maintenance and system calibration.

Calibration

To verify system function & performance, Cadwell recommends that you periodically perform the Hardware Diagnostics Test Suite

Cadwell will inspect essential performance when the user's system is sent in for preventive maintenance.

Essential Performance

Sierra Summit system must deliver electrical stimulation as described in IEC 60601-2-40 without unintended stimulation. A 3.48 K Ohm load is used to verify the values given in the table below.

Stimulator Parameter	Selected Current I(ma)	Selected Pulse width PW (uS)	Allowed Current Range I(ma)	Allowed Pulse Width range PW(uS)
EStim Output Accuracy	100	1000	88 to 112	890 to 1110
	50	100	43 to 57	80 to 120
	25	100	20.5 to 29.5	80 to 120
	1	1000	-1.1 to 3.1	890 to 1110
	0	1000	-2 to 2	0

Stimulator Parameter	Selected Repetition Rate (Hz)	Allowed Repetition Rate Range (Hz)
EStim Output Rep Rate Accuracy	1	0.7 to 1.3
	10	7 to 13
	100	70 to 130

Specifications, Operating Environment & Limits

Please see the **Sierra Summit Specifications** document (P/N 190272-931), for system specifications, compliance standards, and operating and environmental limits.

Electromagnetic Compatibility

This medical electrical equipment needs special precautions regarding Electromagnetic Interference and needs to be installed and put into service according to the Electromagnetic Interference information provided below.

List of compatible cables and accessories.

Sierra Summit Base: 190272-200 Sierra Summit 2 Ch. Amplifier: 190276-200 Sierra Summit 12 Ch. Amplifier: 190280-200 Amplifier Cable: 199263-200 Sierra Summit Software: 369043-200 Y - Power Cord Adapter Cable: 286099-000 Hospital Grade Power Cord: 286002-000	Cadwell Headphones: 199312-200 Insert Earphones: 198235-000 Insert Cable: 199275-200 Bone Transducer: 199276-200 USB Footswitch: 291233-000 Sierra Summit Electrical Stimulator: 190274-200 Ring-Bar Switch Box: 190292-200 Skin Temp Probe: 202600-000 Reflex Hammer: 190282-200 VEP Calibration Sensor: 190283-200 LED Goggles: 199277-200 Isolation Transformer: 232060-000 Medical Grade Power Strip: 291228-000
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Use of accessories and cabling other than those specified in above, with the exception of those sold by Cadwell as replacement parts, may result in increased emissions or decreased immunity of Sierra Summit systems.

Sierra Summit Electromagnetic Disturbances Compliance Summary

Standard/Specification: IEC 60601-1-2:2014

Test Procedure	Description	Modifications	Results
IEC 60601-1-2 (CISPR 11), Class A	Conducted Emissions	NA	Pass
IEC 60601-1-2 (CISPR 11), Class A	Radiated Emissions	NA	Pass
IEC 61000-3-2 (2005) + A1+A2	Harmonic Emissions	NA	Pass
IEC 61000-3-3 (2013)	Voltage fluctuations and flicker	NA	Pass
IEC 61000-4-2 (2008)	Electrostatic Discharge	NA	Pass
IEC 61000-4-3 (2006) + A1+A2	Radiated RF EM Fields and Proximity Fields from wireless communications equipment	NA	Pass
IEC 61000-4-4 (2012)	Electrical Fast Transient Burst	NA	Pass
IEC 61000-4-5 (2005)	Surge	NA	Pass
IEC 61000-4-6 (2013)	Conducted Disturbances	NA	Pass

IEC 61000-4-8 (2009)	Rated power frequency magnetic fields	NA	Pass
IEC 61000-4-11 (2004)	Voltage dips and interrupts	NA	Pass

Table XX Electromagnetic Emissions

Guidance and manufacturer's declaration – Electromagnetic Emissions		
Summit system is intended for use in the electromagnetic environment specified below. The customer or the user of the Summit system should assure that it is used in such an environment.		
Emissions test – IEC 60601-1-2:2014	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Class A. Conducted and radiated emissions	The Summit system is suitable for use in all establishments, other than domestic, and those directly connected to the public low voltage power supply network. 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 Summit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Harmonic Emissions IEC 61000-3-3	Class A	The Summit system is suitable for use in all establishments, other than domestic, and those directly connected to the public low voltage power supply network.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	Cadwell declares the Summit does not produce voltage fluctuations or flicker emissions above the limit.

Sierra Summit should not be used adjacent to or stacked with any other equipment. If adjacent or stacked use is necessary, performance of the Sierra Summit should be observed to verify normal operation in the configuration in which it will be used.

Table XX Electromagnetic Interference

Guidance and manufacturer's declaration – Electromagnetic Interference		
The Summit system is intended for use in the electromagnetic environment specified below. The customer or the user of the Summit system should assure that it is used in such an environment.		
Interference Requirements – IEC 60601-1-2:2014	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	Electrostatic discharge at ANY level will produce noise glitches on the Summit display screen. These noise glitches are easily differentiated from biopotential input signals. ESD noise is unavoidable in high-static environments due to the high input sensitivity of the equipment. To minimize electrostatic effects, floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Large electrostatic discharge may trigger stimulator error dialogue box. A mouse click is required to reset the dialogue box. This is an intentional error message to ensure no possibility of ESD unintentionally triggering the stimulator.
Electrical fast transient/burst (EFTs) IEC 61000-4-4	±2 kV for power supply lines. ±1 kV for input/output lines	EFTs may cause events in the display waveforms. This is an unavoidable phenomenon due to the high input sensitivity of the equipment. These waveform disturbances can be differentiated from physiological events. To minimize these effects, mains power quality should be that of a typical of a professional healthcare environment.
Surge IEC 61000-4-5	±2 kV common mode	Surges may cause events in the display waveforms. This is an unavoidable phenomenon due to the high input sensitivity of the equipment. These waveform disturbances can be differentiated from physiological events. To minimize these effects, mains power quality should be that of a typical of a professional healthcare environment.
Magnetic Fields IEC 61000-4-8	50 A/m 50 Hz or 60 Hz	Mains power quality should be that of a typical professional health care environment.
Voltage dips, short interrupts on power supply input lines	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle	Mains power quality should be that of a typical professional health care environment. If the user requires continued operation during power mains

IEC 61000-4-11	And 70 % UT; 25/30 cycles Single phase: at 0°	interruptions, it is recommended that the Summit be powered from an uninterruptible power supply.
Conducted RF IEC 61000-4-6	3 V m) 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Cascade IOMAX, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
Immunity to RF wireless communications equipment, Table 9, IEC 60601-1-2:2014	All applicable limits from Table 9	Immunity to proximity fields from RF wireless communications equipment. Frequencies 385 MHz to 5,785 MHz.

Field strengths from fixed transmitters cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Summit is used exceeds the applicable RF compliance level above, the Summit performance should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Summit.

Electromagnetic Interference

Recommended separation distances between RF communications equipment and the Cadwell Sierra Summit			
Sierra Summit EMG/EP systems are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sierra Summit can help prevent electromagnetic interference by maintaining a minimum distance between RF communications equipment (transmitters) and the Sierra Summit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}] \sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	d = 0.12 m	d = 0.12 m	d = 0.23 m
0.1	d = 0.38 m	d = 0.38 m	d = 0.73 m
1.0	d = 1.2 m	d = 1.2 m	d = 2.3 m
10	d = 3.8 m	d = 3.8 m	d = 7.3 m
100	d = 12 m	d = 12 m	d = 23 m
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. NOTE 3 Stated separation distances will assure safe operation of the Sierra Summit. However, some noise may present on displayed waveforms.			

Device malfunction or changes in performance

If you suspect that the Sierra Summit is malfunctioning, or that there have been changes in performance that could affect patient safety, you should immediately discontinue use of the device and contact the Cadwell Service Department as soon as possible.

Cleaning and Disinfection

Recommendations:

Perform cleaning and disinfection procedures on a periodic basis to ensure the safe operation of your Sierra Summit system. As you clean, visually inspect the instrument and its components for damage or wear. Contact Cadwell if you notice damage to the exterior of the instrument. Do not attempt to service or repair damaged or inoperable equipment. If you suspect a problem, contact the Cadwell Service Department at 800-245-3001 or 509-735-6481.

While the Sierra Summit EMG/EP system has been carefully designed and manufactured to be as reliable and durable as possible, regular cleaning and inspection of the system components can help the long-term trouble free operation of the system. Do not use abrasive cleaners. Try to avoid extremes of physical stress such as dropping the unit or exposing it to extreme temperatures.

Cadwell recommends that you refer to the *AAMI Standards and Recommended Practices for Sterilization in Health Care Facilities*, or equivalent standard text for detailed disinfection instructions. These standards may be ordered by calling the Association for Advancement of Medical Instrumentation at (703) 525-4890. www.aami.org



Turn off and disconnect all Sierra components before cleaning. Do not attempt to service or repair damaged or inoperable equipment.

Summit Base Unit and Amplifier:

Use a soft cloth to wipe away any dust that has collected on the instrument casing. You can dampen the cloth slightly in a mild soap-and-water solution.

A soft brush or pressurized air duster can also be used to remove dust from hard-to-access areas such as the custom keyboard, alphanumeric keyboard, and between connectors on the rear panel.

Certain cleaning or disinfecting agents may have a degrading effect on your equipment. Consult your facility's infection control policies in selecting the appropriate disinfection products. Non-corrosive disinfecting agents are preferred.

The Summit Base Unit and Amplifier may be disinfected with an intermediate-level surface disinfectant, but certain cleaning agents may have a degrading effect on your equipment. The following list indicates cleaning products the manufacturer of the plastic recommends in order to not cause harm to the plastic enclosure:

- Clinell Universal Wipes
- Clorox Bleach (1:10 in water)
- Clorox Healthcare Bleach Wipes
- Clorox Healthcare Hydrogen Peroxide Wipes
- Hand Soap
- Hydrogen Peroxide (3%)
- Isopropanol 70%

- Lysol Infection Control Quaternary Cleaner (working concentration)
- Sani-Cloth Bleach
- Seventh Generation Disinfecting Wipes
- Sporidicin
- Super Sani-Cloth
- Vesphene (working concentration)
- Virex II 256 (working concentration)
- Windex (blue)

Use of the following cleaner/disinfectants **may cause degradation of the plastic housing.**

- Activated Hydrogen Peroxide (AHP)
- Acetone
- Clorox Disinfecting Wipes (lemon)
- CaviCide
- Envirocide
- Lysol Disinfecting Wipes
- Micro-Kill One Germicidal Wipes
- Opti-Cide Healthcare Wipes
- Oxivir TB
- Sani-Cloth HB
- Sani-Cloth Plus
- CaviWipes
- Formula 409 Cleaner Degreaser
- Sani-Cloth AF3
- Virex TB



Follow product specific disinfectant instructions found on labels.



Turn off the base unit and disconnect the AC power before cleaning. Disconnect all peripheral components before cleaning. Keep all cleaning fluids away from electrical connectors. Do not let solutions seep inside the base unit or amplifier. Do not use abrasive cleansers.



Gloves should be worn when using environmental disinfectants.



Avoid letting liquid seep into any of the internal electronics.

Stimulators:

Visually inspect the stimulator for unusual wear or damage prior to each use. If you notice damage, disconnect the stimulator immediately and contact Cadwell.

Use a soft cloth to clean stimulator parts that come in contact with the patient after each use (e.g., electrical stimulator probes, auditory headphones, insert earphones, bone transducer, and LED Goggles). Properly dispose of the foam tips used with the insert earphones after each use. You can dampen the cloth slightly in a mild soap-and-water solution.

Single use, disposable hypoallergenic headphone earpiece covers are available from Cadwell, part number 096001-000 (box of 100). These covers have a weave design and give full sound quality, comfort and protection. These are perfect for headphones that are used in shared environments.

In cases requiring the full sterilization regimen, the electrical stimulator probes (removed from the stimulator) can be steam autoclaved at 250 °F (121 °C) and 15 psi for 15 minutes, or the standard recommended temperature, pressure, and time for rubber products.

Certain cleaning or disinfecting agents may have a degrading effect on your equipment. Consult your facility's infection control policies in selecting the appropriate disinfection products. Non-corrosive disinfecting agents are preferred.

The Summit Stimulator may be disinfected with an intermediate-level surface disinfectant, but certain cleaning agents may have a degrading effect on your equipment. The following list indicates cleaning products the manufacturer of the plastic recommends in order to not cause harm to the plastic enclosure:

- Clinell Universal Wipes
- Clorox Bleach (1:10 in water)
- Clorox Healthcare Bleach Wipes
- Clorox Healthcare Hydrogen Peroxide Wipes
- Hand Soap
- Hydrogen Peroxide (3%)
- Isopropanol 70%
- Lysol Infection Control Quaternary Cleaner (working concentration)
- Sani-Cloth Bleach
- Seventh Generation Disinfecting Wipes
- Sporidicin
- Super Sani-Cloth
- Vesphene (working concentration)
- Virex II 256 (working concentration)
- Windex (blue)

Use of the following cleaner/disinfectants **may cause degradation of the plastic housing.**

- Activated Hydrogen Peroxide (AHP)
- Acetone
- Clorox Disinfecting Wipes (lemon)
- CaviCide
- Envirocide
- Lysol Disinfecting Wipes
- Micro-Kill One Germicidal Wipes
- Opti-Cide Healthcare Wipes
- Oxivir TB
- Sani-Cloth HB
- Sani-Cloth Plus

- CaviWipes
- Formula 409 Cleaner Degreaser
- Sani-Cloth AF3
- Virex TB



Follow product specific disinfectant instructions found on labels.



Turn off and disconnect stimulators before cleaning. Keep all cleaning fluids away from electrical connectors. Do not let solutions seep inside the stimulators. Do not use abrasive cleansers.



Gloves should be worn when using environmental disinfectants.

Interface Cables, Power Cords, and Accessories:

Visually inspect the interface cables and power cords that are used with components, stimulators, and accessories. If you notice unusual wear or breakage, disconnect the cable or cord immediately and contact Cadwell.

Use a soft cloth to clean interface cables and power cords. You can dampen the cloth slightly in a mild soap-and-water solution. Isopropyl Alcohol may also be used to clean cables. Follow product specific cleaning instructions from the manufacturer of your accessories.



Gloves should be worn when using environmental disinfectants.

Monitor:

To clean dust from monitor's screen, wipe it with a soft cloth or cloth dampened with a non-ammoniated glass cleaner.

Recording Electrodes:

General Electrode Care

The quality of signal acquisition is affected by the condition of your recording electrodes. Routine inspection, careful handling, frequent cleaning, and proper storage are essential practices for properly maintaining them.

For any electrodes not manufactured by Cadwell, follow the manufacturers recommended cleaning procedure first.

For any electrodes manufactured by Cadwell, follow the cleaning instructions sent with the electrodes.

The following maintenance procedures apply to nonspecialized electrodes:

- Electrode preparation and application should be supervised by a qualified healthcare professional.
- Inspect electrodes for wear, breaks, corrosion, debris, or damage prior to use. If electrode wire, termination, or surface area is worn, discard the electrode.
- Handle electrodes carefully, and do not pull on the leads.
- Clean electrodes in warm water, using a toothbrush to scrub the surface of the electrode. If necessary, soak electrodes to loosen debris. (Using a file or steel wool to scrub electrodes may lead to contamination of electrode metal. This can result in signal artifact.)
- For proper sterilization techniques refer to the electrode manufacturer's instructions.
- If necessary, dry electrodes thoroughly to prevent corrosion from hard water deposits.
- Store electrodes in a clean, dry place.
- Do not tangle or kink electrode leads.
- Properly discard disposable electrodes after each use (e.g., disposable needle electrodes and disposable surface electrodes).
- Cadwell is not responsible for injury, infection, or other damage resulting from improper storage, preparation, use, or disposal of electrodes.



Specialized electrodes are often more complex and require special care. Anyone using them should consult the manufacturer for proper maintenance and handling techniques.

Disposal

Disposal of Equipment

Disposal of medical electrical and electronic equipment waste is regulated by many nations, states and facilities.

The **~~crossed-out wheeled bin~~** on the label indicates that the device can be recycled at the discretion of the user or must be recycled under EU law.



Prior to disposing of / recycling electrical and electronic waste, please consider or perform per the applicable regulations:

1. Disinfect / sanitize the equipment to remove any bio-hazards;
2. Sanitize (remove) the Personal Health Information (PHI) present on electronic media through
 - Clearing (using software or hardware products to overwrite media with non-sensitive data),
 - Purging (degaussing or exposing the media to a strong magnetic field in order to disrupt the recorded magnetic domains), or
 - Destroying the media (disintegration, pulverization, melting, incinerating, or shredding).

Further guidance: NIST Special Publication 800-88 Guidelines for Media Sanitization, section 4 Information Sanitization and Disposition Decision Making (available free of charge from <http://dx.doi.org/10.6028/NIST.SP.800-88r1>).

For the EU, disposal must be in conformance with the WEEE directive (2012/91/EU).

Refer to your Cadwell service representative for recommended instructions and addresses for proper return or disposal of electronic wastes relating to Cadwell Brand products.

Customer Support

Domestic customers:

Telephone: 1-800-245-3001

Telephone: 1-509-735-6481

Fax: +1 -509-783-6503

Email: applications@cadwell.com, support@cadwell.com

Web: <https://www.cadwell.com>, <https://cadwell.support>

Monday - Friday, Pacific Standard Time (PST)

Service Support: 6:30 a.m. – 5:00 p.m.

For service-related issues, phone support is provided free of charge for the life of your instrument.

Application Support: 6:30 a.m. – 5:00 p.m.

Call Application Support if you experience difficulty after troubleshooting a problem.

International customers:

Please contact your distributor or email Cadwell at International@cadwell.com

Remote Assistance:

Remote assistance and troubleshooting is available for systems under warranty or service contract. With your permission, a support technician can establish a secure connection to your Cadwell instrument via the internet.

Please call the service department or application support department. A support or service technician will verify your account information and guide you through the steps to begin a remote assistance session.

Cadwell Address

Cadwell Industries, Inc.

909 North Kellogg Street

Kennewick, Washington USA 99336

www.cadwell.com

Warranty Information

New equipment is covered by a 1-year warranty; refurbished equipment is covered by a 6-month warranty.

For equipment warranty details and extended service package information, please see Cadwell's Terms of Service at www.cadwell.com/terms.

Electrode Catalog and eStore

Cadwell has an online electrodes catalog and an eStore to offer competitive pricing, incredible customer service, same day shipping (for orders placed before 2pm Pacific), and the online e-store for a 24/7 shopping convenience.

Go to www.estore.cadwell.com

Representatives are also available to take your order at +1 800-245-3001

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EU Importer contact information:

Cadwell Europe GmbH

Maximilianstr. 54

80538 Munich, DE

International.Support@cadwell.com

- Swiss Authorized Representative contact information:



Axontronic
Chemin de Beree 16B
CH 1010 Lausanne
Switzerland

- Swiss Importer contact information:

Axontronic

Chemin de Beree 16B

CH 1010 Lausanne

Switzerland

info@axontronic.ch

- UK Responsible Person contact information:

UKCApartner4U

7 Campion Way

Bingham, Nottingham NG13 8TR

United Kingdom

office@ukcapartner4u.co.uk

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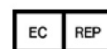


Cadwell Industries, Inc. is an American, family-owned neurophysiology diagnostic and monitoring solutions provider founded in 1979 by brothers John and Carl Cadwell. We engineer innovative and easy-to-use solutions that efficiently improve patient outcomes.

Our core competencies are full-spectrum EEG; Electrodiagnostic solutions for EMG, NCS, and EP with fully integrated Ultrasound; IONM; Sleep Diagnostics including in-lab PSG and HSAT; and a full suite of essential electrodes and accessories. We combine customer insight with decades of employee expertise to create cutting-edge technology and provide market-leading customer support.



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