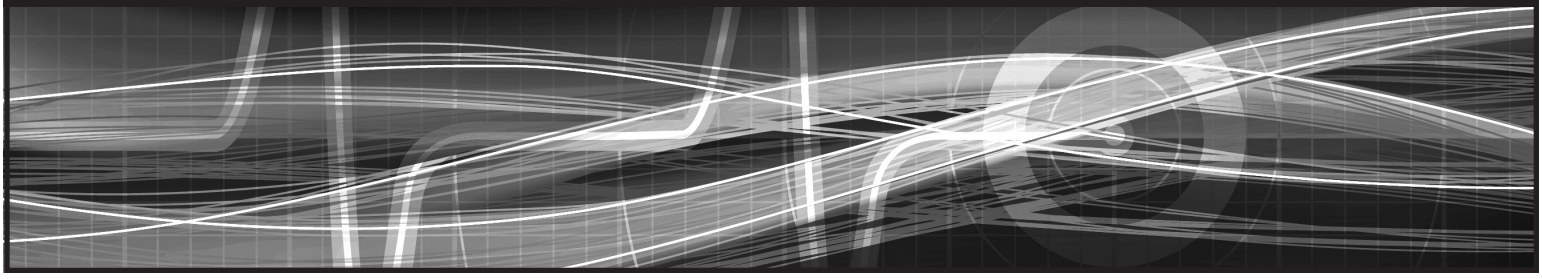
Cadwell® Cascade® PRO Setup Guide

CASCADE® PRO

This quick reference guide is intended to help with the installation and operation of your new Cascade Pro. More detailed operating instructions are provided in the *On-Line Help* that is accessible once you have completed the initial Setup and Startup steps in this guide.

STOP HERE! PLEASE READ THIS ENTIRE GUIDE BEFORE PROCEEDING!

PN# 100822-933 Rev. 2



Cascade Pro Setup Guide

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 Cascade Pro system. It does not provide clinical training. It is assumed that the user has adequate clinical training to perform intraoperative neuromonitoring 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.

Cadwell does not accept any liability for the use or misuse, direct or indirect, of this product. Users must accept all responsibility for any results obtained by or concluded from data obtained by the products. The user must accept all responsibility for results obtained by software from Cadwell.

Trademark Notices
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Cadwell reserves the right to modify, delete, extend, or improve features described herein without notice.

Table of Contents

Intent of Setup Guide

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

- Cadwell Cascade Pro Operator's Manual. Part number 100821-620
- Cadwell Cascade Pro Help File. Part number 369028-620. Available with installed Cascade application and at www.cadwell.com
- Cadwell Cascade Technical Manual. Part number 100820-621
- Cadwell ES-IX Stimulator Setup Guide. Part number 190262-933
- Configuring Cascade on Windows 7. Part number 369028-626
- Cadwell Cascade Installation Instructions. Part number 369028-934
- Cadwell website. www.Cadwell.com
- Cadwell Applications & Service Support. See Cascade Customer Support.

Overview

The Cascade® Pro is designed for intraoperative neuromonitoring (IONM) of evoked potential (EP), transcranial electrical motor evoked potential (TceMEP), electromyography (EMG), and electroencephalogram (EEG) signals.

Intraoperative neuromonitoring is a means of reducing the risk of permanent injury to neural structures during surgical procedures. Changes or abnormalities in the recorded signals may indicate that the surgical procedure is affecting the neural structure.

The Cascade Pro Intraoperative Monitor measures and displays the electrical signals generated by muscles, the central nervous system and peripheral nerves. It acquires the data necessary to perform intraoperative monitoring of neural pathways to prevent damage to neural structures during surgical procedures.

The Cascade Pro product, in its standard configuration, consists of a base unit, one or two 16-channel external amplifiers, and ES-IX stimulator(s). Software in the unit allows users to create different procedure setup files for various kinds of surgical cases.

Cascade Pro Intended Use

The Cascade Pro is an electroneurodiagnostic device designed to measure and display the electrical signals generated by muscle, peripheral nerves and the central nervous system. It will acquire the data necessary for electroencephalography (EEG), transcranial electrical motor evoked potential (TceMEP), electromyography (EMG), nerve conduction velocity (NCV, F wave, and H reflex), evoked potentials (EP, brainstem auditory, visual, somatosensory), and Train of Four (TOF).

Use of the Cascade Pro is to be administered under the direction of a trained physician, surgeon, neurologist, or electrophysiologist in an operating room or clinic.

Setup Instructions

Unpacking the System

Congratulations on selecting the Cadwell Cascade® Pro Intraoperative Monitoring system! It's time to unpack the contents of your system. As you unpack, please carefully check to make sure the contents of the shipping box match the packing slip.

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

You should receive the following as standard items:

- Cascade Pro base unit with detachable power cord
- Cascade Pro external power supply and removable power cord
- Backup Cascade installation software CD
- Two (2) or Four (4), 16-input amplifier extender cables
- If ordered, Laptop or Desktop computer (with built-in Ethernet connection) with AC adapter and/or AC Power Cord

If you purchased your computer from Cadwell, all necessary Windows® and Cascade® software is already installed on your computer from the Cadwell factory and the network card is configured for use. There is no need for you to install any software. Please put the CDs that came with your system in a safe place. They are included as a back-up copy only. Laptop computers may require you to make your own backup CDs for the computer.

NOTE: If you purchased your computer form a source other than Cadwell, you must install software, activate the software licenses, and configure the network card. Please refer to the Software Setup section of the help file or Operator's Manual.

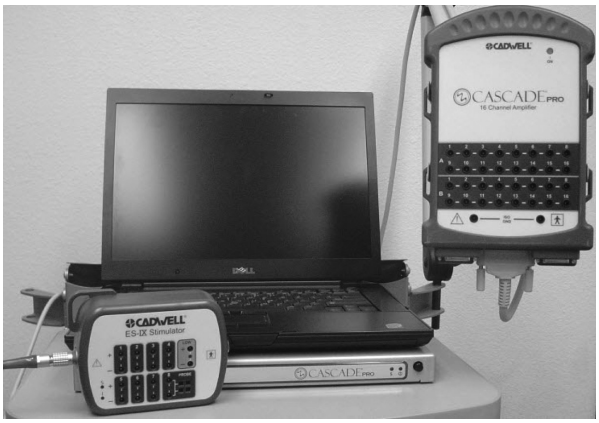
Please check for any optional items you may have ordered. These may include but are not limited to the following:

- ES-IX electrical stimulator
- TCS-1/TCS-1000 Single Output Constant Voltage Transcranial Stimulator
- TCS-4 Multiple Output Constant Voltage Transcranial Stimulator
- Other EP stimulation devices such as insert earphones and goggles.
- ES Detector Module with ES Detector clip(s)
- 2nd Ethernet Card (Desktop) or PCMCIA Ethernet Card (Laptop) with Network cable
- Instrument cart with instructions, grounding cable and screw, and any accessories such as a retractable arm or printer tray
- Printer with cables and instructions
- External keyboard
- External mouse

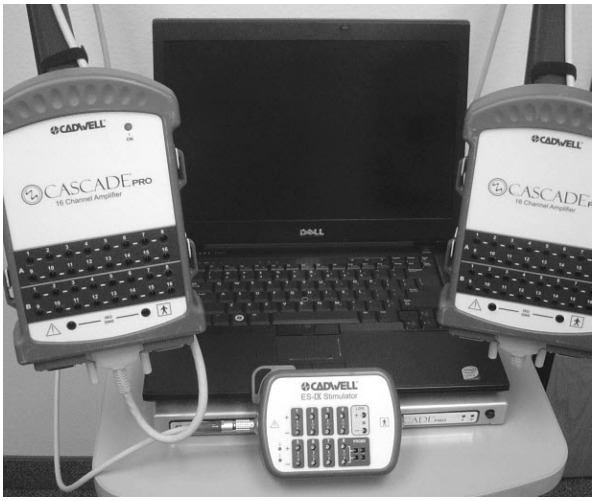
Configure Pro Base Unit

The Cascade Pro supports a variety of configurations to fit your monitoring needs.

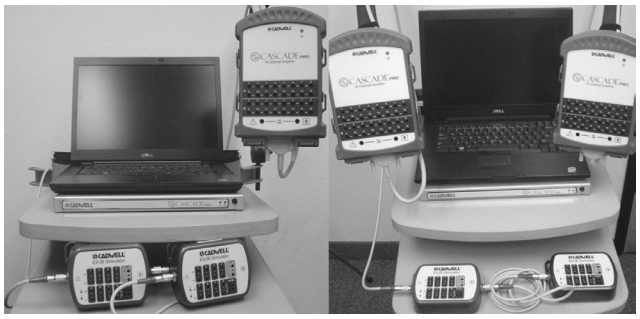
Cascade Pro Laptop system with a single amplifier:



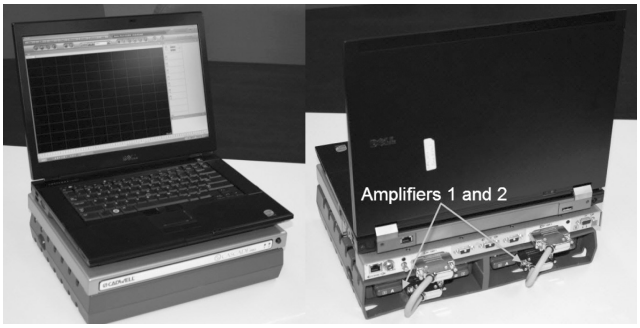
Cascade Pro laptop system with two amplifiers:

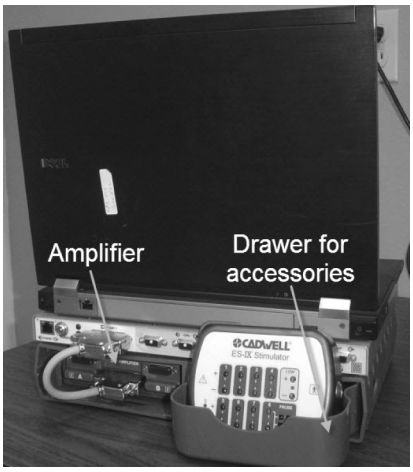


The ES-IX can also be daisy-chained to double your stimulation channels:

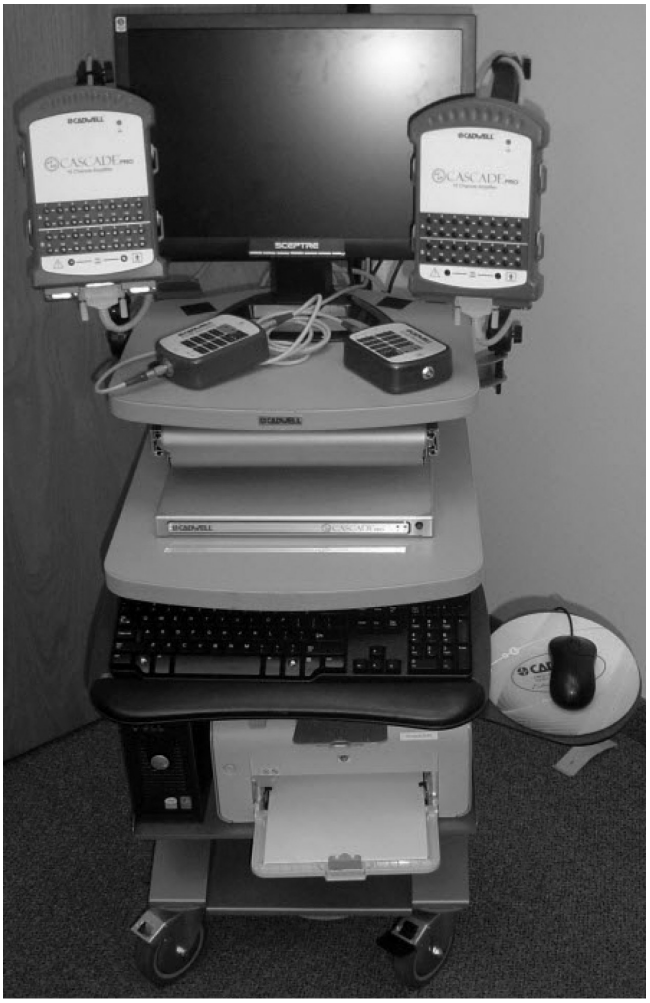


Cascade Pro amplifiers can be mounted on a retractable arm (above), near the bed, or in the Pro amplifier bay (below, top right). Any of these configurations include the option of either one or two amplifiers:





The Cascade PRO also performs extremely well on a trolley cart:

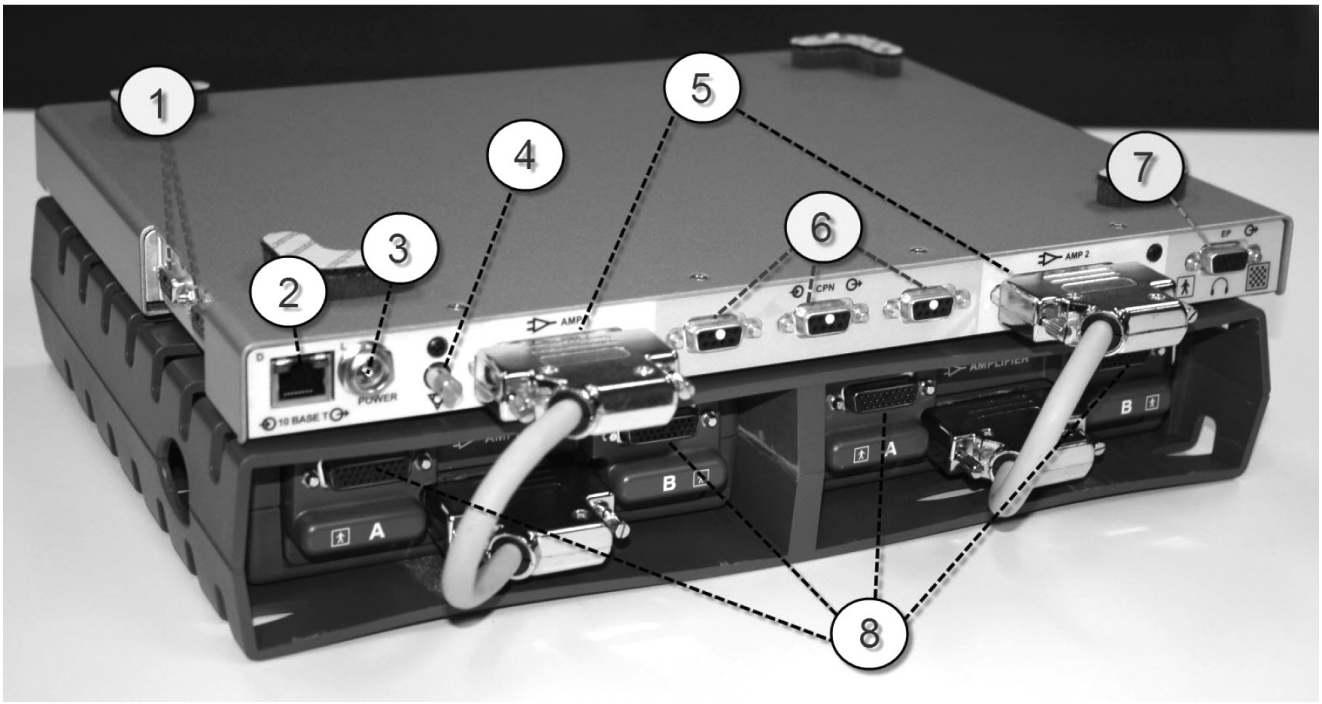


Pro Base Unit Connections

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

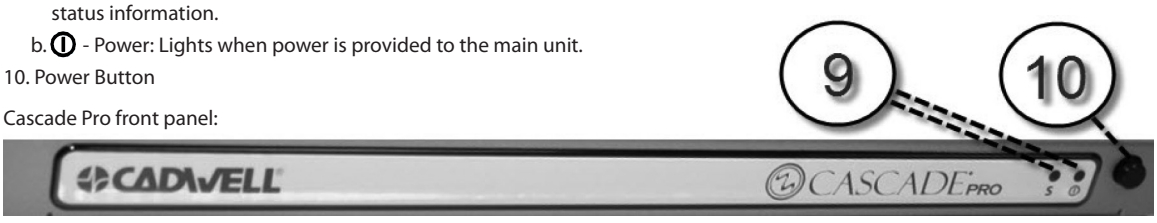
1. High Voltage Stimulators, ESD Detector or LED Goggles/Pad (AUX 1 and 2)
2. 10baseT, (Connection to PC). When powered on, LED lights on the connector panel will indicate system status:
   a. D - Data: Flashes when there is communication between the main unit and the computer.
   b. L - Link: Lights when there is a connection established between the main unit and the computer.
3. Power supply input (Connection to external power supply)
4. Grounding Post (to PC and Trolley Cart)
5. Amplifier Inputs (Amps 1 and 2)
6. CPN inputs (ES-IX stimulator)
7. Evoked Potential Stimulators (EP)
8. Amplifier Input Extender Cable Jacks (Connections A & B on both Amps 1 & 2)

Cascade Pro rear panel:



9. Status and Power Indicator Lights
   a. **S** - Status: Flashes in various patterns to indicate operation and status information.
   b. ⏻ - Power: Lights when power is provided to the main unit.
10. Power Button

Cascade Pro front panel:



The connectors on the Cascade PRO come standard with 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.

Peripheral Devices and Connections

It is important to attach stimulators and other peripheral devices to the correct connector on the Cascade .

Peripheral Device	Connector	Symbol
Amplifier Input Extender Cable Records amplifier input.	Amp A-D	
ES-IX Stimulator	CPN	"CPN"
TCS-1/TCS-1000/TCS-4 Transcranial-electrical motor cortex stimulator is an FDA-approved high-voltage electrical stimulator.	Aux 1 or 2	"AUX 1", "AUX 2"
Audio and Visual Peripherals Headphones, inserts and the pattern reversal monitor are audio and visual stimulators that must be connected to the EP cable port.	EP	
ES Detector Module The electro-surgery (ES) detector mutes EMG audio and pauses EP modes when electro-surgical devices are being used.	Aux 1 or 2	"AUX 1", "AUX 2"
VEP Goggles/LED Pad The Visual Evoke Potential (VEP) goggles are visual stimulators used during surgery.	Aux 1 or 2	"AUX 1", "AUX 2"
CV-2 This electrical cortical stimulator can be set to output two (2) 400-volt stimulations.	Aux 1 or 2	"AUX 1", "AUX 2"

Configuration of Non-Cadwell supplied computers

For computers not purchased through Cadwell, you will need to configure Windows 7 and the Ethernet network card prior to installing the Cascade application software.

Follow the instructions in document 369028-626 Configuring Windows 7 for Cascade.pdf. This document can be found on the installation CD, Files, then Documents folder.

Installing Cascade application software on Non-Cadwell supplied computers

Prior to installing the Cascade application software, you should have completed the configuration process described in the previous section.

Follow the installation instructions (part number 369028-934) that shipped with the Cascade software disc. If you do not have these instructions they can be found on the IONM support page of the Cadwell website (www.cadwell.com).

Minimum Computer Requirements

US & Canada regulatory requirements:
Computer and information technology equipment connected to the console must be third party certified to UL1950 or IEC950.

European Union regulatory requirements:
Computer and information technology equipment connected to the console must be third party certified to EN60950.

Performance requirements:
Refer to Cadwell document 308014-000 for minimum computer performance requirements to run this device.

Getting Started

Turning Equipment On and Off

Do not turn the instrument base on or off while a patient is connected.
To turn the equipment on:

1. Connect the power/com module, amplifier input extender cables, stimulators, and accessories (if not already connected).
2. Turn equipment on in the following order:
   - Instrument base unit
   - Computer
   - Monitor (desktop units only)
   - Printer (if connected)

NOTE: If you are using the isolation transformer, you only need to turn on the isolation transformer power switch.

To turn the equipment off:

1. Close all programs that are running on the computer.
2. On the Windows taskbar, click Start, Shut Down, select the Shut down option, and click OK.
3. Turn off equipment in the following order:
   - Instrument base unit
   - Computer
   - Monitor (desktop units only)
   - Printer

NOTE: If you are using the isolation transformer, turn off only the cart power switch. The monitor, printer, and isolation transformer power switches can remain on. The next time you start the system, turn on only the cart power switch.

NOTE: You do not need to disconnect the power/com, amplifier input extender cables, stimulators, or accessories. You may leave them connected.

Opening and Closing Cascade Software

To open Cascade Pro:

- Double-click the Cascade icon on the Windows desktop, or
- On the Windows taskbar, click Start, Programs, Cadwell, and then Cascade.

To close Cascade Pro:

When you close a patient file or exit from Cascade while in a patient file, all data is automatically saved to the patient's file.

- To close a patient file without exiting from Cascade: From the File menu, click Close Procedure.
- To exit from Cascade: From the File menu, click Exit. You can also click the Red 'X' in the upper right corner. Click Yes to close the Cascade software.

Setup Verification

Follow the instructions in the setup verification procedure (part #: 100820-935) that was shipped with the Cascade Pro system.

Safety Information
General Warnings and Precautions


U.S. Federal law restricts the use of this system by, or under the supervision of, a physician.


This unit is not waterproof. Do not immerse the base unit, power/communications module, stimulus splitters, VEP goggles, auditory stimulators, flash stimulator, system cables, or any other system components in liquid.


Do not try to service unit. Service is to be done by Cadwell and other authorized bodies only.


Adhere to the unit cleaning instructions. Always disconnect equipment from power source and patient before cleaning.


Connection of patient to high frequency electrosurgical equipment and electroneurodiagnostic equipment simultaneously may result in burns at the site of the electrical stimulator and/or amplifier electrodes, and possible damage to the electrical stimulator and/or amplifier.


Inspect cables before and after each use. Discard and replace cable if insulation is damaged or if the cable or connectors are damaged in any manner.


The operator must be trained to be able to recognize the difference between signal artifacts and valid biosignals caused by movements, interference, or misplacement of sensors or electrodes.


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 Cascade system, contact Cadwell.


The manual provides an operational summary for the Cascade system. It does not provide clinical training. The user must have adequate clinical training to perform procedures.


Place system components where they are safe from contact with spilled fluids.


Wrapping or covering the base unit may cause excessive heat buildup leading to amplifier failure.


Patient movement may occur during stimulation leading to inadvertent neural injury. Take adequate steps to avoid stimulation when patient movement could cause injury.


When delivering stimulation that may cause jaw movement, use bite blocks to minimize the risk of tongue-biting injuries and mandibular fracture. Routinely check bite blocks for displacement.


The system is not designed to operate in an explosive environment or in the presence of flammable anesthetics.


The system is designed to be used on one patient at a time. Do not connect multiple patients to one amplifier.


Avoid accidental contact between electrodes connected to patient and other conductive parts, including earth ground.


Avoid accidental contact between unapplied electrodes connected to the amplifier and other conductive parts, including earth ground.


Review TCS amplitude-pulse train safety chart prior to performing TCeMEPs.


Keep anode and cathode stimulating sites in close proximity.


The Cascade Pro amplifier inputs are Type BF rated. Cadwell ensures that no current higher than 50uA flows to or from the applied part if mains voltage is inadvertently connected to the patient.


Transcranial cortical stimulation may not be appropriate for use on patients with a history of skull fracture or neurosurgical procedures to the head. Skull defects could provide high local current densities.


Cortical stimulation may induce seizures and memory problems in those with a history of epilepsy and other disorders with predisposition to seizures (e.g. alcoholism). Ensure that necessary medical precautions are taken in case of such an episode.


Cortical stimulation may induce seizures and memory problems in those with a history of epilepsy and other disorders with predisposition to seizures (e.g. alcoholism). Ensure that necessary medical precautions are taken in case of such an episode.


Display EEG data during cortical stimulation such that seizure activity can be easily detected.


Otherwise unexplained intraoperative seizure and/or arrhythmia are indications to abort transcranial or direct cortical stimulation.


The safety of pulse train frequencies below 250 Hz (interstimulus interval above 4Hz) for cortical stimulation has not been studied in clinical literature.


Operation in close proximity to short wave or microwave therapy equipment may produce instability in the electrical stimulator output.


This system is not MRI compatible.


The system is not defibrillator proof.


The Cadwell flash stimulator must be at least 12 inches (30 cm) away from the patient's eyes. If used on an anesthetized patient a means should be provided to ensure that the eye lids remain closed.


The use of the Cadwell flash stimulator may induce seizures in epileptics or people prone to epilepsy. Persons who are photosensitive to light may have convulsions, seizures, or a myoclonic reaction to the photic stimulator. The operator must be trained to recognize EEG waveforms and patient symptoms that are consistent with a patient's reaction to photic stimulation. The operator must follow laboratory medical policies and procedures when using the flash stimulator to care for the patient undergoing photic stimulation.


When attaching the Cascade Pro system to a recording subject, verify that the subject will not become entangled in the wires. Do not allow the electrode wires to wrap around the subjects neck.


Do not clean Cascade before turning off power supply and disconnecting all Cascade components.


Do not clean Cascade components before turning off power supply and disconnecting the amplifier.

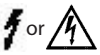
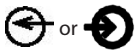

Do not attempt to service or repair damaged or inoperable equipment.

Some of the warnings listed above are referenced from Safety Standards EN 60601-1and EN 60601-2-40.

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

- Use of high current stimulator with intramuscular EMG needle electrodes
- Use of high current stimulator for direct nerve stimulation
- Use of current densities for any electrode exceeding 2mA r.m.s./sq. cm
- Prolonged, rapid, high current stimulation at any site, especially with long pulse durations
- Transthoracic stimulation
- Stimulation with needles having extremely small surface areas that easily exceed 2mA r.m.s./sq. cm. when stimulated
- Use during pregnancy
- Direct nerve stimulation and direct stimulation of the spinal cord, muscle, and brain
- Transcranial and direct electrical stimulation of the brain

Symbols

Symbol	Title/Meaning	Reference
	Attention, consult accompanying documents	IEC 348
	Dangerous voltage	IEC 878
	Power ON	IEC 878
	Power OFF	IEC 878
	Equipotentiality	IEC 878
	Type BF equipment. Isolated patient connection	IEC 878
	Output	IEC 878
	Input	IEC 878
	Variability in steps	IEC 878
	Plus; positive polarity	IEC 878
	Minus; negative polarity	IEC 878
	Direction of nerve depolarization	Cadwell convention
	Visual Evoked Potential Display	Cadwell convention
	Temperature	IEC 878
	Foot Switch	IEC 878
	Headphone	IEC 417
	Amplifier	Cadwell convention
	Reduction of Hazardous Substance Compliant	RoHS
	Link	Cadwell convention
	Status	Cadwell convention
	Data transferring	Cadwell convention
	Trigger	Cadwell convention

Symbol	Title/Meaning	Reference
	EMG/EP/EEG equipment with respect to electric shock, fire, and mechanical hazards only in accordance with UL 2601-1 and CAN/CS A C22.2 No. 601-1 (XXXXX)	ITS
	Declaration of compliance with the provisions of council directive 93/42/EEC concerning medical devices (applies only to equipment so marked and only in the countries stated on the declaration of conformity for the device)	KEMA Medical Notified Body
	Waste Electrical and Electronic Equipment. Do not throw in standard garbage. Recycle or dispose of equipment according to regulatory requirements of your country	WEEE

Operating Environments & Limits

The operating environment for this product should meet the following criteria:

1. An ambient temperature range of 50°F to 104°F (10°C to 40°C).
2. A relative humidity range of 30 percent to 95 percent non-condensing
3. An atmospheric pressure range of 700 hPa to 1060 hPa.

Electromagnetic Compatibility

Please refer to the Cascade Operators Manual for detailed Electromagnetic Compatability information.

Disposal of Equipment

At the end of product life, please take care to appropriately decontaminate the equipment before decommissioning or sending in to Cadwell for service or maintenance.

Please dispose of equipment under the regulatory requirements of your country.

Care, Cleaning and Disposal of Equipment

Please refer to the Cascade Pro Help File on your installation CD for complete instructions on the care, cleaning and disposal of your equipment.

Support & Warranty Information

Limited Warranty

Cadwell warrants for a period of one year from the date of purchase, the system listed against defects in material and workmanship. Notice of a defect and an explanation of circumstances concerning any claim that the system has proven defective in material or workmanship shall be given to Cadwell within two (2) working days of the discovery of the defect in the system. Upon such notice, Cadwell will follow the company service procedures outlined on page 1 (of the warranty).

Cadwell agrees to retrofit equipment. If the company makes standard improvements to components of the equipment covered under this agreement during the term of the warranty and if such improvements are compatible with the equipment located on the customer's premises, then Cadwell will retrofit such physical equipment at no additional charge. Cadwell reserves the right to make changes in specifications, construction or design of its products at any time in such a manner as it may consider necessary or advisable.

Please refer to the Cascade Operators Manual for more detailed information on product warranties.

Using Help Files

By accessing the Cascade Help files you can get the same information about the operation, terminology, and capabilities of the Cascade as are found in the Operator's Manual.

The Help files can be accessed during operation of the Cascade software. From the Help pull-down menu, select Cascade Help Topics.

An electronic copy of the Operator's Manual is available on the software installation CD included with your Cascade system. To access the file, insert the CD into the CD reader on your computer. An installation menu should appear. Click Explore CD. Open the Documents folder and select Cascade Help File. If the installation menu does not appear after inserting the CD, open Windows Explorer, right click on the CD icon, choose Explore and double click the Cascade Help File icon.

Cascade Customer Support

Contact Information

www.cadwell.com

Domestic customers:

Phone: 800-245-3001 or 509-735-6481
Fax: 509-783-6503

International customers:

Please contact your distributor (listings available at www.cadwell.com) or email International@cadwell.com

Support hours

Service department support: Monday through Friday from 6:30 am to 5 pm PST
Application support: Monday through Friday from 6:30 am to 5 pm PST

When to contact Cascade Customer Support

Contact customer support if:

- You continue to experience difficulty after troubleshooting a problem. Cadwell has a rapid, cost-effective method for troubleshooting and servicing equipment. Most problems can be diagnosed over the telephone, and repairs can be performed by sending in the defective part.
- You wish to order optional equipment.

To contact Cadwell for a problem

1. Have your customer identification number and serial number near the phone. Have a person who runs the equipment be prepared to speak to a service technician. This person should be able to provide an accurate description of the problem. It is best if the person calling is in front of the equipment when they call.
2. Call the customer support number, and ask for the service department. The Cadwell service technician will determine if an exchange or repair of parts is necessary and instruct you on appropriate shipping arrangements.

Compliances

Domestic and International Approvals

- Cascade, Cascade Pro, and Cascade PRO are cleared for use by the FDA.
- Cascade, Cascade Pro, and Cascade PRO are Health Canada approved.
- Cascade and Cascade Pro are EU/CE approved.

Cascade Pro PRO meets the following internationally recognized safety standards for Medical Electrical Equipment:

- IEC 60601-1 : General Requirement for Safety
- IEC 60601-1-1 / EN60601-1-1 : Collateral Standard – Safety requirements for medical electrical systems
- IEC 60601-1-2 / EN60601-1-2 : Collateral Standard – Electromagnetic compatibility
- IEC 60601-1-4 : Collateral Standard – Programmable electrical medical systems
- IEC 60601-2-40 : Particular requirements for the safety of electromyographs and evoked response equipment.
- UL 60601-1 : General Requirement for Safety
- CSA 601-1 : General Requirement for Safety

Regulatory Classification Information

- United States: Class II
- Canada: Class II
- European Union: Class IIB (annexes III & V)

Type of Protection Against Electric Shock

- Class I Equipment (with Safety Ground)

Degree of Protection Against Electric Shock

- Type BF Equipment (Floating Inputs)

Degree of Protection Against Ingress of Solids and Liquids

- IP 65 (Dust and splash resistant)
- ES-IX Stimulator meets IP 64 (Dripproof)

Mode of Operation

- Continuous

European Legal Entity
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3951 DB Maarn
The Netherlands
Tel: +31 6 516 536 26
URL: www.cepartner4u.nl

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