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Cascade® IQMAX™

User Guide
Instructions for Setup and Use

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Cascade IOMAX User 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 IOMAX System. It does not provide clinical training. It is assumed that the user has adequate clinical training to perform intraoperative neurophysiological monitoring 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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Table of Contents

User Guide Intent

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

- 100880-620 Cascade IOMAX Help File
- 100880-621 Cascade IOMAX Technical Manual
- 369050-934 Cascade Installation Instructions
- 369050-810 Cascade Surgical Studio Release Notes
- 308014-000 Minimum Computer Specifications

Visit the Cadwell website at www.cadwell.com for more information.

Overview

The Cadwell Cascade IOMAX is a multi-modality intraoperative neurophysiological monitoring system. The Surgical Studio software is designed to take full advantage of the Windows operating system.

The IOMAX can be configured in a portable laptop computer or desktop PC version. Laptop PCs, desktop PCs and all-in-one PCs are available from Cadwell. The portable version comes with a laptop computer and carrying case for portability. The desktop version comes with a mini-tower and LCD monitor or All-in- One PC. A hospital grade cart is available.

The Cascade IOMAX basic system includes a Base Module and Cortical Module and/or Limb Module(s). A USB cable connects the Base Module to the PC. SafeT cables connect from the Base Module directly to the Cortical and Limb Modules and also between the Cortical and Limb Modules. Surgical Studio software is designed for acquiring, storing and reviewing a wide range of intraoperative neurophysiological data, such as EMG, EEG, SSEP, BAEP, VEP, MEP and TOF, and Report Generation using Microsoft® Word®.

Cascade IOMAX Intended Use

The Cascade IOMAX™ Intraoperative Monitor measures and displays the electrical signals generated by peripheral nerves, muscles and the central nervous system. It has a pulse oximeter to detect and display pulse rate and SpO_2 levels in the limbs. The IOMAX acquires, displays, and stores physiologic data generated either spontaneously or elicited by well-defined stimuli. It is intended for use in clinical evaluation of neurophysiologic status, for pre-operative and postoperative assessment of neurophysiologic status, and for intraoperative real-time monitoring of neural pathways.

Use of the Cascade IOMAX is to be administered under the direction of a licensed physician, surgeon, or neurologist, in a professional healthcare facility environment.

Medical Purpose

The IOMAX™ is an electroneurodiagnostic medical device which measures and displays the electrical signals generated by the nervous system. It acquires the data necessary to perform EMG, EP, and EEG testing.

IOMAX™ is intended to be used by personnel trained to perform the intended tests. The system is used primarily in a clinical and/or hospital setting to diagnose neurological abnormalities. It is also used to acquires the data necessary to perform intraoperative monitoring of neural pathways during surgical procedures. It is intended for use during the duration of the surgical procedure and for preoperative and postoperative testing.

Patient Population

Age: newborn to geriatric

Weight: >2.5 Kg

Health: Not relevant

Nationality: Multiple

Patient State: Not relevant; the patient is not the operator.

Patient Condition: Awake, anesthetized, or asleep.

Operating Principle

EMG, EP, and EEG are all electrophysiologic signals. These signals are recorded from various body sites by electrodes placed near the neurological structures. The electrodes are connected to an amplifier, which amplify and digitize the neurological signals. The digitized signals are transmitted to the PC where they are displayed for interpretation by the operator.

Some of the electrophysiologic signals recorded are continuous, such as EEG and most EMG. Others signals are produced by stimulating a body site with electrical, visual, or auditory energy. The electrophysiologic response is recorded (EP).

In Pulse Oximetry, red and infrared signals are transmitted through the body to measure the arterial blood oxygen saturation level. The ratio of red to infrared signals are used to calculate the partial oxygen saturation level. The signals are also used to measure the heart rate.

Setup Instructions

Unpacking the System

Thank you for selecting the Cadwell Cascade IOMAX 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 you can account for all items on the packing list.

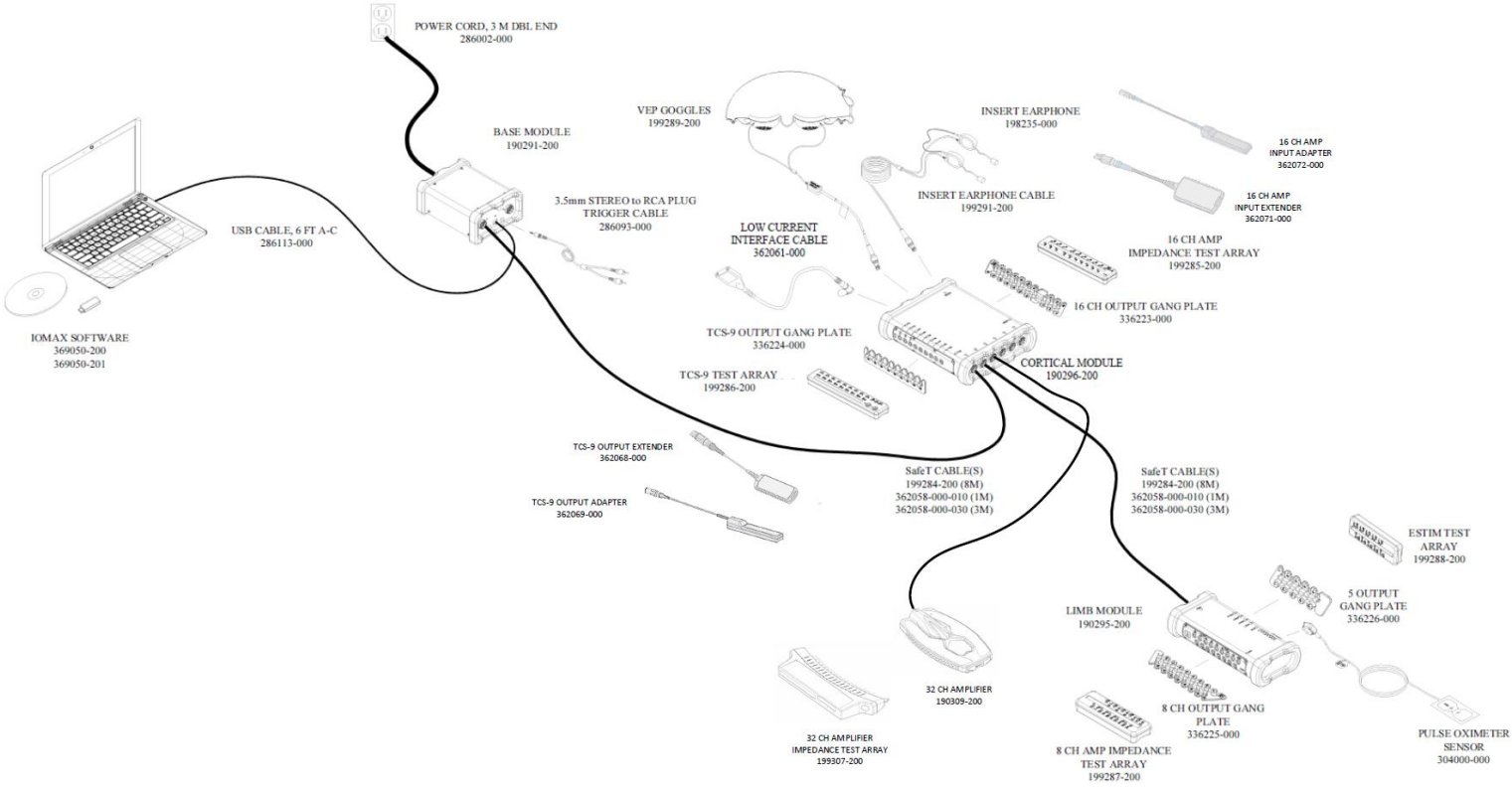
Standard Cascade IOMAX Components:

- IOMAX® Base Module (190291-200) with removable power cord and removable USB cable.
- IOMAX® Cortical Module (190296-200) with SafeT™ cable.
- IOMAX® Limb Module (190295-200) with SafeT™ cable.
- Backup Installation Media (369050-000)
- If ordered, Laptop or Desktop computer with AC adapter and/or AC power cord.

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

- IOMAX® stimulation devices such as insert earphones, LED goggles and low current interface cable.
- Quick Adapts for quick insertion and removal of electrodes.
- Instrument cart with instructions and any accessories like a camera pole, second monitor, and/or printer with cables.
- Isolation transformer (required depending on configuration and accessories)
- External keyboard
- External mouse
- External speaker

System Connection Diagram



Cascade IOMAX Hardware

Figure 1: Base, Cortical, and Limb Modules (left to right) and SafeT Cable (below, center)

The Cascade IOMAX is available in various configurations. A Base Module is always required. Up to one (1) Cortical Module, up to one (1) 32 Channel Amplifier and up to four (4) Limb Modules may be connected simultaneously. Modules are connected to each other using SafeT™ cables.

Base Module

The Base Module is the interface between the PC containing the Surgical Studio software and the rest of the IOMAX system. Communication between the host PC and Base Module is via USB 2.0. The Base Module powers the IOMAX system components (except the host PC) via a medical grade switching power supply and is connected to mains via a detachable hospital grade power cord. It provides for the connection of up to two (2) modules. It has built-in elastomeric bumpers on the front and rear faces to absorb shocks from inadvertent drops. The Base Module has a terminal for connecting a potential equalization conductor; however, Cadwell does not provide an equalization conductor. If required, loosen the nut and connect the user-provided potential equalization conductor. Follow applicable electrical standard for connection to potential equalization busbar.

Base Module Connections

The following connections correlate with the device connection indicated in the image of the Cascade IOMAX Base Module below.

1. Power and USB-CPIN Output
2. USB Type C Input
3. Trigger In 1-2 Connector
4. Trigger Out 1-2 Connector
5. Power Cord Receptacle

Base Module Indicator Lights

The following LED indicators correlate with the image of the Cascade IOMAX Base Module below.

1. Base Module connection status indicator LEDs
2. Base Module USB status Indicator LED
3. Base Module Power Indicator LED
4. Potential Equalization Terminal

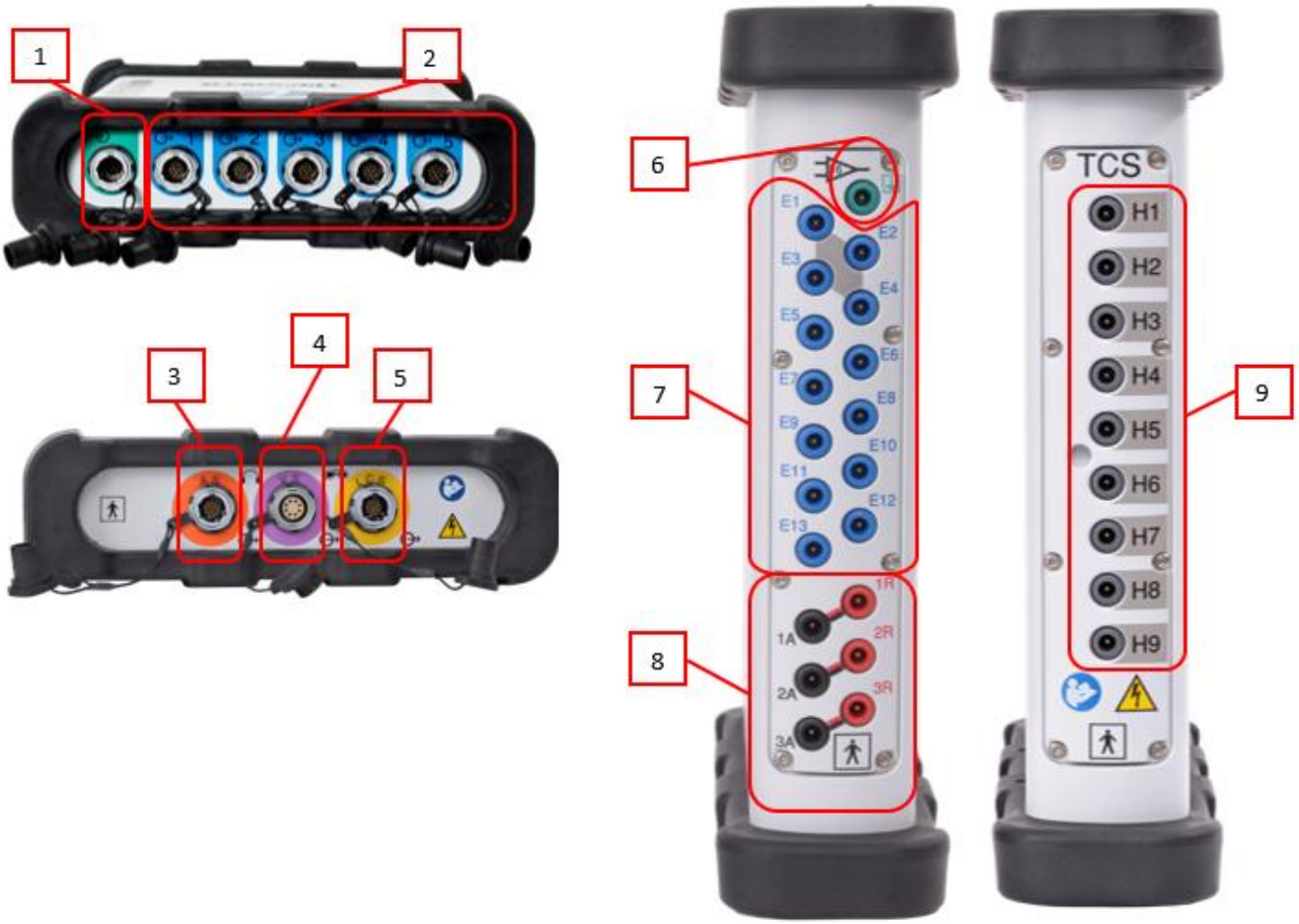
Cortical Module

The Cortical Module is the interface between the Base Module and up to four (4) Limb Modules. Additionally, the Cortical Module has a 16-channel amplifier (0.3 Hz to 5000 Hz), nine (9) transcranial stimulator outputs, and a connection for a visual (photic) stimulator (VS), an auditory stimulator (AS) and a low current stimulator (LCS). Similar to the Base Module, the Cortical Module has built-in elastomeric bumpers on the front and rear faces to absorb shocks from inadvertent drops. The Cortical Module was tested to IP67 for particle and water ingression.

Cortical Module Connections

The following connections correlate with the device connection indicated in the image of the Cascade IOMAX Cortical Module below.

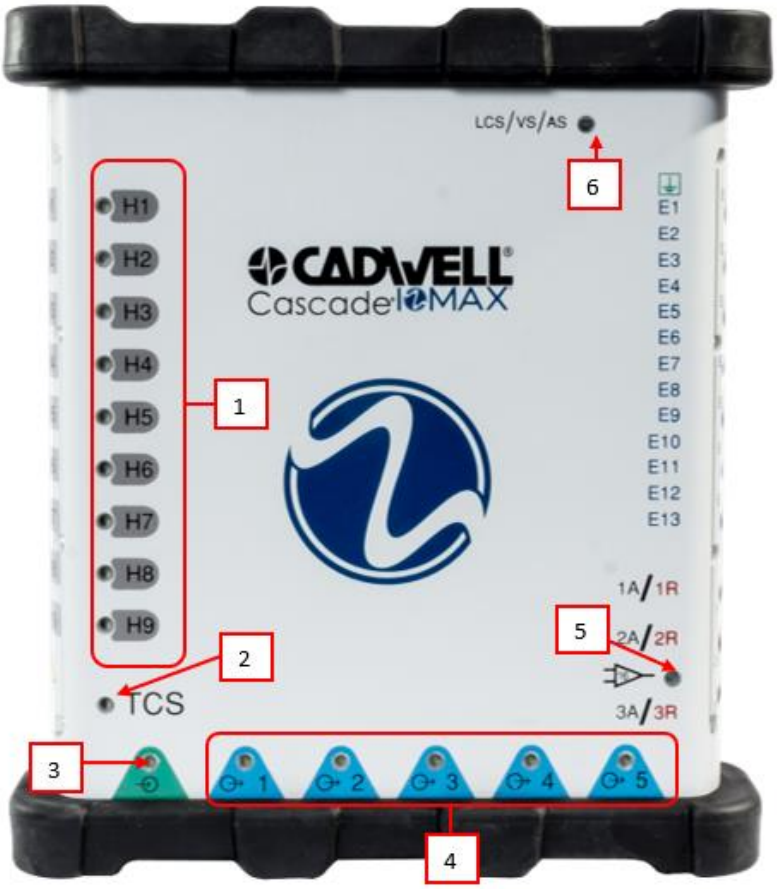
1. Cortical Module Input Connection
2. Cortical Module Output (to Limb Modules) Ports
3. Auditory stimulator output
4. Visual stimulator output
5. Low Current stimulator output
6. 16 Channel Amplifier isolated ground input
7. 16 Channel Amplifier programmable amplifier Inputs
8. 16 Channel Amplifier fixed Active-Reference pair amplifier input
9. TCS-9 programmable outputs



Cortical Module Indicator Lights

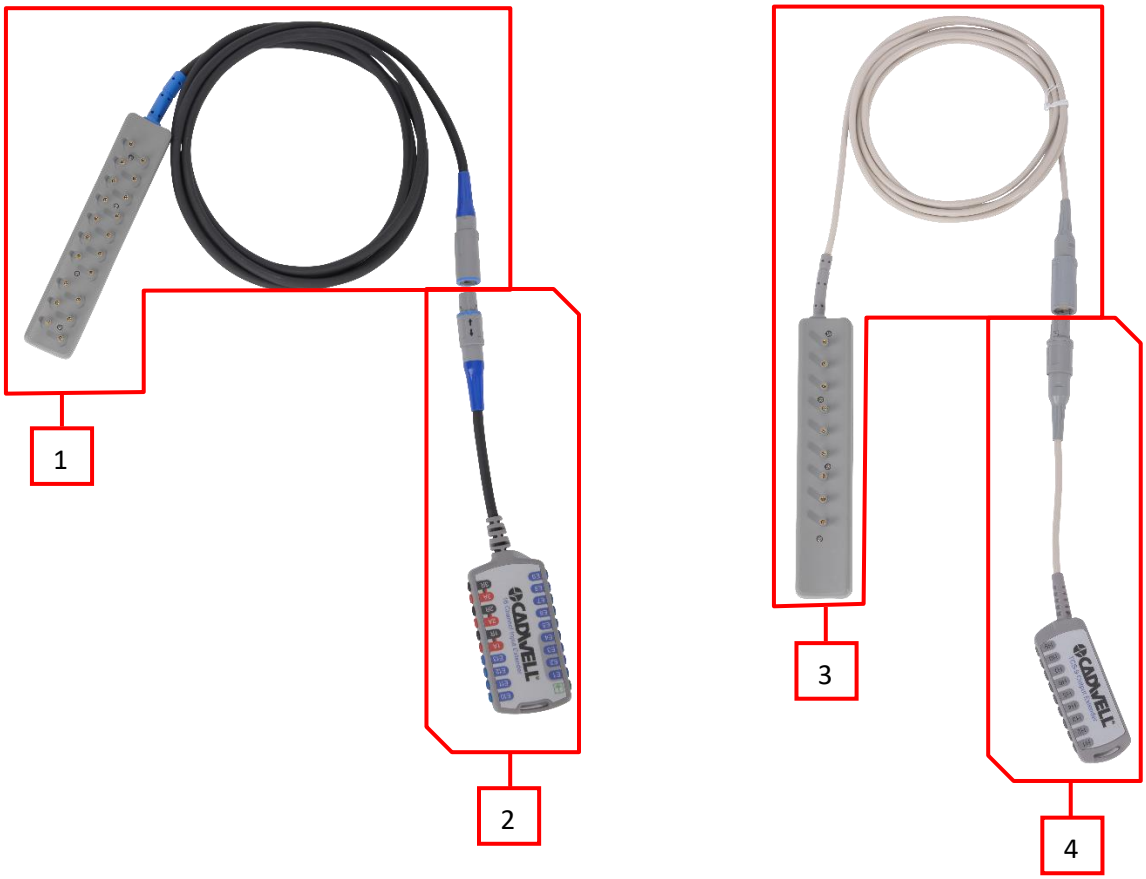
The following indicators correlate with the LEDs indicated in the image of the Cascade IOMAX Cortical Module below.

1. TCS-9 stimulator output indicator LEDs
2. TCS-9 status indicator LED
3. Cortical Module input connection status LED
4. Cortical Module Output connection status LEDs
5. 16 Channel Amplifier status indicator LED
6. Low Current Stim/Visual Stim/Auditory Stim status indicator LED



Cortical Module Extender Pods are available for the TCS-9 and 16 Channel Amplifier to support positioning of the Cortical Module away from the patient's head if required.

1. 16 Channel Amplifier Input Adapter plugs directly into the Cortical Module 16 Channel Amplifier inputs.
2. 16 Channel Amplifier Input Extender connects to the Input Adapter; electrodes are plugged in here.
3. TCS-9 Output Adapter plugs directly into the Cortical Module TCS-9 outputs.
4. TCS-9 Output Extender connects to the Output Adapter; electrodes are plugged in here.



Limb Module

Each Limb Module has an 8-channel amplifier, five (5) 0-100 mA electrical stimulator outputs, and a connection for a SpO_2 sensor. Up to four (4) Limb Modules may be connected to the Cortical Module using a SafeT cable; alternatively, up to two (2) Limb Modules can be connected directly to the Base Module. Similar to the Cortical Module, the Limb Module has built-in elastomeric bumpers on the front and rear faces to absorb shocks from inadvertent drops and was tested to IP67 for particle and wateringression.

Limb Module Connections

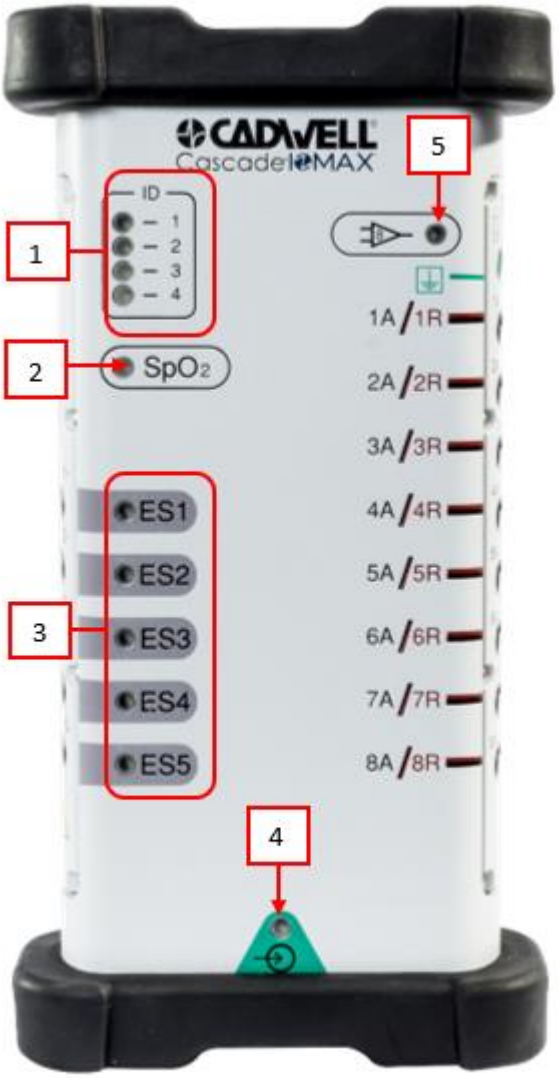
The following connections correlate with the device connection indicated in the image of the Cascade IOMAX Limb Module below.

1. Limb Module I/O port
2. SpO_2 Connector
3. Limb Module EStim outputs
4. 8 Channel Amplifier isolated ground input
5. 8 Channel Amplifier fixed Active-Reference pair inputs

Limb Module Indicator Lights

The following indicators correlate with the LED indicated in the image of the Cascade IOMAX Limb Module below.

1. Limb Module ID indicator LEDs
2. Limb Module SpO_2 status indicator LED
3. Limb Module EStim output status LED
4. Limb Module input connection status LED
5. Limb Module 8 Channel Amplifier status LED



32 Channel Amplifier

The IOMAX 32 Channel Amplifier (0.3 Hz to 500 Hz) is a recording device designed for EEG and direct cortical evoked potentials. Up to one (1) 32 Channel Amplifier can be connected to the IOMAX system via the Cortical Module or directly to the Base Module using a SafeT cable.

The following connections and indicators correlate with the device images below.

32 Channel Amplifier Connections

1. 32 Channel Amplifier input port
2. 32 Channel Amplifier inputs
3. 32 Channel Amplifier isolated ground input (only one ground is required)

32 Channel Amplifier Indicator Lights

1. 32 Channel Amplifier input connection status LED

LCSwap Accessory

The LCSwap switch matrix is an accessory for use with the Cortical Module low current stimulator. It has twelve outputs for connection of a strip or grid electrode and two (2) paired outputs for connection of up to two (2) hand-held stimulation probes. Similar to the Cortical Module, it has built-in elastomeric bumpers to absorb shocks from inadvertent drops. The LCSwap connects to the Cortical Module low current stimulator output using

The following connections and indicators correlate with the device images below.

LCSwap Connections

1. LCSwap output port
2. LCSwap connection cable
3. Outputs for connection of a strip or grid electrode
4. Paired outputs for connection of stimulation probe(s)

LCSwap Indicator Lights

1. LCSwap connection status LED
2. LCSwap stimulation status LED
3. LCSwap Probe 1 status LED
4. LCSwap Probe 2 status LED
5. LCSwap Probe 3 status LED (not currently supported)

SafeT Cables

SafeT™ Cables are Cadwell-designed and developed cables used to connect the Base Module to the Cortical Module (or directly to the Limb Module), and to connect each Cortical Module to up to four (4) Limb Modules. The connectors are keyed and color-coded and correspond to the module input/output port. SafeT cables are available in 3 and 8-meter lengths, and can be used interchangeably for connecting any two modules.

SafeT Cable Connections

1. SafeT Cable input/output connector

Positioning Cascade IOMAX Moules

The Cascade IOMAX system supports a variety of configurations to fit your monitoring needs. The Cascade IOMAX Cortical Module and Cascade IOMAX Limb Modules come with mounting accessories, including a rail bracket (standard) and pole clamp (optional). The Cascade IOMAX modules may be secured under a Jackson Table, under an Andrews Table, hung on an IV pole, hung on the surgical table rail, placed on the floor, or mounted to the equipment shelf.

Rail bracket

Pole Clamp

Personal Computer (PC)

A PC is required for use to run the Cascade Surgical Studio software with the IOMAX system. Either a laptop or desktop PC may be used, and the PC may be purchased from Cadwell and provided with the IOMAX, or the customer may purchase their own PC as long as it meets the minimum computer requirements specified by Cadwell.

Minimum Computer Requirements

Refer to the Minimum Computer Specifications document (PN 308014-000) for current requirements. These requirements represent the minimum computer performance requirements necessary to run the Cascade IOMAX. Your system will run better when used with a computer with a faster processor and more RAM.

Operating System: Windows 7 Professional (SP1, 64-bit) or Windows 10. Windows 10 is recommended.

Cadwell does not recommend using Surgical Studio on a Windows 8 or 8.1 operating system.

Note: Installing Cascade Surgical Studio software on operating systems and computers that are not recommended by Cadwell is not only considered unsafe, but will be unsupported by Cadwell and may void any equipment or software warranty.

Word Process: Microsoft Word Home Office Edition. Word is only required for report generation.

Processor: Dual Core Intel i7, 2.5 GHz or faster. Recommend Quad Core i7.

Hard Disk Drive: 128 GB at 7200 RPM. Recommend SSD.

Memory (DRAM): 8 GB.

Archive Device: Recordable DVD+R/+RW and CD-RW drive to use built-in archive utility in software. Or any Windows unsupported device.

Graphics: 1366 x 768 resolution. Recommend 1920 x 1080 resolution.

Network: A network card or wireless capabilities are required for remote monitoring.

Ports: One (1) available USB 2.0 port (or greater) for IOMAX hardware connection.

US & Canada regulatory requirements:

Computer and information technology equipment connected to the base must be third party certified to UL1950 or IEC950.

European Union regulatory requirements:

Computer and information technology equipment connected to the base must be third party certified to EN60950.

PC Purchased from Cadwell

NOTE: If you purchased your computer from Cadwell, all necessary Windows® and Surgical Studio software are pre-installed on your computer. There is no need for you to install any software. Please store media that shipped with your system in a secure location. These were included as a back-up copy only. Laptop computers may require you to make backup CDs for the computer.

Cadwell also makes available accessories and PC-related interface and peripheral devices such as an external keyboard, mouse, speaker, printer, camera and interconnection cables for the customer as desired.

Configuration of Non-Cadwell Supplied Computers

NOTE: If a computer is purchased from a source other than Cadwell, the Windows Operating System must be properly configured, Surgical Studio Software must be installed and the software license activated.

The reference document *369050-934 Cascade Installation Instructions* will be provided with the system or on the Surgical Studio media in the Documents folder.

Installing Surgical Studio software on Non-Cadwell supplied computers

Prior to installing the Surgical Studio application software, the configuration process described in the previous section must be completed. Follow the installation instructions *369050-934 Cascade Installation Instructions p*rovided on the Surgical Studio media under the main directory.

Basic System Setup

Follow the steps below to turn the IOMAX system on and off, open and close Surgical Studio software, acquire data and generate a report.

Connections and Power Instructions

To turn the equipment on

1. Connect Cascade IOMAX hardware to the system computer, including Base Module, Cortical Module and/or Limb Module(s).
2. Power on the computer and monitor (for desktop configurations only).
3. Log in to Windows.
4. Power on the IOMAX Base Module.

NOTE: 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.

To turn the equipment off

1. Close the Surgical Studio program and any other related programs running on the computer.
2. Shut down Windows if desired.
3. Power off IOMAX Base Module.
4. Turn off monitor (for desktop configurations only).

Open and Close Surgical Studio Software

To Open the Surgical Studio program:

1. To open the application software, double-click the Cascade Surgical Studio icon on your desktop.
2. Log in to Cascade Surgical Studio

NOTE: If your system is not yet configured, use username admin and password admin.

NOTE: It is recommended the user changes the admin password.

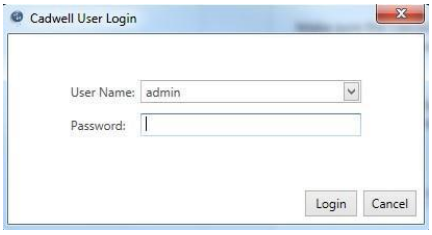
To Close the Surgical Studio program:

1. Click on the red X in the upper right-hand corner of the screen, or:
2. Navigate to the Case Menu and choose Close Case to close the procedure without exiting Surgical Studio. Choose
3. Exit Cascade to exit Surgical Studio completely.

Login Window

After launching the Surgical Studio 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.

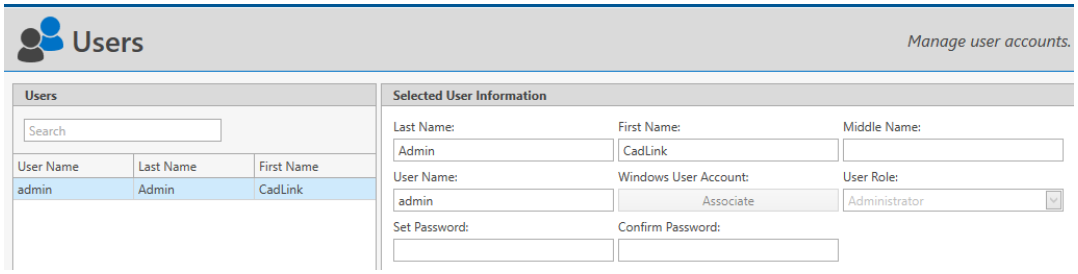
If no users have been created, select the Admin user and enter the password admin.



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

Domain User Accounts

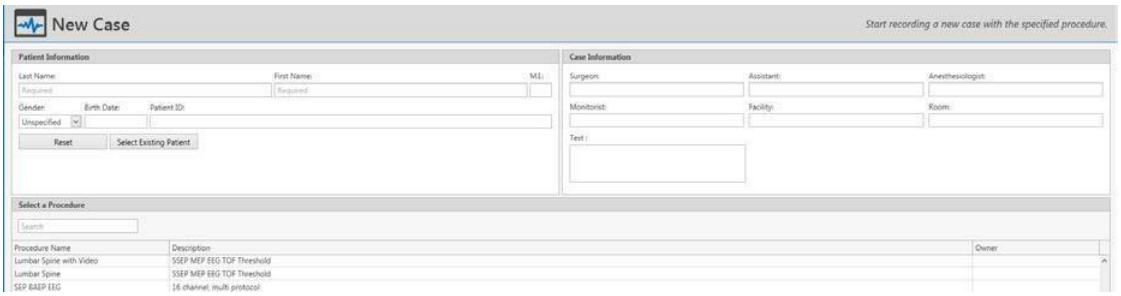
If you are an Active Directory (Domain) user AND have the user in CadLink linked to that domain account, the program will automatically ask you if you want to log in using your domain credentials of the user. Go to Users on the start screen to create or edit users and link to the domain account.



Start a New Case

The Surgical Studio start screen brings the user to the New Case screen automatically. Here the user should enter Patient and Case Information and Select a Procedure. The user can start a case by double-clicking the Procedure Name or single-clicking the Procedure Name and clicking Start Case in the lower right of the screen.

NOTE: If the New Case screen says that no base module is connected, make sure the Cascade IOMAX Base Module is turned On and that the USB cable is attached securely between the computer and the Cascade IOMAX Base Module.



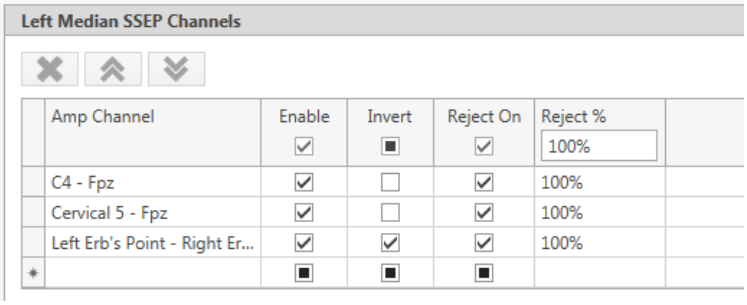
Help File

The Help File is accessible within the Surgical Studio application by hitting F1 or navigating to “?” in the application title bar and choosing “View Help.”

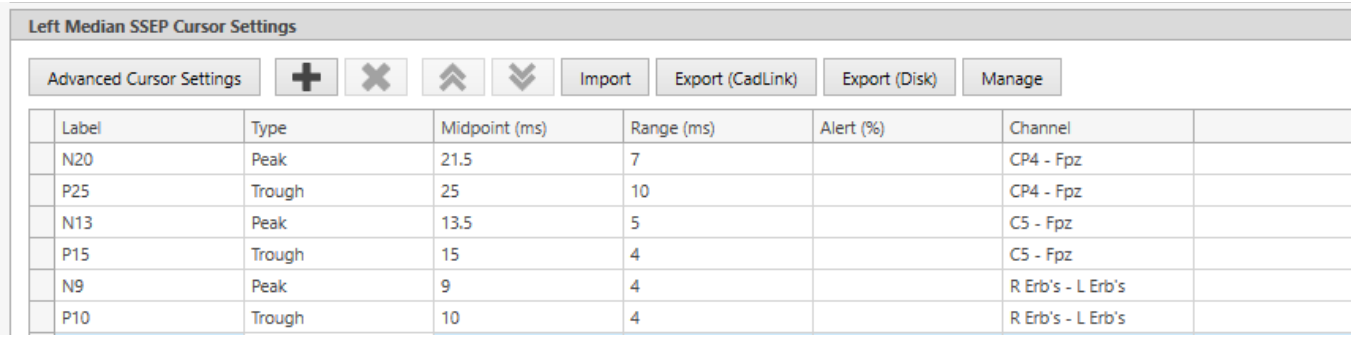
Procedure Setup

Default modes and procedure setups are provided within the Cascade Surgical Studio application. Procedure Setups are made up of Modes. Modes are comprised of Channels, Cursor Settings, General Settings and Stimulus Settings as supported. The example below shows the SSEP Mode’s Channels, Cursor Settings, General Settings and Stimulus Settings.

Channels

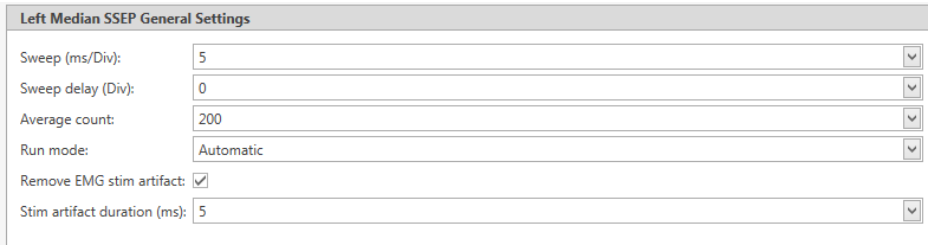


Cursor Settings

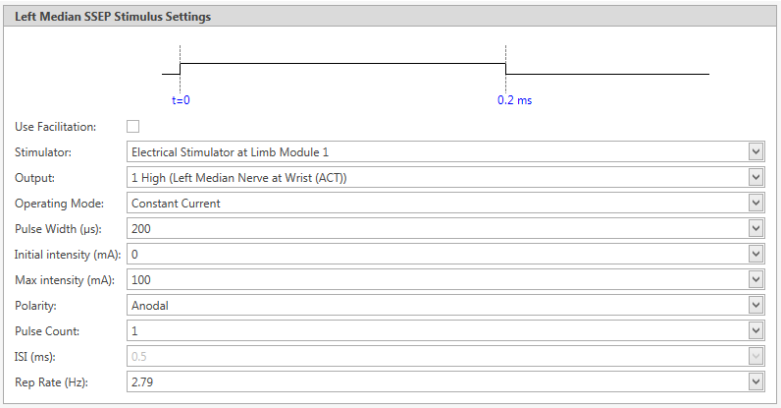


Label	Type	Midpoint (ms)	Range (ms)	Alert (%)	Channel
N20	Peak	21.5	7		CP4 - Fpz
P25	Trough	25	10		CP4 - Fpz
N13	Peak	13.5	5		C5 - Fpz
P15	Trough	15	4		C5 - Fpz
N9	Peak	9	4		R Erb's - L Erb's
P10	Trough	10	4		R Erb's - L Erb's

General Settings



Stimulus Settings



Navigate the Recording Screen

The recording screen is displayed. In the image below, Mode Controls (1) on the left provide easy access to commonly required stimulation and recording parameters. Trace windows (2) are in the center of the screen. Chat and Event Log windows (3) are on the right. The Recording Toolbar (4) at the top of the screen provides access to Procedure Setup, Channel Setup, Impedance and much more. Windows for Mode Controls, Trace Windows, Chat and Event Log may be positioned differently in the procedure setup you choose. The Timebar (5) at the bottom of the recording screen can be used to navigate forward and backward within a live or finished recording.

Somatosensory Evoked Potential (SSEP)

Follow these steps to acquire a somatosensory evoked potential or nerve conduction study (SSEP mode).

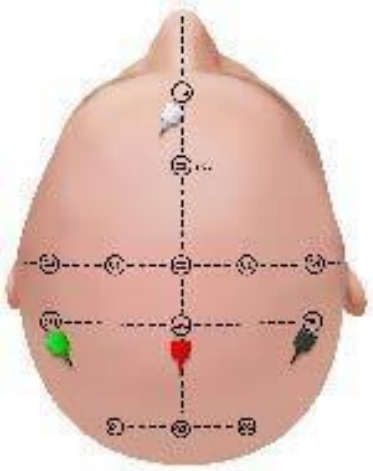
An example is shown. Users should select channels as appropriate for the desired case setup.

1. Place Stimulation Electrodes

Apply surface pads to the wrist as shown. The Cathode (-) should be placed distally. The stimulation leads connect to the Limb Module High Current stimulator output as defined in Channel Setup (Outputs tab) accessible via the Recording Toolbar.

2. Place Recording Electrodes

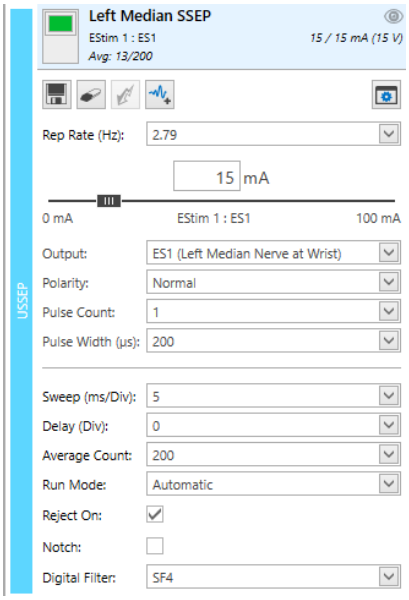
Apply electrodes to the scalp as shown according to the 10-20 System. When stimulating the left median nerve, recording electrodes should be placed at CP4 and FZ. When stimulating the right median nerve, recording electrodes should be placed at CP3 and FZ. There is no need to duplicate FZ when stimulating both left and right median nerves; the FZ reference can be shared by CP3 and CP4 to create two distinct channels. The recording leads connect to the Cortical Module as defined in Channel Setup accessible via the Recording Toolbar.



3. Collect Data

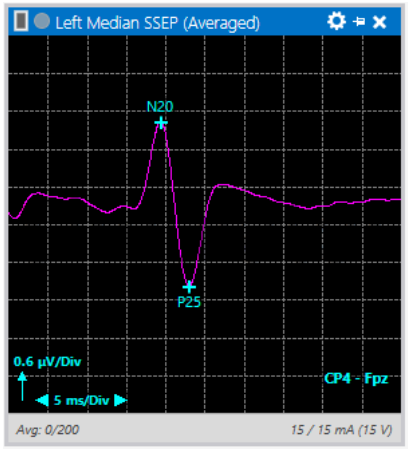
In the Upper SSEP Trace Window, click the Run button. The Run button will turn green when the mode is actively acquiring data. A yellow dot next to the Run button softly flashes to confirm delivery of the stimulus.

Use the Mode Control to adjust the stimulus intensity (mA) until a visible twitch of the thumb is observed. Stimulus is adjusted by entering a desired valued into the box or clicking and dragging the marker on the stimulus intensity bar. A typical stimulus intensity for median nerve SSEP is 15-20 mA. Approximately 200 averages are required to acquire a replicable waveform with clear morphology.



4. Verify Results

The resulting waveform should look similar to the image below with a peak at approximately 20 mSec, followed by a trough. Collect a second waveform to verify replicability. In the footer of the trace window, the sensed current is reported. The sensed value (mA) should approximate the set intensity (mA).



Brainstem Auditory Evoked Potential (BAEP)

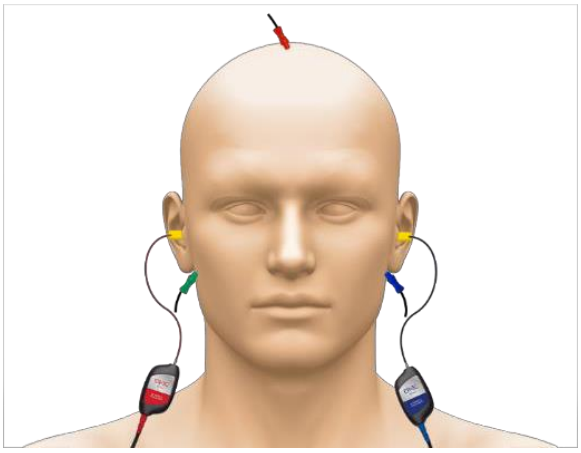
Follow these steps to acquire a brainstem auditory evoked potential (BAEP mode).

1. Set Up Stimulation

Place insert earphones. The blue transducer goes to the left ear; the red transducer goes to the right ear. The tubes connecting the auditory transducers to the insert earphones must be patent.

2. Place Recording Electrodes

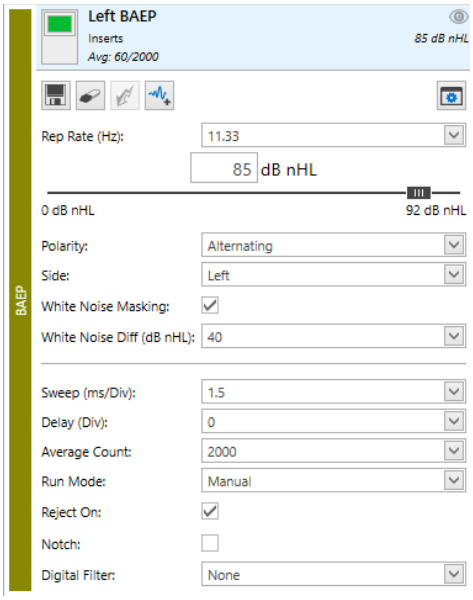
Apply electrodes to the scalp as shown according to the 10-20 System. When stimulating the left auditory pathway, recording electrodes should be placed at A1 and CZ; optionally record from A2-CZ. When stimulating the right auditory pathway, recording electrodes should be placed at A2 and CZ; optionally record from A1-CZ. There is no need to duplicate CZ when stimulating both left and right auditory pathways; the CZ reference can be shared by A1 and A2 to create two distinct channels. The recording leads connect to the Cortical Module as defined in Channel Setup accessible via the Recording Toolbar.



3. Collect Data

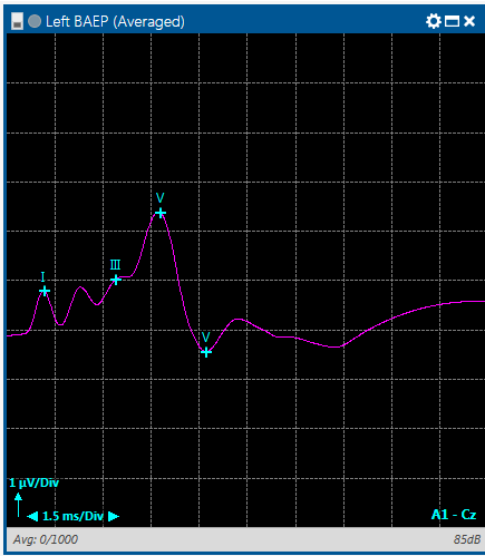
In the BAEP Trace Window, click the Run button. The Run button will turn green when the mode is actively acquiring data. A yellow dot next to the Run button softly flashes to confirm delivery of the stimulus.

Use the Mode Control to adjust the stimulus intensity (dB). Stimulus is adjusted by entering a desired valued into the box or clicking and dragging the marker on the stimulus intensity bar. A typical stimulus intensity for BAEP recordings in the operating room is 85 dB and higher, depending on ambient noise and the patient's hearing status. An Average Count of 1000 or higher is usually needed to acquire a replicable waveform with clear morphology.



4. Verify Results

The resulting multi-phasic waveform should look similar to the image below with a large peak at approximately 5- 6 mSec, followed by a trough. Collect a second waveform to verify replicability.



Visual Evoked Potential (VEP)

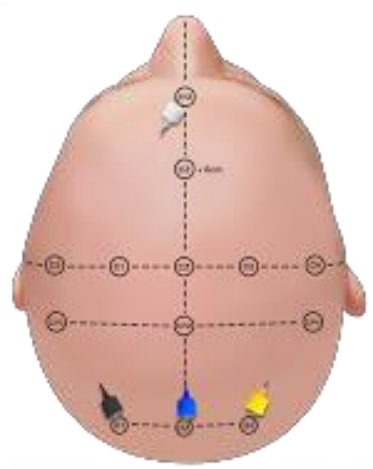
Follow these steps to acquire a visual evoked potential (VEP mode).

1. Set Up Stimulation

Place the LED goggles over the patient's eyes. The goggle foam is disposable and must be attached before placing the goggles; remove the adhesive backing to attach.

2. Place Recording Electrodes

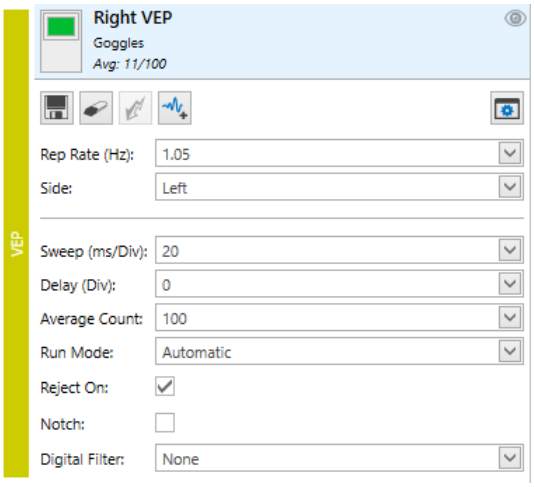
Apply electrodes to the scalp at O1, OZ, O2 and Fpz according to the 10-20 System. When stimulating the left visual pathway, recording electrodes should be placed at O2 and Fpz. When stimulating the right visual pathway, recording electrodes should be placed at O1 and Fpz. There is no need to duplicate Fpz when stimulating both left and right visual pathways; the CZ reference can be shared by O1 and O2 to create two distinct channels. The recording leads connect to the Cortical Module as defined in Channel Setup accessible via the Recording Toolbar.



3. Collect Data

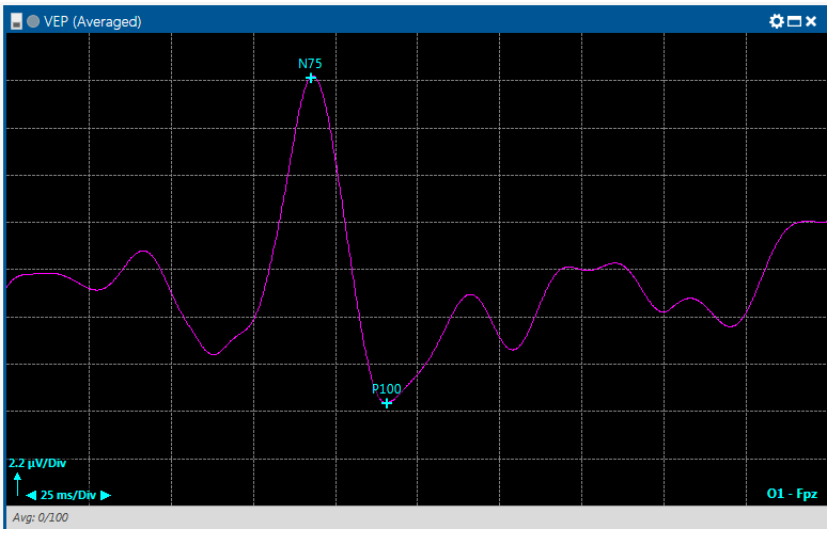
In the VEP Trace Window, click the Run button. The Run button will turn green when the mode is actively acquiring data. A yellow dot next to the Run button softly flashes to confirm delivery of the stimulus.

Use the Mode Control to adjust the Rep Rate (Hz). LED intensity is fixed.



4. Verify Results

The resulting multi-phasic waveform should look similar to the image below with a large peak at approximately 75 mSec, followed by a trough. Collect a second waveform to verify replicability.

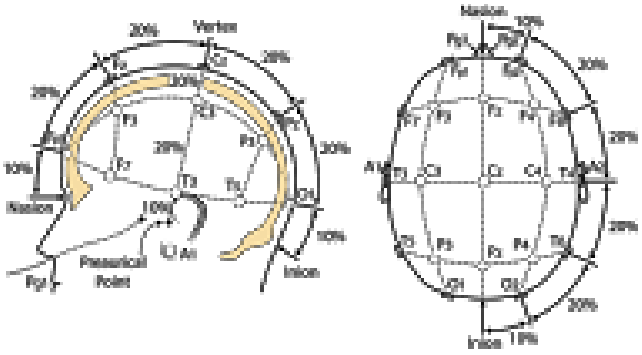


Electroencephalography (EEG)

Follow these steps to acquire electroencephalography (EEG mode).

1. Place Recording Electrodes

Apply electrodes to the scalp as desired according to the 10-20 System. Electrodes used for other modes (such as SSEP) can also be used to record EEG. The recording leads connect to the Cortical Module as defined in Channel Setup accessible via the Recording Toolbar.

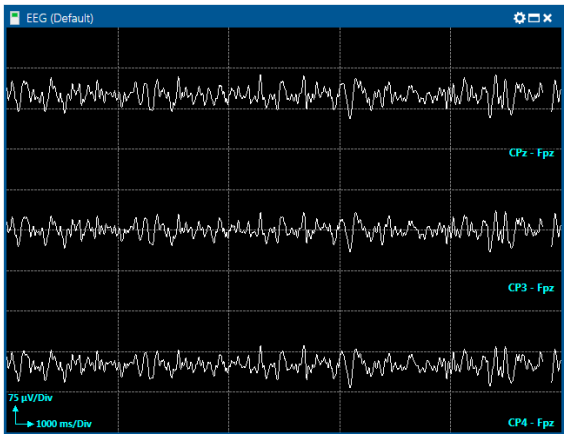


2. Collect Data

In the EEG Trace Window, click the Run button. The Run button will turn green when the mode is actively acquiring data. Right click in the EEG Trace Window and choose Mode Setup to adjust channel settings.

3. Verify Results

The resulting waveforms should look similar to the image below.



Electromyography (EMG)

Follow these steps to acquire free-run electromyography (EMG mode).

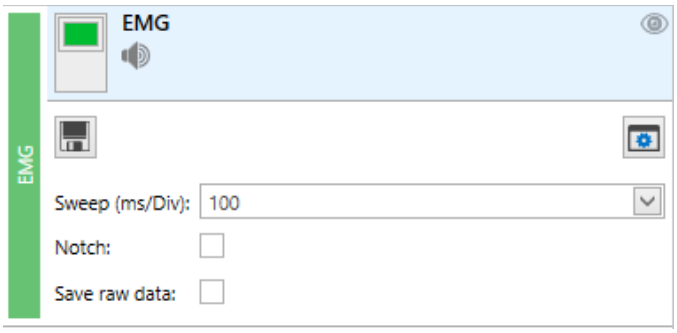
1. Place Recording Electrodes

Apply electrodes to muscles to represent the myotomal levels of interest. The recording leads connect to the Cortical and/or Limb Module(s) as defined in Channel Setup accessible via the Recording Toolbar.

2. Collect Data

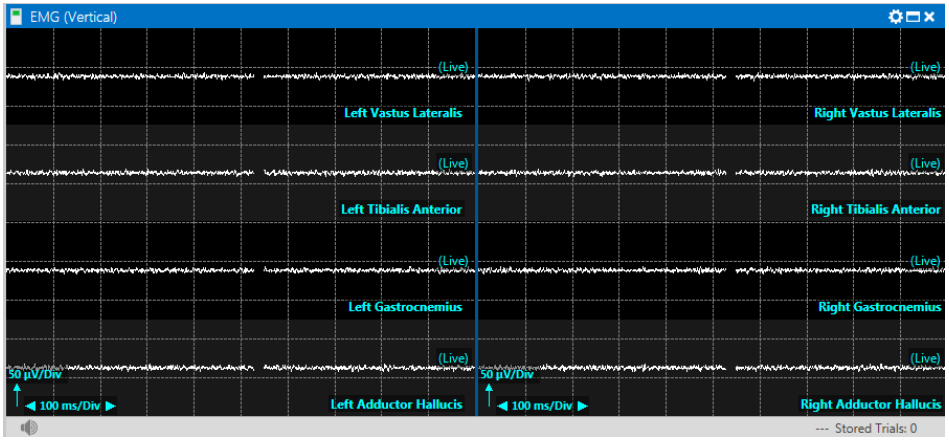
In the EMG Trace Window, click the Run button. The Run button will turn green when the mode is actively acquiring data.

Use the Mode Control to adjust the Sweep (ms/Div) and choose whether to save all raw data.



3. Verify Results

As shown in the image below, a normal free-run EMG response is the absence of activity. Mechanically-induced activity can be characterized as a single spike, burst pattern, train activity or neurotonic discharge.

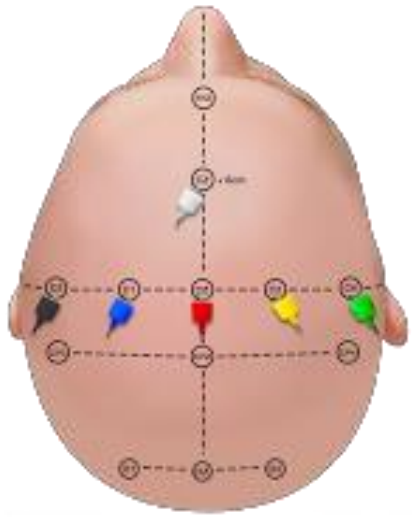


Motor Evoked Potential (MEP)

Follow these steps to acquire a transcranial motor evoked potential (MEP mode).

1. Place Stimulation Electrodes

Stimulation electrodes are placed at measured sites over the motor cortex. Common montages are hemispheric (e.g. C3-Cz, C4-Cz), inter-hemispheric (e.g. C1-C2, C3-C4) or midline (e.g. Cz-1cm – Cz+6cm). Alternative montages may be advantageous for achieving specific results.



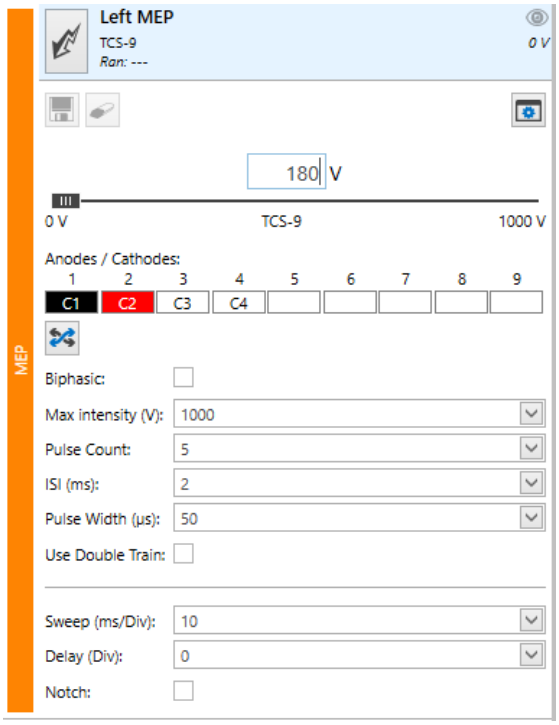
2. Place Recording Electrodes

Responses are recorded from paired electrodes placed in each muscle of interest. An adequate number of muscles should be recorded from to represent responses above (for control) and below the site of surgery. In the image below, responses are recorded from left and right Abductor Pollicis Brevis, Vastus Lateralis, Tibialis Anterior, Gastrocnemius and Adductor Hallucis.

3. Collect Data

In the MEP Trace Window, click the Trigger button. The Trigger button will flash green when the mode is actively acquiring data. A yellow dot next to the Run button will flash once to confirm delivery of the stimulus and then turn off.

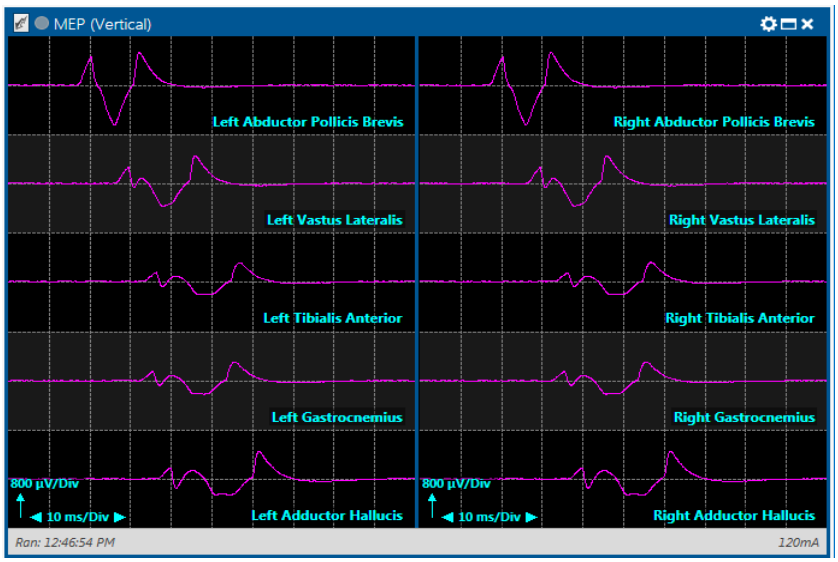
Use the Mode Control to adjust the stimulus intensity (mA or V, depending on whether the mode is set to Constant Current or Constant Voltage). Stimulus is adjusted by entering a desired valued into the box or clicking and dragging the marker on the stimulus intensity bar.



4. Verify Results

The resulting waveforms should look similar to the image below; the latency of the response will depend on the distance from the stimulating electrodes to the recording muscle. Collect a second waveform to verify replicability.

In the footer of the trace window, the sensed current is reported. The sensed value should approximate the requested intensity.



Direct Cortical Stimulation (DCS)

Follow these steps to acquire a direct cortical stimulation (DCS mode).

1. Place Stimulation Electrode(s) and/or Probe(s)

Cortical stimulation may be performed using a strip/grid electrode(s) and/or hand-held stimulation probe, depending on the desired technique(s).

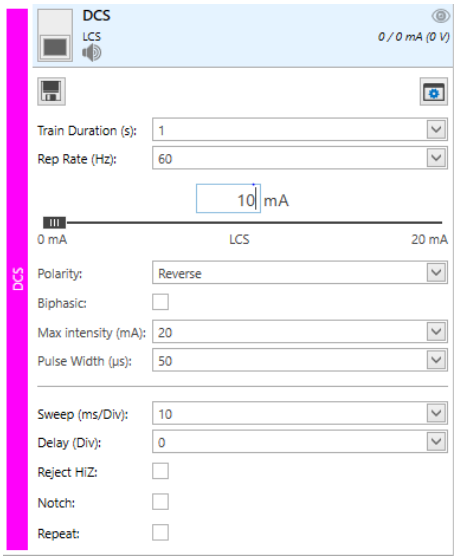
2. Place Recording Electrodes

Responses are recorded from paired electrodes placed in each muscle of interest. An adequate number of muscles should be recorded from to represent responses from cortical areas of interest. In the image below, responses are recorded from left Obicularis Oculi, Obicularis Oris, Masseter, Deltoid, Biceps, Flexor Carpi Ulnaris and Abductor Pollicis Brevis.

3. Collect Data

In the DCS Trace Window, click the Run button. The Run button will turn green when the mode is actively acquiring data. A yellow dot next to the Run button will softly flash to confirm delivery of the stimulus. A Trigger button will appear when the mode is set up for multi-pulse stimulation.

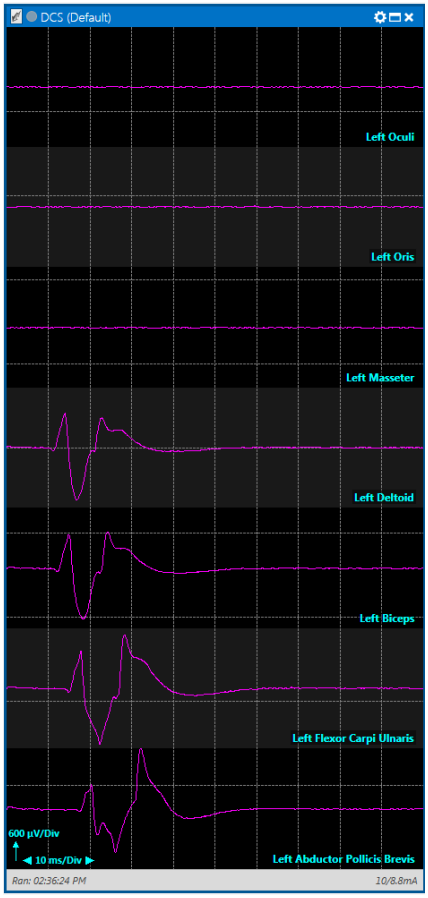
Use the Mode Control to adjust the stimulus intensity (mA) and other parameters to achieve the desired results. Stimulus is adjusted by entering a desired valued into the box or clicking and dragging the marker on the stimulus intensity bar.



4. Verify Results

The resulting waveform should look similar to the image below; the latency of the response will depend on the distance from the stimulating probe/electrodes to the recording muscle. The presence or absence of the response will be determined by the stimulus intensity and parameters as well as the function of the tissue

stimulated (e.g. motor cortex).In the footer of the trace window, the sensed current is reported. The sensed value should approximate the set intensity.

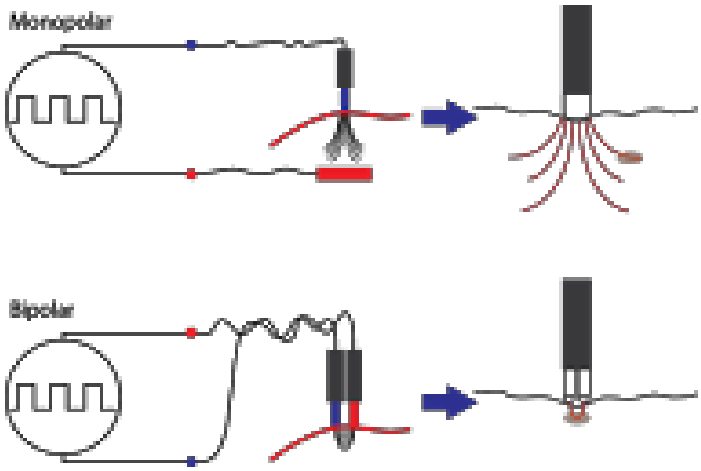


Triggered EMG (TEMG)

Follow these steps to acquire triggered electromyography (TEMG mode).

1. Set Up Stimulation

TEMG typically uses a hand-held stimulation probe for the purposes of localizing, identifying and/or functionally assessing motor nerves. Using a monopolar probe will prioritize sensitivity of the response, whereas using a bipolar probe will prioritize selectivity of the response and limit current spread.



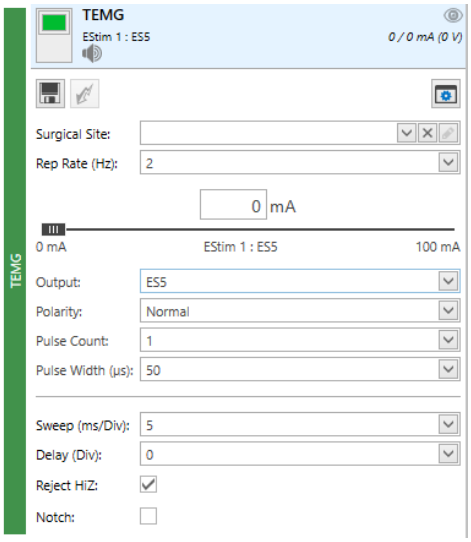
2. Place Recording Electrodes

Apply electrodes to muscles to represent the myotomal levels of interest. The recording leads connect to the Cortical and/or Limb Module(s) as defined in Channel Setup accessible via the Recording Toolbar. These may be the same electrodes placed for EMG mode.

3. Collect Data

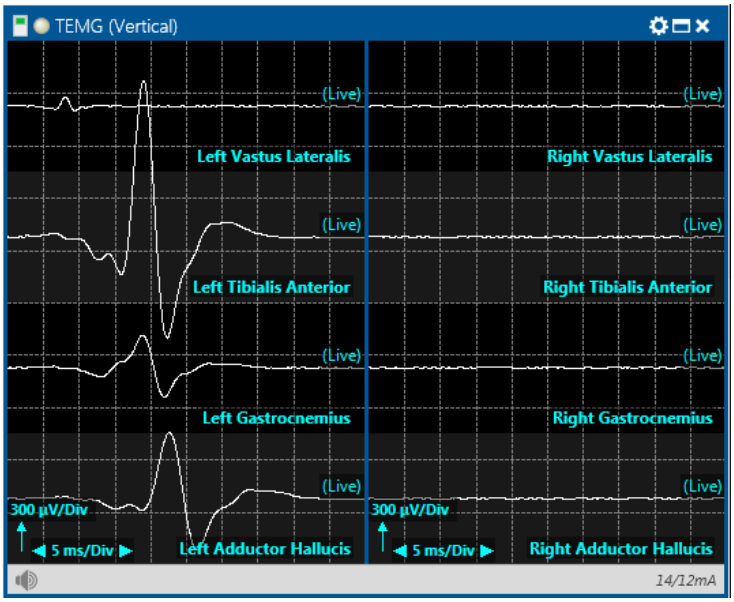
In the TEMG Trace Window, click the Run button. The Run button will turn green when the mode is actively acquiring data.

Use the Mode Control to increase the stimulus intensity (mA) and adjust the stimulation parameters until a response is obtained or a user-defined stimulus intensity limit is reached. Stimulus is adjusted by entering a desired valued into the box or clicking and dragging the marker on the stimulus intensity bar.



4. Verify Results

As shown in the image below, TEMG results in a time-locked response, the latency of which will depend on the distance from the stimulating probe to the recording electrodes. The response will be present in the muscle(s) innervated by the nerve(s) stimulated.



Train of Four (TOF)

Follow these steps to acquire Train of Four (TOF mode).

1. Set Up Stimulation

Apply surface pads to the wrist (as shown) or the ankle. The Cathode (-) should be placed distally. The stimulation leads connect to the Limb Module High Current stimulator output as defined in Channel Setup (Outputs tab) accessible via the Recording Toolbar. These may be the same electrodes used for upper or lower extremity SSEP stimulation. In this example, TOF is stimulated from the left median nerve.

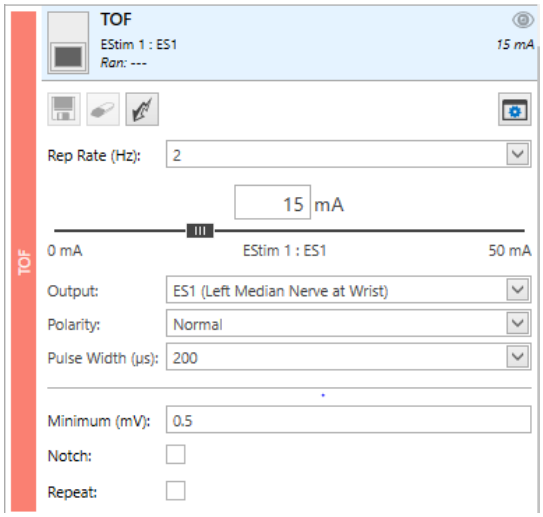
2. Place Recording Electrodes

Record from a muscle distal to the stimulation electrodes. The recording leads connect to the Cortical and/or Limb Module(s) as defined in Channel Setup accessible via the Recording Toolbar. These may be the same electrodes placed for EMG mode. In this example, TOF is recorded from the left Abductor Pollicis Brevis muscle.

3. Collect Data

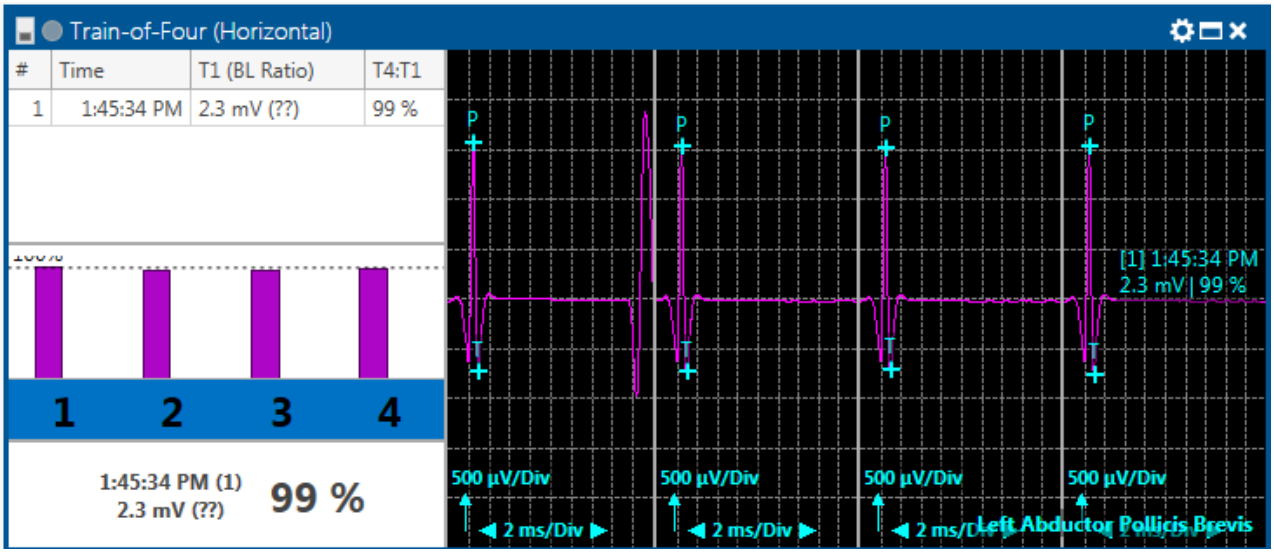
In the TOF Trace Window, click the Run button. The Run button will turn green when the mode is actively acquiring data. A yellow dot next to the Run button softly flashes to confirm delivery of the stimulus. Four stimuli will be delivered, then the mode will turn off.

Use the Mode Control to increase the stimulus intensity (mA) and adjust the stimulation parameters until a response is obtained. Stimulus is adjusted by entering a desired valued into the box or clicking and dragging the marker on the stimulus intensity bar.



4. Verify Results

As shown in the image below, TOF results in response for each of the four stimuli. The ratio of the fourth response to the first response (T4:T1) compares the amplitude of the muscle response.



Pulse Oximetry (SpO_2)

Follow these steps to measure Pulse Oximetry and Heart Rate (SpO_2 mode).

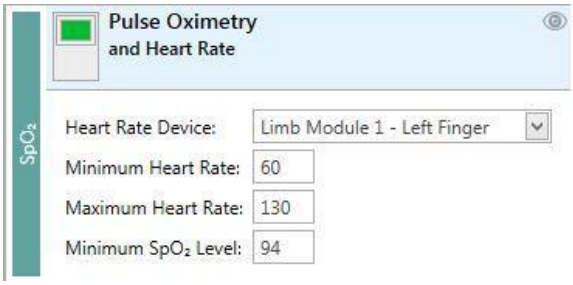
1. Place Recording Electrode(s)

Apply SpO_2 probes to fingers and/or toes, one from each limb for a maximum of four (one per Limb Module). The leads connect to the Limb Module(s) as defined in Channel Setup accessible via the Recording Toolbar.

2. Collect Data

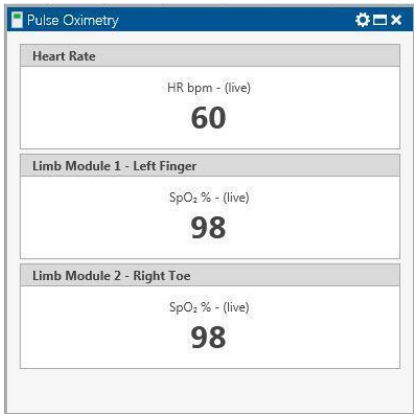
In the Trace Window, click the Run button. The Run button will turn green when the mode is actively acquiring data.

Use the Mode Control to assign the probe for measuring Heart Rate and minimum/maximum values for Heart Rate and SpO_2 levels.



3. Verify Results

Values for Heart Rate and SpO_2 per limb will be populated in the Pulse Oximetry display window. The software displays “??” in the trace window for heart rate and SpO2 if the probe is misaligned, not connected, or in a fault condition.



Information about wavelength range can be especially useful to clinicians.

Wavelengths: Near infrared 940 nm, Red light 660 nm.

The SpO_2 sensor Peak Irradiance value measured at 20 mc through 7 mm aperture equals 0.162 W / m^2.

NOTE: A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor. A Datrend model Oxytest Plus 7 may also be used to perform a basic functionality test of the pulse oximeter (SpO2 and pulse rate). The Oxytest Plus 7 with Software version 2.6B1 must be used (DATREND Systems, Inc.).

NOTE: Pulse oximeter equipment measurements are statistically distributed, only about two-thirds of PULSE OXIMETER EQUIPMENT measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER. IOMAX pulse oximeter is suitable for use with only one sensor provided as part of the equipment.

NOTE: Refer to “Appendix 2: Pulse Oximeter: Summary of Clinical Study” for additional information.

Perform Review

Follow these steps to review a case, either live or following completion of recording:

From the Cascade Surgical Studio start page, click on Review / Resume.

1. Select the case recorded in the previous section.
2. Click Review in the bottom-right of the window.
3. Review the data and verify that the waveforms originally stored in the case are present. Clicking on the time bar or its associated arrow buttons jumps to a specific time in the case and displays the appropriate data for that time.
4. Close the case by selecting Case → Close Case from the main menu. This will return you to the start screen.

Generate a Report

The integrated Report Generator is a simple, Word®-based system that is designed for the easy creation and editing of reports. Reports are generated based on the latest data.

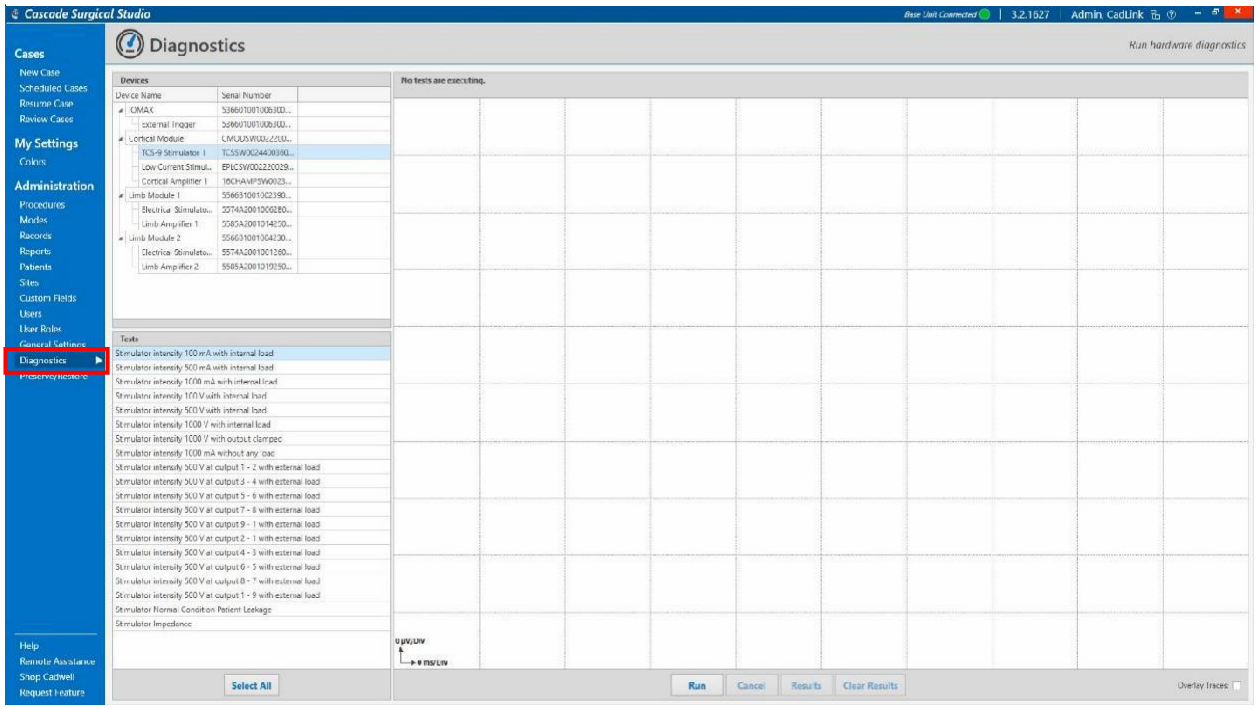
To set up report templates, open Cascade Surgical Studio. On the start screen, click “Reports” in the left toolbar under Administration. To create a new report, click the “New” button to add a report. Enter a report name, and click the OK button. A Microsoft Word document with the Cascade Template Editor Controls will open. Use the Template Editor to develop a template.

Hardware Diagnostics

Prior to performing a procedure, run calibration verification and system diagnostic. Inspect all cables and accessories before and after each use. Discard cable if insulation is damaged or if the cable or connectors are damaged in any manner.

If the equipment is out of calibration, or if system diagnostic shows any failure/error, return the equipment and/or accessories to Cadwell Service Department.

Diagnostics can be accessed via the Surgical Studio start page. Under Administration, click Diagnostics to open the window. In the image below, no tests are running. Refer to the Field Operational Guide (PN 100880-601) for more information.



Test Types

Several different types of amplifier and stimulator diagnostic tests can be run from this window. The type of test is selected from the menu in the upper left-hand corner. Hold Ctrl to multi-select tests or click Select All to choose all tests. Once the type of test has been selected, click on Run Tests to perform the test(s). To view the results of the test, click on the Report button.

Gain

A 100 Hz sine wave is run through the three amplifier gain stages of 100, 1000, and 10,000 uV/div. The peak to peak amplitude of the signal is taken from 10 different sweeps and averaged. The resulting amplitude must be within +/- 10% in order to pass.

Low Cut

A sine wave is run through the amplifier hardware low cut filters. The test checks to see that the amplitude of the calibration signal is 50% reduced at the filter frequency. The peak to peak amplitude of the signal is taken from 10 different sweeps at each low cut setting and is averaged. The amplitude of the signal must be within +/- 15% in order to pass.

High Cut

A sine wave is run through the high cut filter setting. The test checks to see that the amplitude of the calibration is 50% reduced at the filter frequency. The peak to peak amplitude of the signal is taken from 10 different sweeps and is averaged. The amplitude of the signal must be within +/- 30% in order to pass.

Noise

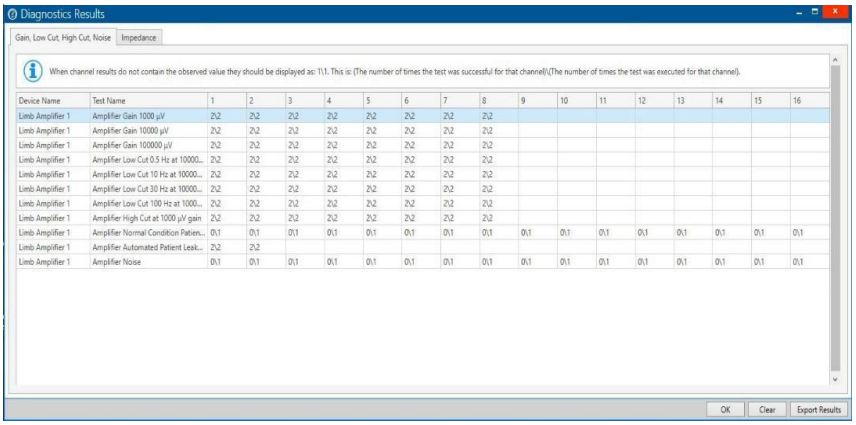
In this test all active and reference inputs are connected internally to ground and the maximum peak to peak amplitude of the noise over several sweeps is calculated. This is a two-part test with measurements being taken in both EMG and an EP modes. The noise level in each channel should be less than 5 uV in order to pass.

Impedance

A special impedance array is used for this test. This array is plugged into each extender pod input and the values are checked against known inputs. A different resistance value is used for each input. As each row is checked the impedance values for the inputs in that row are displayed and are colored green when they pass the test.

Diagnostics Report

When finished with running the Tests, click on the Results button at the bottom of the Diagnostics page.



A new Diagnostics Results window will open. All test results will be displayed in this window. The results for the Gain, Low Cut, High Cut, and Noise tests are listed on the first tab; the Impedance tab shows the results for the impedance test.

The repeat count indicates how many times the test was run and the number listed for each channel indicates how many times that channel passed the test. A reading of –1 indicates the test was not performed. A reading in the channel columns less than the repeat count indicates that the test failed at least once.

Regulatory Information

Cascade IOMAX meets the following internationally recognized safety standards or Medical Electrical Equipment:

AAMI ES 60601-1: 2005 + A1; A2

IEC 60601-1, Edition 3.1, 2012 Medical Electrical Equipment, Part 1

IEC 60601-1-2, Edition 4.0, 2014

EMC test requirements for Medical equipment IEC 60601-2-40, Edition 2.0, 2016 Particular requirements for EMG/EP Devices

IEC 60601-2-26, Edition 3.0, 2012 Particular requirements for Encephalographs

ISO 80601-2-61:2011 Particular requirements for pulse oximeter equipment

IEC 62304, Edition 1.0, 2006 Medical Device Software, Software life cycle processes

ISO 14971: 2007 Application of risk management to medical devices

IEC 60601-1-6, 2010 Usability

Usability IEC 62366, 2010 Application of Usability Engineering to Medical Devices

Regulatory Classification United States: Class II European Union: IIa Canada: Class II

Type of Protection Against Electric Shock: Class I Equipment (Grounded)

Patient Connection Degree of Protection Against Electric Shock: Type BF Equipment (Floating connection)

Degree of Protection Against Ingress of Dust and Liquids: IP67 (Dust and water)

Mode of Operation: Continuous

Essential Performance

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

IOMAX system must deliver electrical stimulation as described in IEC 60601-2-40 without unintended stimulation.

The IOMAX 16 Channel amplifier shall comply with all the essential performance requirements as stated in IEC 60601-2-6:2012

l 201.12.1.101.1 Accuracy of signal reproduction

l 201.12.1.101.2Input dynamic range and differential offset voltage

l 201.12.1.101.3 Input noise

l 201.12.1.101.4 Frequency response

l 201.12.1.101.5 Common mode rejection

The IOMAX system shall comply with all the essential performance requirements as stated in ISO 80601-2-61, Sub-clause 201.12.1 Accuracy of pulse oximeter (SpO_2, Pulse Rate accuracy)

TheSpO_2accuracy of pulse oximeter shall be a root-mean-square difference of less than or equal to 4.0

% SpO_2 over the range of 70 % to 100 % of SaO2. Accuracy determination shall be in accordance with ISO 80601-2-61, sub-clause201.12.1.101.1

Pulse rate accuracy shall be stated as the root-mean-square difference between paired pulse rate data recorded with the pulse oximeter equipment and with a reference method. Accuracy shall be determined in accordance with ISO 80601-2-61, sub-clause201.12.1.104

Safety Information

General Warnings and Contraindications

⚠	WARNING: U.S. Federal law restricts the use of this system by, or under the supervision of, a physician.	⚠	WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth ground.
⚠	WARNING: The Base Module is not waterproof. Do not immerse the Base Module, VEP goggles, auditory simulators, or any other system accessories in liquid. The Cortical Module, Limb module and SafeT® connection cables are rated IP67 (Dust tight, Water Immersion up to 1m). Stop using equipment in the event of fluid ingress.	⚠	WARNING: Misapplication of a pulse oximeter sensor with excessive pressure for prolonged periods can induce pressure injury.
⚠	WARNING: Wrapping or covering the Cascade IOMAX modules may cause excessive heat buildup leading to module failure.	⚠	WARNING: Only Cadwell approved pulse oximeter sensors and connection cables may be used.
⚠	WARNING: 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.	⚠	WARNING: No part of the equipment shall be serviced or maintained while in use with a patient.
⚠	WARNING: 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 block for displacement.	⚠	WARNING: The IOMAX oximeter functionality is not intended to be used as a critical care decision device. It acquires secondary oximetry data for long-term analytical decisions and is intended to be used in combination with IONM acquired data.
⚠	WARNING: 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.	⚠	WARNING: Inspect the LCSwap enclosure for physical damage prior to use. Discontinue use if physical damage to the device is found.

⚠	WARNING: 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 IOMAX system, contact Cadwell or a Cadwell authorized agent.	⚠	WARNING: Discontinue the use of the LCSwap if the female connector for the cable connecting the LCSwap to the Cortical Module is loose.
⚠	WARNING: The manual provides an operational summary for the Cascade IOMAX system. It does not provide clinical training. The user must have adequate clinical training to perform procedures.	⚠	WARNING: Two (2) bed rail brackets (PN 339100-000) are provided as standard with each Cortical and Limb Module. Use two brackets per module when hanging.
⚠	WARNING: Place system components where they are safe from contact with spilled fluids.	⚠	WARNING: The TCS-9 is capable of delivering high levels of electrical stimulation. Implanted biomedical devices should be disabled or used with caution during TCS-9 stimulation.
⚠	WARNING: Amplifier inputs are Type BF rated. BF rating ensures that no current higher than 50µA flows to or from the applied part if mains voltage is inadvertently connected to the patient.	⚠	WARNING: Review TCS-9 amplitude-pulse train safety chart in the IOMAX user manual prior to performing transcranial MEPs.
⚠	WARNING: Patient movement may occur during stimulation leading to inadvertent neural injury. Take adequate steps to avoid stimulation when patient movement could cause injury.	⚠	WARNING: For best performance, TCS intensity levels above 25V or 25 mA are recommended. Below 25 V or 25 mA, use the Limb Module Estim, or the Cortical Module Low Current Stimulator below 20 mA.
⚠	WARNING: Avoid accidental contact between electrodes connected to patient and other conductive parts, including earth ground.	⚠	CONTRAINDICATION: Items related to off label use or misuse.
⚠	WARNING: The system is designed to be used on one patient at a time. Do not connect multiple patients to one amplifier.	⚠	CONTRAINDICATION: The system is not defibrillator proof and should be disconnected from the patient for use of a defibrillator.
⚠	WARNING: Adhere to the cleaning instructions. Do not clean Cascade IOMAX before turning off the Base Module and disconnecting all Cascade IOMAX components. Always	⚠	CONTRAINDICATION: The system is not designed to operate in an explosive environment or in the presence of flammable

	disconnect equipment from the power source and patient before cleaning.		anesthetics.
⚠	WARNING: The Cascade IOMAX system does not incorporate means to protect the patient against burns when used with high frequency equipment.	⚠	WARNING: Make sure the neutral electrode of the high frequency device is properly placed and making proper contact. Please refer to the high-frequency surgical equipment's user documentation for instructions for use.
⚠	CONTRAINDICATION: Avoid trans-thoracic stimulation.	⚠	WARNING: Operation in close proximity to a shortwave or microwave therapy equipment may produce instability in the APPLIED PARTS
⚠	WARNING: Avoid accidental contact between electrodes connected to the IOMAX, but not connected to the patient, and other conductive parts, including those connected to protective earth.	⚠	WARNING: The IOMAX system does not have alarms for SpO2 or pulse rate.
⚠	WARNING: Pulse oximetry probe is not sterile. Do not reuse. If reused it may not provide accurate information.	⚠	WARNING: Use only Cadwell recommended pulse oximeter sensor. Use of other sensors will result in degraded performance or incorrect results.
⚠	WARNING: Excessive movement may cause interference or affect accuracy of the SpO_2 measurement.	⚠	WARNING: Per the sensor manufacturer, circulation distal to the pulse oximetry sensor site should be checked routinely. The site must be inspected every 8 hours to ensure adhesion, skin integrity and correct optical alignment. If skin integrity changes, move sensor to another site.
⚠	WARNING: The IOMAX system components (Base Module, Cortical Module, Limb Module, 32 Channel Amplifier and connecting cables) are not intended to be patient contact devices.		

Cascade® Surgical Studio™ is not intended for intraoperative lateral trans-psoas monitoring (ILTM) using automatic threshold detection. Cadwell disclaims and does not support any use of the Cascade® Surgical Studio™ for ILTM.

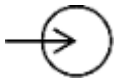
Preventive Maintenance

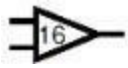
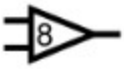
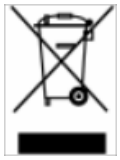
- Inspect cables and connectors before and after each use. Discard and replace cable if insulation is damaged or if the cable connectors are loose or damaged in any manner.
- Preventative maintenance never involves access to the interior of the IOMAX system. It involves regular inspection and cleaning of IOMAX components.
- Perform cleaning and disinfection procedures on a periodic basis to ensure the safe operation of your Cascade IOMAX system. Refer to section titled Cleaning Instructions for more information.
- Do not try to service unit. Service is to be done by Cadwell and Cadwell-authorized agents only. No modification of this equipment is allowed. Do not attempt to service or repair damaged or inoperable equipment.

Factory Calibration

- Device calibration can be verified by the user with Hardware Diagnostics. Refer to section titled Hardware Diagnostics for more information.
- It is recommended to have the Cascade IOMAX system calibrated annually. The IOMAX system is calibrated by Cadwell or a Cadwell-authorized agent. No additional hardware calibration is needed.
- Pulse oximeter equipment is calibrated to display functional oxygen saturation.

Symbols

Symbol	Title / Meaning	Reference
	Attention, consult accompanying documents.	ISO 7010-M002
	Warning, electricity	ISO 7010-W012
	Power ON	IEC 60417-5007
	Power OFF	IEC 60417-5008
	Equipotentiality	IEC 60417-5021
	Type BF equipment. Isolated patient connection.	IEC 60417-5333
	Input	IEC 878
	Output	IEC 878
	Plus - positive polarity	IEC 878
	Minus - negative polarity	IEC 878
	Headphone	IEC 417
	Goggles	Cadwell convention

	16-channel Amplifier	Cadwell convention
	8-channel Amplifier	Cadwell convention
	Isolated (floating) Ground	Cadwell convention
	USB 2.0 Symbol	KEMA Medical
	Waste Electrical and Electronic Equipment Do not throw in standard garbage. Recycle or dispose of equipment according to regulatory requirements of your country.	WEEE
	No SpO2 Alarms	IEC60417-5319
	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)	Intertek
	Fragile Medical Equipment Do Not Drop	Cadwell convention (Device Packaging)
	Humidity Range 10% to 95% Non-Condensing	Cadwell convention (Device Packaging)

Date of Manufacture

The year and month of manufacture, format YYYY-MM, can be derived from the device serial number found on the IOMAX device label(s) as follows:

XXXXXX|XX|X|X|XX|XX|XXX

For example, the following serial number equates to date of manufacture 2016-03 (YYYY-MM):

XXXXXX|XX|X|X|03|16|XXX

Cleaning Instructions

⚠ Always disconnect all components from power before cleaning.

Perform cleaning and disinfection procedures on a periodic basis to ensure the safe operation of your Cascade IOMAX system. As you clean, visually inspect the instrument and its components for damage or wear. Contact Cadwell if you note 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 at800-245-3001.

While the Cascade IOMAX 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. Keep all connector soft caps installed when connectors are not being used (soft caps keep debris and fluids out of connectors when not being used). 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

General Cleaning/Disinfection Recommendations:

1. Disinfect IOMAX modules that may have had contact with mucous membranes or non-intact skin with a high-level disinfectant (e.g. Cidex, Metricide, or Resert).
2. Consult with your facility's infection control policies for guidance in selecting the appropriate disinfection products. Non-corrosive disinfecting agents are preferred.
3. Module cables and modules that come in contact with intact skin but not mucous membranes may be disinfected with an intermediate-level surface disinfectant (e.g. Envirocide, MetriGuard, or Cavi Wipes).
4. Follow product specific disinfectant instructions found on disinfectant labels.
5. For maximum product life, do NOT expose IOMAX system components to prolonged soaking or cleaning with corrosive agents (e.g. bleach water).

Cortical Module and Limb Modules

The Cascade IOMAX cortical and Limb Modules are waterproof to 1 m (with or without the connector soft caps installed). Do not remove or loosen any exterior screws on the modules. Cortical and Limb Modules as supplied by Cadwell may be submerged for cleaning as required. If Cortical or Limb modules are submerged for cleaning, make certain the modules are fully dried prior to reuse.

Prior to clean/disinfection of the Cortical and Limb Modules:

- Remove all cable connections and install all connector caps to protect connector pins.
- The Cascade IOMAX Cortical and Limb Modules have removable bumpers. These may be removed for separate cleaning if required.
- Turn off and disconnect all Cascade components, stimulators, cables and power source.

To disinfect/clean the Cortical and Limb Modules:

- Dust may be removed with a dry or slightly damp soft cloth, a pressurized air duster, or a soft brush.
- To clean/disinfect the Cortical and Limb Module of dried-on matter, see recommendations above. Since these modules are manufactured to be waterproof, soaking the module in a mild soap and water solution prior to wipe-down, or scrubbing with a soft bristled brush is also an acceptable means of cleaning/disinfecting.
- As you clean, visually inspect the modules and their components for damage or wear.
- Contact Cadwell if you notice damage to the exterior of the modules.

Base Module

NOTE: The Base Module is not waterproof, and as such cannot be submersed during cleaning. Prior to cleaning/disinfection of the Base Module

- Remove all cable connections and install both connector caps to protect connector pins.
- Base Module Bumpers are user removable and may be removed as needed for cleaning.
- Turn off and disconnect all Cascade components, stimulators, cables and power source.

To clean the Base Module:

- Dust may be removed with a dry or slightly damp soft cloth, a pressurized air duster, or a soft brush.
- To clean off dried-on matter, wipe down the exterior per the recommendations above.
- As you clean, visually inspect the Base Module and its components for damage or wear.
- Contact Cadwell if you notice damage to the exterior of the module.

Cables and Accessories

- Visually inspect each item for unusual wear or damage prior to each use. If you notice damage, disconnect the item immediately, and contact Cadwell.
- Use a soft clean cloth to clean stimulator parts that come in contact with the patient after each use (e.g., electrical stimulator probes, insert earphone cables and LED goggles).

Disposal of Equipment

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

Please dispose of equipment under 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).

Intended Conditions of Use

Environment

General

- Intended for professional healthcare environment, not intended for home use
- Hospital operating room, ICU, patient room, 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

- Ambient temperature between 50°F and 95°F / 10°C and 35°C
- Relative humidity of 10 to 95 percent non-condensing
- Atmospheric pressure between 700 hPa and 1060 hPa
- Input power: 100-240VAC 50-60Hz 150VA max

Frequency of Use

- Once a day up to 10 times a day on various patients

Mobility

- For use on stationary table or cart
- Not for use during transport

Transportation & Storage Limits

- Do not expose to temperatures below -4°F (-20°C) or Above 149°F (65°C).
- Do not expose to relative humidity below 10 percent or above 90 percent (non-condensing).
- Do not expose to atmospheric pressures below 500 hPa or above 1060 hPa.

Intended User

Education and Training
Minimum: Physician or technician who has had special training in evoked potentials, EEG, nerve conduction and EMG studies. The patient is not the user of the device.
Maximum: None

Knowledge
Minimum: Electrophysiology, including instrumentation, quantification, and statistical analysis.
Maximum: None

Language Understanding
English is required for user manuals, setup guides, etc. Translations of the user interface and user manual will be supported for major languages.

Experience
Minimum: Trained in evoked potentials, EEG, nerve conduction and EMG studies.
Maximum: None

Permissible Impairments
- Mild reading vision impairment or vision corrected to log MAR 0.2 (6/10 or 20/32)
- One arm/hand capable of holding mouse and placing electrodes
  Impaired by 40% resulting in 60% of normal hearing at 500 Hz to 2 kHz

Measurement & Stimulation Sites

Parts of the body or types of tissue applied to or interacted with (IEC 62366 5.1) are as follows:

Measurement/Stimulation Sites:

- Cortical
- Peripheral

Condition:

- Intact skin within and around electrode site when surface electrodes are used
- Punctured skin when subdural electrodes are used
- Intact skin over Oximeter sites

Electromagnetic Compatibility

6.8.2.201 a1) This medical electrical equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided below.

6.8.2.201 a2) Portable and Mobile RF communications equipment can affect medical electrical equipment.

6.8.3.201 a1) List of cables and accessories.

Base module – 190291-200	Insert Earphone Cable - 199291-200
Limb module - 190295-200	Insert Earphones – 198235-000
Cortical module - 190296-200	LED Goggles – 199289-200
Low Current Interface Cable - 362061-000	SpO2 Oximeter Sensor - 304000-000
8m Extender SafeT™ Cable - 199284-200	Trigger In / Trigger Out Cable - 286093-000
0.5m SafeT™ Cable - 362058-000-005	Hospital Grade Y Power Cable - 286081-000
1m SafeT™ Cable - 362058-000-010	1 m USB Cable – 355336-200
2m SafeT™ Cable - 362058-000-020	
3m SafeT™ Cable - 362058-000-030	
4m SafeT™ Cable - 362058-000-040	

6.8.3.201 a2) Use of accessories and cabling other than those specified in 6.8.3.201 a1 above, with the exception of those sold by Cadwell as replacement parts, may result in increased emissions or decreased immunity of Cascade IOMAX systems.

6.8.3.201 a3) Table 201- electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
Cascade IOMAX IOM system is intended for use in the electromagnetic environment specified below. The customer or the user of the Cascade IOMAX should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	Cascade IOMAX uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Group 1 Class A	The Cascade IOMAX system is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purpose. 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 IOMAX, 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 Cascade IOMAX system is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purpose.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	Cadwell declares the Cascade IOMAX does not produce voltage fluctuations or flicker emissions.

6.8.3.201 a4) The Cascade IOMAX system should not be used adjacent to or stacked with any other equipment. If adjacent or stacked use is necessary, performance of the Cascade IOMAX should be observed to verify normal operation in the con- figuration in which it will be used.

6.8.3.201 a5) Immunity justification

Refer to EN60601-1-2 test report summaries above.

6.8.3.201 a6) Table 202 –electromagnetic immunity.

Guidance and manufacturer's declaration – electromagnetic immunity			
Cascade IOMAX systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Cascade IOMAX should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+2 kV contact ±8 kV contact ±15 kV air	+2 kV contact ±8 kV contact ±15 kV air	Electrostatic discharge at ANY level will produce noise glitches on the Cascade IOMAX 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 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±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 commercial or hospital environment.
Surge IEC 61000-4-5	±2 kV common mode	±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 commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % di in UT) for 5 sec	Complies atall line input voltages Complies at 240 V 50 Hz. Turns off at 120 V 60 Hz. Complies at all line input voltages Cascade IOMAX turns off. Restart of software required.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cascade IOMAX requires continued operation during power mains interruptions, it is recommended that the Cascade IOMAX be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field	30 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

6.8.3.201 b) Table 204 –electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
Cascade IOMAX IOM systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Cascade IOMAX should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V 1 = 3 Vrms	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.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E 1 = 3 V/m	Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz 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	Table 9 Limits	All applicable limits from Table 9	Immunity to proximity fields from RF wireless communications equipment. Frequencies 385 MHz to 5,785 MHz.

9, IEC 60601-1- 2:2014			
Note 1 At 80 MHz and 800 MHz, the higher frequency applies. Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Cascade IOMAX is used exceeds the applicable RF compliance level above, the Cascade IOMAX should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Cascade IOMAX. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [v1] V/m.			

6.8.3.201 b) Table 204 –electromagnetic immunity

Recommended separation distances between portable and mobile RF communications equipment and the Cadwell Cascade IOMAX			
The Cascade IOMAX IOM system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cascade IOMAX can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cascade IOMAX 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 Cascade IOMAX. However, some noise may present on displayed waveforms.			

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.

Call the customer support number, and ask for the service department or application support, as applicable to your problem. In either case, the Cadwell support staff will work with you to solve the problem, will determine if an exchange or repair of parts is necessary, and will instruct you on appropriate shipping arrangements as applicable. Please decontaminate equipment as applicable before returning it to Cadwell.

Be Prepared

Have your customer identification number and product serial number available. Be prepared to speak to a service technician and provide an accurate description of the problem. It is best if the person calling already has the equipment before them when they call.

If you have equipment hardware failure, call the customer support number and ask for the service department Ask for Applications Support when having software-related problems. The Cadwell service technician will determine if an exchange or repair of parts is necessary and instruct you on appropriate shipping arrangements.

Support and Warranty Information

Refer to Cadwell document part number 829001-000 New Equipment 1-Year Warranty and Service Information that shipped with your system for details.

Domestic Customers

Telephone: 1-800-245-3001

Telephone: +1 509-735-6481

Fax: +1 509-783-6503

applications@cadwell.com service@cadwell.com

Monday - Friday Pacific Standard Time (PST)

During surgery, support is available. Operating Room (OR) Support: 4:00 a.m. – 5:00 pm

Service Support: 6:30 a.m. – 5:00 p.m. for device-related issues.

Application Support: 6:30 a.m. – 5:00 p.m. for software-related troubleshooting.

International customers

Please contact your distributor or email 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 for Customer Support. A support or service technician will verify your account information and guide you through the steps to begin a remote assistance session.

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 Cadwell www.estore.cadwell.com

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

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