

Cascade IOMAX System Specifications

The Cascade® IOMAX® system is a device intended for use for intraoperative neurophysiological monitoring and for clinical evoked potential studies.

The IOMAX® system consists of:

- Base Module
- Cortical Module
- Up to 4 Limb Modules
- SafeT™ Cables (to interconnect Modules)
- Cascade® Surgical Studio software
- Computer

The IOMAX® system supports up to:

- 80 amplifier channels
- 20 100 mA Electrical Stimulator outputs
- 4 Pulse Oximeters
- 9 Transcranial Stimulator outputs
- 1 Low Current Electrical Stimulator with optional LCSwap® switch matrix
- 1 Auditory Stimulator
- 1 Visual Stimulator
- Quick Adapts for electrode inputs and outputs



Base Module Specifications

Computer Interface	USB 2.0, high speed
Outputs	2 SafeT ports
Trigger Inputs	2 TTL compatible ports (selectable rising or falling edge trigger)
Trigger Outputs	2 TTL compatible ports (multiple pulse durations, positive or negative polarity)
System Electrical	Mains Voltage: 100-240 VAC Mains Frequency: 50-60 Hz Max Power Consumption: 150 VA
Dimensions	6.5" L x 5.2" W x 2.8" H (16.5 x 13.3 x 7.1 cm)
Weight	2.0 lbs (0.9 kg)
Other Features	• Color coded connections • Shock absorbing bumpers • Equipotential ground

Surgical Studio Software Features

- Multi-modality Monitoring (SSEP, MEP, BAEP, VEP, EMG, TEMG, EEG, TOF, DWave, Video, DCS, Pulse Oximetry)
- Trigger In and Out support for interfacing with 3rd party devices
- Multiple stimulation techniques (high rep pulse train, asymmetric double pulse train, peripheral nerve facilitation)
- Automatic stim interleaving
- Impedance display for confirming good contact between electrode and patient for both inputs and outputs
- Streaming audio from channels
- EEG CSA and DSA trending displays for frequency analysis
- MS Word®-based reports
- Review of records (live or off-line)
- Real-time remote monitoring with independent display configuration
- Integrates with CadLink™ HL7® Interface and CadSchedule®
- Waveform Data Output for external research and analysis
- Create and share templates for procedures, modes, and reports
- Integrated hardware diagnostics
- Number of averages per channel: 1 to 10,000
- Averager sensitivity: 0.01 μ V/div to 10 mV/div



Cortical Module Specifications

The Cortical Module consists of an integrated:

- Amplifier
- Transcranial Stimulator
- Low Current Electrical Stimulator
- Auditory Stimulator
- Visual Stimulator

The Cortical Module features:

- Integrated ESU detection
- Waterproof-design up to IP67
- Shock-absorbing bumpers
- Quick mounting of hardware directly on the operating table
- Color coded connection with protected pins



16 Channel Amplifier

Total Inputs	19 inputs (13 referential and 3 differential channels)
Noise (10-3000 Hz)	< 1 μV_{RMS}
Input Impedance	10 M Ω
Sampling Rate	25 kHz
Common Mode Rejection Ratio (CMRR)	> 115 dB
A/D Conversion	16-bit
Notch Filter	50 or 60 Hz
Anti-aliasing Filter	> 40 dB
Maximum Input Range	1 to 100 mV _{pp} (depending on gain)
Frequency Range	0.3 Hz to 5 kHz
Impedance	Measurement of all inputs

Auditory Stimulator

Stimulus Type	Square wave clicks
Stimulus Range	70 to 125 dB peak SPL
Stimulus Polarity	Rarefaction, condensation, or alternating
Stimulus Duration	100 μs
Presentation	Left, right, or bilateral
Repetition Rate	0.5 to 40 Hz (depending on sweep speed and interleave setup)
Audio Transducer	TDH-39 response, 10 Ω insert earphones
White Noise Masking	Contralateral masking from 0-60 dB below stimulus level

Transcranial Electrical Stimulator

Total Outputs	9 outputs (each independently software selectable as anode or cathode)
Output Control Mode	constant voltage or constant current (user selectable)
Stimulus Polarity	Positive, negative, bi-phasic
Voltage Range	0, 50 to 1000 V, 1.0 V steps
Current Range	0, 50 to 1500 mA, 1.0 mA steps
Pulse Duration	50 to 500 μs (based on maximum energy per pulse)
Maximum Electrical Output Energy	50 mJ/pulse into 1 k Ω impedance
Repetition Rate	Up to 2 Hz
Pulse Train Limits	Up to 9 pulses
Interstimulus Interval	1.0 to 9.9 ms
Impedance	Measurement of all outputs

Low Current Electrical Stimulator

Output Control Mode	Constant current
Stimulus Polarity	Positive, negative, bi-phasic
Voltage Range	± 50 V (max)
Current Range	± 0.01 to 20 mA (0.01 mA steps)
Pulse Duration	50 to 1000 μs (based on maximum energy per pulse)
Maximum Electrical Output Energy	0.22 mJ/pulse into 1 k Ω impedance
Repetition Rate	Up to 60 Hz (depending on sweep speed and interleave setup)
Accessories	Low current Interface cable (1 output pair) LCSwap [®] (1 output pair chosen from 12 outputs selectable as anode or cathode; 2 output pairs for probe connections; 1 smart probe connection)



Visual Stimulator

LED Goggles	Red flash, 5 ms duration
Presentation	Left, right, or bilateral
Repetition Rate	0.5 to 15 Hz (depending on sweep speed and interleave setup)

Mechanical

Connections	Five SafeT [™] outputs One SafeT [™] input
Patient Connection Type	1.5 mm touchproof
Dimensions	9.97" L x 8.48" W x 2.38" H (25.3 x 21.5 x 6.0 cm)
Weight	6.0 lbs (2.7 kg)

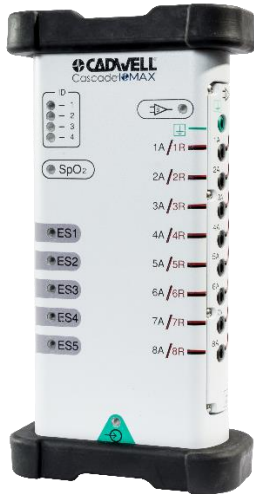
Limb Module Specifications

The Limb Module consists of an integrated:

- Amplifier
- 100 mA Electrical Stimulator
- Pulse Oximeter

The Limb Module features:

- Integrated ESU detection
- Waterproof-design up to IP67
- Shock-absorbing bumpers
- Quick mounting of hardware directly on the operating table
- Color coded connection with protected pins



Pulse Oximeter

Probe	Cadwell disposable probe type (PN: 304000-000)
SpO ₂ Range	70 to 100%
SpO ₂ Accuracy	Arms: $\leq \pm 3\%$ (within SpO ₂ range)
Pulse Rate Range	20 to 250 BPM
Pulse Rate Accuracy	± 3 beats
Mode of Operation	Continuous

Mechanical

Connections	One SafeT™ input
Patient Connection Type	1.5 mm touchproof
Dimensions	9.97" L x 4.82" W x 2.38" H (25.3 x 12.2 x 6.0 cm)
Weight	3.35 lbs (1.5 kg)

32-Channel Amplifier Module Specifications



8-Channel Amplifier

Total Inputs	16 inputs (8 differential channels)
Noise (0.5-1000 Hz)	$< 1 \mu V_{RMS}$
Input Impedance	10 M Ω
Sampling Rate	25 kHz
Common Mode Rejection Ratio (CMRR)	> 115 dB
A/D Conversion	16-bit
Notch Filter	50 or 60 Hz
Anti-aliasing Filter	> 40 dB
Maximum Input Range	1 to 100 mV _{pp} (depending on gain)
Frequency Range	0.5 Hz to 10 kHz
Impedance	Measurement of all inputs

100 mA Electrical Stimulator

Total Outputs	5 output pairs
Output Control Mode	Constant current
Stimulus Polarity	Positive or negative
Voltage Range	400 V (max)
Current Range	2 to 100 mA, 0.01 mA steps
Pulse Duration	50 to 1000 μ s
Maximum Electrical Output Energy	50 mJ/pulse into 1 k Ω impedance
Repetition Rate	Up to 100 Hz (depending on sweep speed, pulse duration, and interleave setup)
Impedance	Measurement of all outputs

Total Inputs	32 inputs (32 referential channels)
Noise (0.3-100 Hz)	$< 1 \mu V_{RMS}$
Input Impedance	> 100 M Ω
Sampling Rate	2 kHz (all channels) 8 kHz (8 channels only)
Common Mode Rejection Ratio (CMRR)	> 110 dB
A/D Conversion	24-bit
Notch Filter	50 or 60 Hz
Anti-aliasing Filter	> 40 dB
Maximum Input Range	1.5 to 35 mV _{pp} (depending on gain)
Frequency Range	0.3 Hz to 500 Hz
Impedance	Measurement of all inputs
Connections	One SafeT™ input
Patient Connection Type	1.5 mm touchproof
Dimensions	7.26" L x 3.83" W x 1.25" H (18.4 x 9.7 x 3.2 cm)
Weight	0.5 lbs (0.23 kg)
Other Features	• Integrated ESU detection • Separate reference from Cortical Module • Color-coded input connection • Connection loop for chain • Water resistant

SafeT™ Cable

- Connects from Module to Module
- Interchangeable between all modules
- Durable, color-coded connections with protected pins
- Waterproof
- Lengths: 3 meter and 8 meter



Optional Software

- CadLink™ Server (remote monitoring and centralized storage of patient records, reports, users, and settings)
- CadLink™ HL7® Interface (EMR connectivity)
- CadSchedule® (scheduling appointments)

Optional Hardware

- Camera
- Cart
- Carry Case
- Isolation Transformer

System Operating Limits

- Temperature: 10°C (50°F) to 35°C(95°F)
- Humidity: 30% to 95%, non-condensing
- Pressure: 700 to 1060 hPa

Transport and Storage Limits

- Temperature: -20°C (-4°F) to 65°C (149°F)
- Humidity: 10% to 95%, non-condensing
- Pressure: 500 to 1060 hPa

Computer / Isolation Transformer Requirements

- Refer to Cadwell document 308014-000 for the latest minimum computer requirements based on current software requirements.
- Refer to Cadwell document 309002-000 to determine if an isolation transformer is required.

Regulatory

Classification Information

- United States: Class II
- Canada: Class II
- European Community: Class IIa

Type of Protection Against Electric Shock

- Class I Equipment (with Safety Ground)

Classification of Patient Connections

- Type BF Equipment (Floating Inputs)

Mode of Operation

- Continuous

System International Safety Standard Compliance

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

- IEC 60601-1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2: Collateral Standard –Electromagnetic Compatibility
- IEC 60601-2-26: Particular requirements for the basic safety and essential performance of encephalographs
- IEC 60601-2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
- IEC 60601-1-6: Collateral Standard: Usability
- IEC 62366: Application of usability engineering to medical devices
- IEC 62304: Medical device software life-cycle processes
- ISO 80601-2-61: Particular requirements for pulse oximeter equipment

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