Nexstim

eXimia TMS Specifications

Stimulation

Nexstim eXimia TMS stimulator and coils are only intended to be used with the Nexstim eXimia NBS (Navigated Brain Stimulation) System for transcranial magnetic stimulation (TMS). As part of the NBS System, eXimia TMS is the only commercially available solution able to provide precise, defined stimulation intensity, and reproducibility for diagnostic clinical and research applications. eXimia TMS offers:

- **Single mobile stimulator unit offering stimulation modes for all standard TMS examinations**
  - Single pulse TMS
  - Paired-pulse TMS (Monophasic pulses)
  - Repetitive TMS
  - Biphasic and Monophasic pulse types
- **Powerful and highly focal electric field (hot spot) for precise, local stimulation**
  - Coil design optimized for field strength and focality
  - Stimulator unit electronics designed for stability, accuracy and precise control of output
- **Single operator use through integrated EMG monitoring and response control (requires eXimia EMG license)**
- **Excellent user ergonomy with upward positioned handles on the coils and foot switch triggering**

Components
1 Stimulator
2 Coil
3 Stimulator controls
4 TMS software

eXimia TMS Components

TMS Software License for eXimia NBS

- Controls for stimulator unit integrated into user interface for eXimia NBS System
- Automatic coil type recognition and temperature control
- Single Pulse and Paired Pulse: stimulus intervals fixed or randomized (range: minimum 500 ms (1500 ms with EMG in use), maximum 10000 ms)
- Paired Pulse: adjustable interval between two pulses (range: 2 ms - 100 ms, in 1 ms steps)
- rTMS: adjustable number of stimuli and frequency (range: 1 Hz - 10 Hz, in 1 Hz steps)

System-guided stimulation intensity adjustment
- System allows user to adjust stimulator output (% of maximum) to correspond to electric field intensity (V/m)
- Display of calculated intracranial electric field intensity (peak field and field distribution) and field direction for targeting and adjustment of stimulation

TMS Hardware

Mobile Stimulator Unit

Stimulation Modes: Single pulse, Paired-pulse (monophasic pulses), rTMS
- Paired-pulse TMS with monophasic pulse shape: adjustable in 1 ms intervals, interval range 2 - 100 ms
- Biphasic: maximum 10 Hz at 50% of maximum stimulator output intensity, 4 Hz at 100% intensity
- Monophasic: maximum 8 Hz at 50% of maximum stimulator output intensity, 3.3 Hz at 100% intensity
- rTMS pulse repetition rate up to 10 Hz at typical motor threshold (healthy subject)
- rTMS burst: number of pulses adjustable, range 1 - 500 (NBS control will stop the burst automatically if temperature limit is exceeded)

Accurate Stimulus Control and Delivery
- Intensity variation +/-1% in repeated stimulation (temperature dependent)
- Pulse timing (post triggering) <0.1 ms
- Stimulator charging time adjustable, range 2 ms - 1000 ms, in 1 ms steps

Trigger and Synchronization Input/Output Lines
- Trig In: single stimulus pulses or pulse sequences
- Gate Out: for synchronizing of EEG or EMG device (pulse 0.1 ms delayed)
- Sync Out: indicates time of stimulation
- Trig1 Out and Trig2 Out: synchronizing of external devices to stimulation pulses, user defined delay in respect to stimulation pulse, adjustable trigger delay value between -4900 ms and 4900 ms in 1 ms steps
- Trigger inputs: pulse width >10 µs, pulse amplitude 3-5 V TTL and CMOS levels accepted, input impedance ~10 kΩ, positive polarity
- Trigger outputs: pulse width ~10 ms, pulse amplitude 5 V TTL, output impedance ~250 Ω, positive polarity

Dimensions (Stimulator Unit Cabinet)
- Height 98 cm (38.6 in), Width 72 cm (28.3 in), Depth 68 cm (26.8 in), Weight ca. 140 kg (308 lbs)

Power Supply Electrical Specifications
- Mains voltage 220 - 240 VAC, 50 - 60 Hz
- Maximum power consumption 2300 VA peak
- Standby power consumption 400 VA
- Fuse 2 x T 10.0 A 250 VAC

General Features of Coils
- Precision manufactured figure 8-shaped coils, windings positioned within 0.55 mm/0.2 degree accuracy
- Coils designed with upward positioned handle to facilitate easy rotation and positioning
- Coils assembled with integral trackers: 4 elements, each with 3 markers
- Number of stimulations before warm up (in accordance with IEC60601-1, initial coil surface temperature 23°C (73.4°F), final coil surface temperature 41°C (105.8°F) maximum):
  100% output, 0.25 Hz, maximum number of TMS pulses ~ 90
  (~ 80 for Focal Monopulse coil)
  75% output, 0.25 Hz, maximum number of TMS pulses ~ 180
  50% output, 0.25 Hz, maximum number of TMS pulses ~ 360
- Coil external dimensions: Height with coil handle 19.0 cm (7.5 in), Width 15.9 cm (6.3 in), Depth 8.7 cm (3.4 in)

Focal Bipulse 8-Coil
- Mean winding diameter ca. 50 mm (2 in), outer winding diameter ca. 70 mm (2.8 in)
- Biphasic pulse shape, ca. 280 µs pulse length
- Maximum stimulating electric field strength 199 V/m (field strength calculated 20 mm below the coil in spherical conductor model representing the human head)
  For comparison: Magstim Biphasic Rapid2 with 9925 8-coil = 136 V/m, Medtronic MagPro Biphasic with MCF-B65 8-coil = 135 V/m
- Focal area of the stimulation hot spot 0.68 cm^2 (hot spot defined as 98% of the maximum stimulating electric field, calculated 20 mm below the coil in spherical conductor model representing the human head)
  For comparison: Magstim 9925 8-coil = 0.88 cm^2, Medtronic/MagVenture C-B60 8-coil = 0.79 cm^2
- In healthy adult subjects, typical motor threshold of hand muscle is approximately 45% of maximum of stimulator output

Focal Monopulse 8-Coil
- Mean winding diameter ca. 59 mm (2.3 in)
- Outer winding diameter ca. 70 mm (2.8 in)
- Monophasic pulse shape, 70 µs rising edge, ~1 ms total pulse length
- Maximum electric field strength 164 V/m (field strength calculated 20 mm below the coil in spherical conductor model representing the human head). For comparison: Magstim BiStim2 Monophasic with 9925 8-coil = 201 V/m, Medtronic MagPro Monophasic with MCF-B65 8-coil = 135 V/m
- Focal area of the stimulation hot spot 0.65 cm^2 (hot spot defined as 98% of the maximum stimulating electric field, calculated 20 mm below the coil in spherical conductor model representing human head). For comparison: Magstim 9925 8-coil =0.88 cm^2, Medtronic/MagVenture C-B60 8-coil = 0.79 cm^2)
- In healthy adult subjects, typical motor threshold of hand muscle is approximately 60% of maximum of stimulator output

Certification

Nexstim is ISO 13485 certified, all Nexstim products comply with relevant safety standards
- eXimia TMS is CE-marked as medical device in the EU, Medical Device Directive 93/42/EEC
- IEC 60601-1 (General requirements for safety), IEC 60601-1-2 (EMC), IEC 60601-1-4 (Programmable electric device)

Note: devices connected to the eXimia TMS must comply with IEC 60601-1 and device-specific medical device standards.

Classification
- MDD Classification IIa
- IP Classification IP00
- Electrical Classification Class I
- Applied Part type BF

Compatibility
eXimia TMS requires Nexstim eXimia NBS.

Caution: The eXimia NBS System (and its components) is an investigational device. Limited by federal (or United States) law to investigational use only.

Nexstim

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