



Celesta

CLINICAL AUDITORY AND VESTIBULAR EVOKED POTENTIAL

DESCRIPTION

Celesta is a pc-based, scalable auditory evoked potential testing system. It can be configured according to user needs with various available modules. It is capable of testing all standard short, medium, and long latency responses. Additionally, Celesta offers a VEMP module and an ACA module, for the automatic acquisition of cortical evoked potentials.

PRODUCT CONFIGURATION:

Celesta is available in different configurations, scaled through the activation of software licenses. The complete exam set includes:

- ABR
- eABR
- EcochG
- MLR
- LLR
- VEMP(cervical and ocular)
- ACA (Aided Cortical Assessment)*

AVAILABLE SIGNALS

Stimulus Types: Click, Chirp, NB Chirp, LS-Chirp, NB LS-Chirp, Tone Burst, White noise (masking), /m/, /g/, /t/, /s/ (speech like, only in ACA)

Click Duration: 100 μ s default (adjustable)

Tone Burst Duration: Up to 50 ms (adjustable)

Tone Burst Window Types: Linear, Rectangular, Hann, Blackman, Gaussian, Hamming, Bartlett

Tone burst frequencies: 250, 500, 750, 1000, 1500, 2000, 3000, 4000

NB-chirp frequencies: 500, 1000, 2000 and 4000Hz

SIGNALS PRESENTATION

Rate: 1 to 100 Hz

Polarity: Rarefaction, Condensation, Alternating

Maximum Output: 142.5 dB peSPL

Maximum Output masking: 95dB SPL

AVAILABLE OUTPUTS AND TRANSDUCERS

AC: Supra-aural headphones (DD45)

Insert earphones (IP-30)

BC: Bone vibrator (B-71)

FF: Free Field Loudspeaker (Canto 5CA, only in ACA)

CALIBRATION

Validity: 12 months.

RECORDING CHANNELS SPECIFICATIONS

Number of channels: 2

Gain: 56 – 96dB

Bandwidth: 0.05-16000 Hz

CMRR: >110dB, typical 120dB @ 50Hz

Input impedance: 10M Ω

Sampling frequency: 48000Hz

A/D: 24bit

Software high pass filter: 10 - 100Hz (adjustable)

Software low pass filter: 100 - 10000Hz (adjustable)

Artifact rejection: adjustable in $\pm 1\mu$ V, $\pm 400\mu$ V, suspendable

Notch filter: 50 or 60Hz

Recording window: max. from -150ms to 1 s (exam dependent)

MECHANICS (MAIN UNIT - BIOAMPLIFIER)

Size (WxDxH):

33 x 22.5 x 4.6 cm / 13 x 8.9 x 1.8in - 7.4 x 17.9 x 2.8 cm / 2.9 x 7 x 1.1in

Weight: 1.2 kg / 2.6 lbs – 0.25 kg / 0.55 lbs

PC MINIMUM REQUIREMENTS

Connection: USB (driverless)

Compatible software: Inventis Maestro

CPU: Intel® i5, 13th generation or above, 16GB RAM

Operating System: Windows 10-64 bits and Windows 11

PC ports required by Celesta:

- 1 USB-C port (USB 4, Thunderbolt 3 or superior)

POWER SUPPLY

Celesta can be powered via USB-C or by means of an external medical grade power supply (Input: 100-240Vac, 47-63 Hz, 0.9-0.34A, Output: 6Vdc, 4.16A max).

FREIGHT PACKING

Size (WxDxH): 30 x 40 x 30 cm / 11.8 x 15.7 x 11.8 in.

Gross weight: 4.2 kg / 9.2 lbs

APPLICABLE STANDARDS

Auditory evoked potentials: IEC 60645-7, Type 1

Stimuli: IEC 60645-3

Electrical safety: IEC 60601-1, IEC 60601-2-40

EMC: IEC 60601-1-2, IEC 60601-2-40

Calibration: ISO 389-6

MDR CLASSIFICATION

MDR 2017/745/EU Classification: Class IIa

Classification rule (Annex VIII, 2017/745): 10

INCLUDED PARTS (code 12380 and 12380-IP)

- Celesta main unit and bioamplifier
- DD45 supra-aural headphones (only if 12380)
- IP-30 insert earphones (only if 12380-IP)
- Bioamplifier mounting plate and lanyard
- Medical grade power supply
- Electronic IFU
- USB connection cable
- eABR trigger cables
- Consumables (electrode cables, snap electrodes, prep gel)
- Inventis Software Suite

OPTIONAL PARTS (with order code)

- 10561: DD45 supra-aural headphones
- 11748: IP-30 insert earphones
- 10245: B-71 bone vibrator
- 12405: VEMP Handheld Patient Monitor
- 12307: FBT Canto5CA speakers (includes cable)
- 10659: Speakers stand
- 12509: Reference microphone (includes cable)
- 12486: Microphone stand
- 10573: VESA mount with transducer hooks



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DISPOSABLES AND CONSUMABLES:

Electrodes:

- Code 12152: Sanibel™ snap electrodes – 60 pieces .
- Code 12392: TM electrode for EcochG – 10 pieces (require cable 12388)
- Code 11126: Gold Tip Trode Electrode for EcochG (10mm) – 20 pieces (require cables 11128)
- Code 11127: Gold Tip Trode Electrode for EcochG (13mm) – 20 pieces (require cables 11128)
- Code 10858**: Ambu® Neuroline™ 720 snap electrodes 720 – 25 pieces
- Code 12379: Sanibel™ Disposable tab electrodes (use with alligator clips) – 60 pieces
- Code 12386: Re-usable disc electrodes, 5 pcs (Blue, Red, White, Yellow, Black)

**** This code is only available for sales in Austria, Australia, Belgium, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Guatemala, Hungary, Ireland, Luxembourg, Malta, Netherlands, New Zealand, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Turkey, UK, USA.**

Electrode cables:

- Code 11128: Electrode cable for tip trodes, 50cm – 2 pieces
- Code 12388: Cable for Sanibel™ TM EcochG electrode
- Code 12387: Universal cable for snap electrodes, 5 pcs (Blue, Red, White, Yellow, Black)
- Code 12390: Alligator clip cable, 5 pcs (Blue, Red, White, Yellow, Black)

Patient preparation items:

- Code 11095: NuPrep™ abrasive gel, 4oz/114g tube – 3 pieces
- Code 10749: Everi™ Abrasive paste, 160g
- Code 11094: Ten-20™ conductive Electrode Paste, 114 g/tube – 3 tubes
- Code 12389: Gauze Swabs – 100 pieces
- Code 12391: 3M Trace prep tape

PRODUCT CODES

- 12380: Celesta – Evoked Potential System (hardware only)
- 12380-IP: Celesta – Evoked Potential System (hardware only)
- 12381: AEP Basic license (includes ABR, eABR)
- 12382: AEP Plus license (includes Basic license, EcochG, MLR, LLR)
- 12383: VEMP license (includes cVEMP and oVEMP)
- 12384: Two-channel enable license
- 12385: Upgrade from AEP Basic license to AEP Plus
- 12510: ACA license for Celesta*

**The ACA license requires the following accessories for its operation:*

- 12307: FBT Canto5CA Speakers (Includes Cable)
- 12509: Reference microphone (includes cable)

Other accessories suggested to ensure the functioning of the exam are:

- 10659: Speaker stand
- 12486: Microphone Stand

Celesta is manufactured by:

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