

SOCRATES

Auditory Evoked Potentials

SOCRATES

A complete clinical system to record auditory evoked potentials



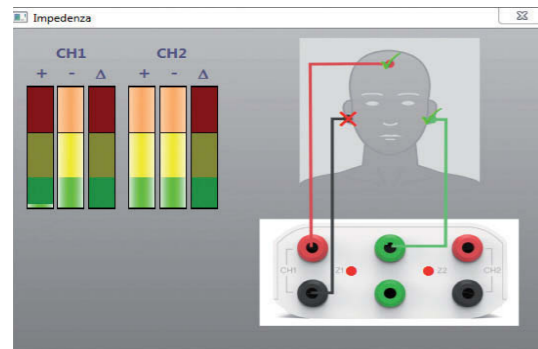
SOCRATES is a PC-based professional medical device which can detect auditory evoked potentials by using two independent channels, allowing the clinician to rapidly obtain a simple and accurate clinical diagnosis. The outcome of careful scientific research in clinical and engineering fields, SOCRATES is able to combine accuracy and simplicity of use, providing the highest qualitative performances even in the most difficult operational conditions. It guides the examiner in the preparation of the patient and quickly offers readable and repeatable graphs.

With a smart design, functional to its high performances, and together with HELIX, a simple software able to manage patients' data and tests in a safe and efficient way, SOCRATES is an essential solution for objective differential diagnosis in the field of otoneurology.

FAST AND EASY TO USE

By using SOCRATES and exploiting the potentialities of the HELIX software, tests can be easily performed, saving test execution time, with:

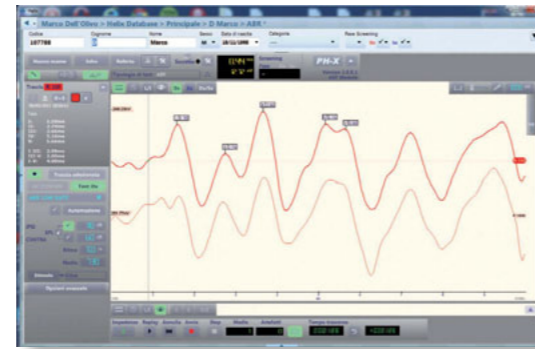
- **Simplified software interface**, to perform tests in a few click or by touchscreen
- **Guided preparation of the patient**, thanks to an intuitive graphic tool
- **Test Automation**: default procedures to automatically perform threshold tests



RELIABLE AND ACCURATE DIAGNOSIS

Thanks to an intensive research and development it has been possible to implement a powerful waveform elaboration, leading to:

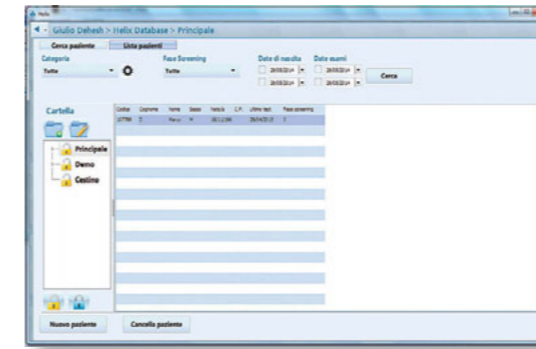
- **High test repeatability and fast test execution**, saving time and resources
- **High protection from artifacts** caused by patient's movements or electrical noise
- **Reduced need to sedate** less cooperative patients (i.e. newborns)



HELIX: EASY MANAGEMENT OF THE PATIENT'S MEDICAL HISTORY

HELIX, the multilanguage software securely and easily manages patients' clinical data, allowing an easy and accurate test execution, thanks to:

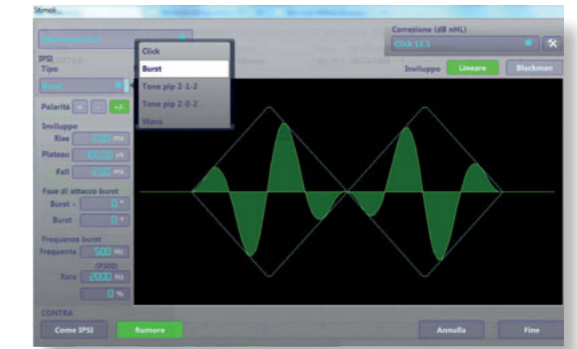
- **Customizable patient folders** and rapid access to the test
- **Automatic statistics** related to the need for screening and clinical management practices
- Execution tests with different devices and from **a single application**



SOCRATES FOR SCIENTIFIC RESEARCH

SOCRATES is the ideal solution both for clinical and scientific research, thanks to its "expert" interface, which allows:

- **A complete programmability** of the stimulus parameters, that can be saved into a library
- **Full control of test parameters**, such as analogic and digital filters, gain, and more
- **Automatic normatives**, to intuitively organize dedicated studies on clinical assessments



SOCRATES

The innovative and combined action of a software and a hardware makes **SOCRATES** a very simple tool to use, able to overcome the greatest operational difficulties, such as myogenic and environmental problems. It guarantees a **better quality of the diagnosis**, drastically reducing the amount of time usually required. Thanks to HELIX you can perform tests using **SOCRATES** as well as manage your patients' database. **HELIX is an intuitive software**, provided with a simplified interface for a fast and simple daily practice, and an expert interface for clinical-science research. Furthermore, **HELIX stores your data in a safe and reliable way**, thanks to the possibility to periodically backup and restore the archive.

Easy to use and with a **smart design**, **SOCRATES** is a complete and reliable professional software, an essential tool both for **daily clinical practice and scientific research**.

workflow accurate and easy to use

By using HELIX you can fully perform an accurate test and manage your patients in a few easy steps:

PREPARATION

- Patient's personal data input
- Guided preparation for correctly monitoring the electrodes
- Computerized impedance control
- Default or customizable test protocols

MEASUREMENT

- Manual or automatic measurement
- Advanced algorithms for managing artifacts and optimizing answers
- Full-screen repeatable graphs
- Automatic calculation of diagnostic parameters

SAVE AND PRINT

- Safe and reliable storage of clinical data
- Graphs comparison available by simply importing previous tests
- Intuitive interface for medical reporting
- Personalized tests printing

NETWORK

- Automatic or manual data backup and restore options
- Possibility to connect databases from several locations and operational sites with a HelixNET license



ABR

ACCURATE AND RELIABLE

SOCRATES allows the execution of ABR tests for the otoneurological purposes and for the threshold estimation, ensuring repeatability of the waveforms, easy test procedures and fast, reliable responses, thanks to:

- Test by Click, Tone Burst, Tone Pip, Logon, Arbitrary stimuli
- Programmable stimulation, available in SPLpe o nHL
- High acquisition quality and speed of test execution optimized by advanced mathematical elaborations
- Default test protocols included



ECOCHG

EASY ELECTROCOCHLEOGRAPHY

SOCRATES allows a fast, accurate and non-invasive execution of the Electrocochleography test, thanks to the innovative elaboration of the responses, as well as the use of the TM-Wick certified electrode, leading to the following advantages:

- Ability to perform the test in outpatient, without the need for sedation.
- Precision and accuracy of the TM -Wick electrode compared to other non-invasive methods
- Automatic calculation of the SP/AP (%) ratio

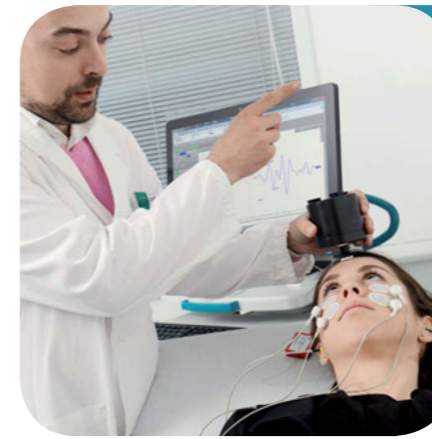


C-VEMPs

BIOFEEDBACK AND RECTIFICATION

SOCRATES allows to perform reliable and accurate C-Vemps, being provided with tools developed to optimize the comparison between the IPSI and CONTRALateral side of stimulation:

- BIO-FEEDBACK LED, directly on preamplifier, to control the muscular contraction level in real time
- BIO-FEEDBACK on the screen monitor, and rejection of the out-of-target responses
- Possibility to enable the rectification of the recordings, for a more accurate calculation of the IADR (%) parameter



O-VEMPs

FAST AND ACCURATE

By using SOCRATES, AC or BC O-Vemp tests will be easy and fast, thanks to:

- Stimulus artifact monitoring, to perform reliable and repeatable results
- Dedicated BC output, for a better operating simplicity
- Integrated amplifier and dedicated calibration interface, allowing to directly connect the bone vibrator, for a considerable cost-saving and a greater efficiency



E-ABR

FOLLOW-UP FOR COCHLEAR IMPLANTS

SOCRATES assists the ENT doctor before, during and after the introduction of a cochlear implant:

- Before, by preliminary using non-invasive ECochG test
- During, by facial nerve monitoring, as the surgeon will rely on an integrated and progressive alarm light and sound
- After, thanks to the reliability of the electric ABR (E - ABR), compatible with all major types of cochlear implant on the market



ASSR

RELIABLE AND FAST

SOCRATES provides the highest reliability in the estimation of the ASSR potentials, ensuring:

- Automatic test for both the ears
- Accurate response, displayed on the screen monitor as a simple audiogram, for right and left ear
- Time to reach the patient's binaural threshold in less than 15 minutes
- Stimulus and test parameters by default or programmable by the expert user

Available Tests

- | | |
|--|-----------------|
| • Click ABR | • AC/BC C-Vemps |
| • Threshold ABR | • AC/BC O-Vemps |
| • Electrocochleography (also non invasive) | • MLR |
| • E-ABR for cochlear implants | • LLR |

Available Tests

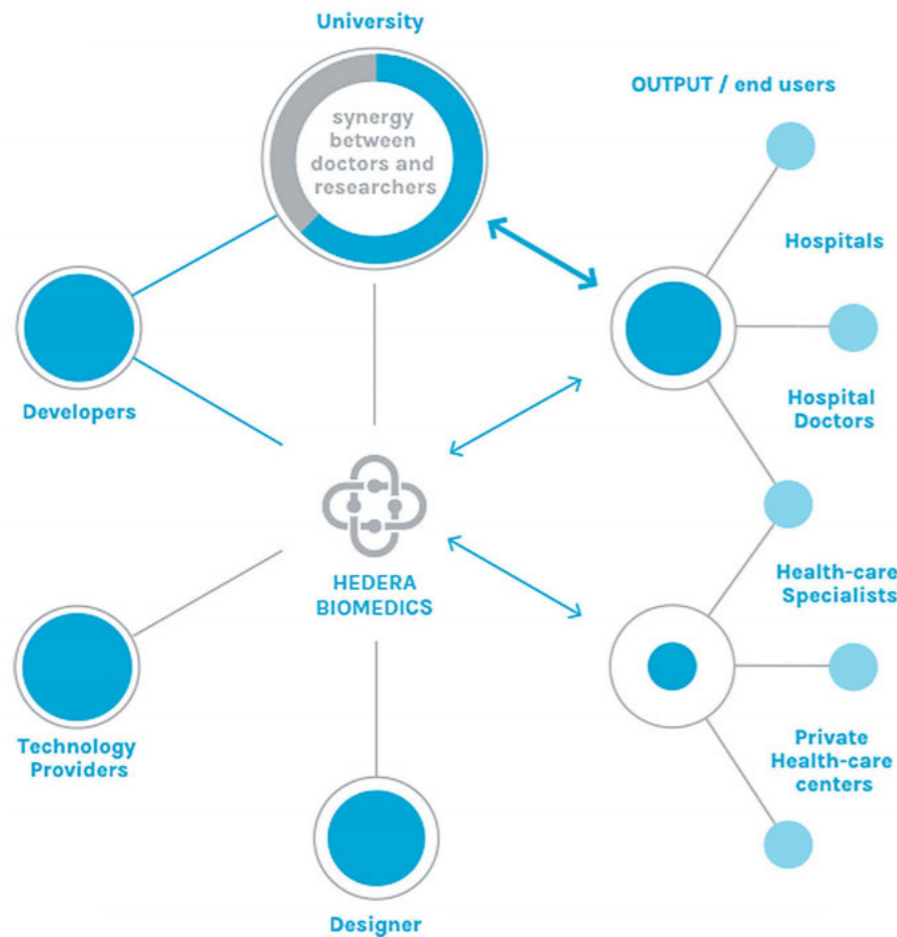
- | | |
|------------------------------|-----------------------------------|
| • P300 | • ASSR automatic and dual channel |
| • MMN with arbitrary stimuli | • ENOG/Blink Reflex |
| • RC-ALT | • Facial Nerve Monitoring |
| • 40Hz | |

RESEARCH

Hedera Biomedics actively promotes the scientific research, as it's aimed at innovation, continuous evolution of efficient solutions, and clinical validations, by a strict collaboration between clinicians and up-to-date technologies. In order to achieve these results, Hedera Biomedics offers advantages and dedicated professional solutions, thought to satisfy both health-care specialists and clinical researchers.

DEVELOPMENT

Hedera Biomedics actively collaborates with the Universities, aiming at the realization of innovative ideas for the efficiency of the daily clinical practices. A constant synergy between doctors and developers leads to develop highly innovative made in Italy equipments. The manufactured solutions will be continuously updated, featuring an excellent price-quality ratio, as a result of a coordinated development in specialized teams.



INFORMATION AND TRAINING

Hedera Biomedics provides its customers with in-situ or remote professional training, both theoretical and practical, organizing national and international workshops and sharing informative through its website www.hederabiomedics.com. You can have access to our material by registering on our website. By subscribing to our newsletter, every clinician and health-care specialist will be acquainted with the news from the development team and with the updates and the informative articles which are the outcome of the fieldwork of our opinion leaders and of our customers too, aiming at creating synergies to optimize diagnostic procedures and dedicated, efficient solutions

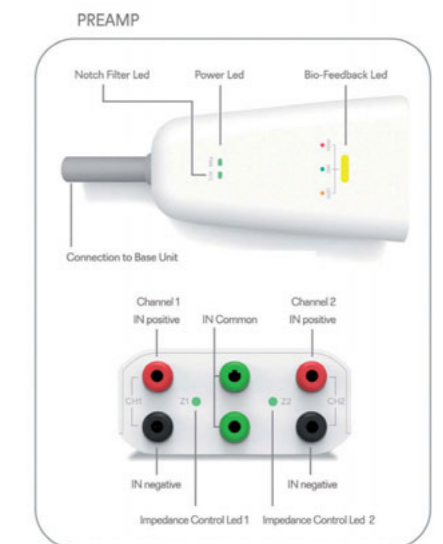
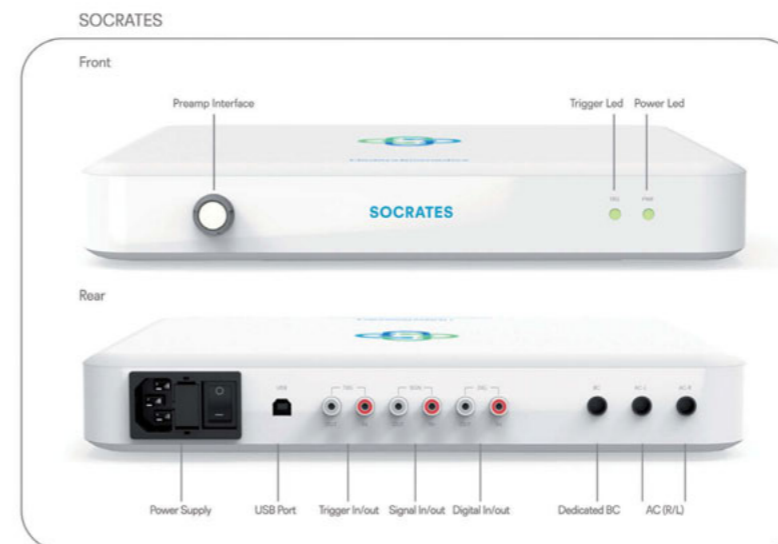
TECHNICAL SUPPORT

Hedera Biomedics provides technical support and training, ensuring high expertise and prompt assistance. Contact us to receive more information about the following services:

- Periodic calibration of ENT equipments
- Corrective maintenance
- Remote support
- Technical consulting
- Free Trial of Hedera Biomedics products
- On-site or Webinar demonstrations of Hedera Biomedics device performances
- On-site or Webinar training courses on the usage and the high-level product support

Technical Data Sheet

| General features | | Stimulation | |
|---------------------------------|---|-------------------------------------|--|
| Channels | Two independent channels | Transducers | Insert ER-3A headphones (automatic 0.8ms delay correction), TDH39 (optional), B71 bone vibrator (optional), B&K Minishaker 4810 bone vibrator (Optional) |
| Power supply | Medical power supply inside | Calibration | Dedicated Software calibration for all the supported Transducers |
| HW/SW interface | USB-PC/Tablet port | Available stimuli | Click, Tone Burst, Tone Pip, Arbitrary (.wav), WBN (masking noise) |
| Connections | AC output (Right, Left) Dedicated BC output, with integrated amplifier Trigger out Signal in-out Digital in-out USB | Programmable parameters | Polarity, rise, plateau, fall, frequency, phase, envelope intensity, rate |
| Test supportati | ABR, ECoChG, MLR, LLR, P300, RC-ALT, 40Hz, MMN, AC C-Vemps, AC-O-Vemps, BC C-Vemps(Optional), BC O-Vemps(Optional), E-ABR, ASSR, Facial Nerve monitoring (available for SOCRATES PRO), Blink reflex (available for SOCRATES PRO), ENOG (available for SOCRATES PRO), Hedera Helix to control stimulation, storage, audiogram visualization, automatic calculations, print, medical reporting. | Intensity | 0-132dB SPL, programmable dBnHL correction |
| Software | Hedera HelixNet optional licence for client-server data sharing from remote locations. | Frequency | 125, 250, 500, 1k, 1.5k, 2k, 3k, 4k, 6k, 8k |
| Automatic software calculations | | Stimulation rate | From 0.1 to 999 pps |
| Latency | Automatic single peak latency calculations, inter-peak latencies, trace comparison for all the available tests ECoChG: SP/AP (%) ratio | Recording | |
| Amplitude | Peak-to-peak amplitude calculation Vemps: IADR(%) Automatically displayed for threshold tests | Test protocol | Default test protocols available, in accordance with international standards Protocol customization by expert operators Auto-termination function, test protocol automation by stimulus intensity. |
| Latency-Intensity function | | Test automation | Programmable by the user |
| Tuning Curve | Automatically displayed for C-Vemps test | Pre-stimulus window | |
| Guided patient preparation | Impedance test displayed, including guided electrode montage and electrode functional test | Algorithms for the elaboration | Simple averaging, weighted averaging, Kalman based averaging |
| Biofeedback | Three colors Led coordinated with graphical feedback on screen monitor for Vemps Three colors Led coordinated with graphical feedback on screen monitor for facial nerve monitoring application (available with SOCRATES PRO) | Test window | Programmable by the user, from 5ms to 999ms |
| Rectification | Muscular contraction calibration and Automatic realtime rectification of the waveform Up to two channels and 8 simultaneous stimulation. Programmable AM, FM, carrier and modulating frequency Audiogram displayed on screen-monitor Amplitude automatic correction | Analogical filters | Programmable by the expert user: HPF from 0,1Hz to 10KHz LPF from 0,1Hz to 10KHz Notch Filter: 50/60Hz |
| ASSR | | Digital filters | Programmable by the expert user: Advanced Hedera 2SBW with programmable Order from 2 to 16 Online and offline smoothing function |
| | | Preamplifier gain | 4 stages of amplification |
| | | Editable gain | From 1 to 30 |
| | | Artifact rejection Impedance Led | Default sensitivity or programmable by the expert user Double three colors led, one per channel, indicating the single electrode impedance level |
| | | A/D converter | 16 bit |
| | | FEATURES | |
| | | Dimensions (mm) | 300X250X40 |
| | | Weight (kg) | 1.5 |
| | | Classification | Class II Type BF (DDM 93/42) |
| | | Standard | EN 60601-1, 60601-2 EN 60645 -1 / ANSI S3.6, TIPO 4 EN 60645 -1 / ANSI S3.6, TIPO 3 |





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