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Bio-logic SYSTEMS CORP One Bio-logic Plaza Mundelein, Illinois 60060-3700 1-800-323-8326 Fax: 847-949-8615

SECTION 2: SUMMARY AND CERTIFICATION

510(K) SUMMARY

SAFETY AND EFFECTIVENESS SUMMARY

Safety and effectiveness information concerning the Scout Sport OAE is summarized below

Because this is not a CLASS III device, the special certification defined for this section is not required.

PREPARED BY:	Bio-logic Systems Corp One Bio-logic Plaza Mundelein, IL 60060
TELEPHONE:	(847)-949-5200
CONTACT PERSON:	Norman E. Brunner
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NAME OF DEVICE:	Scout Sport - a Modification to the Scout (formerly EMAV) Otoacoustic Emissions (OAE) Test Instrument.
COMMON NAME:	Otoacoustic Emissions Test Instrument
CLASSIFICATION NAME:	Audiometer (per CFR 874.1050).
PREDICATE DEVICE:	Bio-logic Scout (formerly EMAV) OAE Instrument (K944735)

DESCRIPTION OF THE DEVICE:

The Scout Sport is a small device measuring 8.5"x4"x2.5" (LxWxD) and weighing 1.45 lbs (0.65 Kg), which is connected to a PC computer through a standard RS-232 serial data communications cable. The Sport contains a single printed circuit board with all electronics necessary for a complete, self-contained auditory testing system. Control commands are sent to this unit from the computer, and data is returned to the computer from the Sport device.

The first Bio-logic product for Otoacoustic Emissions (OAE) testing is the Scout predicate device referenced above. In this system, the hardware and software to perform the CAE test is contained on a computer-installed DSP board made by Ariel Corporation. The DSP software program on the Ariel board is included in the Etymotic Research CUBeDIS OAE product (K930553), which was the predicate device for the Scout 510(k) application. The Ariel board (with DSP software) and ER-10C ear probe is purchased as a kit from Etymotic Research and used as the basis for the Scout product. The Scout PC computer software provides additional features and enhancements over the CUBeDIS product, as described in the Scout 510(k) application.

The new Scout Sport OAE device duplicates the functions of the Ariel DSP board hardware and software in a different hardware package. Because of the size of the Ariel board, and due to the fact that it has to be installed inside a PC computer, the need for a full-length, unobstructed slot in the computer limits the PC's that can accommodate the Scout system. Additionally, it precludes the use of a notebook computer unless a docking station is used to house the DSP board. The new Sport device allows virtually any computer to be used for OAE testing, even notebooks. It also provides simplified cabling arrangements and enhanced portability, which makes it practical to reliably move the test instrument from place to place within the hospital.

The basic functionality of the Scout system is virtually unchanged with the addition of the Sport device. DSP functions within the Sport are designed to duplicate as closely as possible the functions performed by the Ariel board. Extensive testing has been performed to demonstrate this equivalence. In all areas significant to the performance and quality of the OAE testing, these test results show significant correlation to Scout performance, with lower noise levels and increased speed of testing. The Scout PC computer software programs were changed in areas necessary to accommodate the new Sport hardware. I/O port addresses, memory page requirements, and various hardware-related system calls were changed because of the movement of the hardware from the computer internal bus to the serial port.

The Scout Sport is battery-powered, using rechargeable batteries and an external charger connected to the AC power. In addition to the charger connector, there are two other connectors on the box. One connector is a 6-pin mini-din which allows for serial communication to the computer. The other connector is a 7-pin mini-din which connects to the Etymotic ER-10C ear probe. There is a single momentary pushbutton switch on the unit, used to perform a RESTART function by the user. This is necessary because the unit is battery-powered and will automatically shut down when not in use. A 2-row x 16-character LCD display on the Sport is used to communicate various operational messages to the user, such as "Low Battery", "Finished Calibrate", and "DPOAE Test in Progress".

INTENDED USE: The intended use of the Scout Sport Otoacoustic Emissions Test Instrument is to measure or determine cochlear function either by measuring and recording transient (click evoked) otoacoustic emissions or by measuring and recording distortion product otoacoustic emissions utilizing continuous pure tones. This intended use is identical to that of the predicate device.

PATIENT POPULATION: Adults, children and infants.

SAFETY AND EFFECTIVENESS:

Extensive laboratory testing was performed on the Scout Sport OAE Test Instrument to verify proper operation over a wide range of environmental conditions. The following tests were completed according to the corresponding standards or specifications:

Temperature:	a.) Operating: 60 to 90 degrees F b.) Storage: 50 to 110 degrees F
Humidity:	8% to 80% (non-condensing)
Flammability:	UL94V-0

Electromagnetic Compatibility:

Radiated Emissions	CISPR 11 / EN55011
Electrostatic Discharge Immunity:	IEC 801-2
Radiated RF Immunity:	IEC 801-3
Magnetic Fields Emissions:	RE101
Magnetic Field Immunity:	RS101

The Sport is battery-powered, using rechargeable batteries with an external charger connected to the AC power line. This external charger is UL/CSA listed with current leakage of 100 microamps are less. The actual power delivered by the charger to the Sport device is a maximum of 12 volts DC with a maximum power less than 15 watts.

To establish the safety and effectiveness of the software which controls the Scout Sport OAE Test Instrument, the system was validated in accordance with the IEEE Standards for Software Engineering, as well as Bio-logic internal software development policies and procedures modeled after the IEEE Standards. The DSP program in the Scout Sport OAE Box, and changes to the standard Scout PC computer program necessary to accommodate the communication to and setup of the unit, were all developed and tested as specified in these procedures. The system, for which this application is submitted, was verified and validated; it was found to perform in accordance with specifications.

The following comparison is provided as a summary of technological characteristics relative to the predicate device Scout (formerly EMAV). This is to demonstrate that the Scout Sport has no significant differences which would adversely affect product safety and effectiveness.

Parameter for comparison.	Similarity or Difference.
Intended Use	No differences.
Population	No differences.
Hardware Configuration	Original Scout used DSP board inside computer, Sport uses DSP board housed in separate enclosure connected to computer via serial communications cable.
Computer Control Software	Only differences are changes to Scout software required to support the new hardware configuration. No differences in software test algorithms.
Ear Probe System	No differences. Both systems use Etymotic ER-10C probe. Same microphone preamplifier electronics housed in separate box for Scout system is included within Sport box.
Performance	Average noise floor is improved (lower noise) in Sport, over that of Scout
Safety Characteristics	No difference. There is no direct electrical connection to the patient in either case. Maximum sound output of Sport is same as or less than Scout