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*Safety and Effectiveness Summary
Galileo Evoked Potential EEG
Biosound Esaote*

DUPLICATE

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Safety and Effectiveness Summary

The following safety and effectiveness summary has been prepared pursuant to requirements for 510(k) summaries specified in 21 CFR 807.92(a).

807.92(a)(1)

Submitter Information

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807.92(a)(2)

Trade Name: Galileo Evoked Potential

Common Name: Evoked Potential Electroencephalograph

Classification Name(s): Electroencephalograph

Classification Number: 84 GWQ

807.92(a)(3)

Predicate Device(s)

- Phasis Electromyograph K922488
- Nicolet Viking II System K890495

Additional Substantial Equivalence information is provided in the following substantial Equivalence Comparison Table.

807.92(a)(5)

Intended Use(s)

The Galileo Electroencephalograph with Evoked Potential option is indicated for use in the detection and display of evoked responses of electrical activity of the brain and the peripheral nervous system.

Substantial Equivalence Comparison Table

<u>Item</u>	<u>Galileo EP Option</u>	<u>Esaote Phasis K922488</u>
General Structure		
Intended use	Evoked Potentials	EMG-EP
General system approach	Computer based equipment with specialized hardware/peripherals	Same
User input devices	ASCII standard keyboard Function keyboard	Same
User output devices	Digital color monitor Standard Centronics printer Dedicated thermal printer	Same
CPU	MC68000	MC68010
Operating channels	24/32	2-4
Signal acquisition	12 bit A/D conversion	16 bit A/D conversion
Trigger In	TTL	Same
Trigger Out	TTL	Same
Accumulator	32 bit	Same
Preset	1-9999	1-32000
Standard EP Programs		
Somatosensory	Yes	Yes
Auditory	Yes	Yes
Visual	Yes	Yes
P300	Yes	Yes
Electric Stimulator		
Output	Controlled current 0-50 mA	Controlled current 0-100mA
Stimulus indicator	Yes	Yes
Overload indicator	Yes	Yes
Delivered energy limitation	Yes	Yes
Acoustic Stimulator		
Output	Earphone TDH39	Same
Mode	Clicks, Tone, Noise	Same
Polarity	Rarefaction, condensation, alternate	Same
Level	0-130 dB (SPL)	0-124 dB (SPL)
Zero level adjustment	Yes	Yes
Visual Stimulators		
Output for flash stimulator	Yes	Yes
Output	Video composite	Same
Type	Checkerboard, bars, strips	Same
Mode	Reversal, double pattern	Same

Device Description

ACQ board

Analog input	32 channels
Analog output	32 channels
A/D conversion	12 bit, 10 μ sec/point, 4 converters
Accumulator	32 bit
Processor	Motorola MC68000
Resident memory	1 MB
Trigger input	TTL

Stimulators

a- General features

Working class	I type of equipment B (acoustic and visual) I type of equipment CF (electrical)
Safety requirements	meets standard IEC 601-1-1 (CEI 62-5)
Size	220 mm, 450 mm, 80 mm
Weight	approx. 2 Kg
Power supply	+ 15V (0.7 A) -15V (0.7A) +5V (1A)
Power absorption	approx. 25 VA
Working conditions	+5C/ +35C; 30-75%RH

Atm pressure	700/1060 mBar
Storage and conveyance conditions	-10/50C; 10-95% RH
Atm pressure	500/1060 mBar
Degree of protection against infiltration of liquids and solids	IP20

b- Acoustic stimulator

Transducer	Telephonics TDH39
Stimulation modes	Tone, Click, Noise
Stimulation rate	from 50 ms to 9980 ms (step 10 ms)
Tone frequency	250,500,1000,1500,2000,2500,3000,4000,5000,7000 8000 Hz
Stimulus output	Right monoaural, Left monoaural, Right monoaural + controlateral noise, Left monoaural + con- trolateral noise, binaural
Acoustic level	0,10,20,30,40,50,60,70,75,80,90 dB SL
Threshold adjustment	-4,-2,0, + 2, + 4, + 6 dB
Noise level relative to the stimulus's level	-40,-30,-20,-10,0, + 10 dB
Polarity of the stimulus (in Click mode)	Condensation, Rarefaction, Alternate
Duration	tone mode: from 10 to 150 ms, with 10 ms steps click mode: from 50 to 960 μ s, 10 μ s steps

c- Visual stimulator

The stimulator generates two video images (pattern A and B), that are alternatively displayed on screen in response to a trigger command.

Generally, each picture is composed of an arbitrary bit map of 512x256 pixels; in detail the current resident software, divides the image in 5 fields: 4 quadrants and a fixation area. Each field can contain one of the following textures:

- black
- white
- spatial frequency horizontal bars 1
- spatial frequency horizontal bars 2
- spatial frequency vertical bars 1
- spatial frequency vertical bars 2
- spatial frequency chequer board 1
- spatial frequency chequer board 2

and the reverse of all of them.

A composite video signal 1 Vpp is transmitted to the monitor with separate positive synchronisms and 8 contrast levels (2,5,10,20,30,50,75,100%) related to the maximum contrast level set on the .

The line period is 64 μ s, the frame frequency 60 Hz.

d- Electric stimulator

The electric stimulator is *constant current* type.

Other features are:

Amplitude	from 0 to 50 mA, with two scales (0-5 and 0-50)
Precision	+/- 10% full range
Duration	limited to 0.5 millisecc (see Device Hazard Analysis)
Isolation between the applied elements and the ground	1500 V AC (see Device Hazard Analysis)
Patient's safety	limited energy and stimulation frequency; protection against failure of the current sensor
Light indicators	stimulus ON, overload, abnormal functioning.