

- 12 bit AD Converters (2 or 4)
- 4x1 multiplexer (auxiliary channels)
- 12 bit AD Converter
- DSP TMS320C5x
- 512 KB flash RAM + 1256 KB static RAM
- ACIA RS232, with isolation stage (medical isolation IEC60.601)
- Slots PCMCIA II (2)
- 2x8 LCD

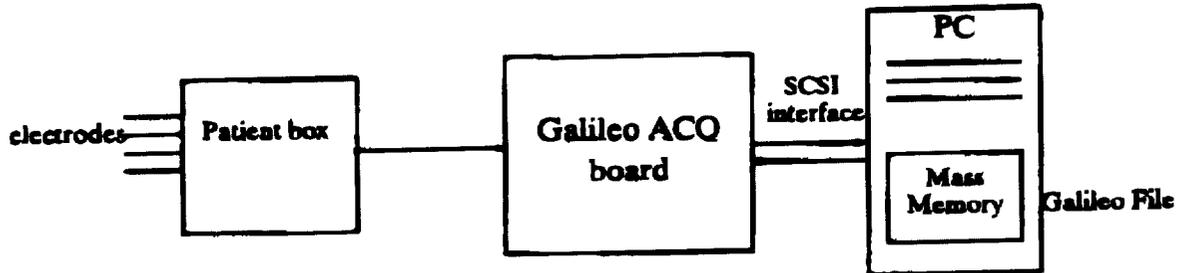
Halley in stand-alone mode

In this working mode, HALLEY performs all the previous functions but, instead of transmitting the data to a GALILEO station, it stores them on a internal mass memory support (PCMCIA removable hard-disk or 2 Flash Memory Cards).

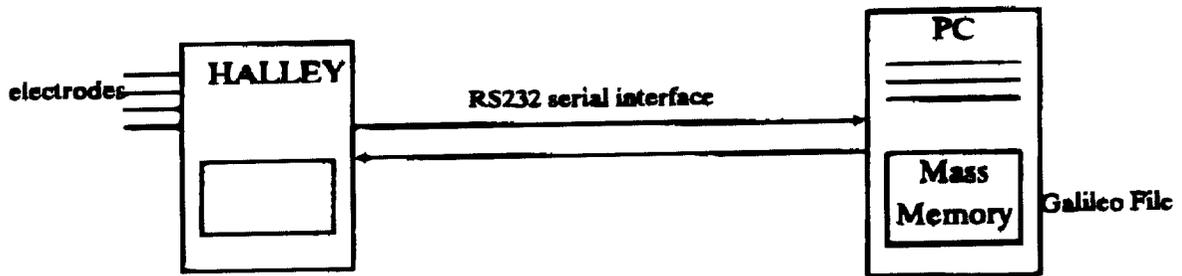
In order to comply with a precise project specification, these memory supports must be directly read and managed from a GALILEO station; therefore, the data are organized and memorized by following the format of the GALILEO standard files. In other words, the files produced by a GALILEO station or by HALLEY are indistinguishable and interchangeable. No compression algorithm is used.

When it works in stand-alone mode, Halley is like as a pocket EEG recorder with a 24 hours autonomy.

Safety and Effectiveness Summary
 Galileo Halley
 Biosound Esaote



2a-Standard GALILEO station



2b-HALLEY in GALILEO station mode



2c-HALLEY in stand-alone mode

Technical Characteristics

| | |
|------------------------------|--|
| Number of channels | 16 or 32 EEG or poligraphic channels, plus 4 DC auxiliary channels |
| Sampling format | 12 bits for the EEG or poligraphic channels, 18 bit for the auxiliary channels |
| Sampling rate | 512 s/sec/channel |
| Resolution | 0.5 μ V/bit |
| Dynamic range | +/-1mV (EEG/poligraphic channels) 128 mV (DC channels) |
| CMRR | > 100 dB |
| IMRR | > 120 dB |
| Noise | < 1.5 μ Vpp |
| Low pass filters | 15-30-60-90-120 Hz |
| Time constant | 0.3-0.1-0.03-0.01 sec |
| Mass memory | one slot for PCMCIA Hard Disk or two slots for PCMCIA Flash Memory Cards |
| Impedance measurement | by means of 30Hz - 0.3 μ A current |
| Power supply | 4 internal alkaline batteries 60x15 mm, 1.5 V or 4 auxiliary external batteries 60x24 mm, 1.5V |
| Interfaces | RS232 PCMCIA 2x8 characters Liquid Crystal Display 2 push-buttons |
| Dimensions | 90x45x150 mm |
| Weight | 450 gr |



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 1997

Mr. Gerald A. Richardson
Official Correspondent
Biosound, Inc.
8000 Castleway Drive
Indianapolis, Indiana 46250

Re: K970703
Trade Name: Halley Input Box
Regulatory Class: II
Product Code: 84GWQ
Dated: February 24, 1997
Received: February 26, 1997

Dear Mr. Richardson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number if (if known): K970703

Device Name: Halley Input Box

Indications For Use:

The intended use is for acquisition and storage of bioelectric signals produced by brain activity for the diagnosis and prognosis of neurological disease.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970703

Prescription Use