Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

K 003154

JAN - 5 2001

510(k) Summary
MIZAR Amplifier
EB Neuro, S.p.A.

510(k) Summary

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

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent
7992 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Colleen Hittle

Date: October 1, 2000

807.92(a)(2)

Trade Name: MIZAR / Basis BE / Sandman Digital

Common Name: Physiological Signal Amplifier

Classification Name(s): Physiological Signal Amplifier

Classification Number: 84GWL

807.92(a)(3)

Predicate Device(s)

Artisan	Medcare Diagnostics	K992283

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

807.92(a)(5)

Intended Use(s)

The MIZAR Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2001

EB Neuro. S.P.A.
c/o Ms. Colleen J. Hittle
The Anson Group
7992 Castleway Drive
Indianapolis, Indiana 46250

Re: K003154
Trade Name: MIZAR/Basis BE/Sandman Digital
Regulatory Class: II
Product Code: GWL
Dated: October 5, 2000
Received: October 10, 2000

Dear Ms. Hittle:

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

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) 594-4595. 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,

Miriam C. Provost for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

Indications for Use Statement

Applicant: EB Neuro, S.p.A.

510(k) Number (if known): K 003154

Device Name: MIZAR / Basis BE / Sandman Digital

Indications For Use:

The MIZAR Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysmnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** Over The Counter_____

(Per 21 CFR, 801.109)

(Optional Format 1-2-96)

Miriam C Provost for
(Division Sign-Off) C. Witten
Division of General Restorative Devices
510(k) Number K003154

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 1/25/10

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K003154/A1

To: Division Director: NE/DONED

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Bring to POS

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: Offoang

Date: 1/29/10

POS

cst PAS
1/29/10

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

Global Headquarters
11001 West 120th Ave.
Broomfield, CO 80021 USA
t: 888.662.7632
f: 303.962.1810
www.embla.com

embla®

CLOSER TO OUR CUSTOMERS™

K003154/A1

January 12, 2010

FDA CDRH DMC
JAN 15 2010
Received

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: **510(k) Notification for a Change in Manufacturer**

Attention: **Document Control Clerk**

Subject: **MIZAR, BASIS BE, SANDMAN DIGITAL – K003154**

Embla Systems Inc. (Registration No.:3005844579) has purchased the rights to market and re-label the subject device.

There is no change in the design (except for labeling with new mfg name), manufacturing location or processes, or the indications for use for the device.

If there any questions regarding this notification, please contact the undersigned.

Sincerely,

Robert Schueppert

Robert Schueppert
Regulatory Manager
Embla Systems, Inc.
11001 W. 120th Ave., Suite 200
Broomfield, Colorado USA
Phone: 303-962-1786
Fax: 303-962-1810

K-24

FDA CDRH DMC

JAN 25 2010

Received

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

MIZAR, BASIS BE, SANDMAN DIGITAL – K003154 Notification for a Change in Manufacturer – Embla Systems

January 12, 2010

TRUTHFUL AND ACCURATE STATEMENT

In my capacity as Manager of Regulatory Affairs for Embla Systems Inc, I hereby certify that all information submitted in this notification is truthful and accurate to the best of my knowledge and that no material fact has been knowingly omitted.

Robert Schueppert

Robert Schueppert
Regulatory Manager
Embla Systems, Inc

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2001

EB Neuro. S.P.A.
c/o Ms. Colleen J. Hittle
The Anson Group
7992 Castleway Drive
Indianapolis, Indiana 46250

Re: K003154
Trade Name: MIZAR/Basis BE/Sandman Digital
Regulatory Class: II
Product Code: GWL
Dated: October 5, 2000
Received: October 10, 2000

Dear Ms. Hittle:

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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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

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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) 594-4595. 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,

Miriam C. Provost for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

Indications for Use Statement

Applicant: EB Neuro, S.p.A.

510(k) Number (if known): K 003154

Device Name: MIZAR / Basis BE / Sandman Digital

Indications For Use:

The MIZAR Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysmnography signals and transmission of these signals to a PC ~~during recording~~ of ~~neurophysiology examinations~~.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** Over The Counter _____

(Per 21 CFR, 801.109)

(Optional Format 1-2-96)

Miriam C. Provost for
(Division Sign-Off) C. Witten
Division of General Restorative Devices
510(k) Number K003154

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Sankar Basu

Subject: 510(k) Number K003154

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form ~~on H Drive~~ 510k/boilers	☐ YES	☑ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☑ Enclosed
(required for originals received 3-14-95 and after)

☑ A 510(k) summary OR ☑ A 510(k) statement

☐ The required certification and summary for class III devices

☑ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☑ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: GWL/84 ; class II

Additional Product Code(s) with panel (optional):

Review: Richard P. Fellen (Branch Chief) — G SDB (Branch Code) — 1-4-01 (Date)

acting

Final Review: Miriam C. Provost for (Division Director) — 1/5/01 (Date)

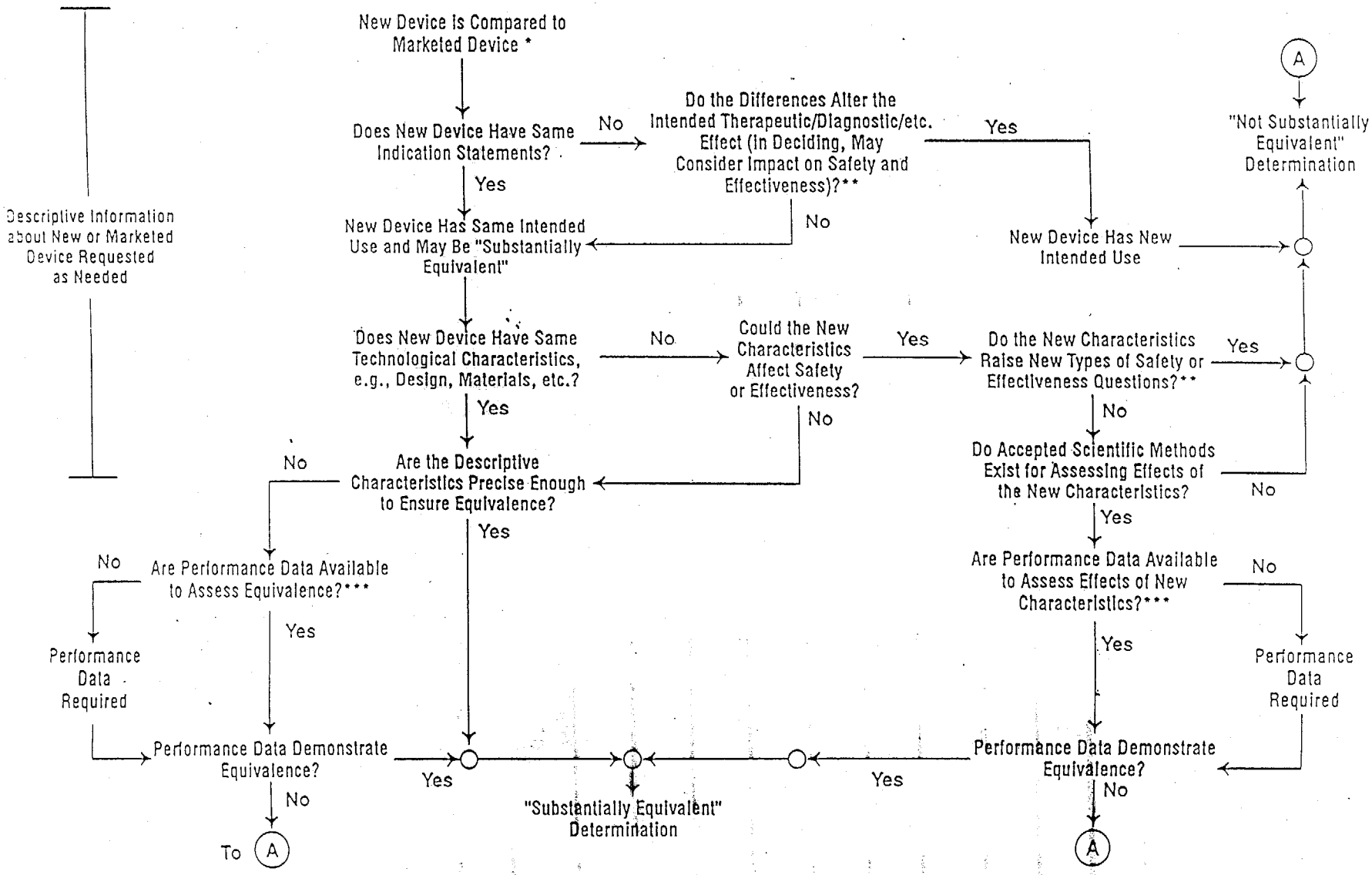
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Revised:8/17//99

4

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Addition[illegible] [illegible]n if the Relationship Between Marketed and "Predicate" (Pre-Am[illegible] [illegible] Reclassified Post-Amendments) Devices Is Unclear.

** This Decision Is Normally Based on Descriptive Information Alone, But Lim[illegible] Test[illegible] [illegible]formation Is Sometimes Required. [illegible] the Literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-510(k)STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name: MIZAR/Basis BE/Sandman Digital | K 003154

Submitter (Company): EB Neuro, S.P.A

Items which should be included *(circle missing & needed information)*	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as:							
a) "Special 510(k): Device Modification"					X		
b) "Abbreviated 510(k)"							
c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO #2 4,5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	SPECIALS YES	SPECIALS NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA		YES		NO		
a) trade name, classification name, establishment registration number, device class					X		
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA						
d) compliance with Section 514 - performance standards	NA						
e) address of manufacturer							
f) Truthful and Accurate Statement							
g) Indications for Use enclosure							
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*							
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals							
k) Proposed Labeling:							
i) package labeling (user info)							
ii) statement of intended use							
iii) advertisements or promotional materials							
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:							
i) Labeling							
ii) intended use							
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing	NA						
vi) safety characteristics	NA						
m) If kit, kit certification							

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							
b) *STATEMENT - INTENDED USE AND INDICATIONS FOR*			* If no - STOP not a special				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) ***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED****			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

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inapplicable requirements or deviations noted below					
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed					
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device					
v) A specification of any deviations from each applicable standard that were applied					
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference					
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations					
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards					

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:					N/A		
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:					N/A		
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:					X		
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with check in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No** **Reviewer:** Sankar Basu

Date: Oct. 20, 2000 **Concurrence by Review Branch:** PMF GSRB

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 003154

Reviewer: Sankar Basu

Division/Branch: DGRND / GSDB

Device Name: MIZAR Amplifier

Product To Which Compared (510(K) Number If Known): Artisan distributed by Medlare Diagnostics (K992283)

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		✓	If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	✓		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety ~~or effectiveness~~ issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is ~~or is~~ not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	✓	
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

Reviewer: Sankar Basu

Doc. No. : K003154

Device Name: MIZAR Amplifier

Indications: The device is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy, polysomnography signals and transmission of these signals to a PC during recording of neurophysiological examinations.

Sponsor: EB Neuro, S.p.A.
via P.Fanfani, 111/a
Florence 50127, Italy

Doc. Recd. In ODE : October 10, 2000

Doc. Recd. By the Reviewer: October 17, 2000

Contact Person: Colleen J. Hittle
The Anson Group
7992 Castleway Dr.
Indianapolis, Indiana 46250
(317)-849-1916

Device Descriptions :

The subject device, MIZAR is an amplifier intended to be used to amplify and filter bioelectric signals captured via a lead or transducer on the surface of the human body. It captures the data, converts it into a digital form, and passes it on to a host computer running appropriate amplification software. Typical fields of application will be EEG, EP, EMG, Polysomnography and General Polygraphy.

The device, MIZAR, developed by EB Neuro is the object of this submission. It is to be marketed by two distributors under the following names: "Basis BE" which is the version of EB Neuro, and "Sandman Digital" which is the version of Nellcor Puritan Bennett's version. The two versions differ only in the name and external labeling.

Typically medical devices like EEG, EMG, or EKG, etc are composed of two main parts:

(1) An amplifier system which after collecting the bioelectric signals through appropriate electrodes or sensors amplify the very low electric signals, condition them and convert them to digital form.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

(2) A computer running an application software that receives the data from the amplifier, displays the data in different format, stores the data and generates graphic and text output.

The MIZAR system is a fully programmable system which can range from 24 to 256 channels. The typical configuration is with 40 channels.

Optionally the system may contain a pulse oximeter circuit, MP 404. The data obtained from the circuit is passed on to the host computer together with other channels data. The MP 404 pulse oximeter module circuit is substantially equivalent to N-395 pulse oximeter module circuit, according to EB Neuro and cleared through K991823 and K993637 which are manufactured by the same company, (b)(4) [redacted] For purposes of this submission MP 404 has been cleared via EB Neuro Memorandum to File. The pulse oximeter option limits the number of signal channels to 40.

The host computer operates under one of the following operating systems:

Microsoft Windows 98 and Microsoft Windows NT.

The software interface to MIZAR consists of two simple modules, a Dynamic Link Library (DLL) and a "device driver" (VXD or SYS) which are furnished by EB Neuro.

The MIZAR System consists of 4 interconnected units: the head box, the amplifier box, the PCMCIA interface and the AC/DC adapter. Optionally the AC/DC adapter can be replaced by an internal battery pack.

Substantial equivalence claim has been made with respect to Artisan Acquisition System cleared through K992283.

COMMENTS:

By comparing the specifications of the MIZAR with the predicate device Artisan one can see many similarities in the specifications. Although the proposed device has larger number of channels for EEG/polygraph we have cleared many such devices upto 128 or 256 channels. The intended uses are the same and all other specifications are within the range for which there cannot be any concern.

The software information has been provided with the hazard analysis. The amplifier has been assessed to carry a minor level of concern.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Electrical testing has been carried out by the sponsor for the electrical safety and passed IEC 601-1 and IEC 601-1-2 (for Electromagnetic Compatibility).

The User Manual has been reviewed in which the labeling, warning, etc have been found to be adequate. Instructions for different software installation have also been listed under the User Manaual.

Recommendation:

The MIZAR System has been found to be substantially equivalent to Artisan System for Data acquisitions, storage and display of all the bioelectric signals captured by electrodes or sensors from the human body. I recommend SE of the proposed device.

Sankar Basu

concur

concur
prep for CMW
1/5/01

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 11, 2000

EB NEURO, S.P.A.
C/O THE ANSON GROUP, LLC
7992 CASTLEWAY DRIVE
INDIANAPOLIS, IN 46250
ATTN: COLLEEN HITTLE

510(k) Number: K003154
Received: 10-OCT-2000
Product: MIZAR, BASIS BE, SANDMAN DIGITAL

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

K003154

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Premarket Submission Cover Sheet

Date of Submission:		FDA Document Number:	

Section A — Type of Submission

- ☒ 510(k)
- ☐ 510(k) Add'l Information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement-Regular
- ☐ PMA Supplement-Special
- ☐ PMA Supplement-30 day
- ☐ PMA Supplement-Panel Track

Section B1 — Reason for Submission - 510(k)s Only

- ☒ New device
- ☐ Additional or expanded indications
- ☐ Change in technology, design, materials, or manufacturing process
- ☐ Other reason (specify):

Section B2 — Reason for Submission - PMA's Only

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Other (specify below)
- ☐ Process change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Response to FDA correspondence (specify below)
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment

Section B3 — Reason for Submission - IDEs Only

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion/extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☐ Additional information
- ☐ Other reason (specify):
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing
  - ☐ Protocol – feasibility
  - ☐ Protocol – other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting
- ☐ IOL submissions only:
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

FDA Document Number:

Section C — Product Classification

Product code: 84GWL

C.F.R. Section: 882.1400

Device class:
- ☐ Class I
- ☒ Class II
- ☐ Class III
- ☐ Unclassified

Classification panel: Neurology

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 84GWL	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
- ☒ 510(k) summary attached
- ☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 992283	Artisan System	1 Medcare Diagnostics
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section E — Product Information - Applicable to All Applications

Common or usual name or classification name:

Trade or proprietary or model name	Model number
1 MIZAR	
2 Basis BE	2
3 Sandman Digital	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1 992283	2	3	4	5	6
7	8	9	10	11	12
13					

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling):

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

FDA Document Number:

Section F — **Manufacturing/Packaging/Sterilization Sites**

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: Applied for 10/5/00	☒ Manufacturer ☐ Contract sterilizer ☐ Contract manufacturer ☐ Repackager/ relabeler

Company/Institution name: EB Neuro, S.p.A.

Division name (if applicable): NA	Phone number (include area code): 011390554565111
Street address: Via P. Fanfani, 111/a	FAX number (include area code): 011390554565123

City: Florence	State/Province:	Country: Italy	ZIP/Postal Code: 50127

Contact name: (b)(6) [redacted]

Contact title: Quality Assurance (SAQ) Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

FDA Document Number:

[redacted]

Company/Institution name: EB Neuro, S.p.A.	FDA establishment registration number: Applied for 10/6/00
Division name (if applicable):	Phone number (include area code): 011390554565111
Street address: Via P. Fanfani, 111/a	FAX number (include area code): 011390554565123

City: Florence	State/Province:	Country: Italy	ZIP/Postal Code: 50127

(b)(6) [redacted]

Title: Quality Assurance (SAQ) Manager

[redacted]

Company/Institution name: The Anson Group, LLC	
Division name (if applicable):	Phone number (include area code): (317) 849-1916
Street address: 7992 Castleway Drive	FAX number (include area code): (317) 577-9070

City: Indianapolis	State/Province: IN	Country: U.S.A.	ZIP/Postal Code: 46250

Contact name: Colleen Hittle

Contact title: Official Correspondent

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

K 003154

510(k) Summary

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

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent
7992 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Colleen Hittle

Date: October 1, 2000

807.92(a)(2)

Trade Name: MIZAR / Basis BE / Sandman Digital

Common Name: Physiological Signal Amplifier

Classification Name(s): Physiological Signal Amplifier

Classification Number: 84GWL

807.92(a)(3)

Predicate Device(s)

Artisan	Medcare Diagnostics	K992283

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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807.92(a)(5)

Intended Use(s)

The MIZAR Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Substantial Equivalence Comparison Table

Item	Medcare Artisan Acquisition System - K992283	EB Neuro MIZAR Amplifier
Intended use	Acquisition of EEG and polygrasomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations	Acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations
EEG/Polygraphic channel	32	32/40/64/96/128
DC channel	16	32/40
A/D conversion	22 bit A/D	16 bit Sigma-Delta A/D effectively transferred to host
Sampling rate	User selectable @ more than 1,024/sec./channel	User selectable up to 32 KHz / channel
CMMR	> 105dB	> 100dB
Noise	< 0.5 µVRms	< 1.5 µVpp
Power supply	Not declared	External IEC 601-1 mains adapter (standard) Internal batteries (optional)
Internal Storage	NO Internal storage	NO Internal storage
Amplifier – PC Interface	PCMCIA	PCMCIA
Other Interfaces	No	(b)(4) [redacted]
Optional Integrated Pulse Oximetry module	Yes	Yes
Use standard sensors and electrodes	Yes	Yes
Dimension	10.1 x 12.8 x 2.8 cm (amplifier) 10.1 x 12.8 x 2 cm (headbox)	25 x 17 x 6.5 cm
Weight	220 g (amplifier) + 200g (headbox)	1.5 KG
Isolation	Fiber optic link	Fiber optic link
Safety Stds	Not declared	IEC 601-1-1 IEC 601-1-2 IEC 601-1-4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

MIZAR Amplifier 510(k) Submission Index

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

THE ANSON GROUP

October 5, 2000

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850-4302

Subject: MIZAR Amplifier

Dear Sir or Madam:

Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, EB Neuro hereby notifies the FDA of its intention to market the above referenced device.

We believe the information contained herein is sufficient for the FDA to reach a decision regarding this submission. Should additional information be required, it can be requested from The Anson Group representative listed below or Carri Graham at the Anson offices.

We appreciate the administrative and scientific considerations relevant to this submission and hope the FDA will reach its decision as expeditiously as possible.

Sincerely,

Colleen J. Hittle

Colleen J. Hittle
The Anson Group
7992 Castleway Drive
Indianapolis, Indiana 46250

Phone: (317) 849-1916
Fax: (317) 577-9070

FDA/CDRH/ODE/DMC
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

Foreward

This submission is organized following the FDA Guidance document for Electroencephalograph Devices dated November 3, 1997.

Much of the information contained within this submission has been provided as received from the manufacturer, EB Neuro located in Florence, Italy. In some areas the English may appear to be a bit broken due to the differences between the Italian and English languages. We believe, however, that in all cases the text is understandable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

Administrative Information

Pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, and Part 807, Title 21 of the Code of Federal Regulations, EB Neuro, S.p.A., submits the following information as premarket notification.

Type of Submission: 510(k)

Proprietary Name:	MIZAR / Basis BE / Sandman Digital
Classification Name:	Physiological Signal Amplifier
Classification Number:	84GWL
Classification:	Class II
Performance Standard:	None established under section 514
Intended Use:	Specific information about uses is provided within. Generally, the MIZAR amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.
Registration:	The device will be manufactured by: EB Neuro, S.p.A. Via P. Fanfani, 111/a Florence 50127 Italy Registration Number: Applied for 10/5/00
Safety and Effectiveness:	Pursuant to the Safe Medical Devices Act of 1990, EB Neuro, S.p.A. will make available to interested parties, the safety and effectiveness information upon which the substantial equivalence determination is based.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

Indications for Use Statement

Applicant: EB Neuro, S.p.A.

510(k) Number (if known): K 003154

Device Name: MIZAR / Basis BE / Sandman Digital

Indications For Use:

The MIZAR Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysmnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR** Over The Counter_____

(Per 21 CFR, 801.109)

(Optional Format 1-2-96)

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

510(k) Summary/Statement Certification

Re: K_____ Check only one

1. 510(k) Summary. Attached is a summary of safety effectiveness information upon which an equivalence determination could be based.

X 2. 510(k) Statement. I certify that, in my capacity as _____

_____, of _____(company), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential

(b) (6) [redacted]

(Signature*) (Typed or Printed Name)

10/6/00
(Dated)

*Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

Truthful and Accurate Statement

Pursuant to 21 CFR 807.87(j), I, (b)(6) [redacted], certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Quality Mgr of EB Neuro, S.p.A., and in reliance thereupon, the data and information submitted in this Premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.

(b)(6) [redacted]

[Signature]

(b)(6) [redacted]

[Typed Name

10/16/00

[Dated]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1 System description

1.1 Background

A number of medical devices are used to detect, graphically record and store for delayed retrieval the electric signal produced by various parts of the human body. An example of such a device may be an electroencephalograph or an electrocardiograph.

Typically these medical devices are composed of two main parts:

a) an amplifier system which collects the bioelectric signals from the surface of the human body through appropriate electrodes or sensors, which intensify the very low signal captured (typically the amplitude range is of the order of the μVolts), condition them (filtering), convert them to digital form.
b) a computer running an application software that receives the data from the amplifier, displays the data in various formats, stores the data and generates graphic and text output for printers.

The MIZAR device developed by EBNeuro is the object of this submission and is the amplifier portion described above. Mizar is intended to be used as the acquisition portion of an entire bioelectric diagnostic system.

1.2 Description of the system

The amplier system which is the subject of this 510(k) submission is being cleared under the name MIZAR, however, it is to be marketed by two distributors under the following names: EB Neuro's version is called "**Basis BE** " (**Basis Brain Explorer**) and Nellcor Puritan Bennett's version is called "**Sandman Digital**". The two versions differ only in name and external labeling. Details on the different labeling are included in this section.

The MIZAR is a fully programmable amplifier system which can range from 24 up to 256 channels. The amplifier receives its power from a dedicated AC/DC adapter, meeting the IEC 601-1 requirements, which feeds a +15VDC. Internally the +15VDC is further isolated by a dedicated DC/DC converter of class BF. Optionally the power may be supplied by an internal battery pack.

The MIZAR amplifier is intended to be used to amplify and filter bioelectric signals captured via a lead or transducer on the surface of the human body. It captures the data, converts it into a digital form, and passes it on to a host computer running appropriate amplification software. Typical fields of application will be: Electroencephalography (EEG), Evoked Potentials (EP), Electromyography (EMG), Polysonography (SLEEP ANALISYS) and General Polygraphy.

The system can configure, amplify and convert to digital form (analog to digital conversion) from 24 (the minimum configuration) to 256 (the maximum expansion) signal channels. The typical and standard configuration is with 40 channels.

Optionally, the system may contain a Pulse Oximeter circuit. The data measured from this circuit is passed to the host computer together with the other channel's data. The MP404 pulse oximeter module circuit, developed by Nellcor Puritan Bennett, is substantially equivalent to Nellcor Puritan Bennett's N-395 pulse oximeter module

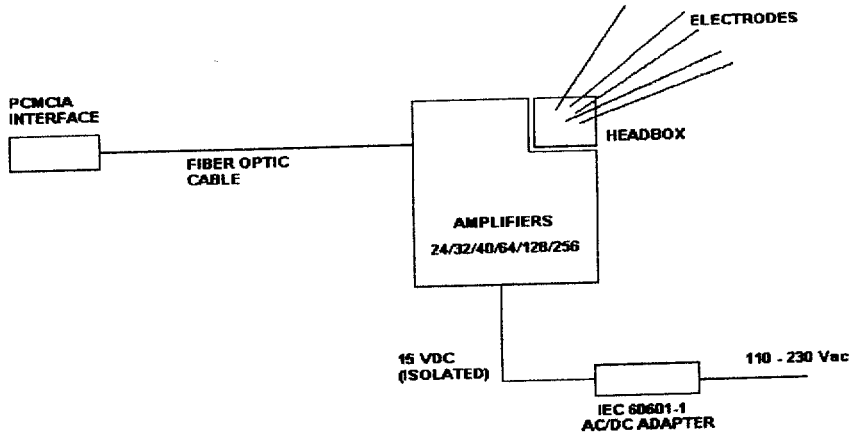
cleared via K991823 and K993637. For purposes of this submission, the MP404 has been cleared via EB Neuro Memorandum to File.

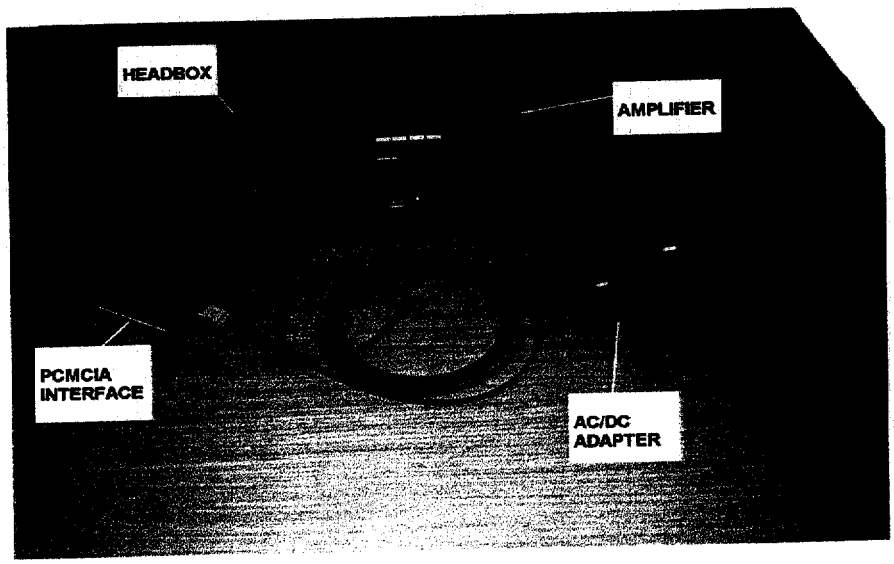
The amplifier simply incorporates this module, providing it with the necessary power and reading its output to pass the measured oximetry to the host computer. The pulse oximeter option limits the number of signal channels to 40. If the pulse oximeter option is installed, it is no longer possible to install the channel expansion board. For the same (physical) reason, if one or more channel expansion boards is installed, it is not possible to install the pulse oximeter option.

The host computer must operate under one of the following Operative Systems:
Microsoft Windows 98
Microsoft Windows NT

The "software" interface to MIZAR consists of two simple modules (a Dynamic Link Library, DLL and a "device driver", VXD or SYS) which are furnished by EB Neuro.

The MIZAR "system" consists of 4 interconnected units : the headbox, the amplifiers box, the PCMCIA interface and the AC/DC adapter. Optionally the AC adapter can be replaced by an internal battery pack, see section 1.3.6.2.





(b)(4)

(b)(

(b)(4)

(b)(4) Software Information

(b)

Fig 4 – block diagram

(b)(4)

(b)(4)

(b)(4) Software Information

(b)(4)

Fig 5 (b)(4)

(b)(4)

(b)(4)

Fig 6 (b)(4) e

In this type of input, the (b)(4)

(b)(4)

(b)(4) [redacted]

Fig 7 (b)(4) [redacted]

(b)(4) [redacted]

NOTE: (b)(4) [redacted]
(b)(4) [redacted]

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(b)(4) [redacted], the description which follows is applicable to all the block type.

(b)(4) [redacted]

(b)(4) Software Information [redacted]

(b)(4) [redacted]

(b)(4) Software Information [redacted]

(b)(4) [redacted]

Fig 8 input analog path

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

The Hybrid amplifier has 3 control inputs:

(b)(4)

(b)(4) Software Information

(b)(4)

Fig 10

(b)(4) Software Information

(b)(4)

(b)(4)

(b)(4) Software Information

(b)(4) Software Information

Fig 11

(b)(4)

(b)(4)

(b)(4)

See section 2 for further details.

(b)(4) Software Information

(b)(4)

(b)(4) Software Information

(b)(4)

Section 2 contains more detail on the overall performance

40

(b)(4) Software Information

(b)(4)

(b)(4) Software Information

(b)(4)

(b)(4) Software Information

(b)(4)

1.3.6.1 Mains power supply

(b)(4)

[redacted]

(b)(4)

[redacted]

Fig 12 (b)(4) Software Information [redacted]

1.3.6.2 Battery power supply

For special application, optionally, the power to the amplifier may be delivered by two commercial battery packs which take the place of the DC/DC isolator inside the amplifier box. (see the figure below).

When the batteries are installed it not possible to power the system by the external AC/DC adapter (the DC IN connector is not mounted in the device).

The batteries are rechargeable. They cannot be recharged while placed inside the amplifier box. To recharge the batteries one must use the external battery charger supplied with the battery option. The batteries are a 2 battery pack containing 7.2 VDC

SONY "InfoLITHIUM" model NP-F730. The battery charger is a SONY model AC – V700. The two pack are serially connected to give an output voltage of 14.4 Volts.

The battery holder is designed in such a way to make it impossible to insert the battery with a reverse polarity. The batteries are protected against the output short circuit (or overcurrent) by an auto-recoverable fuse contained in the battery holder.

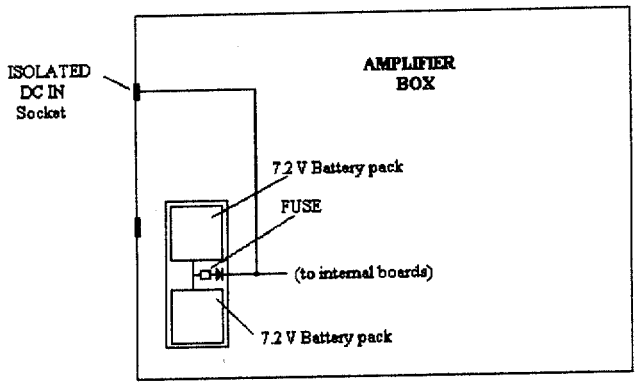

Fig 13 Internal Battery supply

The charge status of the batteries is continuously monitored by the internal DSP and when the battery depletes to a level of charge near the non-functionality area, the system displays a warning message on the LCD display and sends an alarm message to the host system. The host is responsible for the following action at this point.

1.3.6.3 Switching ON or OFF

When power is applied or battery installed, the system automatically goes to a state referred as "sleeping" state (OFF): all the internal circuits are switched off with the exception of a simple circuit which can intercept the pressure of any of the 5 keys of the keyboard placed near to the LCD display. This circuit is designed to use very little current from the power supply so it does not interfere significantly in the duration of the batteries when used.

When a key is pressed, the mentioned circuit enables the internal DC/DC converter and the system goes to the active (ON) status: performs a "Power up Reset" procedure, activates the communication with the host system through the PCMCIA Interface and performs a Self Test Routine whose results are readable by the host system.

The device does not provide a "hardware" method to return to the "sleeping" state. It is the responsibility of the host system to send a "command" that perform this function. There are no means to return to the active state from a host command. Once in the sleeping state, the only way to return to the active state is the pressure of a key on the keyboard. The host system can program a timeout timer which automatically brings the device to the sleeping state at its expiration. Removing the DC input connector (or the batteries) will completely switch off the device.

1.4 Description of the (b)(4) Software Information [redacted]

The figure below shows the interface block diagram:

(b)(4) [redacted]

Fig 14 PCMCIA Interface block diagram

(b)(4) [redacted]

(b)(4)

(b)(4)

(b)(4)

(b)(4) Software Information

(b)(4)

2 System Performance

Due to the characteristic of the analog path and of the A/D converter as explained in the preceding sections the following summarize some important parameters of the amplifiers.

2.1 Resolution, Full Scale Range, Noise

"Differential Input" channels (A,B,C,...H) and "Monopolar Input" channels (1.2.3,...23)

Gain Setting / Resolution	Full Scale Range	Noise(0.1Hz-70Hz)
High 1/8 μV/bit	8000 μVpp	1.5 μVpp max
Low 2 μV/bit	128 mVpp	20 μVpp max

"Monoplar With Attenuator" Input channels (24,...32)

Gain Setting / Resolution	Full Scale Range	Noise(0.1Hz-70Hz)
High 1/8 μV/bit	8000 μVpp	≤ 1.5 μVp-p max ≤ 0.5 μVrms
Low 2 μV/bit	128 mVpp	≤ 20 μVpp max
DC1 10 μV/bit	640 mVpp	≤ 200μVpp max
DC2 20 μV/bit	1.28 Vpp	≤ 500 μVpp max
DC3 100 μV/bit	6.4 Vpp	≤ 1 mVpp max

Expansion board channels

Resolution	Full Scale Range	Noise(0.1Hz-70Hz)
1/8 μV/bit	8000 μVpp	1.5 μVpp max

2.2 Filters

High-Pass:

Standard channels: Either DC or 0.099Hz 1st order filter
Expansion board channels: 0.099Hz 1st order filter

Low-Pass (related to the output of the A/D Converter) :

Frequency cut 0.45 fs (fs = actual sampling rate)
Attenuation 80dB $f \geq 0.55$ fs

2.3 Sampling Rate

Max Sampling Rate

Up to 32768 Hz / channel

The maximum sampling rate depends on the number of channel simultaneously acquired:

Number of acquired channel	Max Sampling Rate
1 16	32768 Hz
16 32	16384 Hz
32 64	8192 Hz
> 64	4096 Hz

Selectable Sampling Rate

With the limit of the maximum sampling rate showed above, the sampling frequency is host selectable for each group of 4 channels.
The frequency must be a power of 2 with a minimum of 128 Hz (128,256 ..... 32768 Hz)

2.4 Sampling Skew

All acquired channels will be sampled simultaneously (no sampling skew).

2.5 Common mode rejection ratio (CMRR)

The fabrication process of the hybrid circuit guarantee a CMRR greater than 100 dB. The wiring path of the printed circuit boards of the headbox and of the interconnecting system is designed in a way to guarantee that the impedance of both leads of any input circuit of all amplifiers is at best balanced.

2.6 Input Impedance

The design of the hybrid circuit guarantee an input resistance greater than 100 Mohms. The same is true for the expansion boards channels

2.7 Impedance Checking

Impedance checking is performed injecting on all electrodes under measure a 20 Hz sinusoidal current of 0.01 μA.

The 40 electrodes of the standard main ACQ board are measured in two groups of 20 electrodes each. The electrodes of each expansion board are measure all together (32 electrodes).

The current is limited by design: the circuit is designed in such a way that also in presence of any Single Fault Condition (SFC) the current flow in the patient is under the limit imposed by IEC 601-1.

2.8 Calibration

The system provides two kinds of "calibration":

Physical system calibration - This is standard calibration where a physical signal is injected into each channel and the signal is measured for amplitude. The signal is sinusoidal and is generated on the amplifier it is available on the 'C' sockets. The reading is filtered and averaged to obtain accurate calibration constants that are stored in the PCMCIA adapter. The DSP on the PCMCIA adapter scales every channel to eliminate gain differences between channels. (This is important when the software must subtract channels from each other). The amplifier serial number is passed to the PCMCIA adapter to eliminate the chance of using calibration constants for the wrong amplifier. The host system is capable of interrogating the serial number of the current amplifier box and the date of last successful physical calibration along with the actual calibration constants (so that limits can be checked to ensure that calibration was successful and the hardware does not fall outside limits). This is a physical system calibration. It should not be required to run this for every study as the gain drift of the amplifiers should be low. This operation is performed in any case under the control of the host computer.

For reasons of noise, there are no internal switches to facilitate disconnecting the patient when running calibration. While no safety hazard is posed, the patient signals would appear mixed with the calibration.

Two devices may be supplied by EBNeuro to facilitate entire system physical calibration.

- Calibration "headbox" - A headbox shall be supplied by EBNuero internally wired such that the calibration signal will be simultaneously applied to all channels.

- Calibration "plug" - This plug may be plugged into the headbox. It is wired such that the calibration signals are simultaneously connected to every channel.

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System Record Calibration - Calibration of the type normally performed at the beginning and end of every study need not be a complete physical end-to-end calibration. At the beginning and end of every study a "digital" calibration should be performed. Under the host computer control, the amplifier generates digital numbers that look like the standard square-wave 50μV calibration that typical users are accustomed to. This is important for verifying filter and gain settings and for setting reference levels in a record.

Proposed Labeling

Affixed Labels

The Amplifier box and the mains adapter are the two energized parts of the system.
The figures below show the proposed ID (Manufacturer) label of the amplifier box in the two current different versions and of the mains adapter.

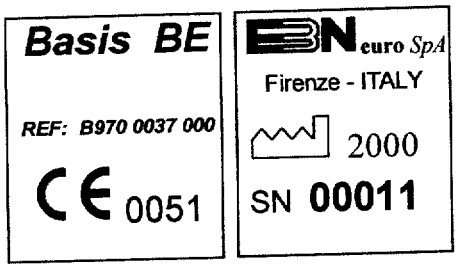


Fig 1 - Identification Label - EBNeuro "Basis BE" version

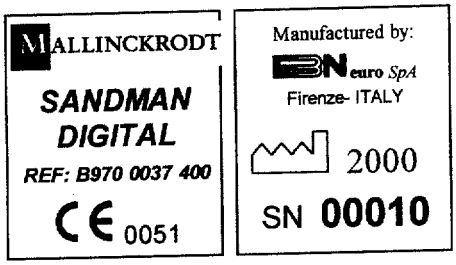


Fig 2 - Identification Label - Nellcor Puritan Bennet (MALLINCKRODT) "Sandman Digital" version

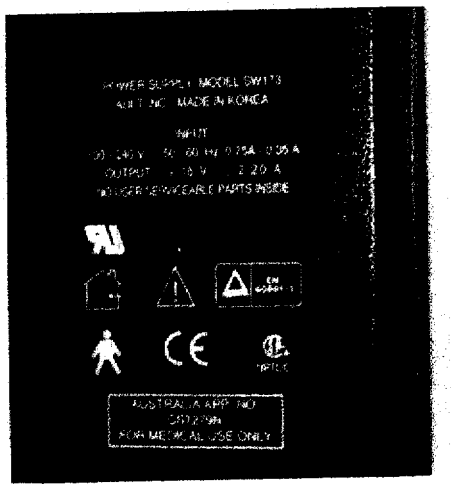
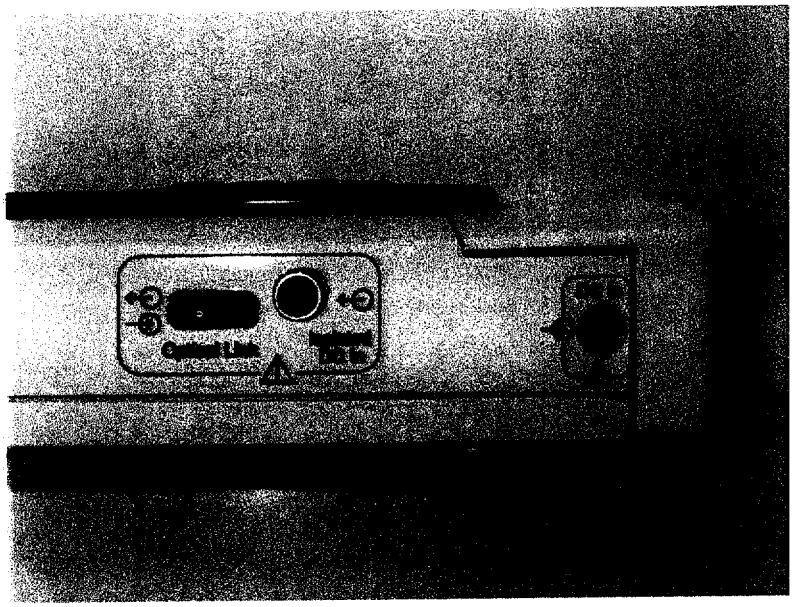


Fig 3 - Mains (AC/DC) adapter Labeling

All other proposed external labeling affixed to the amplifier box are detailed in the figures which follows:
For further information refer to the user manual



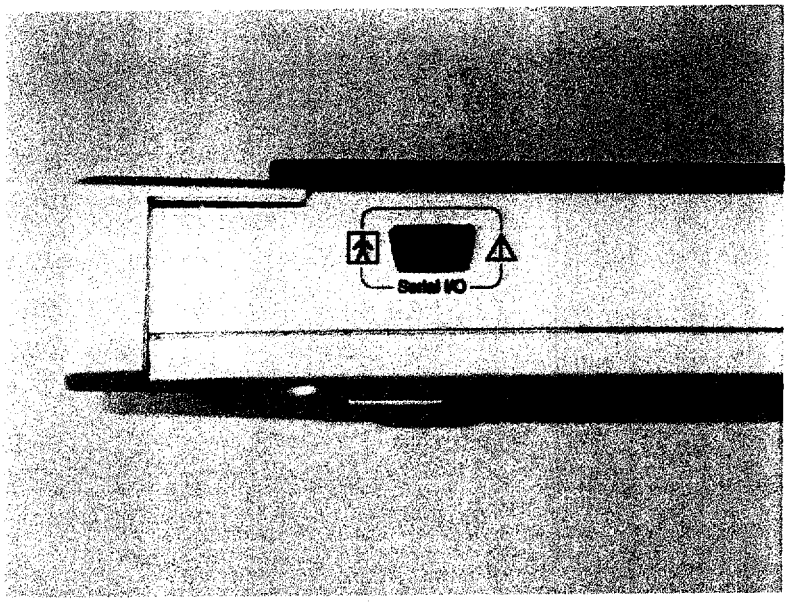


Fig 4 - Amplifier box left and right side labeling

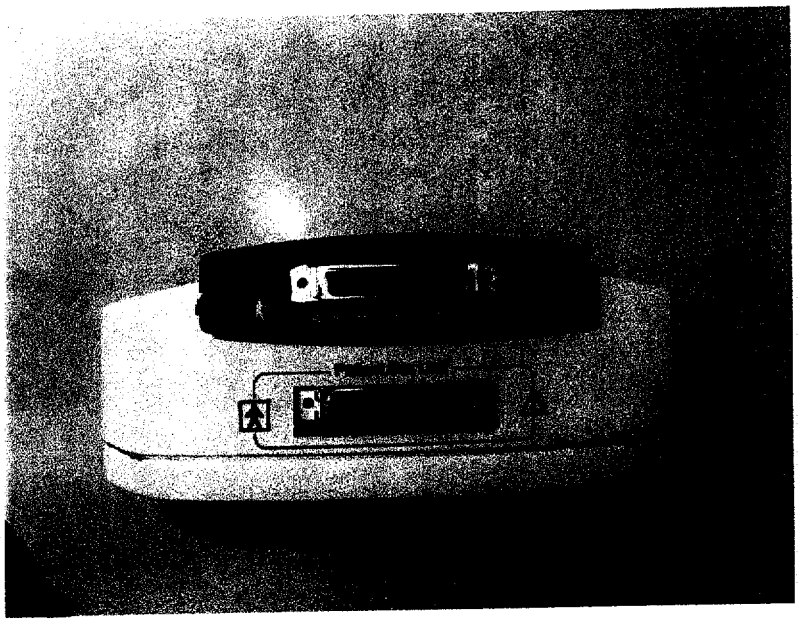


Fig 5 - headbox connection labeling

WARNING
Read instruction manual before using.
Do not remove cover . Refer servicing to qualified personnel

CAUTION
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

Fig 6 - Warning & Caution Labels

When the Pulse Oximetry option or the Expansion board channel is installed, near the related connector is affixed one of the following label

PULSE OXIMETRY SENSOR

EXPANSION CH INPUT

Fig X - 7 Options labeling

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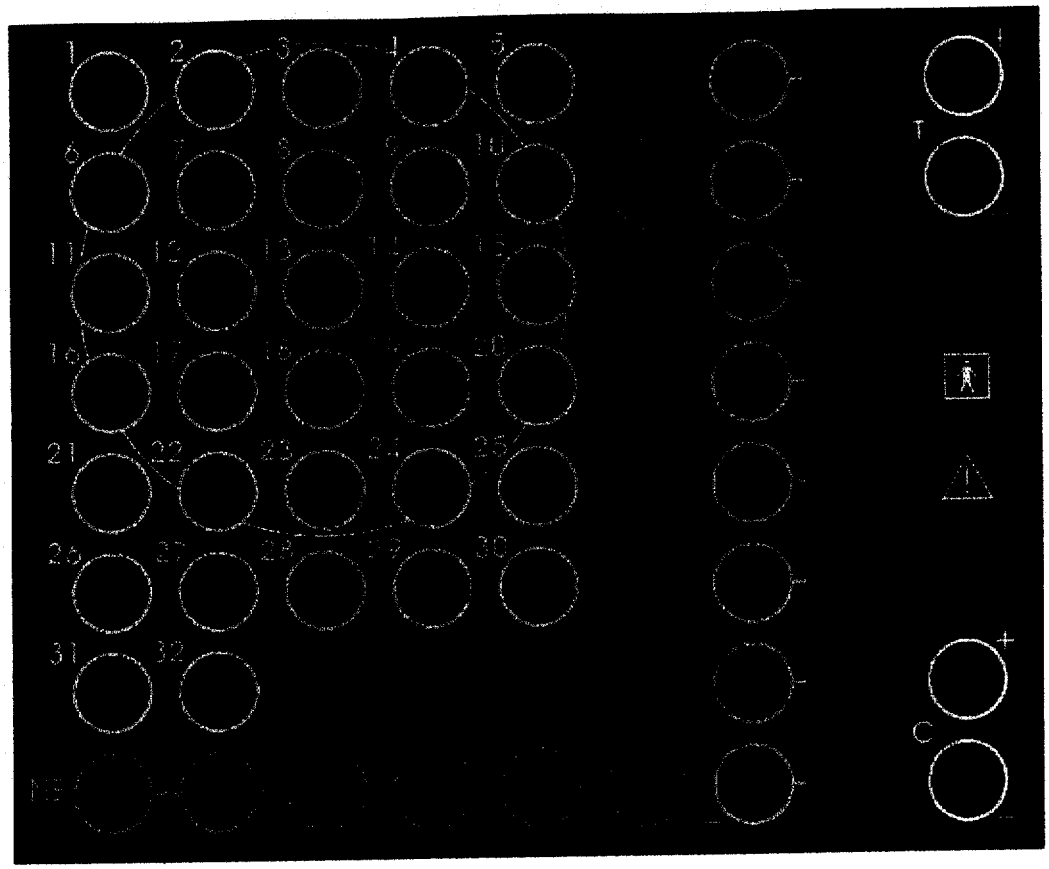

Fig 8 – Headbox socket labeling

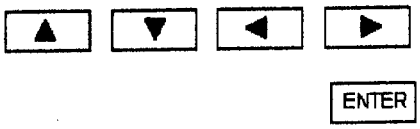

Fig 9 - keyboard labeling

On the PCMCIA Interface the following two labels are affixed :

PCMCIA INTERFACE
REF B9100370500 ⚠
S/N 00010

BN MFG S.p.A.
Firenze ITALY
1999

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Substantial Equivalence Comparison Table

Item	Medcare Artisan Acquisition System - K992283	EB Neuro MIZAR Amplifier
Intended use	Acquisition of EEG and polygrasomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations	Acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations
EEG/Polygraphic channel	32	32/40/64/96/128
DC channel	16	32/40
A/D conversion	22 bit A/D	16 bit Sigma-Delta A/D effectively transferred to host
Sampling rate	User selectable @ more than 1,024/sec./channel	User selectable up to 32 KHz / channel
CMMR	> 105dB	> 100dB
Noise	< 0.5 µVRms	< 1.5 µVpp
Power supply	Not declared	External IEC 601-1 mains adapter (standard) Internal batteries (optional)
Internal Storage	NO Internal storage	NO Internal storage
Amplifier – PC Interface	PCMCIA	PCMCIA
Other Interfaces	No	(b)(4) [redacted]
Optional Integrated Pulse Oximetry module	Yes	Yes
Use standard sensors and electrodes	Yes	Yes
Dimension	10.1 x 12.8 x 2.8 cm (amplif) 10.1 x 12.8 x 2 cm (headbox)	25 x 17 x 6.5 cm
Weight	220 g (amplif) + 200g (headbox)	1.5 KG
Isolation	Fiber optic link	Fiber optic link Patient isolation BF type
Safety Stds	Not declared	IEC 601-1-1 IEC 601-1-2 IEC 601-1-4

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MEDCARE™

ARTISAN*™

The Craftsman of Comprehensive Polysomnography and Neurodiagnostics

As the craftsman of advanced digital amplification, Artisan™ brings technology and design to an unprecedented level of flexibility. Offering state-of-the-art micro-electronics for versatile recording of EEG and polygraphic signals in any configuration, Artisan also provides for portable applications with the use of a laptop computer.

Artisan serves as the perfect tool for multi-media integration and synchronization with REMbrandt™ and Da Vinci™, Medcare Diagnostics' advanced polysomnography and neurodiagnostic systems.

Featuring 32 channels for common reference of bipolar measurement of AC signals such as EEG, ECG, EMG, EOG, and respiration, Artisan also provides 16-channel for connection with the external equipment of your choice for applications such as capnography, PH, or esophageal pressure. Artisan provides your choice of easy snap-in headboxes/jackboxes. Optional, integrated 3-channel oximeter interface for SaO_2, cardio-tachogram, and finger-pulse.

Medcare Diagnostics USA office
401 Creekside Drive
Buffalo, NY 14228
Tel: 716-691-0718
Toll-free: 888-662-7632
Fax: 716-691-1004

Medcare Automation BV – European office
Tel: (0031) 20 346 0130
Fax: (0031) 20 346 0121

www.4medcare.com

Artisan System Includes:

- Complete integration with REMbrandt polysomnographic and Da Vinci neuro-diagnostic software
- Compatible with standard PCMCIA interface for "plug-and-play" on desktop, tower, and notebook PC configurations
- All channels fully isolated with optical isolators
- Choice of standard sensors and electrodes for polysomnography and EEG
- Compact dimensions enable easy system placement
- High-tech fiber-optic links of 500 ft or more (152.4 m) between patient and control room

Specifications:

CMRR: > 105 dB

Noise: < 0.5 μVRms

Sample rates: User-selectable at more than 1,024 per second per channel

AC channels: 22-bit A/D converter per channel for wide, dynamic range

Amplifier Dimensions: 3.9 x 5.0 x 1.1 in. (10.1 x 12.8 x 2.8 cm)

Amplifier Weight: 7.7 oz (220 g)

Headbox/Jackbox Dimensions: 3.9 x 5.0 x .8 in. (10.1 x 12.8 x 2.0 cm)

Headbox/Jackbox Weight: 7.0 oz (200 g)

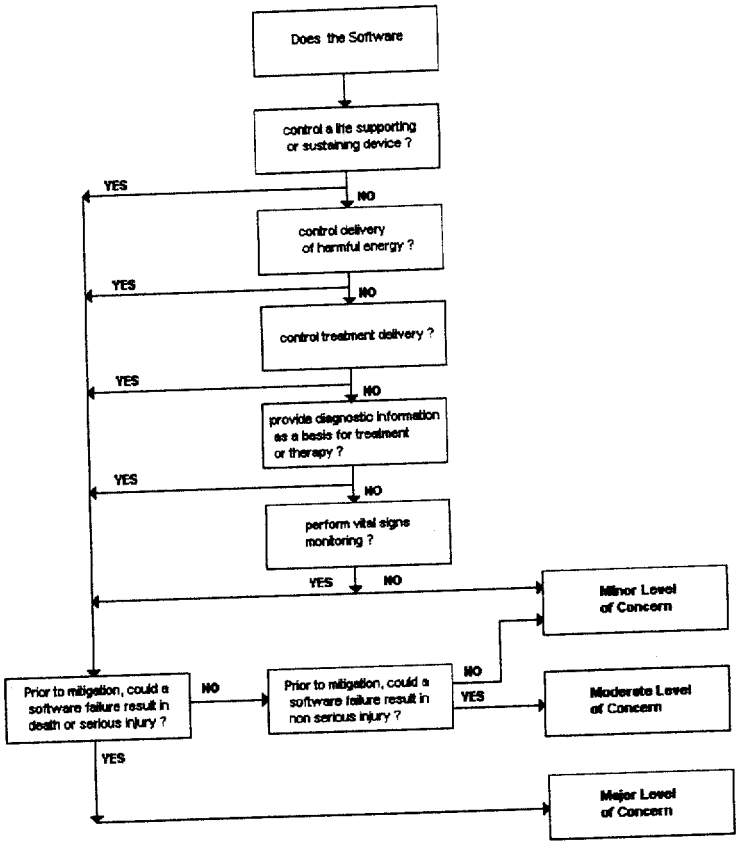
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1 Software Information

The information in this section is given in accordance with the "**Guidance for the Content of Premarket Submission for Software Contained in Medical Device**" issued by FDA on May 29,1998. In the rest of this section this guidance will be referred to as "Software Guidance"

1.1 Level of Concern

The amplifier object of this document has been assessed to carry a **Minor Level of Concern**. This decision has been made by using the flow-chart available in section 2 of the Software Guidance and reproduced below.



This determination implied answering the following questions

Does the software control a life supporting or sustaining device ?

No, the software embedded on the Mizar is only used to get the physiological data and to pass them to the host computer.

Does the software control delivery of harmful energy ?

No, the software control no delivery of energy at all.

Does the software control treatment delivery ?

No, the device is not a treatment device and therefore no treatment is delivered.

Does the device provide diagnostic information as a basis for treatment or therapy ?

No, the software embedded on the Mizar is only used to get the physiological data and to pass them to the host computer. The software does not interpret the acquired data in any way, nor the software assign any "meaning" to particular signals.

Prior to mitigation, could a software failure result in death or serious injury ?

No, in case of software failure the data passed to the host computer may be corrupted and consequently not usable. In case of corrupted data the host computer software and clinical judgment would be exercised to override the information provided by the amplifier.
Calibration signal may be used in case of doubts.
The monitored data is not intended to alarm or trigger alarm for any conditions.

Prior to mitigation, could a software failure result in non serious injury ?

No, for the same reason as stated in the question above

Conclusion

The device carries a **Minor Level of Concern**

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1.2 Software Description

(b)(4)

[redacted]

1.2.1 Device Features Controlled by Software.

(b)(4)

[redacted]

(b)(4)

[redacted]

1.2.2 Other Features Controlled by Software.

(b)(4)

[redacted]

1.2.3 Software Limitations, Customization and Update.

(b)(4)

[redacted]

(b)(4)

[redacted]

1.2.4 Operational environment.

(b)(4)

[redacted]

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1.3 Software Architecture.

1.3.1 Introduction.

(b)(4)

[redacted]

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1.3.2 Software Flowchart.

(b)(4)

[redacted]

1.4 Device Hazard Analysis

(b)(4)

[redacted]

1.5 Design Specification

(b)(4)

[redacted]

1.6 Traceability Analysis

(b)(4)

[redacted]

1.7 Development

(b)(4)

[redacted]

1.8 Validation, Verification and Testing

(b)(4)

[redacted]

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1.9 Revision Level History

(b)(4)

[redacted]

1.10 Unresolved Anomalies

The software carrying a minor level of concern, no documentation concerning unresolved anomalies is included in the submission.

1.11 Release Version Number

The software was released with the version number 01.00

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Risk Analysis

1.1 Purpose

(b)(4)

[redacted]

1.2 Risk Analysis Method

(b)(4)

[redacted]

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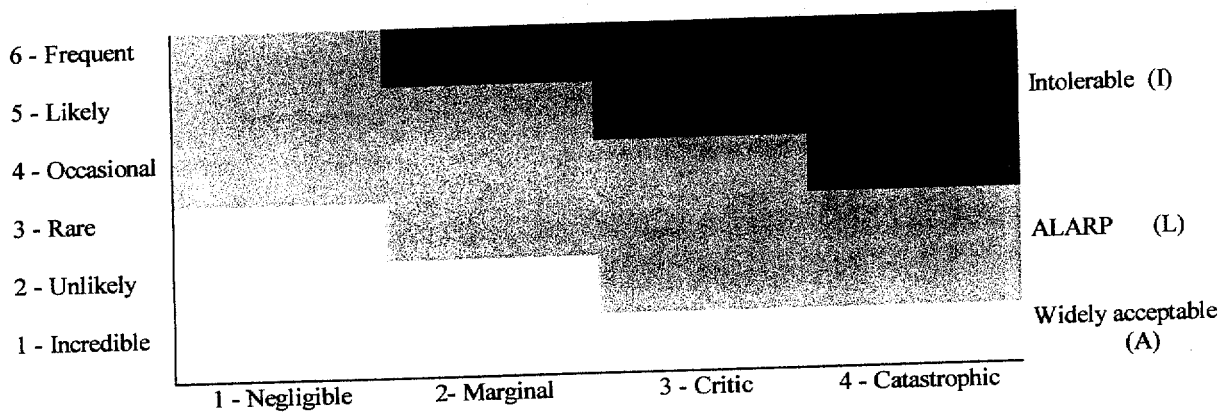
Level of Risk

This is the association of the severity and the occurrence. There are defined 3 "zone" of risk: Intolerable, ALARP, Widely acceptable



- **Intolerable (I) :** The risk is intolerable. Methods must be adopted to reduce the severity of the risk and/or its frequency of occurrence.
- **ALARP (L) :** As Low As Reasonably Possible region. Risk is tolerable only if the risk management cost (to further reduce the risk) is too high in comparison to the benefits
- **Widely accepted (A) :** the risk is acceptable

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1.3 Risk Management

(b)(4)

[redacted]

2 Intended Use

The MIZAR is an amplifier system that amplifies bioelectric signal captured through appropriate sensors from the surface of the human body, converts those signal in digital form and pass these data to an host system. The device performs no elaboration on the signal other than filtering and conversion to digital form.

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3 General Hazard Analisys

The device carries a Minor Level of Concern : this assumption is based on the following factors:

- The possible risk or danger to the patient or user from use of the device.

  There is no risk of injury to the patient or operator due to the use of this device. It is powered by an AC adapter meeting the IEC 601-1 standards requirements which supplies a low voltage (15 V) to the unit. Inside the unit is a DC/DC isolator which further isolates the device from the input DC voltage. The inner DC/DC adapter also meets the IEC 601-1 standards. Optionally it may be powered by an internal battery pack which is not recharged inside the device. The device is fully compliant with the requirements of the normative IEC 601-1-1 (medical devices safety) and IEC 601-1-2 (EMC)

- The degree to which the device can influence therapy or patient diagnosis.

  The device does not control, either directly or indirectly, any therapy administration. It does not monitor the status of critical physiologic parameters and has no alarming mechanism for this purpose. The device does not provide any patient diagnosis.

In conclusion the MIZAR system is a non invasive data-collecting device that pose no risk to the patient or to the operator.
The device is intended only to collect and pass to an host system information that the host system should use for its own purposes.

The device fully conforms to the requirements of the IEC 601-1-1 and IEC 601-1-2 so the hazard related to safety and environmental aspects (EMC) are not treated in this document due to the fact that the risk management is covered by the requirements of the mentioned normative.

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4 Software Hazard Analysis

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[redacted]

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(b)(4) Software Hazard Analysis

[redacted]

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(b)(4) Software Hazard Analysis

[redacted]

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(b)(4)

5 Hazard Analysis and Risk Management Summary

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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Hardware Safety and Environmental Testing Summary Table

Performance Category	Requirements	Reference	Results
(b)(4) [redacted]			

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Hardware Safety and Environmental Testing Summary Table)

Performance Category	Requirements	Reference	Results

Electromagnetic Compatibility

The device conforms to the requirements of the IEC 601-1-2 .

Test are done under the following test methods :

(b)(4)

[redacted]

Passed by testing.

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Hardware Safety and Environmental Testing Summary Table

Performance Category	Requirements	Reference	Results

(b)(4)

[redacted]

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The MIZAR Operator Manual which follows is page numbered independently from the other pages contained in this submission.

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MIZAR

Bioelctric Signal Amplifier System

"*Basis* BE" & "*Sandman Digital*" version

Operator Manual

PRELIMINARY

EDITION:

September 2000

EBNeuro
- FLORENCE -
ITALY

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1 INFORMATION ABOUT SAFETY

1.1 INFORMATION ABOUT THE MANUAL

This document contains proprietary information. No part of this publication may be photocopied or reproduced without the prior written permission of EBNeuro.

Information in this document is subject to change and revision without notice.

Issues:

First edition: B830 0037 400 - Rev. A July 2000

This manual is to be considered as a component of the equipment. When installing the equipment for the first time, the user should accurately check the content of the Manual in order to verify its integrity and completeness.
In the event the Operator Manual should be ruined, incomplete or inadequate, please contact EBNeuro in order to immediately restore or replace the uncompliant Manual.

The official versions of the Operator Manual, of which EBNeuro is directly responsible, are the Italian and the English versions. For countries in which languages other than Italian or English are spoken, the official Manual is the one in the English version. EBNeuro does not undertake any responsibility for any translations in other languages made by distributors or users.

The observance of the operating procedures and of the warnings described in this Manual is a basic requirement for the correct working of the equipment and to guarantee the patient's and the user's safety.
The Manual must be read in every part in front of the equipment before using it, in order to become familiar with the operating procedures, the commands, the connections to the peripheral instruments, and the precautions for a correct and safe usage.

The Operator Manual should be kept, complete and readable in every part, in a safe place, and, at the same time, it should be rapidly accessible to the user when using the equipment.

The equipment Service Manual is available on request. This Manual contains all information directed to the qualified staff in charge for servicing.

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Conventions

In this Owner's Manual the following conventions are used:

Bold is used to emphasize a word or a sentence or to recall the names of the operating functions.

Italic is used for the document titles, for references to literature, for foreign language or conventional words.

VIDEO CHARACTERS are used for messages or operating functions that can be displayed on the equipment monitor.

NOTE

The notes contain important information to be underlined with respect to the rest of the text. They generally contain information useful for the user to correctly perform and use the operating procedures of the equipment.

WARNING

Warning messages appear in the Manual prior to procedures or operations that should be observed in order to avoid any data losses or damages to the equipment.

ATTENTION

Attention messages appear in the Manual with reference to the description of procedures or operations that, if not performed correctly, could cause damages to the user or the patient.

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1.2 DECLARATION OF RESPONSIBILITY BY THE MANUFACTURER

EBNeuro is responsible for safety, reliability and performances of the equipment only when the equipment is used in compliance with the following conditions:

- Modifications or servicing must be performed by qualified staff expressly authorized by EBNeuro.
- The equipment must be opened and its internal parts must be accessed to by maintenance qualified staff only expressly authorized by EBNeuro.
- The environment where the equipment is used must be in compliance with the safety prescriptions.
- The electric wiring of the building must be designed according to the standards and perfectly working.
- Parts of the equipment that can be replaced by the user and accessories, must be replaced with items of the same kind and with the same characteristics.
- The connection of the equipment with peripherals or other instruments supplied by the mains must be performed according to the EN 60601-1-1 standards (standards for electromedical systems) and to the EN 60601-1-2 standards (standards for electromagnetic compatibility).
- Usage and maintenance of the equipment and of its accessories must be performed in compliance with the instructions described in this Manual.
- This Manual must be kept complete and readable in every part..

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1.3 Usage Restrictions and Safety Precautions

In order to guarantee the patient's and the user's safety as well as a correct working of the equipment, it is necessary to operate within the consented restrictions and adopt all the precautions listed below:

ATTENTION

Prior to usage, verify that all the safety requirements are satisfied.
The equipment must not be supplied by or connected to other instruments until such safety conditions are restored.

1.3.1 Electric Safety

Leakage current

The maximum patient leakage current from the MIZAR amplifier, measured according to the test methods of IEC 601-1 is less than 100 μA.

- **However take care when using the equipment at the same time with other instruments.** In the event the patient is connected to several instruments at the same time, it is necessary to remember that the sum of the dispersion currents determined by each instrument may exceed this value.

Patient Connection

All patient connection to the MIZAR amplifier are through the MIZAR headbox using the input sockets provided, or through the dedicated connector of the channels expansion boards when using more than 40 channels. Any patient electrodes connected to the MIZAR by any other means constitutes an unsafe condition that could result in injury or death to the patient.

ATTENTION

All connections on the headbox are isolated from AC power ground.
Do NOT join these connections to earth ground or AC power ground since such an action constitute an unsafe condition that could result in serious injury or accidental death to the patient.

The electrode and sensor through which the signal is captured from the body of the patient are not part of the amplifier system, in any case it is mandatory to use only electrode or sensor approved for commercial use by FDA (USA) or CE marked (EEC)

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To ensure the safety of the patient and the operator, please follow all the warnings and caution listed in this manual

- **Take care when using the equipment at the same time with other instruments**. In the event the patient is connected to several instruments at the same time, it is necessary to remember that the sum of the dispersion currents determined by each instrument may endanger his life.

- **Take care when using the equipment at the same time with other radio-frequency instruments**. In the event the equipment is used in a surgery room at the same time with a radio knife (Radio-Frequency instrument = RF), it is necessary to hold the radio knife point as far as possible from the electrodes, in order to reduce as much as possible the risk of RF currents making on such electrodes and the consequent burns. Therefore it is necessary to use electrodes with a larger surface contacting the patient body, in order to limit the RF current density to acceptable values. In case it is not possible to use the proper electrodes, it is recommended to disconnect the patient from the equipment before using radio-frequency instruments.

- **The equipment is not protected against the defibrillator discharges**. Please remember that the equipment is not protected against the defibrillator discharges; for this reason, in the event it should be necessary to use the defibrillator, it is necessary to disconnect the patient from the equipment in order to avoid the risk of patient being burned in the electrode contact areas and the equipment undergoing severe and irreversible damages.

- **Avoid contact of patient and electrodes with conductive metal items**. When the equipment is connected to other instruments supplied by the mains, the whole input circuit to which the patient is connected is electrically isolated (*floating* isolation). It is necessary to avoid the patient and any conductive part connected to the patient (electrodes, connectors, and transducers) coming into contact with conductive parts (ground included). Please observe this precaution to avoid compromising the equipment isolation level.

- **Replace damaged parts immediately**. Cables, connectors, accessories, or other parts of the equipment must be replaced immediately when damaged or not working correctly. In these cases, contact the nearest authorized servicing center.

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1.4 safety of the operational environment

- **The equipment is not designed to be used in locations with inflammable vapors or gases that may cause explosions**. The equipment must not be used in atmospheres with a high concentration of oxygen or in buildings where inflammable substances or anesthetic agents are present. The atmosphere is considered as oxygen-saturated when the oxygen or nitrous oxide (NO_2) concentration contained in the environment is over 24%.

- **The equipment and its internal parts are not protected against the inflow of liquids.** Avoid submitting the equipment to the risk of water dripping, sprinkling or immersion and using the equipment where such risks are present. Devices in which liquids have accidentally penetrated must be immediately cleaned and checked by authorized qualified staff.

- **Use the equipment within the environmental limits of specified temperature, humidity and pressure**. The equipment is designed to work in environmental conditions that, in compliance with the IEC 601-1 directions, are defined as standard:

- temperature	+5°C / +40°C
- relative humidity	30% / 75% RH
- atmospheric pressure	700 / 1060 hPa

- **Be careful using the equipment when it is moved between locations with different temperatures to avoid any possible condensation phenomenon**. If the equipment is stored or kept in a cold place and is rapidly moved to be used in a warmer building, condensation phenomena may occur (humidity or misting over the internal or external surface of the equipment). In this case it is necessary to wait for humidity to be completely evaporated before supplying and using the equipment.

- **Make sure the electric wiring of the building is efficient in case of connection to other mains powered devices**. When the equipment is connected to peripherals or other mains powered devices, make sure that the latter are connected only to mains outlets with protective grounding. This protection is fundamental for the patient's and the user's safety: therefore, it is necessary that the electric wiring of the building guarantees an efficient protective grounding.

- **Be careful using the equipment in locations disturbed by strong magnetic fields**. The equipment is compliant with the EMC requirements (Electromagnetic Compatibility) according to what specified by IEC 601-1-2 standards. In every case it is recommended to keep the equipment away from disturbance sources and induced electromagnetic fields surpassing the values prescribed by the standard in order to avoid any possible instabilities and malfunctioning of the equipment

- **Be careful using the equipment near short-wave or micro-wave devices**. If the equipment is used in an area where there are also therapeutic short-wave or micro-wave devices, it is necessary to remember that these may cause instability and interfere with the correct working of the equipment. Do not place the equipment near X-ray or diathermy devices

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1.5 GRAPHIC SYMBOLS IN COMPLIANCE WITH THE IEC 601-1 STANDARDS

The following table shows description and localization of all graphic symbols in compliance with the IEC 601-1 (CEI 62-5) safety standards present on the equipment panels and on any other instruments or external devices to which the equipment may be connected.

IEC 601-1 SYMBOL	DESCRIPTION	POSITION
	Alternate current	Symbol placed on the connection points between the equipment and the mains.
	Equipotential terminal	Symbol placed on the outlet connecting the equipment to the equipotential node of the building, if any.
	Protective earth	Symbol placed on the connection points between the equipment and the protective grounding.
	High voltage	Symbol placed on circuits or equipment parts with high voltage.
	Attention! Refer to the attached instructions.	Symbol placed on items for which it is important to read the Owner's manual for relevant information (see ATTENTION paragraph).
	Off (disconnected from the mains)	Symbol placed on the off/on positions of the equipment power switch.
	On (connected to the mains)	Symbol placed on the off/on positions of the equipment power switch.
	Device with BF-type applied items	Symbol placed on items applied to the patient with a BF-protection level.
	Device with B-type applied items	Symbol placed on items applied to the patient with a B-protection level.
	Device with CF-type applied items	Symbol placed on items applied to the patient with a CF-protection level (see NOTE below).

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1.6 OTHER GRAPHIC SYMBOLS

The following table shows description and localization of all symbols placed on the equipment panels and on any other instruments or external devices to which the equipment may be connected.

SYMBOL	DESCRIPTION	POSITION
	Input	Symbol placed on the signal input or mains voltage input connectors of the equipment.
	Output	Symbol placed on the signal output or the mains voltage output connectors of the equipment.
+	**Positive**	Symbol placed on the battery insertion points. The symbol indicates the position of the battery positive pole.
—	**Negative**	Symbol placed on the battery insertion point. The symbol indicates the position of the battery negative pole.
	Optic stimulator	Symbol placed on the optic stimulator connection point.
LOT	**Lot number**	Symbol placed on the identification label of the medical device together with the device lot number.
REF	**Reference number**	Symbol placed on the identification label of the medical device together with the device reference number.
SN	**Serial number**	Symbol placed on the identification label of the medical device together with the device serial number.
	Date of manufacture	Symbol placed on the identification label of the medical device together with the device manufacture date.
	Use by	Symbol placed on the identification label of the medical device together with the device expiration date.
	Do not reuse	Symbol placed on the identification label of the medical device. This symbol indicates that the device is a disposable one and cannot be used more than once.

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SYMBOL	DESCRIPTION	POSITION
STERILE	**Sterile**	Symbol placed on the identification label of the medical device indicating a sterile device.
STERILE	**Sterilization with steam or dry heat**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (steam or dry heat).
STERILE EO	**Sterilization with ethylene oxide**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (ethylene oxide).
STERILE R	**Sterilization by irradiation**	Symbol placed on the identification label of the medical device indicating a sterile device and the sterilization method used (irradiation).

1.7 ATTENTION SYMBOL

The ATTENTION symbol shown below, placed on the equipment casing, refers the user to the Operator Manual for information, warnings and suggestions which are particularly important for a correct and safe use of the equipment.

In particular, when it is placed on points connecting cables to peripherals, this symbol refers the user to carefully read the Operator Manual for instructions concerning the nature of such cables and peripherals and the modalities for a correct and safe connection.
For location of the ATTENTION symbols placed on the equipment, please refer to chapter "*Installation and connections*" of this Operator Manual. This chapter shows the pictures of the equipment panels with the corresponding commands, connections, symbols, and labels. Each attention symbol comes with a detailed explanation of its meaning.

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1.8 PRODUCT TRACEABILITY

In order to guarantee the traceability of the product, according to what stated in the EN 46001 quality standards and the 93/42/EEC European Directive on Medical Devices and FDA QRS requirements, EBNeuro kindly requests the original equipment owner to communicate to our main offices of any conveyance of the product to a third party, by sending a photocopy of the proper duly filled-in Product traceability form **(see enclosure 1.7)**, or by communicating in writing the data indicated in the form. The data concerning the device can be found on its identification label.

The form shall be sent either directly or through any subsidiary or the nearest authorized distributor to the Quality Assurance Department of any EBNeuro operating office.

1.9 VIGILANCE SYSTEM

The device is subject to a vigilance system (post-marketing vigilance) that EBNeuro and their distributors and retailers apply to the products they put on the market to safeguard the patient and the physician from serious or potentially serious hazards during the normal use of the equipment, in order to be able to remove the source of such hazards with the best efficiency and timing.

To the purpose of helping EBNeuro take any timely and effective corrective measure, it is extremely important that the user performs a careful inspection of the equipment performances in order to identify or foresee any dangerous situation for the patient's and the user's health.

For this reason, the user shall give immediate communication of any malfunction or deterioration of the characteristics or the performances of the equipment or any mistake found in these instructions that caused or could cause serious damages to the patient's and the user's health.
In this case, the user may send a photocopy of the proper duly filled-in *Post-Marketing Vigilance Form* **(see enclosure 1.8)**, or communicate in writing the data indicated in the form.

The form shall be sent either directly or through any subsidiary or the nearest authorized distributor to the Quality Assurance Department of any EBNeuro operating office.

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enclosure 1-7

PRODUCT TRACEABILITY FORM

To: EBNeuro S.p.A.
Servizio Assicurazione Qualità
Via Pietro Fanfani, 111/A
50127 Firenze - Italy

System/device name.....

Device code/reference number (REF)
.....

Device serial (SN)/lot number(LOT) .....

Name and address of the former owner.....
.....
.....
.....

Name and address of the present owner.....
.....
.....
.....

Date:.....

signature

.....

(please name in full)

(ref. Operator Manual code B830 0037 400 Rev. A)

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enclosure 1-8

POST-MARKETING VIGILANCE FORM

To: EBNeuro S.p.A.
Servizio Assicurazione Qualità
Via Pietro Fanfani, 111/A
50127 Firenze - Italy

System/device name.....

Device code/reference number (REF)
.....

Device serial (SN)/lot number(LOT) .....

Description of the real or potential hazard.....
.....
.....
.....
.....

User's comments/suggestions.....
.....
.....
.....
.....

User's address.....
Phone..... Fax .....

Department where the device is installed.....
Person in charge of the department.....

Date:.....

signature

.....

(please name in full)

(ref. Operator Manual code B830 0037 400 Rev. A)

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1.10 PARTICULAR WARNINGS FOR CRITICAL COMPONENTS

The instrument is provided with a LCD (Liquid Crystal Display), and it uses (optionally) Li-Ion rechargeable batteries, which contain small quantities of toxic materials.
In order to avoid personal injuries and to reduce the negative impact on the environment, make sure you carefully follow these instructions:

LDC Display:
The LCD is fragile (glass) and must be treated with much care: for this reason we recommend to protect the PC with the proper carrying bag during transportation or when it is not used.
In the event the LCD glass should break and liquid spill out of it, make sure you do not touch it.
Wash with water for at least 15 minutes any body part that may have been in contact with it carefully. Should you experience any symptom after this period, ask for immediate medical help.

Batteries:
Avoid terminal parts of the battery pack coming in contact with metal objects.
Keep the battery pack away from heat sources or flames.
Do not immerse the battery pack and avoid exposing it to rain or humidity.
Avoid directly hitting the battery pack.
Do not attempt to disassemble, burn or cause short-circuits to the battery. Such operations may cause a fire or emission of toxic chemical substances.

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1.11 INFORMATION ABOUT RECYCLING OF MATERIALS

In accordance with the specific European directives, EBNeuro aims to continuously improve the design and the fitting of electromedical devices in order to reduce as much as possible any negative impact on the environment caused by the management of component parts, consumer materials, packaging and discharge of devices when at their "end of life".

Packaging materials were conceived and produced so as to allow the re-usage and the salvage, including recycling, of most part of materials and to reduce the quantity of garbage or residual products for discharge as much as possible. In particular, packaging materials have been produced so as to limit the presence of harmful metals and of other dangerous substances to minimum quantities in emissions, ashes or lixiviation residual products. The total concentration levels of heavy metals such as Lead, Cadmium, Mercury and hexavalent Chrome contained in the packaging materials are in accordance with the limits established by the directives in force related to this subject.

In order to cause minimum consequences to the environment, the design of the device includes the highest possible miniaturization of the circuits, with the least possible differentiation of materials and components, with a selection of substances that guarantee the highest possibility to recycle and re-use the components and to discharge them without risks for the environment.

The device is designed to guarantee the easy separation or disassembling of the materials containing polluting substances from the others, in particular during the operations of servicing and replacing parts. In particular, the largest plastic components are marked according to their plastic contents in order to make it easier to recycle the product.

ATTENTION

Please refer to local codes for proper disposal/recycle requirements of packaging and consumer materials and of the device when at its "end of life".

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1.12 BIOCOMPATIBILITY AND INFECTIONS CONTROL

No system component is intended to be in contact with the patient.

All body contacting materials are not a part of the system; electrodes and sensors must meet the requirements of FDA (USA) or MDD directive 93/42/EEC .

1.13 DECLARATION OF CONFORMITY

CE MARK

The equipment has been manufactured by applying the quality guarantee system approved for design, manufacturing and final check of the product and meets the requirements of Annex II of the 93/42/EEC Directive on Medical Devices (MDD).
For these reasons the equipment is marked with the CE mark.

1.14 CAUTION FOR THE U.S. MARKET

Federal law restricts this device to sale by or on the order of a physician.

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2 System description

Background

A number of medical devices are used to detect, graphically record and store for delayed retrieval the electric signal produced by various parts of the human body. An example of such a device may be an electroencephalograph or an electrocardiograph.

Typically these medical devices are composed of two main parts:

a) an amplifier system which collects the bioelectric signals from the surface of the human body through appropriate electrodes or sensors, which intensify the very low signal captured (typically the amplitude range is of the order of the μVolts), condition them (filtering), convert them to digital form.
b) a computer running an application software that receives the data from the amplifier, displays the data in various formats, stores the data and generates graphic and text output for printers.

The MIZAR device developed by EBNeuro is the object of this submission and is the amplifier portion described above. Mizar is intended to be used as the acquisition portion of an entire bioelectric diagnostic system.

Description of the system

The amplier system which is the subject of this 510(k) submission is being cleared under the name MIZAR, however, it is to be marketed by two distributors under the following names: EB Neuro's version is called "**Basis BE** " (**Basis Brain Explorer**) and Nellcor Puritan Bennett's version is called "**Sandman Digital**". The two versions differ only in name and external labeling. Details on the different labeling are included in this section.

The MIZAR is a fully programmable amplifier system which can range from 24 up to 256 channels. The amplifier receives its power from a dedicated AC/DC adapter, meeting the IEC 601-1 requirements, which feeds a +15VDC. Internally the +15VDC is further isolated by a dedicated DC/DC converter of class BF. Optionally the power may be supplied by an internal battery pack.

The MIZAR amplifier is intended to be used to amplify and filter bioelectric signals captured via a lead or transducer on the surface of the human body. It captures the data, converts it into a digital form, and passes it on to a host computer running appropriate amplification software. Typical fields of application will be: Electroencephalography (EEG), Evoked Potentials (EP), Electromyography (EMG), Polysonography (SLEEP ANALISYS) and General Polygraphy.

The system can configure, amplify and convert to digital form (analog to digital conversion) from 24 (the minimum configuration) to 256 (the maximum expansion) signal channels. The typical and standard configuration is with 40 channels.

Optionally, the system may contain a Pulse Oximeter circuit. The data measured from this circuit is passed to the host computer together with the other channel's data. The pulse oximeter module circuit is developed by Nellcor Puritan Bennet. The amplifier simply incorporates this module, providing it with the necessary power and reading its output to pass the measured oximetry to the host computer. The pulse oximeter option limits the number of signal channels to 40. If the pulse oximeter option is installed, it is no longer possible to install the channel expansion board. For the same (physical) reason, if one or more channel expansion boards is installed, it is not possible to install the pulse oximeter option.

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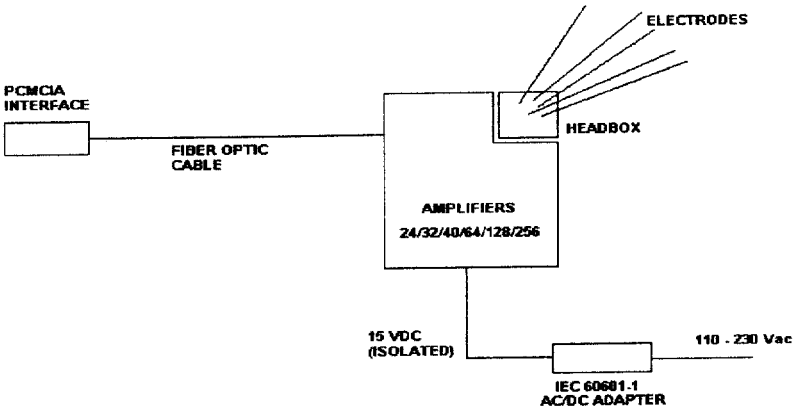
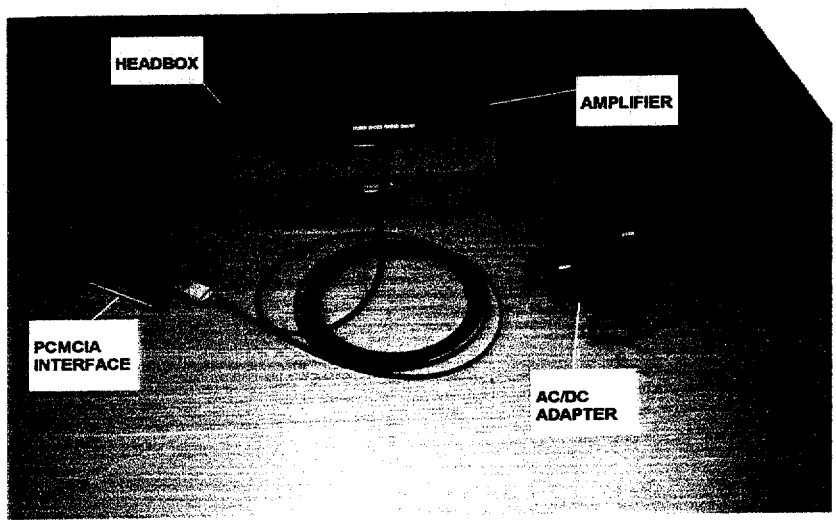
The host computer must operate under one of the following Operative Systems:
Microsoft Windows 98
Microsoft Windows NT

The "software" interface to MIZAR consists of two simple modules (a Dynamic Link Library, DLL and a "device driver", VXD or SYS) which are furnished by EB Neuro.

The MIZAR "system" consists of 4 interconnected units : the headbox, the amplifiers box, the PCMCIA interface and the AC/DC adapter. Optionally the AC adapter can be replaced by an internal battery pack, see section 1.3.6.2.





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The **headbox** physically connects the source of signals (the patient) to the amplifier.

The **amplifier box** has the following functions:
intensify signals from the electrodes
reference input channels
generate calibration pulse
provide dynamic range (gain), sampling rate and active channels selection
provide impedance testing capabilities
provide anti-aliasing filtering to optimize A/D conversion
provide A/D conversion
transmit the digital data through the fiber optic link to the PCMCIA interface

The **PCMCIA interface** has the following functions:
Receives the digital data from the amplifier box
Rearranges the data in a format more readable by the PC
Provides the PC interface through a dual-port memory
Programs the amplifier (through the fiber optic link) in response to commands from the PC

The **AC/DC adapter** provides an isolated +15V DC to the internal BF DC/DC isolator. The +15V DC is isolated from the mains in accordance with the IEC 601-1 safety standards. (class I, type B).

2.1 Description of the headbox

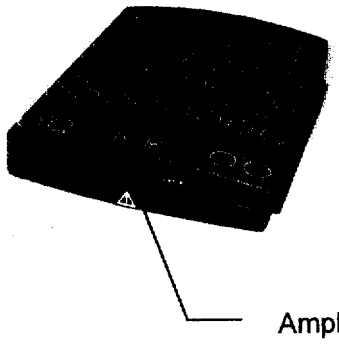
The headboxbox contains the connecting point for the electrodes
There are a total of 68 socket which accept 1.5 mm electrode safety pin plug.
Each headbox can accommodate 32 AC/DC monopolar channels, 1 reference channel, 8 AC/DC bipolar channel.

Normally the headbox is "plugged" in the amplifier box but it can be detached and connected to the amplifier by a six foot cable. This cable, referred in the following as "extension cable", when in use, should be kept clear of other devices or cords (for best performances)

Connectors

The headbox has two connectors : the Amplifier connection port and the ExtensionCable/Prewired headset Port

Amplifier Connection
This connector (50 pin male SCSI II – Microcentronics type) connects the headbox to the amplifiers directly or by means of the "extension" cable



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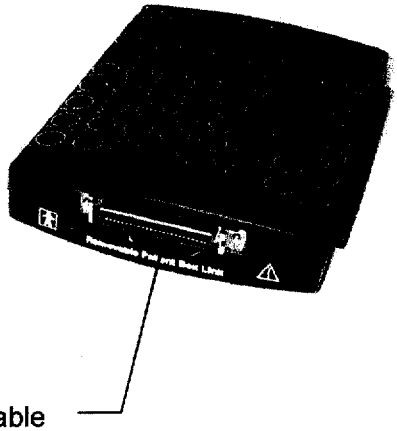
Removable Patient box Link / Prewired headset

This connector (50 pin female SCSI II – Microcentronics type) is used for two different purpose

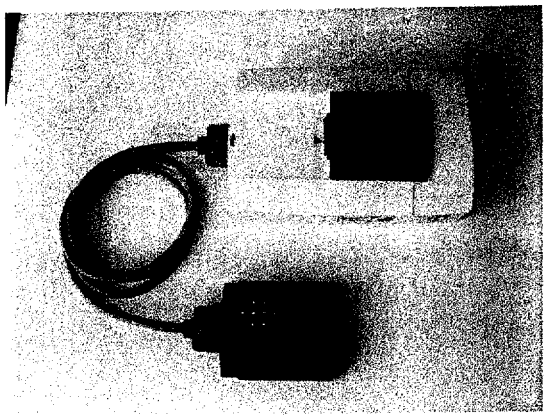
- to link the headbox to the amplifier box through an "extension cable" which allows the removal of the headbox from the amplifier box and to use the headbox "detached" from the amplifier (see figure below)
- connect a prewired headset which collects signals to the headbox

ATTENTION

to meet IEC 601-1 requirements, when not used the "Removable Patient Box Link" connector must be covered by an appropriate plastic cover



Removable Patient Box Link



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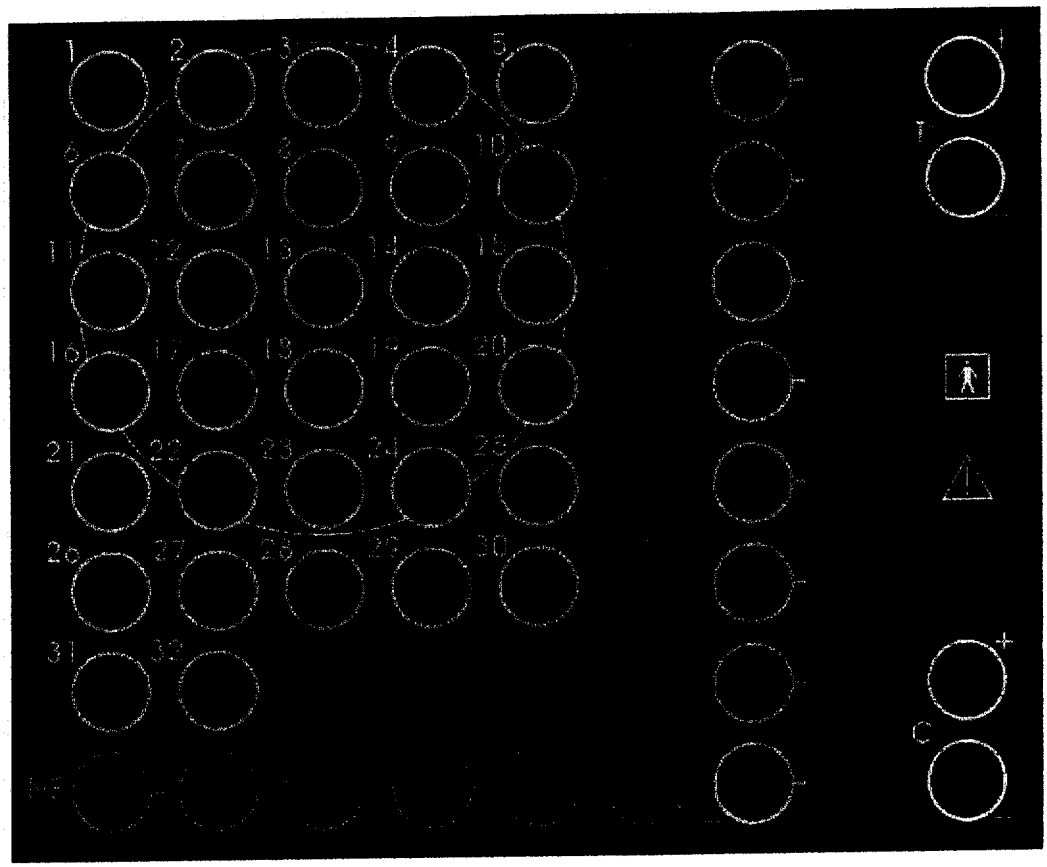
Headbox Socket



The headbox has 6 type of socket : Monopolar Inputs, Bipolar Inputs, Reference, Neutral (patient Ground), Temperature and Calibration

Monopolar Inputs : labeled with a number ranging from "**1**" to "**32**"; these inputs accept primary electrode site and signals. The electrode from the subject are plugged into the socket on the headbox. The amplified signal is the difference of potential between the electrode and the Reference electrode.

Bipolar Inputs : labeled with a letter ranging from "**A**" to "**H**"; these inputs accept primary electrode site and signals. The electrode from the subject are plugged into the socket on the headbox. The amplified signal is the difference of potential between the "+" and "-" electrode of each inputs.

Reference : three paralleled socket labeled "**RL**"; the reference electrode should be connected to one of these socket. Monopolar inputs are referenced to this signal.

Neutral (Isolated Ground) : labeled "**NE**"; there are 13 paralleled socket with this function; They may be used to connect the patient ground or to create patient ground referenced inputs, (such as respiratory belts, nasal/oral sensors etc)
Leakage current is prevented from finding a direct path to the subject.

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Temperature: this two socket labeled **T°** are provided for input becoming from a temperature probe.
Notice that this input is NOT enabled when using the headbox connected to the amplifier with te extension cable.

Calibration: this two socket labeled **C** are provided for outputting the calibration signal (when enabled) : this may be used to connect the signal to any inputs to test the whole chain including the lead used for the connection.
Notice that this input is NOT enabled when using the headbox connected to the amplifier with te extension cable.

NOTE – using more than 40 channels

When using one or more channels expansion board (64 channel each board) the input for these extra channels are not on the headbox but on the related connector provided on each channel.
In this case you need necessarily a prewired headset or a special cable to connect to these channels.

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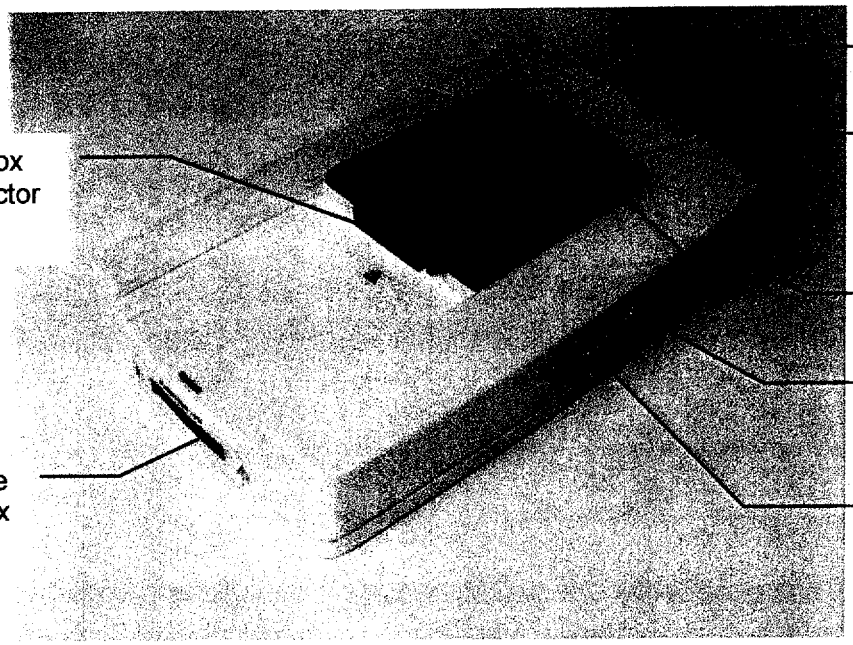
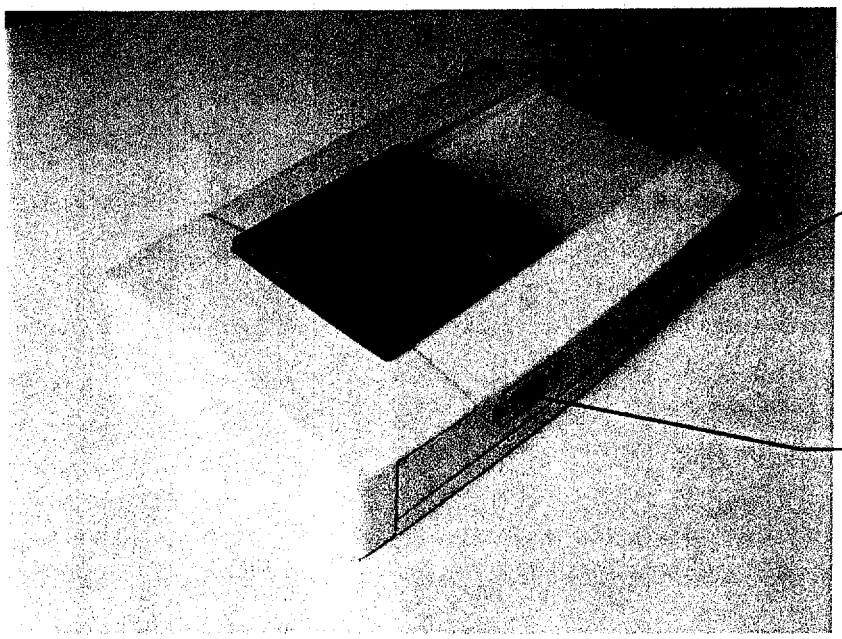
2.2 Amplifier box description

The amplifier box has 6 external connectors, an "output" device made by a graphic LCD display and an "input" devices made by a set of 5 keys. (see the two following figures).





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Connectors

Headbox Connection
This connector (50 pin female SCSI II – Microcentronics type) connects the headbox directly to the amplifiers when the headbox is "plugged" in the amplifier case.

Remote Patient box Link
This connector (50 pin female SCSI II – Microcentronics type) is used
- to connect the headbox to the amplifier through the extension cable
- to connect a prewired headset which collects signal to the headbox

ATTENTION

to meet IEC 601-1 requirements, when not used the "Removable Patient Box Link" connector must be covered by an appropriate plastic cover

Fiber Optic : this ports links the amplifier and the PCMCIA interface. The fiber optics achieve an absolute level of isolation from the "PC" side. The PC and the PCMCIA interface should be placed outside of the "patient area". If this is not possible the PC should be powered through a dedicated isolation transformer.

Serial I/O : this D type 9 pin cannon is used to connect an optional external device through an isolated serial interface. This interface is reserved for future expansion.

ATTENTION

This connector is electrically wired on the isolated part of the device.
It must be used to connect only devices specified by EBNeuro .
Do not connect any other device since such an action may constitute an unsafe condition that could result in serious injury or accidental death to the patient.

DC power in : this 4 pin socket is used to feed dc power (15 VDC) to the amplifier.
The DC power is supplied by the external IEC 601-1 AC/DC adapter.
The socket is a special type socket to minimize the risk to plug with devices "other" than the right one.

ATTENTION

Use only to connect to the mains adapter provided by Ebneuro with the system.
(Ault Inc mod SW173 – EBNeuro ref B973 065 009)

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ISOLATED DC power in : this 4 pin socket is used to feed dc power (15 VDC) to the amplifier.
In this case the DC power is supplied by an external power supply which must meet the requirement of IEC 601-1 and its output must be of BF type.
This is intended as a reserved input provided for future expansion of the system.
The socket of the two DC input are of different type to avoid the possibility to connect one in place of the other.

ATTENTION

This connector must be used only to connect devices specified by EBNeuro. Do not connect any other device since such an action may constitute an unsafe condition that could result in serious injury or accidental death to the patient.

Pulse Oximetry Probe / Expansion Channels :

This 15 pin Microcentronics male connector links the internal pulse oximeter circuit (when installed) to the finger probe provided to measure the oximetry.
This connector must be used to connect ONLY the Nellcor Puritan Bennet Pulse Oximetry Cable mod MC-10 and related sensors.

ATTENTION

The amplifier uses (optionally) a Nellcor Puritan Bennet (NPB) MP404 Pulse Oximetry Module inside.
Use only with NPB MC-10 cable and NPB DS-100A Oxigen sensor or equivalent.

When the channels expansion board are installed in this place there is the input connector for the extra channels added to the system.
Remember that channels expansion board and pulse oximeter option cannot be present at the same time.

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LCD Display

This graphic display is used by the firmware of MIZAR only to signal the "ON" status and the result of its internal autotest at power up.
Apart from this, the display is under the complete control of the host computer that, through the communication protocol can access this display and write anything it wants.
The MIZAR firmware is involved only in executing the command coming from the host computer.

Keyboard

This 5 keys are directly used by MIZAR only to "pass" the amplifier from the stand by mode to the active mode.
When in the active mode, when the user presses a key, the related code is passed to the host computer.
MIZAR does not assign any particular meaning to any of these codes : their management is under the complete control of the host computer software.

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2.3 PCMCIA Interface description

The PCMCIA interface is substantially the bridge between the amplifier and the host computer.
The interface is linked to the amplifier by a bi-directional fiber optic link
Through this link the interface receives the digital data from the amplifier and sends programming information to the amplifier.
The interface is "seen" by the PC like a static ram card in which the PC can read or write some structure defined by the *Computer-MIZAR communication protocol.*

The interface has 2 external connectors : the PCMCIA standard connector to fit in a standard PCMCIA socket and the fiber optic cable connector

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3 Power supply

The amplifier may be powered by three methods, and an alternative, system.

1. The first (standard) is from mains through a commercial AC/DC adapter which feeds an internal DC/DC isolator
2. Provision have been made to power the unit by an external mains adapter which feeds the unit with an isolated DC supply with a BF type DC output. The mains adapter must meet the requirements of the IEC 601-1 standards. This applies to a different socket than that provided for the case 1. The two power input socket (DC IN and ISOLATED DC IN) are NOT INTERCHANGEABLE . This method is not commercially released and it is intended for future expansion of the system. Normally the ISOLATED DC IN Socket is actually covered by a plastic cover.
3. The third method is through an internal battery pack.

3.1 Mains power supply

The external AC/DC is a Class I mains adapter with a DC OUTPUT of 15 VDC / 2.2A.
The adapter meets the requirements of the IEC 601 –1 standards .
The output is a type B output

The output of the AC/DC adapter feeds the internal DC/DC isolator which meets the requirement of the IEC 601-1-1; The output of the DC/DC isolator is of type BF.
The output of the DC isolator feeds the various DC/DC converter placed on the main ACQ board.
The DC/DC converter generates the various supplies for the internal circuitry.

NOTE

The ISOLATED DC IN socket is not currently used and is intended for future development of the system.
Due to mechanical properties it is impossible to plug the output of the AC adapter into the "Isolated DC IN" socket

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3.2 Battery power supply

Optionally, the power to the amplifier may be delivered by two commercial battery packs which take the place of the DC/DC isolator inside the amplifier box. (see the figures below)

When the batteries are installed it is not possible to power the system by the external AC/DC adapter (the DC IN connector is not accessible in the device).

Battery type

The battery consists of a 2 battery pack of 7.2 VDC **SONY "InfoLITHIUM" model NP-F730**.

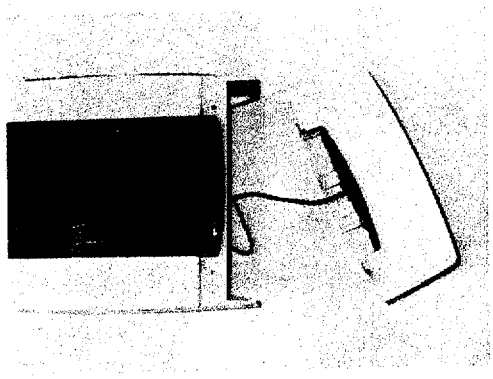
Recharging the batteries

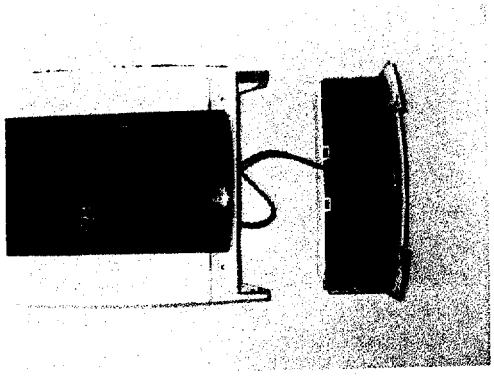
The batteries are not rechargeable when installed into the device.
To recharge the batteries should be removed and recharged through the related external battery charger.
The battery charger is a **SONY model AC – V700**.
To recharge please follow the instructions which come with the battery pack and the battery charger.

Inserting or removing batteries

To insert or remove batteries act as follow :

1. Remove the two screws holding the cover of the battery holder on the bottom of the amplifier box
2. Extract the battery holder pulling it toward the external portion of the housing





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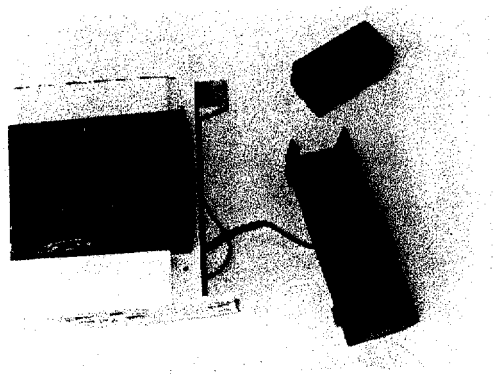
3. The two battery packs can now be extracted simply by sliding them toward the external portion of the battery holder.



4. Reverse if you are inserting the battery pack. Be sure to insert firmly .
5. Reinsert the battery holder in its housing
6. Place the battery housing in its original position
7. Replace the two screws to fix the battery holder.

The battery holder is designed in such a way to prevent insertion of the battery with a reverse polarity.

3.3 Switching ON or OFF

When power is applied or battery installed, the system automatically goes to a state referred to as "sleeping" state (OFF) : all the internal circuits are switched off with the exception of a simple circuit which can intercept the pressure of any of the 5 keys of the keyboard placed near the LCD display.
This circuit is designed to sink a very little current from power supply so it does not interfere significantly with the duration of the batteries when used.

When a key is pressed the mentioned circuit enables the internal DC/DC converter, the system goes to the active (ON) status : performs a "Power up Reset" procedure, activates the communication with the host system through the PCMCIA Interface and performs a Self Test. Routines whose result are readable by the host system.

The device does not provide a "hardware" means to return to the "sleeping" state.
It is the responsibility of the host system to send a "command" that performs this function.
There is no means to return to the active state from a host commands : once in the sleeping state the only way to return to the active state is the pressure of a key on the keyboard.

The host system can program a timeout timer which automatically brings the device to the sleeping state at its expiration.

Removing the DC input connector (or the batteries) will, of course, switch completely off the device.

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4 Calibration

MIZAR system provides two kind of "calibration"

4.1 Physical system calibration

This is standard calibration where a physical signal is injected into each channel and the signal is measured for amplitude. The signal is sinusoidal and is generated on the amplifier it is available on the 'C' sockets. The reading is filtered and averaged to obtain accurate calibration constants that are stored in the PCMCIA adapter. The DSP on the PCMCIA adapter scales every channel to eliminate gain differences between channels. (This is important when the software must subtract channels from each other).
The amplifier serial number is passed to the PCMCIA adapter to eliminate the chance of using calibration constants for the wrong amplifier. The application software must be capable of interrogating the serial number of the current amplifier and the date of last successful physical calibration along with the actual calibration constants (so that limits can be checked to ensure that calibration was successful and the hardware does not fall outside limits). The application software should not permit operation unless the last successful calibration falls within an acceptable date range.
This is a physical system calibration. It should not be required to run this for every study as the gain drift of the amplifiers should be low. This operation is performed in any case under the control of the host computer.
For reasons of noise, there are no internal switches to facilitate disconnecting the patient when running calibration. While no safety hazard is posed, the patient signals would appear mixed with the calibration. Two devices may be supplied by EBNeuro to facilitate entire system physical calibration.

- Calibration "headbox"

A headbox shall be supplied by EBNuero internally wired such that the calibration signal will be simultaneously applied to all channels.

- Calibration "plug"

This plug may be plugged into the headbox. It is wired such that the calibration signals are simultaneously connected to every channel.

4.2 System Record Calibration

Calibration of the type normally performed at the beginning and end of every study need not be a complete physical end-to-end calibration.
At the beginning and end of every study a "digital" calibration should be performed. Under the host computer control, the amplifier generates digital numbers that look like the standard square-wave 50μV calibration that typical users are accustomed to. This is important for verifying filter and gain settings and for setting reference levels in a record.

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5 Software Installation

5.1 Host Computer Requirements

The MIZAR system does require that the host computer

- Is provided with Windows 95/98 or Windows NT Operating System
- Is provided with a PCMCIA adapter with at least one type III slot capable of powering the PCMCIA card with the 3.3 VDC.
- Under Windows NT the System Soft Cardwizard must be previously installed

The following assumes that the PCMCIA driver has been correctly installed and is correctly running on the related host computer.
The operation for installing the PCMCIA driver hardware and software are outside the scope of this manual. Refer to the documentation of the host computer for details.

5.2 Installing the MIZAR software drivers

5.2.1 Under Windows 95/98

The MIZAR amplifier is managed under Windows 95/98 by two software modules: a Dynamic Link Library (DLL) and a device driver (VXD).
Their names are MIZAR:DLL and MIZAR.VXD.
These two files must be copied in the working directory of the application software running on the host computer.
The application driver interfaces with the MIZAR DLL which, in turn interfaces with the device driver.
For detail on the interface between the application software and the MIZAR DLL refer to the documentation describing the MIZAR communication protocol.

5.2.2 Under Windows NT

The MIZAR amplifier is managed under Windows NT by two software items: a Dynamic Link Library (DLL) and a device driver (SYS).
Theirs name are MIZAR:DLL and MIZAR.SYS.

To install this software simply run the program BCARD.INF provided by EBNeuro in the diskette accompanying the MIZAR system.

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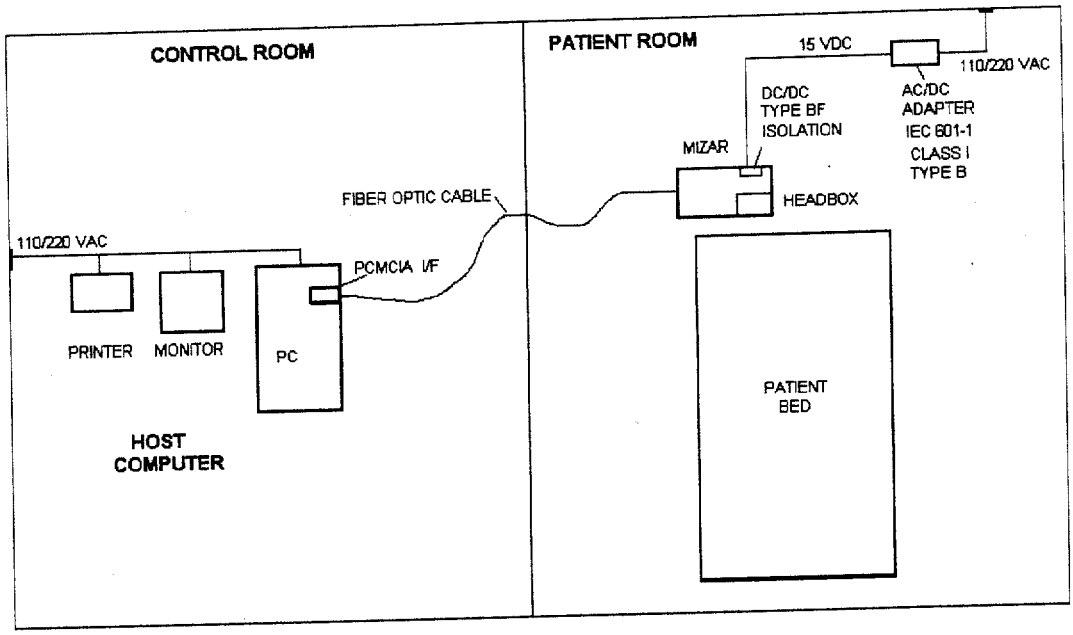
6 Connections

To install the MIZAR amplifier simply:

1. Insert the PCMCIA interface in a PCMCIA type III slot on the host computer
2. Connect the fiber optic cable on both sides (one side to the PCMCIA interface and the other to the Amplifier box.
3. Connect the DC input from the AC/DC adapter to the Amplifier box : automatically MIZAR will enter in the stand-by mode.
4. Press any of the 5 user keys on the MIZAR to switch the amplifier to the active state.

The figure below shows a typical MIZAR system installation.



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7 Maintenance

To ensure that the MIZAR amplifier works effectively we recommend that the following maintenance operations be performed on a regular schedule basis.

7.1 Calibration

Monthly perform a "Physical system" calibration (see section 4)

7.2 Cables and connectors

Monthly check cables for abrasion and wear. Replace any cable with exposed wire or shield.
Check the connectors on the ends of cable for bent or broken pins. Replace the cable with damaged connector.
Check the connector on the MIZAR amplifier, headbox and PCMCIA interface for broken or damaged contacts. If you find a damaged connector refer to qualified Technical Support service.

7.3 Cleaning

It is necessary to keep the equipment clean in order to avoid dust deposits, which could interfere with the efficiency of all the system components. To clean the external surface of the equipment use a cloth lightly moistened with warm water and soap. Wipe the washed parts with a dry cloth.

WARNING

Do not immerse the equipment nor its parts in liquids, do not oil any part of it and avoid cleaning the external surface with alcoholic disinfectants that could cause damage and discoloration of the printed surfaces

ATTENTION

Before cleaning any part of the equipment disconnect the equipment from the power supply or remove the internal batteries (if battery option is installed) and disconnect the device from any other equipment or external devices.

ATTENTION

Make sure no liquid seeps into the instrument and check it's complete dryness before reconnecting to the power supply (or inserting the batteries) or before connecting it with other devices, switching it on.

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8 Technical Characteristics

Product name	EBN version : **Basis BE** NPB version : **Sandman Digital**
Description	Active, non invasive, medical device.
Intended use	Acquisition of EEG and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations

Classification according to MDD 93/42/EEC Class II b

Safety Stds	IEC 601-1 IEC 601-1-2 IEC 601-1-4

Type of protection against electric shocks	Class I or Internal power source
Protection level against electrical direct and indirect contacts	BF type (patient input)
Protection level against inflow of solids and liquids	Common (IP20)

8.1 Environmental Condition

Usage temperature	+5 °C to +40 °C
Relative humidity	30% / 75% RH
Atmospheric pressure	700 / 1060 hPa
Storage Temperature	-30 °C to +60 °C (relative humidity up to 95% non-condensing. Pressure 500 / 1060 hPa) Max 15 weeks

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8.2 Amplifiers

Operating channels	24/32/40 64/128/..256	(40 standard) (with expansion boards)
EEG/Polygraphic channel	32/40/64/...256	
DC channel	up to 40	
Impedance measurement	By means of 20 Hz - 0.01 μA/electrode current	
A/D conversion	16 bits Sigma-Delta A/D	(effectively transferred to host)

Resolution, Full Scale Range, Noise

Channels A,B,C,...H and Channels 1.2.3,...23

Gain Setting / Resolution	Full Scale Range	Noise(0.1Hz-70Hz)
High 1/8 μV/bit	8000 μVpp	1.5 μVpp max
Low 2 μV/bit	128 mVpp	20 μVpp max

Channels 24,25,26...32

Gain Setting / Resolution	Full Scale Range	Noise(0.1Hz-70Hz)
High 1/8 μV/bit	8000 μVpp	≤ 1.5 μVp-p max ≤ 0.5 μVrms
Low 2 μV/bit	128 mVpp	≤ 20 μVpp max
DC1 10 μV/bit	640 mVpp	≤ 200μVpp max
DC2 20 μV/bit	1.28 Vpp	≤ 500 μVpp max
DC3 100 μV/bit	6.4 Vpp	≤ 1 mVpp max

Expansion board channels

Resolution	Full Scale Range	Noise(0.1Hz-70Hz)
1/8 μV/bit	8000 μVpp	1.5 μVpp max

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Filters

High-Pass:
Channels A,B,...H and channels 1,2,3,...32 : Either DC or 0.099Hz 1st order filter
Expansion board channels : 0.099Hz 1st order filter

Low-Pass (related to the output of the A/D Converter) :
Frequency cut 0.45 fs (fs = actual sampling rate)
Attenuation 80dB $f \geq 0.55$ fs

Sampling Rate

Max Sampling Rate

Number of simultaneously acquired channel	Max Sampling Rate
1 16	32768 Hz
16 32	16384 Hz
32 64	8192 Hz
> 64	4096 Hz

Selectable Sampling Rate

128,256,512,.... 32768 Hz (with the limit of maximum sampling rate)

Sampling Skew

All acquired channels will be sampled simultaneously (no sampling skew).

CMMR >100 dB

IMRR >120 dB

Max DC Offset (AC mode) ± 300 mV

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Amplifier – PC Interface	PCMCIA (fiber optic link)
Other Interfaces	128x64 graph LCD display 5 push button
Power supply	External IEC 601-1 type I B AC/DC adapter Internal batteries (optional)
Power Consumption	900 mA typ (with 40 channels)
Case	Plastic
Dimension	250 x 170 x 65 mm
Weight	1.5 KG
Isolation	Fiber optic link

8.3 Headbox

Case	Plastic
Dimension	126 x 96 x 25 mm
Electrode connectors	32 active – one active connection to each input (monopolar) 16 active – two active connection to each input (bipolar) 3 for reference electrode 13 for patient ground 2 for temperature probe input 2 for calibration signal output
Connection to Amp Extension Cable	50 pin Microcentronics male / 50 pin Microcentronics male Shielded (max 2 m)

8.4 PCMCIA Interface

Case	Type III PCMCIA Interface
Dimension	105 x 55 x 11 mm
Power Supply	3.3 V @ 100 mA directly from the PCMCIA connector

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8.5 AC/DC Adapter

Case	Plastic
Dimension	129 x 77 x 40 mm
Input	100....250 VAC 50/60 Hz
Output	15 VDC - 2.2 A
Safety	IEC 601-1 class I type B

8.6 Options

Battery Specification

Battery Type	2 battery packs Li-ion type SONY NP-F730
Capacity	2700 mAh
Endurance	1 hour minimum from battery full charged
Battery charger	External. SONY AC-V700
Charge Time	180 minutes (full charge)

Pulse Oximetry boards

Mount a Nellcor Puritan Bennet MP404 Pulse Oximetry Module
(Refer to NPB documentation for specifications and accessories)

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Product Labeling

Proposed Labeling

Affixed Labels

The Amplifier box and the mains adapter are the two energized parts of the system.
The figures below show the proposed ID (Manufacturer) label of the amplifier box in the two current different versions and of the mains adapter.

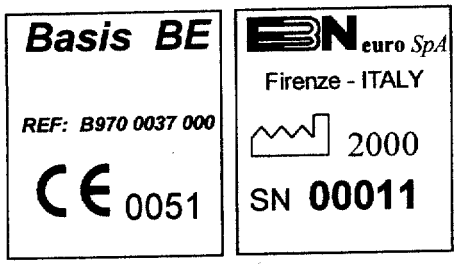


Fig 1 - Identification Label - EBNeuro "Basis BE" version

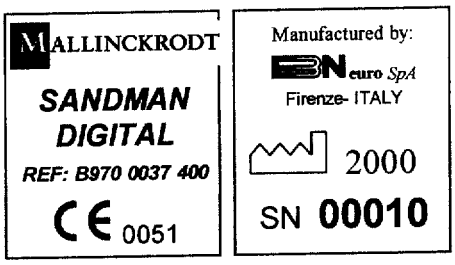


Fig 2 - Identification Label - Nellcor Puritan Bennet (MALLINCKRODT) "Sandman Digital" version

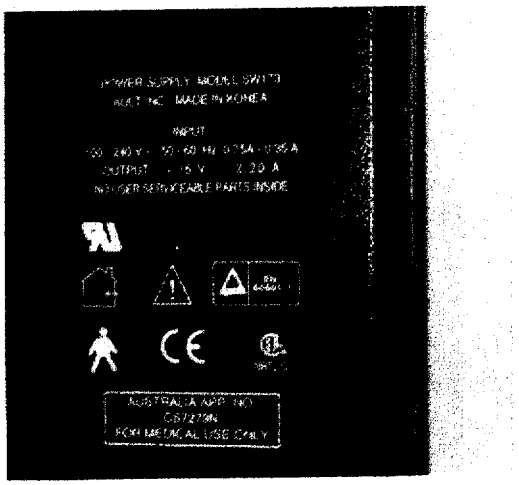
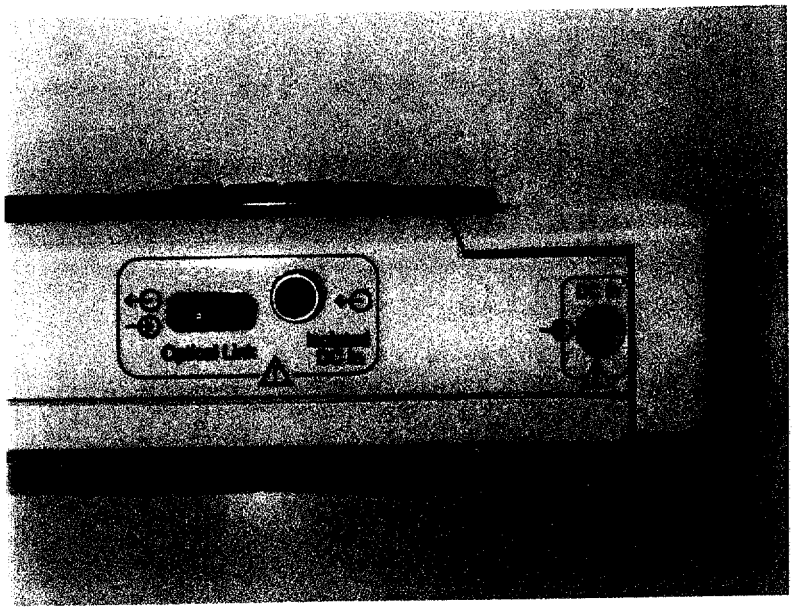


Fig 3 - Mains (AC/DC) adapter Labeling

All other proposed external labeling affixed to the amplifier box are detailed in the figures which follows:
For further information refer to the user manual



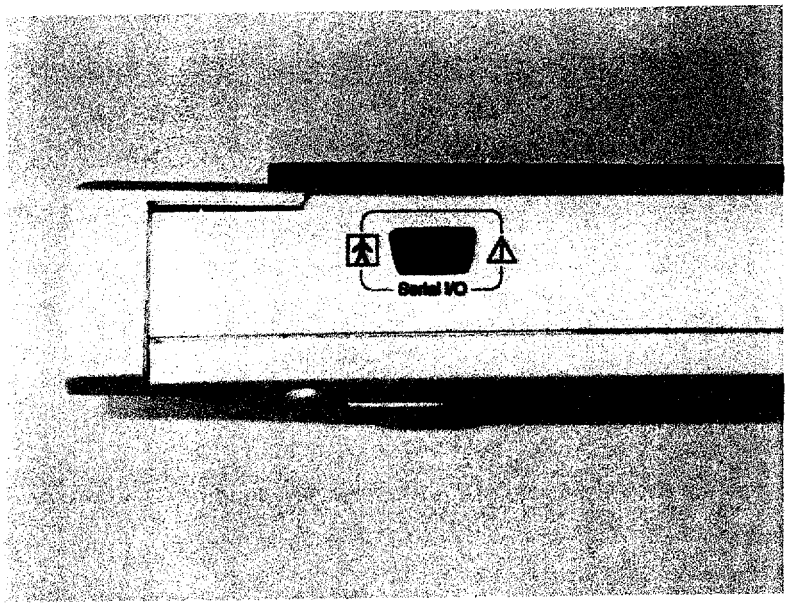


Fig 4 - Amplifier box left and right side labeling

123

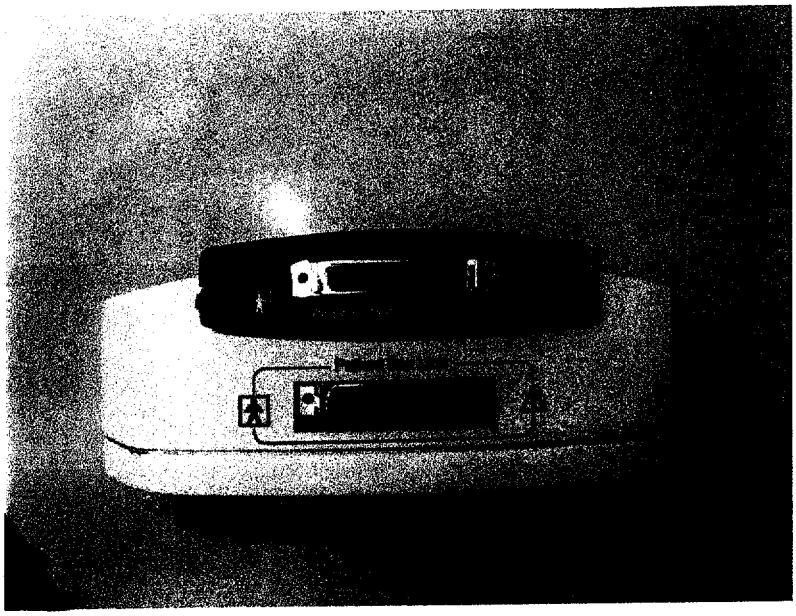


Fig 5 - headbox connection labeling

WARNING
Read instruction manual before using.
Do not remove cover . Refer servicing to qualified personnel

CAUTION
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

Fig 6 - Warning & Caution Labels

When the Pulse Oximetry option or the Expansion board channel is installed, near the related connector is affixed one of the following label

PULSE OXIMETRY SENSOR

EXPANSION CH INPUT

Fig X - 7 Options labeling

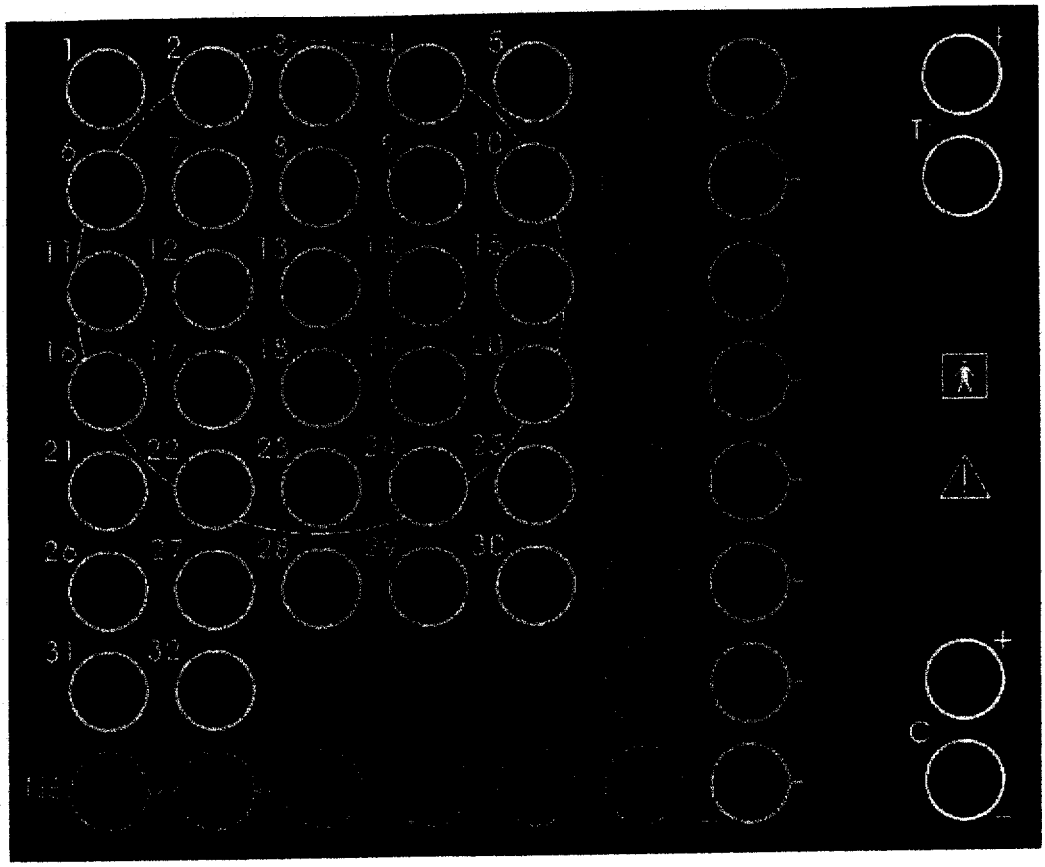


Fig 8 – Headbox socket labeling

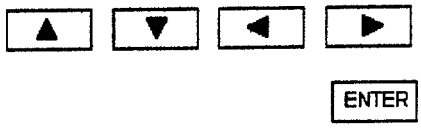


Fig 9 - keyboard labeling

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On the PCMCIA Interface the following two labels are affixed :

PCMCIA INTERFACE
REF B9100370500 ⚠
S/N 00010

BN Micro S.p.A.
Firenze ITALY
1999

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5099; Released by CDRH on 10-21-2015

Marketing Brochure

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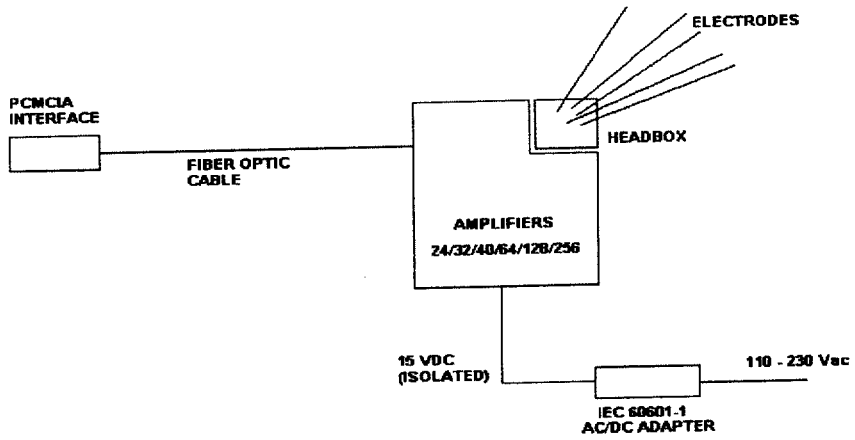
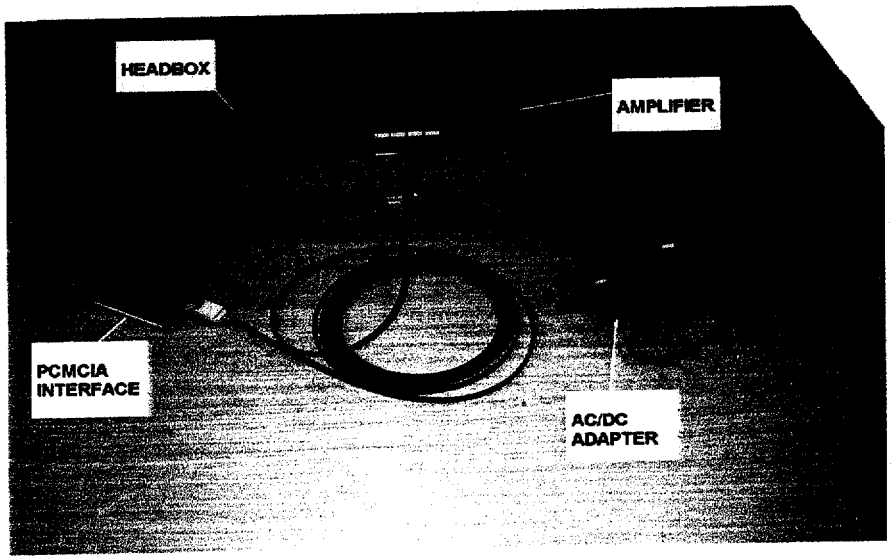
Draft

MIZAR
Bioelectric Signal Amplifier System





The MIZAR is a fully programmable amplifier system which can range from 24 up to 256 channels. The amplifier receives its power from a dedicated AC/DC adapter, meeting the IEC 601-1 requirements, which feeds a +15VDC. Internally the +15VDC is further isolated by a dedicated DC/DC converter of class BF. Optionally the power may be supplied by an internal battery pack.

The MIZAR amplifier system is intended to be used to elaborate upon the bioelectric signal captured via a lead or transducer on the surface of the human body using an application software running on a host computer. The system captures the data and converts it into a digital form and passes it to the software running on the host computer. Typical fields of application will be: Electroencephalography (EEG), Evoked Potentials (EP), Electromyography (EMG), Polysonography (SLEEP ANALISYS) and General Polygraphy.

The system can collect, amplify and translate in numeric form (analog to digital conversion) from 24 (the minimum configuration) to 256 (the maximum expansion) signals. The typical and standard configuration is with 40 channels.