DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2001

Mr. George Papagiannis, M. Eng.
Quality Assurance and Regulatory Affairs
Stellate Systems
345 Victoria Avenue, Suite 300
Westmount, Quebec
Canada H3Z 2N2

Re: K010728
Trade/Device Name: HARMONIE-Schwarzer EEG System
Regulation Number: 882.1400
Regulatory Class: II
Product Code: GWQ
Dated: March 9, 2001
Received: March 12, 2001

Dear Mr. Papagiannis:

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 legally marketed predicate 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 requirements, 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.

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) 594-4659. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

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

Attachment A

Indications for Use Statement

510(k) Number: K010728

Device Name: HARMONIE-Schwarzer EEG System

Indications for Use:

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In no way are any of the system functions represented as being in and of themselves diagnostic. The system requires competent user input, and its output must be reviewed and interpreted by a physician or other trained health care professional who will exercise professional judgment in using this information.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010728

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. George Papagiannis, M.Eng.
Quality Assurance and Regulatory Affairs
Stellate Systems
345 Victoria Avenue, Suite 300
Westmount, Quebec
Canada H3Z 2N2

APR - 9 2012

Re: K010728
Trade/Device Name: HARMONIE-Schwarzer EEG System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ
Dated (Date on orig SE ltr): March 9, 2001
Received (Date on orig SE ltr): March 12, 2001

Dear Mr. Papagiannis:

This letter corrects our substantially equivalent letter of May 21, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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(Division Sign-Off)
Division of General, Restorative
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510(k) Number K010728

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DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
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APR - 9 2012

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Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ
Dated (Date on orig SE ltr): March 9, 2001
Received (Date on orig SE ltr): March 12, 2001

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Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
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Center for Devices and
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510(k) Number: K010728

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010728

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Memorandum

Date: March 30, 2012

To: Record

From: Quynh Hoang, FDA/CDRH/ODE/DONED/NNDB Chief Q Hoang 3/30/2012

Through: Malvina Eydelman, FDA/CDRH/ODE/DONED Director KLA for MBE 4/9/12

Subject: Summary of Supervisory Assessment of Project to Reorganize Product Codes under 21 CFR 882.1400

I have randomly selected files that are more recent (K043309, K051883, K060900, K071899 and K080217) and performed an audit to confirm the newly re-assigned procodes. Based on this review, I concur with the recommendations from the members of this Project and recommend that all the correction letters be processed.

DEPARTMENT OF HEALTH & HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Center for Devices & Radiological Health
Division of Ophthalmic, Neurological and ENT Devices

510(k) CORRECTION
K010728

Date: **August 9, 2011**
To: **FILE**
From: Sara Doll Aguel, Biomedical Engineer – DONED/NNDB
Through: Quynh Hoang MS, Branch chief (DONED/NNDB) _____
Subject: **Corrected SE Letter to reflect new product code structure under 21 CFR 882.1400 (Electroencephalograph).**

SUMMARY:

DONED/NNDB has undertaken a project to reorganize the product codes within 21 CFR 882.1400 (Electroencephalograph) from one product code (GWQ) to twelve. These new product codes are as follows:

New Product Code	Device/Product Name
	Hardware
GWQ	1. Full-montage Standard Electroencephalograph
OMC	2. Reduced- Montage Standard Electroencephalograph
OMA	3. Amplitude-Integrated Electroencephalograph
OLV	4. Standard Polysomnograph with Electroencephalograph
OLY	5. Magnetoencephalograph
	Software
OMB	6. Automatic Event Detection Software for Full-Montage Electroencephalograph
ORT	7. Burst Suppression Detection Software for Electroencephalograph
OLZ	8. Automatic Event Detection Software for Polysomnograph with Electroencephalograph
OLT	9. Non-Normalizing Quantitative Electroencephalograph Software
OLU	10. Normalizing Quantitative Electroencephalograph Software
OLW	11. Index-generating Electroencephalograph Software
OLX	12. Source Localization Software for Electroencephalograph or Magnetoencephalograph

We are correcting this SE letter to reflect the new product codes and definitions. We recommend the new 21 CFR 882.1400 (Electroencephalograph) product codes for this 510(k) be:

Product Code	Device/Product Name	Intended Use/ Indication for Use:	Technical method	Physical state
Primary				
OLV	Standard Polysomnograph with Electroencephalograph	Acquire, display, store, and archive electroencephalographic signals from the brain and other signals (such as electromyography, respiratory and/or oximetry signals) for sleep recordings. May also be used to allow on-screen review, user-controlled annotation and user-controlled marking of data.	Uses electrodes placed on the scalp, within the brain, or other locations, via user-specified locations, to record and display electrical activity of the brain and other organs	May include standard polysomnography recording hardware (e.g. headbox, cables, computer, monitor, wireless) and basic software (e.g. used to display, store, archive, or manually annotate data). Does NOT include electrodes, vital signs monitors, polysomnography devices without electroencephalograph, more complex software used to analyze electroencephalograph data or software used to automatically detect events.
Secondary				
GWQ	Full-montage Standard Electroencephalograph	Acquire, display, store, and archive electroencephalographic signals from the brain using a full montage array (i.e., 16 or more electrodes) and user-specified locations	Uses electrodes (16 or more) placed on the scalp or within the brain, via user-specified locations, to record and display electrical activity of the brain	May include standard electroencephalograph recording hardware (e.g. headbox, cables, computer, monitor, wireless) and basic software (e.g. used to display, store, archive, or manually annotate data). Does NOT include electrodes, more complex software used to analyze electroencephalograph data or automatically detect events, electroencephalograph used for polysomnography or sleep studies, or electroencephalograph with less than 16 electrodes.

Sara Aguel 10/6/11

Sara Doll Aguel, Biomedical Engineer (08/09/2011)
Neurodiagnostic and Neurotherapeutic Devices Branch
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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9200 Corporate Boulevard
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MAY 21 2001

Mr. George Papagiannis, M. Eng.
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Re: K010728
Trade/Device Name: HARMONIE-Schwarzer EEG System
Regulation Number: 882.1400
Regulatory Class: II
Product Code: GWQ
Dated: March 9, 2001
Received: March 12, 2001

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Sincerely yours,

for Mark N Melkerson

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

Attachment A

Indications for Use Statement

510(k) Number: K010728

Device Name: HARMONIE-Schwarzer EEG System

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010728

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

Memorandum

om: Reviewer(s) - Name(s) Yung Pak

Subject: 510(k) Number K010728

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 N/A
- ☑ 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: §4 GWQ, class II Reg. # §52.1400

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

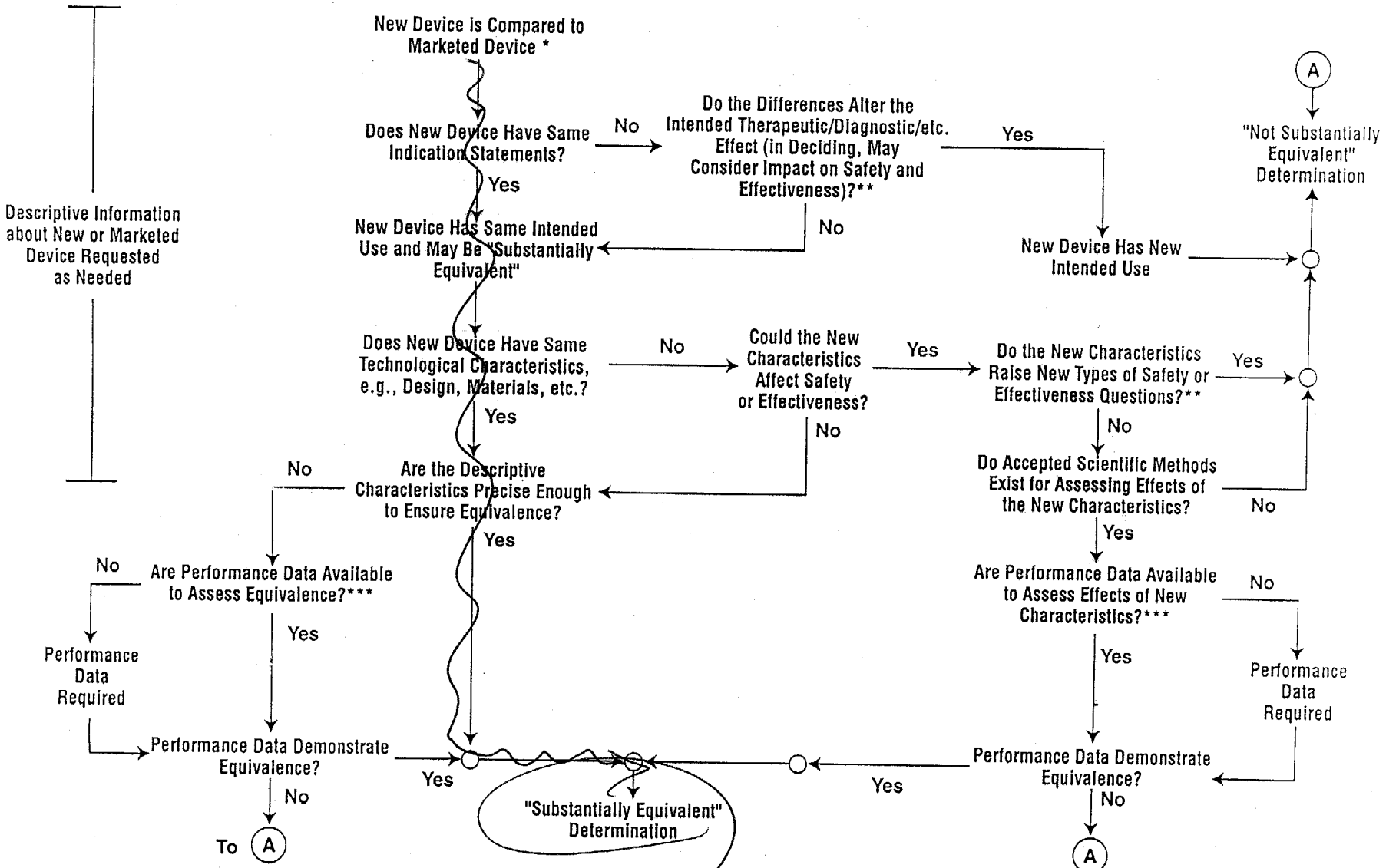
Review: Neil R Ogden (Branch Chief) GSDB (Branch Code) 5/15/01 (Date)

Final Review: Mark N Melkerson (Division Director) for 5/18/01 (Date)

Revised:8/17//99

4

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



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.

*** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

DGRND/GSDB

K010728

Reviewer: Yung Pak
Mechanical Engineer

General Surgical Devices Branch:
(HFZ-410)

Proprietary Trade Name: HARMONIE-Schwarzer EEG System
Common Name: Electroencephalograph (EEG)
Product to which compared: Neurofax EEG-1100A(K992742)

Intended/Indications for Use

The HARMONIE-Schwarzer EEG System is indicated for the recording and study of EEG and other physiological signals and patient video obtained during routine EEG exams, Long-Term Monitoring in Epilepsy (LTM) and sleep studies (polysomnography or PSG) in clinical environments.

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This is SE indication.

Device Description

The HARMONIE-Schwarzer EEG System is an Electroencephalograph in which EEG and PSG signals are amplified, filtered and digitized in the Schwarzer headbox. Stellate HARMONIE software for Microsoft Windows implements signal recording and review functions, specifically designed for EEG/PSG studies.

The EEG System is modular comprising a single PC or a number of PCs and peripheral devices that can be networked and arranged to suit individual needs. The peripheral devices comprise of patient interface box, control box, power supply for control box, optical drive, printer(s), video recorder, video monitor, and video camera.

The following table describes device specification compare to the predicate device:

Specification	HARMONIE-Schwarzer EEG System	Neurofax EEG-1100A (K992742)
Input Impedance	≥100 MΩ	100 MΩ
Noise level	<1.5 uVp-p, 0.53-70 Hz	<3 uVp-p, .53-120 Hz
CMRR	≥ 100 dB	≥ 105 dB
High pass filter	0.016 Hz	?
Low pass filter	300 Hz, -20 dB/oct	300 Hz, -18 dB/oct
Resolution	16 bits	16 bits
Max sampling frequency	1000 Hz	1000 Hz
Signal transmission	Fiberoptic cable	Electrical conductor cable
Waveform	0.5 Hz square	0.25 Hz step or 10 Hz sine
Voltage	50 uV	2- 1000 uV

As you can see, the device specification is very similar between the new device and the predicate device.

Conformance to Recognized Standards

The sponsor certified that their device conforms to the following FDA recognized standards:

- IEC 601-1 Medical electrical equipment: General requirements for safety
- IEC 601-1-1 Medical electrical equipment: General requirements for safety; Safety requirements for medical electrical systems
- IEC 601-1-2 Electromagnetic compatibility – Requirements and test
- IEC 601-1-26 Medical electrical equipment: Particular requirements for the safety of electroencephalographs

Software

The sponsor provided software requirements specification, software hazard analysis, software test specification and results, which are adequate for this type of device.

Biocompatibility/Sterilization

The patient contacting electrode is a legally marketed device.

Labeling

The sponsor provided users manual that contains precautions, warnings, installation and setup, which are adequate for this type of device.

Substantial Equivalence (SE) Decision Making Documentation

	YES	NO	
1. IS PRODUCT A DEVICE?	X	_	IF NO, STOP
2. DEVICE SUBJECT TO 510(k)?	X	_	IF NO, STOP
3. SAME INDICATION STATEMENT?	X	_	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?	X	_	IF YES, GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	_	_	IF YES, GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	X	_	IF YES, STOP -> SE

Reviewer Recommendation:

Substantially equivalent.

ProCode: 84 GWQ
Regulation No: 882.1400
Class: II

Yung Pak 5/14/01
Yung Pak Date
Mechanical Engineer

Neil R.P. Ogden 5/15/01
Neil Ogden Date
Chief, General Surgical Devices Branch

/ X / Concur
/ / Do Not Concur

Standards Data Form for Abbreviated 510(k)s

510(k) Number: K010728

Standard Organization No: International Electrotechnical Commission (IEC)

Standard Identification No: IEC 601-1, IEC 601-1-1, IEC 601-1-2

CDRH Internal Reference No: 353, 354, 355

Declaration of Conformity Elements:			
Any Adaptations Applied	yes	no	√
Any Requirements Not Applicable	yes	no	√
Any Deviations Applied	yes	no	√
Any Differences in Device Tested and Finished Product	yes	no	√
*Is There a Third Party or Test Lab Involved	yes	no	√

Was there another standard used in the review of this submission? yes no √

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name: Harmonie-Schwarzer EEG System	K010128
Submitter (Company): Stellate Systems	

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" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,6		✓ GO TO # 5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS							✓ IF ITEM IS NEEDED
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA		YES		NO		
	SPECIALS		ABBREVIATED		TRADITIONAL		AND IS MISSING
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class			✓		✓		
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)*			NA		NA		
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)			NA		NA		
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			NA		NA		

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	

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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			NA				
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.			NA				
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			✓				

	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		NA			
iv)	An identification, for each consensus standard, of any requirements that were not applicable to the device		NA			
v)	A specification of any deviations from each applicable standard that were applied		NA			
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		NA			
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		NA			
d)	Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards		NA			

5. Additional Considerations: (may be covered by Design Controls)							
a)	Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	NA					
i)	component & material	↓					
ii)	identify patient-contacting materials	↓					
iii)	biocompatibility of final sterilized product	✓					
b)	Sterilization and expiration dating information:	NA					
i)	sterilization method	↓					
ii)	SAL	↓					
iii)	packaging	↓					
iv)	specify pyrogen free	↓					
v)	ETO residues	↓					
vi)	radiation dose	✓					
c)	Software validation & verification:	✓					
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 checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No** **Reviewer:** Yung Pak

Date: 5/1/01 **Concurrence by Review Branch:**

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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

March 12, 2001

STELLATE SYSTEMS
345 VICTORIA AVE., SUITE 300
WESTMOUNT, QUEBEC,
CANADA
ATTN: GEORGE PAPAGIANNIS

510(k) Number: K010728
Received: 12-MAR-2001
Product: HARMONE-SCHWARZER
EEG SYSTEM

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

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K010728

Stellate Systems

March 9, 2001

VIA FEDERAL EXPRESS

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

RE: Abbreviated 510(k) Notification
HARMONIE-Schwarzer EEG System

Dear Reviewer:

This premarket notification is submitted pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in accordance with the ODE guidance for Abbreviated 510(k) requirements and the "EEG Devices Guidance for 510(k) Content" (Draft Document, Ver 1.0, 6/25/97).

Stellate Systems wishes to notify the Office of Device Evaluation of our intention to promote the **HARMONIE-Schwarzer EEG System** for the recording and study of EEG and other physiological signals obtained during routine EEG exams, long-term monitoring in epilepsy (LTM) and sleep studies (polysomnography or PSG) under the direct supervision of a physician or other trained health care professional.

Two copies of this Premarket Notification are being submitted in accordance with 21 CFR 807.

As it is equally important to us to serve our customers and ensure continuous compliance with FDA regulations and statutes, we would appreciate any suggestions for changes to our labeling prior to the promotion of this system.

If you have any questions regarding this submission, please do not hesitate to contact me by phone at (514) 486-1306 ext. 105, by fax at (514) 486-0694, or by e-mail to gpapagiannis@stellate.com.

Respectfully,

George Papagiannis, M.Eng.
QA & Regulatory Affairs

RECEIVED
MAR 12 11 12 AM '01
FDA/CDRH/ODE/DHC

NE II
5K2S 14

Stellate Systems

Establishment Registration Number: 9680936

Abbreviated 510 (k)

HARMONIE-Schwarzer EEG System

Class II, 84 GWQ

March 9, 2001

Table of Contents

Attachments

CDRH Submission Cover Sheet

Date of Submission: MARCH 9, 2001

FDA Document Number:

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modular submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☑ Original submission: ☐ Traditional ☐ Special ☑ Abbreviated ☐ Additional information: ☐ Traditional ☐ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

Section B Applicant or Sponsor

Company / Institution name: STELLATE SYSTEMS		Establishment registration number: 9680936
Division name (if applicable):		Phone number (include area code): (514) 486-1306
Street address: 345 VICTORIA AVENUE, SUITE 300		FAX number (include area code): (514) 486-0694
City: WESTMOUNT	State / Province QUEBEC	Country: CANADA H3Z 2N2
Contact name: GEORGE PAPAGIANNIS		
Contact title: QA & REGULATORY AFFAIRS		Contact e-mail address: GPAPAGIANNIS@STELLATE.COM

Section C Submission correspondent (if different from above)

Company / Institution name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code): ( )
Street address:		FAX number (include area code): ( )
City:	State / Province:	Country:
Contact name:		
Contact title:		Contact e-mail address:

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Section D1 — Reason for Submission — PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement

- ☐ Process change
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)

- ☐ Response to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site

- ☐ Other reason (specify):

- ☐ Change in design, component, or specification:
  - ☐ Software
- ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
- ☐ Other (specify below)

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
- ☐ Shelf life
- ☐ Trade name
- ☐ Other (specify below)

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor

- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
- ☐ Device defect
- ☐ Amendment

- ☐ Change in ownership
- ☐ Change in correspondent

Section D2 — Reason for Submission — IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request

- ☐ Other reason (specify):

- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ 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

Section D3 — Reason for Submission — 510(k)

- ☑ New device
- ☐ Additional or expanded indications
- ☐ Other reason (specify):

- ☐ Change in technology
- ☐ Change in design

- ☐ Change in materials
- ☐ Change in manufacturing process

Section E Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 84 GWQ	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	K992742	Neurofax, Model EEG-1100A	Nihon Kohden America
2	K960273	HARMONIE-SENSA Software	Stellate Systems
3	K982351	LUNA Software	Stellate Systems
4			
5			
6			

Section F Product Information — Applicable to All Applications

Common or usual name or classification name:
Electroencephalograph

	Trade or proprietary or model name	Model number
1	HARMONIE-Schwarzer EEG System	
2		
3		
4		
5		

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

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

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

Section G Product Classification — Applicable to All Applications

Product code: GWQ
C.F.R. Section: 882.1400
Classification panel: Neurology

Device class:
☐ Class I ☑ Class II
☐ Class III ☐ Unclassified

Indications (from labeling):
Recording and study of EEG and other physiological signals obtained during routine EEG exams, Long-Term Monitoring in Epilepsy (LTM) and sleep studies (polysomnography or PSG) in clinical environments.

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission

☐ Original ☑ Add ☐ Delete	FDA establishment registration number:	☑ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: Schwarzer GmbH		Establishment registration number:	
Division name (if applicable): Medical Diagnostic Equipment		Phone number (include area code): (+490) 89 - 8 39 42-0	
Street address: Baermannstr. 38		FAX number (include area code): (+490) 89 - 8 39 42-186	
City: Munich	State / Province:	Country: Germany	
Contact name: Dr. Elke Kinzel			
Contact title: QA & Regulatory Affairs Manager		Contact e-mail address: ekinzel@schwarzer.com	
☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	
Contact name:			
Contact title:		Contact e-mail address:	
☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	
Contact name:			
Contact title:		Contact e-mail address:	

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Executive Summary

Stellate Systems develops software for the recording and study of EEG and other physiological signals obtained during routine EEG exams, long-term monitoring in epilepsy (LTM) and sleep studies (polysomnography or PSG). The software consists of three primary modules, which are marketed under the proprietary names HARMONIE, SENSA (K960273), and LUNA (K982351.)

In conjunction with commercially available recording devices (EEG machines, amplifiers and polygraphs), the software facilitates digital recording of EEG and/or other polygraphic signals, review and analysis, archiving and reporting capabilities.

Under a recent contractual agreement with Schwarzer GmbH of Munich, Germany, Stellate Systems intends to introduce to the North American market the Schwarzer EEG/PSG headboxes and amplifiers.

Stellate Systems does not intend to modify any of the Schwarzer devices. They will be integrated at Stellate Systems in Montreal, Canada with the HARMONIE software, which has been modified to implement the necessary device driver and user interface.

Pending 510(k) clearance, the stand-alone EEG system will be marketed under the proprietary name **HARMONIE-Schwarzer EEG System**.

In order to establish the safety and effectiveness of the proposed system, and for the purposes of this submission, we have compared the **HARMONIE-Schwarzer EEG System** to Neurofax, Model EEG-1100A (K992742) by Nihon Kohden America and to our HARMONIE, SENSA (K960273) and LUNA (K982351) software.

We believe the proposed system is substantially equivalent to the predicate devices. Furthermore, following a risk analysis and an evaluation of Schwarzer's Technical File, we are confident that the proposed system does not raise any additional safety or effectiveness issues.

Device Trade Name	**HARMONIE-Schwarzer EEG System**
Applicant / Manufacturer	Stellate Systems 345 Victoria Avenue, Suite 300 Westmount, Quebec Canada H3Z 2N2 Establishment Registration Number: 9680936
Contact Person	George Papagiannis QA & Regulatory Affairs Tel: (514) 486-1306, ext. 105; Fax: (514) 486-0694 E-mail: gpapagiannis@stellate.com
Original Equipment Manufacturer	Schwarzer GmbH Medical Diagnostic Equipment Baermannstr. 38 Munich, Germany
Contact Person	Dr. Elke Kinzel QA & Regulatory Affairs Manager Tel: +490 89-8 39 42-0; Fax: +490 89-8 39 42-186 E-mail: ekinzel@schwarzer.com
Device Classification Name	Electroencephalograph
Classification / Panel	Class II §882.1400 / Neurology
Product-Code	84 GWQ
Predicate Devices	1. Neurofax, Model EEG-1100A, **K992742** 2. HARMONIE-SENSA Software, **K960273** 3. LUNA Software, **K982351**
Proposed Labeling / Intended Use	The HARMONIE-Schwarzer EEG System is intended for the recording and study of EEG and other physiological signals and patient video obtained during routine EEG exams, Long-Term Monitoring in Epilepsy (LTM) and sleep studies (polysomnography or PSG). The indications for use statement can be found in **Attachment A**. See **Attachment H** for draft device labeling and instructions for use.

Performance Standards

No mandatory performance standards have been established under Section 514 of the Food, Drug and Cosmetics Act.

Conformance to Recognized Standards

Under section 514(c) of the Federal Food, Drug, and Cosmetic Act we have included a Declaration of Conformity (**Attachment D**) to the following harmonized standards:

- IEC 601-1:1988 + A1:1991 + A2:1995
  (Medical electrical equipment - Part 1: General requirements for safety)
- IEC 601-1-1:1992
  (Collateral Standard: Safety requirements for medical electrical systems)
- IEC 601-1-2:1993
  (Collateral Standard: Electromagnetic compatibility - Requirements and tests)
- IEC 601-1-26:1994
  (Medical electrical equipment - Part 2: Particular requirements for the safety of electroencephalographs)

The Declaration of Conformity applies to the Schwarzer headboxes, PTMS data acquisition cards and accessories, when configured and operated in the specified computer system in accordance with the accompanying instructions for use (**Attachment J**.)

Copies of the following test reports demonstrating compliance with the above standards are kept on file at Stellate Systems, Montreal, Canada.

1. **IEC 601-1 / IEC 601-2-26 Test-Report No. 01/203.7.019/01**
   TUV Product Service Munich

   The report is valid for the EEG headbox with 34 inputs (P/N 210 026) and PSG headbox with 42 inputs (P/N 210 031)

   This report is valid also for the EEG headbox with 66 inputs (P/N 210 033) with the exception of

   - Patient leakage current measurements after humidity preconditioning treatments (subclause 19.4.h2) and
   - Dielectric strength measurements after humidity preconditioning treatments, (clause 20);

   because this headbox is based on the same technology as the headboxes listed above (with identical amplifiers) but increased number of amplifiers. Test report No. 4310-030745, dated 5/8/98, addresses measurements after humidity preconditioning treatments of the headbox with 66 inputs (part no. 210 033).

2. **IEC 601-1-2 Test-Report No. 25/97**
   Mooser Consulting GmbH

   This report is valid for all EEG/PSG headboxes (field strength 3V/m, 26 MHz – 1000 MHz)

510(k) Statement	A 510(k) statement as required by 21 CFR 807.93 can be found in **Attachment B.**
Truthful and Accurate Statement	A statement as required by 21 CFR 807.87(j) can be found in **Attachment C.**

Basic Device Description

The HARMONIE-Schwarzer EEG System is intended to provide clinicians with the means to record and study EEG and other physiological signals obtained during routine EEG exams, Long-Term Monitoring in Epilepsy (LTM), and sleep studies (polysomnography or PSG).

Figures 1-3 show typical system configurations for the intended applications. The system comprises the following key components:

1. Schwarzer headboxes/amplifiers and their accessories
2. Schwarzer PTMS data acquisition cards
3. Cables from the cards to the headbox
4. Computer system
5. Schwarzer PTMS Software Device Driver
6. HARMONIE Software

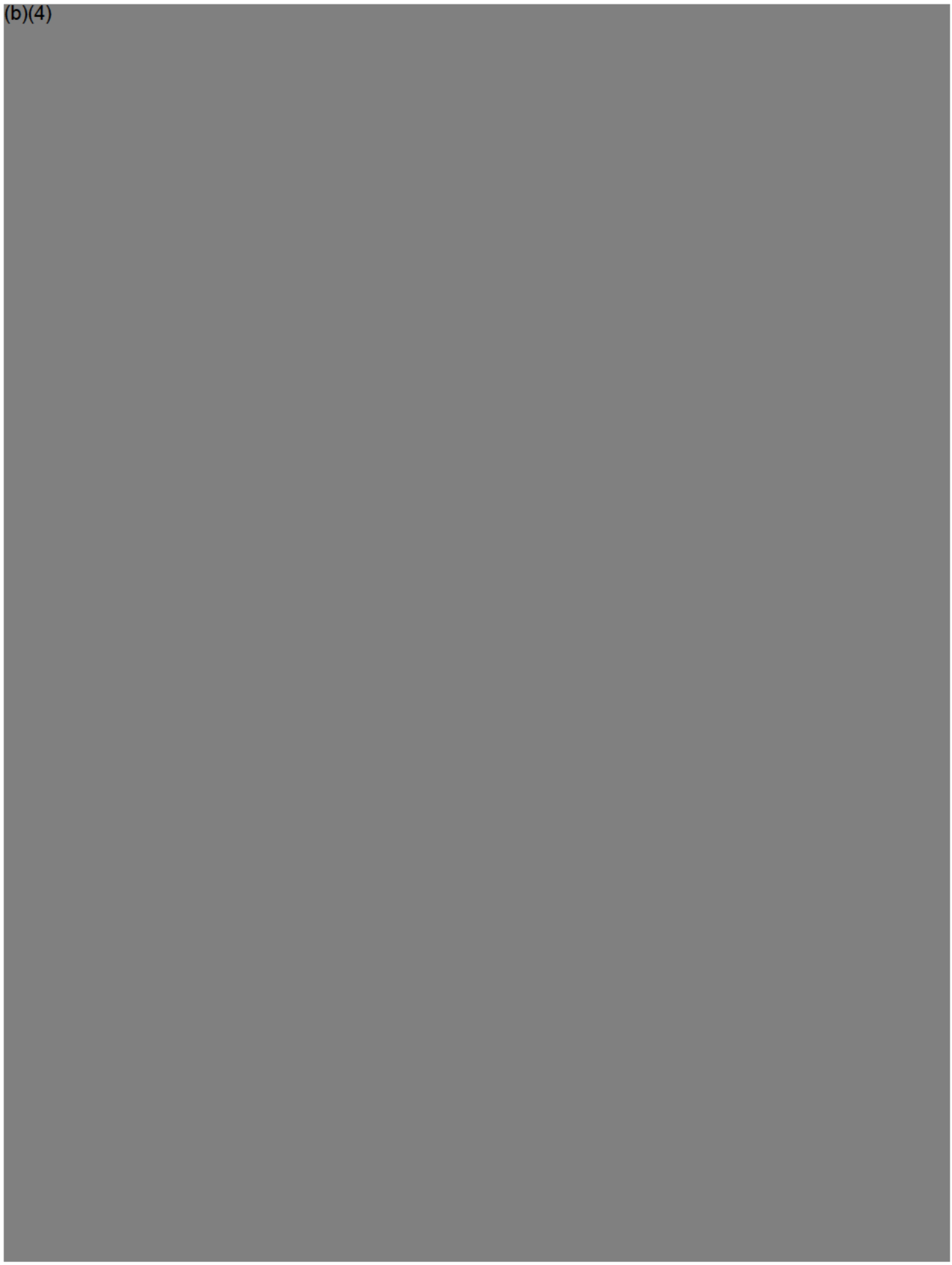
EEG and PSG signals are amplified, filtered and digitized in the Schwarzer headbox. The digitized signals are opto-electronically decoupled for transmission through fiberoptic cables to a data acquisition card (PTMS) in a personal computer system. Optical isolation at the headbox, between the computer and the amplifiers, ensures the patient's electrical safety. Optical transmission from the headbox to the computer eliminates electromagnetic disturbances, and guarantees a good signal to noise ratio. A detailed description of these components and the associated accessories is presented in the proposed Instructions for Use (**Attachment J.**)

Stellate HARMONIE is a software package for Microsoft Windows, which implements signal recording and review functions, specifically designed for EEG/PSG studies. Optionally, the software supports simultaneous patient video acquisition and digitization through an MPEG-1 encoder card, and synchronization with an external photic stimulator. The function of HARMONIE is described in detail in its User's Guide (**Attachment K**).

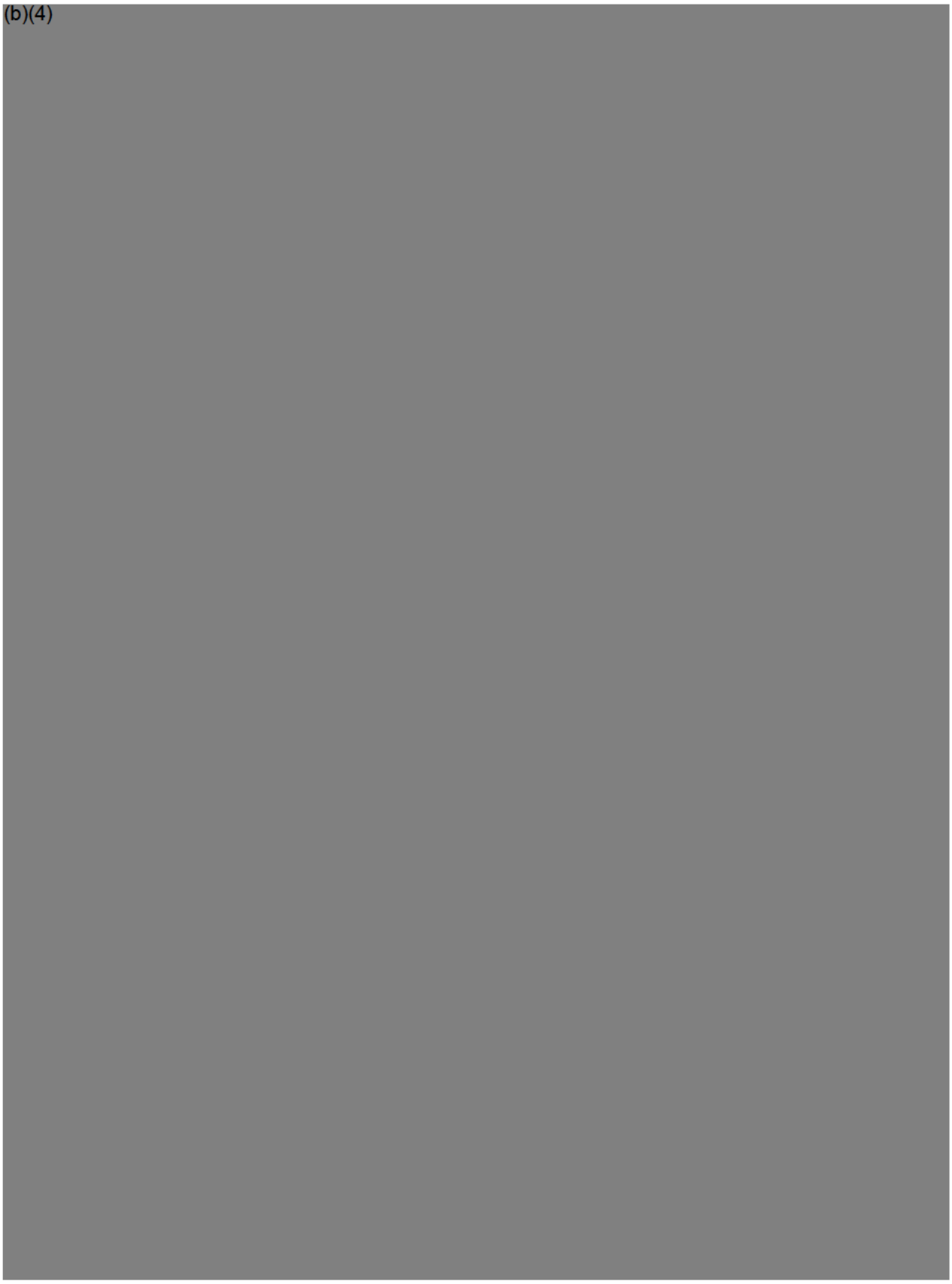
Stellate HARMONIE implements the software device driver and user interface to Schwarzer's data acquisition card, headbox and amplifier system. A detailed description of the user interface is presented in the proposed Instructions for Use (**Attachment J.**)

Stellate SENSA and LUNA are add-on software modules that extend the functionality of HARMONIE with event-driven recording capabilities, event marking tools, and quantitative analysis and reporting functions. SENSA is specifically designed for use in long-term monitoring (LTM) epilepsy studies. LUNA offers specific tools that are commonly used in sleep studies (PSG or polysomnography). The functions of these two software modules are described in detail in their respective User's Guides (**Attachment K.**)

(b)(4)



(b)(4)



(b)(4)

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List of System Components and Accessories

Headboxes & Headbox Adapters	
PART NO.	**DESCRIPTION**
	NOTE: Input jacks are contact-protected (touch-proof) according to DIN 42802.
210 026	**Electronic EEG headbox** with 34 inputs: 27 EEG amplifiers, 6 polygraphy inputs, and one input for respiration.
503 133	**Mini headbox adapter**. Extends through a flat ribbon cable all inputs of the EEG and PSG headboxes (P/N 210 026 and P/N 210 031).
210 031	**Electronic PSG headbox** with a total 42 inputs when used with the polygraphy adapter (P/N 210 069). 35 inputs on the headbox: 27 EEG amplifiers, 6 polygraphy inputs, one input for respiration, and a built-in pressure sensor for CPAP.
210 069	**Polygraphy adapter** box with integrated body position sensor and piezo sensor and belt for thoracic effort, and inputs for ECG, abdominal effort, tracheal microphone, airflow and SpO2 sensors.
210 071	**Mini headbox adapter for PSG**. It extends 14 inputs of headbox 210 031 to provide bipolar inputs and labeling for 4 EEG, 1 EOG and 3 EMG.
210 033	**Electronic EEG headbox** with 66 inputs: 65 EEG amplifiers, and one input for respiration.
503 134	**Mini headbox adapter**. Extends through a flat ribbon cable inputs 1-33 or 34-65 of the 66ch EEG headbox (P/N 210 033).
Headbox Accessories	
385 085	**Fiberoptic cable** connecting the headbox to the PTMS card in the computer. Nominal length is 5m. Maximum length: 35m.
383 123	**Flat ribbon cable** connecting a headbox to the corresponding mini headbox adapter (P/N 503 133 or 503 134). Nominal length: 3m.
555 003	**Snap-on electrode cable for ECG** (1.5m) with 4-mm touch-proof safety connector according DIN 42802.
593 101	**Airflow transducer** (2m) with 1.5mm touch-proof safety connector according to DIN 42802. Made in USA by Pro-Tech (Respiratory airflow sensor #1222).
593 150	**Tracheal microphone** (2m) with 1.5mm touch-proof safety connector according to DIN 42802. Made in USA by Pro-Tech (snore sensor.)
593 152	**Abdominal effort belt** (2m) with 1.5mm touch-proof safety connector according to DIN 42802. Made in USA by Pro-Tech (Piezo Respiratory Effort Sensor.)
555 002	**Pulse oximetry cable** for Nonin 8500 Pulse Oximeter. Made in USA by Nonin.
503 264	Mobile **EEG stand** for EEG and PSG headboxes (P/N 210 026 and 210 031.)
503 371	Mobile **EEG stand** for 66ch EEG headbox (P/N 210033.)

Digital Data Acquisition & Processing	
PART NO.	**DESCRIPTION**
374 913	**PTMS256 digital signal processor board** (128ch - 256 FIFO.)
374 918	**PTMB3** board to connect a second headbox to PTMS256.
374 924	**PTMS6 external trigger input board.**
Computer System	
HSYS-REC-xxxNT	**HARMONIE Computer System.** Intel Pentium processor ≥ 600 MHz; ≥ 128 MB RAM; with 1 ISA Slot; ≥ 6 GB HDD 17"-21" Monitor; Microsoft Windows NT Specified to meet IEC 950 and 89/336/EEC; UL/CSA/CE-marked.
HSYS-CART-xxxxx	**HARMONIE System Cart** (Made in USA by Anthrocart.) **with Medical-Grade Isolation Transformer** (Made in USA by Dale Technology, Model UIT630; 750 W.) Specified to meet IEC 60601-1; UL/CSA/CE-marked.
Data Acquisition Accessories	
AMP-CBL-SPBB-10	**Push Button** (1-piece molded plastic with 10m cable, BNC-M terminated.)
AMP-CBL-SPTMS6	**Push Button Adapter Cable for the PTMS6**. 4 BNC-F connectors.

Schwarzer Technical Report: EEG Amplifiers

The following is an excerpt of an internal and confidential Schwarzer technical report detailing the design and performance characteristics of the amplifiers found in the Schwarzer headboxes.

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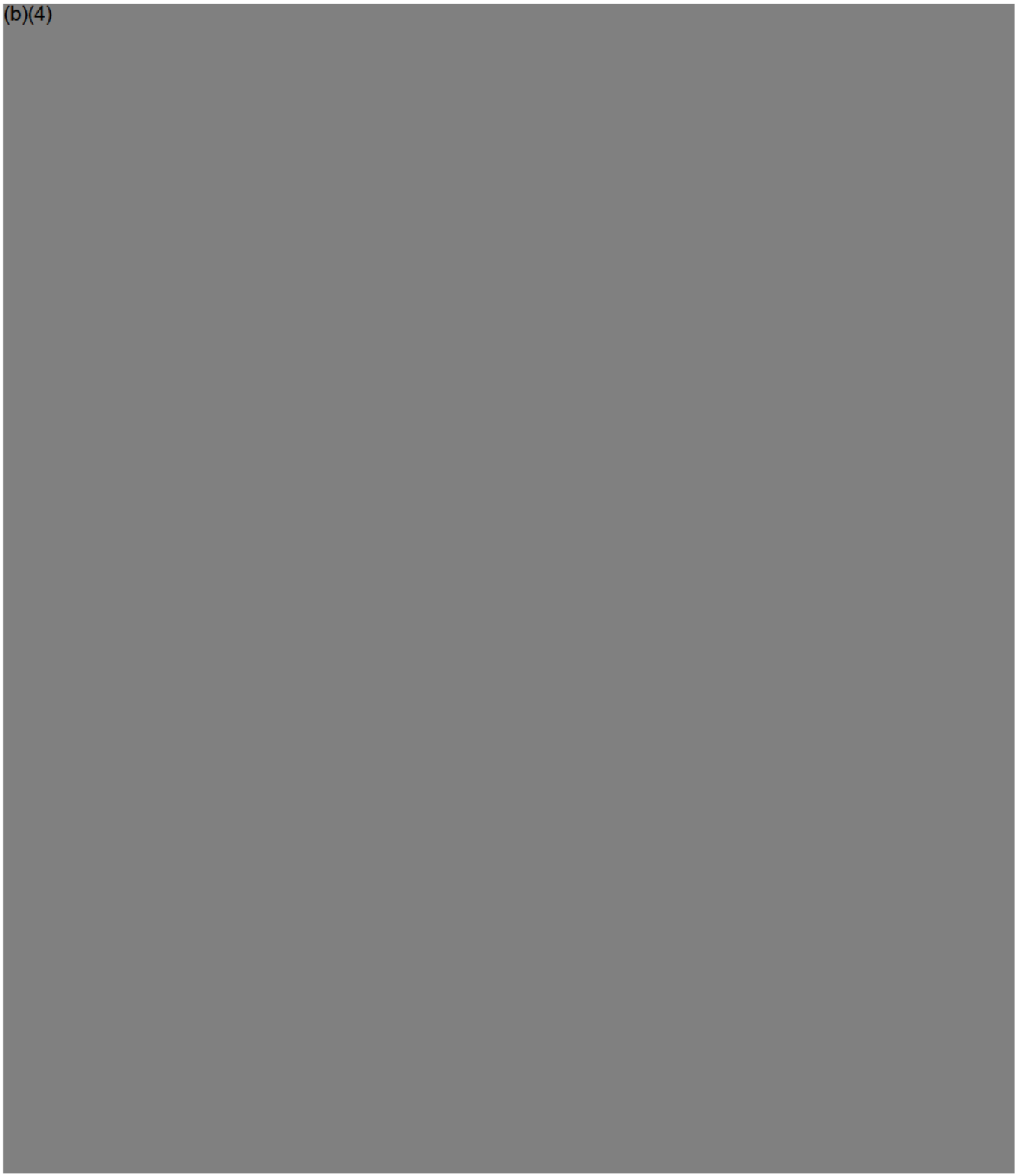

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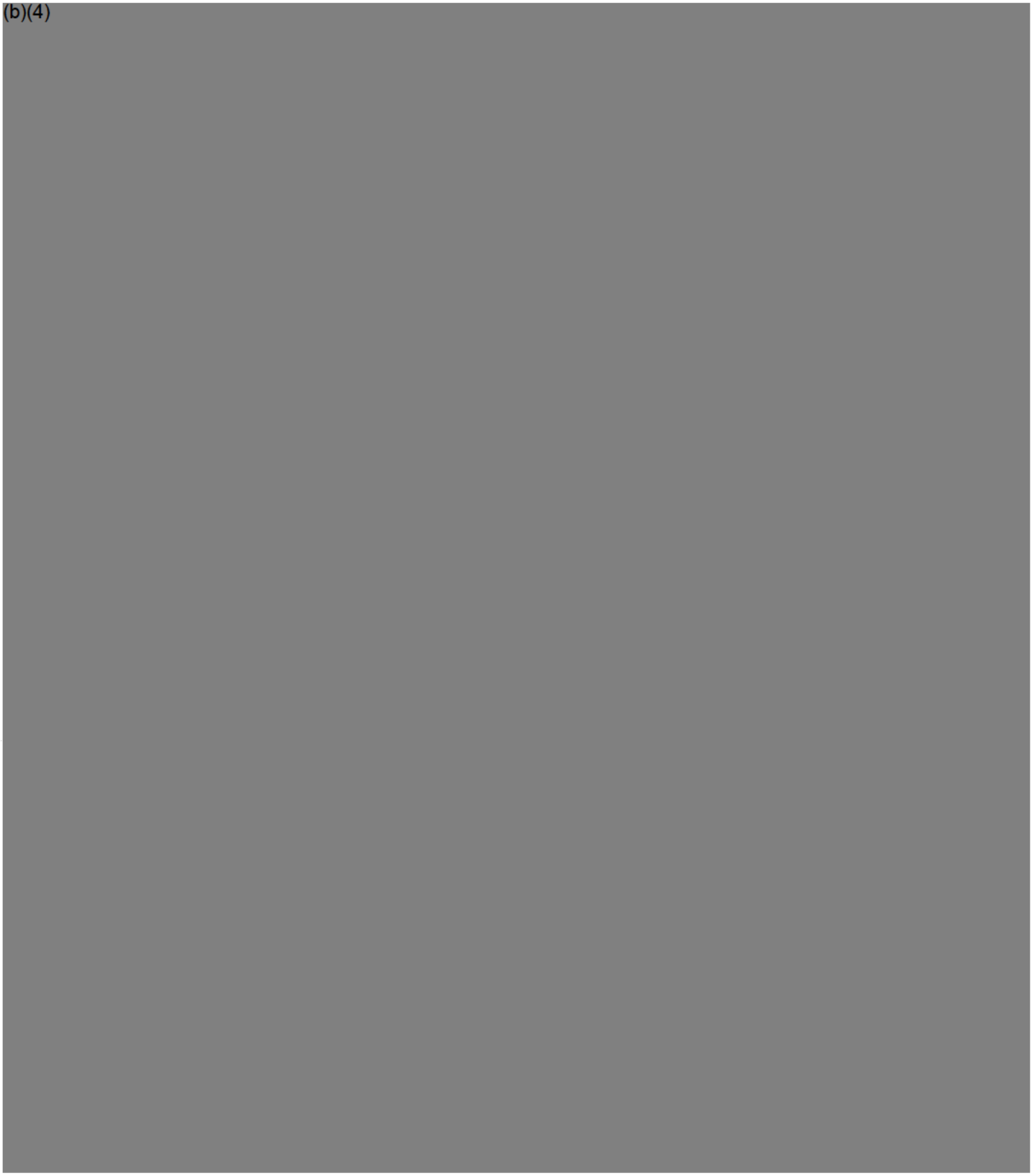

Substantial Equivalence Comparison

In addition to the preceding Schwarzer Technical Report, the following sources of information were used as the basis of comparison to predicate device:

1. 510(k) Summary: K992742. Neurofax, Model EEG-1100A. Nihon Kohden America. (**Attachment H**)
2. Operator's Manual. Neurofax Electroencephalograph, EEG-1100A. Nihon Kohden America. January 2000. (**Attachment I**)
3. Draft user instructions for the HARMONIE-Schwarzer EEG System (**Attachment J**)
4. HARMONIE User's Guide, Version 5.0. (**Attachment K**)

Comparison of Technological Characteristics to Predicate Devices		
	Neurofax EEG-1100A K992742	**HARMONIE-Schwarzer**
Indications for Use	The EEG-1100A is intended to record, measure and display cerebral and extracerebral activity for EEG and Sleep Studies. These data may be used by the clinician in Sleep Disorders, Epilepsies and other related disorders as an aid in diagnosis. The device is intended for use by medical personnel in any location within a medical facility, laboratory, clinic or nursing home or outside of a medical facility under the direct supervision of a medical professional.	The HARMONIE-Schwarzer EEG System is indicated for the recording and study of EEG and other physiological signals and patient video obtained during routine EEG exams, Long-Term Monitoring in Epilepsy (LTM) and sleep studies (polysomnography or PSG) in clinical environments. The HARMONIE-Schwarzer EEG System is indicated for use with patients of all ages under the direct supervision of a physician or other trained health care professional. In no way are any of the system functions represented as being in and of themselves diagnostic. The system requires competent user input, and its output must be reviewed and interpreted by a physician or other trained health care professional who will exercise professional judgment in using this information
Target Population	All ages	
Software Specification	**HARMONIE, SENSA (K960273), LUNA (K982351)**	**HARMONIE-Schwarzer**
Data Acquisition, Review and Reporting		
Data Acquisition	New Device Driver for Schwarzer PTMS data acquisition (DSP) card *	
Review & Reporting	IDENTICAL	
Operating System		
	Windows NT	

* The user interface of the Schwarzer PTMS device driver is presented in **Attachment J**.

Comparison of Technological Characteristics to Predicate Devices		
Specification	**Neurofax EEG-1100A K992742**	**HARMONIE-Schwarzer**
EEG Headbox		
	JE-425A (10-20 type)	**Schwarzer 210026 (10-20 type)**
EEG inputs	25	27
Multi-purpose inputs	11	6
Respiration inputs	3 (flow, chest, abdomen)	1 (flow)
Reference input	1	1
Ref. Input for BN derivation	2	—
Electrode lead check	YES	
Impedance check	YES	
Impedance threshold preset	2, 5, 10, 20, 50 KΩ	
High impedance indicators	LED indicators for all inputs	
Impedance check current	?	2.3 μA (10 Hz sine)
	JE-209A with JE-213A and JE-214A	**Schwarzer 210033 (up to 2 headboxes)**
EEG inputs	64 + 64 = 128	64 (+ 64 = 128)
Respiration inputs	3 (flow, chest, abdomen)	1 (flow)
Reference input	1	1
Bipolar inputs	8	—
Stimulator switching inputs	—	YES
Impedance check	YES	
Impedance threshold preset	2, 5, 10, 20, 50 KΩ	NO. Available only in software
High impedance indicators	LED indicators for all inputs	NO. Available only in software
PSG Headbox		
	JE-425A (10-20 type EEG/PSG headbox)	**Schwarzer 210031 (10-20 type) with 210069 polygraphy adapter**
EEG inputs	25	27
Multi-purpose inputs	11	6
Respiration inputs	3 (flow, chest, abdomen)	1 (flow)
Other dedicated inputs	—	8 (CPAP, ECG, flow, chest, abdomen, sound, body pos, SpO2)
Reference input	1	1
Ref. input for BN derivation	2	—
Electrode lead check	YES	
Impedance check	YES	
Impedance threshold preset	2, 5, 10, 20, 50 KΩ	
High impedance indicators	LED indicators for all inputs	
Impedance check current	?	2.3 μA (10 Hz sine)

Comparison of Technological Characteristics to Predicate Devices		
Specification	**Neurofax EEG-1100A K992742**	**HARMONIE-Schwarzer**
Amplifiers		
	JE-425A	All models
Input impedance	100 MΩ (JE-425A)	≥ 100 MΩ (All models)
	200 MΩ (JE-209A)	
Internal noise level	< 3 μVp-p, .53-120Hz (JE-425A)	< 1.5 μVp-p, 0.53-70Hz (All models)
	< 1.5 μVp-p, .53-120Hz (JE-209A)	
CMRR	≥ 105 dB (JE-425A)	≥ 100 dB (All models)
	≥ 110 dB (JE-209A)	
High-pass filter	?	0.016 Hz (6 dB/oct)
Low-pass (anti-alias) filter	300 Hz, -18 dB/oct (JE-425A)	300 Hz, -20 dB/oct (All models)
	300/600/1200/3000Hz (JE-209A)	
A/D Conversion		
Resolution	16 bits	
Max sampling Frequency	1,000 Hz (JE-425A)	1,000 Hz (All models)
	1,000 / 2,000 / 5,000 /10,000 Hz (JE-209A)	
Signal Transmission	Electrical conductor cable	Fiberoptic cable
Software Filters		
50 or 60 Hz Line filter	YES	
High-pass filter	.016 to 159 Hz (-6 dB/oct)	.1/.3/.53/1.6 Hz (-12 dB/oct)
Low-pass filter	15/30/35/60/70…1200 Hz (-12db/oct)	15/30/60/70/300 Hz (-12 dB/oct)
ECG and other filters	Software selectable	Software programmable
Calibration		
Waveform	0.25Hz step or 10 Hz sine	0.5 Hz square
Voltage	2 - 1,000 μV	50 μV
Electrode Switching		
Patterns / Mappings	36 sets of programmable montages	Software programmable
Reference selection	YES	
Accessories		
Support for Photic Lamp	YES	Astromed-Grass PS-40 Photic Stimulator Specified
Photic stimulation mark	YES	—
External signal mark	YES	Yes with PTMS6 Marker/Trigger board
Headbox stand	YES	
Electrodes / Conductive Gel	YES	Astromed-Grass Electrodes Specified
Respiratory transducers	YES	Pro-tech/Nonin transducers Specified

Comparison of Technological Characteristics to Predicate Devices		
Specification	**Neurofax EEG-1100A K992742**	**HARMONIE-Schwarzer**
Safety		
IEC 60601-1: 1988 + A1: 1991 + A2: 1995	YES	
IEC 60601-1-1: 1992 + A1: 1995	YES	
IEC 60601-1-2: 1993	YES	
IEC 60601-2-26: 1994	YES	
IEC950	Specified for all computer equipment	
Protection against shock	Class I, Type CF	
Protection against harmful ingress of water	Not protected (IPX0)	
Operation in the presence of flammable gas	Not suitable	

Design Verification & Validation

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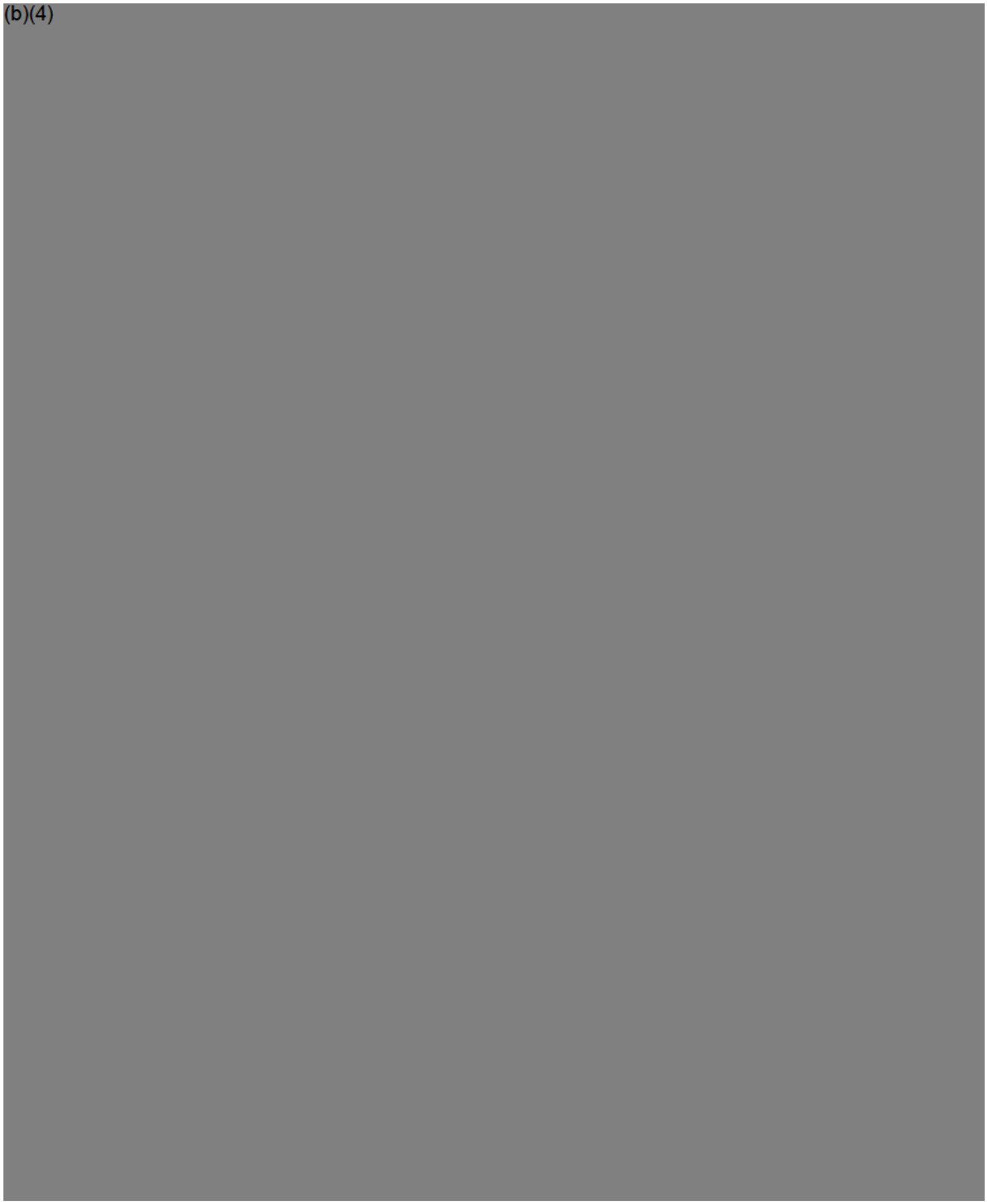

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Attachment A

Indications for Use Statement

510(k) Number: _____

Device Name: HARMONIE-Schwarzer EEG System

Indications for Use:

The HARMONIE-Schwarzer EEG System is indicated for the recording and study of EEG and other physiological signals and patient video obtained during routine EEG exams, Long-Term Monitoring in Epilepsy (LTM) and sleep studies (polysomnography or PSG) in clinical environments.

The HARMONIE-Schwarzer EEG System is indicated for use with patients of all ages under the direct supervision of a physician or other trained health care professional.

In no way are any of the system functions represented as being in and of themselves diagnostic. The system requires competent user input, and its output must be reviewed and interpreted by a physician or other trained health care professional who will exercise professional judgment in using this information.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

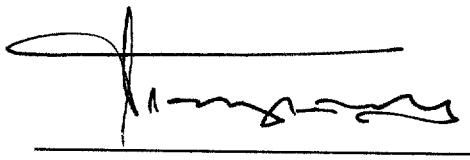
Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Attachment B

510(k) Statement

[As required by 21 CFR § 807.93]

I certify that, in my capacity as the *Director, QA & Regulatory Affairs of Stellate Systems*, 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 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 commercial information, as defined in 21 CFR 20.61.



March 9, 2001

George Papagiannis, M.Eng.
QA & Regulatory Affairs

Date

Attachment C

Truthful and Accurate Statement

[As required by 21 CFR § 807.87(j)]

I certify that, in my capacity as *President* of *Stellate Systems*, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Jean Gotman, Ph.D.
President

8 March 2001
Date

Attachment D

Declaration of Conformity to Recognized Standards

schwarzer
Meßgeräte für die Medizin

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY
DÉCLARATION DE CONFORMITÉ

No. 20000427

Wir / We/ Nous,

Schwarzer GmbH, Meßgeräte für die Medizin
Bärmannstraße 38, D-81245 München

erklären in alleiniger Verantwortung, daß die nachfolgend aufgelisteten Produkte der Klasse IIb, auf die sich diese Erklärung bezieht,	declare under our sole responsibility that the products of medical device class IIb listed below to which this declaration relates	déclarons sous notre seule responsabilité que les produits de la classe IIb cités sur la liste suivante auxquels se réfère cette déclaration,
Elektronischer EEG-Ableitkopf mit 24 Kanälen Artikel-Nr. 210032	**Electronic EEG headbox with 24 channels Part-No. 210032**	**Têtière électronique pour EEG avec 24 canaux Ref. No.: 210032**
Elektronischer EEG-Ableitkopf mit 32 Kanälen Artikel-Nr. 210025, 210026, 210027, 210028, 210029, 210031	**Electronic EEG headbox with 32 channels Part No. 210025, 210026, 210027, 210028, 210029, 210031**	**Têtière électronique pour EEG avec 32 canaux Ref. No.: 210025, 210026, 210027, 210028, 210029, 210031**
Elektronischer EEG-Ableitkopf mit 65 Kanälen Artikel-Nr. 210033	**Electronic EEG headbox with 65 channels Part-No. 210033**	**Têtière électronique pour EEG avec 65 canaux Ref. No.: 210033**
mit der/den folgenden Norm(en) oder normativen Dokument(en) übereinstimmen.	are in conformity with the following standard(s) or normative document(s)	sont conformes à la (aux) norme(s) ou au(x) document(s) normatif(s) suivant(e)(s).

EN 60 601-1: 1990 + A1:1993 + A2:1995, EN 60 601-1-2: 1993, EN 60601-1-4: 1997, EN 60601-2-26: 1994

Gemäß den Bestimmungen der Richtlinie 93/42/EWG (MDD) und des Medizinproduktegesetzes (MPG).	Following the provisions of Directive 93/42/EEC (MDD).	Conformément aux dispositions de la Directive 93/42/CEE.
Die Produkte werden in der EG hergestellt, erfüllen die grundlegenden Anforderungen von Anhang 1 MDD und sind mit CE 0123 gekennzeichnet. Die förmliche Überprüfung wurde gemäß Anhang 2 MDD durchgeführt und durch das EG-Zertifikat Nr. G1 97 05 1254 014 bestätigt.	The products are manufactured in the EC, fullfill the essential requirements of Annex 1 of the MDD and are marked with CE 0123. The conformity assessment procedure was performed according to Annex 2 MDD and is certified by the EC Certificate No. G1 97 05 12154 014.	Les produits sont fabriqués en CE, remplissent les exigences essentielles de l'annexe 1 MDD et sont marqués CE 0123. La vérification en bonne et due forme a été exécutée conformément à l'annexe 2 MDD et a été confirmée par le certificat de la CE No. G1 97 05 12154 014.

München/ Munich/ Munich, 27.04.2000

Jürgen Neubert
Geschäftsführer / Managing Director / Gérant

Formblatt 089 066 5 Datei: 20000427.doc

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schwarzer
Meßgeräte für die Medizin

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY
DÉCLARATION DE CONFORMITÉ

No. 20010131

Wir / We / Nous,

Schwarzer GmbH
Meßgeräte für die Medizin / Medical Diagnostic Equipment
Baermannstraße 38
D-81245 München / Munich

erklären in alleiniger Verantwortung, daß die nachfolgend aufgelisteten Produkte der Klasse I, auf die sich diese Erklärung bezieht,	declare under our sole responsibility that the products of medical device class I listed below to which this declaration relates	déclarons sous notre seule responsabilité que les produits de la classe I cités sur la liste suivante auxquels se réfère cette déclaration,
PTMS1, **Signalprozessorplatine,** **Artikel-Nr. 374 913**	**PTMS1,** **signal processor board,** **part-no. 374 913**	**PTMS1,** **carte processeur de signaux,** **article no. 374 913**
PTMS256, **Signalprozessorplatine,** **Artikel-Nr. 374 912**	**PTMS256,** **signal processor board,** **part-no. 374 912**	**PTMS256,** **carte processeur de signaux,** **article no. 374 915**
PTMS3, **Zusatzplatine für 8 bipolare DC-Eingänge,** **Artikel-Nr. 374 915**	**PTMS3,** **additional board for 8 bipolar dc inputs,** **part-no. 374 915**	**PTMS3,** **carte d'additif pour 8 entrées DC bipolaires,** **article no. 374 915**
PTMS6, **Zusatzplatine für externe Trigger-Eingänge,** **Artikel-Nr. 374 924**	**PTMS6,** **additional board for external trigger inputs,** **part-no. 374 915**	**PTMS6,** **carte d'additif pour entrées déclenchement,** **article no. 374 915**
mit der/den folgenden Norm(en) oder normativen Dokument(en) übereinstimmen.	are in conformity with the following standard(s) or normative document(s)	sont conformes à la (aux) norme(s) ou au(x) document(s) normatif(s) suivant(e)(s).

EN 60 601-1: 1990 + A1:1993 + A2:1995, EN 60 601-1-2: 1993, EN 60601-2-26: 1994

Gemäß den Bestimmungen der Richtlinie 93/42/EWG (MDD), Anhang VII.	Following the provisions of Directive 93/42/EEC (MDD), Annex VII.	Conformément aux dispositions de la Directive 93/42/CEE (MDD), Annexe VII.
Die Produkte werden in der EG hergestellt, erfüllen die grundlegenden Anforderungen von Anhang 1 MDD und sind mit CE gekennzeichnet.	The products are manufactured in the EC, fullfill the essential requirements of Annex 1 of the MDD and are marked with CE.	Les produits sont fabriqués en CE, remplissent les exigences essentielles de l'annexe 1 MDD et sont marqués CE.
Das Qualitätsmanagementsystem entspricht EN ISO 9001 sowie EN 46001. Es ist zertifiziert durch den TÜV Product Service, Zertifikat Q1 96 08 12154 013.	The quality management system fullfills the requirements of EN ISO 9001 and EN 46001. It is certified by TÜV Product Service, certificate Q1 96 08 12154 013.	Le système de management de la qualité est conforme aux normes européennes EN ISO 9001 et EN 46001. Il est certifié par TÜV Product Service, certificat Q1 96 08 12154 013.

UMDNS-Code 11-467

München / Munich, 2001-01-31

Jürgen Neubert
Geschäftsführer / Managing Director / Gérant

Formblatt 089 061 3 Datei: 20010131.doc

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Attachment E

Declaration of Conformity to Design Controls

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Jean Gotman, Ph.D.
President & Product Manager

8 March 2001
Date

Product Development

The product development process at Stellate Systems is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Jean Gotman, Ph.D.
President & Product Manager

8 March 2001
Date

OEM Product Development

Schwarzer GmbH, Medical Diagnostic Equipment holds the following certificates (attached):

EN ISO 9001: 1994
EN 46001: 1996
EC Certificate per EEC Directive 93/42/EEC (MDD), Annex II

Notified Body: TUV Product Service GmbH (ID No. 0123)

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

CERTIFICATE

(b)(4)

No. Q1 99 05 12154 017

(b)(4) certifies that

Schwarzer GmbH

Baermannstr. 38
D-81245 Munich - Germany

in the facility:

Schwarzer GmbH
Baermannstr. 38, D-81245 Munich - Germany

for the following area:
Medical Devices for Cardiology, Neurology, Somnology, Electric and Magnetic Stimulation, Respiration Therapy

has established and is maintaining a quality system which meets the requirements of:

EN ISO 9001 : 1994
EN 46001 : 1996

as documented in audit report no. (b)(4)

This certificate is valid until 04/2002.

Munich, May 31, 1999

(b)(4)
ACCREDITED CERTIFICATION BODY
FOR QUALITY SYSTEMS

Deutscher Akkreditierungs Rat
DAR

TGA-ZM-60-95-11

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(b)(4)

EC Certificate

No. G1 97 05 12154 014

Decision according to Annex II, Clause 3 of Council Directive 93/42/EEC concerning medical devices.

The Certification Body of (b)(4) certifies that

Schwarzer GmbH

Bärmannstraße 38

81245 Munich
Germany

in the facilit(y)ies

- **Schwarzer GmbH**
  D - 81245 München

for the products / product categories

Medical Devices for Neurology, Cardiology and Monitoring; Stimulators for EMG

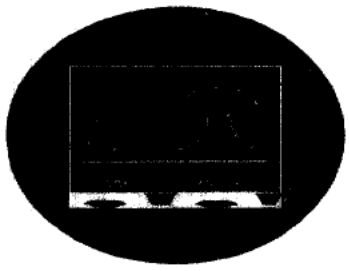
maintains a quality system, which ensures that the product(s) conform(s) with the essential requirements of the Directive, which apply to them at every stage from design to final controls.

Reasoned assessment see audit report no.: (b)(4) .

Provided the agreed periodical surveillance is carried out, this certificate is valid until 05-15-2002.

Released with the above mentioned certificate number by the Certification Body of

(b)(4)



Department: MUCMED1/ap
Date: 05-15 -1997

TÜV PRODUCT SERVICE GMBH is notified body according to the Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

(b)(4)

Attachment F

Risk Analysis

Stellate HARMONIE

Schwarzer EEG Headbox

Stellate Systems

Doc No. (b)(4)

Risk Analysis Summary

(b)(4)

Rev. (b)

March 1, 2001

For Internal Use Only

Please verify the validity of this document when it is not stamped "CONTROLLED COPY" in red ink.

(b)(4)

DATE
8 March 2001
8 March 2001
8 March 2001
8 March 2001
8 March 2001

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Attachment G

Internal Test Protocols & Sample Test Reports

Stellate HARMONIE

Schwarzer EEG/PSG Headbox

Schwarzer 66ch EEG Headbox

Attachment H

510(k) Summary for Neurofax EEG-1100 by Nihon Kohden

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1999

Ms. Bonnie Bishop
Regulatory Affairs Manager
NIHON KOHDEN AMERICA, INC.
2601 Campus Drive
Irvine, California 92612

Re: K992742
Trade Name: Neurofax Model EG-1100A Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: August 13, 1999
Received: August 16, 1999

Dear Ms. Bishop:

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.

1/8

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,

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

Enclosure

NIHON KOHDEN AMERICA, INC.
August 12, 1999

510(k) NOTIFICATION
EEG-1100A EEG/PSG Recorder

G. Indications for Use Statement

510(k) Number (if known): K992742

Device Name: EEG-1100A

Indications for Use:

The EEG-1100A is intended to record, measure and display cerebral and extracerebral activity for EEG and Sleep Studies. These data, may be used by the clinician in Sleep Disorders, Epilepsies and other related disorders as an aid in diagnosis.

The device is intended for use by medical personnel in any location within a medical facility, laboratory, clinic or nursing home or outside of a medical facility under direct supervision of a medical professional.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992742

Prescription Use X
(Per 21 CFR 801.109)

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OCT 14 1999

NIHON KOHDEN AMERICA, INC.
August 12, 1999

510(k) NOTIFICATION
EEG-1100A EEG/PSG Recorder

K992742

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
2601 Campus Drive
Irvine, California 92612-1601
Phone: (949) 250-3959
Fax: (949) 250-3210

Primary Contact:
Bonnie Bishop, Regulatory Affairs Manager
(949) 250-3959 ext. 4401

Alternate Contact:
Gary Reasoner, Director of Product Operations
(949) 250-3959 ext. 3387

The device has been classified as Class 2 by the Neurology Device Classificaiton Panel under 21 CFR Part 882.1400 "Electroencephalograph" per GWQ and the under 21 CFR Part 882.1890 "Evoked Response Photic Stimulator" per GWE.

Common names for the EEG-1100A device include Electroencephalograph (EEG) and Polysomnograph (PSG).

The predicate marketed device is the Nihon Kohden EEG-2100 per 510(k) # K944678, commercial distribution certification dated 5/22/98.

Nihon Kohden's, model number EEG-1100A intended to record, measure and display the physiological data required for EEG and sleep studies (Polysomnography or PSG). These data, may be used by the clinician in Sleep Disorders, Epilepsies and other disorders as an aid in diagnosis. This device is intended for use by medical personnel. The device will be available for use within a medical facility, laboratory, clinic or nursing home or outside of a medical facility under direct supervision of a medical professional.

The device complies with IEC 601-1 subclause 56.3(c) as implemented by 21 CFR Part 898 Performance Standard for Electrode Lead Wires and Patient Cables. No other special controls or performance standards are known or established for this device.

The EEG-1100A device is not sterile.

The device does not directly contact patients. Accessories that contact patients, such as electrodes, are the same accessories as used with the predicate or are comprised of the same component materials with the same design and manufacturing processes as the predicate accessories. The device may also use commercially available electrode and sensor products. Therefore, good laboratory practice studies were not required per 21 CFR part 58.

The EEG-1100A was subjected to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software functions of acquiring, processing, displaying and recording of all functions of the device. The results confirmed that the device performed within specifications.

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SECTION 3 - PROPOSED LABELING

A. Intended Use
The EEG-1100A is intended for medical purposes to record, measure and display cerebral and extracerebral activity for EEG and Sleep Studies. These data, may be used by the clinician in Sleep Disorders, Epilepsies and other related disorders as an aid in diagnosis.

B. Device/Package Labels
The proposed product labels for the device is located in Attachment 1.

C. Proposed Packaging
Packaging for the EEG-1100A is depicted in Attachment 2.

D. Instructions for Use
The proposed instructions for use are provided with each packaged device and are presented in Attachment 9.

E. Advertisement/Promotional Literature
To date no advertisement or promotional literature has been created for the EEG-1100A for distribution in the United States.

F. Contraindications, Precautions & Warnings
Warnings and cautions are listed in the Operator's Manual as shown in Attachment 3.

Attachment I

Partial Operator's Manual for Neurofax EEG-1100 by Nihon Kohden

EEG- 1100A
EEG- 1100J
EEG- 1100K

OPERATOR'S MANUAL

Neurofax

ELECTROENCEPHALOGRAPH

EEG-1100

Features

Acquiring the EEG waveforms

1. Variety of Electrode Junction Boxes

- 10- 20 type JE-425A Electrode junction box
  This junction box has 41 electrode jacks: 25 electrode jacks in the electrode position layout, 11 multi-purpose input jacks, 3 RESP jacks, 2 BN jacks.
- JE-209A Electrode junction box (Option)
  Up to 128 electrode jacks can be used by combining the JE-209A electrode junction box and a 10-10 type JE-210A mini junction box (option), or matrix type JE-213A mini junction box (option) and JE-214A mini junction box (option).
- JE-212A Electrode junction box (Option)
  Up to 192 electrode jacks can be used by combining the JE-212A electrode junction box and JE-213A mini junction box and two JE-214A mini junction box.

	Mini junction box (Number of electrode jacks)	Total number of electrode jacks
JE-209A	JE-210A (128), or JE-213A (64) and JE-214A (64)	128
JE-212A	JE-213A (64) and two JE-214A (64)	192

The JE-209A and JE-212A electrode junction box converts the acquired EEG waveforms to digital signals at sampling speeds of up to 10 kHz. The input impedance is 200 MΩ and CMRR is 110 dB.

2. One-touch Selection of Measurement Conditions

You can assign different measurement conditions to 36 different patterns. A pattern includes the preset montage, amplifier settings and waveform settings. Waveform settings are position, display ON/OFF, color, amplitude limit and comment for waveform. Selecting different patterns lets you quickly and easily set up the desired measurement conditions.

3. Easy Electrode-skin Impedance Check and Electrode Lead Check

You can check all electrodes for electrode-skin impedance by pressing the CHECK key on the electrode junction box or clicking the Impedance check button on the screen. The impedance check results are indicated on the electrode position layout on the electrode junction box and screen.
An electrode lead check function is provided in the JE-425A electrode junction box.

4. **Variety of Reference (Monopolar) Derivations**
   Easy switching from same-side hemispheric earlobe derivation (standard) to single-side hemispheric earlobe (A1 → A2, A1 ← A2, A1 ↔ A2, A1 + A2), vertex (VX), averaged (AV), balanced non-cephalic (BN), source derivation ($) or an original (Org) reference derivation. The original reference (Org) switches all A1 and A2 to the averaged voltage of C3 and C4 (or F3 and F4).

5. **Versatile Photic Stimulator**
   Three preset photic stimulation programs for adults and children for routine and special use. Single, double and random pulse stimulation are also available.

6. **ECG Rejection Filter**
   This filter reduces ECG artifact superimposed on the EEG waveforms. This filter is available during both acquisition and review.

7. **64 Channel EEG Waveform Display with Various Information**
   Up to 64 channels of 5, 10, 20, 30 second or 5 minute waveforms, corresponding to one 30 cm page of recording paper, can be simultaneously displayed on a high resolution color monitor. Time marks, time scale, marker channel, montage name, and events can also be displayed on the screen. You can also change the waveform color and amplitude limit for specific channels, or turn the waveform display on/off.

8. **Waveform Annotation (Attaching Event Names)**
   While acquiring the EEG waveforms, you can annotate the EEG waveforms with an event name from the preset event list or with the keyboard. Also when you change the pattern, the pattern name is automatically entered. The event names (annotations) are displayed beside the EEG waveforms and saved with the waveforms as an event.

9. **Waveform Amplitude and Time Interval Measurement**
   The amplitude, frequency and time interval of the EEG waveforms can be automatically measured by vertical and horizontal cursors when the waveforms are frozen.

10. **External Signal Input and Analog signal Output**
    When the optional QA-101A Analog input board and/or QD-101A Analog output board is installed, up to 32 channel of analog signals can be input and/or output.

Reviewing the EEG waveforms

1. **File Management**
   The EEG data files with patient information and volume name of the disk are automatically registered in the database. To review EEG data, you can search for a data file by several methods: patient name, ID number, examination date, or any combination of search items and in a specified range.

2. **Calling Up and Displaying Specific Waveforms**
   You can call up any saved waveform by a variety of methods. For example, if you specify a specific event name, a waveform which contains the specified event name is displayed on the screen.
   You can display any part of the waveform by clicking on the event jump bar.

3. **Re-format and Re-filtering**
   You can review waveforms and data using different montage settings, amplifier settings (sensitivity, high-cut filter, time constant), and display speeds. (The raw data originally sampled is saved in the referential format.)

4. **Variety of Review Modes**
   - Review the waveforms at the acquisition display speed. (IRIG output is available in this mode.)
   - Review the waveforms forward or backward at high speed.
   - Scroll the displayed waveforms forward or backward one second.
   - Scroll the displayed waveforms forward or backward one page.

5 **Event Name (Annotation) Editing**
   While reviewing waveforms, you can add, delete, and change the event names.

6. **Complete, High-quality Documentation with a Laser Printer**
   You can print the currently displayed waveforms, or any part of the EEG waveforms with event log and patient information on the laser printer (locally purchased).

7. **EEG Data File Compatibility**
   The EEG data files saved in EEG-2110 digital EEG, digital EEG system (PC with the QP-223A/AK acquisition program kit) can be reviewed in this digital EEG.

Communication

1. Communication with an external instrument (networking) is optionally available.

2. The EEG-1100 software is Windows compatible so you can copy the acquired EEG waveforms and patient information to other Windows applications such as word processors or spreadsheets.

Composition

The following components are required for operation.

PC unit, CC-0018
Main unit, CA-0050 (100 V) or CA-0051 (200 V)
Display (17 inch, locally purchased, EIZO T57S or compatible)
Electrode junction box, JE-425A
Electrode junction box stand, KC-001A
Flash lamp assembly, LS-703A
Flash lamp stand, KC-001A
Laser printer (locally purchased, HP LaserJet 4,000 series recommended)
Medical isolation transformer for the laser printer (locally purchased, SM-310V or compatible)
Cart, KD-015A or 016A (option)

Use only the following magneto-optical disk and drive models. Other models my not function properly.

- Magneto-optical disk drive: SONY model RMO-S551/S
- Magnet-optical disk: SONY model, 512 bytes/sector

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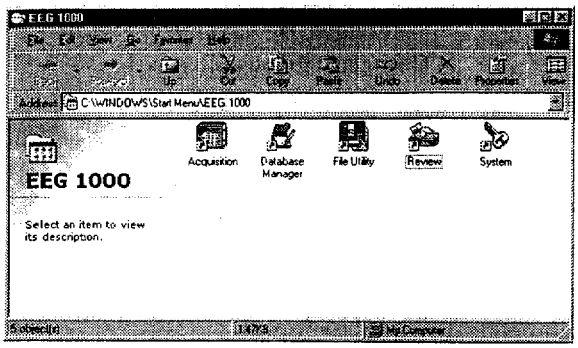
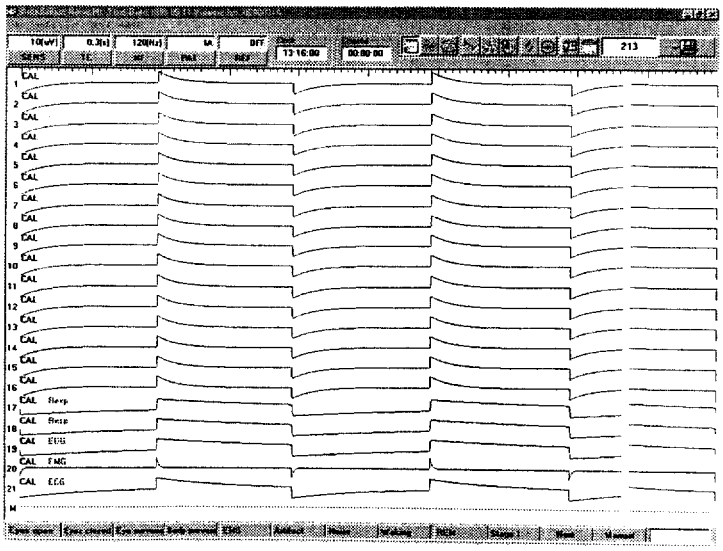
General Functions and Screens

Menu window



Acquisition screen:
EEG measurement



Use this screen to acquire EEG waveforms

- Entering the patient information
- Checking the skin- electrode contact impedance
- Recording the calibration waveforms. The calibration mode and voltage can be selected
- Acquiring the EEG waveforms
- Entering events
- Setting and performing the activation (photic stimulation and hyperventilation)
- Using the timer
- Changing the pattern
- Changing the amplifier settings for all channels
- Changing the amplifier settings for an individual channel
- Changing the waveform display mode
- Measuring waveform amplitude and time interval
- Using the AC filter and/or ECG filter
- Selecting and deleting the electrodes for AV derivation
- Adjusting BN balance for BN derivation
- Temporarily changing the reference electrode
- Saving the acquired EEG waveforms, patient information and events in a file

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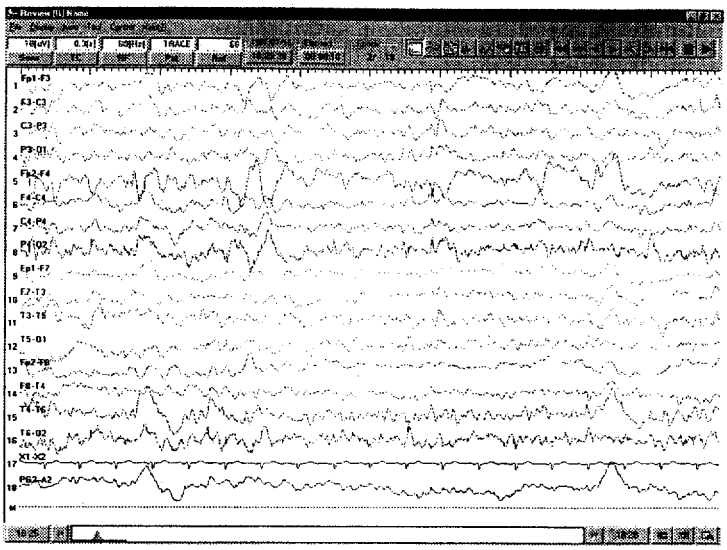
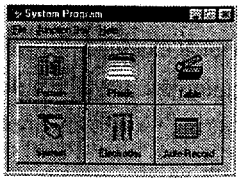
Review screen:
EEG review



Use this screen to review, display and print the saved waveforms

- Selecting the EEG file
- Displaying the waveform from a selected file
- Changing the waveform display mode
- Editing the events
- Changing the calibration mode and voltage
- Entering events
- Changing the pattern
- Changing the amplifier settings for all channels
- Changing the amplifier settings for an individual channel
- Measuring waveform amplitude and time interval
- Using the AC filter and/or ECG filter
- Selecting and deleting the electrodes for AV derivation
- Adjusting BN balance for BN derivation
- Temporarily changing the reference electrode
- Selecting and printing parts of the waveforms
- Selecting and saving parts of the waveform in a file

System Program:



Use the System program to change settings

- Programming the pattern
- Programming the automatic photic stimulation mode
- Selecting the electrode junction box
- Editing the list of preset selectable items for patient information records
- Changing the DC input/output settings
- Changing all settings to the default settings
- Changing the electrodes to be saved
- Changing the system settings
- Saving the system settings in a file
- Calling up the system settings stored in the file

How to Use Windows

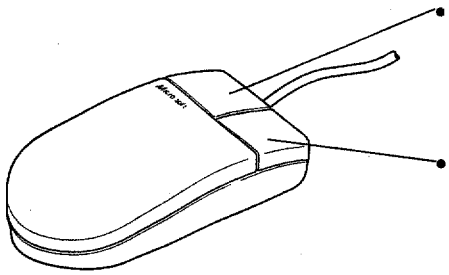
This section briefly explains how to use Windows. For a detailed explanation, refer to your Windows manual. With the mouse, you can do all operations to measure, review and print the EEG waveforms.

Using the Mouse

Mouse Pointer:

When you move the mouse on the desk, the mouse pointer (arrow-shaped cursor on the screen) follows the movement of the mouse. The mouse pointer indicates which area of the screen will be affected when you press the mouse button.

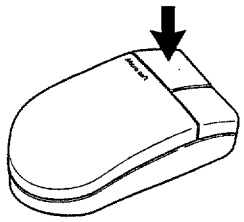
Mouse Buttons



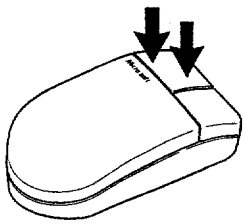
- Left mouse button:
  Select measurement condition or settings, or execute an action.

- Right mouse button:
  Alternates the selection of two cursors for the Voltage cursors, Time cursors, or Ruler when you measure waveform amplitude or time (duration). When clicked on the EEG waveform, the Event dialog box appears.

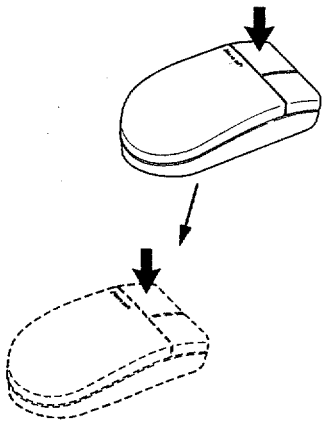
Mouse Button Operations



1) Click
   Quickly press and release the left mouse button. Use this operation to select measurement condition or settings.



2) Double-click
   Click the left mouse button twice in rapid succession. Use this operation to open an icon or execute an action.



3) Drag
   Press and hold down the left mouse button while you move the mouse. Use this operation to change the waveform display position or change the size of a window.

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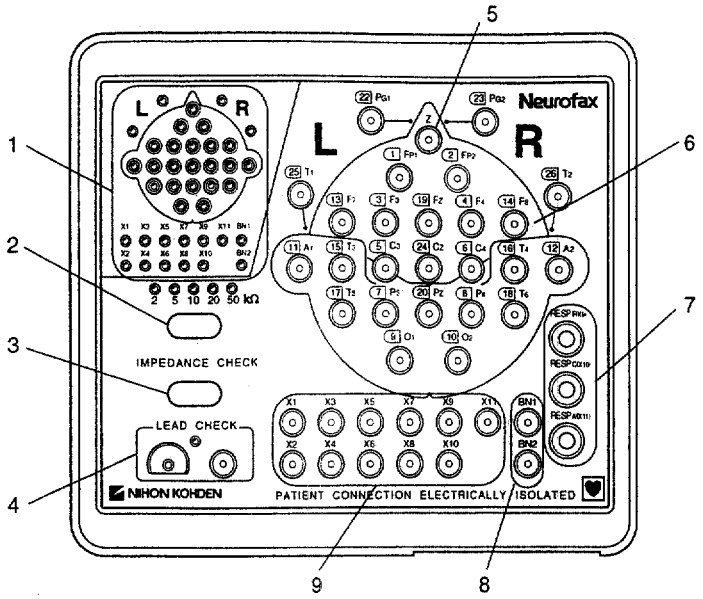
JE-425A Electrode Junction Box



Name	Function
1. Impedance display LED	After the skin-electrode contact impedance check, a lit LED indicates an electrode impedance higher than the preset value.
2 Impedance preset key	Selects a preset impedance (threshold) for evaluation. The LED indicates the selected impedance.
3. Impedance check key	Measures skin-electrode contact impedance at the electrode junction box. Press for about one second. The check result is displayed on the screen and a lit LED on the electrode junction box indicates an electrode impedance higher than the preset value.
4. LEAD CHECK terminal	Checks the electrode lead wire. Plug the lead tip into the electrode jack and touch the electrode to this terminal. If the lead wire is broken, the LED does not light.
5. Z jack	Reduces the artifact when the electrode for Z on the patient is connected to the Z jack. Be sure to attach the Z electrode to the patient during measurement.
6. Electrode jack	Connects the EEG disk electrode.
7. RESP jack	Connects the thermistor pickup (option) or 3 port respiration pickup system (option) for measuring the respiration waveforms.
8. BN Jack	Use in BN reference derivation.
9. Extra input jack	Inputs biological signals other than the EEG.

NOTE

The X9 to X11 jacks and the RESP jacks cannot be used simultaneously.

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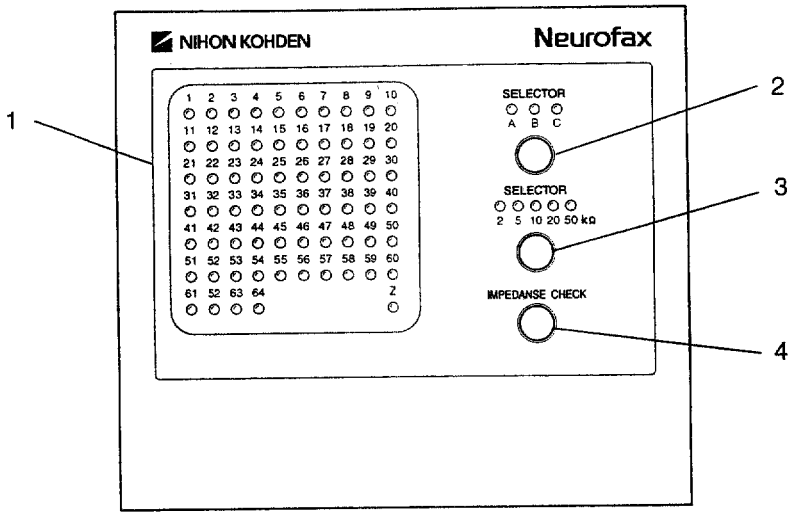
JE-209A/JE-212A Electrode Junction Box (Option)

WARNING

When using the JE-209A or JE-212A Electrode junction box, the JE-210A, JE-213A or JE-214A Mini junction box must be connected to the electrode junction box. Failure to follow this warning may cause serious electrical shock or other injury.



Name	Function
1. Impedance display LED	After the skin-electrode contact impedance check, a lit LED indicates an electrode impedance higher than the preset value.
2. A, B, C SELECTOR	Selects the electrode jack group.
3. 2, 5, 10, 20 50 Ω SELECTOR	Selects a preset impedance (threshold) for evaluation. The LED indicates the selected impedance.
4. Impedance check key	Measures skin-electrode contact impedance at the electrode junction box. Press for about one second. The check result is displayed on the screen and a lit LED on the electrode junction box indicates an electrode impedance higher than the preset value.

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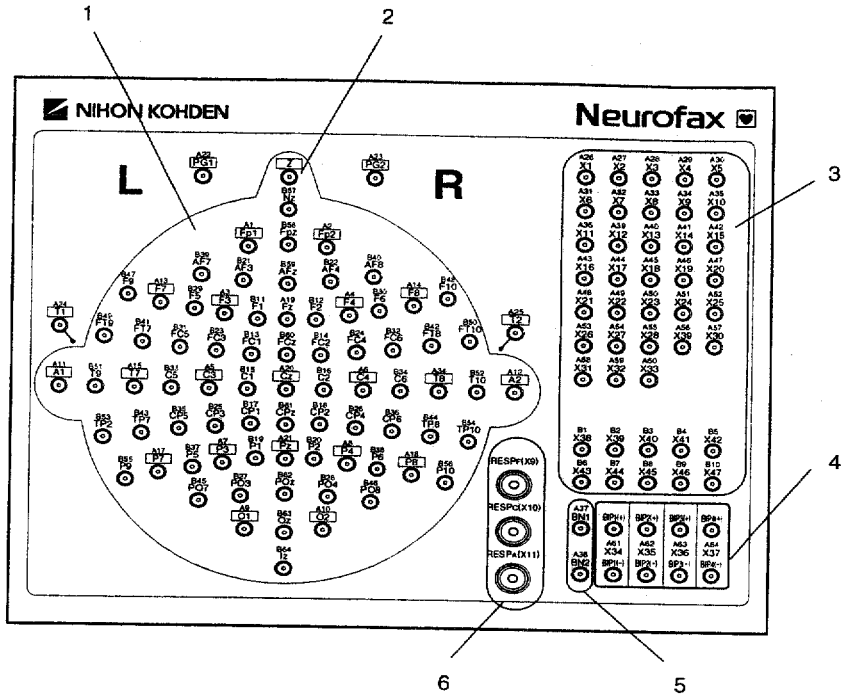
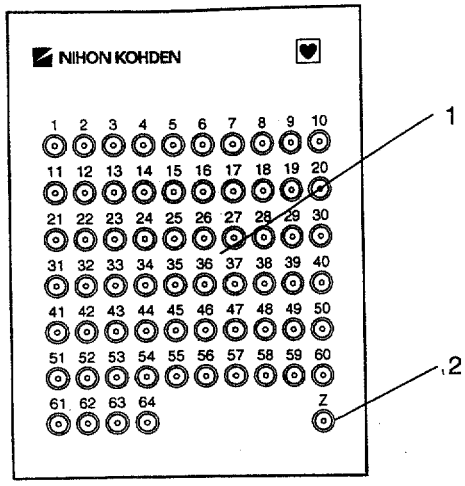
JE-210A Electrode Junction Box (Option)



Name	Function
1. Electrode jack	Connects the EEG disk electrode.
2. Z jack	Reduces the artifact when the electrode for Z on the patient is connected to the Z jack. Be sure to attach the Z electrode to the patient during measurement.
3. Extra input jack	Inputs biological signals other than the EEG.
4. BIP jack	For bipolar deviation. Use this jack to measure the limb electromyograph.
5. BN Jack	Use in BN reference derivation.
6. RESP jack	Connects the thermistor pickup (option) or 3 port respiration pickup system (option) for measuring the respiration waveforms.

JE-213A/214A Mini Junction Box (Option)



Name	Function
1. Electrode jack	Connects the EEG disk electrode.
2. Z jack (JE-213A only)	Reduces the artifact when the electrode for Z on the patient is connected to the Z jack. Be sure to attach the Z electrode to the patient during measurement.

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Specifications

Data Acquisition

JE-425A Electrode junction box

Number of input jacks	
EEG inputs on electrode position layout:	25
Extra inputs:	11 (X1 to X11)
Reference input for feedback:	1 (Z)
Reference inputs for BN derivation:	2 (BN1 and BN2)
Respiration inputs:	3 {RESP F (flow), RESP C (chest), RESP A (abdomen)}
Input impedance	100 MΩ
Internal noise level	Less than 3 μVp-p (0.53 Hz to 120 Hz)
CMRR	105 dB or greater
High-cut filter	300 Hz (-18 dB/oct)
A/D conversion	16 bits
Sampling and hold	All electrodes at a time
Sampling frequency	1,000 Hz

JE-209A/212A Electrode junction box

Number of input jacks: The JE-209A and JE-212A Electrode junction boxes must be used with the following mini junction box combinations

	Mini junction box (Number of input jacks)	Total number of input jacks
JE-209A	JE-210A (128)	128
	Or, JE-213A (64) and JE-214A (64)	128
JE-212A	JE-213A (64) and two JE-214 (64)	192

Respiration inputs	JE-209A: 3 {RESP F (flow), RESP C (chest), RESP A (abdomen)}
	JE-212A : Not provided
Bipolar inputs	JE-209A: 8
	JE-212A: Not provided
Input impedance	200 MΩ
Internal noise level	Less than 1.5 μVp-p (0.53 Hz to 120 Hz)
CMRR	110 dB or greater
Time constan	2 or 10 s, selectable
High-cut filter	300, 600, 1,200 or 3,000 Hz (-18dB/oct), depending on the sampling frequency
A/D conversion	16 bits
Sampling and hold	All electrodes at a time
Sampling frequency	1,000, 2,000, 5,000 or 10,000 Hz, selectable

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Data Processing

Sensitivity	
EEG INPUT:	OFF, 1, 2, 3, 5, 7, 10, 15, 20, 30, 50, 75, 100, 150, 200 μV/mm
DC INPUT:	OFF, 10, 15, 20, 30, 50, 70, 100, 150, 200 mV/mm
Time constant	0.001, 0.003, 0.03, 0.1, 0.3, 1.0, 2.0, 5.0, 10.0 s
(Low-cut filter)	0.016, 0.03, 0.08, 0.16, 0.53, 1.6, 5.3, 53, 159 Hz (-6 db/oct)
High-cut filter	15, 30, 35, 60, 70, 120, 300, 600, 1,200 (-12 db/oct), 50 (RAPID), 3,000 Hz (-18 db/oct)
AC filter	50 or 60 Hz, (rejection ratio: 1/25 or more)
Calibration waveform	
Waveform shape:	0.25 Hz step wave or 10 Hz sine wave
Voltage:	2, 5, 10, 20, 50, 100, 200, 500, 1,000 μV
ECG elimination filter	Available in acquisition and review modes
Impedance check	
Indication on the screen:	All electrodes are displayed on the screen in electrode position layout. Electrodes with impedance higher than the preset impedance threshold are highlighted.
Indication on LED:	LEDs on the electrode junction box with impedance higher than the preset impedance threshold light.
Impedance threshold:	2, 5, 10, 20 and 50 kΩ
Pattern	36 sets of programmable montages combined with programmable individual amplifier settings
Reference electrode selector	A1 → A2, A1 ← A2, A1 ↔ A2, A1 + A2, VX, AV (with unsuitable electrode deletion function), BN, Aav, Org, S.D and OFF.
Marking signal	Photic stimulation mark, Hyperventilation mark, External signal mark

Display

Display resolution	Up to 1600 × 1200 dots
Number of display channels	Up to 64 and one mark channel
Display modes	Overwrite and page-by-page
Waveform display color	8 or 16 colors
Waveform display ON/OFF	Provided
Waveform position adjustment	Provided
Waveform freeze	Provided
Display of patient image through video camera	Available with optional board
Waveform sweep speed	5, 10, 20, 30 s or 5 min /page
Timing mark	0.1, 1 s
Time scale	OFF, 0.2, 1 s
Event mark	Displays at the bottom of the screen

Acquisition Mode

Timer function	Elapsed recording time of each pattern indication, up to 99 min 59 s
HV timer function	Elapsed recording time of HV and post HV time
Data Storage device	Hard disk drive (standard), magneto-optical disk drive (option)

Review Mode

Changeable items	Montage, sensitivity, high-cut filter, time constant, reference electrode, and display speed
Display skip functions	Specified event, page by page, and specified time
Display modes	Continuous, high speed, high speed with pause, manually page-by-page, and manually second-by-second
Display information	Event, channel number, and montage

Photic Stimulator

Maximum flash energy	1.28 J or more
Stimulation mode	3 automatic (30 steps, programmable), 1 manual, and single
Mode of operation	Continuous operation with intermittent loading
Duty cycle	Max. 5 minutes continuous operation in 30 minutes
Automatic stimulation	
Stimulus rate	0.5, 1 to 33 (1 Hz steps), 50 and 60 Hz
Stimulation period	1 to 99 seconds in 1 second steps
Pause period	1 to 30 seconds in 1 second steps
Manual stimulation	Manually set frequency and stimulation period
Photic frequency	0.5 Hz, 1 to 33 Hz in 1 Hz steps, 50 and 60 Hz
Stimulation time	1 to 99 s in 1 second steps and continuous stimulation (FREE: Max. 5 min)
Pulse mode	Normal, random, and double
Random stimulation	1 to 33 Hz in 1 Hz steps within ±50%
Single stimulation	Manual key operation single stimulation or automatic single stimulation by external trigger signal.
Trigger input	TRIGGER IN jack (TTL level)
Trigger output	TRIGGER OUT jack (TTL level)

Hyperventilation

	When the optional ZE-510AK Hyperventilation unit is connected.
Hyperventilation interval	2, 3, 4 or 5 s
Stimulation time	1, 2, 3, 4 or 5 min

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Safety

Safety standard	IEC 60601-1 (1988) IEC 60601-1 Amendment 1 (1991) IEC 60601-1 Amendment 2 (1995) IEC 60601-2-26 (1994) EN 60601-1-1 (1992-06) with AMI (1995)
Type of protection against electric shock	Class I
Degree of protection against electric shock	Type CF
Degree of protection against harmful ingress of water	Not protected (IPX0)
Degree of safety of application in flammable gas	Not suitable for use in the presence of a flammable anaesthetic mixture with air or oxygen or nitrous oxide
Mode of operation	Continuous

Electromagnetic Compatibility

IEC60601-1-2 (1993)

Dimensions and Weight

KD-015A Cart (option)	620 (W) × 850 (D) × 1,320 (H) mm, 45.5 kg
KD-016A Cart (option)	620 (W) × 850 (D) × 830 (H) mm, 36 kg
PC unit	205 (W) × 439 (D) × 444 (H) mm, 15 kg
Main unit (EEG-1100A/J/K/G)	210 (W) × 470 (D) × 348 (H) mm, 20 kg
JE-425A Electrode junction box	211 (W) × 78 (D) ×183 (H) mm, 1.7 kg

Power Requirements

Line voltage	AC 100, 110, 117, 220, 230 or 240 V
Line frequency	50/60 Hz
Power consumption	Max. 550 VA

Operation Conditions

Temperature	10 to 35° C (50 to 95° F)
Humidity	30 to 80 %
Atmospheric pressure	70 kPa to 106 kPa

Transport and Storage Conditions

Temperature	-20 to 60° C (-4 to 140° F)
Humidity	20 to 90 %
Atmospheric pressure	70 kPa to 106 kPa

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Attachment J

Proposed User Instructions for the HARMONIE-Schwarzer EEG System

Stellate Systems

HARMONIE - schwarzer
EEG

Instructions for Use

DRAFT

March 9, 2001

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1.0 Introduction

The HARMONIE-Schwarzer EEG System is intended to provide clinicians with the means to record and study EEG and other physiological signals obtained during routine EEG exams, Long-Term Monitoring in Epilepsy (LTM), and sleep studies (polysomnography or PSG).

Figures 1-3 show typical system configurations for the intended applications. The system comprises the following key components:

1. Schwarzer headboxes/amplifiers and their accessories
2. Schwarzer PTMS data acquisition cards
3. Cables from the cards to the headbox
4. Computer system
5. Schwarzer PTMS Software Device Driver
6. HARMONIE Software

EEG and PSG signals are amplified, filtered and digitized in the Schwarzer headbox. The digitized signals are opto-electronically decoupled for transmission through fiberoptic cables to a data acquisition card (PTMS) in a personal computer system. Optical isolation at the headbox, between the computer and the amplifiers, ensures the patient's electrical safety. Optical transmission from the headbox to the computer eliminates electromagnetic disturbances, and guarantees a good signal to noise ratio. A detailed description of these components and the associated accessories is presented in the proposed Instructions for Use (***Attachment J.***)

Stellate HARMONIE is a software package for Microsoft Windows, which implements signal recording and review functions, specifically designed for EEG/PSG studies. Optionally, the software supports simultaneous patient video acquisition and digitization through an MPEG-1 encoder card, and synchronization with an external photic stimulator. The function of HARMONIE is described in detail in its User's Guide (see ***Attachment K***).

Stellate HARMONIE implements the software device driver and user interface to Schwarzer's data acquisition card, headbox and amplifier system. A detailed description of the user interface is presented in the proposed Instructions for Use (***Attachment J.***)

Stellate SENSA and LUNA are add-on software modules that extend the functionality of HARMONIE with event-driven recording capabilities, event marking tools, and quantitative analysis and reporting functions. SENSA is specifically designed for use in long-term monitoring (LTM) epilepsy studies. LUNA offers specific tools that are commonly used in sleep studies (PSG or polysomnography). The functions of these two software modules are described in detail in their respective User's Guides (see ***Attachment K.***)

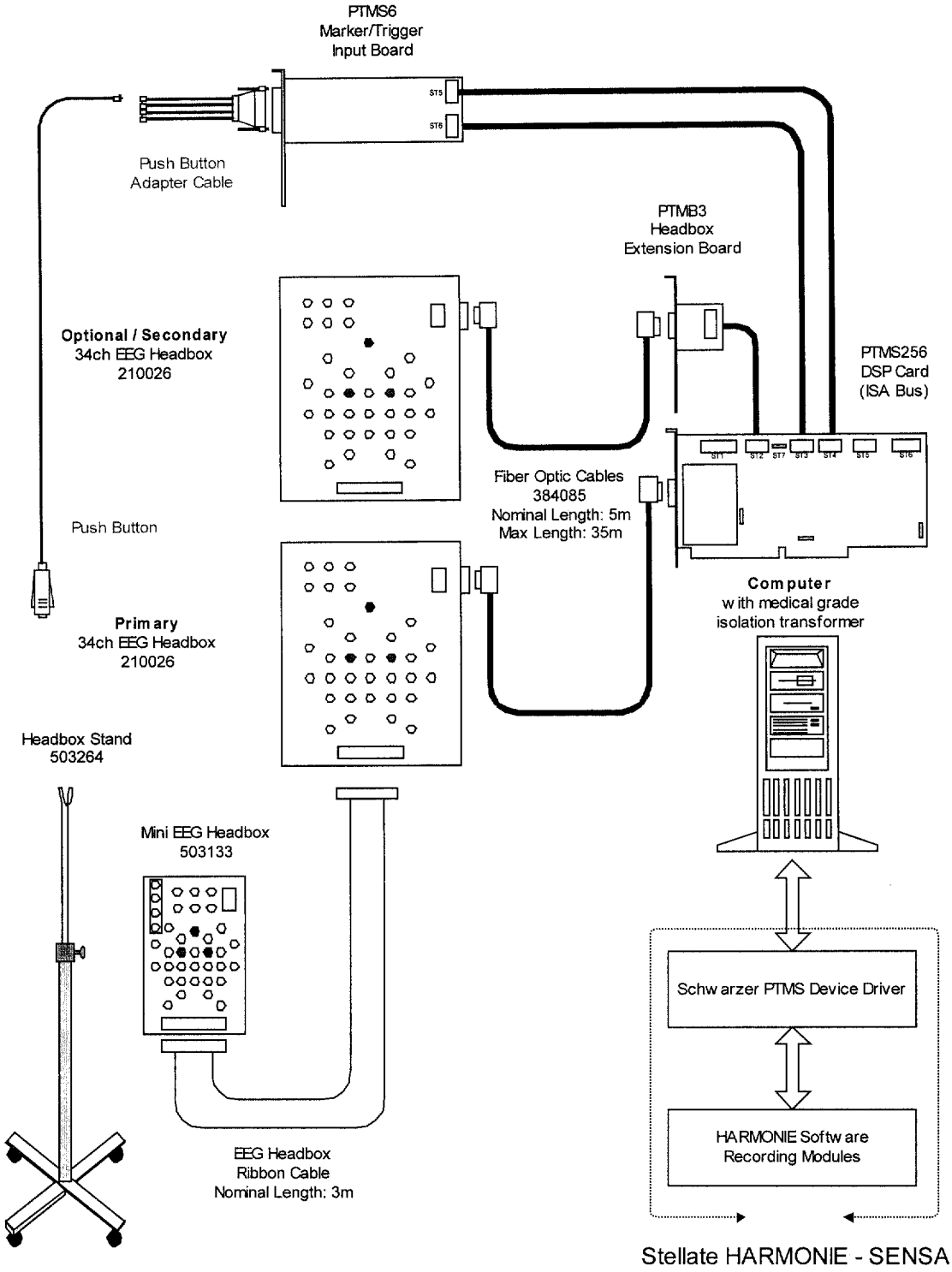

Figure 1. The HARMONIE-Schwarzer EEG System configured for EEG or LTM. The 34-ch headbox (P/N 210026) provides 27 EEG channels, 1 respiratory input, and 6 general purpose polygraphy inputs. A second headbox can be connected to provide additional channels. Channel mappings and filter settings are user configurable with the Schwarzer PTMS Device Driver. All 34 inputs can also be accessed on the optional mini headbox adapter (P/N 503133.)

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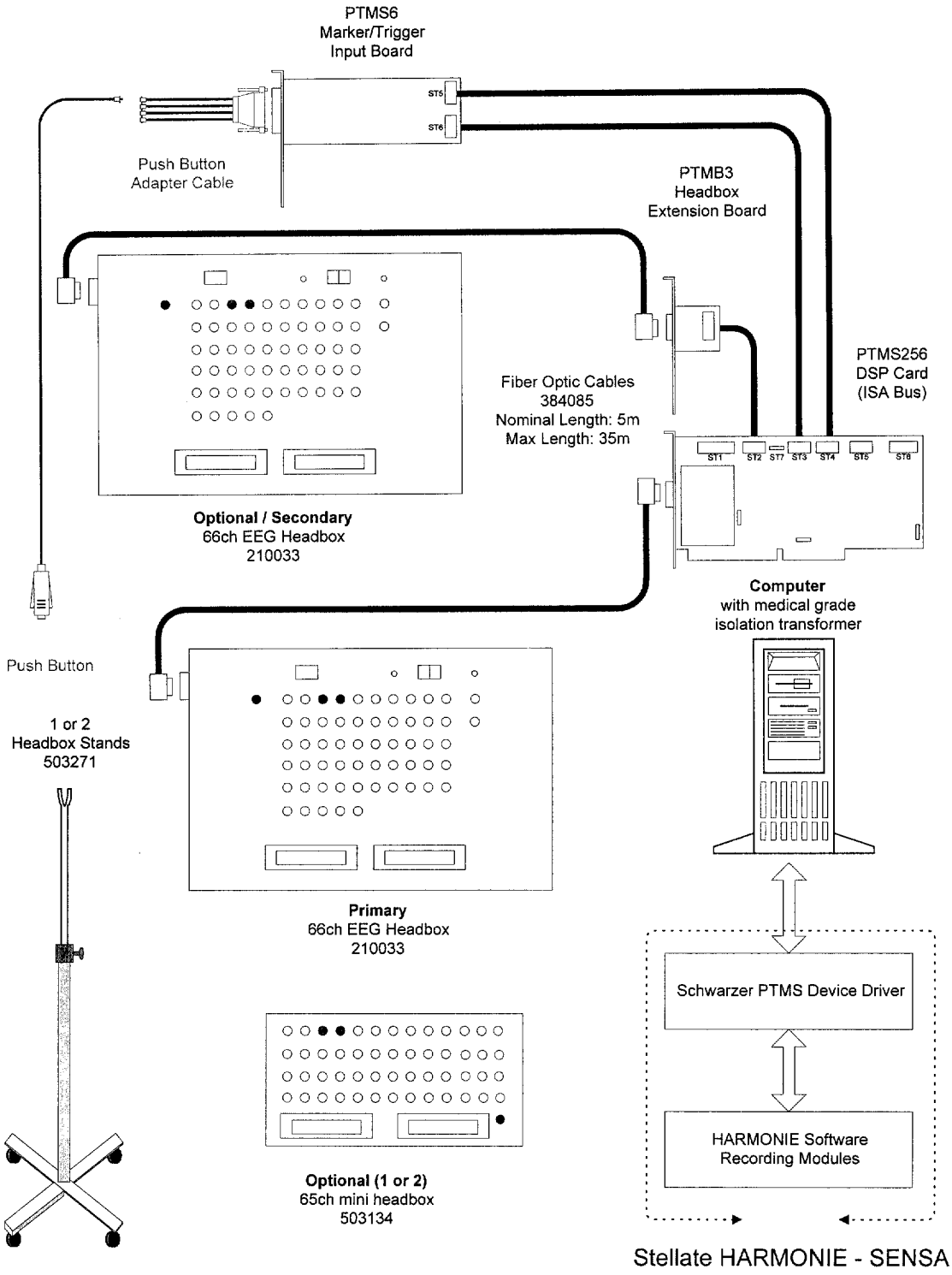

Figure 2. The HARMONIE-Schwarzer EEG System configured for LTM. A 66-ch headbox (P/N 210033) provides 65 EEG channels and 1 respiratory input. Two headboxes can be connected to allow recordings of up to 128 channels. Channel mappings and filter settings are configured with the Schwarzer PTMS Device Driver. All 65 EEG channels can also be accessed on the optional mini headbox adapter (P/N 503134.)

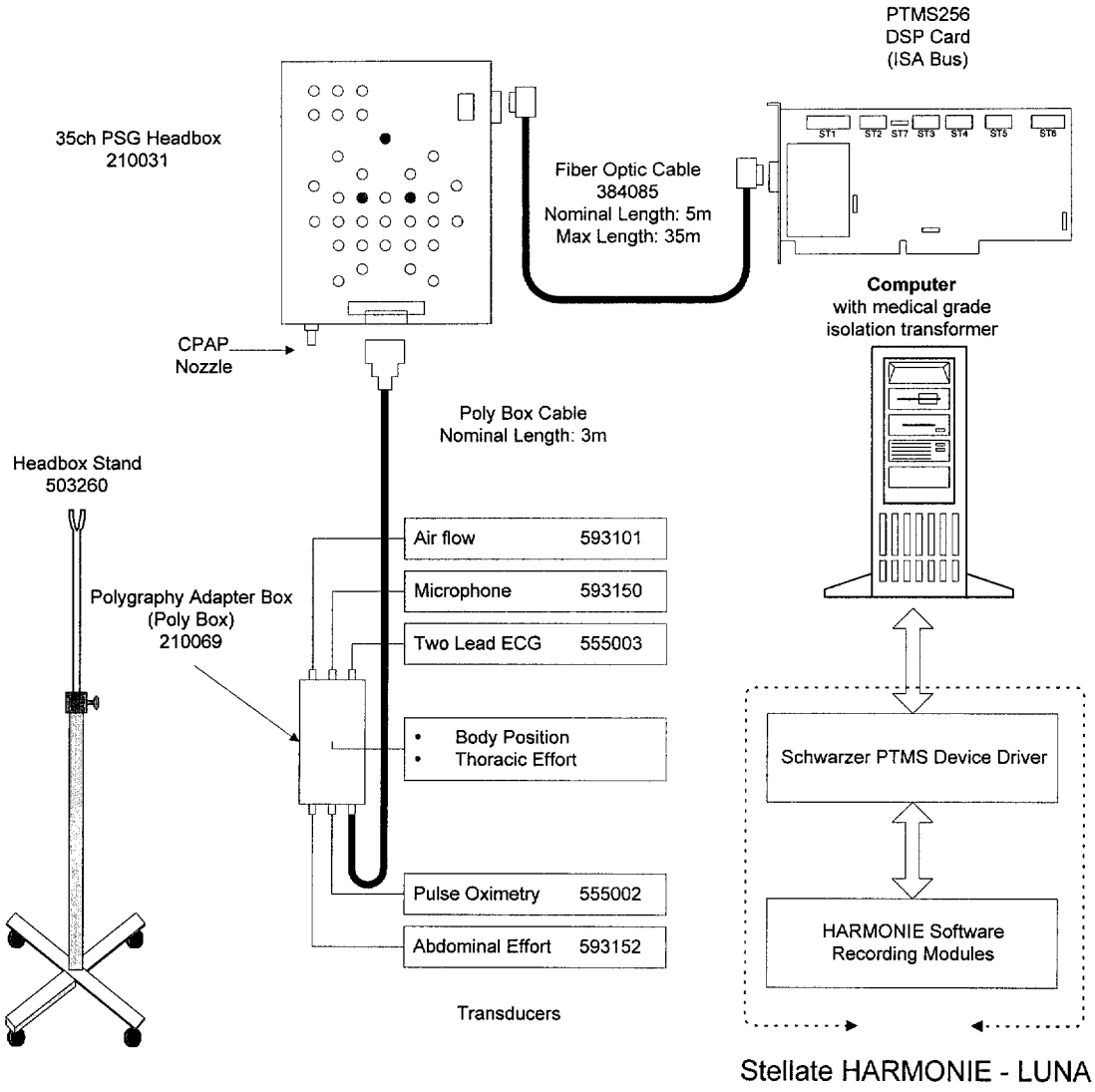

Figure 3. The HARMONIE-Schwarzer EEG System configured for Sleep Studies (PSG). The 35-ch headbox (P/N 210031) provides 27 EEG channels, 6 polygraphy inputs, one input for respiration, and a built-in pressure sensor for CPAP measurements. The polygraphy adapter box (P/N 210069) provides 7 more inputs for ECG, abdominal and thoracic effort sensors, body position, sound, airflow, and SpO2 (pulse oximetry sensor). Channel mappings and filter settings are configured with the Schwarzer PTMS Device Driver.

2.0 Important Safety Notes

Before starting the system, ensure that all instruments are in regular condition and that no visible (mechanical) damages exist that may endanger the safety of the operator or the patient.

The headbox is connected to the computer through a fiberoptic cable (P/N 384 085). Please ensure that this cable is not bent.

The EEG-amplifiers inside the headbox have extremely high input impedance (100 MOhm, parallel approx. 200 pF) in order to obtain good EEG leads at higher electrode resistances. To protect the patient and the sensitive amplifiers from electrostatic discharges, TOUCH the housing of the headbox BEFORE touching the patient or the electrodes.

The Schwarzer PTMS256 signal processor board meets the requirements of the medical device directive 93/43/EEC. This is documented by the CE-mark and an accompanying declaration of conformity.

The declaration of conformity given by Schwarzer and the CE-mark only refer to the board's properties as described in the corresponding technical documentation.

According to directive 93/42/EEC the Schwarzer PTMS256 signal processor board is only licensed for operation with accessories listed in this manual.

Tests in Schwarzer reference systems have shown that the PTMS256 signal processor board and headboxes meet the requirements of the following harmonized standards.

- IEC 601-1:1988 + A1:1991 + A2:1995
  (Medical electrical equipment -
  Part 1: General requirements for safety)
- IEC 601-1-1:1992
  (Medical electrical equipment-
  Part 1: General requirements for safety;
  1. Collateral Standard: Safety requirements for medical electrical systems)
- IEC 601-1-2:1993
  (Medical electrical equipment;
  Part1: General requirements for safety;
  2. Collateral Standard: Electromagnetic compatibility - Requirements and tests)
- IEC 601-2-26:1994
  (Medical electrical equipment
  Part 2: Particular requirements for the safety of electroencephalographs)

Do not use the declaration of conformity as a substitute for the documented test of the completely assembled system according to the relevant valid regulations and standards.

The Schwarzer EEG/polygraphy headboxes and authorized accessories conform to the specifications of the medical device directive 93/42/EEC, especially concerning the safety and electromagnetic compliance. This is documented by the CE-mark and an accompanying declaration of conformity.

Conformity to safety standards is only assured when the headboxes are used according to these instructions, in a system that meets the requirements of the Medical Device Directive 93/42/EEC.

The following has to be observed especially:

a) The headboxes are constructed in accordance with IEC 60601-1, Protection Class I Type CF. They are intended for the recording of body action potentials and the connection of pick-up sensors for the analysis of body functions. The housing of the headboxes is connected to a signal processor board (PTMS256) through functional earth.

The insulated (ungrounded) headboxes meet the highest standardized safety standard (type CF). This is indicated by the symbol on the instrument's side.

The combination with other instruments is only allowed if the safety of patients, operators, and surroundings is not impaired.

If a safe combination (coupling) is not obvious from the instrument data, the user has to ascertain – by asking the manufacturer or an expert for more information – that the intended coupling will not impair the necessary safety of all involved instruments.

Instruments of Protection Class I are constructed to guarantee the safety of patients and operators in case of malfunction through the protective conductor. The instrument must be operated with an electrical installation that meets the relevant national Electrical Code.

b) During corticography (examinations within or at the brain) the instrument is only allowed to be operated in medical-used rooms with potential equalisation – required according to the relevant national standard – that has been checked for unrestricted effectiveness. If you use the instrument during examinations within or at the brain, the relevant regulations and national standards for electrical medical instruments in intracardiac surgery have to be observed analogously.

c) The headboxes are not equipped with a safety device to avoid burning the patient during simultaneous use of high-frequency surgery instruments.

d) Patients with cardiac pacemakers can be examined without danger using standard headboxes.

e) Operating the Instrument in Explosion-Prone Rooms
The instrument (except the lead electrodes and their connecting cables) must not be operated in explosion-prone areas. Please obey the relevant national regulations.

f) Electromagnetic Compliance
While operating the instrument, it is recommended not to use a mobile telephone. Under unfavourable circumstances, this may lead to artefacts in the recording.

g) Extensions, Modifications and Repairs
The manufacturer is responsible for the safety, reliability and service of the instrument only if:

- It is proven that equipment connected to the headbox meet the corresponding specifications of the IEC 60601 standards for electrical medical instruments. Further it has to be guaranteed that all configurations meet the system standard IEC 60601-1-1. (The person who connects additional instruments to the signal input or signal output is the system configurator, and therefore responsible for meeting the system standard IEC 60601-1-1. Please ask your local specialized dealer, or the technical service for further information).
- All extensions, adjustments, changes or repairs are carried out by people who are authorized by the manufacturer
- The electrical installation of the respecting room meets the relevant national regulations.
- The device is employed in accordance with the instructions for use.

An attestation that contains the kind and extent of the repair, as well as date, company name and signature has to be demanded from the repairer.

h) Maintenance
For patients' and operators' safety as well as to maintain the diagnostic quality of the recording, periodical maintenance should be carried out at two year intervals after putting the instrument into operation. The highest priority of these examinations concerns the safety of the complete EEG device.

Examination and maintenance have to be carried out by competent, authorized personnel.
For these tasks we recommend a Schwarzer-authorized customer service.

During maintenance the following items have to be checked, and if necessary cleaned, adjusted or repaired:

- Mechanical condition of the headbox.
- Readability of all labels that are important for the operation (i.e. identification label and the safety labels).
- Function of the operating elements.
- Operational reliability of the functional earth (test current < 1 A).
- Patient leakage current according to IEC 66001-1:1988 + A1:1991 + A2:1995, clause 19.
- Earth leakage current according to IEC 60601-1:1988 + A1:1991 + A2:1995, clause 19.
- Simple function test.
- Measuring the impedance while a patient is connected (only if all items listed above have been completed successfully (e.g. without defects). Please note: with open inputs, the indicated impedances are higher than 100 kΩ.

3.0 List of System Components and Accessories

Headboxes & Headbox Adapters	
PART NO.	**DESCRIPTION**
	NOTE: Input jacks are contact-protected (touch-proof) according to DIN 42802.
210 026	**Electronic EEG headbox** with 34 inputs: 27 EEG amplifiers, 6 polygraphy inputs, and one input for respiration.
503 133	**Mini headbox adapter**. Extends through a flat ribbon cable all inputs of the EEG and PSG headboxes (P/N 210 026 and P/N 210 031).
210 031	**Electronic PSG headbox** with a total 42 inputs when used with the polygraphy adapter (P/N 210 069). 35 inputs on the headbox: 27 EEG amplifiers, 6 polygraphy inputs, one input for respiration, and a built-in pressure sensor for CPAP.
210 069	**Polygraphy adapter** box with integrated body position sensor and piezo sensor and belt for thoracic effort, and inputs for ECG, abdominal effort, tracheal microphone, airflow and SpO2 sensors.
210 071	**Mini headbox adapter for PSG**. It extends 14 inputs of headbox 210 031 to provide bipolar inputs and labeling for 4 EEG, 1 EOG and 3 EMG.
210 033	**Electronic EEG headbox** with 66 inputs: 65 EEG amplifiers, and one input for respiration.
503 134	**Mini headbox adapter**. Extends through a flat ribbon cable inputs 1-33 or 34-65 of the 66ch EEG headbox (P/N 210 033).
Headbox Accessories	
385 085	**Fiberoptic cable** connecting the headbox to the PTMS card in the computer. Nominal length is 5m. Maximum length: 35m.
383 123	**Flat ribbon cable** connecting a headbox to the corresponding mini headbox adapter (P/N 503 133 or 503 134). Nominal length: 3m.
555 003	**Snap-on electrode cable for ECG** (1.5m) with 4-mm touch-proof safety connector according DIN 42802.
593 101	**Airflow transducer** (2m) with 1.5mm touch-proof safety connector according to DIN 42802. Made in USA by Pro-Tech (Respiratory airflow sensor #1222).
593 150	**Tracheal microphone** (2m) with 1.5mm touch-proof safety connector according to DIN 42802. Made in USA by Pro-Tech (snore sensor.)
593 152	**Abdominal effort belt** (2m) with 1.5mm touch-proof safety connector according to DIN 42802. Made in USA by Pro-Tech (Piezo Respiratory Effort Sensor.)
555 002	**Pulse oximetry cable** for Nonin 8500 Pulse Oximeter. Made in USA by Nonin.
503 264	Mobile **EEG stand** for EEG and PSG headboxes (P/N 210 026 and 210 031.)
503 371	Mobile **EEG stand** for 66ch EEG headbox (P/N 210033.)

Digital Data Acquisition & Processing	
PART NO.	**DESCRIPTION**
374 913	**PTMS256 digital signal processor board** (128ch - 256 FIFO.)
374 918	**PTMB3** board to connect a second headbox to PTMS256.
374 924	**PTMS6 external trigger input board**.
Computer System	
HSYS-REC-xxxNT	**HARMONIE Computer System.** Intel Pentium processor ≥ 600 MHz; ≥ 128 MB RAM; with 1 ISA Slot; ≥ 6 GB HDD 17"-21" Monitor; Microsoft Windows NT Specified to meet IEC 950 and 89/336/EEC; UL/CSA/CE-marked.
HSYS-CART-xxxxx	**HARMONIE System Cart** (Made in USA by Anthrocart.) **with Medical-Grade Isolation Transformer** (Made in USA by Dale Technology, Model UIT630; 750 W.) Specified to meet IEC 60601-1; UL/CSA/CE-marked.
Data Acquisition Accessories	
AMP-CBL-SPBB-10	**Push Button** (1-piece molded plastic with 10m cable, BNC-M terminated.)
AMP-CBL-SPTMS6	**Push Button Adapter Cable for the PTMS6**. 4 BNC-F connectors.

4.0 Schwarzer Headboxes

4.1. Electronic EEG Headbox with 34 Inputs (P/N 210026)

27 EEG amplifiers, 6 polygraphy inputs, and one input for respiration. The same inputs can also be accessed on the **mini headbox adapter** (P/N 503133). Input jacks are contact protected, according to DIN 42802.

Attention: Electrode inputs F3, F4 and N have to be connected at every montage. However, these electrodes must not necessarily be contained in the selected montage.

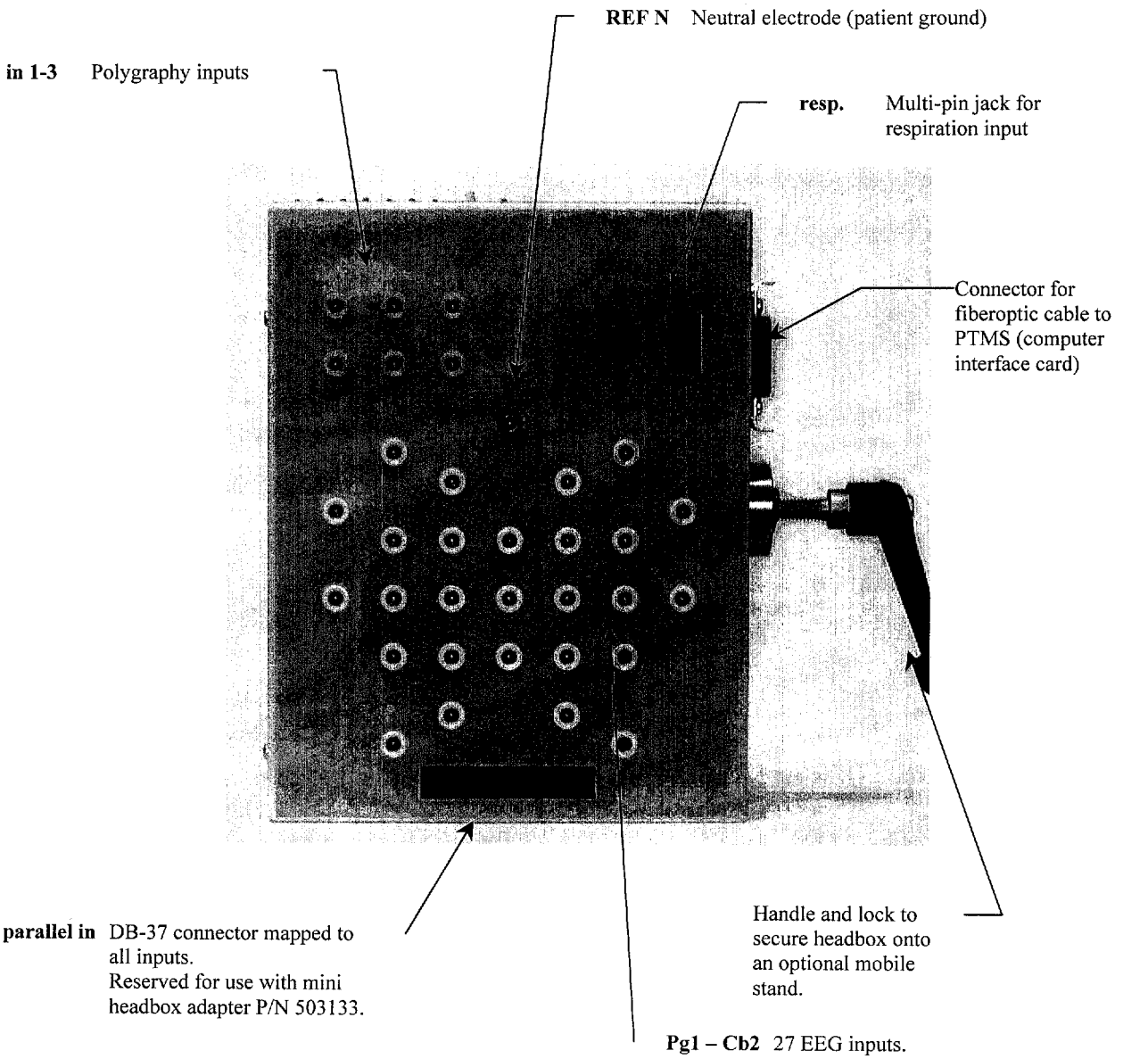

Figure 4. Schwarzer 34-ch EEG headbox P/N 210026.

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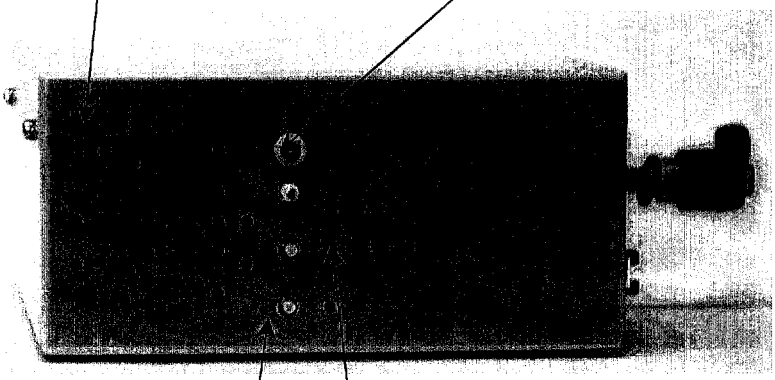

Figure 5. Impedance measurement controls located on the side panel of the Schwarzer EEG and PSG headboxes (P/N 210026 and P/N 210031). **Attention:** Electrode inputs F3, F4, P3, P4 and N have to be connected for correct impedance measurement. However, these electrodes must not necessarily be contained in the selected montage.

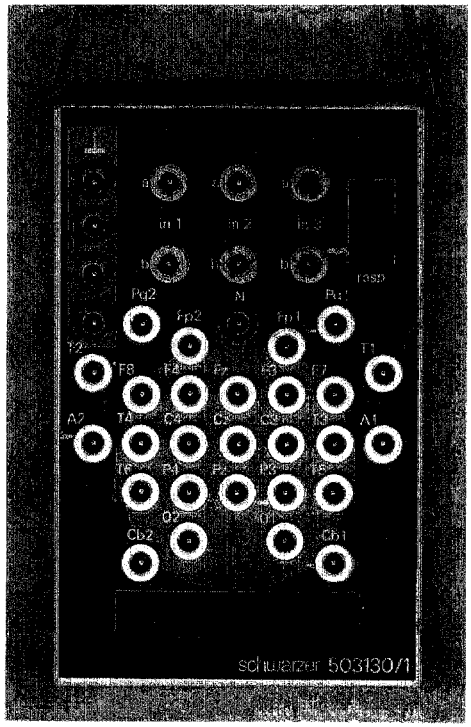

Figure 6. Schwarzer mini headbox adapter P/N 503133. All inputs are mapped through a flat ribbon cable to the corresponding inputs on the EEG or PSG headboxes (P/N 210026 and P/N 210031). Approx. Dimensions are L14 x W9 x H2 cm.

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4.2. Electronic PSG Headbox with 42 Inputs (P/N 210031)

35 inputs on the headbox: 27 EEG amplifiers, 6 polygraphy inputs, one input for respiration, and a built-in pressure sensor for CPAP measurements.

Attention: Electrode inputs F3, F4 and N have to be connected at every montage. However, these electrodes must not necessarily be contained in the selected montage.

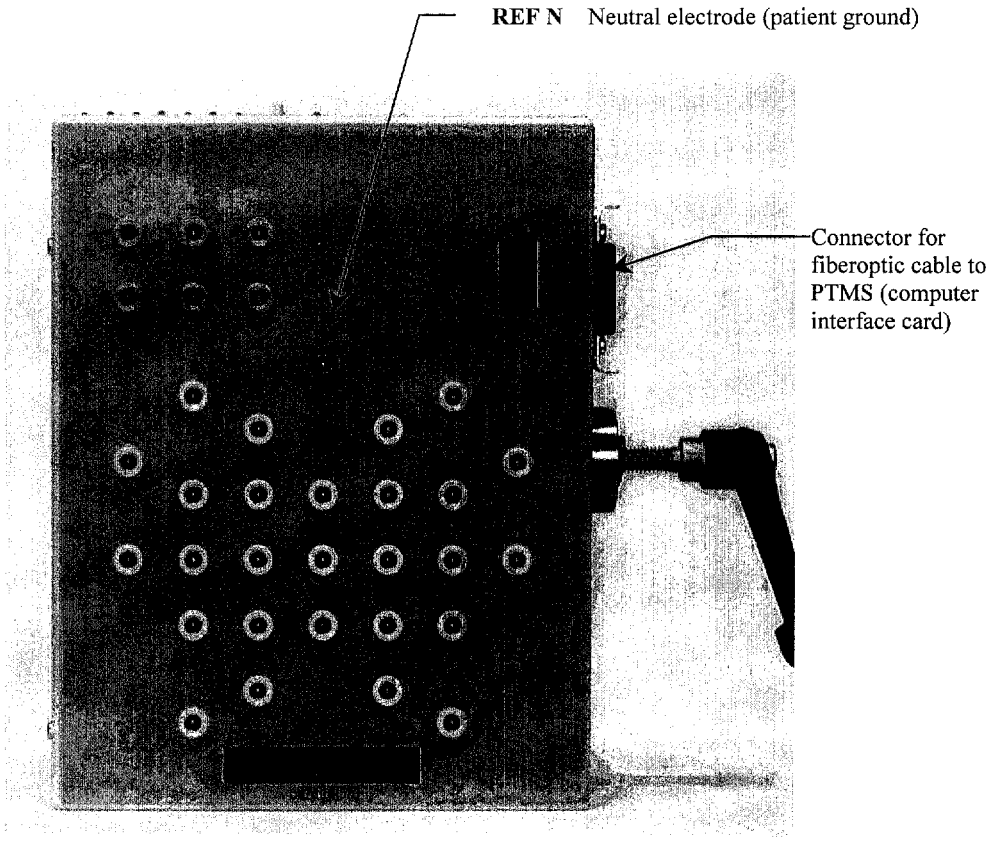

Figure 7. Schwarzer 35-ch PSG headbox P/N 210031.

7 inputs more inputs are available on the **polygraphy adapter** (P/N 210069): ECG, abdominal and thoracic effort sensors, sound, airflow, body position, and SpO2

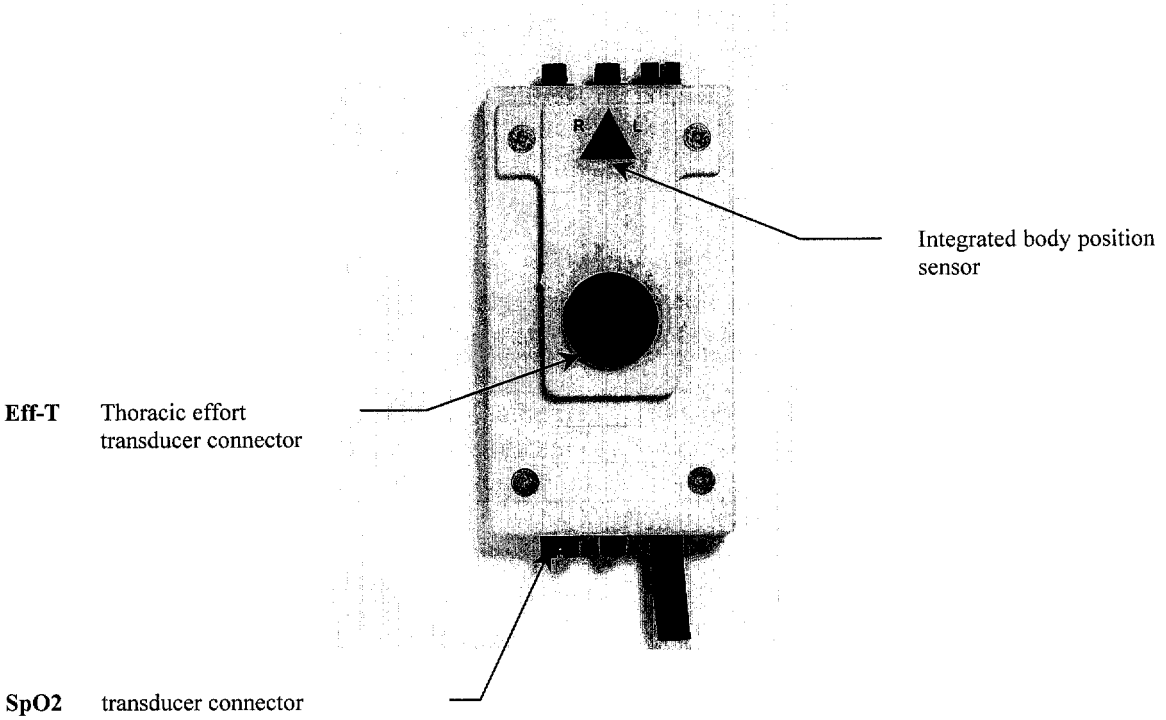

Figure 8. Schwarzer 7-ch Polygraphy Adapter P/N 210069. It is attached to the patient with the chest belt (P/N 503146). Approx. dimensions L9.5 x W5 x H2 cm. Cable length 3m.

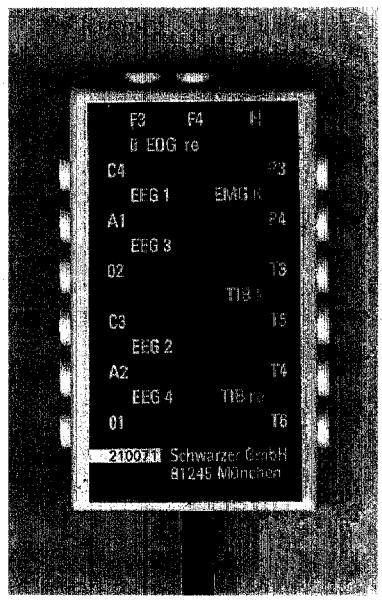

Figure 9. Schwarzer Mini headbox adapter for PSG. It extends 14 inputs of headbox 210 031 to provide bipolar inputs and labeling for 4 EEG, 1 EOG and 3 EMG. Approx. Dimensions: L9.5 x W6 x H2 cm. Cable length 3m.

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4.3. Electronic EEG Headbox with 66 Inputs (P/N 210033)

66 inputs on the headbox: 65 EEG amplifiers, 1 input for respiration. Optionally, inputs 1-33 and respiration can be connected through a ribbon cable (P/N 383123) from *parallel in 1*, and inputs 34-65 through *parallel in 2*, to a mini 64-ch headbox adapter P/N 503134. Input jacks are contact protected according to DIN 42802.

Caution: If cables other than those supplied by Schwarzer (P/N 383 123) are connected to the *parallel in 1* or *parallel in 2* connectors, it must be strictly heeded that there isn't any connection between pin 34 and/or pin 36 and the patient. Otherwise the headbox is not of type CF.

Attention: Electrode inputs 3, 4 and N have to be connected at every montage. Electrode inputs 3, 4, 7, 8 and N have to be connected for correct impedance measurement. However, these electrodes must not necessarily be contained in the selected montage.

128 EEG-channels (2 x 64) are available if two headboxes are interconnected as follows: Input 3 of the first headbox has to be connected with input 3 of the second headbox, and input 4 of the first headbox with input 4 of the second one.

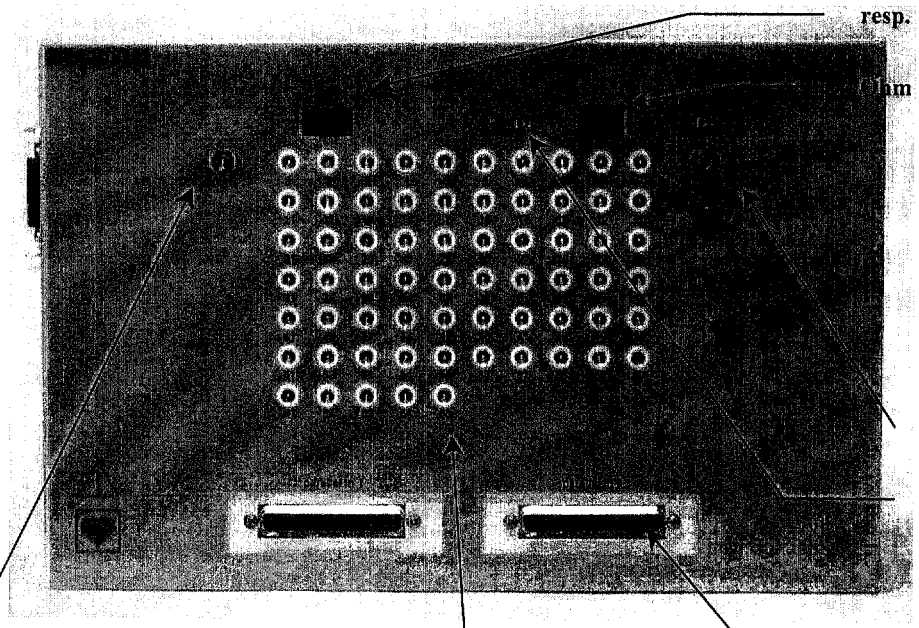

Figure 10. Schwarzer 66-ch EEG headbox P/N 210033.

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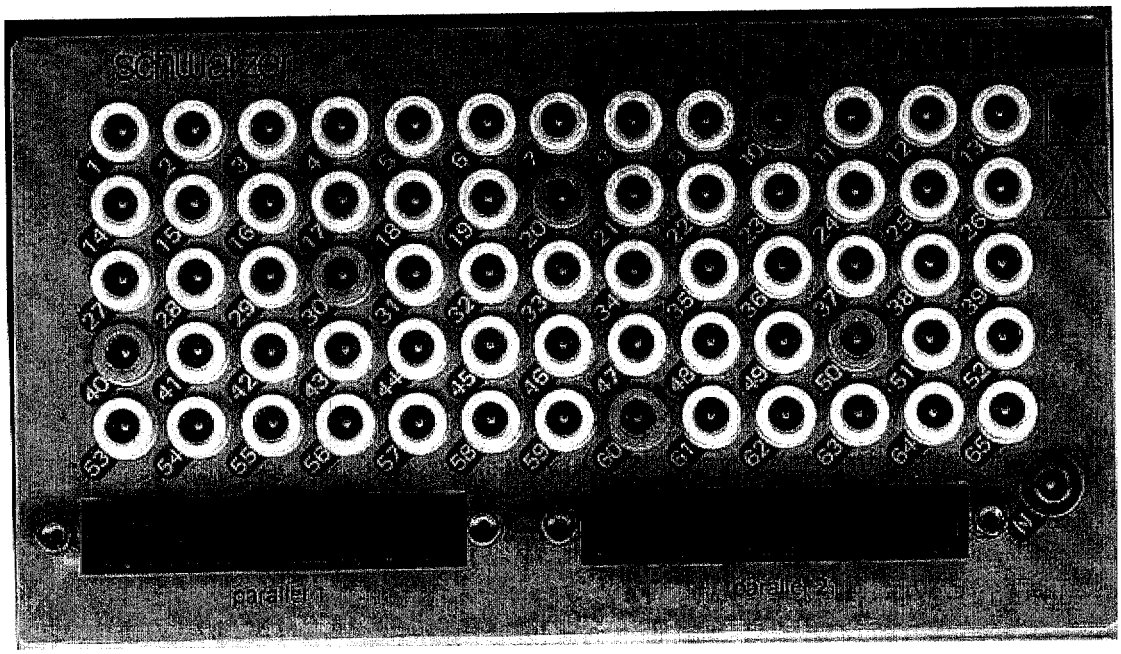

Figure 11. Schwarzer 65-ch mini headbox adapter P/N 503134. All inputs are mapped through a two flat ribbon 3m cables (P/N 383 123) to the corresponding inputs on the 66-ch EEG headbox (P/N 210033). Approx. Dimensions are L17 x W9.5 x H2.5 cm.

4.3.1. Stimulator Connections to 66-ch EEG Headbox

stim on The yellow LED is ON when an electrode input is interconnected with a stimulator input under software control.

stim in + Stimulator input, for stimulator signals of positive polarity

stim in - Stimulator input, for stimulator signals of negative polarity

Maximum stimulator voltage: 200 V.

The stimulation pulse can be applied on any electrode except electrodes 3 and 4, and will be superimposed to the EEG signal of the selected electrodes. The amplifier inputs of the stimulated electrodes will not be disconnected. They are protected by additional 100 kΩ resistors.

Attention: Electrode inputs 3 and 4 cannot be used for stimulation, as the reference for all amplifiers is created with these inputs.

When two headboxes are interconnected for 128-ch EEG, one stimulator can be applied on both headboxes., Connect stimulator inputs on the headboxes in parallel (positive-to-positive, and negative-to-negative). Then connect the stimulator to either headbox.

Caution: The stimulator that will be connected has to meet the requirements of IEC 60601-1 and the European Medical Devices Directive 93/42/EEC, and must have an ungrounded stimulator output of type BF or CF (according to IEC 60601-1).

5.0 Schwarzer PTMS256 Digital Signal Processor Board

The Schwarzer PTMS256 digital signal processor board is able to process up to 128 channels of EEG and polygraphy data.

The data, which are already digitized in a Schwarzer headbox, are transferred through optical fibre cable (part number 384 085) to the PTMS256.

A second headbox can be connected by means of the PTMB3 extension board (part number 374 918).

External trigger inputs (ex. Push Button) are available with the Schwarzer PTMS6 board (part number 374 924).

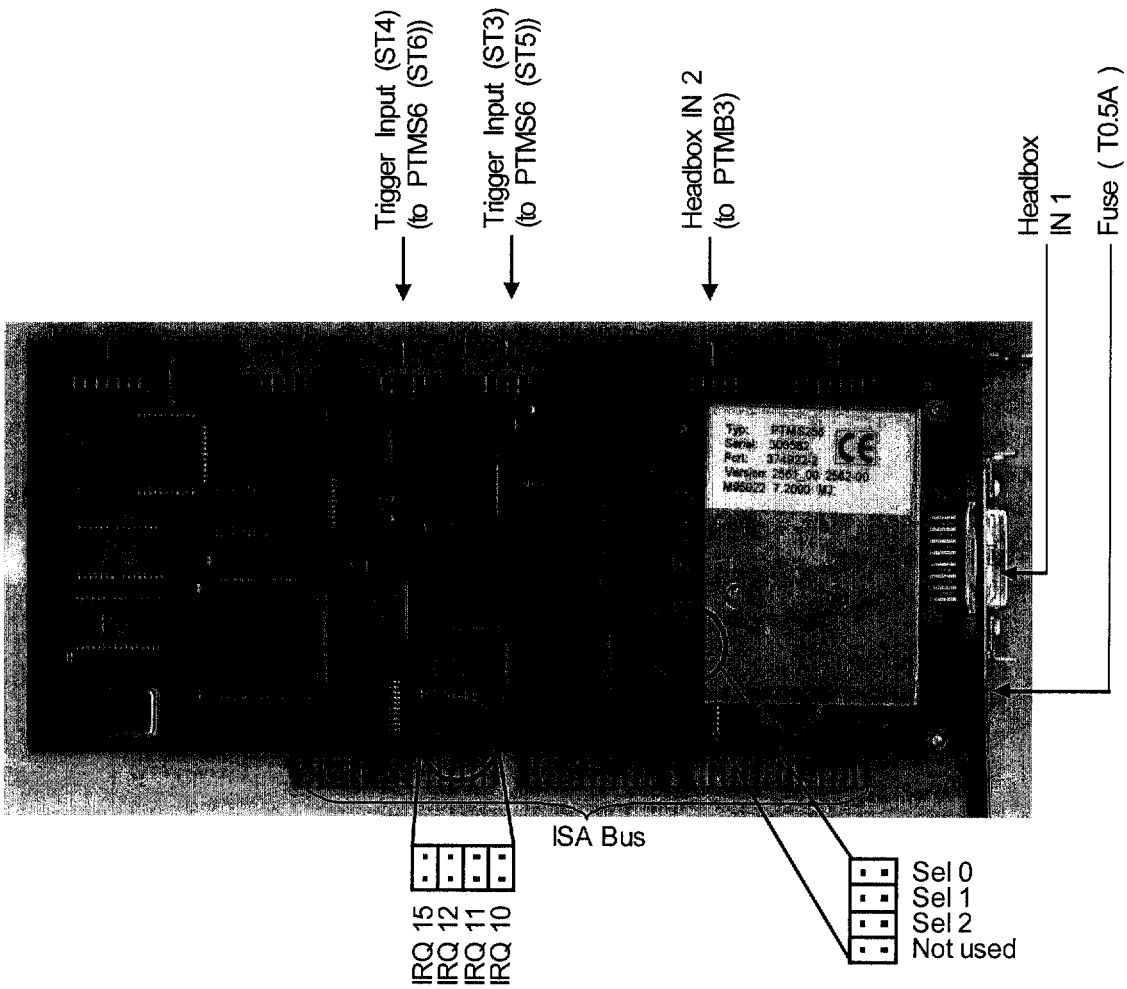

Figure 12. Schwarzer PTMS256 digital signal processor board.

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5.1. PTMS6 Board for External Trigger Inputs (P/N 374 924)

The marker/trigger board PTMS6 is an extension board to the Schwarzer DSP board PTMS256 and is intended as a input for marker/trigger signals (Push Button, Patient Connect/Disconnect).

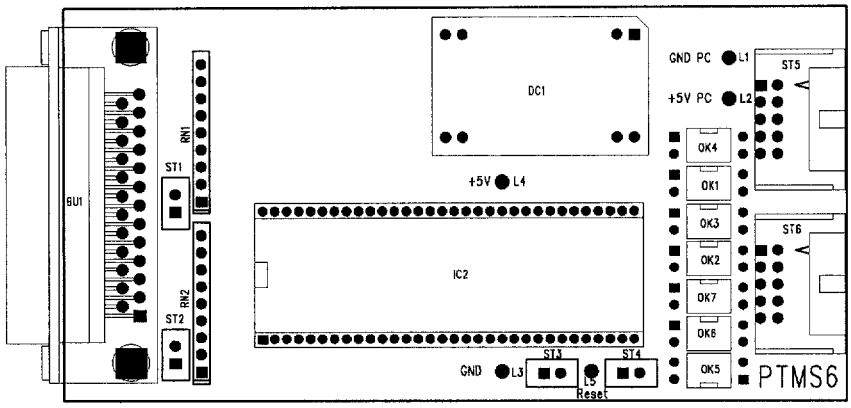

Figure 13. Schwarzer PTMS6 Marker/Trigger input board.

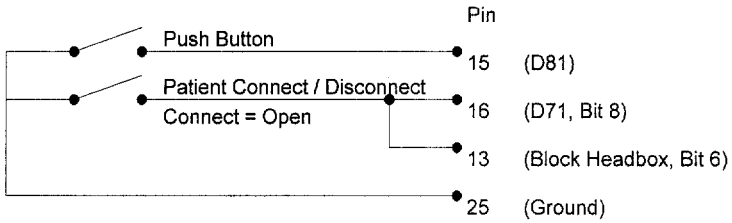

Figure 14. Example of external wiring of PTMS6.

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5.2. Installing the PTMS256 Signal Processor Board

Caution: Sensitive electronic components may be damaged by static electricity. Therefore, discharge the static electricity of your body by touching an earthed surface – e.g. a metallic part of the computer's housing - before modifying the hardware.

The manufacturer is not liable for damages, which result directly or indirectly from improper installation of components by non-authorized service staff.

Switching on the system during installation may hurt the operator and damage the system components and the signal processor board as well.

1. Switch off the computer and pull off the power cable.
2. Remove the cover of the computer. For instructions refer to your computer manual.
3. Configure the hardware according to your requirements so that the system has no conflicts with other PC components. The following default values are set at the factory: IRQ 15, base IO-address 0320H.

   Do not change the default IRQ 15. Do not connect any device to IDE controller 2.

   Base IO-Address: The necessary I/O-range is 8 addresses (start address plus 08). No other PC unit should use this address range (start address plus 08).

IO-address	100	108	238	300	308	320	330	340
Sel 0	short	open	short	open	short	Open	short	open
Sel 1	short	short	open	open	short	Short	open	open
Sel 2	short	short	short	short	Open	Open	open	open

1. Select a free ISA-socket for the PTMS256 on the computer board. Remove the socket cover. Hold the upper edge of the PTMS256 and insert it carefully into the socket until it fits. Fix the holder with a screw.
2. Mount the cover to the computer.
3. When you restart the computer, disable the secondary IDE controller in the system bios.

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6.0 Schwarzer PTMS Software Device Driver

Stellate HARMONIE implements the software and user interface (device driver) to Schwarzer's data acquisition card, headbox, and amplifier system.

6.1. Important Notes

Verify that the headbox selected corresponds to the headbox being used, and that it is connected to the correct A/D Board input.

When using two headboxes, inputs 3 and 4 of headbox 1 (labelled F3 and F4) must each be connected to inputs 3 and 4 of headbox 2.

The first headbox must always be connected (it is not possible to record with only the second headbox connected).

When headbox 1 is disconnected, the PTMS enters internal calibration mode and EEG traces display the calibration signal. When this occurs, use the following procedure:

1. Verify that the fiber optic cable is not damaged.
2. Reconnect the headbox.
3. In Observer, switch the Trace Restore mode ON and then OFF, using the Trace Restore button  .

When headbox 2 is disconnected, the signal from headbox 1 remains valid. The EEG signal from headbox 2 enters internal calibration mode. When this occurs, use the following procedure:

1. Verify that the fibre optic cable is not damaged and is properly connected.
2. Verify that extension board PTMB3 is properly connected to the PTMS card.

Electrodes in positions 3 and 4 (labelled F3 and F4) must always be attached to the patient (even if the signals from these electrodes are not stored), since all signals are measured versus the reference calculated as the average of these two signals. If the electrodes in positions 3 and 4 get disconnected, the data will be invalid.
If either electrode 3 or 4 gets disconnected, the recording montage becomes noisy. This does not affect the reformatting montage.

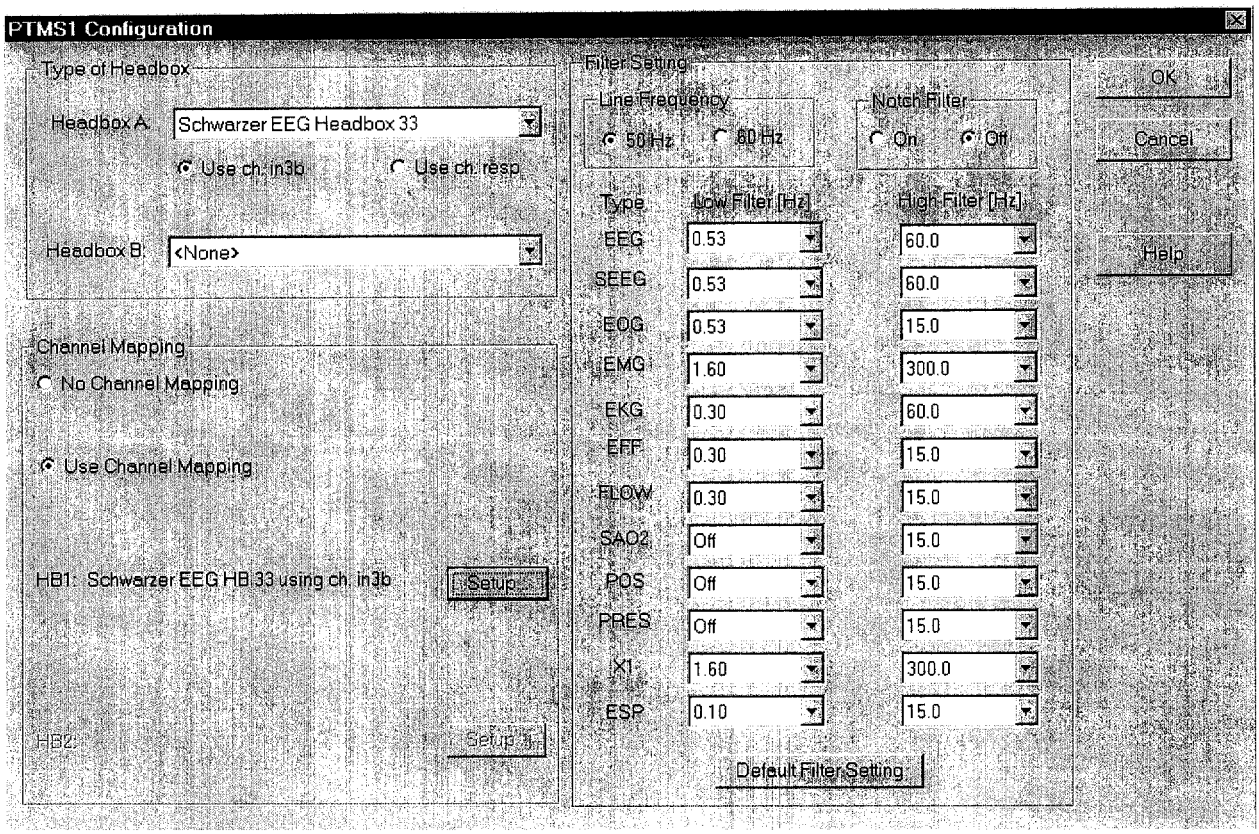
For the system to properly measure electrode impedance values, electrodes in positions 3, 4, 7, 8 (labelled F3, F4, P3 and P4), and REFN must always be attached to the patient (even if the signals from these electrodes are not stored). On 34-ch EEG and 42-ch PSG headboxes inputs 7 and 8 are labelled P3 and P4. respectively. On 66-ch headboxes, inputs 7 and 8 are labelled 7 and 8. (If electrodes in position 3, 4, 7, 8, and REFN get disconnected, the impedance measurement will be invalid).

The neutral electrode "REF N" must always be attached to the patient (typically on the forehead). If the neutral electrode gets disconnected, the data will be invalid.

Handle the fiber optic cable with care, since it is fragile.

6.2. Configuring the PTMS256 Software Device Driver

The PTMS1 Configuration dialog box is used for selecting and configuring Schwarzer headboxes. The settings are described below.



6.2.1. Headbox Selection

Headbox A: Lists the Schwartzer headboxes that can be selected as the first headbox. The following headboxes are listed:

- Schwarzer EEG HB 33 Selects the 34-ch EEG headbox
- Schwarzer PSG HB Selects the 42-ch PSG headbox
- Schwarzer EEG HB 65 Selects the 66-ch EEG headbox

Use ch. In3b: Specifies that channel 33/65 is a non-respiratory channel.

Use ch. Resp: Specifies that channel 33/65 is a respiratory channel.

Headbox B: Lists compatible headboxes that can be selected as the second headbox. Thus, two 34-ch EEG or two 66-ch EEG headboxes can be selected.

6.2.2. Channel Mapping

No Channel Mapping: Disables channel mapping for the headbox(es).

Use Channel Mapping: Enables channel mapping for the headbox(es).

HB1: Used for setting up the channel mapping for Headbox A. The corresponding **Setup** button accesses the **Edit Channel Mapping** dialog box.

HB2: Used for setting up the channel mapping for Headbox B. The corresponding **Setup** button accesses the **Edit Channel Mapping** dialog box.

Attention: Verify that each mapping configuration corresponds to the headbox being used.

Any one of the following default mapping configurations can be used.

Headbox A

34-ch EEG headbox without respiratory channel

1	Fp1	**9**	O1	**17**	T5	**25**	T1
2	Fp2	**10**	O2	**18**	T6	**26**	A2
3	F3	**11**	Pg1	**19**	Cb1	**27**	A1
4	F4	**12**	Pg2	**20**	Cb2	**28**	I1a
5	C3	**13**	F7	**21**	Fz	**29**	I1b
6	C4	**14**	F8	**22**	Cz	**30**	I2a
7	P3	**15**	T3	**23**	Pz	**31**	I2b
8	P4	**16**	T4	**24**	T2	**32**	I3a
						33	I3b
* Only the G1 electrode lead is shown, G2 is left blank by default.							

Headbox A

34-ch EEG headbox with respiratory channel

1	Fp1	**9**	O1	**17**	T5	**25**	T1
2	Fp2	**10**	O2	**18**	T6	**26**	A2
3	F3	**11**	Pg1	**19**	Cb1	**27**	A1
4	F4	**12**	Pg2	**20**	Cb2	**28**	I1a
5	C3	**13**	F7	**21**	Fz	**29**	I1b
6	C4	**14**	F8	**22**	Cz	**30**	I2a
7	P3	**15**	T3	**23**	Pz	**31**	I2b
8	P4	**16**	T4	**24**	T2	**32**	I3a
						33	Resp
* Only the G1 electrode lead is shown, G2 is left blank by default.							

Headbox B

34-ch EEG headbox without respiratory channel

1	Fp1B	**9**	Pg1B	**17**	Cb1B	**25**	A1B
2	Fp2B	**10**	Pg2B	**18**	Cb2B	**26**	I1aB
3	C3B	**11**	F7B	**19**	FzB	**27**	I1bB
4	C4B	**12**	F8B	**20**	CzB	**28**	I2aB
5	P3B	**13**	T3B	**21**	PzB	**29**	I2bB
6	P4B	**14**	T4B	**22**	T2B	**30**	I3aB
7	O1B	**15**	T5B	**23**	T1B	**31**	I3bB
8	O2B	**16**	T6B	**24**	A2B	**32**	
						33	
* Only the G1 electrode lead is shown, G2 is left blank by default.							

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Headbox A

66-ch EEG headbox without respiratory channel

1	A1	**9**	A9	**17**	A17	**25**	A25
2	A2	**10**	A10	**18**	A18	**26**	A26
3	A3	**11**	A11	**19**	A19	**27**	A27
4	A4	**12**	A12	**20**	A20	**28**	A28
5	A5	**13**	A13	**21**	A21	**29**	A29
6	A6	**14**	A14	**22**	A22	**30**	A30
7	A7	**15**	A15	**23**	A23	**31**	A31
8	A8	**16**	A16	**24**	A24	**32**	A32
* Only the G1 electrode lead is shown, G2 is left blank by default.							

33	A33	**41**	A41	**49**	A49	**57**	A57
34	A34	**42**	A42	**50**	A50	**58**	A58
35	A35	**43**	A43	**51**	A51	**59**	A59
36	A36	**44**	A44	**52**	A52	**60**	A60
37	A37	**45**	A45	**53**	A53	**61**	A61
38	A38	**46**	A46	**54**	A54	**62**	A62
39	A39	**47**	A47	**55**	A55	**63**	A63
40	A40	**48**	A48	**56**	A56	**64**	A64
						65	A65

Headbox A

66-ch EEG headbox with respiratory channel

1	A1	**9**	A9	**17**	A17	**25**	A25
2	A2	**10**	A10	**18**	A18	**26**	A26
3	A3	**11**	A11	**19**	A19	**27**	A27
4	A4	**12**	A12	**20**	A20	**28**	A28
5	A5	**13**	A13	**21**	A21	**29**	A29
6	A6	**14**	A14	**22**	A22	**30**	A30
7	A7	**15**	A15	**23**	A23	**31**	A31
8	A8	**16**	A16	**24**	A24	**32**	A32
* Only the G1 electrode lead is shown, G2 is left blank by default.							

33	A33	**41**	A41	**49**	A49	**57**	A57
34	A34	**42**	A42	**50**	A50	**58**	A58
35	A35	**43**	A43	**51**	A51	**59**	A59
36	A36	**44**	A44	**52**	A52	**60**	A60
37	A37	**45**	A45	**53**	A53	**61**	A61
38	A38	**46**	A46	**54**	A54	**62**	A62
39	A39	**47**	A47	**55**	A55	**63**	A63
40	A40	**48**	A48	**56**	A56	**64**	A64
						65	Resp

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Headbox B

66-ch EEG headbox without respiratory channel

1	B1	**9**	B11	**17**	B19	**25**	B27
2	B2	**10**	B12	**18**	B20	**26**	B28
3	B5	**11**	B13	**19**	B21	**27**	B29
4	B6	**12**	B14	**20**	B22	**28**	B30
5	B7	**13**	B15	**21**	B23	**29**	B31
6	B8	**14**	B16	**22**	B24	**30**	B32
7	B9	**15**	B17	**23**	B25	**31**	B33
8	B10	**16**	B18	**24**	B26	**32**	B34
* Only the G1 electrode lead is shown, G2 is left blank by default.							

33	B35	**41**	B43	**49**	B51	**57**	B59
34	B36	**42**	B44	**50**	B52	**58**	B60
35	B37	**43**	B45	**51**	B53	**59**	B61
36	B38	**44**	B46	**52**	B54	**60**	B62
37	B39	**45**	B47	**53**	B55	**61**	B63
38	B40	**46**	B48	**54**	B56	**62**	B64
39	B41	**47**	B49	**55**	B57	**63**	B65
40	B42	**48**	B50	**56**	B58	**64**	
						65	

Note: Do not attempt to record more than 128 channels, since the driver does not allow the recording to proceed with montages that result in files with more than 128 channels.

Headbox A

42-ch PSG Headbox

1	Fp1	**9**	O1	**17**	T5	**25**	T1
2	Fp2	**10**	O2	**18**	T6	**26**	A2
3	F3	**11**	Pg1	**19**	Cb1	**27**	A1
4	F4	**12**	Pg2	**20**	Cb2	**28**	I1a
5	C3	**13**	F7	**21**	Fz	**29**	I1b
6	C4	**14**	F8	**22**	Cz	**30**	I2a
7	P3	**15**	T3	**23**	Pz	**31**	I2b
8	P4	**16**	T4	**24**	T2	**32**	I3a
* Only the G1 electrode lead is shown, G2 is left blank by default.							

33	I3b	**40**	Pres				
34	Resp	**41**	Bpos				
35	Thor	**42**	Mic				
36	Abdo						
37	Flow						
38	ECG						
39	SpO2						

6.2.3. Filter Settings

Line Frequency: Specifies the notch/line frequency. Users can set the frequency to 50 or 60 Hz.

Notch Filter: The On/Off options enable or disable the notch/line filter.

Low Filter (Hz): Each list specifies the low filter for a specific channel type. This filter is implemented as two cascaded Order-1 Butterworth filters (12db/oct overall roll-off).

High Filter (Hz): Each list specifies the high filter for a specific channel type. This filter is implemented as two cascaded Order-1 RC-Type (12db/oct overall roll-off) for the frequencies < 300 Hz.

Default Filter Settings: This button resets all low and high filters to their default values according to the following table.

Channel Type	Definition	Transducer Type	Default Filters (Hz)	
			Low	High
EEG	Electroencephalogram	Standard Surface Gold or Silver/Silver Chloride Electrodes	0.53	70
SEEG	Stereotactic electroencephalogram	Cortical Grids or Depth Electrodes	0.53	70
EOG	Electrooculogram	Standard Surface Gold or Silver/Silver Chloride Electrodes	0.53	15
EMG	Electromyogram	Standard Surface Gold or Silver/Silver Chloride Electrodes	1.6	300
EKG	Electrocardiogram	Standard Surface Gold or Silver/Silver Chloride Electrodes	0.3	30
EFF	Thoracic/Abdominal Respiratory Effort	Strain Gauge	0.3	15
FLOW	Nasal Airflow	Thermocouple	0.3	15
SPO2	Oxygen Saturation	IR Flex Sensor or Finger Clip	Off	15
POS	Body Position	Mercury Switches	Off	15
PRES	Positive Airway Pressure	Pressure Gauge	Off	15
X1	DC Input	Tracheal Microphone	1.6	300
ESP	Electrical Scalp Potential	Standard Surface Gold or Silver/Silver Chloride Electrodes	0.1	15

6.3. Calibration

Refer to the appropriate section of the ***Stellate HARMONIE Reference Manual***.

In Observer, Calibration (**CAL**) Mode allows to configure the software with the amplifier gain, which is supplied by the manufacturer (Schwarzer).

Caution: Do not use the default values provided by HARMONIE. Instead, enter the calibration values listed in the Table below. Enter either gain\offset or two-point calibration, according to units & type.

Headbox Description	Input Low	Input High	Units	Output Low (V)	Output High (V)	Gain (Slope)	Offset (Intercept)	Units
34-ch EEG								
33 EEG	-50	+50	µV	-0.0704	+0.0704	1408	0	-
Resp	-50	+50	µV	-0.0704	+0.0704	1408	0	-
35-ch PSG								
33 EEG	-50	+50	µV	-0.0704	+0.0704	1408	0	-
Resp	-50	+50	µV	-0.0704	+0.0704	1408	0	-
PAP	0	45	cmH_20	0	4.5	0.1	0	V/cmH_20
7-ch POLY								
Thor Effort	-50	+50	µV	-0.0058	+0.0058	116	0	-
Abdo Effort	-50	+50	µV	-0.0076	+0.0076	152	0	-
Air-Flow	-50	+50	µV	-0.1135	+0.1135	2270	0	-
ECG	-50	+50	µV	-0.0125	+0.0125	250	0	-
SpO2	0	100	%	0	2	0.02	0	v/%
Body Pos	0	2300	mV	0	2.3	1	0	-
Sound	-50	+50	µV	-0.0055	+0.0055	110	0	-
66-ch EEG								
65 EEG	-50	+50	µV	-0.0704	+0.0704	1408	0	-
Resp	-50	+50	µV	-0.0704	+0.0704	1408	0	-

6.4. Impedance Testing

In Observer, Impedance (**ETEST**) Mode sets the headbox into an impedance-testing mode, which is equivalent to pressing the corresponding (Ohm) button on the headbox.

See the ***Stellate HARMONIE Reference Manual***, page 7-34.

6.5. Patient Connect/Patient Disconnect (PC/PD) Switch

Each time a patient disconnects from or re-connects to the system, the patient or clinician may use a PC/PD switch to provide patient connect/disconnect information in the Recording Log.

6.6. Electric Stimulation

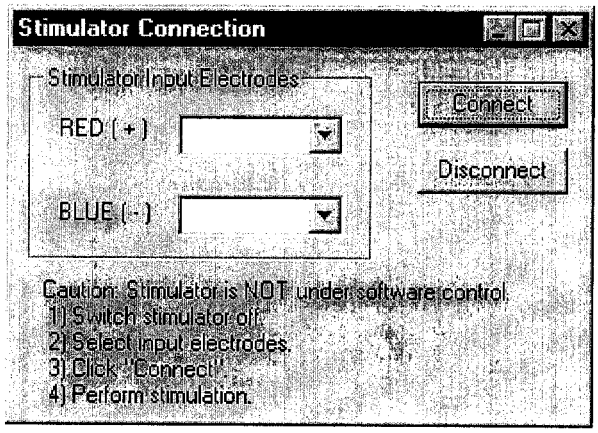
Ensure that the stimulator is connected to the proper jacks on the headbox.

When two headboxes are interconnected for 128-ch EEG, one stimulator can be applied to both headboxes. Connect the stimulator inputs on the headboxes in parallel (positive-to-positive, and negative-to-negative). Then connect the stimulator to either headbox.

Attention: Do not run an electric stimulation while the system is in ETEST or CAL mode, since this will result in invalid data.

Caution: The stimulator is not under software control. It must be operated by the attending physician. Follow the procedure shown on the **Stimulator Connection** dialog box.

The dialog box is used for selecting which electrodes are connected to the stimulator. The required settings are described below.



Red (+)/Blue (-): Select the stimulation electrodes/channels. Only electrodes that are available in the recording montage are listed.
(Both fields are disabled once the stimulator has been connected).

Connect: Click to connect the selected electrodes to the stimulator.
(Disabled once the stimulator has been connected).

Disconnect: Click to disconnect the selected electrodes from the stimulator.
(Disabled once the stimulator is disconnected).

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Appendix

A Pin Assignments for Schwarzer Headbox Connectors

A.1 Pin Assignments on EEG (P/N 210026) and PSG (P/N 210031) Headboxes

parallel in DB-37 connector				
Pin	**Assignment**		**Pin**	**Assignment**
Pin 1	Input Fp1		Pin 20	Input Cb2
Pin 2	Input Fp2		Pin 21	Input Fz
Pin 3	Input F3		Pin 22	Input Cz
Pin 4	Input F4		Pin 23	Input Pz
Pin 5	Input C3		Pin 24	Input T2
Pin 6	Input C4		Pin 25	Input T1
Pin 7	Input P3		Pin 26	Input A2
Pin 8	Input P4		Pin 27	Input A1
Pin 9	Input O1		Pin 28	Input in 1 a
Pin10	Input O2		Pin 29	Input in 1 b
Pin 11	Input Pg1		Pin 30	Input in 2 a
Pin 12	Input Pg2		Pin 31	Input in 2 b
Pin 13	Input F7		Pin 32	Input in 3 a
Pin 14	Input F8		Pin 33	Input in 3 a
Pin 15	Input T3		Pin 34	Not used
Pin 16	Input T4		Pin 35	Not used
Pin 17	Input T5		Pin 36	Not used
Pin 18	Input T6		Pin 37	N
Pin 19	Input Cb1			

Resp. DB-9 connector (for air flow sensor)	
Pin	**Assignment**
Pin 1	AC-input
Pin 2	Power for capacitive transducers
Pin 3	Ground
Pin 4	Power for 2nd thermistor
Pin 5	Not used
Pin 6	Power for thermistor
Pin 7	DC-input
Pin 8	Ground
Pin 9	Free

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A.2 Pin Assignments on 66-ch EEG Headbox (P/N 210033)

parallel in 1 DB-37 connector					**parallel in 2** DB-37 connector			
Pin	**Assignment**	**Pin**	**Assignment**		**Pin**	**Assignment**	**Pin**	**Assignment**
Pin 1	Input 1	Pin 20	Input 20		Pin 1	Input 34	Pin 20	Input 53
Pin 2	Input 2	Pin 21	Input 21		Pin 2	Input 35	Pin 21	Input 54
Pin 3	Input 3	Pin 22	Input 22		Pin 3	Input 36	Pin 22	Input 55
Pin 4	Input 4	Pin 23	Input 23		Pin 4	Input 37	Pin 23	Input 56
Pin 5	Input 5	Pin 24	Input 24		Pin 5	Input 38	Pin 24	Input 57
Pin 6	Input 6	Pin 25	Input 25		Pin 6	Input 39	Pin 25	Input 58
Pin 7	Input 7	Pin 26	Input 26		Pin 7	Input 40	Pin 26	Input 59
Pin 8	Input 8	Pin 27	Input 27		Pin 8	Input 41	Pin 27	Input 60
Pin 9	Input 9	Pin 28	Input 28		Pin 9	Input 42	Pin 28	Input 61
Pin10	Input 10	Pin 29	Input 29		Pin10	Input 43	Pin 29	Input 62
Pin 11	Input 11	Pin 30	Input 30		Pin 11	Input 44	Pin 30	Input 63
Pin 12	Input 12	Pin 3	Input 31		Pin 12	Input 45	Pin 31	Input 64
Pin 13	Input 13	Pin 32	Input 32		Pin 13	Input 46	Pin 32	Input 65
Pin 14	Input 14	Pin 33	Input 33		Pin 14	Input 47	Pin 33	Not used
Pin 15	Input 15	Pin 34	Ground		Pin 15	Input 48	Pin 34	Ground
Pin 16	Input 16	Pin 35	Respiration		Pin 16	Input 49	Pin 35	Not used
Pin 17	Input 17	Pin 36	Ground		Pin 17	Input 50	Pin 36	Ground
Pin 18	Input 18	Pin 37	N		Pin 18	Input 51	Pin 37	N
Pin 19	Input 19				Pin 19	Input 52		

Resp. DB-9 connector (for air flow sensor)	
Pin	**Assignment**
Pin 1	AC-input
Pin 2	Power for capacitive transducers
Pin 3	Ground
Pin 4	Power for 2nd thermistor
Pin 5	Not used
Pin 6	Power for thermistor
Pin 7	DC-input
Pin 8	Ground
Pin 9	Free

B Environmental Protection

Already during the development of Schwarzer-medical diagnostic instruments the principal demands of environmental protection - "avoid emissions and preserve resources" - are taken into account. Long lifespan and good serviceability confirm these efforts. With the exchange and repair of assemblies, Schwarzer takes care that high grade mechanical and electronic parts are used as long as possible and subsequently become recycled or disposed of, without polluting the environment.

B.1 Emissions

The EEG-/Polygraphy-headboxes do not produce harmful emissions.

B.2 Waste Disposal

Scrap instruments	Classification: Electronic scrap On customer's request the Schwarzer GmbH accepts scrap instruments for waste disposal. As far as possible, single assemblies will be repaired and reused as spare parts. The rest is separated in the different materials and given to an acknowledged disposal company.
Acceessories: Cables, electrodes, electrode leads	Classification: Electronic scrap As far as possible, these parts are repaired by Schwarzer GmbH. They can be disposed of in the same way as scrap instruments.
Packing Material:	Classification: Waste for salvage Packing material should be disposed of according to the relevant national regulations. On customer's request packing material can be returned to Schwarzer GmbH or Stellate Systems who will reuse it (if possible) or give it to an acknowledged disposal company.

C Cleaning Requirements

The headbox and the optical fibre can be rubbed off with a moist cloth (water). Diluted liquid household detergents (no scouring agents) or diluted alcohols may be used as cleaning agents.

Ensure that no liquid gets into any headbox.

When cleaning other system components (e.g. EEG-unit, monitor, printer etc.), please follow the corresponding instructions.

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D Technical Specifications

D.1 Schwarzer PTMS256 Digital Signal Processor Board

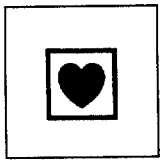
Voltage	+5 V, +12 V, -12V, dc
Fuse	1 x 0.5 A slow
Current consumption	
without headbox	0.5 A at +5 V; 0.08 A at +12 V; 0.06 A at –12 V
with headbox	1.25 A at +5 V
External trigger-inputs with PTMS6-board	16 bit
Environmental data during operation	
Temperature	10°C...40°C
Rel. humidity	30%...95%, non condensing
Atmospheric pressure	700...1200 hPa
Storage and Transportation	
Temperature	-20°C...60°C
Rel. humidity	30%...95%, non condensing
Atmospheric pressure	700...1200 hPa
Dimensions (l x w x h)	
PTMS256	219 mm x 107 mm x 18 mmm
PTMB3	50 mm x 42 mm x 20 mm
PTMS6	125 mm x 58 mm x 20 mm

D.2 Schwarzer Headboxes

Input impedance	100 MΩ
Input noise	< 1,5 μV_{ss} (filter 70 Hz)
Common mode rejection	> 100 dB (100 000 : 1) at 50 Hz
Electrode impedance measuring	
Headboxes 210026, 210031	LED-display, limit values (5-10-20-50 kΩ) selectable
Headbox 210033	Impedance values are transmitted to the software
Signal transfer	Digital via optical fibre cable, electrical separation from the computer system
Input for stimulator voltage	
Headbox 210 033 only	Max. 200 V
Power supply	15 V
Power consumtion	
Headboxes 210026, 210031	< 3 W
Headbox 210033	< 4 W
Environmental data during operation	
Temperature	10°C ... 40°C
Rel. humidity	25% ... 95%, non condensing
Atmospheric pressure	700 ... 1200 hPa
Storage and Transportation	
Temperature	-20°C ... 60°C
Rel. humidity	25% ... 95%, non condensing
Atmospheric pressure	700 ... 1200 hPa
Dimensions (h x w x d)	
Headbox 210026	207 mm x 200 mm x 77 mm
Headbox 210031	221 mm x 200 mm x 93 mm
Headbox 210033	215 mm x 325 mm x 135 mm
Weight	
Headbox 210026	approx. 1.8 kg
Headbox 210031	approx. 2.1 kg
Headbox 210033	approx. 4.7 kg
EMI immunity against high frequency electromagnetic fields	according to IEC 60601-1-2; field strength 3V/m, 26 MHz – 1000 MHz
Patient safety	Class I equipment, type CF applied part according to IEC 60601-1

E Symbols & Identification Labels

This symbol means: *Obey instructions for use!*

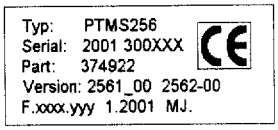


This symbol indicates an instrument of type *CF*.

CE

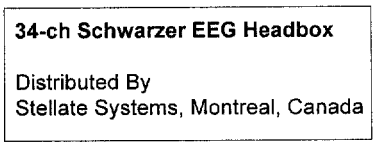
The CE symbol integrated in the type identification label confirms the conformity with the Medical Device Directive 93/42/EEC.

Example of a type identification label, attached to the side of the headbox.



Example of a type identification label, attached to the PTMS256 digital signal processor board.

Classification according to specifications: Class 1 according Annex IX, rule 12, Medical Device Directive 93/42/EEC. Suitable for medical devices of class IIa and IIb if the corresponding complementary type acceptance tests are executed.



Example of the Stellate Systems identification label, attached to main components, including the headboxes and the PTMS digital signal processor board.

Schwarzer GmbH, Medical Diagnostic Equipment offers certificates of conformity to the following Quality System standards in manufacturing:

- EN ISO 9001:8.94,
- EN 46 001:12.93 and
- EEC-Directive 93/42/EEC Annex 2.

Notified Body: TÜV PRODUCT SERVICE GMBH, CE-identification number 0123.