Elekta Neuromag® TRIUX

EEG Cap User's Manual

Article number: NM24405A-B (February 2014)
Language: English

ELEKTA

Manufacturer:

Elekta Oy
Siltasaarenkatu 18-20 A
FI-00530 Helsinki, Finland
Tel: +358 9 756 2400
Fax: +358 9 756 24011
Web: www.elekta.com

Printing history	Neuromag p/n	Date
First edition	NM24405A	27.9.2011
Error correction	NM24405A	26.10.2011
Second edition: Fig A2 changed	NM24405A-A	30.1.2012
Third edition: 32-channel caps, digitization order	NM24405A-B	5.2.2014

CE
0537

List of symbols

The following symbols are used in the system and in the manuals. Familiarize yourself with each symbol and its meaning before operating this system.

Caution, consult accompanying documents. Parts of the product are marked with this symbol when it is necessary for the user to refer to important operating and maintenance instructions given in the manuals accompanying the system. In the manuals, it also calls attention to specific instructions. These instructions may contain procedures, practices, conditions or the like which must be correctly performed or adhered to in order to ensure safe operation and to avoid damage to the patient, operator, or the system.

Consult instructions for use. Parts of the product are marked with this symbol when it is necessary for the user to refer to important operating and maintenance instructions given in the manuals accompanying the system. In the manuals, it also calls attention to specific instructions. These instructions may contain procedures, practices, conditions or the like which must be correctly performed or adhered to in order to ensure correct operation and/or increased safety and to avoid damage to the system

Type BF (body floating) equipment symbol. The applied parts (parts in direct contact with the person being investigated with the system) and the type plate are marked with this symbol to indicate that they fulfill the leakage current requirements of the safety standard IEC 60601-1.

Alternating current (power line) symbol

Protective ground (earth) terminal symbol. Used to identify terminals which are intended for connection to an external protective conductor for protection against electrical shock in case of a fault, or to the terminal of a protective ground (earth) electrode.

Static electricity symbol. The parts of the system marked with this symbol indicate the presence of components susceptible to static electricity and require the use of special static-electricity preventing techniques.

Non-ionizing radiation, RF transmitter. Marking on equipment or equipment parts that include RF transmitters or that intentionally apply RF electromagnetic energy

Separate collection of waste electrical and electronics equipment (WEEE) necessary (European Union directive 2002/96/EC on WEEE)

Date of manufacture: year (four digits) followed by month.

Warnings, cautions, and notes

WARNING 0.0: Warnings are directions which, if not followed, could constitute a health hazard, cause fatal or serious injury, or lead to erroneous clinical diagnosis and possibly to clinical mistreatment.

CAUTION 0.0: Cautions are directions which must be followed in order to ensure safe and efficient operation and to avoid damage to system.

Note: *Notes provide advice and recommendations for safe and efficient use of the product as well as highlight unusual points.*

1 General information

1.1 Scope

This manual instructs the safe use of the following parts with Elekta Neuromag® TRIUX:

- NM23905N Small EEG cap, 32 channels, size 46-52 (factory code: NM24430N)
- NM23906N Medium EEG cap, 32 channels, size 52-58 (factory code: NM24431N)
- NM23907N Large EEG cap, 32 channels, size 58-64 (factory code: NM24432N)
- NM23890N Small EEG cap, 64 channels, size 46-52 (factory code: NM24301N)
- NM23891N Medium EEG cap, 64 channels, size 52-58 (factory code: NM24302N)
- NM23892N Large EEG cap, 64 channels, size 58-64 (factory code: NM24303N)
- NM23895N Medium EEG cap, 128 channels, size 52-58 (factory code: NM24304N)
- NM23896N Large EEG cap, 128 channels, size 58-64 (factory code: NM24393N)

The factory codes given in parentheses refer to the cap only (printed on cap cables). The commercial codes marked on package refer to the complete delivery comprising the cap (factory code), support CD, and this manual (NM24405A-B).

For the use of the Elekta Neuromag® TRIUX, and the EEG subsystem in general, see *Elekta Neuromag® TRIUX User's Manual*.

1.2 Intended operation

1.2.1 Intended use

The EEG caps for Elekta Neuromag® TRIUX are intended to make electrical connections between the subject's intact scalp and the EEG channel inputs of the Elekta Neuromag® TRIUX.

The Elekta Neuromag® TRIUX is intended for use as a magnetoencephalographic (MEG) device which non-invasively detects and displays biomagnetic signals produced by electrically active nerve tissue in the brain. When interpreted by a trained clinician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions.

1.2.2 Indications for use

The Elekta Neuromag® TRIUX non-invasively measures the magnetoencephalographic (MEG) signals (and, optionally, electroencephalographic (EEG) signals) produced by electrically active tissue of the brain. These signals are recorded by a computerized data acquisition system, displayed, and may then be interpreted by trained physicians to help localize these active areas. The locations may then be correlated with anatomical information of the brain. MEG is routinely used to identify the locations of visual, auditory, somatosensory, and motor cortex in the brain when used in conjunction with evoked response averaging devices. MEG is also used to non-invasively locate regions of epileptic activity within the brain. The localization information provided by MEG may be used, in conjunction with other diagnostic data, in neurosurgical planning.

1.2.3 Intended patient and user groups

No specific limitations within the intended use and indications use apply with respect to patient group with respect to patient age, weight or health. Since the cap is not intended to be sterile it is intended for use on healthy scalp skin only.

The intended user groups include trained medical professionals (e.g. nurse, EEG technologist, physician) and trained scientific research professionals (e.g. researcher, research assistant)

1.2.4 Intended conditions for use

The intended sites for use include hospital or research institution MEG site with normal bed-side or examination room hygienic requirements. The caps are intended to be used for a limited period of time (typically 1 hour) at a time and cleaned after each use. The cap can be used multiple times. Although the cap is movable the dedicated connector limits its use to Elekta Neuromag® TRIUX (not mobile).

1.3 Classification

The EEG caps are classified as an accessory of Class I according to European Council Medical Devices Directive 93/42/EEC as amended by 2007/47/EEC.

Note that EEG system in Elekta Neuromag® TRIUX where this cap is intended to be connected as an accessory is of Class IIa.

1.4 Final disposal

'Final disposal' is disposal of the equipment or any part of it, in such a way that it can no longer be used for its intended purpose(s).

Never dispose of the caps into the domestic waste stream.

Disposal must always be executed in an environmentally sensitive manner that complies with all local and international regulations and laws. The caps should be disposed of as electronic and electrical waste.

Where applicable, information will be available for treatment facilities and recyclers in accordance with Article 11 of directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE).

1.5 Materials information

The parts of caps in contact with the head are made of materials listed in Table 1.1

Table 1.1 Materials of the cap.

Part	Material
Textile	Polyamide (70%), elasthane (30%)
Electrode pin	Sintered Ag/AgCl
Electrode support assembly	PVDF (polyvinylidene fluoride), POM (polyoxymethylene)

2 Warnings and precautions

Read these warning notices before using this device and follow the hazard information at all times when using it.

WARNING 1.1: Use the cap only on intact, non-injured skin. Do not use on patients with easily transmissible dangerous diseases. Clean the caps after each use.

CAUTION 1.1: Keep the connectors of the EEG cap dry and clean. Spillage of liquids on the connectors or the connection housings may cause deteroriated EEG-signal quality or electrical isolation.

CAUTION 1.2: Always double-check that the cap and the cap adapter connectors are connected as instructed in this manual.

CAUTION 1.3: Always check that cables and connectors are not damaged, especially after cleaning.

CAUTION 1.4: After electrodes have been attached onto the subject's head, avoid contact of conducting parts of the electrodes,including reference (REF) and isolated preamplifier signal ground (GND) electrodes, to actual ground or other conducting parts which may be grounded or become live at mains voltage. Do not ground subject to actual ground (e.g. the wall of the magnetically shielded room). Do not place conducting grounded objects near the subject that he/she may touch while connected to the equipment.

CAUTION 1.5: Avoid getting the EEG paste or gel to the eyes or mouth. Use only non-toxic pastes approved for clinical use.

CAUTION 1.6: Handle the caps carefully to avoid contamination from magnetic material. Clean the caps after each use and store them in a place free from dust, dirt etc.

CAUTION 1.7: Since the EEG in the Elekta Neuromag® TRIUX is not defibrillation proof, disconnect the cap cables before defibrillation.

3 Main parts

The main parts of the cap are shown in Fig. 1.1.

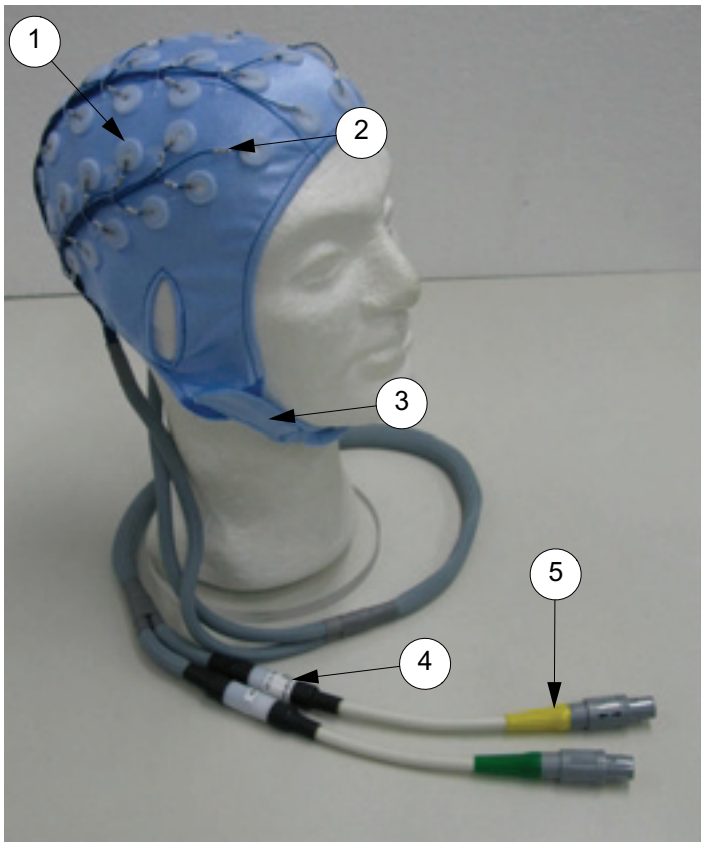


Figure 1.1 The main parts of the cap. 1: Electrode assembly with electrode pin and plastic support ring, 2: electrode wire with identification label, 3: elastic textile cap with chin strap, 4: connection housing, 5: electrode cable connector with color coding ring.

The electrodes of the electrode caps listed above are made of sintered Ag/AgCl and tested to be non-magnetic. The sintered Ag/AgCl electrodes do not need chloriding. Note that electrode caps available commercially elsewhere may be incompatible with MEG.

The electrode cap is made of elastic fabric. The Ag/AgCl electrodes snap into plastic electrode holders on the cap. A 6-mm opening in the plastic holder provides easy access to the skin underneath.

As the electrodes and the electrode cap are very close to the neuromagnetometer sensors, they are particulary prone to causing magnetic artefacts. Even a thin layer of magnetized material or a small particle of ferromagnetic dust can produce magnetic artefacts on one or several MEG channels.

4 Directions for use

Perform the following steps to prepare an acquisition with one of the EEG caps listed above:

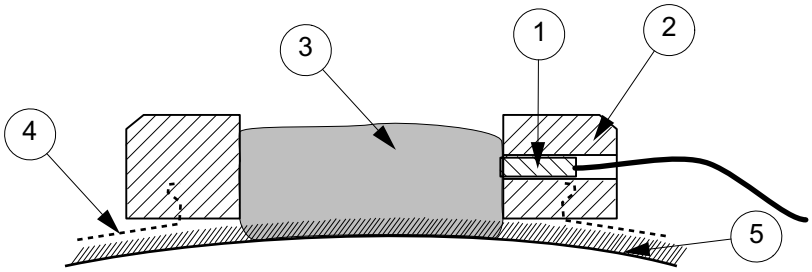


Figure 1.2 Cross-section of the electrode-skin interface of the electrode cap. 1: Electrode, 2: Plastic holder, 3: Electrode paste, 4: Elastic fabric, 5: Hair and skin

1. Attach the cap to the subject's head symmetrically. Adjust the position of the cap to locate the electrodes properly. The electrode Cz should be positioned halfway the nasion to inion and halfway between the pre-auricular points. Tighten the straps under the jaw so that the cap fits tightly but comfortably. Do not overtighten or use too small cap.

2. Apply liquid electrode gel, such as OmniPrep® Skin Preparation (D. O. Weaver & Co., Aurora, CO, USA) or equivalent, to a cotton swab. This paste includes particles to abrade the skin. Rub the skin *gently*, ensuring that the gel wets the skin even if the hair is very thick. Prepare each electrode in the same manner.

Note: Do not scratch the skin so that it gets injured. Use single-use or disinfected applicators only and apply gel and electrode paste from a clean container to avoid infections.

3. Inject electrode paste, such as Grass® EC2™ (Grass Instruments, Quincy, MA, USA) or equivalent, with a syringe to form the actual bridging from the skin to the electrode (see also Fig. 1.2.). Do not use a hypodermic needle on the syringe, a blunt needle can be used. Press the electrode with your fingers against the skin while squeezing the syringe. The electrode paste hardens quite rapidly. A piece of paper tissue compressed on the electrode helps in drying the paste. The paste can, however, be washed away easily with ordinary soap or mild dish care detergent, such as Fairy™, and water. Repeat this procedure for each electrode opening. Refer also to the instructions given by the electrode/ gel manufacturers. Prevent the paste or gel from entering the eyes or mouth of the patient.

Note: Use only non-toxic pastes approved for clinical use with Ag/AgCl electrodes.

4. After this, attach the non-magnetic reference (REF) and ground (GND) electrodes (single electrodes). Clean the skin e.g. with alcohol, peel off the protective film and attach the electrode to the skin of the patient. The reference electrode acts as a reference for all the unipolar channels of the cap, and the ground electrode is used to set the patient to common potential with the preamplifiers to reduce common-mode interference. Line frequency ripple and drift may be further reduced by using active grounding as explained in the *Elekta Neuromag® TRIUX User's Manual*. Both the reference and ground electrodes must be connected. Place the reference electrode according to the electrode derivation used. The placement of the ground electrode is not critical, and it is typically placed in an inactive area such as the cheek of the patient. In SEF measurements, place the ground electrode close to the stimulating electrode to minimize artifacts. For reference, ground, and most bioamplifier channels, single-use electrodes (included in the system delivery) are suitable.

5. After electrodes have been attached onto the subject's head, avoid contact of conducting parts of the electrodes, including reference (REF) and isolated preamplifier signal ground (GND) electrodes, to actual ground or other conducting parts which may be grounded or become live at mains voltage. Do not ground subject to actual ground (e.g. the wall of the magnetically shielded room). Do not place conducting grounded objects near the subject that he/she may touch while connected to the equipment.

6. When combined MEG-EEG measurement is performed using the EEG cap, exact locations of the electrodes are defined by digitizing them. EEG electrode positions are needed if modeling of the EEG signals is required in the analysis phase. The default digitization order for EEG electrodes is sequential by channel number. However, this is not the physical order of the electrodes in the cap, and thus the digitization can be time-consuming and possibly prone to errors. Therefore, enhanced digitization order following the physical order of the electrodes on the cap is available on *SW24407N Support CD for EEG caps* (revision C or newer), delivered with the caps. The enhanced digitization configuration file on CD needs to be installed in the data acquisition workstation. If the cap digitization orders are not present in your system and you need a copy of the CD or assistance in installation, contact your Elekta representative.

7. Proceed normally with the digitization of anatomical landmarks and HPI coils. Before starting the EEG digitization, instead of "Sequential" digitization order, select the "EEG Cap nn" (nn is the number of electrodes on the cap) in the lower part of the "EEG electrodes" partition of the digitization window. Start the EEG electrode digitization by digitizing the reference electrode. After each successfully digitized electrode, DACQ moves to the next and shows the number of the EEG channel on the lower part of the "EEG electrodes" window. After "EEG ref" DACQ displays "EEG001", "EEG020", "EEG002" and so forth. The order of digitization proceeds from frontal to occipital channels, and from left to right, in the order depicted in Figures A.1 through A.3 of Appendix A, depending on the number of channels. DACQ only displays the EEG channel numbers, not the channel names that are marked on the EEG caps; the channel number can be found from Figures A.1 through A.3 if needed. However, this should not be necessary in the everyday use if the suggested order is used. During the digitization, follow the appearance of the digitized electrodes to the EEG electrodes digitization display. In case of errors, use previous and next buttons and digitize again. Note, however, that in single operator mode it is not possible to go back to the previous electrodes after the last electrode has been digitized. When all the electrodes are digitized, stop as usually by clicking the digitization pen far away from the EEG cap. Refer to *Elekta Neuromag Data Acquisition User's Manual* for detailed digitization instructions. See also the channel layouts in the Appendix A.

8. Connect the EEG cap to the EEG interface on the side panel of the Elekta Neuromag® TRIUX (see Fig. 1.3). The connectors on the panel have color codings that must match with the mating adapter cable connector. For information connector colors and corresponding channels are listed in Table 1.2.

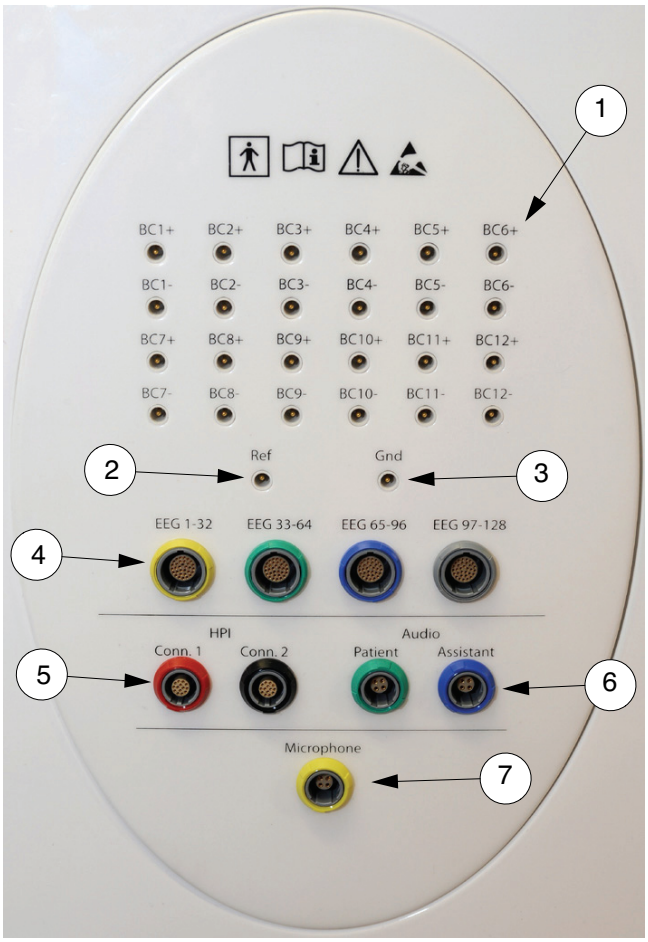


Figure 1.3 The side panel of Elekta Neuromag® TRIUX. 1: Bioamplifier connectors for single electrodes, 2: reference electrode connector, 3: ground electrode connector, 4: cap connectors, 5: head position indicator (HPI) connectors, 6: audio interface connectors, 7: microphone connector.

9. After finishing the acquisition, disconnect the electrode cap from the corresponding connectors. The cap can normally be removed easily from subject's head. If it does not get loose easily, wet the cap and hair with a hand shower. Avoid water from entering the cap connectors. The paste and gel can be removed from the hair by ordinary shampoo and water.

Table 1.2 Connector colors and channels. For 64 channel EEG caps only first two connectors are used.

Cap connector color	Channels
yellow	1-32
green	33-64
blue	65-96
grey	97-128

5 Storing and maintenance

5.1 Storing

The electrode caps should be stored carefully, preferably hanging in dry room air. Do not keep the caps on a table where they might be contaminated with magnetic particles. Wash them carefully after each use (see cleaning instructions below).

WARNING 1.2: Handle the caps carefully to avoid contamination from magnetic material. Clean the caps after each use and store them in a place free from dust, dirt etc.

5.2 Maintenance

Thorough cleaning of the electrode cap after each use prolongs the lifetime of the cap and ascertains proper connection between the electrodes and the patient's scalp:

CAUTION 1.8: During the entire cleaning, keep the connectors and connection housings dry.

1. Immediately after each acquisition session, soak the electrode cap with electrodes in place and single electrodes in plain lukewarm water for 20 minutes or until most of the paste is disolved into the water.

Note: *Do not soak the cap for more than 60 minutes to prevent corrosion.*

2. Remove the remaining paste with a handheld shower. As the elastic textile material does not withstand high temperatures without losing its elastic properties do not use hot water (over 40 degrees Celsius).

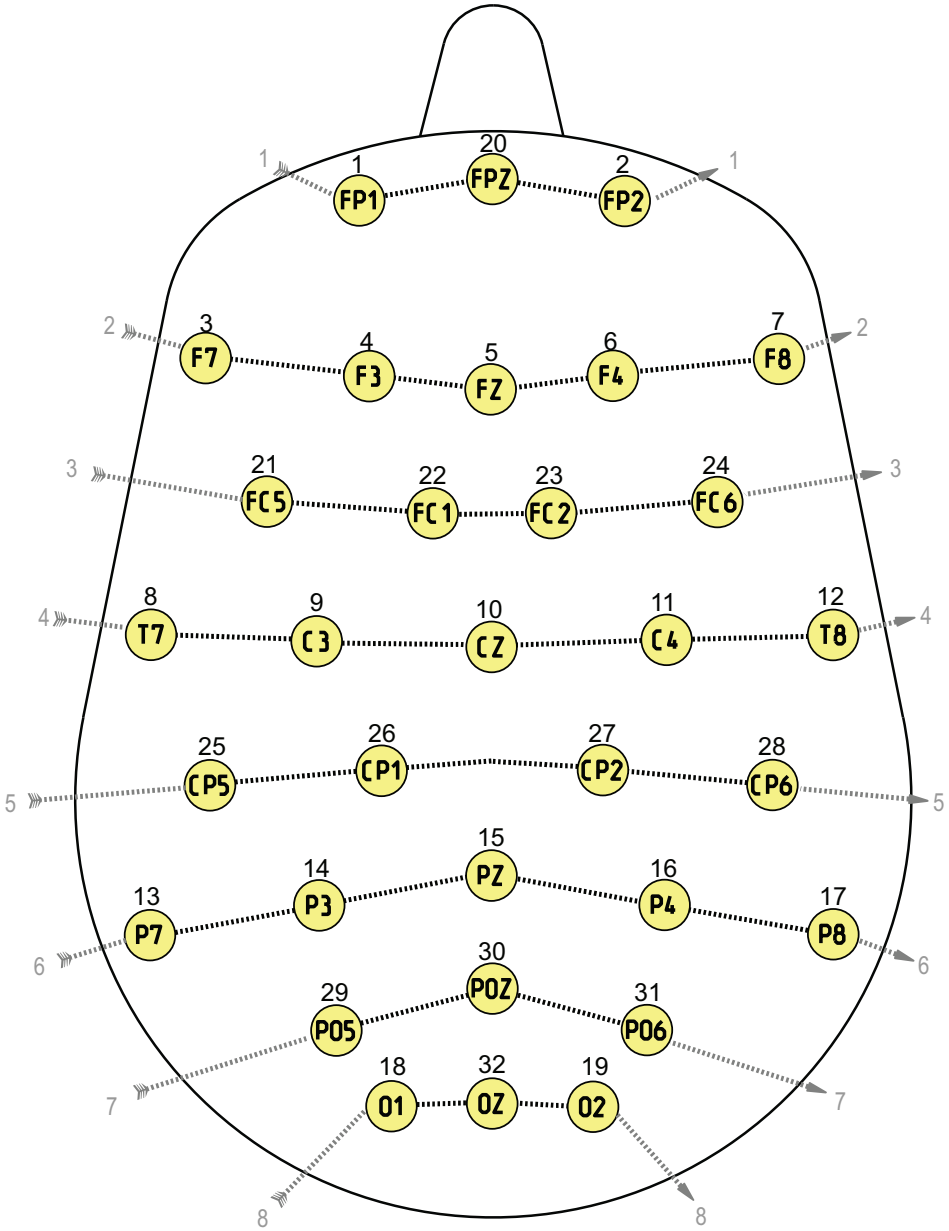
Note: *Keep the connectors above the level of water source.*

3. Use a soft, small brush to remove paste that does not dissolve with the shower. Use the brush carefully. Do not use a hard brush or any hard tool. The wiring of the cap breaks easily if brushed too harshly. or the cap is bent extensively. Use ordinary soap or mild dish care detergent, such as Fairy™, diluted in water if necessary to clean the residue. Be careful not to let water into the cap connectors at any time. Do not leave old paste to harden in the electrode cavity as it may be difficult to remove later. Pure alcohol can be used for disinfection. Do not use autoclaving.

4. Allow the electrode cap to dry properly before storing or next use. Do not use a hot air blower. A fan circulating room-temperature air maybe used if necessary to speed up the drying.

APPENDIX A Electrode cap layouts

A.1 32-channel electrode cap layout

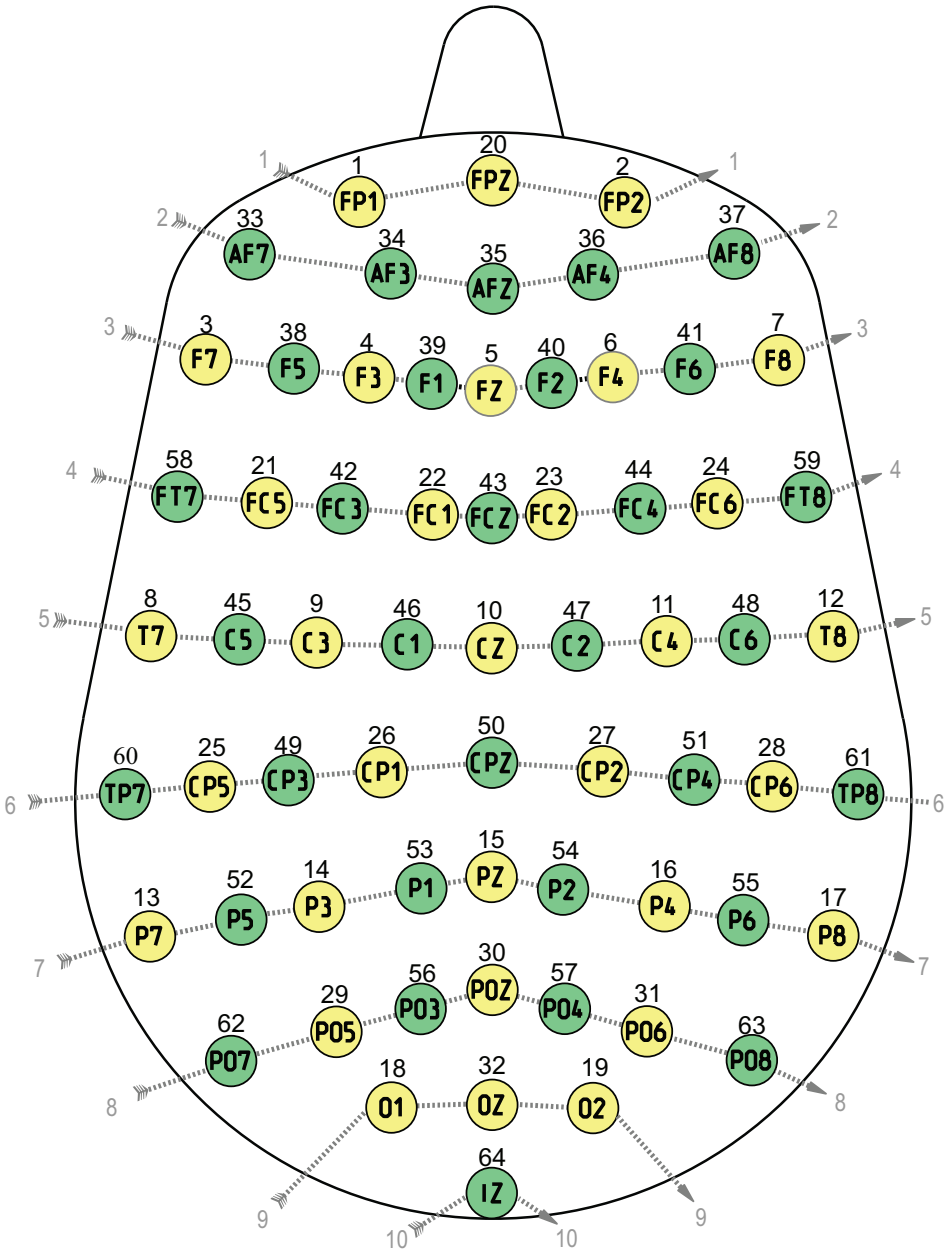


A.1 Layout of the 32-channel electrode caps. The labels (1,2...) above the electrode locations refer to the channel number. The dotted lines with arrow heads and numbers 1 through 8 indicate the order of digitization.

Table 1 Electrode locations and channel numbers of the layout in Fig. A.1. The column "cable" refers to cable pin number (Y: yellow).

Loc.	Channel	Cable
FP1	1	Y1
FP2	2	Y2
F7	3	Y3
F3	4	Y4
FZ	5	Y5
F4	6	Y6
F8	7	Y7
T7	8	Y8
C3	9	Y9
CZ	10	Y10
C4	11	Y11
T8	12	Y12
P7	13	Y13
P3	14	Y14
PZ	15	Y15
P4	16	Y16
P8	17	Y17
O1	18	Y18
O2	19	Y19
FPZ	20	Y20
FC5	21	Y21
FC1	22	Y22
FC2	23	Y23
FC6	24	Y24
CP5	25	Y25
CP1	26	Y26
CP2	27	Y27
CP6	28	Y28
PO5	29	Y29
POZ	30	Y30
PO6	31	Y31
OZ	32	Y32

A.2 64-channel electrode cap layout

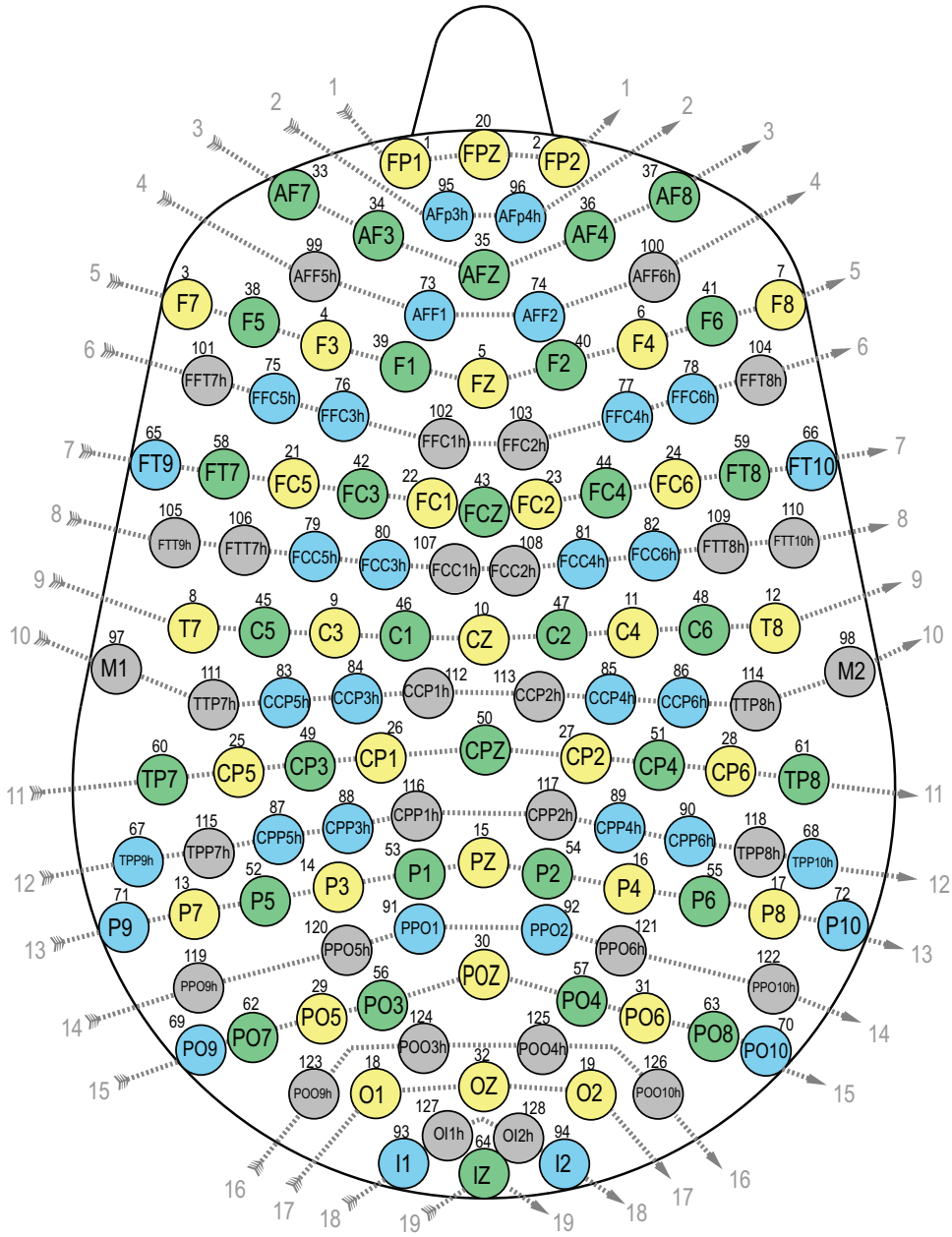


A.2 Layout of the 64-channel electrode caps. The labels (1,2...) above the electrode locations refer to the channel number. The dotted lines with arrow heads and numbers 1 through 10 indicate the order of digitization.

Table 2 Electrode locations and channel numbers of the layout in Fig. A.2. The column "cable" refers to cable pin number (Y: yellow, G: green).

Loc.	Channel	Cable	Loc.	Channel	Cable
FP1	1	Y1	AF7	33	G1
FP2	2	Y2	AF3	34	G2
F7	3	Y3	AFZ	35	G3
F3	4	Y4	AF4	36	G4
FZ	5	Y5	AF8	37	G5
F4	6	Y6	F5	38	G6
F8	7	Y7	F1	39	G7
T7	8	Y8	F2	40	G8
C3	9	Y9	F6	41	G9
CZ	10	Y10	FC3	42	G10
C4	11	Y11	FCZ	43	G11
T8	12	Y12	FC4	44	G12
P7	13	Y13	C5	45	G13
P3	14	Y14	C1	46	G14
PZ	15	Y15	C2	47	G15
P4	16	Y16	C6	48	G16
P8	17	Y17	CP3	49	G17
O1	18	Y18	CPZ	50	G18
O2	19	Y19	CP4	51	G19
FPZ	20	Y20	P5	52	G20
FC5	21	Y21	P1	53	G21
FC1	22	Y22	P2	54	G22
FC2	23	Y23	P6	55	G23
FC6	24	Y24	PO3	56	G24
CP5	25	Y25	PO4	57	G25
CP1	26	Y26	FT7	58	G26
CP2	27	Y27	FT8	59	G27
CP6	28	Y28	TP7	60	G28
PO5	29	Y29	TP8	61	G29
POZ	30	Y30	PO7	62	G30
PO6	31	Y31	PO8	63	G31
OZ	32	Y32	IZ	64	G32

A.3 128-channel electrode cap layout



A.3 Layout of the 128-channel electrode cap. The labels (1,2...) above the electrode locations refer to the channel number. The dotted lines with arrow heads and numbers 1 through 19 indicate the order of digitization.

Table 3 Electrode locations and channel numbers. of the layout in Fig. A.3. The column "cable" refers to cable conductor number (Y: yellow, G: green, B: blue, H: grey).

Loc.	Channel	Cable	Loc.	Channel	Cable	Loc.	Channel	Cable	Loc.	Channel	Cable
FP1	1	Y1	AF7	33	G1	FT9	65	B1	M1	97	H1
FP2	2	Y2	AF3	34	G2	FT10	66	B2	M2	98	H2
F7	3	Y3	AFZ	35	G3	TPP9h	67	B3	AFF5h	99	H3
F3	4	Y4	AF4	36	G4	TPP10h	68	B4	AFF6h	100	H4
FZ	5	Y5	AF8	37	G5	PO9	69	B5	FFT7h	101	H5
F4	6	Y6	F5	38	G6	PO10	70	B6	FFC1h	102	H6
F8	7	Y7	F1	39	G7	P9	71	B7	FFC2h	103	H7
T7	8	Y8	F2	40	G8	P10	72	B8	FFT8h	104	H8
C3	9	Y9	F6	41	G9	AFF1	73	B9	FTT9h	105	H9
CZ	10	Y10	FC3	42	G10	AFF2	74	B10	FTT7h	106	H10
C4	11	Y11	FCZ	43	G11	FFC5h	75	B11	FCC1h	107	H11
T8	12	Y12	FC4	44	G12	FFC3h	76	B12	FCC2h	108	H12
P7	13	Y13	C5	45	G13	FFC4h	77	B13	FTT8h	109	H13
P3	14	Y14	C1	46	G14	FFC6h	78	B14	FTT10h	110	H14
PZ	15	Y15	C2	47	G15	FCC5h	79	B15	TTP7h	111	H15
P4	16	Y16	C6	48	G16	FCC3h	80	B16	CCP1h	112	H16
P8	17	Y17	CP3	49	G17	FCC4h	81	B17	CCP2h	113	H17
O1	18	Y18	CPZ	50	G18	FCC6h	82	B18	TTP8h	114	H18
O2	19	Y19	CP4	51	G19	CCP5h	83	B19	TPP7h	115	H19
FPZ	20	Y20	P5	52	G20	CCP3h	84	B20	CPP1h	116	H20
FC5	21	Y21	P1	53	G21	CCP4h	85	B21	CPP2h	117	H21
FC1	22	Y22	P2	54	G22	CCP6h	86	B22	TPP8h	118	H22
FC2	23	Y23	P6	55	G23	CPP5h	87	B23	PPO9h	119	H23
FC6	24	Y24	PO3	56	G24	CPP3h	88	B24	PPO5h	120	H24
CP5	25	Y25	PO4	57	G25	CPP4h	89	B25	PPO6h	121	H25
CP1	26	Y26	FT7	58	G26	CPP6h	90	B26	PPO10h	122	H26
CP2	27	Y27	FT8	59	G27	PPO1	91	B27	POO9h	123	H27
CP6	28	Y28	TP7	60	G28	PPO2	92	B28	POO3h	124	H28
PO5	29	Y29	TP8	61	G29	I1	93	B29	POO4h	125	H29
POZ	30	Y30	PO7	62	G30	I2	94	B30	POO10h	126	H30
PO6	31	Y31	PO8	63	G31	AFp3h	95	B31	OI1h	127	H31
OZ	32	Y32	IZ	64	G32	AFp4h	96	B32	OI2h	128	H32

Corporate Head Office:

Elekta AB (publ)
Box 7593, SE-103 93
Stockholm, Sweden

Tel +46 8 587 254 00
Fax +46 8 587 255 00
info@elekta.com

Regional Sales, Marketing, and Service:

North America
Atlanta, USA

Tel +1 770 300 9725
Fax +1 770 448 6338
info.america@elekta.com

Europe, Latin America, Africa, Middle East & India

Tel +44 1293 544 422
Fax +44 1293 654 321
info.europe@elekta.com

Asia Pacific
Hong Kong, China

Tel +852 2891 2208
Fax +852 2575 7133
info.asia@elekta.com