Elekta Neuromag® TRIUX

Safety Instructions

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ELEKTA

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US6538436 (Interference suppression)
US6876196 (Head position determination)
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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. Parts of the system are marked with this symbol when it is necessary for the user to draw attention to avoiding a potential hazard or to ensure safe, correct or improved operation and to avoid damage.

Refer to the instruction manual. Parts of the system are marked with this symbol when it is *mandatory* for the user to refer to instructions given in the manuals accompanying the system to in order to ensure safe operation. In the manuals, it also calls attention to these instructions.

Consult instructions for use. Parts of the system are marked with this symbol when it is necessary for the user to refer to instructions given in the manuals accompanying the system. In the manuals, it also calls attention to these instructions. They intend to ensure correct or improved operation and/or increased safety and to avoid damage.

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.

Disposal instruction symbol. Separate collection of waste electrical and electronics equipment (WEEE) necessary (European Union directive 2012/19/EU on WEEE).

Date of manufacture: year (four digits) followed by month and day (if applicable).

Warnings, cautions and notes

WARNING 0.0: Warnings are directions which, if ignored, can 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 you must obey to ensure safe and efficient operation and to avoid damage to the system.

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

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1 Overview of the Elekta Neuromag® TRIUX

1.1 Intended use

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 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 cortices in the brain when used in conjunction with evoked response stimulators. 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

1.3 Intended user education level

The Elekta Neuromag® TRIUX is intended to be used by medical professionals trained to use the product.

WARNING 1.1: Only trained clinicians who are capable of judging the relevance and quality of data may interpret the data for clinical purposes.

1.4 General information

Elekta Neuromag® TRIUX (articles NM23900N, NM25000N) allows simultaneous measurement of 306 MEG and, optionally, 32, 64, or 128 scalp EEG signals over the whole head. Activity of several sources all over the cortex can thus be monitored. In addition, 12 auxiliary polygraphic bipolar biopotential signals (a.k.a. bioamplifier channels) can be acquired.

Elekta Neuromag® TRIUX MEG channels are based on 306 superconducting thin-film sensors inside a cryogenic Dewar vessel. The probe unit, which comprises a gantry supporting the Dewar with sensor array, the patient bed, and the patient chair are operated inside a magnetically shielded room. The MEG electronics unit outside the magnetically shielded room reads out the sensor outputs through the filter unit, digitizes the signals, and routes the data to the main data acquisition workstation, which also controls the electronics and data acquisition.

A head position indicator (HPI) subsystem and a three-dimensional digitizer are also included to determine the position of the head with respect to the sensor array.

The subsystem including the bioamplifiers and the optional EEG channels comprises an interface for electrodes, a computer-controlled preamplifier unit, an isolation amplifier with a feedthrough filter, and main electronics. The electrode interface and preamplifier unit are built in the MEG probe unit inside a magnetically shielded room. The rest of the electronics resides outside the magnetically shielded room. The Bioamplifier/EEG subsystem is an integral, permanently built-in part of the Elekta Neuromag® TRIUX designed to be used in conjunction with MEG measurements as an additional optional source of information. It cannot be used as a stand-alone unit outside of the magnetically shielded room.

WARNING 1.2: The Bioamplifier/EEG subsystem is not certified for use with implanted electrodes. It may only be used for recording potentials from the intact body surface.

Elekta Neuromag® TRIUX includes a workstation for performing and controlling measurements and for processing of data. The software includes programs for data acquisition, electronics control, and data display. Typically, another optional workstation is also included for off-line analysis of data. The optional data analysis software includes source modeling, signal processing, magnetic resonance image (MRI) integration, visualization of combined structural and functional data, and reporting tools.

A technical description of the workstation is found in *Elekta Neuromag® TRIUX Technical Manual*.

2 Safety instructions and precautions

CAUTION 2.1: This section contains important information concerning the safe use of the product and maintaining reliable operation. Read the instructions entirely before using the product.

For units equipped with the internal helium recycler, see also the safety instructions in *Elekta Neuromag® TRIUX Internal Helium Recycler, Instructions for Use*.

2.1 Use of liquid Helium

The Dewar is a vacuum-insulated vessel containing liquid Helium at a cryogenic temperature. Since the cold liquid is potentially dangerous, certain precautions must be made in order to assure completely safe operation of the device.

WARNING 2.1: Wear protective gloves to avoid skin contact with liquid Helium or exhaust gas or any objects that have recently been in direct contact with liquid or evaporated gas. During transfer, monitor pressure gauges and do not let pressure to rise above limits described in section 3.2.

WARNING 2.2: Beware of the extremely cold, non-life-supporting gas.

2.1.1 Properties of Helium

- Helium liquid or gas is nonflammable and nontoxic
- Helium is one of the noble gases (He, Ne, Ar, Kr, Ra)
- Helium gas is odorless and colorless
- Helium gas is seven times lighter than air
- Helium gas is not life-supporting: it may replace air thus reducing the relative oxygen content in closed rooms if evaporated rapidly in large quantities, resulting in a risk of suffocation
- Boiling point 4.2 K (–269°C or -452°F)
- Density of liquid 0.125 kg/liter
- The liquid evaporates very easily (latent heat of evaporation 20.9 kJ/kg = 2.6 kJ/liter).
- One liter liquid corresponds to approx. 750 liters of gas (+20°C, 101,3 kPa).
- Skin contact with liquid or cold gas or cooled objects may cause severe frostbite
- Flow of cold Helium gas makes a very good thermal contact with any surface it passes by; unprotected skin cools below freezing point in seconds

- Dangerous pressures may arise as a result of rapid vaporization inside closed vessels
- Liquid Helium can cryopump other gases such as nitrogen, oxygen, water vapor, which at liquid Helium temperature solidify. This may lead to blocking of the vents and consequently buildup of dangerous pressures in cryogenic vessels. See Sect. 2.1.3.

2.1.2 Structural safety

- The Dewar has a good thermal insulation to minimize Helium boil-off.
- The insulating vacuum is properly sealed and all parts are fabricated leak-tight.
- Because of the thermal insulation, all parts of the Dewar that may come into contact with the user remain at room temperature at all times during normal operation.
- The cooling capacity of the evaporating cold Helium gas is employed to minimize the unavoidable heat leak from room temperature to the cryogenic temperature. Therefore, under normal operating conditions the outflowing exhaust gas is warmed up to essentially room temperature before leaving the Dewar. However, during increased outflow occurring normally only during liquid Helium refills, the gas exiting from Dewar may be extremely cold. Skin contact with the exhaust line tubings should then be avoided.
- The Helium space of the Dewar is vented to prevent buildup of pressure due to evaporating liquid Helium.
- The outflowing gas is directed via an exhaust line to open air outside the building or to gas-recovery system (if applicable).
- The dedicated exhaust line together with the sealing of the Helium space of the Dewar keeps a slight overpressure to prevent cryopumping of other gases from the atmosphere.
- The top flange of the Dewar is equipped with pressure relief valve and a rupturing membrane which will let gas out, should the pressure inside the Dewar rise for some reason. Also, a pressure gauge is attached on the top flange.
- The safety pressure relief which is based on rupturing membrane vents via a separate safety exhaust duct to outside of the building.
- The gantry is designed to keep the Dewar in proper position.

WARNING 2.3: The structural integrity of the Dewar should not be damaged in any way. Absolutely no holes may be drilled to the Dewar.

- Hard shocks to the Dewar must be avoided.

WARNING 2.4: The Dewar vacuum must not be opened to atmospheric pressure under any circumstances.

- The Dewar is equipped with a vacuum lock valve and is sealed by means of a blind flange to prevent accidental opening and leakage through the vacuum lock. The vacuum lock is operated with a separate vacuum-valve adapter.

CAUTION 2.2: The exhaust line must be open at all times

WARNING 2.5: Do not tilt or tip the storage Dewar.

- The exhaust line should be reasonably leaktight and lead out of the magnetically shielded room to open air or to the recovery system.
- The magnetically shielded room must be properly ventilated. For details, see *Elekta Neuromag® TRIUX Site Planning Guide*.
- The overpressure inside the Dewar (with respect to atmospheric pressure) should be kept below 10 kPa (0.1 bar) even during refill. Should the pressure rise, a safety relief valve will open at 10 kPa (0.1 bar). If for some reason the pressure rises even further, a rupturing membrane will break approximately at 60 kPa (0.6 bar), letting gaseous Helium to escape via the safety exhaust duct to the outside of the building.
- The fixed L-siphon (see section 3.2) used in the Helium refills and located on top of the Dewar is normally sealed with a plug that has an additional relief valve which effectively vents the cold Helium space directly into the atmosphere through the siphon in the unlikely case all other exhaust routes get blocked.
- When transferring liquid Helium, transfer instructions should be obeyed (see section 3.2).
- Transfer of liquid Helium can be carried out by a single person. For safety reasons it is, however, highly recommended that another person is present to assist or call for help in possible abnormal conditions. This is especially important if the transfer is carried out off-hours.

WARNING 2.6: Do not leave anybody alone inside a closed magnetically shielded room without the presence of another person outside the room!

- The liquid Helium level and boil-off rate should be monitored regularly. Substantial increase of boiloff rate may indicate the need to re-evacuate the vacuum. The vacuum pump-out must be left to trained service personnel.
- See also Section 2.1.3 concerning cryopumping.

2.1.3 Cryopumping

At liquid Helium temperature all common materials are solid. This means that the vapor pressure of for example the atmospheric gases (nitrogen, oxygen, water) is practically zero in any volume containing liquid Helium. This leads to so-called cryopumping of these gases: any Helium vessel left open to atmosphere will very effectively suck in large amounts of these gases. Water freezes and may block the Helium vessel or a transfer siphon. Oxygen in the probe unit Dewar causes large irregular low frequency drifts of MEG signals because the magnetic susceptibility of the paramagnetic oxygen in its solid form is very high.

CAUTION 2.3: To prevent cryopumping, observe the precautions listed below:

- All Helium vessels must be sealed from the atmosphere and properly vented, via a back flow valve or a sufficiently long and narrow exhaust tube.
- Do not leave the fixed L-siphon at the top of the Dewar open. Block the opening with the dedicated plug when not transferring Helium.
- Do not leave the boil-off tube vent directly into the room. Use silicon hose to lead the exhaust vent out from the magnetically shielded room. If the hose breaks during transfer, replace it with a new hose as soon as possible
- Do not remove the fixed siphon or the boil-off tube from the top plate. The openings must be plugged with rubber bungs (provided in the Cryogenic Accessory Kit) if the fixed siphon or the boil-off tube are ever removed even for a short while.
- If the safety exhaust rupture membrane accidentally breaks, the opening must be plugged with a large rubber bung and the membrane replaced (provided in the Cryogenic Accessory Kit) .

2.2 Electrical safety

All Elekta Neuromag® TRIUX SQUID sensor electronics is operated using low-voltage (max. 15 V=, 24 V~) power supplies connected to the mains through an isolation transformer. To avoid electrical interference, most parts are shielded and grounded (class I according to IEC 60601-1). The probe unit is operated inside a magnetically shielded room to avoid electromagnetic interference.

2.2.1 Patient environment

Since medical electrical equipment (such as Elekta Neuromag® TRIUX) may be used simultaneously or connected with other equipment (for example with third-party devices like stimulators or auxiliary non-medical devices) forming a medical electrical system, the concept of patient environment is important for electrical safety.

The patient environment is defined as any volume in which intentional or unintentional contact can occur between a patient and the medical electrical equipment or between a patient and other persons touching the parts of the medical electrical equipment. Inside the patient environment, the level of electrical safety of all parts belonging to the medical electrical system must comply with that of medical devices. Outside the patient environment, the level of safety of the system parts must be equivalent to their respective international safety standards, depending on whether the medical electrical system component is medical or non-medical.

Examples of non-medical devices that might be used simultaneously with a medical devices include, for example, computers connected to a drive a stimulator (which itself is a medical device if connected to a patient inside patient environment). The electrical safety of such computers must comply with a level equivalent to standard IEC60950 (normal IT equipment) if located outside of patient environment. However, the safety of all parts inside the patient environment must comply with a level equivalent to the medical standard IEC60601-1.

No exact dimensions for the patient environment are given in the standards. A value justified in practice is an area within 1.5 meters from the patient while positioned for diagnosis. For an MEG system, this means in practice that

- the inside of the magnetically shielded room except for the frontmost wall of the magnetically shielded room is within patient environment
- an area 1.5 meters around the 3-D digitizer is inside the patient environment

2.2.2 Patient connections

All applied parts of MEG equipment connected to the patient are made of electrically insulating materials only. They are classified as BF (body floating) type according to IEC 60601-1.

Helmet-shaped sensor assembly is located inside a double-walled isolating (fiber reinforced plastic, vacuum gap) Dewar vessel, making no electrical contact to the patient. The device does not generate radiation. During the measurement, it is not possible for the patient to get in contact with grounded parts.

Head position coils on small printed circuit boards are spiral-shaped. The coils are driven from an isolated power supply, connected to isolated leads, and cast with isolating epoxy. No electrical contact to the patient is thus made. Current fed to coils is typ. 100 µA, and the resulting field less than 1 nT.

The Bioamplifier/EEG subsystem contains an applied part of BF type (body floating) in galvanic contact with the patient. The applied part has been carefully designed and built to fulfill the safety regulations as set by international standards IEC60601-1 and IEC60601-2-26. The Bio/EEG preamplifiers are optically isolated, and the power supply of the preamplifiers is provided with safety isolation transformer.

WARNING 2.7: To eliminate any risk of electrical shock hazard the Bioamplifier/EEG subsystem must be properly installed by authorized service personnel and used as part of the Elekta Neuromag® TRIUX according to manuals and assembly instructions. Internal cabling must not be changed.

WARNING 2.8: The Bioamplifier/EEG subsystem is not certified for use with implanted electrodes. It may only be used for recording potentials from the intact body surface.

WARNING 2.9: After electrodes have been attached onto the patient'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 patient to actual ground (e.g. the wall of the magnetically shielded room). Do not place conducting grounded objects near the patient that he/she may touch while connected to the equipment.

Note: *The Bioamplifier/EEG subsystem cannot be used as a standalone unit outside of the magnetically shielded room.*

WARNING 2.10: Do not use conducting EEG paste to attach HPI coils.

There are no internal operator-serviceable parts inside. Head position indicator coils, electrode caps, headboxes, and electrode interface in the side panel of the probe unit are the only operator-accessible parts of the Bioamplifier/EEG subsystem. Use only headboxes and electrode caps supplied with the product or available as options.

2.2.3 Power supplies and grounding

The main electronics is powered through medical safety-isolating transformer connected to electronics cabinet outlets. These sockects are intended only for main electronics equiment located inside the cabinets. Connecting other electrical equipment to them effectively forms an medical electrical system (see also 2.2.5), and can result in reduced level of electrical safety. Also, internal power cabling must not be changed. For schematic diagrams of the powering, refer to *Elekta Neuromag® TRIUX Technical Manual*.

CAUTION 2.4: The power supply of the electronics must be connected only to the power outlets inside the electronics cabinet which are connected to mains via an isolation transformer. Do not connect other electrical equipment to these sockets as this may result in reduced electrical safety. Also, internal power cabling must not be changed.

CAUTION 2.5: The 3-D digitizer power supply unit must be connected to mains via an isolation transformer supplied with the Elekta Neuromag® TRIUX.

CAUTION 2.6: The isolation transformers also provide step-up or step-down voltage conversion if needed. Inside the main electronics cabinet the mains voltage is 230 V~.

CAUTION 2.7: The RF line filters in stimulus cabinet contain capacitors with large capacitance. Thus voltage may remain across terminals even after the power has been switched off from the filter. The filters have built-in resistors which discharge the terminals in less than 10 seconds. All shielding covers must be in place before applying power to the filter. The filters may only be installed permanently; mains plug connection of the filter is prohibited.

CAUTION 2.8: There are no operator serviceable parts inside the power supply units. Do not open the covers.

The Elekta Neuromag® TRIUX, except for the Bioamplifier/EEG and HPI applied parts discussed below, is permanently grounded (class I equipment according to IEC 60601-1) at a single point (main grounding point) located at the filter unit cabinet between the electronics cabinet and the magnetically shielded room (see Fig. 2.1).

CAUTION 2.9: The grounding cables must not be disconnected.

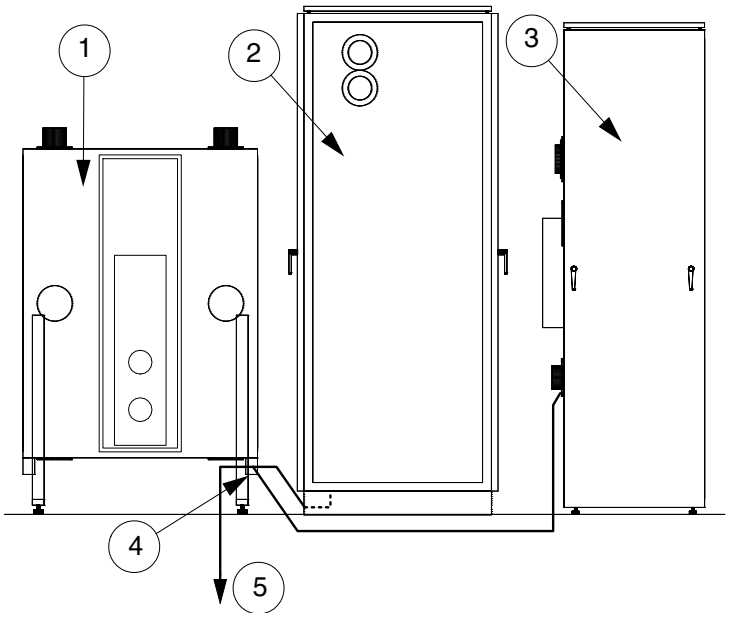

Figure 2.1 *Grounding principle. 1: RF feedthrough filter cabinet, 2: main electronics cabinet, 3: stimulus cabinet, 4: main grounding point, 5: to main gound at electric switchboard (building transformer ground).*

CAUTION 2.10: The Elekta Neuromag® TRIUX must not be grounded to any other place than the main grounding point. This is very important since otherwise ground loops will be formed resulting in artefacts in the measurements.

The grounding of Elekta Neuromag® TRIUX has been carefully designed. Do not add any equipment to the system or change any cabling without considering the possible side-effects. If in any doubt, contact Elekta.

The applied parts of HPI coils, bioamplifiers, optional EEG channels are electrically floating, i.e., isolated from ground. They must not be grounded in any circumstances. For potential equalization between the isolated preamplifier and the patient it is necessary to connect the patient to the isolated signal ground of the preamplifier. For that purpose, a terminal labelled ”GND” is available in the electrode interface panel. To limit the patient current flowing through that terminal to a safe level, the preamplifier signal ground connection is provided through a current-limited ground driver of the preamplifier (see *Elekta Neuromag® TRIUX User's Manual*). The isolated preamplifier signal ground is not directly accessible when headboxes and electrode caps supplied with the product or available as options are used. The isolated preamplifier signal ground, which is only available internally, must not be connected directly to patients as the maximum allowable current may be exceeded in a fault condition.

2.2.4 Fire safety

The power supply units are protected by mains (primary) fuses. All fuses are accessible at the back plane of the MEG preamplifier power supply unit with the correct values of the fuses marked in the immediate vicinity. A “T” before the rated current in amperes indicates slow (time-lag, slow blow) type and a “F” fast type. If no type has been indicated, use fast type fuses.

CAUTION 2.11: To avoid risk of fire and of electric shock ALWAYS use only correct-rated fuses as replacement.

The Elekta Neuromag® TRIUX is also equipped with temperature sensors in power supplies to detect over-heating.

CAUTION 2.12: Overheating is normally a symptom of a fault. To reduce risk of fire the reason must be resolved if the thermal shutdown repeats.

The Elekta Neuromag® TRIUX is not category AP or APG (for definition, see Appendix). It is not intended, designed, nor certified for use within an environment containing flammable anaesthetic mixture with air, oxygen, or nitrous oxide.

WARNING 2.11: Do not bring flammable anaesthesics into the magnetically shielded room or into the equipment area of the Elekta Neuromag® TRIUX.

2.2.5 Third-party devices and other auxiliary user-supplied equipment

As described above in section 2.2.1, other equipment connected simultaneously to the patient or to the Elekta Neuromag® TRIUX form a medical electrical system. Such combination may compromise the electrical safety without proper precautions. Also, the electromagnetic compatibility (see section 2.6.1) may be jeopardized.

Elekta assumes responsibility only for third-party equipment or components that are expressly recognized as compatible by Elekta. Elekta assumes no responsibility for the compatibility, fitness for use, or safety of third-party equipment not expressly recognized as compatible by Elekta.

WARNING 2.12: The use of unapproved third-party equipment, may lead to serious injury and/or damage to the equipment.

To avoid risk of electrical shock, equipment supplied by the user and connected to patients must comply with isolation requirements similar to or better than this system. For connection of these devices, isolated and filtered power outlets are provided in the stimulus cabinet. Maximum current available is 10 A (total).

WARNING 2.13: Parts of user-supplied equipment inside the patient environment (see section 2.2.1) must fulfill leakage current requirements according to the norms IEC 60601–1 for medical electrical equipment with BF type applied parts or better. Although the individual devices fulfill the leakage current requirements set forth in standards, a possible hazard exists caused by the summation of leakage currents when several pieces of equipment are interconnected.

CAUTION 2.13: If any of the equipment connected to the the stimulus trigger interface unit is patient-connected, all other equipment connected to the same interface unit must fulfill the safety requirements of IEC 60601-1 for medical electrical equipment.

Note: *The power outlets in the electronics and stimulus cabinets may only be used for the connection of system components or equipment needed during service and maintenance operations (electronics cabinet) or for compatible user-supplied auxiliary equipment (stimulus cabinet).*

2.2.6 Defibrillators

Note: *The Bioamplifier/EEG subsystem is not protected against cardiac defibrillator discharge. Damage to the front end may result if a defibrillator is used on a patient connected to the electroencephalograph. In case of a need for defibrillation, disconnect the electrodes if possible. This is carried out quickly by unplugging the electrode cap or headbox connectors and the single electrodes (if any) from the electrode interface panel.*

The Elekta Neuromag® TRIUX cannot be used with treatment devices feeding energy to the patient such as high-frequency surgical equipment.

2.2.7 Changes to the product

Any changes to the equipment provided by Elekta may only be performed by persons expressly authorized to do so by Elekta. Such changes must comply with best engineering practices, effective laws, and regulations that have the force of law within the applicable jurisdiction.

CAUTION 2.14: Changes, additions, or maintenance to the equipment performed by persons without appropriate qualifications, and training, may introduce risks of serious injury and/or damage to the equipment. Furthermore, such alterations may void the warranty of the Elekta Neuromag® TRIUX. No modification of this equipment is allowed without authorization from the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted in order to ensure safe use of the equipment.

2.3 Mechanical safety

The weight of the fully loaded Dewar including liquid helium and the Dewar supporting cradle moving with the sensors is approximately 200 kg. To ensure that the Dewar is prevented from falling down from lower or upper seated measurement positions under any circumstances it is equipped with two completely separate and parallel support mechanisms. The lifting motor and the safety latches on both sides of the Dewar cradle, engaged in measurement positions, can both withstand alone an four-fold overload compared with the normal working condition. In supine position, the end stoppers prevent the cradle from coming out even if a fault occurs, e.g. the lifting rope breaks. To ensure safety even in case of a single fault the Dewar must be in one of the three secured measurement positions with latches engaged while a patient is positioned under the Dewar. For position changing instructions, see *Elekta Neuromag® TRIUX User's Manual*.

WARNING 2.14: The measurement position must not be changed while the patient is under the probe unit.

WARNING 2.15: Do not place the patient under the probe unit except when the green *OK* light is lit on the position indicator display.

The patient is released from the helmet in the lower or upper seated measurement position by releasing the elevation mechanism of the chair and pulling the chair from underneath the Dewar. For instructions, see *Elekta Neuromag® TRIUX User's Manual*.

In the supine measurement position release the upper patient bed and pull it out. For instructions, see *Elekta Neuromag® TRIUX User's Manual*.

CAUTION 2.15: Care should be excercised to prevent limbs, fingers, or toes being left between moving parts of the chair or bed and probe unit or doorway. Instruct the patient to keep hands on the table or armrests.

Have the unit regularly serviced according to the maintenance program (see *Elekta Neuromag® TRIUX User's Manual*). This must be accomplished by trained service personnel only.

2.4 Trapped flux in the sensors

Strong magnetic fields in the vicinity of the sensors may cause magnetic flux to be trapped in the superconducting thin films due to their limited capability of repelling magnetic flux completely. In particular, if magnetized objects like magnetic electrodes or hairpins are brought inside the helmet against the surface, flux trapping may occur.

Trapped magnetic flux in the dc SQUID manifests itself as a greatly reduced modulation depth of the flux vs. current characteristics. The point of operation also changes. As a result, the SQUID feedback loop may not lock any more after flux trapping or the noise level may be increased, resulting in deteroriated signal quality. Flux trapped in the flux transformer structures may manifest itself as discrete jumps in the output level causing rejections of evoked data.

Normal performance may, however, be recovered by detrapping (see section 2.4.2). In the detrapping procedure, the trapped flux is removed by increasing the temperature above superconductive transition temperature using heaters mounted on each triple sensor element. In order to minimize the delay due to the flux detrapping in a measurement certain precautions should be noticed.

2.4.1 Preventive measures

The only way of avoiding trapped flux is to avoid bringing permanently magnetized objects in the vicinity of the Dewar. Therefore:

- Items unnecessary for the measurement should be removed (hairpins, jewelry, eyeglasses etc.)
- Test the objects worn by the patient, particularly on the head like electrodes, before the patient goes under the Dewar. In particular, test a new batch of electrodes before they are taken into use.
- To test whether an object is magnetic or not: First, test whether the object attaches to an ordinary bar magnet. If it does, the object is magnetic and it should absolutely be kept out of the magnetically shielded room. If the object is not attracted to the bar magnet, do a test with the Elekta Neuromag® TRIUX. Ask for someone to assist you in the test. First, carefully remove everything possibly magnetic from your pockets, wrist watch, belt, eyeglasses etc. Go with the object to be tested inside the magnetically shielded room and close the door. Ask the assisting person to start acquisition of data and watch the raw data display as described in the *Elekta Neuromag Data Acquisition User's Manual*. Wave your bare hand under the magnetometer helmet to verify that it does not cause any noticeable signals. Then, take the object under test in your hand and wave it first 1 m away from the helmet to see whether it causes any disturbances. If not, move it closer and finally under the helmet if still no disturbances are see. If, however, disturbances are seen the object is too magnetic for MEG and it should be avoided in measurements.

Note: *Do not bring the bar magnet inside or even close to the magnetically shielded room. Do not attach the bar magnet to the magnetically shielded room wall as it will magnetize the wall material to saturation, severely degrading the shielding performance.*

- Avoid bringing magnetic objects and devices (e.g. heavy tools or devices with electric motors) into the magnetically shielded room. If it is absolutely necessary, keep them as far as possible from the sensors and their power cords as far as possible from the probe unit. Nonmagnetic tools are also commercially available.
- Do not use electronic flash inside the magnetically shielded room.
- Avoid discharges of static electricity on any part of the probe unit. The humidity in the magnetically shielded room should be controlled according to *Elekta Neuromag® TRIUX Site Planning Guide*.
- The electrodes and electrode caps should be stored carefully, preferably hanging in dry room air. Do not keep the electrodes and the caps on a table where they might be contaminated with magnetic particles. Wash them carefully after each use (see cleaning instructions and instructions supplied with the electrode cap in *Elekta Neuromag® TRIUX User's Manual*).

Note: *The connectors used in the headbox may contain a thin intermetallic layer of magnetic material. To avoid magnetic artefacts during MEG measurements, do not bring the headbox close to the helmet and keep it steady. Put it on the bed or on the removable table of the chair at least 0,5 m away from the helmet. Do not put it in the patient's lap or on the chest as movement caused by respiration may produce an artefact. A detchable headbox support attached to the probe unit is also provided.*

2.4.2 Detrapping

The Elekta Neuromag® TRIUX triple sensors are equipped with heaters. To detrap a sensor, invoke program *Tuner* from the *Tools* Menu of the Data acquisition program. Then, activate the heater from the program. You can heat any sensor element (three channels) at a time or all sensor elements sequentially (*Heat all* command). Detrapping all channels takes about one minute. Measure the noise level of the sensor, and, if necessary retune the sensor. For further details, refer to *Sensor Tuner User's Manual*.

2.5 Electrodes

In combined MEG/EEG measurements, the choice of proper electrode materials and paste/gel is very important.

As the electrodes and the electrode cap are very close to the magnetometer sensors, they are particulary prone to cause magnetic artefacts. Even a thin layer of magnetic material or a small particle of ferromagnetic dust can cause magnetic artefacts to one or more MEG channels.

When operated in dc-coupled mode electrochemical battery potentials generated in electrodes are amplified by the preamplifier. This causes a risk of saturating the amplifiers. In fact, even in ac coupled mode saturation may occur if the electrochemical potential exceed specified limits (see *Elekta Neuromag® TRIUX Technical Manual*) since frontmost amplification stage is internally always dc coupled. Furthermore, if the connection between the electrode and skin is not stable movements tend to change the electrode potential and cause severe low frequency noise or drift.

Note: *The use of sintered Ag/AgCl electrodes is recommended since they are known to minimize the electrochemical battery potentials, they are non-magnetic (see section 2.4), and relatively easy to obtain. It is best to have all electrodes made of same material and to use the same electrode paste/gel. Specifically, all the electrodes of the unipolar channels and the reference channel must be of same material and use the same electrode paste/gel. In order to maintain good performance, the AgCl coating must cover the whole electrode surface; worn or scratched coating may result in electrochemical battery potentials saturating the amplifier. Sintered Ag/AgCl, because of their construction, resist mechanical wearing much better than coated solid metal electrodes*

Note: *Gold-coated electrodes are not recommended since most often they contain a magnetic intermetal layer making them incompatible with MEG measurements. Also, some commercially available Ag/AgCl electrodes contain nickel or other magnetic material; all electrodes must therefore be tested before using them with MEG (see section 2.4.1.).*

The electrodes in caps supplied with the Elekta Neuromag® TRIUX as an option are made of sintered Ag/AgCl and tested to be non-magnetic.

Note: *Electrode caps available commercially elsewhere may be incompatible with MEG.*

For cleaning, disinfecting, and maintenance of the electrodes, refer to *Elekta Neuromag® TRIUX User's Manual* and electrode cap documentation.

WARNING 2.16: Avoid getting the electrode paste or gel to the eyes or mouth. Use only non-toxic pastes approved for clinical use.

2.6 Electromagnetic compatibility

CAUTION 2.16: Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC). It needs to be installed and put into service according to the EMC information provided in this manual and *Elekta Neuromag® TRIUX Technical Manual*.

CAUTION 2.17: Portable and mobile RF communications equipment (e.g. mobile phones) can disturb medical electrical equipment.

WARNING 2.17: Do not use stimulators or other equipment containing magnetic material in parts in the immediate vicinity of the probe unit or which produce high electromagnetic fields inside the magnetically shielded room as this may deteriorate signal quality and lead to incorrect results.

Note: *Elekta assumes responsibility only for electromagnetic compatibility of such third-party equipment or components that are expressly recognized as compatible by Elekta. Elekta assumes no responsibility for the electromagnetic compatibility of third-party equipment not expressly recognized as compatible by Elekta.*

2.6.1 Electromagnetic interference

The probe unit including the Bio/EEG preamplifiers and the electrode interface is placed inside a magnetically shielded room, and all cables to the inside of the room have been carefully filtered. This immunity can, however, easily be corrupted by careless setups of additional equipment. This is especially important for MEG recordings.

WARNING 2.18: Radiofrequency (RF) electromagnetic intereference may deteriorate signal quality and lead to incorrect results. Do not use any own wiring leading from outside to inside of the magnetically shielded room without proper RF filtering.

To maintain high level of electromagnetic interference immunity, all cables coming to the magnetically shielded room must be properly filtered. Radiofrequency transmitters, like mobile phones as well as mains operated devices and active digital electronics inside the magnetically shielded room, must be avoided altogether. Use of the stimulus cabinet outside of the magnetically shielded room is highly recommended for other equipment. There is a direct access from the stimulator cabinet to the inside of the magnetically shielded room, and the stimulus cabinet is equipped with signal and mains feedthrough filters. Place, for example, the isolation units of somatosensory stimulators inside the stimulus cabinet. To avoid radiated intereference via cabling, digital electronics which is active during measurement should, however, be avoided also inside the stimulus cabinet.

2.6.2 Electrostatic discharges

Note: *The probe unit and the electronics contain static electricity sensitive components. To prevent flux trapping or permanent damage certain precautions are necessary. Pins or connectors marked with the ESD symbol should not be touched and connections should not be made to these connectors unless ESD precautionary procedures are used.*

Note: *It is recommended that the meaning of the ESD symbol should be explained to all staff involved in the use of the Elekta Neuromag® TRIUX. They should also receive training covering the precautionary procedures described below.*

Precautions to avoid damage to equipment due to static electricity:

- The properly grounded and shielded cabinets and racks are the most effective shield against damage. In normal operation, there are no parts inside the main electronics cabinet or the probe unit the user needs to access. Do not remove any covers and do keep the cabinet doors closed.
- Do not touch the pins of connectors or cables, the electronics backplane, or the electronics boards before grounding yourself properly.
- Ground yourself with a grounding wrist strap or by touching any metallic parts of the magnetically shielded room or inside the electronics cabinets. To minimize the danger of electric shock it is recommended to use a grounding strap specially made for this purpose that contains a built-in series resistance. Connect it to the cabinet frame or wall of the magnetically shielded room.
- To prevent static electricity discharge to preamplifiers while connecting or disconnecting head position indicator coils, electrodes or electrode caps, the relative humidity of the air inside the magnetically shielded room should be over 30%, preferably between 40% and 70% (see *Elekta Neuromag® TRIUX Site Planning Guide*).
- Leave electronics service to trained service personnel.
- Do not disconnect the electronics cables or boards from the top flange of the probe unit or electronics cabinet or any other internal cables.
- Handle electronics boards only on static-electricity-free surfaces
- All strain relievers and covers must be in place before connecting power to the electronics. Follow proper power-up instructions (see *Elekta Neuromag® TRIUX User's Manual*).

2.7 Information security

All workstations delivered by Elekta are factory-configured with predefined user accounts and default passwords. Upon commissioning, all user passwords must be immediately changed to secure ones in order to protect the workstations against intrusions and malware.

CAUTION 2.18: Not following the instrucions presented here may cause incorrect operation of the system which can lead to an incorrect diagnosis, or disclosure of sensitive patient information.

To maintain information security, all users should change their passwords at frequent intervals and to keep the password in a safe place.

- Choose a password with at least 8 characters and a mix of different character types.
- Never use names, words found in a dictionary, phone numbers, dates, or simple combinations of the same.
- Never use a keyboard pattern, such as lines of keyboard keys or sequences of digits.
- Use a sequence of random characters, including a mix of upper and lower case letters, and punctuation marks.
- An easy way to generate a secure password is to start with a phrase, verse, or line from a song. Take first letters of words and transform some characters into numbers or punctuation marks resembling the original letter, also inserting additional punctuation and/or digits if appropriate. Use also a mix of upper and lower case.

Furthermore, the entire data acquisition system as well as all data analysis workstations must always be protected against intrusions by means of a firewall. Consult your Elekta service representative for further information on configuring the firewall hardware to protect the Elekta Neuromag® TRIUX.

Do not connect other devices to the data acquisition network, disconnect devices, or alter the data acquisition network or its configuration in any way.

When connecting other devices, except those that are explicitely allowed by Elekta, to the MEG laboratory side network, or changing the laboratory network configuration, the possible risks must be analyzed and handled, by the user organization.

If any other programs, except those explicitely approved by Elekta, are installed on the data acquisition workstation, including possible patches to operating system and other updates or upgrades, they must be validated by the user organization.

The web browser in the workstation installation is intended to be used only to browse files stored in the workstation and other safe locations. Though the operating system (Linux) is relatively safe, browsing files in Internet is still dangerous and not allowed. If you can browse the internet, please consult your IT or Elekta service since this means that your firewall is not properly configured.

Login access to the data acquisition workstation should be given only to persons who have right to access the patient information stored on the workstation. Although restricted visibility of the patient information is provided between project groups, the system architecture does not prevent unauthorized access to patient-specific information. To avoid exposure of patient information, do not include the name or other explicit identification information in any field of the patient record.

Note also that the workstations must be physically protected. The data on the disks is not encrypted and thus in principle accessible by anyone who has access to the physical disks. In addition to loosing sensitive information stored in the workstation, it opens may possibilities for several different kinds of attacs against the security, which may compromise also other systems which share user credentials like passwords.

2.8 Other warnings

MEG data can be inherently be explained by many different source distributions, and measurements often contain various kinds of artefacts. Data used for clinical purposes must be interpreted by a trained clinician who is capable of judging the relevance and quality of data.

WARNING 2.19: Only trained clinicians who are capable of judging the relevance and quality of data may interpret the data for clinical purposes.

Errors and artefacts in the data may, e.g., result from external interference or from patient head movements or inoptimal placement inside the probe unit helmet, especially for persons with small heads or for children.

WARNING 2.20: Excercise care when measuring and interpreting data from small infants or persons with small heads.

WARNING 2.21: Data quality should always be monitored during acquisition. Also, eventual interference should be checked before acquisition.

WARNING 2.22: Large metallic objects located near the 3D-digitizer may adversely affect the accuracy of the readings and thus the accuracy of source localization.

Note: *In case of studying patients or small children an accompanying person in the magnetically shielded room is highly advisable, particularly if it is likely that the patient cannot call for help or get out in case of emergency. Audio and video monitoring is also recommended. Test the audio and video monitoring before use.*

Note: *If stimulation is used, it is important to test the stimuli before the actual acquisition. To prevent sensory damage or miscomfort to the patient and incorrect interpretation of measurement results, it is important to verify that the delivered intensities are correct and that the physical stimuli and their planned trigger line assignments match, e.g. there are no swaps or mixups.*

Note: *When digitizing the HPI coils, place the goggles firmly on the patient's head and tighten the strap.*

2.9 Getting the patient out in case of emergency

Note: *Remove the safety belts (if used).*

Note: *In all measurement positions disconnect the Bioamplifier/EEG- and HPI-cable connectors prior to moving the patient if possible.*

In the supine measurement position and when head support is used, release the lock of the upper bed and then pull the upper bed outwards.

If the head support of the upper bed is not used, pull first the patient's upper body so that the patient's head is out of the helmet on the bed. Release the lock if applic ble.

In the lower or upper seated measurement position one should first lower the seat of the chair by pushing down constantly the release pedal and then by pulling the chair from underneath the helmet using the handle.

3 Cryogenics

3.1 Precautions

WARNING 3.1: As to potential hazards and necessary precautions for handling liquid and gaseous Helium, refer to Section 2.1 in addition to this Section. Before attempting to transfer liquid Helium read first that section and these instructions entirely.

When refilling the Dewar with liquid Helium one must be aware of and respect the following physical facts:

- Liquid Helium is very cold and the latent heat of evaporation is very low. Therefore, Helium stays in liquid form only in specially designed vessels or transfer tubes. If the liquid gets in contact with objects at temperatures higher than 4 K it will immediately evaporate and expand. At room temperature the volume of the gas is 750 times larger than the liquid volume. This means that a potential for dangerous pressure rise always exists if this cryogenic liquid is handled carelessly or left to warm up in a completely closed volume.
- At liquid Helium temperature all common materials are solid. This means that the vapor pressure of for example the atmospheric gases (nitrogen, oxygen, water) is practically zero in any volume containing liquid Helium which leads to cryopumping (see 2.1) of these gases: any Helium vessel left open to atmosphere will very effectively suck in large amounts of these gases. Water freezes and may block the Helium vessel or a transfer siphon. Oxygen in the probe unit Dewar causes large irregular low frequency drifts of MEG signals because the magnetic susceptibility of the paramagnetic oxygen in its solid form is very high.. Because of the above, all vessels containing liquid Helium must be sealed from the atmosphere and properly vented, via a back flow valve or a sufficiently long and narrow exhaust tube.
- Flow of cold Helium gas makes a very good thermal contact with any surface it passes by: unprotected skin cools below freezing point in seconds.
- Even after warming up to room temperature the odorless and colorless gas may cause a risk of suffocation if ventilation is not taken care of. Breathing Helium gas does not bring about any physiological unpleasent symptoms before dizziness. The pitch of the voice of the person characteristically raises when a large fraction of air is replaced with Helium gas.

You should avoid using magnetic tools and electrical equipment, like hot air guns inside the magnetically shielded room. If absolutely necessary, they must be kept more than one (1) meter away from the sensor array. For sensor detrapping, see section 2.4.2.

3.2 Helium transfer procedure

If the internal helium recycler option is installed, this section is not applicable. See *Elekta Neuromag® TRIUX Internal Helium Recycler, Instructions for Use*.

Familiarize yourself with safety instructions before transferring Helium.

WARNING 3.2: Wear protective gloves to avoid skin contact with liquid Helium or exhaust gas or any objects that have recently been in direct contact with liquid or evaporated gas. During transfer, monitor pressure gauges and do not let pressure to rise above limits described below.

This section gives instructions how to transfer liquid Helium using the manual pressurizing unit. For instructions how to transfer with pressurized Helium from a gas cylinder (pressurizing unit available as an option), refer to *Liquid Helium transfer with pressurized Helium gas User's Manual*.

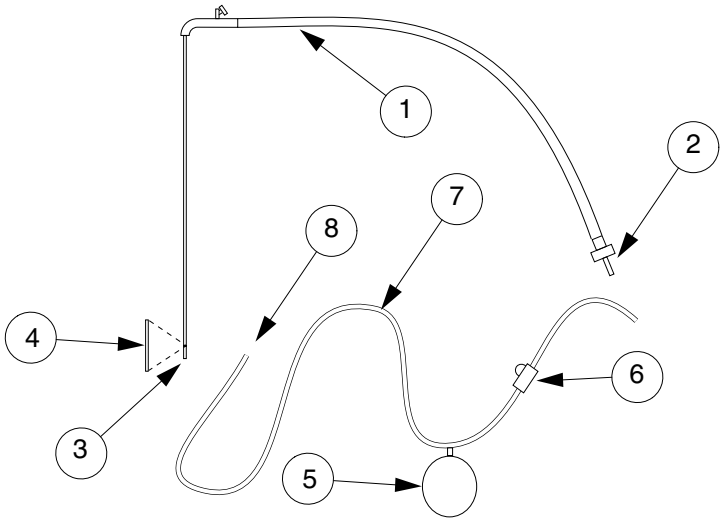

Figure 3.1 *Parts needed in liquid Helium transfer. 1: Flexible siphon, 2: siphon tip, 3: filter unit, 4: extension tube (optional), 5: manual pressurizing unit, 6: hose clamp, 7: transfer exhaust silicon hose, 8: connection to storage Dewar venting port. The other end of the silicon hose may be left free or connected to Helium recovery system (if installed).*

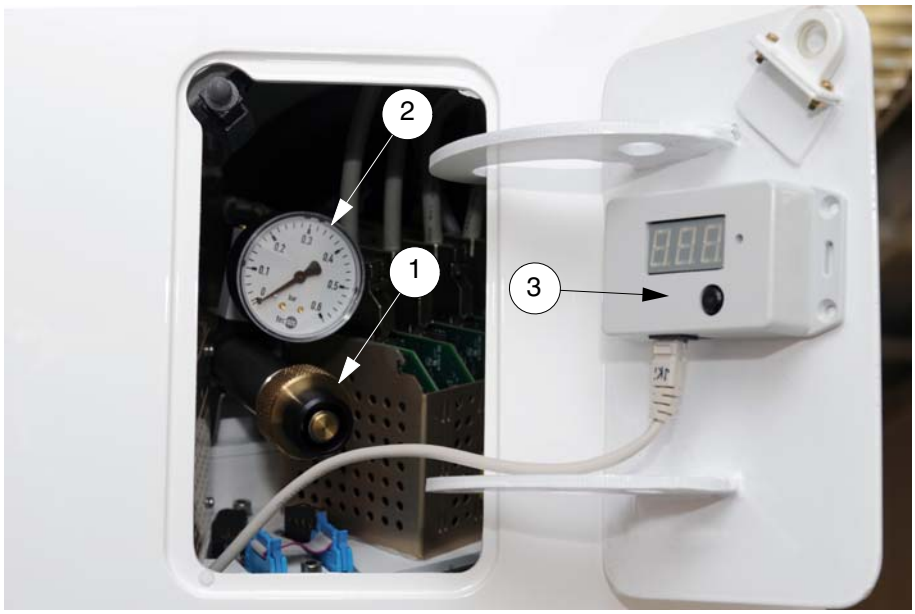

Figure 3.2 The liquid Helium filling port on the upper part of the probe unit front face. 1: Fixed L-siphon port with plug, 2: pressure gauge, 3: liquid Helium level local display.

Figure 3.3 The plastic cap for flexible siphon.

Figure 3.4 Inserting the flexible siphon into fixed siphon.

1. For helium refill, at least 90 liters of liquid Helium is needed in a nonmagnetic storage container is needed. When scheduling liquid Helium orders from the supplier (100 liter containers recommended) please note that the amount of liquid in storage dewars will boil off with a rate of typically 1-2 liters per 24 hours.

2. If the exhaust line is equipped with an electrical Helium gas flow meter (outside of the MSR, not installed on most sites), bypass the meter by opening the bypass valve.

3. Move the probe unit to supine position.

4. Move the storage container to the magnetically shielded room entrance and connect the exhaust of the storage container to the transfer exhaust hose. The hose includes a rubber balloon pump (manual pressurizing unit) and a plastic hose clamp valve, see Fig. 3.1. Close the hose clamp, then open the exhaust valve on the storage container and let the pressurizing unit balloon fill up. Then close the exhaust valve, open the hose clamp, and squeeze the balloon. Repeat this procedure 2–3 times, it will flush air out of the transfer hose and balloon. Close the hose clamp and the safety relief valve of the storage container.

5. Clean your hands. Check that the filter unit at the tip of the thin, stiff part of the transfer siphon is in place (see Figure 3.1). The siphon extension tube can be used if needed. The extension tube is mounted between the filter unit and the vertical part of the siphon.

6. Check that the Helium exhaust line is unobstructed.

7. Put thick protective gloves supplied in the Cryogenic accessories kit on. Lower the transfer siphon very slowly into the storage container. Block the transfer exhaust hose with the plastic hose clamp valve. Close the relief valve of the storage container. Helium gas should be let flow through the siphon in order to get air out of it and to precool it. *Beware the extremely cold gas stream*. When the Helium gas flow starts to resemble a white flame open the hose clamp and temporarily plug the open end of the transfer siphon with a plastic plug supplied (see Fig. 3.3). Continue to lower the siphon to the bottom of the storage container.

8. Move the storage container into the magnetically shielded room. Leave the door open. If you have a long siphon (can be ordered separately) the storage container can be left outside of the room. If you have a long siphon with the storage container outside of the room, ground the braided cover of the siphon to the magnetically shielded room wall and support the long flexible tube at least at one point; the exact realization of such arrangements is site-dependent.

9. Use thick protective gloves and beware of the cold Helium flowing out. Remove the plastic cap covering the siphon tip. Loosen the plug at the fixed L-siphon port of the probe unit of the Elekta Neuromag® TRIUX. Replace the plug *as quickly as possible* with the tip of the flexible siphon (see Fig. 3.4). During the short interval when the fixed siphon on the probe unit is unplugged there should be Helium flowing out of the fixed siphon as well as from the flexible siphon. If this is not the case there might be a plug of frozen air in the siphon, see *Elekta Neuromag® TRIUX User's Manual*. Secure the siphon in place by tightening the knurled sleeve nut on the siphon. Place the plug of the fixed siphon to a place where it is readily available, e.g., the plug holder at the cover of the refill opening.

10. Block the transfer balloon exhaust hose with the plastic clamp again and pump gently with the rubber balloon. Follow the pressure from the probe unit of the Elekta Neuromag® TRIUX pressure gauge (see Fig. 3.2); *do not let the pressure rise over 0.1 bar (10 kPa)*. The pressure rises quickly at first. When the flow of liquid starts after a few minutes the pressure goes down for a moment and then rises again to approximately 0.04 — 0.07 bar (4–7 kPa) depending on the flow impedance of the exhaust line. After the liquid starts flowing you can usually pump the balloon continuously until the transfer is complete. Follow the liquid helium transfer progress with the local liquid Helium level display. When the desired Helium level is reached, release the transfer exhaust hose clamp valve and let the pressure stabilize for a couple of minutes.

11. Detach the siphon from the probe unit when the pressure has decreased. Have the plug ready. Pull the tip of the siphon out and insert the plug as quickly as possible. Tighten the plug. Move the storage container out of the magnetically shielded room and lift the siphon out. Use gloves to avoid frost bite. Close the exhaust valve on the storage container. Disconnect the transfer hose and open the relief valve on the storage container.

12. Close the bypass valve (if installed) of the electrical gas flow meter.

13. Return the storage container to its place.

Note: *After finishing transfer, check that all valves are in their normal positions, that is, vessels containing liquid helium are vented through their proper return lines and all the other valves are closed.*

Note: *Make sure to switch off the local liquid Helium level display.*

Note: *Do not change the probe unit position immediately after transfer as the thermal insulation on the exhaust lines is very cold and might break easily. Allow 1 hour before changing position.*

3.3 Troubleshooting transfer problems

Use caution and care when handling the Helium storage containers. One liter of liquid Helium corresponds to approximately 750 liters of Helium gas at 20°C, 101.3 kPa (NTP, Normal Temperature and Pressure). Cold Helium may cause frost bites and it may replace breathing air. However, there is no need to be alarmed when liquid Helium is properly handled.

WARNING 3.3: Beware of the extremely cold, non-life-supporting gas.

The following hints may help you in solving problems which may arise during a transfer:

3.3.1 Overpressure

- The pressure in the probe unit of the Elekta Neuromag® TRIUX goes high.

  Release the hose clamp valve blocking the transfer exhaust hose (see Fig. 3.1). If the pressure still keeps increasing, open the relief valve on the storage container and the siphon precooling valve. Watch out for the eventual stream of extremely cold gas.

  The relief valve of the probe unit will open when the pressure inside the Dewar is 10 kPa (0.1 bar). If the pressure goes up further to approximately 60 kPa (0.6 bar), the safety rupture membrane on the top plate breaks and Helium gas will flow though the emergency duct. Should this happen or if the membrane breaks by itself, plug the safety duct with a rubber bung contained in the Cryogenic accessory kit after the pressure has decreased. To plug the duct, release the hose clamp attaching the flexible duct to the fiberglass feedthrough tube at the back of the gantry, remove the duct from the feedthrough and plug the duct end. Try to identify the cause of the pressure rise, and have the safety rupturing membrane replaced by Elekta service.

3.3.2 Leaks

- The frozen silicon exhaust hose of the probe unit breaks because of thermal stresses and helium leaks into the magnetically shielded room.

  This may be associated with a loud popping sound and a greyish cloud of gas caused by condensing moisture. This may sound and look dramatic but *do not panic*.

  Should this happen, open the hose clamp valve at the transfer exhaust hose of the storage container and let the pressure drop. *Beware of the extremely cold, non-life-supporting gas*.

  You may wish to step out of the magnetically shielded room while waiting for the pressure to drop. Replace the broken silicon hose when it has warmed up sufficiently. There is a spare hose and plastic connection pieces in the Cryogenic Accessory Kit provided with the Elekta Neuromag® TRIUX.

- The joint between the storage container and flexible siphon stiff part leaks.

  The stiff part of the flexible siphon is sealed with an o-ring which can be tightened. If the seal starts to leak, the o-ring will be cooled and become very hard whereby it will not be able to tighten the joint properly. Release pressure from the storage container and let the joint warm up. Try tightening the o-ring seal or replace the o-ring (can be found in the cryogenic accessory kit) if necessary. The flexible siphon stiff part has an outer diameter of 12 mm, and the storage container o-ring should have correspondingly an inner diameter of 12 mm. A half-inch inner diameter will not be tight enough. Use vacuum grease (also in the Cryogenic accessory kit).

4 Method of coregistration of MEG sources and anatomy

In order to be able to locate signal sources relative to the head, one must know the position of the head within the probe. For this purpose we use a head position indicator (HPI) system. Before the measurement, one attaches small coils to the head and digi- tizes their locations on the head. These coils are then used during the measurement to measure the location of the head.

The Elekta Neuromag® TRIUX internally uses device coordinate system. The recorded signals represent field components at fixed sensor locations in the device coordinate system. The origin of this coordinate system is located at the center of the posterior part of the helmet with x-axis from left to right, y-axis pointing from back to front, and z-axis pointing up. Thus the position of subject's head in respect to the measurement probe does not affect the way the signals are recorded.

The results of source modeling calculations are presented in a more relevant coordinate system, namely the head coordinate system (also called the anatomical coordinate system). This is essential in order to integrate the source model into an anatomical image, e.g. magnetic resonance image.

The head coordinate system is defined as follows: The x-axis passes through the preauricular points with positive values on the right, the y-axis will be perpendicular to the x-axis, passing through the nasion and the positive axis pointing towards the nose, and the z-axis will point up, perpendicular to the xy-plane. This is illustrated in figure below. LPA and RPA stand for the left and right peri- or preauricular points, respectively. LPA, RPA and nasion are called the anatomical landmarks or cardinal points.

To establish the coordinate transformation between the head coordinate system and the device coordinate system the anatomi- cal landmarks have to be expressed in the device coordinate sys- tem. This is done indirectly by using HPI coils whose locations can be measured with respect to the anatomical system and also with respect to the device coordinate system. The former mea- surement is called Head digitization and the latter HPI measure- ment. The combination of these two measurements results in a coordinate transformation between device coordinate system and head coordinate system.

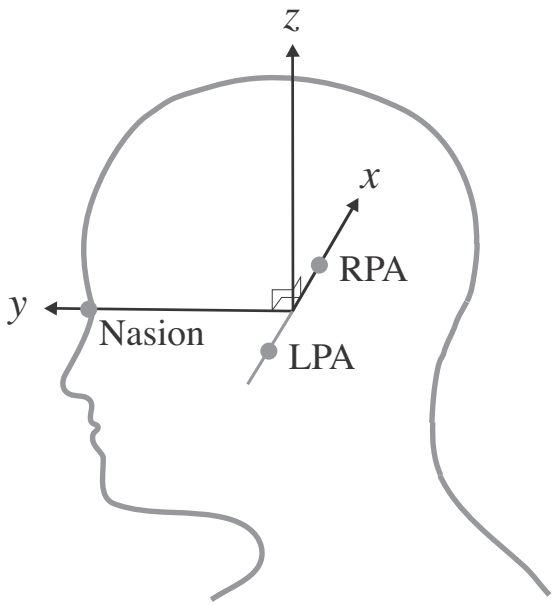

Figure 4.1 Head (anatomical) coordinate system.

5 Maintenance

5.1 Maintenance program

The following maintenance program is recommended:

- Before every measurement: check artefacts and noise (check made by user)
- Every morning: check Helium level, check MEG noise by recording signals without patient, determine need for tuning, tune if necessary (made by user). For bioamplifier and EEG channels verify the operation by using the internal calibration signal (test made by user).
- After every Bioamplifier/EEG measurement: cleaning of electrodes and electrode caps, check for wear (made by user)
- According to a site-specific user-derived schedule, about once a week: liquid Helium refill (made by user). A fixed weekly schedule is recommended. Not necessary if the internal helium recycler is used.
- Regular: phantom measurements, daily or at least once a week, are recommended (made by user). See *Elekta Neuromag® TRIUX User's Manual*.
- Weekly: free disk space monitoring and cleanup. See *Elekta Neuromag® TRIUX User's Manual*.
- Once every year: annual preventive maintenance service (made by authorized service personnel)

5.2 Cleaning

The HPI coils and the painted parts of the Elekta Neuromag® TRIUX can be cleaned and disinfected with pure alcohol. Acetone is not recommended as it may damage the insulating surface.

The upholstering of the patient's bed and chair, and the wooden digitization chair are cleaned with soap water or ordinary mild dish care detergent.

For cleaning the electrode caps, refer to the instructions delivered with the caps.

The white cover of the phantom can be cleaned with with soap water or ordinary mild dish care detergent.

The workstation and its display included in the Elekta Neuromag® TRIUX must be cleaned with agents and wipes specifically designed for this purpose. Do not spill liquids inside the keyboards or other devices where they can cause short-circuits and damage to the devices.

Note: *When cleaning the probe unit, especially the interior of the helmet (= outer surface of the helmet), observe that risk of flux trapping to sensors exists, resulting in artefacts. Therefore, magnetic objects like wristwatches, belt buckles, magnetic buttons on sleeves etc. must not be brought in the vicinity of the Dewar. Refer to section 2.4.*

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Human Care Makes the Future Possible

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