

Elekta Neuromag® TRIUX Stimulus System User's Manual



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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, 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 mis-treatment.



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.

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1 General

This document applies to the following stimulus generation devices, used together with Elekta Neuro-mag® TRIUX:

- NM21711N Audiovisual stimulus presentation system (Stim2)
- NM21709N Somatosensory stimulator

Both devices have their own manuals that cover the use of the devices alone. This document contains important information on the installation and use of the stimulus devices together with the Elekta Neuro-mag® TRIUX.

The stimulus generation devices listed above may be connected to accessories and consumables:

- NM24034N High-fidelity visual stimulator (video projector and screen)
- NM24035N Auditory stimulator (headphones)
- 961460 Replacement felt tip (for somatosensory stimulator electrode)

2 Installation



CAUTION 1.1: Improper installation of the stimulus equipment can result in increase of the noise level of the MEG channels due to RF-leakage and/or unwanted ground loops.

2.1 Audiovisual stimulus system

Install the Stim2 system as described in the Stim2 manual with following additions (see figure 1.1):

The Stim to Scan cable (4) is connected to the trigger I/O unit (EL21715N). The video signal is routed from the PC via a video splitter cable (1), which divides the signal to the PC display (cable 2) and Data projector in NM24034N (fiber 3). The audio signal is connected from the left and right audio outputs on the audio unit to the audio input of the Elekta Neuromag® TRIUX. The audio signal cables 8 and 9 are installed to filter cabinet at the factory.

Note: The shield clamp and the ferrites in cables (8) and (9) must be kept intact to retain the EMC properties of the system

Note: The data projector must be connected using the optical cable (3) supplied with the NM21711N Audiovisual stimulus presentation system (Stim2).

The patient/subject headphones NM24035N are connected to the audio stim. out -connector at the gantry side panel, as described in the *Elekta Neuromag® TRIUX User's Manual*.

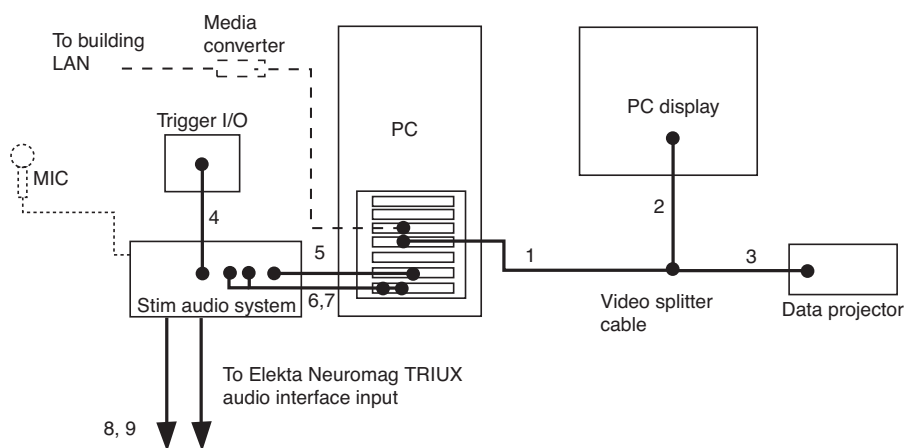


Figure 1.1 The signal connections of the Stim2 system. The connections between the Stim audio system and the PC (cables 5-7) are as shown in the Stim2 manual

Note: The response pad of the Stim2 system does not fulfill the EMC requirements of the Elekta Neuromag system and, therefore, cannot be used inside the Magnetically shielded room.

The Stim2 PC, the audio system, and the PC monitor must be powered from the medical isolation transformer delivered with the Stim2 system. If the PC is connected to the building network, an optical LAN must be employed to keep the system electrically isolated from the network. The data projector, which is located outside of the magnetically shielded room is separated with an optical fiber delivered with the audiovisual stimulus system.



WARNING 1.1: All the equipment connected to the system must either be powered from a medical isolation transformer or separated otherwise to fulfill the requirements of IEC 60601-1.



WARNING 1.2: All applied parts must be of type BF or better. Although the devices connected simultaneously to the patient fulfill individually the leakage current requirements set forth in the standards, a possible hazard exists caused by the summation of leakage currents.

The trigger lines are connected to the trigger interface unit of the Elekta Neuromag® TRIUX. The connections depend on the measurement setup. For more information, see the *Stim2 manual*, *Elekta Neuromag® TRIUX User's Manual* and the *Elekta Neuromag® TRIUX Data Acquisition User's Manual*.

Note: *The remote control of the video projector operates normally wireless but if needed, it can be also operated in wired mode. The remote control cable must not enter the magnetically shielded room permanently. Place the wired remote control unit outside the magnetically shielded room, near the door entrance.*

2.2 Electrical stimulators

The electrical stimulators are installed inside the stimulus cabinet. The stimulators are powered from the sockets inside the cabinet.



CAUTION 1.2: The electrical stimulators must be installed in the stimulus cabinet. The cabinet doors should be kept closed during the measurement to avoid RF interference.

The electrode leads are connected to the units as instructed in the unit's own manual, and routed to the Magnetically Shielded Room via the stimulus cabinet feedthrough. The trigger inputs of the units are connected to the outputs of the trigger interface unit of the Elekta Neuromag MEG-system installed inside the stimulus cabinet. The exact connections depend on the measurement setup. For more information, see *Elekta Neuromag® TRIUX User's Manual* and the *Elekta Neuromag® TRIUX Data Acquisition User's Manual*.

3 Notes on the use of the stimulators with the Elekta Neuromag® TRIUX

3.1 General



WARNING 1.3: Always test the stimuli, their intensity, and the stimulus sequence without the subject before starting the measurement.



WARNING 1.4: Always double-check that the stimuli are applied to the correct sides of the subject (left to left, right to right).



WARNING 1.5: Check the stimulus timing (delay, jitter) in actual setup before timing-critical measurements.



WARNING 1.6: To avoid infection, dispose the disposable patient contact parts and clean the non-disposable parts after each measurement.

3.2 Visual stimuli

- The trigger vs. stimulus onset delay depends on the projector model and the stimulus system setup. *The delay should be measured and taken into account in timing-critical measurements.*
- The trigger vs. stimulus onset jitter depends on the projector model, refresh frequency, and resolution. The jitter of the used setup must be checked before timing-critical measurements.
- To avoid jitter, refresh rates above 60 Hz are not recommended. Screen resolutions of 1024x768 and 1280x1024 work fine but resolutions up to native resolution of the projector may be used. Refer to documentation supplied with the projector.
- Single-chip DLP projectors are known to create a "rainbow effect", caused by time-multiplexing of colours, which can cause unwanted brain responses in certain type of stimuli. Therefore, 3-chip DLP projectors as contained in the NM24034N High-fidelity visual stimulator are preferred.
- The "black flash" due to non-symmetric black-to-white vs. white-to-black transition time of the pixels of the LCD-projectors can cause unwanted brain responses in certain type of stimuli.
- The brightness of the projector can harm the eyes of the subject if the beam is pointed directly to the eyes without the back-projection screen between the projector and the subject. Always have the back-projection screen between the subject and the projector before turning the projector on.



WARNING 1.7: The projector light can harm the eye if the beam is pointed directly to the eye.

- The brightness of the projector can be reduced by adjusting the picture brightness (picture menu in projector), selecting single lamp mode, and low lamp power (projector setup menu in projector). Refer to documentation supplied with the projector.
- The brightness of the projector can be further reduced with neutral density filters, e.g. Heliopan ND 0,3 ES 100. Such a filter is included in the NM23117N Periscope assembly. The filters absorb the infrared radiation generated by the projector and, thus, warm up. Always ensure that the selected filter does not get damaged or cause damage because of warming up.

3.3 Auditory stimuli

- Switch on the auditory system and test the stimulus before inserting the ear insets to the subject's ears.



CAUTION 1.3: Sound pressure levels of about 80 dB SPL and higher can cause permanent damage to hearing.

- The audio feedthrough filter of the Elekta Neuromag system causes 6,5 dB attenuation to the audio signal. Thus the nominal sound pressure level at the subject headphones inside MSR is 6,5 dB SPL smaller than the nominal dB SPL level selected at the Stim2 program.
- The frequency response of the subject headphones is flat only within approximately +/- 3 dB. Thus changing the frequency without changing the nominal dB SPL setting can change the real dB SPL level up to 6 dB. If essential, the absolute sound pressure level of the given stimuli should be measured prior the measurement.



CAUTION 1.4: If essential, the absolute sound pressure level of the given stimuli should be measured prior the measurement.

- Connecting headphones to the Neuroscan Audio System stereo headphone connector while having the unit connected to the subject headphones via the mono outputs and audio filter will reduce the sound pressure level at the subject headphones significantly.



CAUTION 1.5: Connect the Stim Audio System only to one set of headphones at the time.

- The delay from the trigger onset to the tone onset at the subject headphones can depend on the system setup. The delay and jitter should be measured and taken into account in timing-critical measurements. Selecting refresh rates higher than 60 Hz may cause jitter in auditory stimulus presentation.
- The foam ear inserts of the headphones are disposable. Use one pair for one subject only. The plastic pieces connecting the silicone tube and the foam ear inserts are not disposable.
- In a typical setup, two silicone tubes are connected together to make the distance from the audio box to the sensor array longer. The audio boxes are magnetic and produce magnetic artefacts when moved or when the sound is presented.

Note: The audio boxes should be placed on the side of the chair, as far as possible from the sensor array, and fixed well.

3.4 Electric stimuli



CAUTION 1.6: Always connect the electrode lead first to the stimulator, then to the subject.

- Check that the stimulus amplitude is set to zero before switching on the stimulator
- If EEG/EOG is used, connect the EEG ground electrode close (<200 mm) to the electrical stimulus electrode to minimize the stimulus artefact. Ensure that the EEG ground electrode-to-skin contact is best possible. The EEG ground electrode should be connected only to the EEG ground connector in the EEG interface panel under the gantry cover. The EEG ground is floating (BF type) and fulfills the leakage current requirements of IEC60601-1.



CAUTION 1.7: To minimize stimulus artefact connect the EEG (isolated) ground electrode close to the electrical stimulus electrode.

Use of the stimulus electrodes:

- Soak the felt tips with physiological saline solution bath
- Insert 6 mm felt tips to the gold-plated electrode cups and soak the tips with physiological saline solution
- Press the soaked felt tips against the skin area to be stimulated
- When looking for the correct stimulus amplitude, always start from zero and go up with small increments. Typical values are 5-15 mA for 0.2 ms pulse duration.



CAUTION 1.8: Pay attention to the gain multiplier setting of the Digitimer somatosensory electric stimulator. When set to 10, the maximum electric current is 100 mA. The power supplied to the patient depends on the combination of repetition rate, pulse duration, and pulse intensity, and for safety reasons it is limited by the Digitimer stimulator. Refer to the Digitimer operator's manual for details.



CAUTION 1.9: Connecting two Digitimer somatosensory electric stimulators on the patient may cause additional noise on the MEG channels due to radio-frequency (RF) load. Should this be the case, only one stimulator should be connected at a time.

- Once the correct amplitude and location is found, secure the electrode with the velcro strap
- The felt tips are disposable. Use one pair for only one subject and measurement
- Wash the electrodes after use with water and ordinary soap or mild dish care detergent. Be careful not to let water into the connectors. Allow to dry. Pure alcohol can be used for disinfection

4 System features

4.1 Audio filter (passive), technical properties

- Attenuation 6,5 dB +/- 0,5 dB @ 5 Hz - 15 kHz
- Input impedance 470 Ω - 1 K Ω @ 200 Hz - 15 kHz (with 300 Ω headphones connected)
- Max Uin: 10 Vrms @ 100 Hz - 20 kHz, 9 Vrms @70 Hz 5 Vrms @ 40 Hz, 2 Vrms @ 20 Hz
- Common mode rejection ratio > 60 dB @ 3 kHz
- Channel separation > 80 dB @ 3 kHz

4.2 Typical delay and jitter values

The following values are measured with standard stimulus system and the premium projector. The values can depend on the system setup, used projector model, refresh rate, and resolution, so the values presented herer are only representative examples. *Always measure the delay and jitter of the stimuli in the actual setup before timing-critical measurements.*

4.2.1 Visual stimulus

Values measured with the Stim2 system, premium projector (Panasonic PT-DS100EX) at 60 Hz refresh rate and 1280 x 1024 resolution and an optical DVI cable (Opticis M1-1000). The picture was set to non-scaling mode (pixels shown 1:1).

- Delay from trigger onset to stimulus onset: approx. 25 ms
- Jitter less than 0.2 ms

4.2.2 Auditory stimulus

Values measured with the passive audio filter, Stim2 system, and Nicolet 300 Ω headphones connected to the audio stim. -connector in the gantry side panel at 60 Hz refres rate.

- Delay from trigger onset to stimulus onset: approx. 9 ms
- Jitter less than 0.1 ms

4.2.3 Electric stimulus

Values measured with digitimer DS7A stimulator.

- Delay from trigger onset to stimulus onset: < 50 μ s
- Jitter less than 1 μ s

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