IMPORTANT USER NOTICE

We are providing the information in this Notice to notify you of an important issue that may exist on your equipment, and to inform you of any actions needed to safeguard smooth system operation. We ask that you please read and understand the content of this notice and implement any recommendations provided.
We also need you to acknowledge and accept this Notice by signing and returning the statement on the Acknowledgement page.
We advise you to insert this Notice in the applicable copy of the User Manual.

EEG settings change when resetting channels

Product: Elekta Neuromag® TRIUX

Reference number (Field Change Order, FCO): 145-03-601-114

Scope:	Elekta Neuromag TRIUX systems with DACQ 6.0.3 or lower
Description:	During our continuous surveillance of product quality we have found out that resetting channels in Elekta Neuromag® TRIUX changes the EEG settings. This happens when you reset the channels through the main acquisition window menu option.
Clinical impact:	The issue is not safety critical and does not affect the quality of your MEG localization results. The issue has an impact on the amplitude of the EEG data measured with Elekta Neuromag® TRIUX.
Solution:	We aim to provide a fix to the issue in a future software update. In the meanwhile, we provide simple options that you can apply as a workaround for the issue. See next pages for detailed information. Please, ensure all the users are aware of this issue and the workarounds described in this Notice.
Technical Reference:	N/A
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

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1 Details

Resetting channels in Elekta Neuromag TRIUX may change the EEG settings. This happens when you reset the channels through the main acquisition window menu option. See Figure 1. Avoid using this option during the measurement (after you have pressed **GO!**).

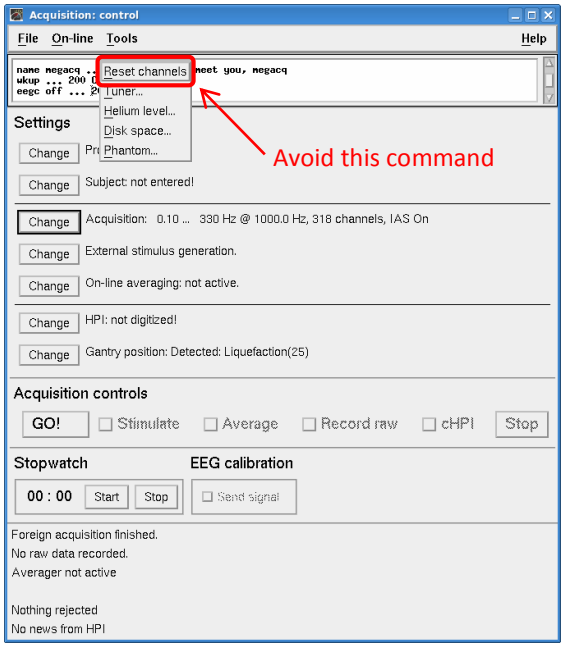

*Figure 1 Avoid the main acquisition window **Tools -> Reset channels** command, if you are measuring EEG.*

2 Workarounds

2.1 Use Sensor Tuner to reset MEG channels only

The Sensor Tuner program contains a reset option that does not affect EEG channels. It only resets the MEG channels. If you are in the middle of a measurement, and you need to reset channels, use the Sensor Tuner to reset the MEG channels in the following manner:

1. In the main acquisition window, open Sensor Tuner by selecting **Tuner…** from the **Tools** menu.
   *NOTE: Be careful not to press the **Reset channels** command, which is just above **Tuner…** command. Preferably, open the Sensor Tuner before starting the measurement.*
2. In the Sensor Tuner main window, select **Reset channels** from the **Commands** menu. See Figure 2.

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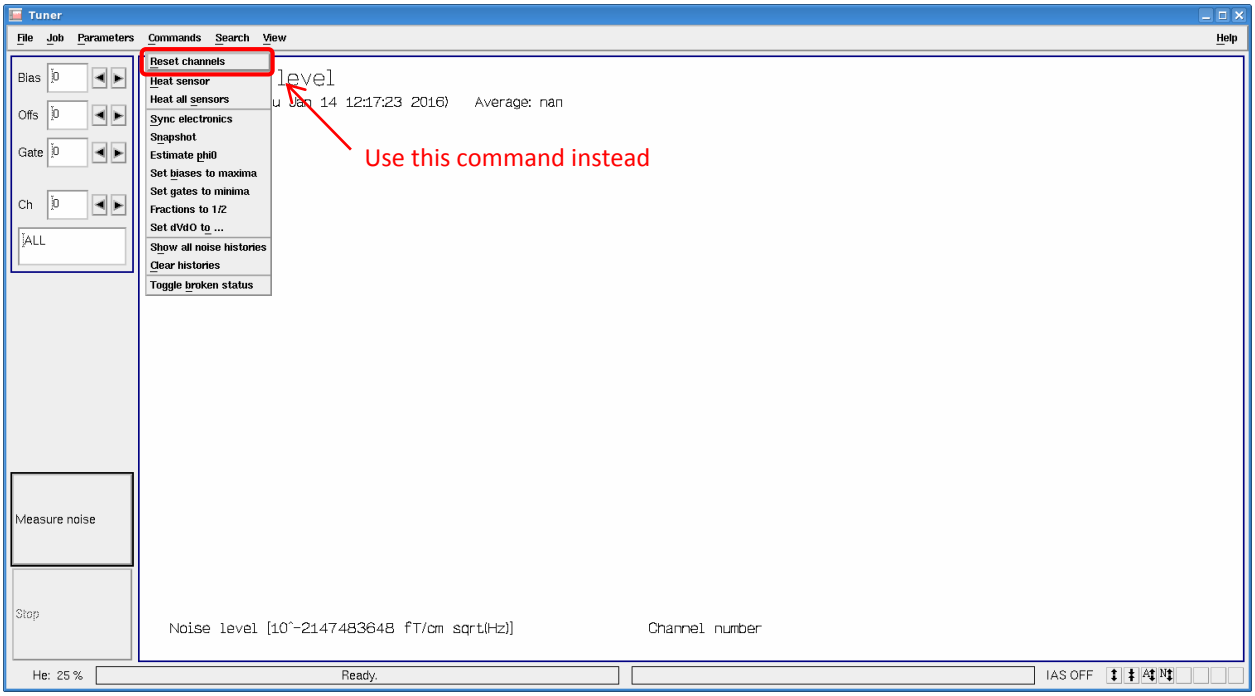

*Figure 2 Use the Tuner's **Commands -> Reset channels** command to avoid changes in EEG gain.*

2.2 After reset, stop and start a new measurement

If you have accidentally reset the channels using the acquisition system main window option during a measurement, the only way to recover is to stop the current measurement and start it again.

You can save your current measurement data, but note that unfortunately the EEG settings and the EEG data have been altered after the reset was applied. Your EEG data prior to the reset is intact and can be safely used.

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IMPORTANT USER NOTICE ACKNOWLEDGEMENT

Please complete the details below and sign the appropriate acknowledgement section:

- Existing installations; Acknowledgement by the customer
- New installations: New installation confirmation by the installing Elekta or Representative employee

Please return this report to your local Elekta Office or Representative, as soon as possible and within 30 days at the latest.

***The information in this Notice has been provided to address an issue and therefore the customer is expected to acknowledge and accept the recommendations given, and ensure they are implemented. By refusing to implement the recommendations, the customer assumes full responsibility and liability for all matters (including costs, losses, claims, and expenses) resulting, whether directly or indirectly from not implementing such recommendations. Further the customer will hold Elekta harmless from all matters (including costs, losses, claims and expenses) resulting, whether directly or indirectly from not implementing such recommendations.**
Failure to sign and return the acknowledgement may affect any follow-up actions necessary for us to take.

Classification:	Important User Notice	FCO Ref:	145-03-601-114
Description:	EEG gain may change when resetting channels		
Scope:	Elekta Neuromag TRIUX systems with DACQ 6.0.3 or lower		

Hospital:	
Device Serial No(s):	Location or Site No:

Acknowledgement to be signed by customer*:
I acknowledge that I have read and understood this Notice and accept implementation of any given recommendations:

Name: Title:

Signature: Date:

New installation confirmation to be signed only by the installing Elekta or Representative employee:

I acknowledge that the customer is informed on content of this notice and has been inserted in the applicable copy of the User Manual:

Name: Title:

Signature: Date:

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