

nëo™ Deployment Guide

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1. General Information

1.1 About this Document

With this document eemagine Medical Imaging Solutions GmbH provides instructions to distribution partners to support the local system setup of an aEEG and EEG monitoring system, briefly just **nëo™**.

It consists of the **nëo™ monitor** software, and the **nëo™** system hardware components.

Each **nëo™** that you install and deploy in the field must be registered at eemagine with a unique *Inst-ID* that you receive with the documents accompanying each **nëo™** component delivery. Please ensure that you and the end customer can document and find this *Inst-ID* easily when needed. The *Inst-ID* is required for any support or warranty related activities.

To obtain the necessary technical qualification to setup **nëo™** from the delivered hard- and software components, you must have accomplished a training given by an appointed person. An appointed person is, who was trained himself or herself in the installation procedures.

Please make sure you verified yourself as a trained person before you proceed with any installations by submitting the form in Section **nëo™** system installation training form to support@ant-neuro.com

Further you should have experience in setting up Windows operating systems in general especially with regards to power options, USB options, hardware drivers, installed software applications and services.

Please be aware that **nëo™** is not solely a software but an integral aEEG + EEG monitor, consisting of the **nëo™ monitor** software, the EEG recording hardware as well as compatible PC hardware. A successful installation procedure is assured and documented by an acceptance test form covering the complete **nëo™** deployment. This acceptance test must include all additional accessories.

Please avoid installation of any additional software other than specified, that could be potentially running simultaneously with **nëo™** and therefore block computer resources crucial for uninterrupted EEG acquisition. The same holds for adding peripheral hardware, such as USB storage media or similar. These are unsupported system extensions being candidates for causing issue on the data acquisition process.

This document is intended to help educate, advise and support eemagine GmbH distribution partners to produce **nëo™**. Please be aware, that this deployment document is inappropriate for end users of the system.

1.2 Safety Warnings

Make sure to read, understand and comply with all safety warnings and other information provided in the *user guide* of nëo™, eego™ amplifier and all other user information for components that you may combine with the system and that is delivered to the end customer.

In case of any doubts, contact support@ant-neuro.com with your related questions.

1.3 Contact Information

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1.4 Deployment Structure

The deployment is structured in sections for simplification.

All sections are described in detail with only few technical prerequisites assumed or unexplained in order to allow for a-priori understanding and offer recapitulation of the steps to a trained person.

Sections

❖ Hardware system setup including EEG amplifier, system cart and PC

Finalized by

- ✓ “Checklist: Hardware Setup”

❖ Software setup and OS configuration

Finalized by

- ✓ “Checklist: Software Setup”

❖ On site deployment and user configuration

Finalized by

- ✓ “Checklist: Technical Setup” and
- ✓ “Acceptance Test Run – On Site Deployment”

❖ Update and maintenance

Finalized by

- ✓ “Acceptance Test Run – Software Update” or
- ✓ “Acceptance Test Run - System Maintenance”

❖ System acceptance testing

- Purpose: assuring system is operational and safe, when
 - Being installed and configured at the user site
 - Being updated or maintained at the user site

Finalized and documented with a

- ✓ “System Acceptance Test Form - nëo Systems and Solutions”

❖ Supporting documents

- Training Form - nëo End-Users
- Training Form – Installation of nëo Systems and Solutions
- License Request Form - nëo
- System Acceptance Test Form - nëo Systems and Solutions

1.5 Disclaimer

We have attempted to write this document as accurately as possible. However, mistakes are bound to occur, and we reserve the right to make changes to the products, which may render parts of this document invalid. No part of this document may be copied or reproduced without the explicit permission of the authors.

2. Hardware Installation

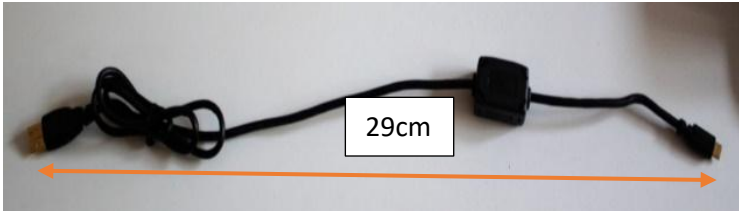
2.1 Preparation

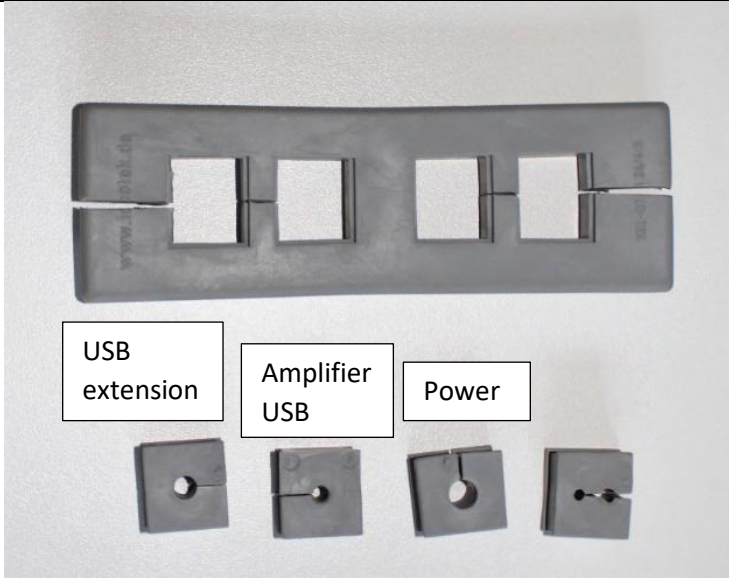
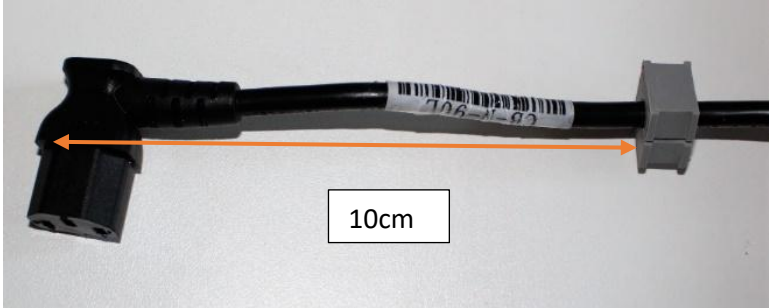
#	Step Name	Description									
1.	Unboxing and documentation check of nëo™ items	- Please check the delivery note document you received with the delivered nëo™ components against the actual items contained in the packages. Please locate each part individually, e.g. eego™ amplifier and installation medium for the nëo™ monitor software. - Make sure to keep all packaging material and repack the items according to the original packing for dispatching to the end-customer. - Make sure to keep all user documentation included and forward it to the end user. - Confirm that serial numbers and product codes on all items match with the listing in the delivery note. - Please have all material parts available before proceeding to the next steps defined below.									
2.	External mouse and keyboard (Optional)	To simplify the software setup procedure, we recommend to use external USB mouse and keyboard. <u>Note:</u> Both mouse and keyboard <u>are not</u> part of the nëo™ system definition and must not remain connected to the system at the end-customer site! Please make sure to disconnect them after the installation.									
3.	Hardware tools recommended for the setup	<table border="0"> <tr> <td>Allen key (Tool 1)</td> <td></td> <td>2.5 mm</td> </tr> <tr> <td>Wrench (Tool 2)</td> <td></td> <td>7mm</td> </tr> <tr> <td>Torx Wrench (Tool 3)</td> <td></td> <td>T10</td> </tr> </table> <u>Note:</u> Additional tools might be included with the system delivery. Depending on the pre-assembly state, not all tools might be required.	Allen key (Tool 1)		2.5 mm	Wrench (Tool 2)		7mm	Torx Wrench (Tool 3)		T10
Allen key (Tool 1)		2.5 mm									
Wrench (Tool 2)		7mm									
Torx Wrench (Tool 3)		T10									
4.	Installation ID	From the shipment documents please make sure you have received an Installation ID reference, e.g.									

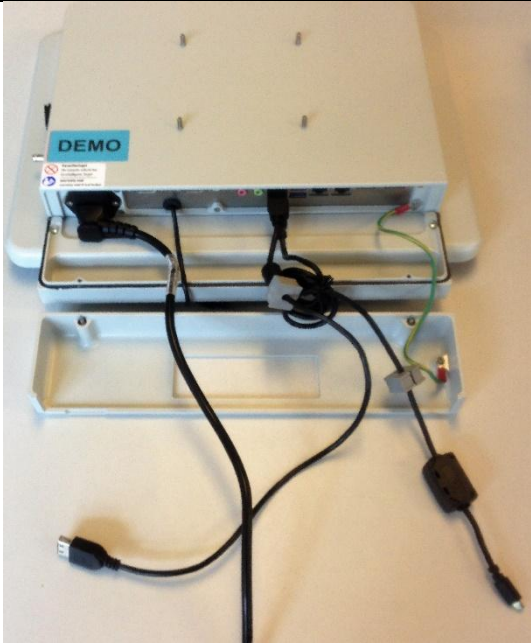
		Inst-01234 • Please continuously use this ID as a reference for the tracing and communication of all information and changes related to the system with eemagine. • We will as well refer to this Installation-ID reference when assisting you to support and maintain nëo™. • Provide the Installation ID as reference to eemagine whenever you need support.
5.	Mounting variant	Check the mounting type ordered for the nëo™ system. Depending on the mounting type, follow chapter 2.4, 2.5, or 2.6, respectively. Mounting on ITD vexio-cart 35E Mounting on GCX VHRS Variable Height Roll Stand Mounting on a table stand with VESA 100 mount

2.2 Cable attachment to the PC

This chapter explains how to attach various cables to the AiO-PC.

#	Step Name	Description
1.	Open the PC cover	Unscrew two Torx T10 screws from the backside of the PC by using Tool 3. Remove the cover from the housing.  Figure 1: Torx screw position
2.	Adjusting the length of the amplifier USB cable	- Roll up the amplifier USB cable and fix with twist tape. - For the EE-511 amplifier the cable is directly attached to the amplifier. Further the cable does terminate on the opposite side in a USB type C connector. Use the USB type C to USB type A adapter delivered with your system to convert to USB type A. Otherwise follow the same instruction as for EE-411.  Figure 2: Amplifier USB cable adjusted  Figure 3: USB Type C to Type A adapter required for deployment with an EE-511 amplifier
3.	Preparing cable entry frame	Dissemble cable entry frame from PC.

		 <i>Figure 4: Cable entry frame with grommets (rubber protectors)</i>
4.	Attaching cable grommets	- Attach a cable grommet (rubber protector) to the amplifier USB cable.  <i>Figure 5: The first grommet with the amplifier USB cable</i> - Attach a cable grommet to the USB extension cable.  <i>Figure 6: The second grommet with the USB extension cable</i> - Attach a cable grommet to the power cable.  <i>Figure 7: The third grommet with the power cable</i>
5.	Connect cables to PC	Connect the cables to the PC.

		 <i>Figure 8: Cable connections to the PC</i>
6.	Connecting cable grommets with cable entry frame	Assemble the 3 grommets to the cable entry frame.  <i>Figure 9: Cable entry frame with grommets and cables</i>
7.	Connecting cable entry frame with housing cover	Connect cable entry frame with housing cover.  <i>Figure 10: Cable entry frame is connected to housing blind</i>
8.	Closing Housing	Attach the cover to the main housing. Use 2 screws inside the holes to fix 2 parts together. Tool 3, tightening torque: finger tight.

		Make sure not to jam or bend any cables too strongly when closing the cover!  <i>Figure 11: PC housing with closed cover</i>
9.	Secure the USB cable opening	Cover the USB extension cable opening with a cap  <i>Figure 12: protection cap</i>

2.3 Amplifier mounting preparation

This chapter explains how to attach the EEG amplifier onto the mounting plate.

Notes:

- The amplifier and mounting plate might come pre-assembled. In this case, please skip this chapter.
- If your nëo mounting plate has version 1.0 (check the mounting plate label), then please refer to the deployment guide revision 7.



Figure 13: Example of nëo mounting plate (version 2.0)

#	Step Name	Description
1.	Inspection	• Make sure that the content inside the plastic bag is complete.  <i>Figure 14: Contents from the plastic bag without tools</i>
2.	Attaching the amplifier to the mounting plate	• Remove the safety pad from the plate. Collect 4 of the 8 spacers and knurled nuts. (Leave the other 4 spacers in the screws).

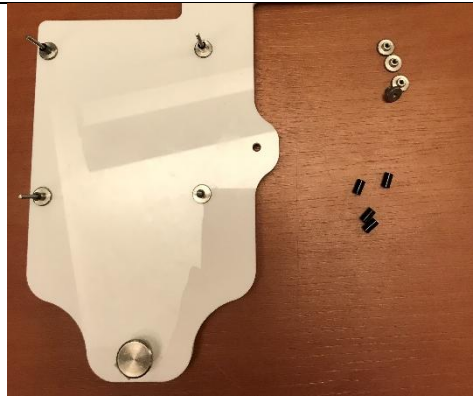


Figure 15: Mounting plate, distance pieces and knurled nuts

- Insert the amplifier into the screws. Ensure that the manufacturer label is facing upright as shown in Figure 16. The ANT Logo should not be visible and be facing downward. Add the distance pieces from the top into the screws.

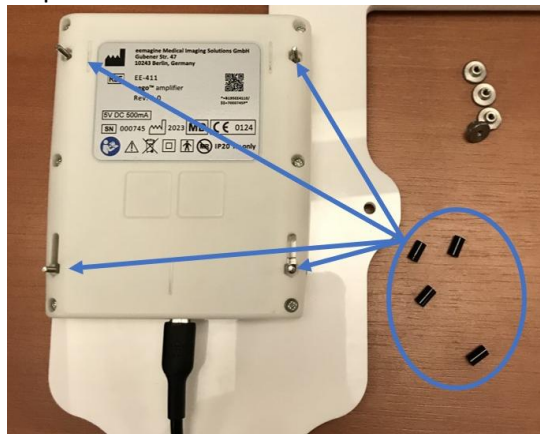


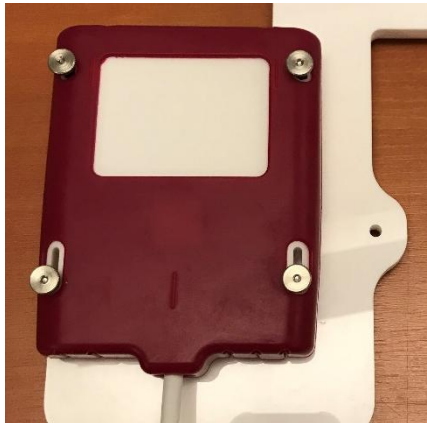
Figure 16: The distance pieces added



Figure 17: The knurled nuts screwed

Note 1:

Assemble the amplifier as shown in Figure 16 and 17: The tyco 50 connector input is at the top and the micro USB connector is at the bottom. Ensure that the amplifier manufacturing label is visible. If the label is upside down, rotate the amplifier 180

		degrees. The ANT logo should be facing downward and not be visible. <u>Note 2:</u> The images and main text refer to the EE-411 amplifier but the exact same steps are followed, the same materials are used, and the same orientation of the components relative to each other is chosen when assembly is done with an EE-511 amplifier. Only relevant difference is that the EE-511 amplifier is to be assembled with its softshell attached. Further the USB interface has a direct pigtail cable connection of sufficient length to connect directly with the AiO computer. The connector is of Type C so an adapter is needed to transfer Type C to Type A on the computer side.  <i>Figure 18: EE-511 mounted with softshell.</i>
3.	Drag protection	- Loosen the knurled nuts at the bottom of the mounting plate and remove the white plastic clip.  <i>Figure 19: The white plastic clip removed</i> - Connect the white plastic clip to the USB amplifier cable.

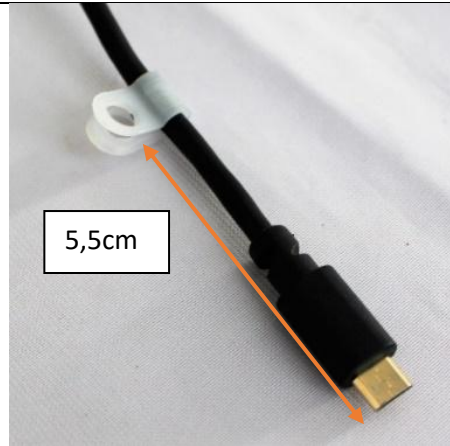


Figure 20: The white plastic clip attached to the USB amplifier cable.

- Connect the USB amplifier cable to the amplifier and tighten the white plastic clip with the knurled nut.



Figure 21: USB cable connected to the amplifier without the drag protection tightened



Figure 22: USB cable now tighten with the knurled nut to complete the drag protection

Note:

The USB-C cable of the EE-511 amplifier itself has a drag protection.

Therefore, this step is not necessary for the EE-511. The plastic clip and the knurled nuts can be removed.

2.4 ITD vexio-cart montage – cable wiring and amplifier montage

This chapter explains how to montage the AiO-PC to the ITD vexio-cart 35E and how to attach the eego amplifier mounting plate to the backside of the AiO-PC.

Note: The ITD vexio-cart 35E is normally used for installations in Europe.

1. Attach the PC to the cart

- Unscrew 4 knurled nuts from the PC.



Figure 23: Take off the knurled nuts from the PC

- Attach PC to the VESA mount. Fix the PC to use 3 hex-standoffs (from the plastic bag of the amplifier mounting plate set) through the VESA mount on the cart. Tight them by using Tool 2. Tightening torque: finger tight. Use a knurled nut to fix the bottom left.



Figure 24: PC with 3 hex-standoffs and the knurled nut

2.	Power cable management	- Put the power cable inside the cable channel.  <i>Figure 25: Power cable inside the cable channel</i> - Attach covers to the cable channel.  <i>Figure 26: Cover for cable channel</i>
3.	Attaching mounting plate to the PC	Put an isolation piece over each of the 3 hex-standoffs.



Figure 27: 3 isolation pieces over the 3 hex standoffs

- Preassemble 3 pieces of the screws and holder rings.



Figure 28: Preassembled screws and holder rings

- Position the 3 holes in the mounting plate over the 3 hex-standoffs. Use the 3 preassembled screws with holder rings to attach the mounting plate to PC. The side of the mounting plate with the amplifier should be facing towards the PC (see Figure 27). Tool 1, tightening torque: finger tight.



Figure 29: Mounting plate attached to the PC

- Put a cover cap over the 3 screw heads.



Figure 30: Mounting plate with cover caps

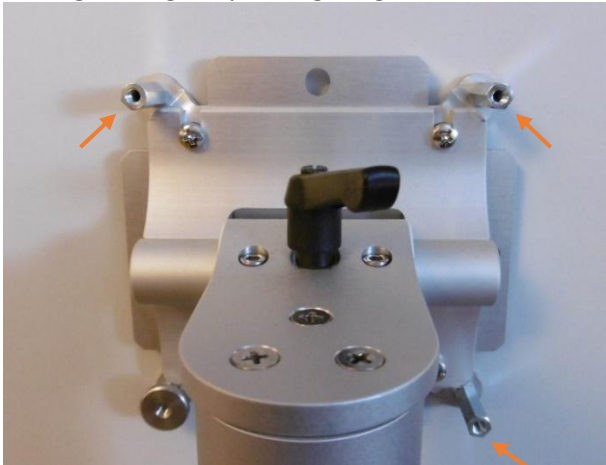
Note:

In the case there is no clicking sound while pressing the cover cap to the holder ring, disassemble the connection and rotate the holder ring. Try again.

2.5 GCX VHRS Roll Stand montage – cable wiring and amplifier montage

This chapter explains how to montage the AiO-PC to the GCX VHRS Variable Height Roll Stand and how to attach the eego amplifier mounting plate to the backside of the AiO-PC.

***Note:** The GCX VHRS Variable Height Roll Stand is normally used for installations in the US.*

1.	Attach PC to the cart	- Unscrew 4 knurled nuts from the PC.  <i>Figure 31: Take off the knurled nuts from the PC</i> - Attach 3 hex-standoffs to the PC through the VESA mount on the cart. Tool 2, tightening torque: finger tight.  <i>Figure 32: PC with 3 hex- standoffs</i> - Use only one remaining knurled nut. Insert a metal distance piece under the knurled nut. This prevents the knurled nut from interfering with the VESA mount.
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		 Distance piece <i>Figure 33: The distance piece and the knurled nut</i>
2.	Power cable management	Wind the power cable around the cable holder. Make sure that the remaining cable has sufficient length in case the pole is fully extended.  <i>Figure 34: Power cable around the holder</i>
3.	Attaching mounting plate to the PC	- Preassemble 3 pieces of the screws and holder rings.  <i>Figure 35: Preassembled screws and holder rings</i> - Position the 3 holes in the mounting plate over the 3 hex-standoffs. Use the 3 preassembled screws with holder rings to attach the mounting plate to PC. The side of the mounting plate with the amplifier should be facing towards the PC (see Figure 32). Tool 1, tightening torque: finger tight.



Figure 36: Mounting plate attached to the PC

- Put a cover cap over the 3 screw heads.



Figure 37: Mounting plate with cover caps

Note:

In the case there is no clicking sound while pressing the cover cap to the holder ring, disassemble the connection and rotate the holder ring. Try again.

2.6 Table stand montage

This chapter explains how to montage the AiO-PC to a table stand with VESA 100 mount and how to attach the eego amplifier mounting plate to the backside of the AiO-PC.

1.	Assembling of the table stand	Assemble the table stand according to the enclosed instructions.  <i>Figure 38: Assembling of the table stand</i>
2.	Attach PC to the table stand	- Unscrew 4 knurled nuts from the PC.  <i>Figure 39: Take off the knurled nuts from the PC</i> - Attach 3 hex-standoffs to the PC through the VESA mount on the cart. Tool 2, tightening torque: finger tight. Use a knurled nut to fix the bottom left.



Figure 40: PC to the table stand attached

3. Attaching mounting plate to the PC

- Put an isolation piece over each of the 3 hex-standoffs.



Figure 41: 3 isolation pieces over the 3 hex standoffs

- Preassemble 3 pieces of the screws and holder rings.



Figure 42: Preassembled screws and holder rings

- Position the 3 holes in the mounting plate over the 3 hex-standoffs. Use the 3 preassembled screws with holder rings to attach the mounting plate to PC. The side of the mounting plate with the amplifier should be facing towards the PC (see Figure 40). Tool 1, tightening torque: finger tight.



Figure 43: Mounting plate attached to the PC

- Put a cover cap over the 3 screw heads.



Figure 44: Mounting plate with cover caps

Note:

In the case there is no clicking sound while pressing the cover cap to the holder ring, disassemble the connection and rotate the holder ring. Try again.

2.7 Checklist – Hardware Installation

After having completed all steps of the hardware setup, please print and fill in the checklist below to ensure a correct assembly!

#	Test	Description	Pass / fail /NA
1.	The cable wiring is correct	Amplifier USB cable, USB extension and PC power are connected to their sockets on the PC.	
2.	PC housing is closed	The backside cover is attached to AiO PC. Cable grommets are in place.	
3.	PC attached to the VESA mount properly	Check if the PC is properly attached to the VESA mount and the screws are secure.	
4.	The handle is fixed	The handle does not wobble and is firmly attached.	
5.	The basket is fixed	The basket does not wobble and is firmly attached.	
6.	The cable holder is fixed	The cable holder does not wobble and is firmly attached.	
7.	The main pole is fixed on the foot	The pole and foot are fixed and do not wobble.	
8.	Check roll function	Release the brakes on all wheels and make sure the cart moves smoothly.	
9.	Check break function	Apply the brakes to the wheels and make sure they brake properly.	
10.	Amplifier is mounted and connected	The eego amplifier is mounted on between the backside of the AiO-PC and the mounting plate. The amplifier USB cable is connected to the amplifier and PC.	
11.	Drag protection of the amplifier is working	Pull the amplifier USB cable and check that the cable does not come off the amplifier.	
12.	The USB extension is secured	The USB extension cable opening is covered with the protective cap.	
13.	Height adjustment knob fastened properly (only for GCX roll stand)	Make sure that the cart's height adjustment does not move accidentally by itself.	

3. Software Installation

Note:

If you ordered a PC with pre-installed nëo™ **monitor** software, you can skip this chapter and continue with chapter 4.

3.1 System Configuration and Software Installation

As nëo™ is an integral clinical aEEG monitoring system, the Windows operating system (OS) on the PC needs to be configured to present only the nëo™ **monitor** software to the user. All general-purpose functionality of the OS shall be hidden.

#	Step Name	Description
1.	Install Windows 10 Enterprise LTSC or Windows 11 Enterprise LTSC or Windows 10 Pro	- Make sure the PC-hardware for deploying the nëo™ monitor software has one of the following Windows operating system variants installed: ✓ Microsoft Windows 10 Enterprise LTSC (2016 / 2019) ✓ Microsoft Windows 11 Enterprise LTSC () ✓ Microsoft Windows 10 Professional We strongly recommend using the Enterprise LTSC version as it is supported with security updates for 10 years after its release, and intentionally receives no feature updates. Undesired Windows features like the Windows Store and bundled apps are not included in this edition.
2.	Disable USB boot	- Reboot and enter the PC's BIOS settings - Disable booting from USB drive in the BIOS of the PC. - See the PC's manufacturer documentation for details.
3.	Configure user account "neo"	<u>After Windows installation: configure user account for nëo™</u> Start the computer and wait until it signs into Windows automatically for the first time as "User". To create a new "neo" account <u>with administrator rights</u> - In Windows 10, click the Start -> Settings -> Accounts -> Family & other people. In this dialog, select "Add someone else to this PC" - User the following credentials: ✓ User name: neo ✓ Password: neo <default> ✓ Password hint: support@eemagine.com

		Change the account type to “Administrator” <u>Note:</u> The user password should be changed to a password of the end user’s choice during on-site deployment of the system.
4.	Delete obsolete default user account	Switch the user to neo, again open Start -> Settings -> Accounts -> Family & other people and delete the default “User” account, which will not be used further.
5.	Set administration password	Set an administrator password to protect the computer against unintended or unqualified configuration changes. - Open “Control Panel -> System and Security -> Administrative Tools -> Computer Management” In the Local Users and Groups dialog window - navigate to “Local Users and Groups -> Users” - Right-click on “Administrator” and choose “Properties” ✓ Disable the “account is disabled” checkbox, to activate this account - Click Ok to apply the changes and close Administrator Properties - Again right-click on “Administrator”, choose “Set Password...” - When prompted with general information about admin password changes, choose to “Proceed”. ✓ Enter the new password for the administrator (twice) ✓ Click OK to apply the new password system wide ✓ Note the password immediately to the installation-ID record on the license request form, so it will not get lost <u>Note:</u> The default admin password suggestion is “neoAdmin2018”. <u>Important:</u> Store the administrator password at a safe place that could be a printout copy or a location on a secured server. This is crucial information to keep access to the PC for configuration and update purposes. If it gets lost, data might become inaccessible and thus lost!
6.	Activate Windows	Make sure a valid license was entered into Windows 10. Windows is therefore readily activated. To do so, open the Windows start menu and type “activated”, choose “See if Windows is activated”. ⇒ Activation: Windows is activated with a digital license.

7.	Install Windows Updates	Make sure all available Windows updates are installed. Do the following to let Windows install all pending OS updates from the internet. • Open “Start -> “Windows Settings -> Update & Security -> Check for updates” • Repeat clicking on “Check for updates” until Windows finds no more updates and states • Make sure optional updates are installed too
8.	Disable automatic updates	Automatic Windows updates need to be disabled. However, update notifications shall still be received. In Windows 10, this can be done using the group policy editor “GP-Edit”. • Click on Start and type “cmd” and select the “Command prompt” suggestion. • In the command prompt type “gpedit.msc” and hit enter In the upcoming group policy editor, navigate to • “Computer Configuration -> Administrative Templates -> Windows Components -> Windows Updates” • Click on Edit policy setting to open the Configure Automatic Updates dialog. • Select “Enabled” in the left pane. • Click on the “Configure Automatic Updating” ComboBox. • Select “Notify for download and notify for install”. ⇒ See Figure 55: Group policy editor
9.	Standard driver installation	Open the Windows Device Manager and check that no drivers are missing. Missing drivers are shown as a yellow exclamation mark. <u>Note:</u> Only in the case a driver is missing, try a Windows update and the PC manufacturer as sources to obtain the driver.
10.	Power settings	Correct power settings are <u>a must</u> to assure constantly high system performance for long term EEG monitoring and database recording Open “Control Panel -> System and Security -> Power Options” • Choose “Create a power plan”, name it “neo”. This is the power plan that adjustments will be applied to subsequently. ⇒ See Figure 52: Change plan settings for new "neuro" Power Options profile

		- Select the newly created “neo” power plan to make it active and click on “Change plan settings”, then on “Change advanced plan settings” to open a dialog listing all available power settings. ⇒ See Figure 53: Open advanced power settings - Make sure the following settings are disabled to assure constantly high system performance: ⇒ See Figure 54: Adjust advanced (detailed) power options ✓ USB settings -> USB selective suspend setting: Disabled ✓ Hard disk -> Turn off hard disk after: 0 = never ✓ Sleep -> Sleep after: 0 = never ✓ Sleep -> Allow hybrid sleep: Off ✓ Hibernate -> Hibernate after: 0 ✓ Sleep -> Allow wake timers: Disable ✓ Power buttons and lid: Power button action: do nothing ✓ Power buttons and lid: Sleep button action: do nothing ✓ Display -> Turn off display after: Never ✓ Display -> Enable adaptive brightness: Off ✓ Desktop background settings -> Slide Show: Paused ✓ Wireless Adapter Settings -> Power Saving Mode: Maximum Performance ✓ PCI Express -> Link State Power Management: Off <u>Note 1:</u> Setting names and availability may change slightly with the PC hardware and OS software updates. Please always set the mode that corresponds to the best performance. <u>Note 2:</u> Please make sure the newly created power plan is selected when you close the menu.
11.	Prevent users from changing power plan	Set the power plan in the 'Local Group Policy Editor': 1. Open 'edit group policy' window 2. Go to 'Computer configuration'-'>'Administrative templates'-'>'System'-'>'Power Management'-'> open from right side window 'Specify a custom active power plan' by double clicking 3. Click 'Enabled' 4. Then give the Custom Active Power Plan (GUID) value in the box and click apply and ok. To get Custom Active Power Plan (GUID) value: 5. Open cmd with admin rights. 6. Type “powercfg -getActiveScheme”

		7. This will give the power scheme GUID number of the custom power plan created for neo. 8. Copy this number and put into 'Specify Custom Active Power Plan' window in Custom Active Power Plan (GUID) value in the box of 'Local Group Policy Editor'. Go to power option again and confirm that the created power plan 'neo' cannot be changed.
12.	Bitlocker-HDD Encryption: General remarks	Microsoft BitLocker HDD encryption needs to be enabled as a means of user- and program- data protection. Data protection is required by local law of some destination countries of nëo™, which makes drive encryption obligatory. In case of questions regarding the local requirements, please contact support@eemagine.com. <u>Note:</u> Microsoft Bitlocker secures critical credentials in a hardware storage module called TPM. TPM can provide these credentials automatically to users.
13.	Bitlocker: Remarks on using Bitlocker with HDD encryption with TPM	This option describes how Bitlocker can be configured to permanently encrypt the HDD utilizing the TPM hardware module inbuilt in the PC to automatically authorize decryption of HDD during startup. <u>Note:</u> There is an alternative option to configure Bitlocker decryption authorization as a PIN request at each Windows startup, that does not utilize and thus not require a TPM module. This alternative configuration is explained in ➔ Appendix 69.
14.	Bitlocker: Turn the TPM module on	Make sure the TPM is turned on or turn it on. • Open the “tpm.msc” configuration tool from the Windows command prompt. • Make sure the TPM is turned on or turn it on if the option “Turn the TPM on” is available from the dialog. • If there is no option “Turn the TPM on”, check the BIOS options that might allow to activate a hidden TPM module and continue with the 1st and 2nd bullet point. In case no TPM module is available, Bitlocker might still be activated with the alternative PIN approach ➔ See Appendix 69.
15.	Bitlocker: Turn the encryption on	Use Bitlocker’s management dialog to enable the Bitlocker encryption. • Use the Windows search to find the “Manage Bitlocker” tool and start it. • In the dialog, find the options next to the C:\ drive icon. • Choose “Turn on Bitlocker” for that drive ⇒ See Figure 63: Bitlocker Installation Step 1/6

		Follow the instructions in the upcoming guided installer. - When prompted to “Choose how to unlock your drive at startup”, select “Let Bitlocker automatically unlock my drive”. ⇒ See Figure 64: Bitlocker Installation Step 2/6 - When prompted “...to back up your recovery key”, select “Save to file” and store the recovery key on the USB key. Retaining a printout copy is recommended for safety. ⇒ See Figure 65: Bitlocker Installation Step 3/6 - When prompted to choose “...how much of your drive to encrypt”, select “Encrypt used disk space only (faster and best for new PCs and drives”. ⇒ See Figure 66: Bitlocker Installation Step 4/6 - When prompted to “Choose which encryption mode to use”, select “New encryption mode (best for fixed drives on this device)”. ⇒ See Figure 67: Bitlocker Installation Step 5/6 - When prompted “Are you ready to encrypt this drive”, enable the checkbox “Run Bitlocker system check”. ⇒ See Figure 68: Bitlocker Installation Step 6/6 ✓ Restart the PC, when requested <u>Important:</u> When prompted to store the Bitlocker recovery key, choose to make a printout and additionally store it as a file to an external location, such as a backup HDD or server. Reference the recovery key with the Inst-ID of the system. Only the recovery key will allow access to the data in case BitLocker has locked the drive to protect it. Without the key, all data on the drive will be lost!
16.	Enable on-screen touch keyboard	- In Windows 10, click the Start -> Settings -> Devices -> Typing ✓ Make sure the option “Show the touch keyboard when not in tablet mode and there’s no keyboard attached” is enabled. Enabling this option will only show effect in Windows 10 Desktop mode.
17.	Disable Windows 10 Edge Swipe Gestures	To avoid switches from nëo™ to Windows, by default active Edge Swipe Gestures need to be disabled. This can be completed by creating a registry key setting as follows:

		- Start the windows registry editor (search for “regedit.exe”) - In the registry editor, search for the following key or create it, if it is not yet existent: - HKEY_LOCAL_MACHINE\SOFTWARE\Policies\Microsoft\Windows\EdgeUI - For this key, create the following DWORD (32-bit) value: - Name: AllowEdgeSwipe ✓ Value: 0 (zero).
18.	Set the taskbar to automatically hide if not being used	- Use the search function to type “Taskbar setting” and proceed to the recommended option - The next window shows a tab with “taskbar behaviors” → unfold it - Tick in the field “automatically hide the taskbar” - Close the settings
19.	TeamViewer	Download and install the TeamViewer-Host module in the latest version, that can be obtained free of charge from the following website: https://www.teamviewer.com TeamViewer will allow eemagine support to access nëo™ remotely for maintenance and to assist the end-customer, when requested. To install Teamviewer, do the following: - start the Teamviewer installer - On the 1st dialog page, click “Next” to proceed ⇒ See Figure 57: Teamviewer Installer Step 1/6 - On the 2nd dialog page (“Environment”), select “Company / Commercial use” ⇒ See Figure 58: Teamviewer Installer Step 2/6 - On the 3rd dialog page, accept the license agreement ⇒ See Figure 59: Teamviewer Installer Step 3/6 - On the 4th dialog page, set a computer name and don’t apply a password → skip password ⇒ See Figure 60: Teamviewer Installer Step 4/6 - On the 5th dialog page, select “I don’t want to create a Teamviewer account now.” ⇒ See Figure 61: Teamviewer Installer Step 5/6 - From the 6th (last) dialog page, please check that Teamviewer starts ⇒ See Figure 62: Teamviewer Installer Step 6/6

		- After installation, set the startup type of the Teamviewer service to manual: - Open the Windows Services via services.msc - Double-click on the Teamviewer service - Change the startup type to “Manual” <u>Note:</u> Installing TeamViewer is optional, but it is strongly recommended for fast trouble shooting should there ever be a problem with the system.
20.	Install nëo™ monitor software	- Make sure you’re logged in as user “neo” - Attach the white USB memory stick, that is contained in the system delivery and contains the nëo™ monitor software installer. The following batch file will start the SQL and nëo™ monitor installers automatically in a terminal window. - Please run “install_neonatal.bat” - Await the SQL installer to finish in the terminal window. This might take 5-10 minutes. - Afterwards, the nëo™ monitor installer dialog shows up. Acknowledge all installer questions to proceed to the installation. - Await the successful installation message of the installer. Confirm this message to finalize the installation. - Restart your PC in order to apply all configuration changes.
21.	Install SQL Management Studio	SQL server 2017 needs a separate installation of SQL management studio for database administration. The installer can be found on the USB stick containing all software installers. - Copy the installer file from the USB memory stick to the desktop - Run the installer and restart the system when requested - Choose “Install” - Await finalization and restart the PC
22.	Request Software license for nëo™ monitor	nëo™ monitor is shipped without software license. You will be supported to obtain the license by eemagine’s support. The next steps will explain which information is necessary for license creation and receipt. Double click the nëo™ monitor icon on the desktop to start the software for the 1st time.

		• The licensing dialog is presented, consisting of an upper- and a lower license code-section. • Click on the “Generate License Request Code” button to generate a “license request code”. • Send this request code via email to support@eemagine.com together with the filled license request form for the system you are setting up ✓ See License request form page 64 • In return to your request and the filled license request form, you will receive the license code that is to be copied into the lower section of the nëo™ monitor license dialog. • Click OK to activate the license ✓ nëo™ monitor will show up and present its start screen • To exit the software in order to proceed to the next step: Attach a USB keyboard to the USB breakout adapter if not yet done. • Select the sandwich button in the left upper corner and click "Quit" to close the nëo™ monitor software. When the pop-up window “Do you want to restart nëo or shutdown the PC?” appears, press ALT + F4. This will close the software and allow access to the desktop.
23.	Wallpapers	Set the nëo™ wallpapers as Windows Lock screen and Windows Background for the neo user account. The wallpaper images can be found on the USB memory stick that contains the software installer. Lock screen: ○ DDE-OP-0156_neo_wallpaper_1920x1080_....jpg Background: ○ DDE-OP-0156_2_neo_wallpaper_Please_wait_1920x1080_....jpg • First, copy both images to C:\ProgramFiles\ • Open “Start -> Windows Settings -> Personalization -> Background” and click on “Browse” to select the wallpaper image. • On the left-hand side of the window, switch to “Lock screen” and click on “Browse” to select the 1st image for this purpose.

		Both sites Lock screen and Windows background appear coherently. The Windows background shows a "Please wait..." text at its bottom.
24.	disable autoplay functionality for usb drives	- Press Win+R → type gpedit.msc and click OK - Select Administrative Templates \ Windows Components in the tree view - Double click the "AutoPlay Policy" item, see that its set as not configured, select enabled, and change the "Turn off Autoplay on" to All Drives - Hit the OK button and the modify will take effect after reboot.
25.	Date and time	Set the time and date, language according to the system destination and end-user requirements. Open "Start -> Windows Settings -> Time & language" ⇒ Enable "Set time automatically" ⇒ Choose the correct time zone of the destination country ⇒ Add the related language to the system, please note that only in case there is at least and english language package remaining support can be received.
26.	Startup něo™ monitor automatically	Add the něo™ monitor software to Windows startup. - In a Windows-Explorer Windows, type "shell:startup" into the address bar and hit enter. ✓ The startup directory will open The startup directory contains shortcuts to all applications, which Windows is supposed to startup automatically. - Add a shortcut to "C:\Program Files\NeonatalApp\neonatal_.exe"
27.	Windows Security: General remarks	něo™ offers network data export and remote support as features, which need granted access to the local network and the internet. Other access to něo™ monitor over the network should be disabled.
28.	Windows Security: Firewall	Go to "Control Panel -> System and Security -> Firewall". On the left-hand side, click on "Allow an app or feature through Windows Firewall". In the upcoming dialog window, disable all checkboxes to close all ports and to prevent any app or service from network communication. Afterwards, only allow apps or features that are needed (granted exceptions):

		• Network discovery: enabled • SMB1 disabled (see next step) • SMB2 and SMB3: enabled (see next step) • Printer Sharing: enabled • TeamViewer: enabled • Windows Updates: disabled
29.	SMB network settings	SMB network file access needs to be allowed in order to permit network data export. • SMB v. 2 and v. 3 are permitted incl. signature • SMB v. 1 is not supported due to security limitations To enable or disable SMB-Features in Windows refer to the following MSDN article: https://support.microsoft.com/en-us/help/2696547/detect-enable-disable-smbv1-smbv2-smbv3-in-windows-and-windows-server
30.	Cleanup	• Delete the installer and any other tools used during installation from the AiO-PC. Please also empty the waste basket. • Remove all software from the computer that is not part of standard Microsoft Windows and not required for running nëo™ monitor. • In particular any advertisement-, trial- and 3rd party firewall software added by the supplying computer manufacturer needs to be removed! <u>Important:</u> <i>eemagine will neither support nor guarantee performance of the system, if additional software remained on the computer, as in this case interferences and interruptions of EEG data acquisition cannot be excluded. In case you add other software to the PC, operational state and system performance is in your responsibility and requires your validation before putting the system in use.</i>
31.	Turn on UAC (user account control)	• Open the Registry Editor. • Expand HKLM\SOFTWARE\Microsoft\Windows\CurrentVersion\Policies\System. ✓ Set the value to 1.
32.	Change account type to Standard User	• Open the Window User account settings via Settings → Accounts → Family & other people ✓ Change the account type for the “neo” user to Standard User

3.2 Checklist - Software Installation

After having completed all steps of the software installation, please print and fill in the checklist below to ensure a correct configuration!

#	Test	Description	Pass / fail /NA
1.	Are all Windows updates installed?	Open "Start - > Search for "Updates" and select "Check for Updates" and press the button "Check for updates". Make sure that "Your device is up to date" or "You're up to date" is stated Optional updates must be installed and can be found under Advanced options in Windows 11.	
2.	Are all drivers installed?	Make sure all USB devices that belong to the system are connected, particularly the eego™ amplifier. Open the "Control Panel -> System and Security -> System -> Device Manager" Confirm that the list of devices does not show any yellow or red question- or exclamation marks.	
3.	neo user + Admin password never expire	Check under computer management that the password for neo user and administrator never expire.	
4.	Are Windows edge Swipe gestures disabled?	Touch test that Windows desktop edge swipe gestures don't show effect after adjusting the registry setting. This can be done panning with one finger alongside the right border of the screen. The charms menu should not open.	
5.	Is the touch keyboard enabled?	Remove USB keyboard + mouse. Open notepad application. Check that the on-screen keyboard is displayed when tapping in the text area.	
6.	Is the newly created power plan selected?	Open "Control Panel -> Power Options" Confirm "neo" is selected as power plan.	
7.	Is SQL Management Studio installed?	Open "Start" and type "SQL Server Management Studio" and open the matching suggestion. The SQL Management Studio will show up. If this happens, the test is successful and SQL M.S. can be closed.	
8.	Is USB AutoPlay disabled?	Insert a USB memory stick to any USB port of the PC. Insertion causes no reaction of the PC, especially Windows-Explorer won't show up.	

9.	Are date, time and language correctly set according to the end-user requirements?	Open "Control Panel -> Clock, Language, and Region" and check that all three items are set correctly • Date and Time • Language • Region	
10.	Password protection	Restart the PC and wait until Windows to complete boot. PC requires a password before logging into the OS.	
11.	Is nëo™ monitor starting after OS startup?	Restart the PC and wait until Windows to complete boot. nëo™ monitor starts up automatically at the end of Windows start.	
12.	Does the Standard User have permission to change and save Neo settings?	• Inside the Neo program, click on the hamburger menu on the top left, then select "Technical Setup". • Enter the pin (0000). • Go to "General settings" and change the language to a different one than it was before. • Check the bottom right corner and see a floppy disk icon. If it is colourful, click on it and, if settings are saved, the test was successful. If it is greyed out, the test was unsuccessful. • Change back to the English language and save.	

4. End-User Site Deployment

The deployment at the end-user site consists of

1. Hardware set-up of pre-assembled system (PC, amplifier) and compatible accessories (e.g. Cart, XC-810 EEG touchproof adapter etc.). Please refer to the user documentation of the accessories on how to connect it with the nëo™ system hardware.
2. Configuration of nëo™ **monitor** software, see section 4.1.
3. Acceptance tests, see section 4.2.
4. Completing the acceptance test form, see section 9.4.
5. Performing user training and completing the training form, see section 9.1.

4.1 Checklist – Technical Setup

The nëo™ **monitor** software has a workflow called “Technical Setup” that contains all software configuration parameters. The application menu on the nëo™ **monitor** start screen contains the

 **Technical setup** menu item.

After selecting the Technical Setup, a password inquiry will pop up. Enter the password (default password is 0000). Run through the settings in the checklist below and adjust according to the end users’ needs. Depending on the local preferences, additional settings might be adjusted.

Note:

Deciding on the configuration requires knowledge and experience with clinical EEG recording parameters. Make sure to have the following checklist approved by an appropriate representative from the end-user’s site.

Checklist – Technical Setup

#	Name	Selected setting	Approved by
1.	General -> Language <i>Set local language</i>		Date:
2.	General -> Units <i>Select metric or imperial unit(s).</i>		Name:
3.	General -> Impedance <i>Select the electrode type used for this installation, if applicable.</i> <i>Adjust automatic impedance check time interval</i>		Position:
			Signature:

4.	General -> Filter <i>Adjust the Notch frequency according to the local power line hum frequency (50Hz / 60Hz)</i>		
5.	Display -> Color theme <i>Dark or light</i>		
6.	Display -> View settings <i>Default EEG sensitivity</i>		
7.	Display -> Screen calibration <i>Calibrate the screen with a ruler.</i>		
8.	Hardware setup <i>User-specific electrode positions</i>		
9.	Montage <i>User-specific re-referencing</i>		
10.	Protocol <i>User-specific selection of hardware setup, montage(s) and view settings</i>		
11.	Annotations <i>Note that annotations are language-specific.</i>		
12.	Passwords (Technical set-up, Review) <u>Caution:</u> Do not forget your password. In case the password is lost, please contact the manufacturer. <u>Caution:</u> Do not share the password with unauthorized persons.		

13. Changes in other settings

4.2 Acceptance Test Run – On site deployment

The following table defines a System Acceptance test run after completing the end-user site deployment.

#	Reference	Test name
1.	→ Test1	Basic functional test
2.	→ Test2	Export to default location
3.	→ Test3	IEC 62353: Visual inspection
4.	→ Test4	IEC 62353: Protective earth resistance -- R_{PE}
5.	→ Test5	IEC 62353: Insulation resistance -- R_{IR}
6.	→ Test6	IEC 62353: Insulation resistance -- R_{IR}
7.	→ Test7	IEC 62353: Insulation resistance -- R_{IR}
8.	→ Test8	IEC 62353: Equipment leakage current -- $I_{L,Eq.}$
9.	→ Test9	IEC 62353: Applied part leakage current -- $I_{L,Ap.}$

Notes:

- The tests are described in section 7 System Acceptance Testing.
- The acceptance tests shall be documented using the nëo™ system acceptance test form in section 9.4.

5. Updating nëo monitor

An update of the nëo™ **monitor** requires 3 steps:

1. Update of the software, see section 5.1.
2. Confirmation and adjustment of the nëo™ **monitor** settings.
3. Running the acceptance test defined in section 5.2.

Additional helpful equipment: external keyboard

5.1 Installation of a nëo™ monitor Software Update

The chapter explains how to apply an updated version of the nëo monitor software.

#	Step	Description
1.	Backup	Start nëo™ monitor software. Backup neonatal database to external HDD
2.	Uninstallation as Admin	Restart the PC Login with the “Administration” account Open the control panel and choose “Programs” • Uninstall the “NeonatalApp product bundle”
3.	Log in neo user	Restart the PC Log in as “neo” user.
4.	Update SQL Server Security <i>(Required only for software version 1.2 and below)</i>	• Start SQL Management Studio • Login • Right click on <PC name>\SQLEXPRESS64 server instance to select “Properties” • Go to page “Security” • In first section “Server authentication” select: “SQL Server and Windows Authentication” • Confirm with “OK” • Right click on <PC name>\SQLEXPRESS64 server instance to select “Restart” • Close SQL Management Studio
5.	Wallpapers <i>(Required only for software version 1.2 and below)</i>	Set the nëo™ wallpapers as Windows Lock screen and Windows Background for the neo user account. The wallpaper images can be found on the USB memory stick that contains the software installer. Lock screen: ○ DDE-OP-0156_neo_wallpaper_1920x1080_....jpg Background: ○ DDE-OP-0156_2_neo_wallpaper_Please_wait_1920x1080_....jpg

		- First, copy both images to C:\ProgramFiles\ - Open “Start -> Windows Settings -> Personalization -> Background” and click on “Browse” to select the wallpaper image. - On the left-hand side of the window, switch to “Lock screen” and click on “Browse” to select the 1st image for this purpose. <i>Note:</i> Both images (Lock screen and Windows background) look very similar. The only difference is the “Please wait...” text at the bottom of the Windows background image.
6.	Install .net 4.8 framework for neo Pcs with an LTSB version older than 1903	In case you have an older ACL PC that has an LTSB version older than 1903 get an offline installer for .net 4.8 framework (runtime) from the website: https://dotnet.microsoft.com/en-us/download/dotnet-framework/net48 - Under the table advanced downloads select the line for “offline installer” the column “ run apps-Runtime”(not the developer packs) : - NDP48-x86-x64-AllOS-NEU.exe will be downloaded !!! The offline installer is important cause there might be no internet access on the nëo™ Pc in the hospital Transfer it the nëo™ PC and start the .exe while being logged in as a neo user (Enter Administrator credentials (default is “neoAdmin2018”) Now it should be possible to proceed with the nëo™ installer. (following step)
7.	Install new nëo™ monitor software	Double click on install_neonatal.bat. Enter Administrator credentials (default is “neoAdmin2018”). Proceed until the software is successfully installed. Finally, restart the PC.
8.	Update of database	After the reboot, login as a neo user The nëo™ monitor software should start automatically and will start upgrading the database, make sure there is no unexpected shutdown during that time Once the database has been successfully upgraded the protocol view will show up
9.	Creating a new config file	Close the software Quit the software and bypass the upcoming watchdog pressing the button Alt+F4 on the external keyboard Open the file explorer and type %allusersprofile% In the opened directory pick the following path → eemagine_medical....\defaultDomain_path..... and the latest version of neo Rename the user.config in that directory into e.g: “leg.config”

		Start neo again it will automatically start with a fresh config add related verifier passwords to enable the technical workflow and review workflow again Adjust the technical options again towards the users needs e.g language, default filters, color theme and
10.	Install Windows Updates	Make sure all available and optional Windows updates are installed. Do the following to let Windows install all pending OS updates from the internet. • Open “Start -> “Windows Settings -> Update & Security -> Check for updates” • Repeat clicking on “Check for updates” until Windows finds no more updates and states • Make sure required reboots are also done “You’re up to date” In Windows 11, optional updates can be found under Advanced options.
11.	Check the auto-start	After restart, log in as neo user and make sure that: ✓ nēo™ monitor starts up automatically at the end of Windows start ✓ nēo™ monitor is able to reach the database
12.	Security setting check	Please make sure all security settings are configured as defined in section 3.1: • Windows Security – General Remarks → Step 26 • Windows security – Firewall → Step 27 • SMB network settings → Step 28

5.2 Checklist – Technical Setup

Re-run through the configuration of **něo™ monitor** software, see section 4.1, and make sure that all parameters are still correct. Print the checklist and have it signed again. This is a mandatory step.

5.3 Acceptance Test Run – Software Update

The following table defines the mandatory System Acceptance test after completing a **něo monitor** update.

#	Reference	Test name
1.	→ Test1	Basic functional test
2.	→ Test2	Export to default location

Notes:

- The tests are described in section 7 System Acceptance Testing.
- The acceptance tests shall be documented using the **něo™** system acceptance test form in section 9.4.

6. System Maintenance

6.1 Windows Software- and Security Updates

Automatic windows updates are disabled on the nëo™ PC. This is to prevent the system from running into unknown configuration states and to assure uninterruptedly high system performance during operation to record EEG data.

In order to assure the nëo™ system employs the latest security updates, the hospital's local IT-administrator must regularly and manually install the latest Windows software- and security updates. After each Windows update, run the mandatory acceptance test defined in section 6.2.

#	Step	Description
1.	PC login as Admin	Start the PC Login to the "Administrator" account to obtain full rights for updating the system.
2.	Download & Install OS- and Security-Updates	Check for Windows updates by opening: → "Start -> Settings -> Update and Security -> Windows Update" Confirm download and installation of the update and await the process to finalize. Optional updates must also be downloaded and installed. In Windows 11, optional updates can be found under Advanced options.
3.	Restart PC and check availability of further updates	After updating, restart the PC and repeat step 2. until no further updates are found.
4.	Update Windows Defender	Check for updates in the Windows Security Virus & threat protection screen to check for the latest updates.
5.	Check the auto-start	After restarting, log in as neo user and make sure that: ✓ nëo™ monitor starts up automatically at the end of Windows start ✓ nëo™ monitor able to reach the database

6.2 Acceptance Test Run – Windows Software- and Security Updates

The following table defines the mandatory System Acceptance test after each Windows OS update.

#	Reference	Test name
3.	→ Test1	Basic functional test
4.	→ Test2	Export to default location

Notes:

- The tests are described in section 7 System Acceptance Testing.
- The acceptance tests shall be documented using the nëo™ system acceptance test form in section 9.4.

6.3 Servicing

The following steps should be performed as part of the annual servicing.

Note:

Local regulation might require a tighter schedule for servicing.

#	Step	Description
1.	Check for Windows Software- and Security updates	See section 6.1.
2.	Check for sufficient disk space	Start neo, check for sufficient remaining recording space for the protocol with the most EEG channels. The remaining recording time is given at the bottom of each protocol tile at the start page of neo. In case there is not enough recording space left, backup the database and delete old recordings.
3.	Re-run deployment acceptance tests	Execute and file all tests as defined in section 4.2.

7. System Acceptance Testing

This chapter describes how to set-up and run the system acceptance tests. Tests are sorted in sections:

- Functional system tests
- Safety tests according IEC 62353

To document your tests in accordance to IEC 62353, fill in your test results in a printout of the → 9.4 nëo™ system acceptance test form!

Note:

The functional system tests require to short-circuit the EEG IN input stage of the EE-411 amplifier. We recommend using the following equipment:

- RC-811 “EE-4XX short circuit adapter”.

The safety tests require a temporal electrical connection to the EEG IN stage of the EE-411 EEG amplifier or the XC-810 EEG touchproof adapter. We recommend using the following equipment:

- M01770 “Test adapter for EE-4xx”,
- M02409 “1 pol GND touch proof Test Adapter” (10 pieces required),
- M02407 “Connection board for EE-2xx test set M01769, EE-4xx test set 1770”.

All equipment can be purchased from eemagine GmbH.

7.1 Functional Tests

#	Test	Description
Test1.	Basic functional test	Preparation: • Make sure all cables at the backside of the AiO-PC are correctly and firmly connected. Adjust, if necessary. • Connect shortcut test adapter [RC-811] to the EEG input of the EE-411 amplifier. Test steps: • Start nëo™ • Select “Full” protocol to record all EEG channels. When topographic impedance view shows up, wait a few seconds (5s) to measure. ✓ Impedance for each channel must be $\leq 1k\Omega$ • Proceed to online monitoring by clicking the bottom right corner button with “EEG” trace icon. Switch to Referential montage. ✓ All EEG channels of the protocol must be displaced as signal traces ✓ Each channel shows low noise amplitude with absolute value less than $< +2\mu V$ • Remain in online monitoring (recording) for 5 minutes • Assign subject to the recording. Do so by selecting the navigation button in the bottom right corner of the screen. • A list view of all subjects shows up, allowing to select one for assigning the EEG. In the top left corner, a button with “+” icon allows to create a new subject. • After assigning an existing subject from the list (or creating a new subject with “+”), return to online monitoring by selecting the navigation button in the bottom right corner. ✓ The view changes back to aEEG + EEG monitoring. The bottom right corner button now carries a rectangle icon indicating “Stop”. • Stop online monitoring by selecting the navigation button in the bottom right corner. Confirm to leave online monitoring when prompted.

		✓ Screen switches to nëo's main page, showing protocol tiles and "Review". • Click "Review" and select the subject and recording from the test recording session. ✓ Review screen shows aEEG and EEG traces as well as annotations that have been created/present during online monitoring. Checks for test passed (during Review): ✓ No "amplifier disconnect" annotation markers present throughout the 5 minute recording ✓ No further errors indicated as annotation markers or toast messages throughout the reviewed 5 minute recording ✓ EEG and aEEG shown • Close Review and return to nëo's main page by selecting the navigation button with "Stop" icon in the bottom right screen corner.
Test2.	Export to default location	Preparation: • Make sure that the end user's desired export options are set (location / path / format / data) Test steps: • Open the recording from test step 1 in review. • In the application menu (three stacked dashes icon in the top left corner button), select "Export". • Confirm when prompted to export. Checks for test passed: ✓ Exported EEG and aEEG files can be found at the specified location. <u>Recommendation:</u> For good documentation, a copy of the exported EEG of the short-circuit test (test 1) should be stored with a reference to the system's Inst-ID.

7.2 Safety Tests according IEC-62353¹

To run electrical safety tests, an IEC 62353 capable and conformant electrical test device (also called safety analyzer) is required. Test devices are available from a multitude of manufacturers.

Please feel free to contact support@eemagine.com in case of questions or to get a recommendation on a suitable test device.

Test3.	Regular Visual inspection IAW IEC 62353	Check for any signs of wear or deviations related to the items in the following list. Checks: • Labeling is legible and complete. • Integrity of mechanical parts. • Service port has no signs for malfunction. • All screws are tightened. • No coloring gradient or degradation on any of the housings or accessory parts. Degradation could otherwise indicate exposure to irregular heat. • No signs of contamination or spillage. • Accessories are complete, intact and compatible with the system. • The documentation is complete and reflects the present system revision.
Test4.	IEC 62353: Protective earth resistance -- R_{PE}	Preparation: Please establish the electrical connections between your IEC 62353 test device (safety analyzer) and the system according • Please establish the electrical connections between your IEC 62353 test device (safety analyzer) and the system according ⇒ See Figure 51: Protective earth resistance test • In particular, connect the system mains to your test device and attach the test devices probe element to the GND pin of the AiO-PC. The GND pin is located on the backside of the device besides its service ports.

¹ MEDICAL ELECTRICAL EQUIPMENT – RECURRENT TEST AND TEST AFTER REPAIR OF MEDICAL ELECTRICAL EQUIPMENT

		- Moreover, use the probe tool to measure protective earth resistance on all available accessible conductive parts. Test run: - Switch the test device to resistance testing mode. Find more advice in the manual of your specific test device. - Measure! - Note down the <u>highest</u> recorded value. Check: $R_{PE} < 500m\Omega$
Test5.	IEC 62353: Insulation resistance: -- R_{IR} <i>Between mains parts and accessible conductive parts.</i>	Preparation: - Please establish the electrical connections between your IEC 62353 test device (safety analyzer) and the system ⇒ See Figure 46: Insulation resistance test – mains parts and accessible conductive parts. - Set the probe tool on all available accessible conductive parts (e.g. system device enclosures and service ports) iteratively. Test run: ▶ Switch the test device to insulation resistance testing mode. Find more advice in the manual of your specific test device. - Measure! ▶ Note down the <u>lowest</u> recorded value. Check: ✓ $R_{IR} > 70M\Omega$
Test6.	IEC 62353: Insulation resistance -- R_{IR} <i>Between mains parts and applied parts.</i>	Preparation: Please establish the electrical connections between your IEC 62353 test device (safety analyzer) and the system ⇒ See Figure 47: Insulation resistance test – mains parts and applied parts

		- Switch the test device to insulation resistance testing mode. Find more advice in the manual of your specific test device. Test run: - Set the probe tool on all available applied parts (e.g. headbox inputs) iteratively. - Measure! - Note down the <u>lowest</u> recorded value. Check: ✓ $R_{IR} > 70M\Omega$
Test7.	IEC 62353: Insulation resistance -- R_{IR} <i>Between applied parts and accessible conductive parts.</i>	Preparation: - Please establish the electrical connections between your IEC 62353 test device (safety analyzer) and the system ⇒ See Figure 48: Insulation resistance test - applied parts and accessible conductive parts - Switch the test device to insulation resistance testing mode. Find more advice in the manual of your specific test device. Test run: - Set the probe tool on all available applied parts iteratively. - Measure! - Note down the <u>lowest</u> recorded value. Check: ✓ $R_{IR} > 70M\Omega$
Test8.	IEC 62353: Equipment leakage current -- $I_{L,Eq.}$ <i>Between mains parts and applied parts. Test 1.</i>	Preparation: - Please establish the electrical connections between your IEC 62353 test device (safety analyzer) and the system ⇒ See Figure 49: Leakage current test - equipment and touch proof leakage current

		▶ Switch the test device to leakage current testing mode. Find more advice in the manual of your specific test device. Test run: ▶ Set the probe element on all available applied parts iteratively. ▶ Measure! ▶ Note down the <u>highest</u> recorded value. Check: ✓ $I_{L,Eq.} < 100\mu A$
Test9.	IEC 62353: Applied part leakage current -- $I_{L,Ap}$. <i>Between applied parts and accessible conductive parts.</i> Attention: mains voltage on applied- and accessible conductive parts during test! <u>Do not touch!</u>	Preparation: ▶ Please establish the electrical connections between your IEC 62353 test device (safety analyzer) and the system ⇒ See Figure 50: Leakage current test - mains voltage on applied parts and accessible conductive parts ▶ Switch the test device to leakage current testing mode. Find more advice in the manual of your specific test device. Test run: ▶ Set the probe element on all available accessible conductive parts iteratively. ▶ Measure! ▶ Note down the <u>highest</u> recorded value. Check: ✓ $I_{L,Ap.} < 5000\mu A$

8. Repair / RMA²

This chapter explains the procedure to get materials repaired by eemagine GmbH. Note that eemagine GmbH will only accept warranty repair orders from its direct contracting parties and only for parts the direct contracting party purchased from eemagine GmbH.

#	Step	Description
1.	Contact eemagine support	Contact our support team under support@eemagine.com Mention that you need an RMA for nëo. Provide the system's Installation ID number. The Inst-ID is printed on the support voucher document you obtained as part of the system delivery. For cap related issues, provide in addition: • serial number • product code • failure description For Amplifier related issues, provide in addition: • serial number • failure description For AiO-PC related issues, provide in addition: • serial number • failure description If in doubt about the faulty part, provide at least: • Installation ID • A detailed description about the problem: The functionality you work with, what you would expect to happen and what you observed happening instead.
2.	Fill out RMA form	eemagine support will come back to you within one working day to acknowledge that we have received your message and assign a "claim ID" reference. Please use this reference throughout the following repair process. eemagine support will analyze your claim as soon as possible and might come back to you with further questions. If analysis shows that a part needs repair or replacement, the RMA process is started: • eemagine support will send you an RMA form. • Use this RMA form, fill in missing details and additional information to explain the defect. • Make sure to comply with all regulations and terms on the RMA form. • Print and sign the RMA form.

² RMA: Return Material Authorization

3.	Shipment	Send the defect part(s) and the signed RMA form to eemagine's address provided on the form. Important: • Make sure the claim ID is always provided with the shipment! • Never send any equipment without having received and filled the RMA form! • Direct shipments of repair items by the end-customer to eemagine should be avoided and require extra arrangements and explicit prior approval by eemagine support!
4.	Inspection Estimated repair costs Cost acceptance & repair Return shipment Payment	The items received by eemagine support will be inspected for failures. For out-of-warranty repairs, eemagine support will communicate the expected repair price to you. As soon as you agree on paying the repair costs, repair will be started. Depending on the agreed shipment route, eemagine logistics will send all repaired items back to you or the end-customer. For out-of-warranty repairs, eemagine will invoice you for the repair.
5.	Acceptance test at end-user	Upon receipt and installation of the repaired parts at the customer site, an acceptance test needs to be run and documented, as explained in section 4.2 of this guide.

9. Supporting Documents and Forms

9.1 nëo™ end-user training form

Training Form - nëo™ End-Users				
Training date:		Location:		
Name:		Company:	Trainer	Signature:
Trainees				
	Second name	First name	Institution	Position
01				Signature
02				
03				
04				
05				
06				
Training contents				
Trainees and trainer verify with above signatures that a full training with regard to nëo™ aEEG monitor was given and that all trainees are fully capable of using nëo™ on their own. The trainees declare that they will comply with the requirements given in the nëo™ User Guide. The trainees were informed about the intended use of nëo™ and the safety warnings for the system.				

9.2 nëo™ system installation training form

Training Form - Installation of nëo™ Systems and Solutions

Training date: Location:

Name: Company: **Trainer**
Signature:

	Trainees				
	Second name	First name	Company	Function	Signature
01					
02					
03					
04					
05					
06					
07					
08					
09					
10					

Trainees and trainer verify with above signatures that a full training with regard to nëo™ system installations was given and that all trainees are fully capable of performing installations for nëo™ systems and solutions on their own including validation. The trainees declare that they will comply with all requirements given in the document “nëo™ Deployment Guide” based on the latest revision that was effective on the date of the training.

9.3 nëo™ monitor software license request form

License Request Form - nëo™				
Date:		Installation ID:		
Operator (performing the installation)				
Name:		Company:		Trained on:
	Institution / Company	Name of Responsible	Function	
ANT Partner				
Distributor				
End User				
Purchase Order(s) - all purchase orders placed with eemagine/ANT to complete the solution				
	Purchase order ID	Order date	Purchased by	
01				
02				
Deliveries - eemagine/ANT delivery note IDs for all system parts used for building the solution				
	Delivery note ID	Comments	Supplier	
01				
02				
03				
Main solution components				
	Manufacturer	Product name	Product code	Version
				Serial number
01 Computer				
02 EEG amplifier				
03				
04				
05				
06				
Computer Operating System				
Windows version:		64bit/32bit:		System language:

9.4 nëo™ system acceptance test form

The acceptance test form qualifies for warranty and support

Acceptance Test Form - nëo™ Systems and Solutions			
Date:		Test Run:	
		Inst-ID:	
Operator (performing the validation)			
Name:		Company:	
		Trained On:	
<i>Medical device(s) with IEC 60601-1 compliance included in the system test</i>			
Name:		RN:	
		SN:	
Name:		RN:	
		SN:	
Name:		RN:	
		SN:	
Acceptance Tests			
#	Test description	Pass/Fail/NA	Expected result to <i>pass</i> test
Test1.	Basic functional test $[\mu V_{pp}]$ = "microvolt peak-to-peak"		Check in review: A ✓ All protocol channels are displayed as EEG traces ✓ Low noise amplitude with absolute values less than $U_{noise} < 2\mu V \triangleq 4\mu V_{pp}$ ✓ None of the channels show solely flat-line signal ✓ Impedance values are displayed as below 1kΩ ✓ No "amplifier disconnect" markers in aEEG trace ✓ No further error markers in aEEG trace

Test2.	Export to default location		Check after exporting: ✓ EEG and aEEG files are created at the expected export location
Test3.	IEC 62353: Visual inspection		Check for any signs of deviations related to: ✓ Labeling is legible and complete ✓ Integrity of mechanical parts ✓ Service port has no sign of malfunction ✓ All screws are tightened ✓ No coloring degradation ✓ No signs for contamination or spillage ✓ Accessories are complete and compatibility ✓ Documentation is complete and reflects the present system revision

Test4.	IEC 62353: Protective earth resistance -- R_{PE}		$R_{PE} < 500m\Omega$ (enter highest recorded value)
Test5.	IEC 62353: Insulation resistance -- R_{IR} <i>Between mains parts and accessible conductive parts.</i>		$R_{IR} > 70M\Omega$ (enter lowest recorded value)
Test6.	IEC 62353: Insulation resistance -- R_{IR} <i>Between mains parts and applied parts.</i>		$R_{IR} > 70M\Omega$ (enter lowest recorded value)
Test7.	IEC 62353: Insulation resistance -- R_{IR} <i>Between applied parts and accessible conductive parts.</i>		$R_{IR} > 70M\Omega$ (enter lowest recorded value)
Test8.	IEC 62353: Equipment leakage current -- $I_{L,Eq.}$ <i>Between mains parts and applied parts.</i>		$I_{L,Eq.} < 100\mu A$ (enter highest recorded value)
Test9.	IEC 62353: Applied part leakage current -- $I_{L,Ap.}$ <i>Between applied parts and accessible conductive parts.</i> <i>Attention: mains voltage on applied- and accessible conductive parts during test! Do not touch!</i>		$I_{L,Ap.} < 5000\mu A$ (enter highest recorded value)

Overall assessment (choose one):

- ☐ No safety or functional deficiencies detected
- ☐ Deficiency detected but no direct risk to continue clinical use. Correction required.
- ☐ Deficiency detected. Equipment should be taken out of service and repaired.

Next recurrent test planned in (choose one):

- ☐ 12 months
- ☐ 24 months
- ☐ __ months

Responsible for next recurrent test and date of: _____ / _____

Test Operator Signature / Date: _____ / _____

10. FAQ – Frequently asked Questions

FAQ 1. How can I obtain technical assistance with nëo™ or help in case of questions?

Answer: Please be very welcome to contact eemagine-support at any time!
We are regularly available on the following channels:

❖ Skype

Skype name: [eemagine_support](#)

Please be welcome to get an instantaneous response from an engineer on Skype on working days from 9am to 4pm. Berlin, Germany, time zone: UTC+1.

❖ Email

Contact: support@eemagine.com

To get qualified help on technical questions, to request remote assistance, to initiate a repair or to express a complaint or your satisfaction, always reach us under this email address. An initial response will come within 24 hours on working days.

Note:

If the problem is related to a particular device or part, please provide a) the product code from its label, b) its serial number and c) your failure description when requesting help from eemagine support.

FAQ 2. What do I need to do if a required system test fails?

Answer: Please contact eemagine support to get advice on how to fix the problem.
Please provide the available system details, including:

- the failing test
- the application log-file

Note: → FAQ 4 explains where to locate the log-files.

FAQ 3. How can the nëo™ monitor software application be closed to maintain the system?

Option 1: Restart the system, log in using the Administrator account.

Option 2: Attach a USB keyboard to the USB breakout adapter. Quit the nëo™ monitor software. Press ALT + F4 once the pop-up window “Do you want to restart nëo or shutdown the PC” appears.

FAQ 4. Where do I find the nëo™ monitor log files?

Answer: Log files can be found in the hidden neo user system directory %localappdata%.

- a. Close the **nëo™ monitor** application as described in FAQ3, Option 2.
- b. Type %localappdata% (till vs. 1.4.0)/ %allusersprofile% (from vs. 1.4.1 on) into your Windows Explorer's address bar
- c. Go to the subdirectory \eemagine_Medical_Imaging_GUID, where GUID is a unique identifier on each system.

Tip:

If unsure which log-file is the right one to choose, simply zip all log-files in %localappdata%\eemagine_Medical_Imaging_GUID and provide this zipped file to eemagine support.

FAQ 5. *Where can I find the user guides for the neo™ and the eego amplifier hardware?*

Answer: The user guides can be found on the USB thumb drives delivered with your neo™ and your amplifier.

FAQ 6. *I'm using needle electrodes and the displayed impedances always remain too high. What can I do about it?*

Answer: Make sure to have pre-selected needle electrodes in **nëo™ monitor** software settings. Go to Technical Setup → General Settings → Impedance and signal quality settings.

- ✓ Select: "Always subcutaneous needle" or "Always ask".

FAQ 7. *Impedances don't decrease during setting up the subject for EEG. What's wrong?*

Answer: Please check for the following possible root causes:

- a. Reference and/or GND electrode is not yet gelled. Please gel these first!
- b. Headbox- or electrode connectors are not yet connected. Please connect them!
- c. Wrong recording protocol is chosen. Please select the protocol that represents your EEG recording setup!
- d. Wrong electrode type selected, e.g. single lead needle electrodes instead of EEG cap. Please adjust nëo's setting, see FAQ 6.
- e. Broken cap. Follow the instructions to return the material and contact eemagine support to request an RMA.

FAQ 8. *The warning "Non-physiological data detected" appears during EEG recording. What does it mean and what can I do to prevent it?*

Answer: Please check for the following possible root causes:

- a. Make sure all electrodes have proper electrical connection to the skin by checking their impedance value.
- b. If only a single electrode is affected, try to replace it. Replacement is of course only possible in setups using the headbox adapter, which provides access to single electrode leads.
- c. Make sure there are no unnecessary sources of intense electromagnetic activity nearby present. These are for instance cell phones or any sort of unshielded electric device.
- d. If you find the system environment is affected by strong hum noise and can't be improved by displacing the sourcing devices, you may still lower nëo's sensitivity to

artifacts in Technical Setup → General settings → Impedance and signal quality settings. → The relevant setting is named “low” sensitivity

- e. If all before mentioned steps did not help, please repeat acceptance test 1 (recording with short circuit test adapter) to check for a defect amplifier.

FAQ 9. *The recording specifically shows strong hum noise. By which means can I reduce it?*

Answer: Please try the following approaches to reduce the hum noise:

- a. Make sure the notch filter is enabled and set to the correct 50Hz/60Hz mains frequency according to your national power grid specifications.
- b. Check the environment for unnecessary electric devices and displace all other electrical equipment away from the nëo™ monitor system.

Note: Never place additional electrical equipment, which does not belong to the system, onto the nëo cart!

- c. Use the shortest applicable electrode cables to avoid the cables winding up in loops forming further electrical inductivities, unintentionally.
- d. Make sure nëo monitor is connected to an electrically grounded, wall mounted mains power socket.
- e. Move nëo™ monitor to another room of your institution. Check again for the presence of hum noise. In case hum-noise was reduced, identify and remove the noise source in your original recording room or consider switching to another room, if possible.
- f. If none of the aforementioned approaches helped, please feel free to contact eemagine support for further help.

FAQ 10. *There is an error message “Amplifier disconnected”. What might be the reason and how can I resolve it?*

Answer: The amplifier connection was found to be interrupted. Check the USB connection at the amplifier and the PC. Check all cable connections below the service cover plate are well fixated. For this check, you need to remove the Torx T10 screws of the service port cover plate.

FAQ 11. *nëo displays the toast-notification error message “Not enough disk space left” or “Low disk space”. What do I need to do?*

Answer: Please do the following:

- a. Backup the database
- b. Please find and delete old recordings and subjects that are no longer needed via nëo’s Technical Setup to free more disk space.

FAQ 12. *How do I backup nëo’s database?*

Answer: Please follow these steps:

- a. Start nëo

- b. Attach a NTFS-formatted external USB hard drive with sufficient free disk space.
- c. Open the Technical settings workflow
- d. Run “Backup” from the nëo’s application menu.
- e. Await the backup operation to finish. Backup might take up to an hour, depending on the size of the database.

FAQ 13. How can a database backup get restored?

Answer: Microsoft SQL Management Studio can be used to restore a database backup. Please contact eemagine support for assistance!

Warning: *The SQL Management Studio is a powerful tool largely exceeding the functionality for database restore. If used improperly, the tool is capable enough to affect data integrity and to delete data. Always make sure to have a current database backup before using Microsoft SQL Management Studio.*

FAQ 14. How can recording data get exported and transferred to another PC for review?

Answer: Single EEG/aEEG recordings can be exported to file during both monitoring and review. Please follow these steps:

- a. Open a recording and select “Export” from the nëo menu. This can be done during monitoring or offline review.
- b. Await the export operation to finish, which takes a few seconds.
- c. The exported recording can be found at your default export location, as defined in the Technical Settings.

Note 1: Online export during monitoring will contain all data that is available to the moment when the export operation was triggered by the user.

Note 2: The exported EEG file can be reviewed with a multitude of typical EEG review and analysis software packages. We recommend the “ASA – Advanced Signal Analysis” software.

Note 3: Batch export of multiple recordings at a time or exporting data from multiple nëo™ systems to a central storage location is currently not supported.

FAQ 15. When browsing the network for storage servers, not all devices are shown. Which network setting might be responsible?

Answer: Some network storage servers are configured to use the SMB.V1 protocol. SMB.V1 is deprecated due to its outdated security standards and therefore disabled by default in nëo™.

However, SMB.V1 can technically still be enabled in “Control Panel -> Programs -> Turn Windows features on or off” and check “SMB 1.0/CIFS File Sharing Support”.

Note: We discourage using SMB.V1 and recommend reconfiguration of the storage server to SMB.V2 and/or SMB.V3 by your responsible local administrator in order to meet today's security standards.

FAQ 16. *How can the BSR be zero whereas the IBI is unequal to zero*

Answer: We define three levels when analyzing the EEG: "majority burst", "majority suppression" and "in between", i.e. neither of the first two levels.

- BSR is the ratio between "majority suppression" and "majority burst" during the last 10 minutes of the EEG.
- IBI is the average time interval between two "majority burst" intervals during the last 10 minutes.

At times when there are no majority suppression intervals, but only some majority burst intervals present in the EEG, the BSR is zero, but the IBI will not be zero.

Literature: K. Palmu, S. Wikström, E. Hippeläinen and S. Vanhatalo, "Detection of 'EEG bursts' in the early preterm EEG: Visual vs. automated detection," Clinical neurophysiology, vol. 121, pp. 1015-22, July 2010.

FAQ 17. *How are BSR and IBI indicators derived from the EEG channels?*

Answer: For each channel, burst and suppression intervals are calculated for the last 10 minutes. From there, majority burst and majority suppression intervals are defined as the times where the majority of channels display burst or suppression, respectively. Finally, BSR (burst suppression ratio) is calculated as the ratio between majority suppression interval length and majority burst interval length. IBI (inter-burst interval) provides the average duration between two majority burst intervals.

Literature: K. Palmu, S. Wikström, E. Hippeläinen and S. Vanhatalo, "Detection of 'EEG bursts' in the early preterm EEG: Visual vs. automated detection," Clinical neurophysiology, vol. 121, pp. 1015-22, July 2010.

FAQ 18. *The nëo™ monitor AiO-PC gets warm/hot, is that normal?*

Answer: Temperatures up to 54°C (130°F) on the backside of the PC can occur during normal operation. Make sure to comply with the environmental limits defined in the nëo™ user manual! Do not obstruct the air flow around the device!

FAQ 19. *The aEEG view display contains single aEEG values with increased amplitude at regular intervals. How is this to be interpreted?*

Answer: Long EEG recording periods (several hours) are supported by regular impedance measurements to control the electrode skin connection quality. The impedance measurement introduces a slight artefact in the first seconds of EEG recorded directly after the impedance measurement. As a result, the first aEEG sample after impedance measurement might have a slightly increased amplitude.

FAQ 20. The aEEG view display contains gaps, i.e. periods with no data. How is this to be interpreted?

Answer: aEEG can only be calculated for times in which EEG was measured. If EEG recording is interrupted for more than 7 seconds, no aEEG will be displayed for that time span. Longer interruptions can be caused by (manual) impedance measurements or disconnecting the amplifier's USB cable.

Note: The EEG display doesn't show gaps for periods where no data were recorded. Instead, a dashed line will indicate a discontinuity of data recording.

FAQ 21. Why do channels show flat lines when using needle electrodes?

Answer: DC offset or small static charges may build on needle electrodes. There are different DC offsets depending on the electrode type, material and tissue. Steel needle electrodes show higher DC offsets than other common electrode materials like Silver-Chloride electrodes and adhesive hydrogel electrodes. The level of DC offsets depends on many factors including environmental (e.g., temperature) and patient-related parameters (e.g., tissue oxygenation, tissue condition, body temperature) and thus may differ in every recording with needle electrodes.

Since the EEG signal is very small, it must be amplified significantly prior to recording and display. The DC offsets often have a much higher level than the EEG signals amplitude. The input range of the amplifier corresponds to the maximum amplitude (EEG signal + DC offset) that can be recorded before saturation or flatlines occur. If the physical signal (which includes the EEG signal and DC offset) exceeds the input range, this excess is clipped and not measured, resulting in saturation or flatlines.

The input signal range of the eego amplifier can be adjusted by trained technicians via the software settings. By increasing the input range, the amplifier will in many cases be able to measure and display the EEG signal of needle electrodes without saturation. Please see Appendix 11.4 for instructions on how to increase the input range to 1000 mV.

Note: DC offsets also differ considerably between needle electrode types. We therefore recommend using only needle electrodes approved by ANT Neuro for use with the nëo monitor.

FAQ 22. Why do channels show flat lines when using needle electrodes?

Answer:

- Type %allusersprofile% into your Windows Explorer's address bar
- Go to the subdirectory \eemagine_Medical_Imaging_GUID, where GUID is a unique identifier on each system.
- Open the folder structure containing the correct nëo version you are going to use
- Delete the D000 folder
- Close the file explorer and start again nëo monitor → the license request window should appear now again and this time pick the "license request code" and request the license

11. Appendix

11.1 Diagrams for IEC-62353 Safety Tests

Functional test: short circuit headbox inputs.

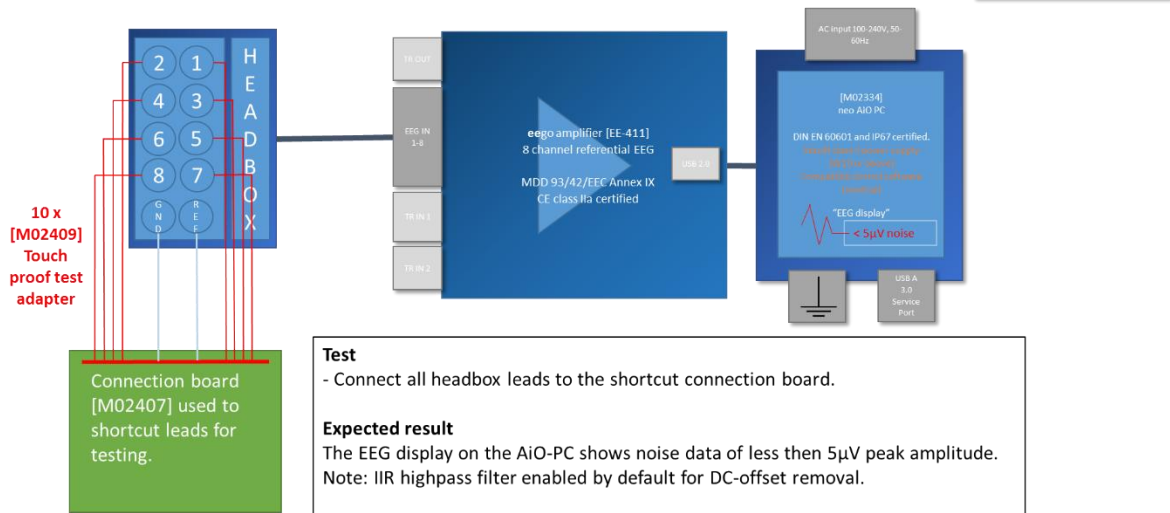


Figure 45: Headbox input shortcut noise

Insulation resistance test: mains parts and accessible conductive parts.

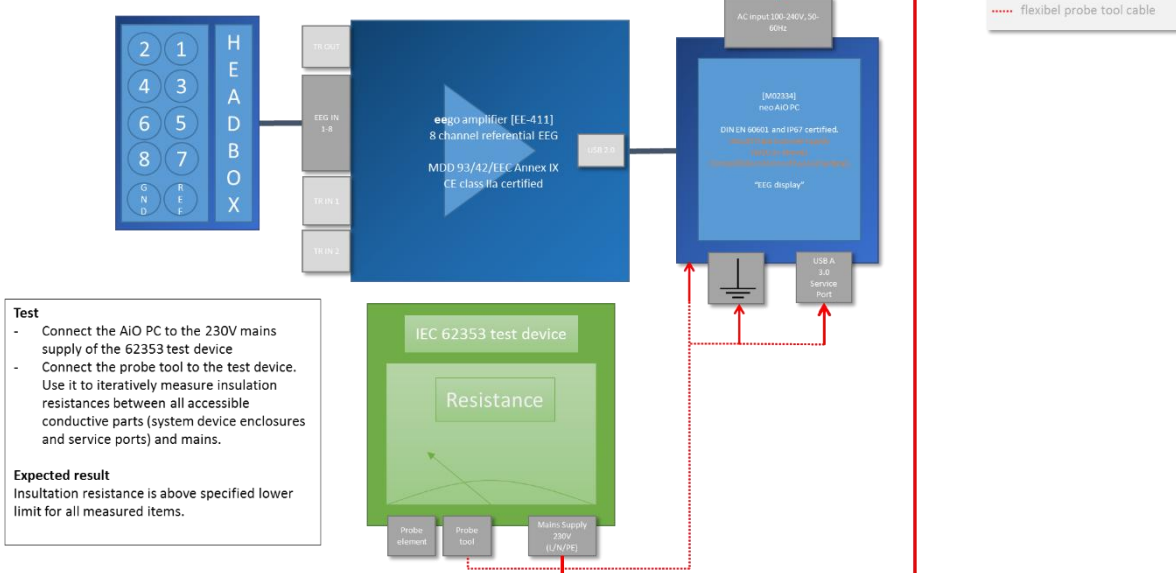


Figure 46: Insulation resistance test – mains parts and accessible conductive parts

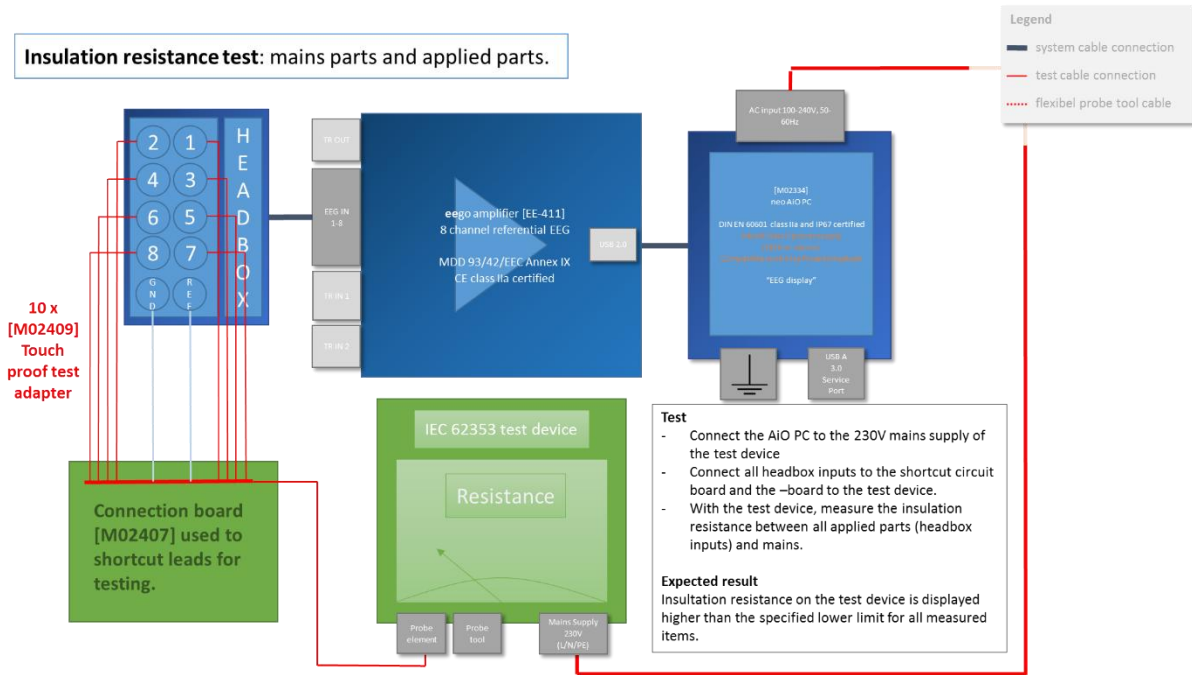


Figure 47: Insulation resistance test – mains parts and applied parts

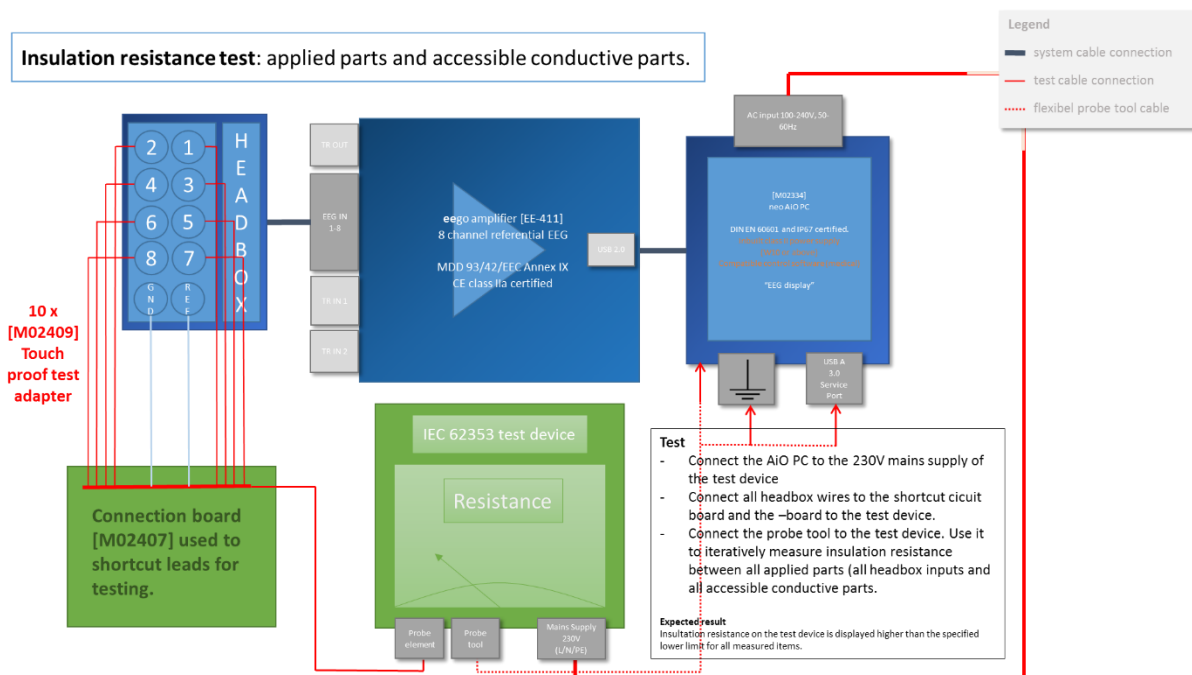


Figure 48: Insulation resistance test - applied parts and accessible conductive parts

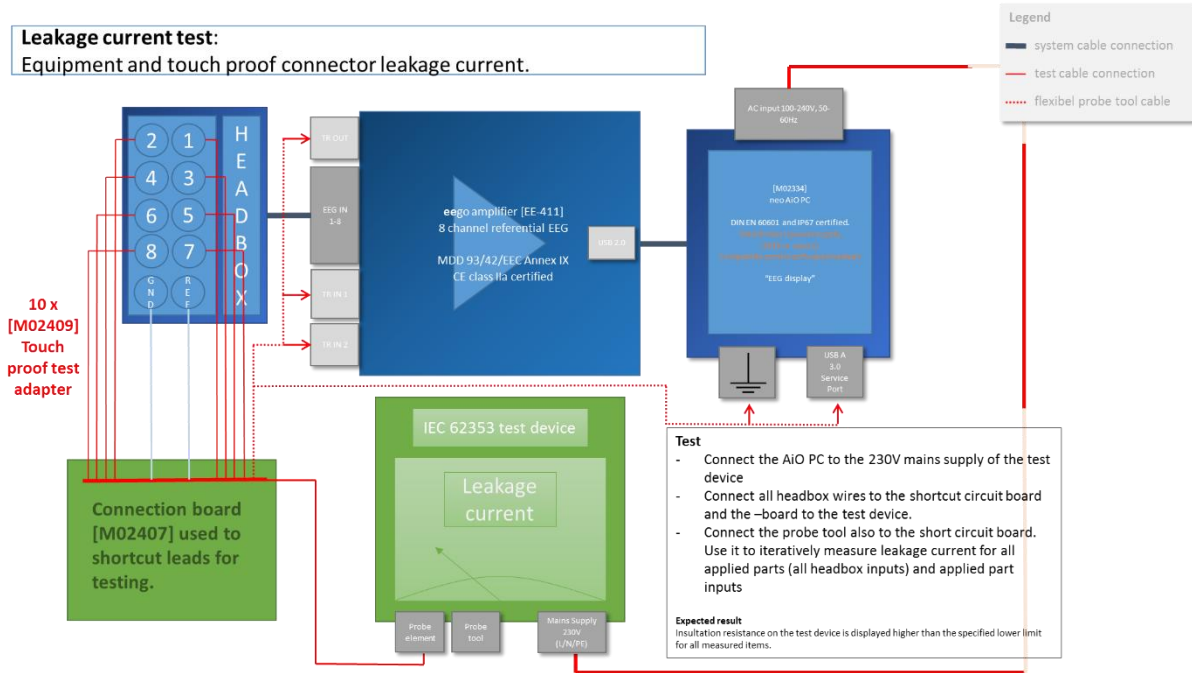


Figure 49: Leakage current test - equipment and touch proof leakage current

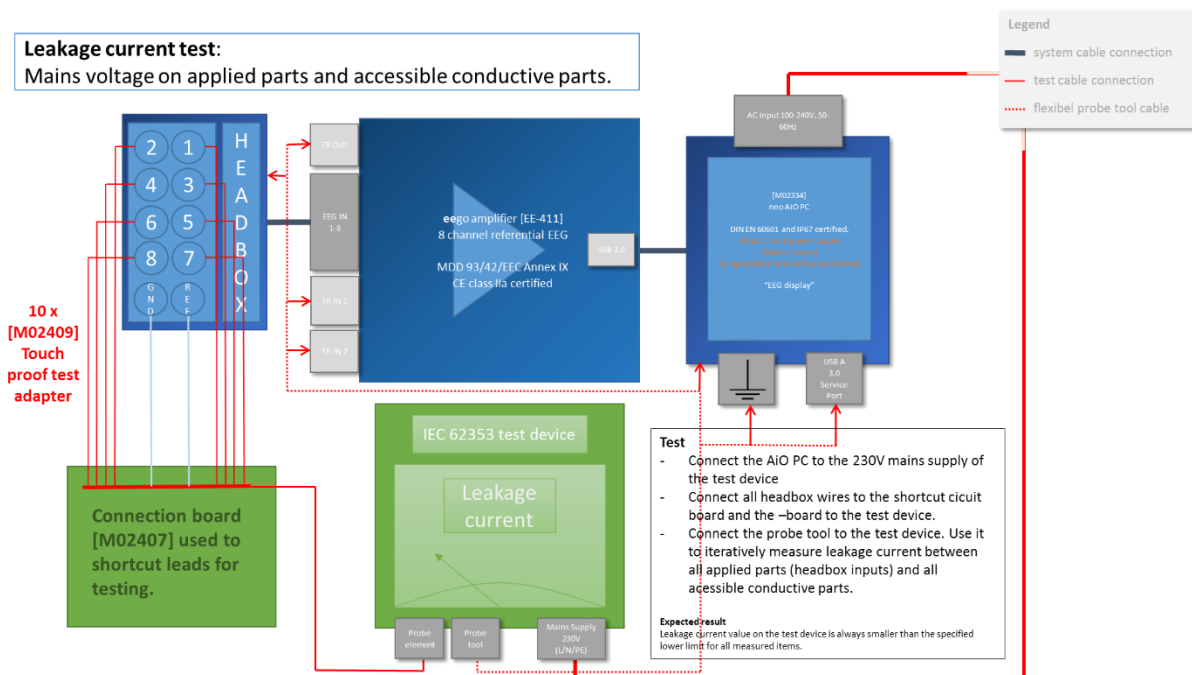


Figure 50: Leakage current test - mains voltage on applied parts and accessible conductive parts

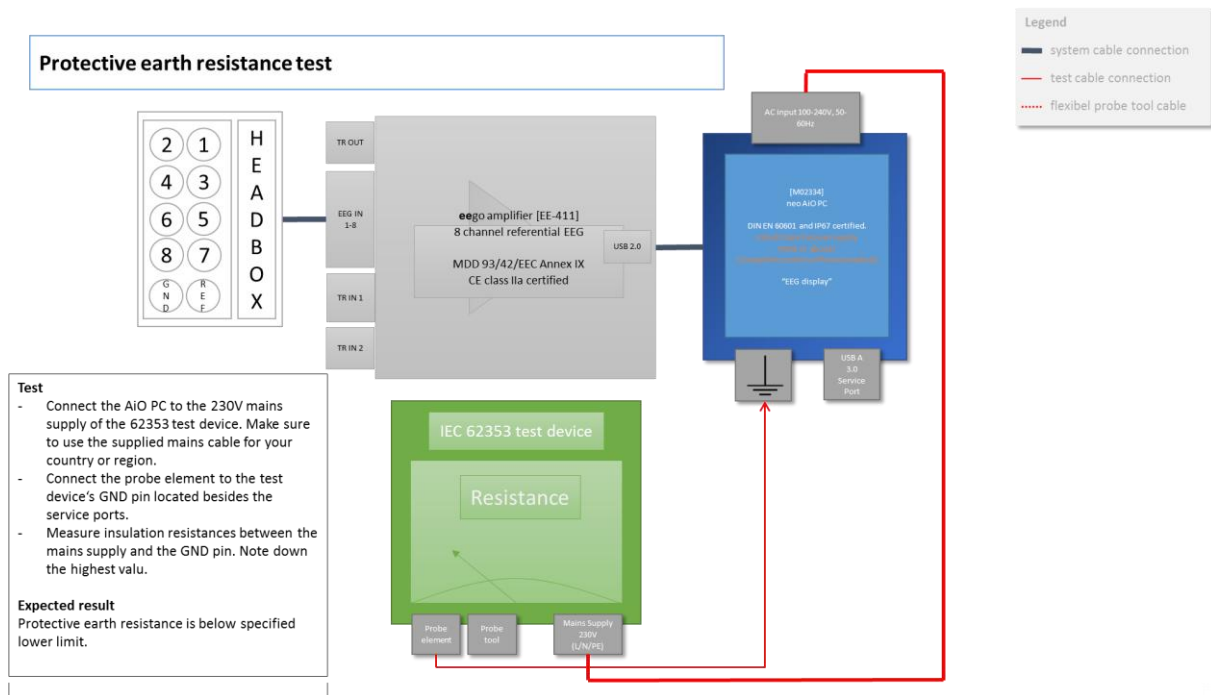


Figure 51: Protective earth resistance test

11.2 Alternative Bitlocker activation without TPM using startup PIN

Note:

This Bitlocker configuration will require entering a PIN during PC startup, when Windows based touch input capabilities are not yet available. Therefore, please consider that either a hardware keyboard or a BIOS based on-screen keyboard will be available. Otherwise don't use this Bitlocker configuration.

	Prepare Bitlocker HDD encryption without TPM: Disable TPM module to use Bitlocker with a Pin instead	To activate and configure Bitlocker to request a PIN from the user during Windows startup for HDD decryption, the TPM module needs to be disabled first. An enabled TPM module would otherwise hide the option to define a PIN during Bitlocker activation. To disable the TPM module, do one of the following • Start the "TPM.msc" module from the command line. In the dialog, click on "turn off the TPM". • Enter the computer BIOS, search TPM configuration parameters. Disable or hide the TPM, if possible. After restarting Windows and opening the Bitlocker management dialog, a notification message that a TPM module is not available is displayed.
	Prepare Bitlocker HDD encryption without TPM: Adjust Group Policy settings to disable TPM usage	Prepare the Windows GPO (group policy) to allow Bitlocker to be enabled without TPM: • Please open the Local Group Policy Editor from the command line by typing "gpedit" and pressing enter: ⇒ See Figure 55: Group policy editor • In the GPO-Editor, navigate to "Local Computer Policy -> Computer Configuration -> Administrative Templates -> Windows Components -> BitLocker Drive Encryption -> Operating System Drives". • On the right-hand side of the GPO-Editor, double click on "Require additional authentication at startup", which presents the Bitlocker settings in a new dialog: ⇒ See Figure 56: Bitlocker GPO settings ✓ Enable "Require additional authentication at startup" ✓ Enable "Allow Bitlocker without a compatible TPM, (requires...)" ✓ All other options can keep their defaults, although they refer to an enabled TPM.

		Close the dialog by clicking OK. Preparation done.
	Enable Bitlocker HDD encryption without TPM	<u>Bitlocker – enable HDD encryption</u> - Please open Control Panel -> System and Security -> BitLocker Drive Encryption - Click on “Turn on BitLocker” to open the Bitlocker Drive Encryption dialog. ⇒ See Figure 63: Bitlocker Installation Step 1/6 - Choose “Enter a pin” to unlock the HDD at startup - Imagine a secret pin. - Enter the chosen pin twice, as prompted. ✓ Don’t forget to document the Bitlocker pin you have chosen with a reference to the Inst-ID of the system! - Click on Next IMPORTANT: when prompted to store the BitLocker recovery key, choose to make a printout and additionally store it as a file to an external location, such as a backup HDD or server. Reference the recovery key with the Inst-ID of the system. ⇒ See Figure 65: Bitlocker Installation Step 3/6 It is only the recovery key that will allow access to the data, in case BitLocker will have locked the drive to protect it. Otherwise, all data will get lost. - Click on Next - Choose “Encrypt used disk space only”, when being prompted on how much drive to encrypt. - Click on Next ✓ Make sure “Run BitLocker system check” is enabled - Click on Continue and restart the PC

		✓ During restart, Bitlocker will request its newly set password • Enter the password to continue Windows startup. • In Windows' system tray, that is the bottom right corner of the taskbar, make sure the Bitlocker symbol is active and indicating HDD encryption is in progress. Drive encryption will take about 10 minutes – 1 hour, depending on the volume of data present on the HDD. After drive encryption is completed, another system reboot is required. After rebooting, drive encryption is completed and active. ✓ Bitlocker is active. Done.
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11.3 Windows configuration dialog pictures

This paragraph lists screenshots of Windows and the nēo™ monitor software, that the installation steps referred to.

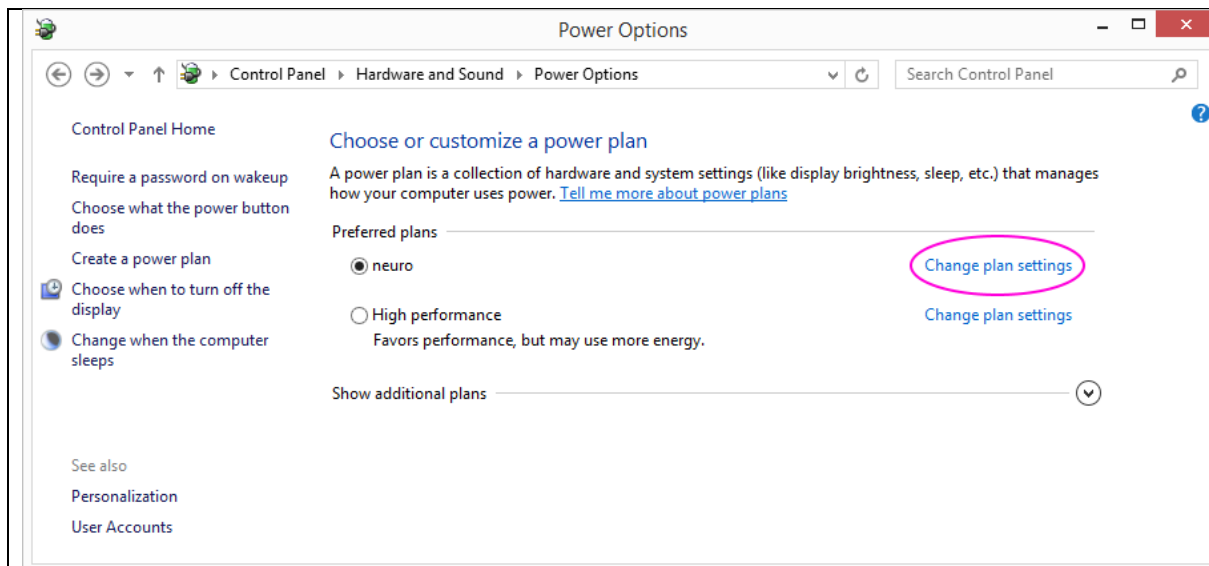


Figure 52: Change plan settings for new "neuro" Power Options profile

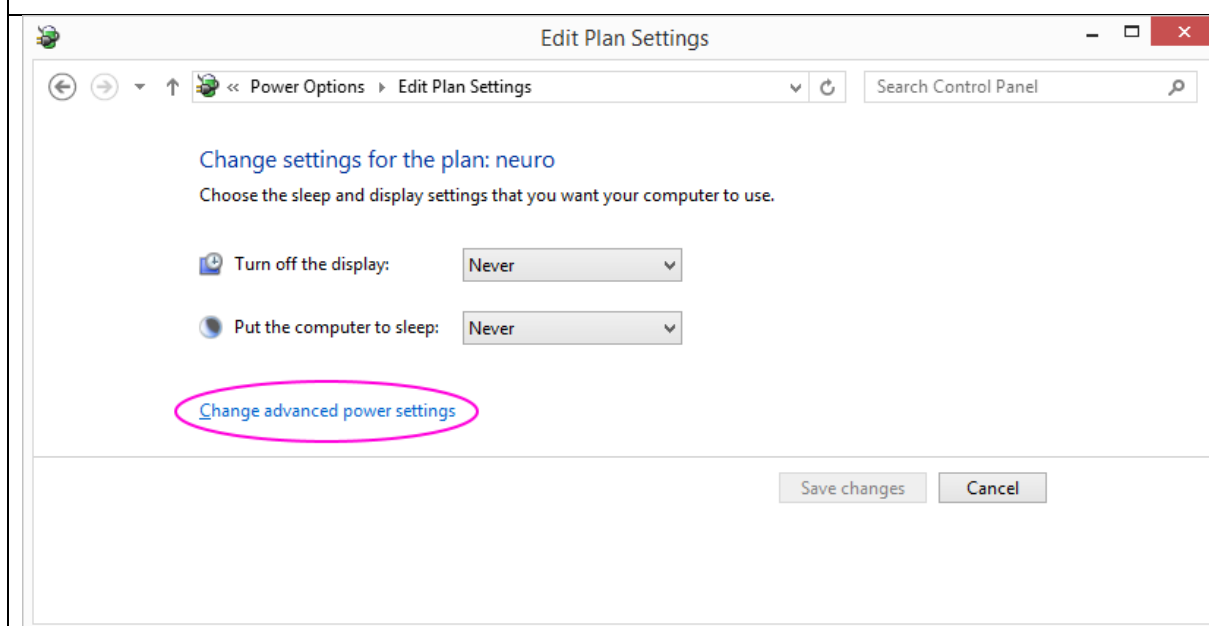


Figure 53: Open advanced power settings

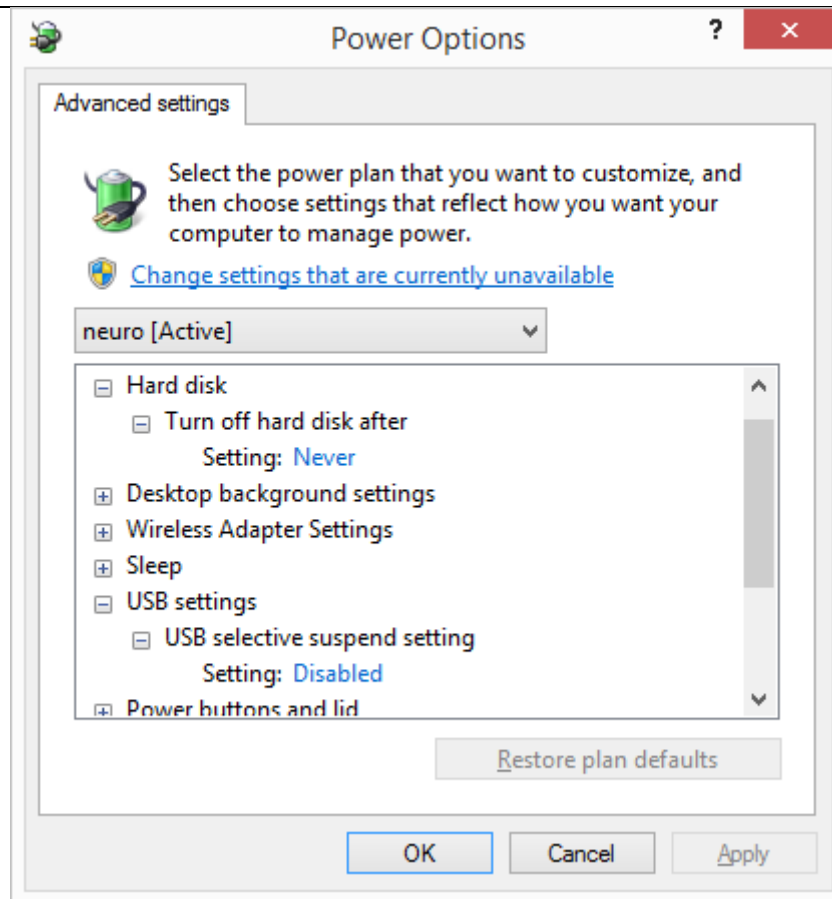


Figure 54: Adjust advanced (detailed) power options

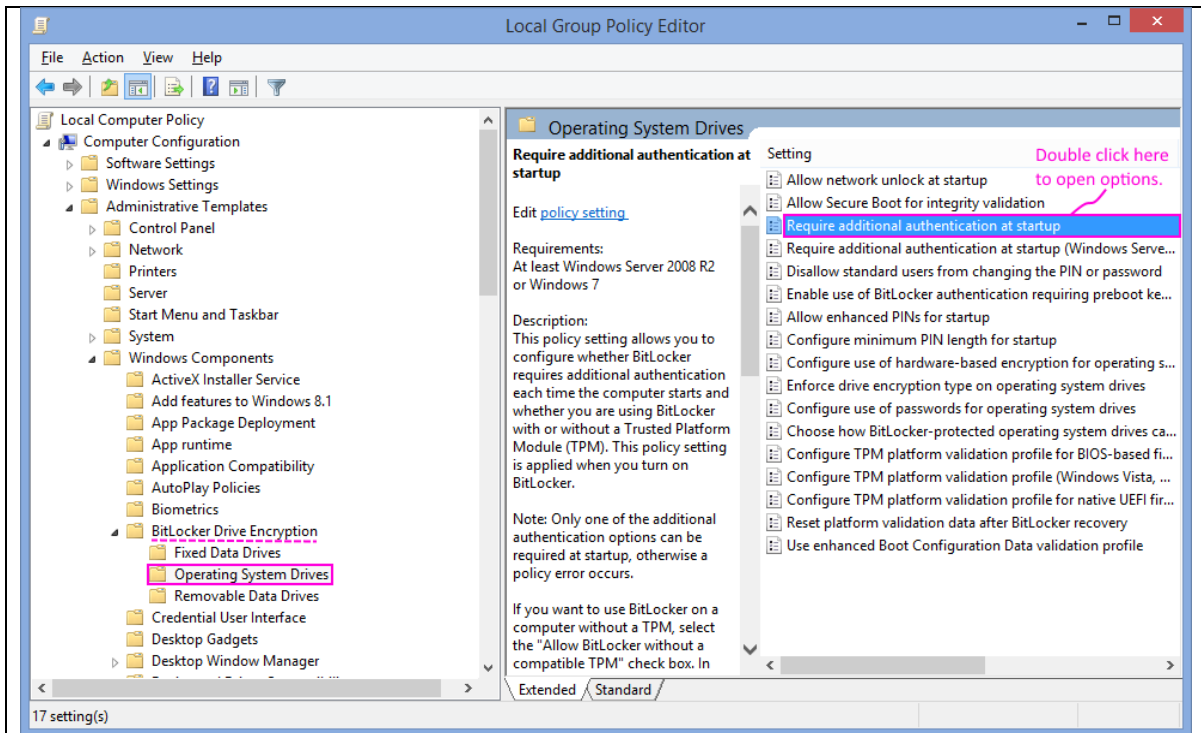


Figure 55: Group policy editor

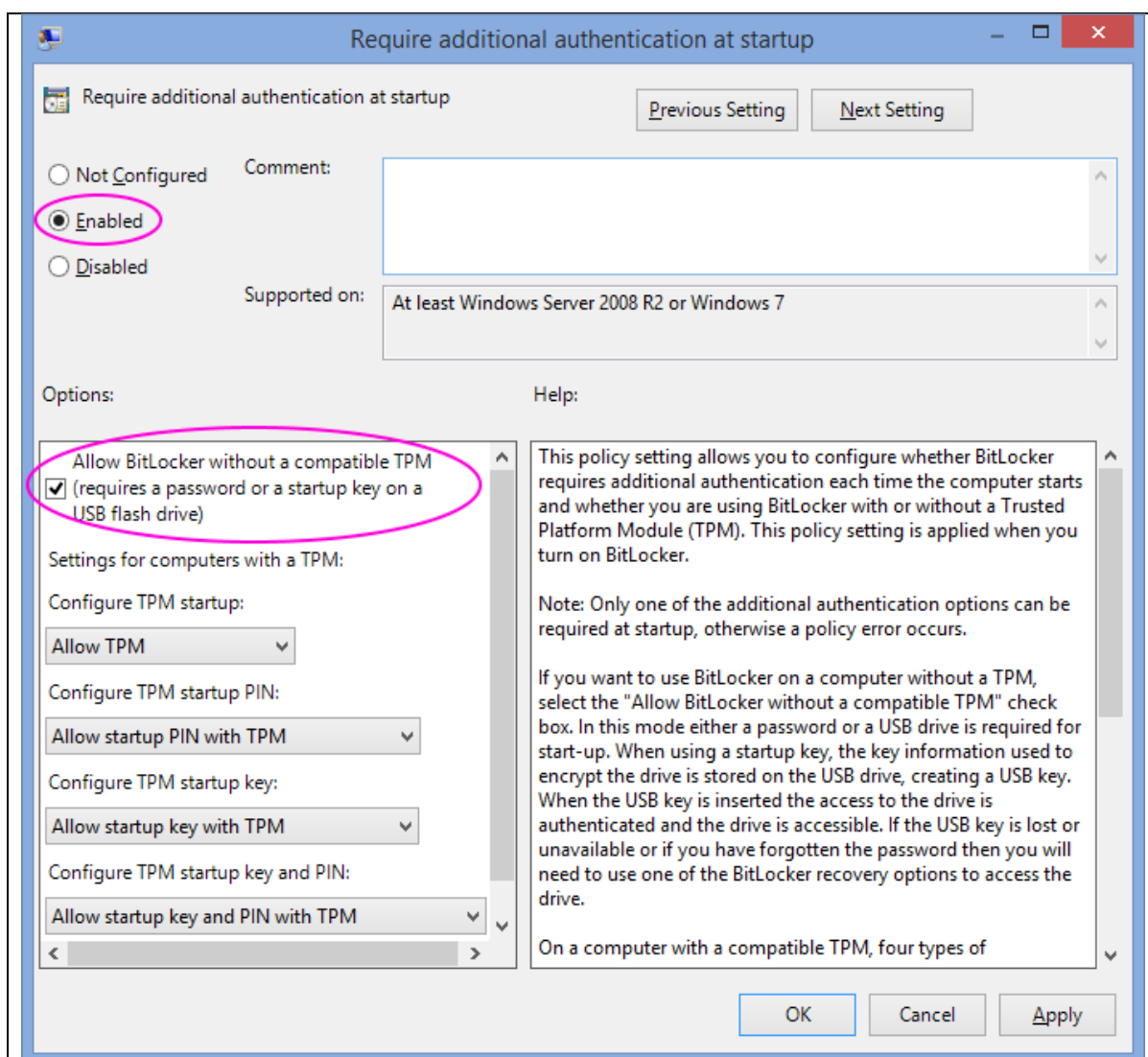


Figure 56: Bitlocker GPO settings

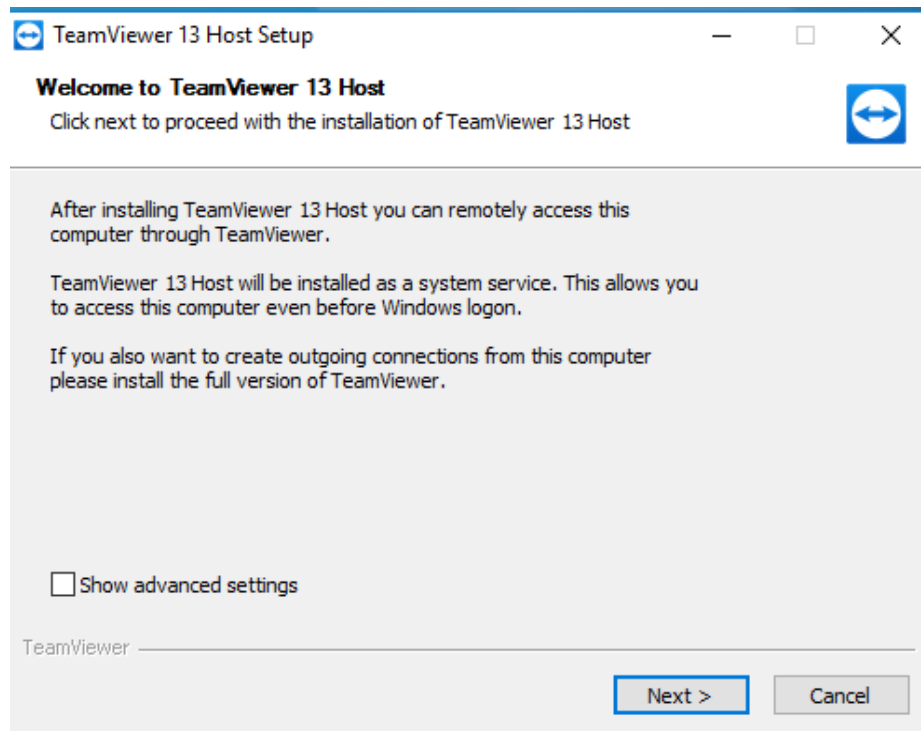


Figure 57: Teamviewer Installer Step 1/6

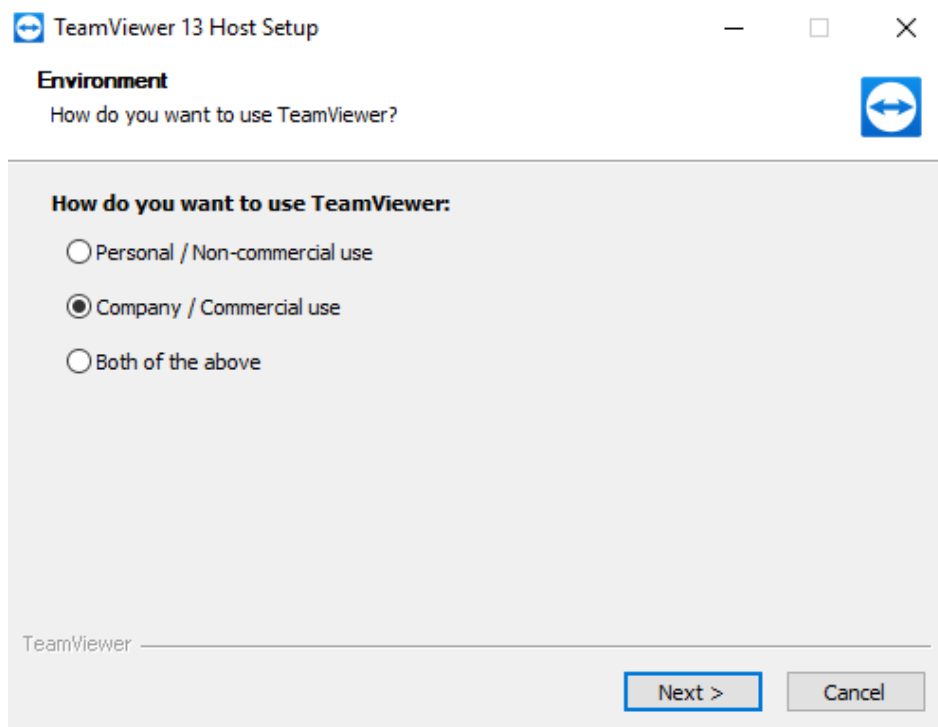


Figure 58: Teamviewer Installer Step 2/6

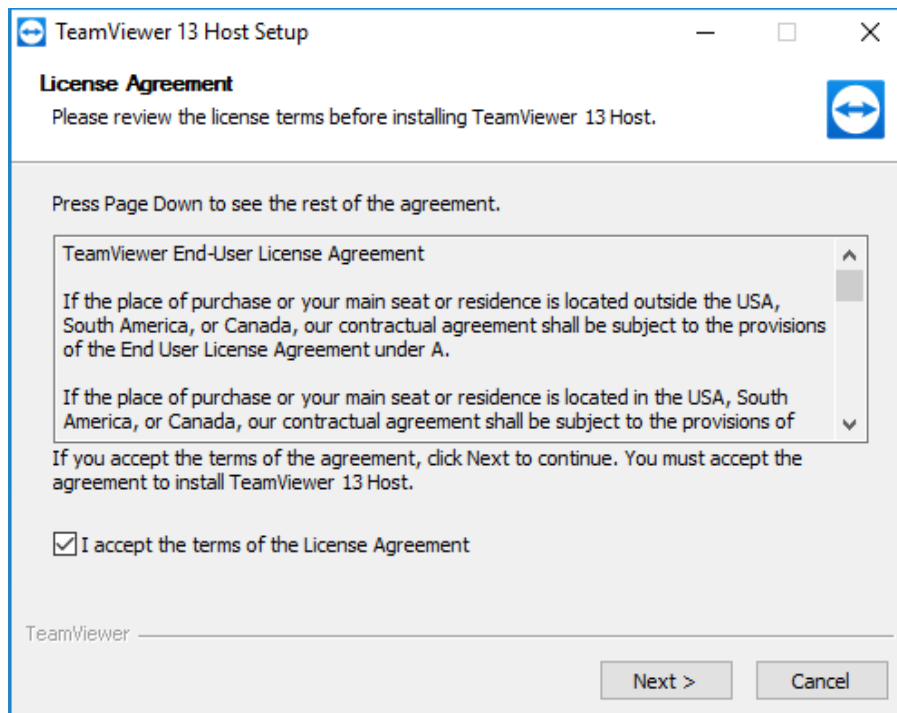


Figure 59: Teamviewer Installer Step 3/6

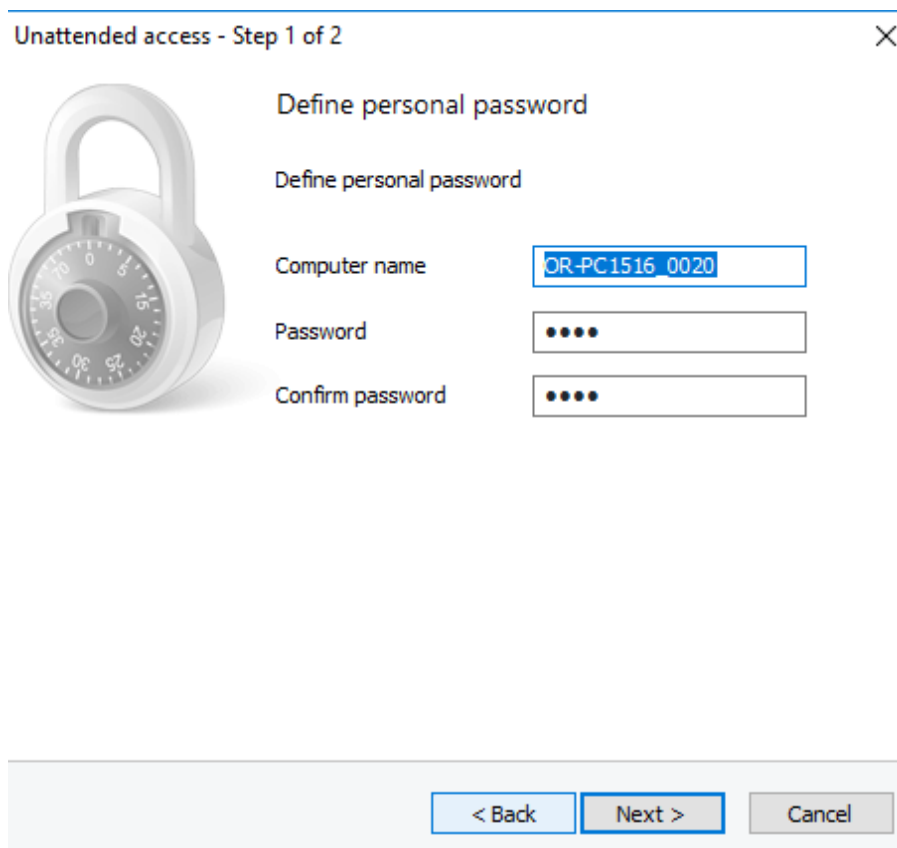


Figure 60: Teamviewer Installer Step 4/6

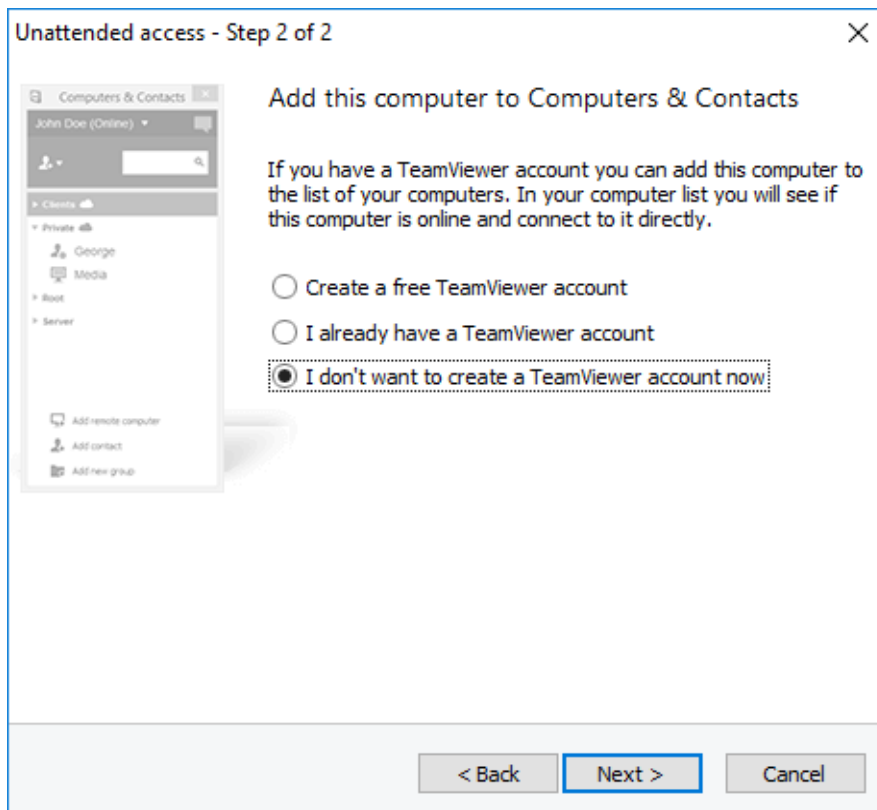


Figure 61: Teamviewer Installer Step 5/6

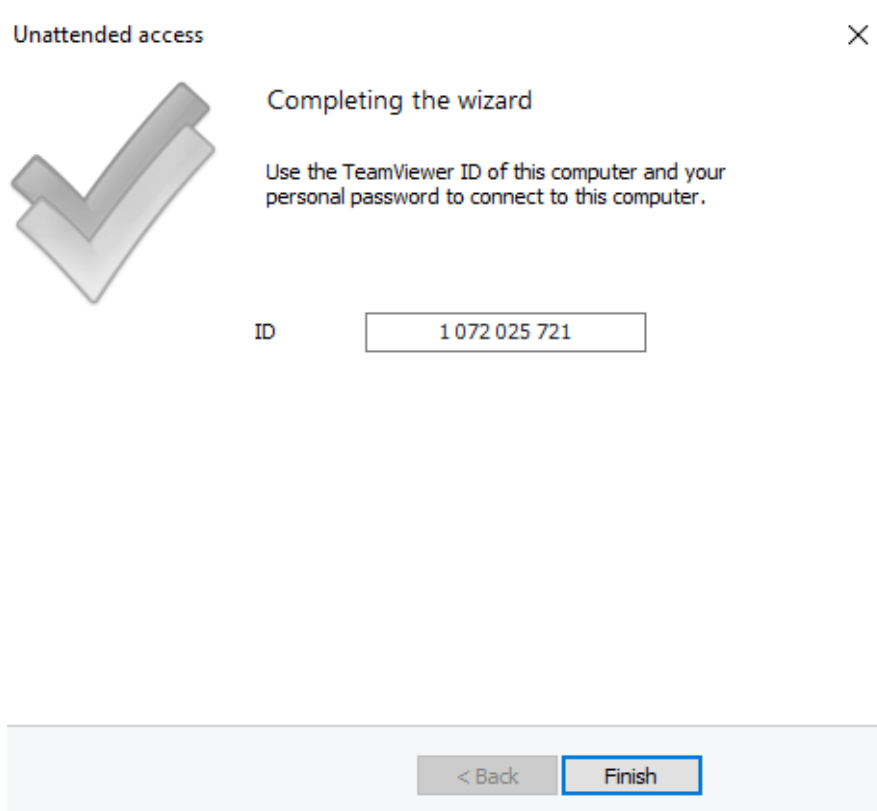


Figure 62: Teamviewer Installer Step 6/6

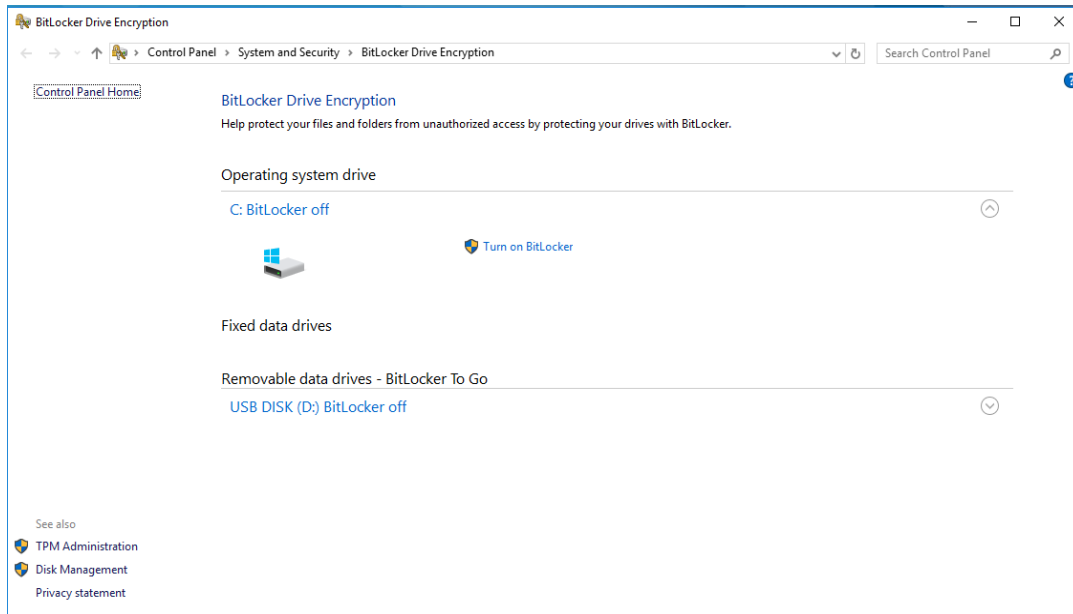


Figure 63: Bitlocker Installation Step 1/6

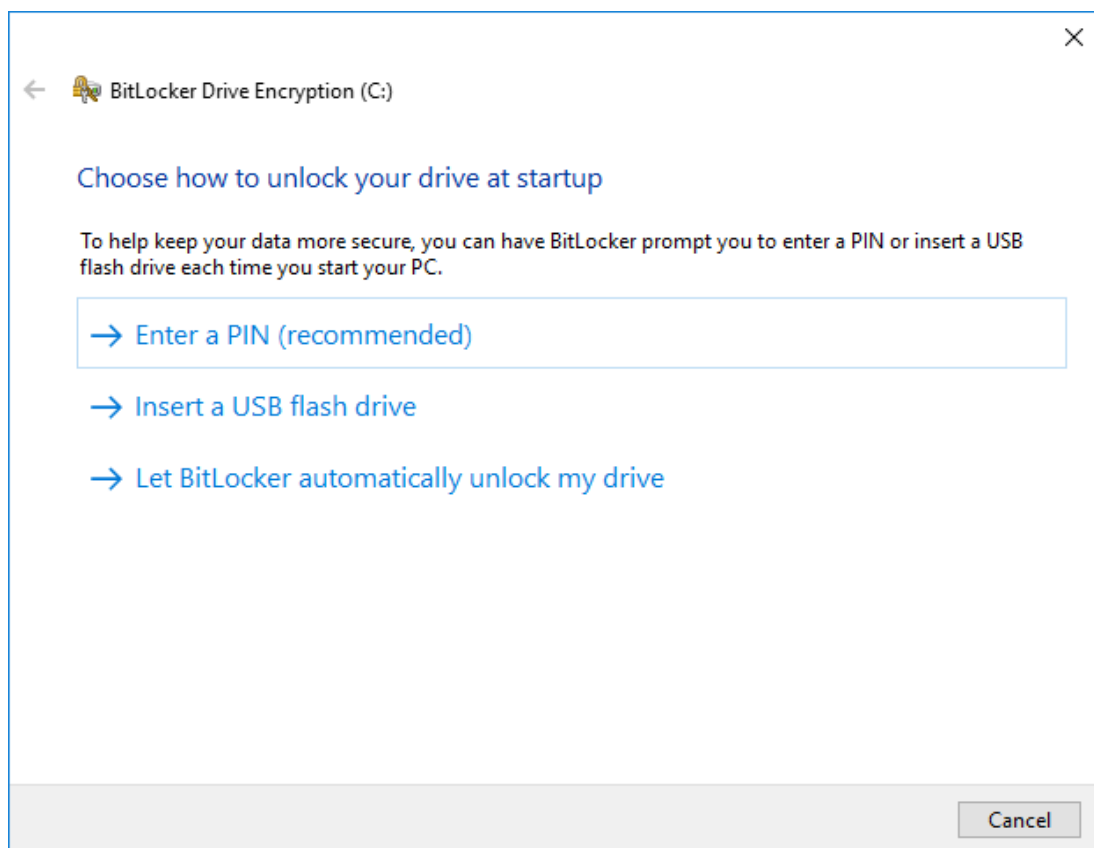


Figure 64: Bitlocker Installation Step 2/6

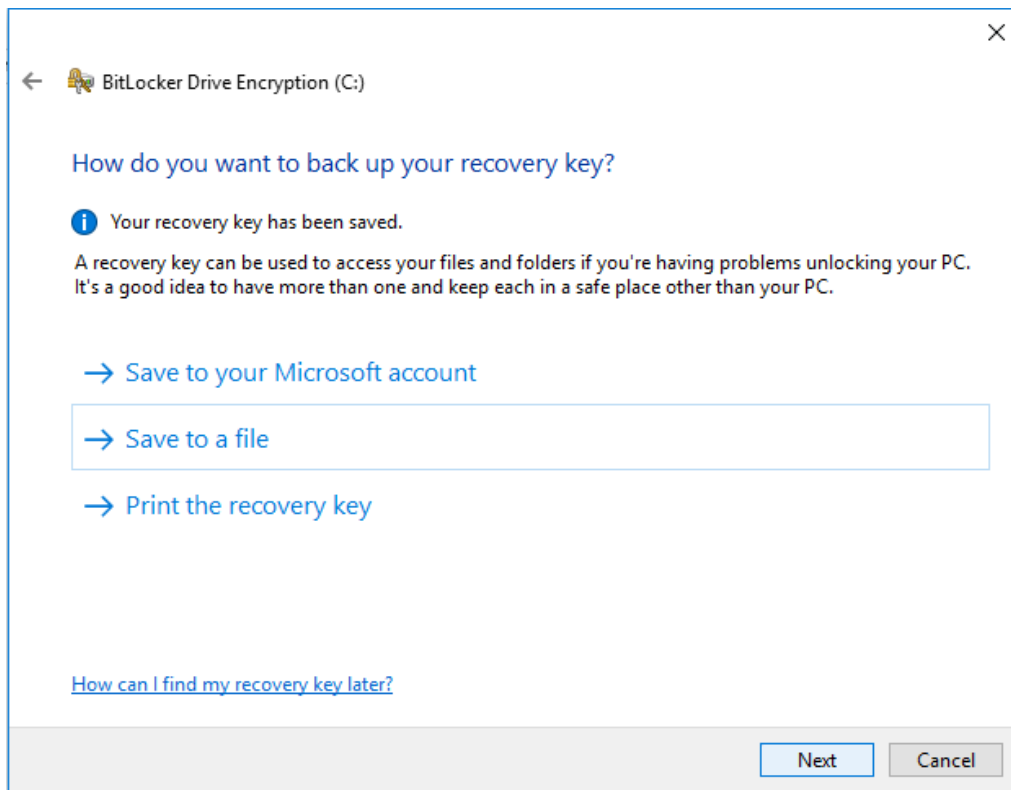


Figure 65: Bitlocker Installation Step 3/6

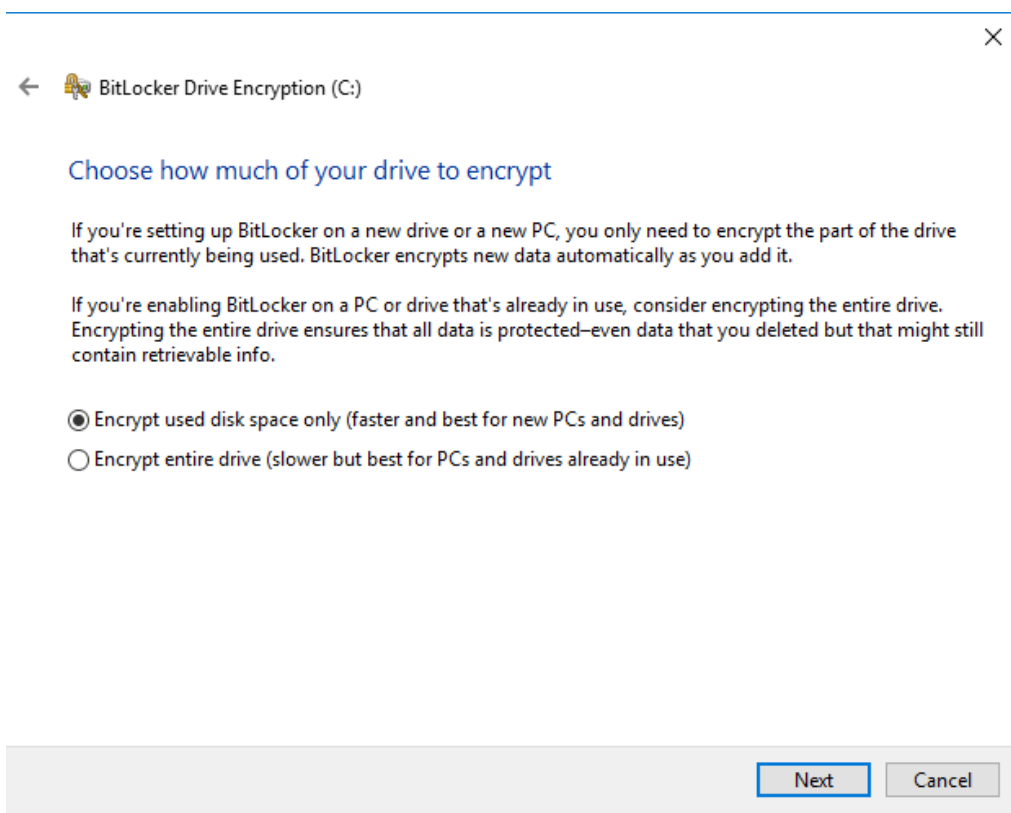


Figure 66: Bitlocker Installation Step 4/6

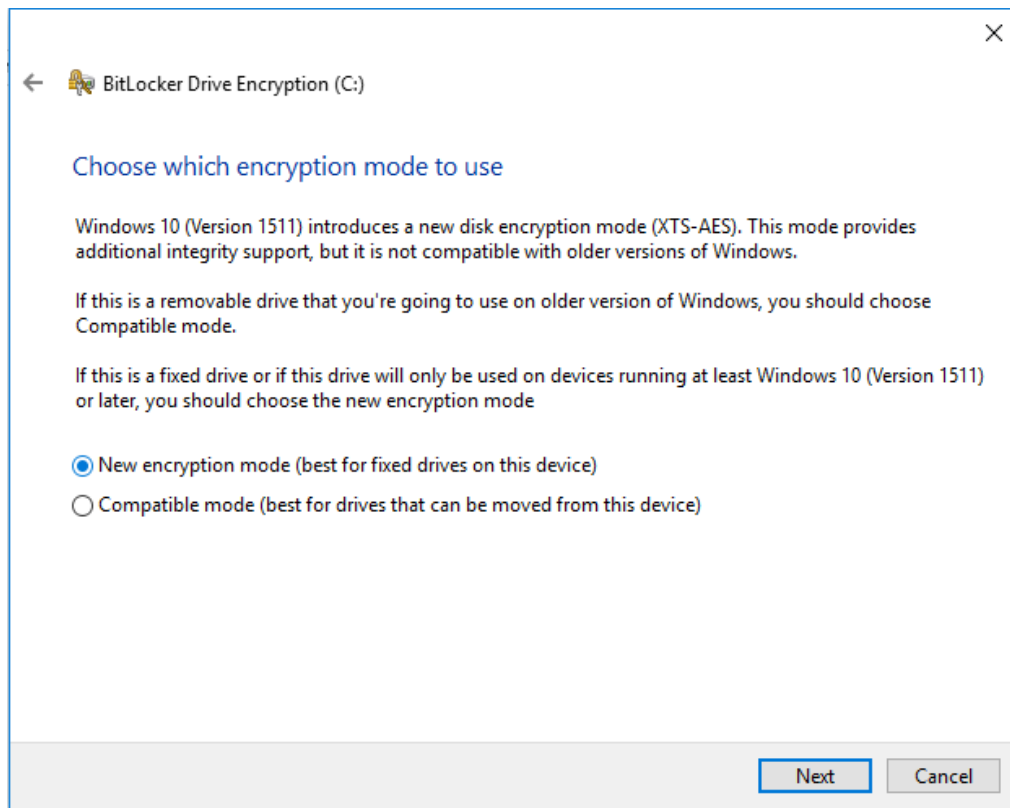


Figure 67: Bitlocker Installation Step 5/6

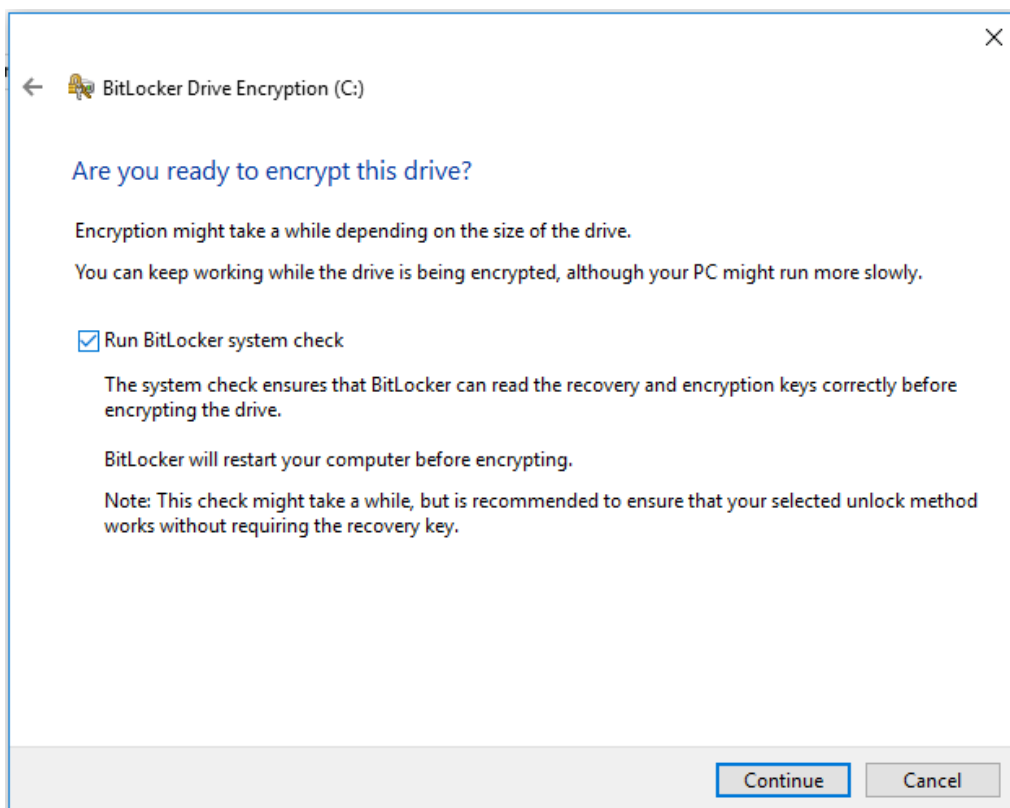


Figure 68: Bitlocker Installation Step 6/6

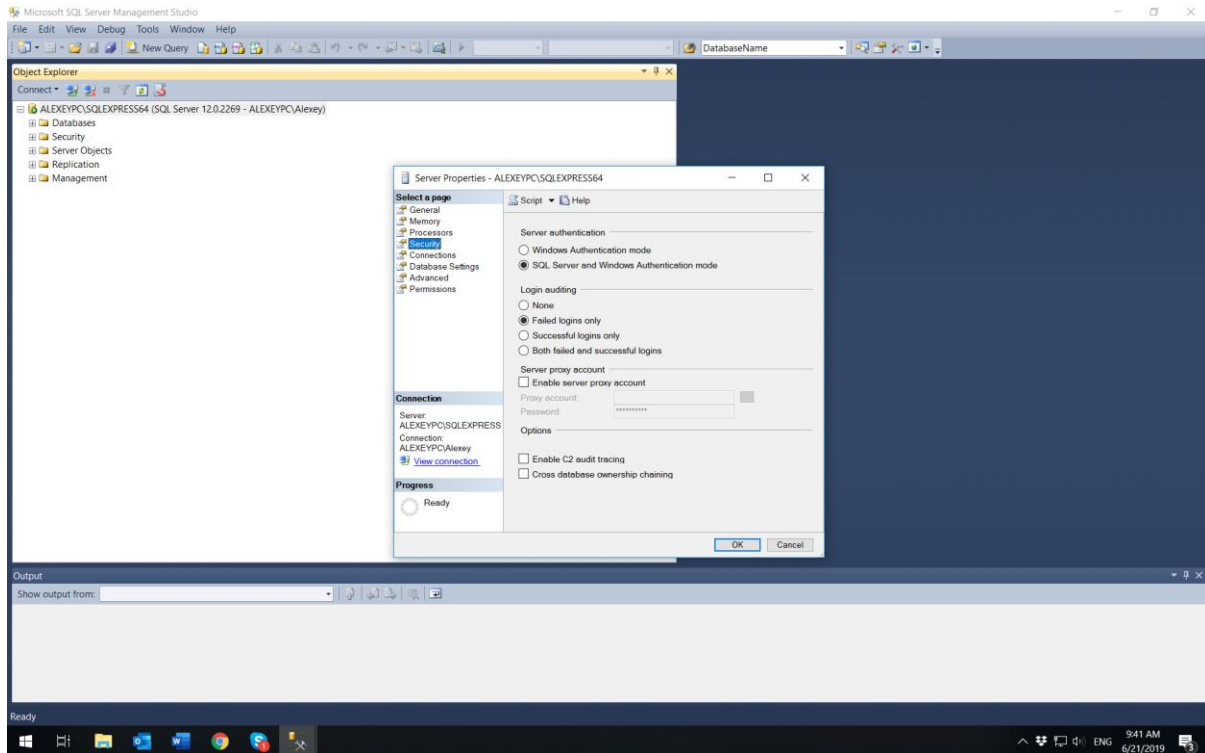
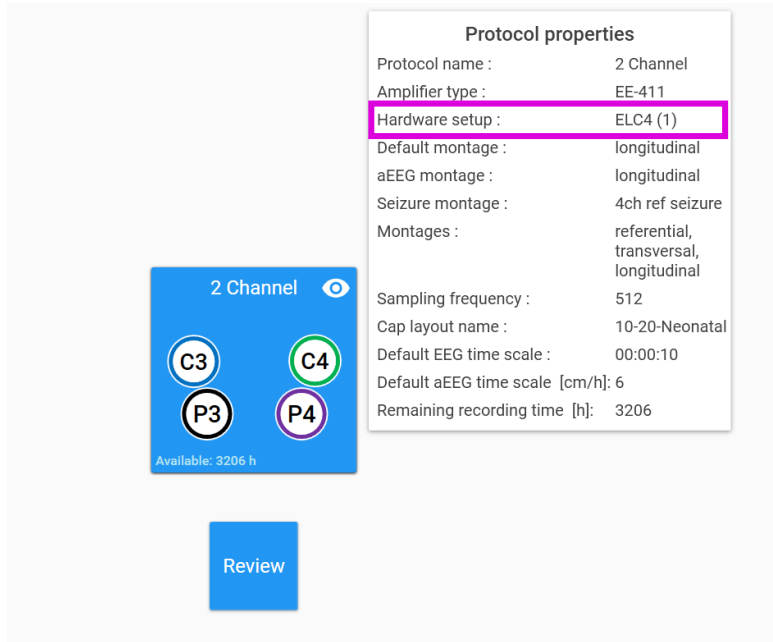


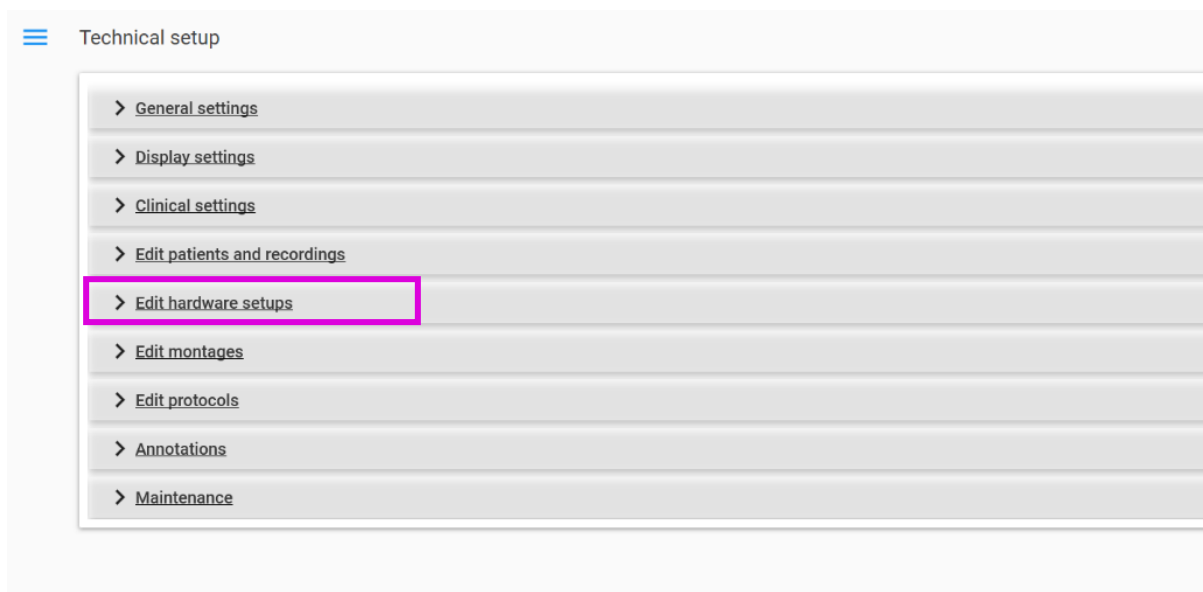
Figure 69: SQL Server Management Studio, "SQL Server and Windows Authentication mode" configuration.

11.4 Instructions for adjusting the input signal range

Step 1: Confirm what protocol(s) the hospital uses and note the hardware setup by selecting the “eye” button. For example, the 2 Channel protocol uses ELC4 (1) as its hardware setup.



Step 2: Proceed to Technical setup (default password: 0000) → Edit hardware setups



Step 3: Make a copy of the noted hardware setup by selecting the copy page button. In this example, ELC4(1) will be duplicated. ELC is short for electrodes and the difference between ELC4(1) and ELC4(2) are the electrode/channel positions, which can be viewed with the eye button.

☰ Edit hardware setups

	Name	Amplifier model	Channels	Reference electrode label	Date modified	
	ELC2 (1)	EE-411	2	REF	4/29/2019 3:20 PM	   
	ELC2 (2)	EE-411	2	REF	4/29/2019 3:20 PM	   
	ELC4 (1)	EE-411	4	REF	4/29/2019 3:20 PM	   
	ELC4 (2)	EE-411	4	REF	4/29/2019 3:20 PM	   
	ELC8 (1)	EE-411	8	REF	4/29/2019 3:20 PM	   



Step 4: A prompt to name the copy of the hardware setup will appear. Rename to “ELC4 (1) – 1Volt”.

☰ Edit hardware setups

	Name	Amplifier model	Channels	Reference electrode label	Date modified	
	ELC2 (1)	EE-411	2	REF	4/29/2019 3:20 PM	   
	ELC2 (2)	EE-411	2	REF	4/29/2019 3:20 PM	   
	ELC4 (1)	EE-411	4	REF	4/29/2019 3:20 PM	   
	ELC4 (2)	EE-411	4	REF	4/29/2019 3:20 PM	   
	ELC8 (1)	EE-411	8	REF	4/29/2019 3:20 PM	   

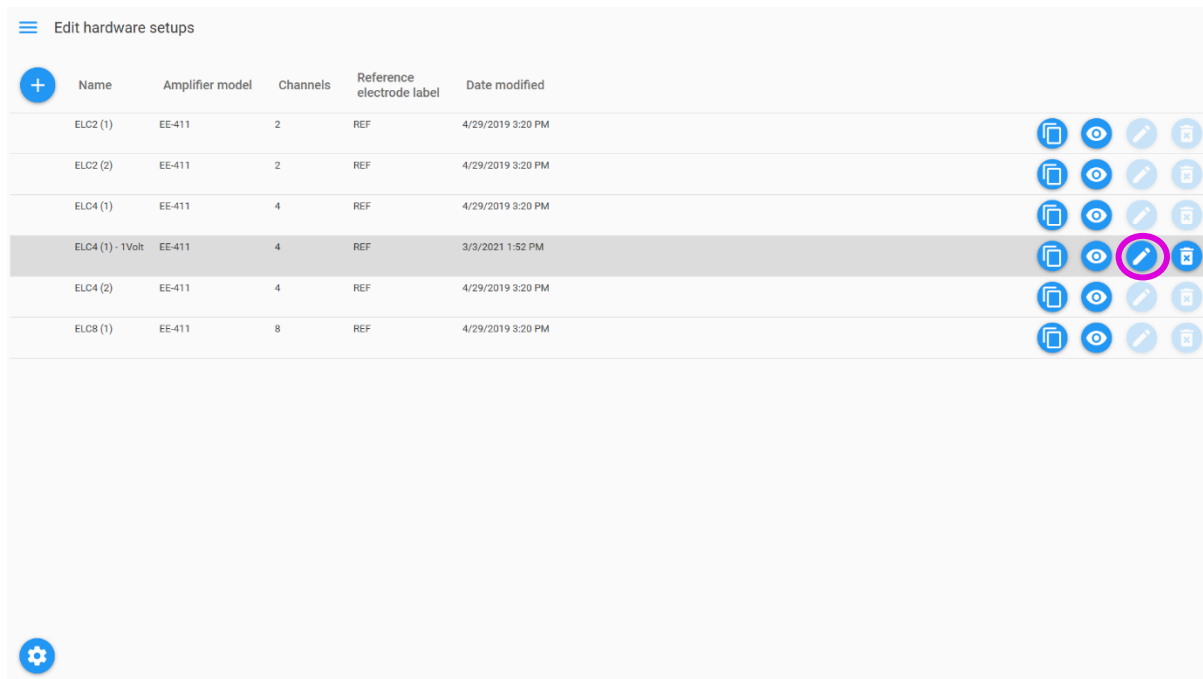
Hardware setup name:

ELC4 (1) - 1Volt

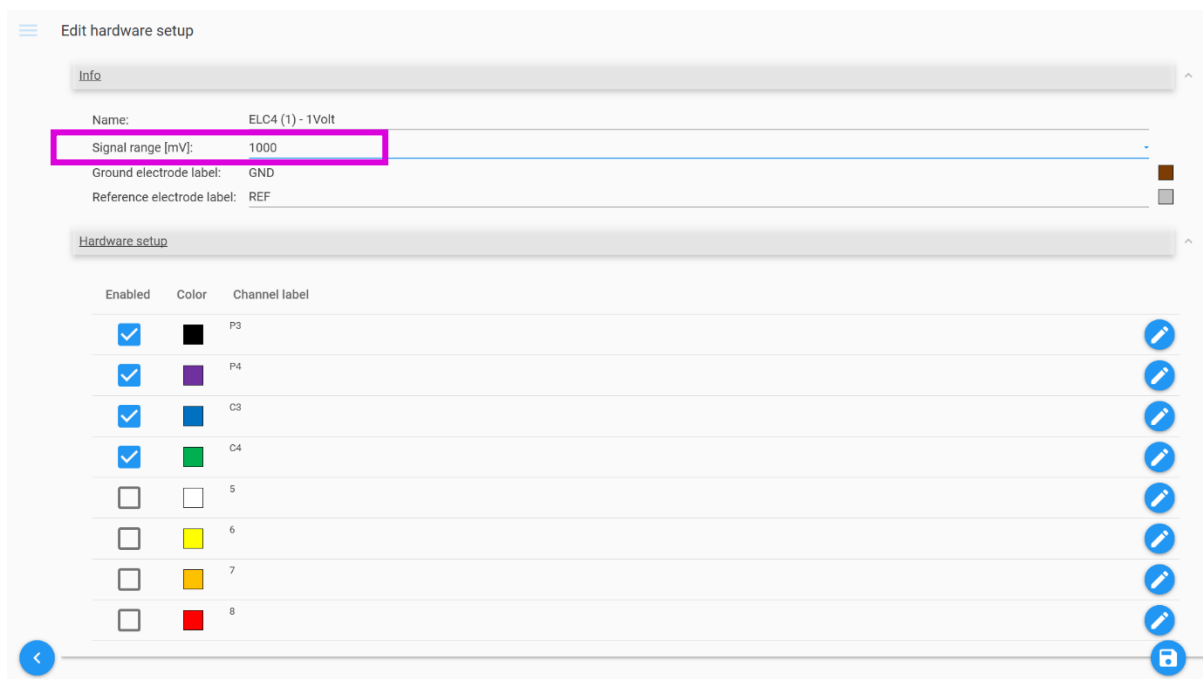
Cancel Copy



Step 5: Once the copy of the hardware setup is done, select the pencil button to edit.



Step 6: Adjust the Signal range (mV) from 750 to 1000 and save by selecting the floppy disk button in the lower right hand corner.



Step 7: Confirm that the new hardware setup created has a signal range of 1000 mV and has the intended electrode/channel positions by selecting the eye button. Once confirmed return to the Technical setup main menu.

Edit hardware setups

	Name	Amplifier model	Channels	Reference electrode label	Date modified	
	ELC2 (1)	EE-411	2	REF	4/29/2019 3:20 PM	
	ELC2 (2)	EE-411	2	REF	4/29/2019 3:20 PM	
	ELC4 (1)	EE-411	4	REF	4/29/2019 3:20 PM	
	ELC4 (1) - 1Volt	EE-411	4	REF	3/3/2021 1:53 PM	
	ELC4 (2)	EE-411	4	REF	4/29/2019 3:20 PM	
	ELC8 (1)	EE-411	8	REF	4/29/2019 3:20 PM	

Hardware setup properties

Name : ELC4 (1) - 1Volt

Signal range [mV]: 1000

Ground electrode label : GND

Reference electrode label : REF

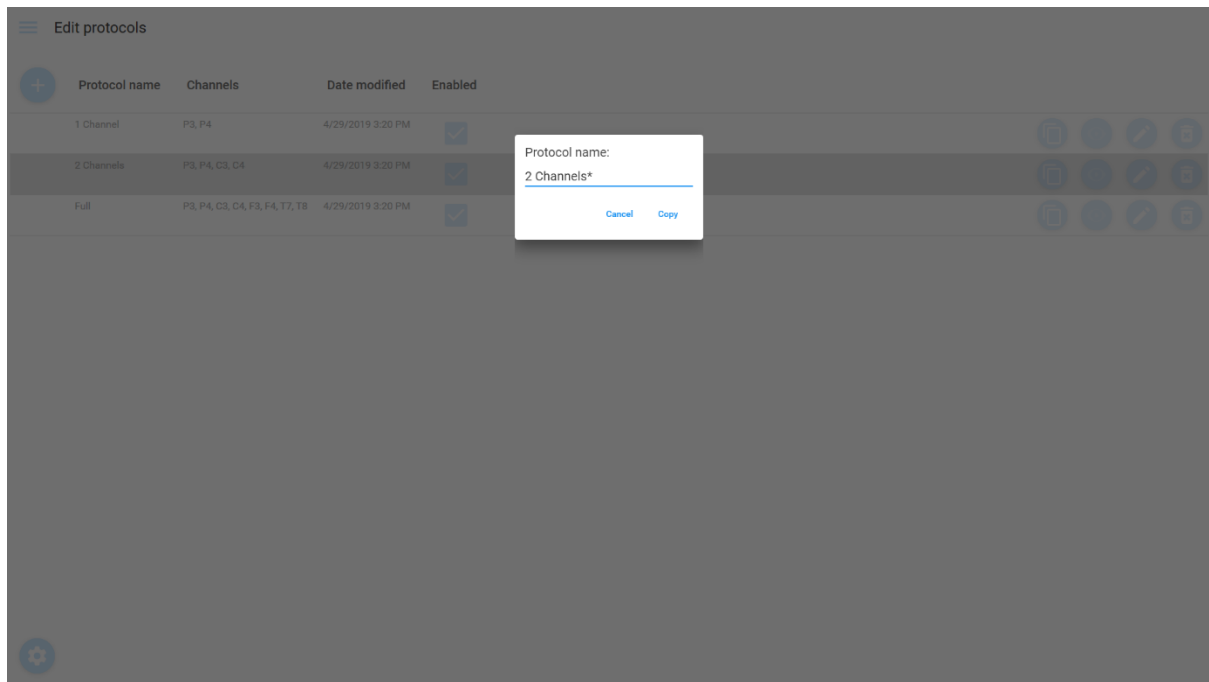
Channels : P3, P4, C3, C4

Step 8: Select Edit protocols and make a copy of the intended protocol by selecting the copy page button.

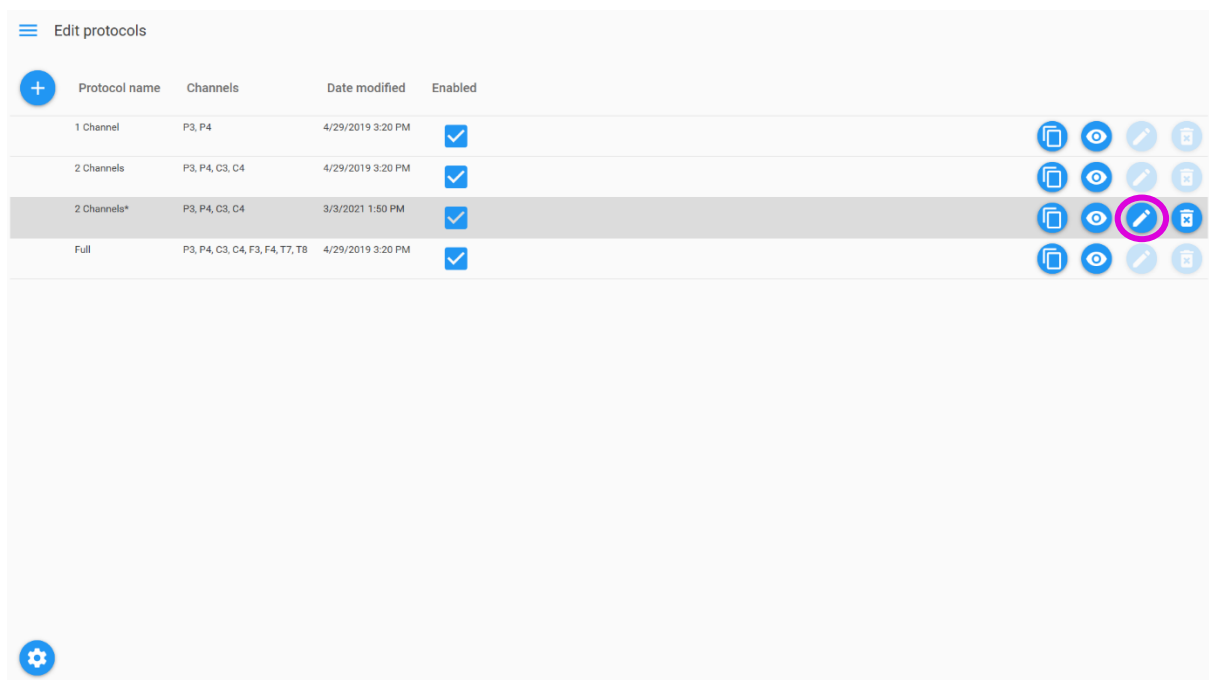
Edit protocols

	Protocol name	Channels	Date modified	Enabled	
	1 Channel	P3, P4	4/29/2019 3:20 PM	☒	
	2 Channels	P3, P4, C3, C4	4/29/2019 3:20 PM	☒	
	Full	P3, P4, C3, C4, F3, F4, T7, T8	4/29/2019 3:20 PM	☒	

Step 9: A prompt to name the copy of the protocol will appear. Rename to “2 Channel*”.



Step 10: Once the copy of the protocol is done, select the pencil button to edit.



Step 11: Within hardware setup, select the newly created hardware setup “ELC4 (1) – 1Volt”. Save by selecting the floppy disk button in the lower right hand corner.

Edit protocol

Info

Protocol name: 2 Channels*

Date modified: 3/3/2021 1:50 PM

Amplifier type: EE-411

Sampling frequency [Hz]: 512

Cap layout name: 10-20-Neonatal



Time scales

Default EEG time scale [s]: 10

Default aEEG time scale [cm/h]: 6

Hardware setup

Hardware setup: ELC4 (1) - 1Volt

Montages

Montages:				
referential	C4, P4, C3, P3	8448eb8c	☒	
transversal	F4, C4, T8, F3, C3, T7	4be83a8e	☐	
referential	F4, C4, P4, T8, F3, C3, P3, T7	ac063a77	☐	
longitudinal	C4, C3	e4cb82a3	☒	
transversal	C3, P3	32ae966d	☒	

Step 12: Confirm that newly created protocol “2 Channel*” has the correct hardware setup and is enabled. All other protocols not used should be disabled, e.g. “2 Channel” protocol.

Edit protocols

Protocol name	Channels	Date modified	Enabled
1 Channel	P3, P4	4/29/2019 3:20 PM	☐
2 Channels	P3, P4, C3, C4	4/29/2019 3:20 PM	☐
2 Channels*	P3, P4, C3, C4	3/3/2021 1:53 PM	☒
Full	P3, P4, C3, C4, F3, F4, T7, T8	4/29/2019 3:20 PM	☐

Protocol properties

Protocol name: 2 Channels*

Amplifier type: EE-411

Hardware setup: ELC4 (1) - 1Volt

Default montage: longitudinal

aEEG montage: longitudinal

Montages: referential, longitudinal, transversal

Sampling frequency: 512

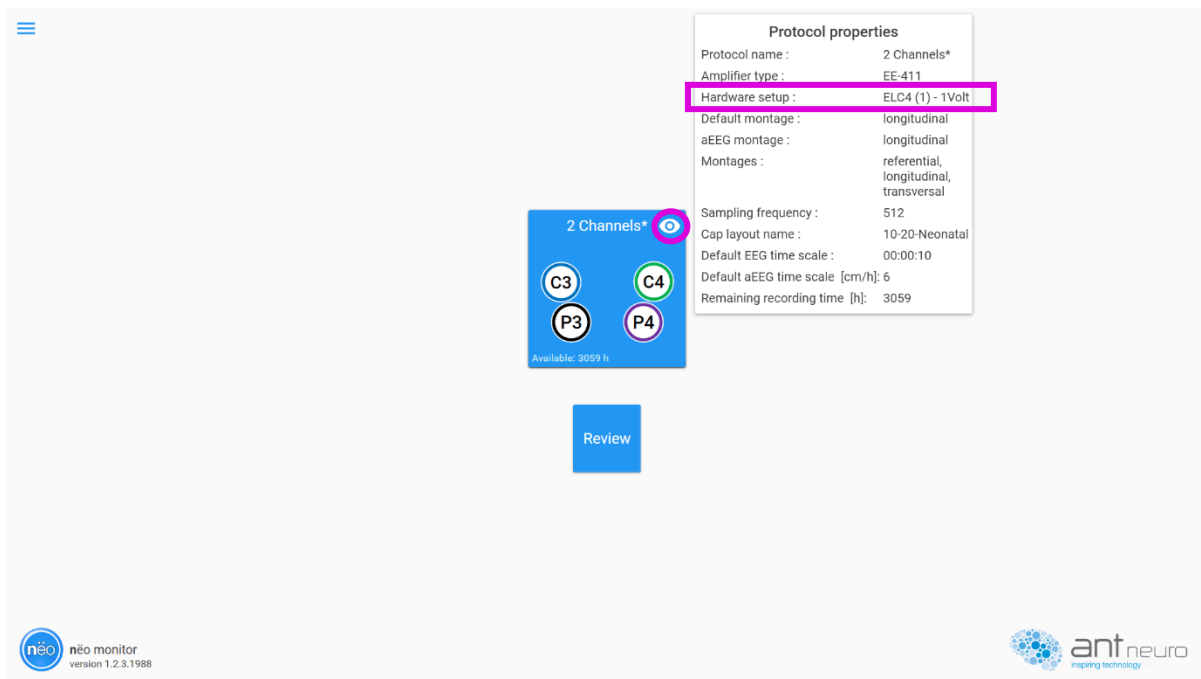
Cap layout name: 10-20-Neonatal

Default EEG time scale: 00:00:10

Default aEEG time scale [cm/h]: 6

Remaining recording time [h]: 3059

Step 13: The newly created protocol with the updated hardware setup is now present on the start screen. Selecting the eye button will display the details of the protocol.



11.5 Software Configuration via Settings

#	Step Name	Description
	Close the neo™ monitor software	Make sure all instances of neo are closed
	Locate settings file	- Open a windows explorer window on the neo user and navigate to: - Path: %allusersprofile%/ Eemagine_Medical_Imaging_/ DefaultDomain_Path_<app_key>/<version>/ user.config
	Open config file	- Open "user.config" in a text editor - This is a xml-file and follows a usual xml structure
	Add/ set user config value	- All changeable setting values are in the subgroup <userSettings>, which then contain the settings categories: <Neonatal.SharedSettings.Properties.<SettingsCategory>> (If it does not exist it needs to be added, with its declaration in the configuration/ configSections/sectiongroup section of the same file) - Find or add settings key in the respective category section: <pre><setting name="<settingsName>" serializeAs="String"> <value><serialized value></value> </setting></pre>
	Example RenderSettings: ShowValueLabels	<pre><userSettings> ... <Neonatal.SharedSettings.Properties.RenderSettings> ... <setting name="ShowValueLabels" serializeAs="String"> <value>True</value> </setting> ... </Neonatal.SharedSettings.Properties.RenderSettings> ... </userSettings></pre>