



Urgent Medical Device Correction Notification

December 23, 2014

Dear Valued Customer,

You are receiving this urgent Field Correction notice because you have purchased one or more Protektor IOM Systems and Remote Review software. Action is required by you to ensure the appropriate use of these products when using Natus Remote Review software (Portal).

It was detected that when using remote monitoring with local acquisition system configured to block remote acquisition changes; if the remote user tries to stop the free run waveform group, the system will display a message informing the user that they do not have sufficient privilege to perform this action. After this point, the freerun waveform on the remote system will no longer update the physiological data, but will update the timestamp in the label. After the analysis of the source code for EPWorks, it was determined that all the conditions sufficient to cause this defect were present in EPWorks versions prior to version 6.0. All other indications of the software (local monitoring and acquisition) are not impacted by this issue.

EPWorks 6.0 software is now available to fix this defect. In addition, the new version addresses two other issues identified in the software when used with the Protektor32 system:

1. When the Protektor 32 stimulates in biphasic mode the firmware limits the number of stims to 2, as it should be. However when switching back to monophasic mode, the software does not reset the number of stims from 2 to whatever is specified.
2. Using single-shot low-voltage biphasic stimulator will block further use of the electrical stimulator until reset

Please follow attached instructions to perform a successful update of the EPWorks software for your Protektor32 or Protektor System. Once completed, please complete and return the attached "Previous Version Removed from Use Confirmation Form".

If there are any issues encountered during this process, please contact Natus Technical service for assistance:

Tel: 800-387-7516

Email: Oakville_Technical_Service@xltek.com or ots@natus.com

Best Regards,

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Installing EPWorks Protektor32 / Protektor

----- PLEASE READ THE DOCUMENT FULLY BEFORE INSTALLING SOFTWARE -----

There are four (4) potential steps in the process:

1. Removing a previous installation (If necessary)
2. Installing the EPWorks Application Software
3. Updating firmware
4. Installation clean-up.

Please contact Natus Technical service should your require assistance: Tel: 800-387-7516

Email: Oakville_Technical_Service@xltek.com or ots@natus.com

SPECIAL NOTE: *If the software is being installed on a Protektor32 - Please ensure that the "Firmware Update for Protektor32" section is followed after the software installation, but before the software is run.*

SPECIAL NOTE: When installing EPWORKS 6.0 Build 96, you must be logged in as ADMINISTRATOR

1. Removal of a previous installation

All earlier versions of EPWORKS must be un-installed prior to installing EPWORKS 6.0. (If the earlier software version is not removed the installation process will detect the previous version and will block the new install until it is removed) - To uninstall an older version of EPWorks, go to Control Panel-->Add/Remove Programs-->Select EPWorks from the list and choose Uninstall. Reboot the system.

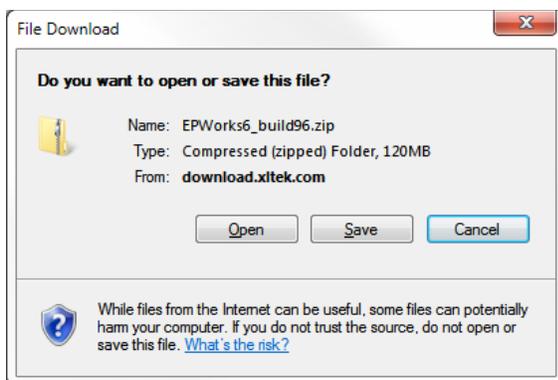
To preserve test protocols and EEG montages: Backup the full contents of the folder C:\Program Files\XLTEK\EPWorks\UserData\ and restore it to the same location once new version is installed.

NOTE: on Windows 7 64-bit system the path is slightly different: C:\Program Files (x86)\XLTEK\EPWorks\UserData\

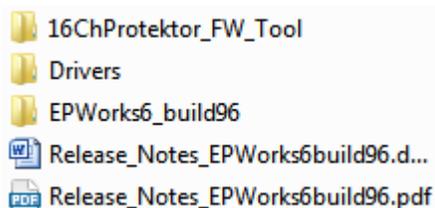
2. EPWorks application software

Copy the ZIP file obtained from the Natus website onto the desktop of the EPWorks system.

DOWNLOAD link- EPWorks 6.0 Build 96 is: http://download.xltek.com/pub/IOM/EPWorks6_build96.zip



Save to your local drive. Once Saved Select Open, the following folders are contained:



Double click EPWorks6_Build96 and run SETUP.exe

The installation is automatic from this point on, the full EPWorks and Portal suite is installed in the default location. (Unlike previous versions of the software, there are no codes to be entered.)

When done go into the DRIVERS folder.

NOTE: If the O/S is WIN7 64 Bit- install XLTEKUSB.X64.Install.msi

NOTE: If the O/S is XP- install XLTEKUSB.X86.Install.msi

When complete reboot the system.

For remote review systems, if EPWorks/Portals will be used from a user account with non-administrative privileges the first time EPWorks is run from the main user account go to the Tools menu and select 'Allow Non-Admin Users' option.

3. First Running of EPWorks after installation

After the installation of the new release, acquisition stations should run through an acquisition test to ensure that any necessary firmware updates are performed.

Ensure that the Protektor / Protektor32 is fully connected (all Acquisition / Stim boxes) and is powered on. (Power Lights-LED should all be green)

Start a new study. If there is any need for a firmware update, the system will automatically prompt you with directions on how to proceed. Not all systems will need to have firmware updated, if no message about firmware is shown, you can proceed to step 4.

Please Read and follow the on-screen directions exactly as prompted, failure to do so may cause the firmware to be improperly installed.

During this process - do not turn off or disconnect the headbox unless explicitly directed to do so by the system.

Once the system informs you that the firmware is successfully installed, the system will continue into the test.

4. Installation cleanup / completion

Once installation is complete, the Zip file and the extracted folder can be dragged into the recycle bin for deletion.

EPWorks software is now fully installed and ready for use.

