

Important Safety-Information

Mandatory Software Update

for Pentacam® AXL

Immediate action is mandatory

15. November 2017

Customer Address

This letter addresses all users, operators and distributors of the Pentacam® AXL software

Dear valued customers,

Thank you for using the Pentacam® AXL software. The safety, quality and your contentment is our highest priority.

In order to assure a reliable usage of the Pentacam® AXL which meets your and our expectations as well as patients safety, OCULUS Optikgeräte GmbH plans a mandatory field safety action.

This letter informs you about the mandatory software update for your Pentacam® AXL.

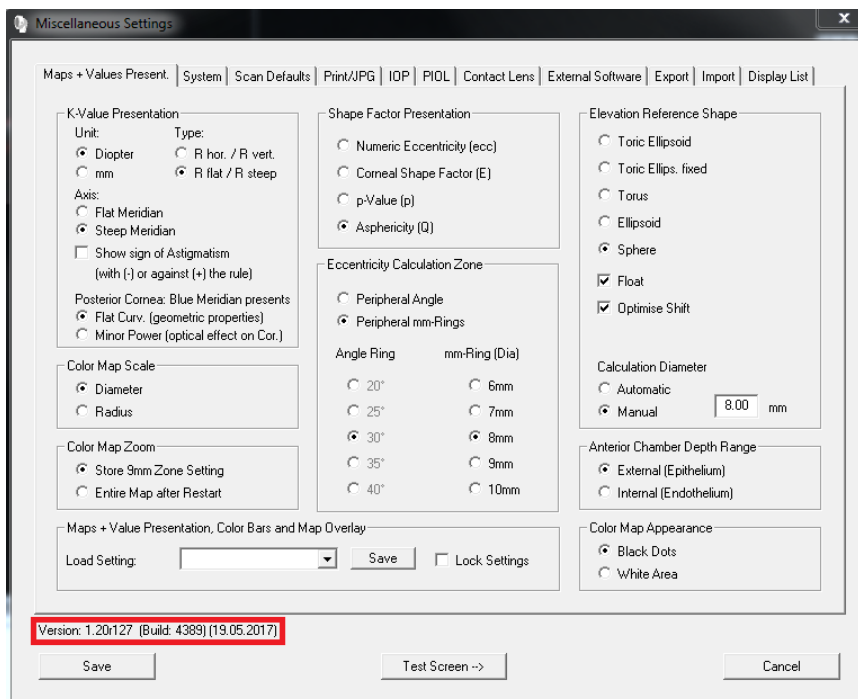
Affected are the Pentacam® AXL software versions 1.21r01, 1.21r03, 1.21r11, 1.21r13. Other software versions are not affected.

The mentioned Pentacam® AXL software versions above do have a software anomaly which may result in erroneous coloured display of the quality specification value.

The instruction on how to identify the Pentacam® AXL software version number can be found on the next pages.

Identification of the Pentacam® AXL software version number

1. Start the Pentacam® AXL software
2. Select on patient in the patient data management
3. Click to the button „Pentacam“ and the Pentacam® AXL Software starts automatically
4. Click in the Pentacam® AXL software to the button „Settings“ and select in the drop-down menu the button „Miscellaneous Settings“
5. The Pentacam® AXL software version number can be found in the lower left hand side , see picture below.



Perform the software update

In order to correct the software error it is mandatory to update all Pentacam® AXL who have the software installed version 1.21r24

The attachment to this letter contains a USB stick and an instruction how to perform the Pentacam® AXL software.

In case you do have any problems performing the mandatory software update, please **contact your local distributor**.

Dissemination of the described information:

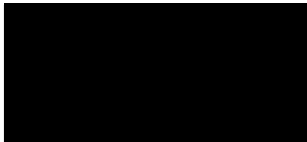
Assure in your organization, that all users of the mentioned products above and all persons in charge have detailed knowledge about this important safety information. In case you are distributing these products, forward a copy of this information to the respective persons.

Please save a copy of these information until the software update procedure is finished.
The German authority named "Bundesinstitut für Arzneimittel und Medizinprodukte" has received a copy of this important safety information already.

OCULUS Optikgeräte GmbH
Andreas Steinmüller
Medical Device Reporting Officer
Münchholzhäuser Str. 29
35582 Wetzlar
Tel.: 0641 2005405

E-Mail: softwareupdateAXL@oculus.de

Signature



Attachment:

- A: Mandatory confirmation of the Pentacam® AXL Software-Update
- B: Instruction Pentacam® AXL Software Update

USB thumb drive with Software Update Version 1.21r24

Attachment A: Mandatory confirmation of the Pentacam® AXL software

Please return the completed form to:

OCULUS Optikgeräte GmbH
Andreas Steinmüller
Müncholzhäuser Str. 29
35582 Wetzlar

FAX: 0641-2005-542

Email: softwareupdate@oculus.de

- Herewith I confirm the receipt of the Important Safety-Information regarding the mandatory software update for Pentacam® AXL.
- Herewith I confirm that I have forwarded these information and the mandatory actions to my employees and co-workers.
- Herewith I confirm, that the mandatory software update was installed on all working places on which the Pentacam® AXL software is running or that this procedure was performed by an authorized distributor.

Pentacam serial number: _____

Signature: _____

Name: _____

Date: _____

Hospital or Clinic name: _____

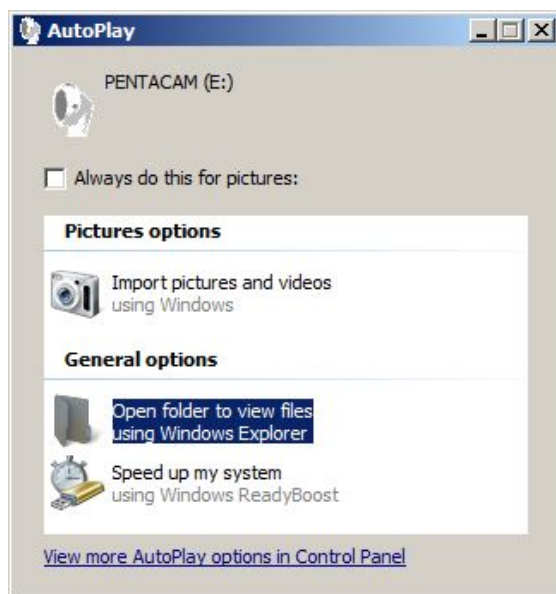
Address: _____

Attachment B: Instruction Pentacam® AXL Software Update

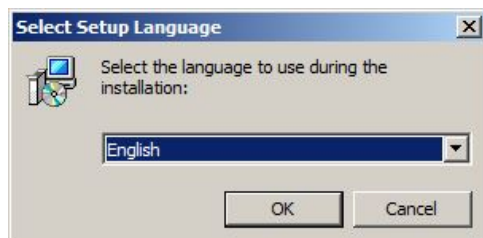
The Pentacam® AXL software update has to be performed on every workstation or computer where the Pentacam® AXL software is installed.

Routine:

1. Switch-off the Pentacam® AXL head
2. Close the Pentacam® AXL Software and the OCULUS patient data management
3. Make sure you are logged-in as administrator
4. Take out the USB-stick from the package and plug it into a free USB-slot. The following message appears:



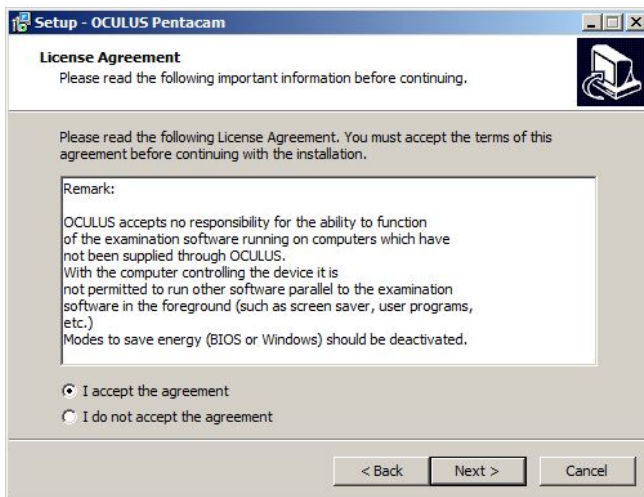
5. Click to „Open folder to view files using Windows Explorer“
6. Double/click to the file „Pentacam_1-21r24_Setup.exe“, the installation process starts now
7. Select the respective language and click to the button „OK“



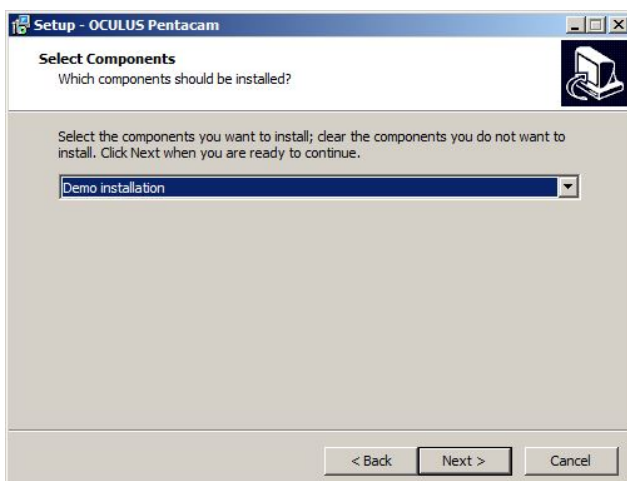
8. Click to the button „Next“



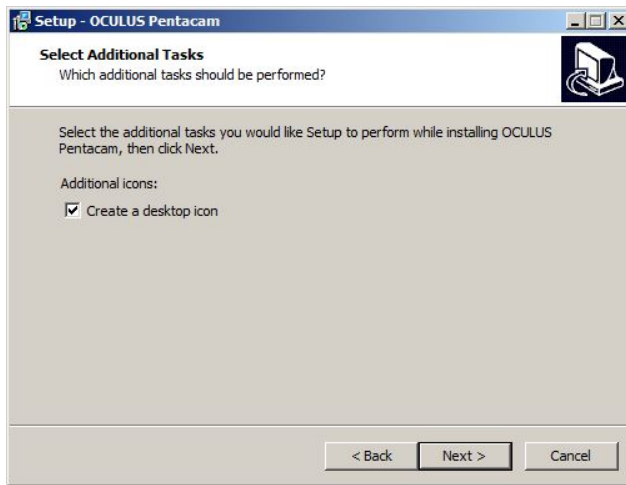
9. Select „I accept the agreement“ und click to the button „Next“



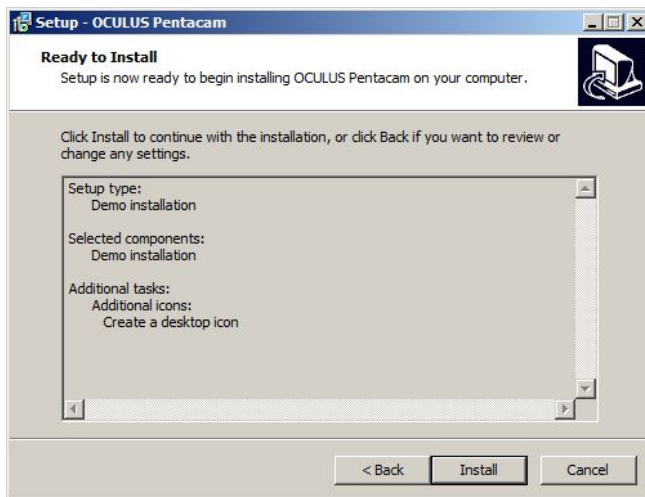
10. Select “Full installation” and click to the button „Next“ again



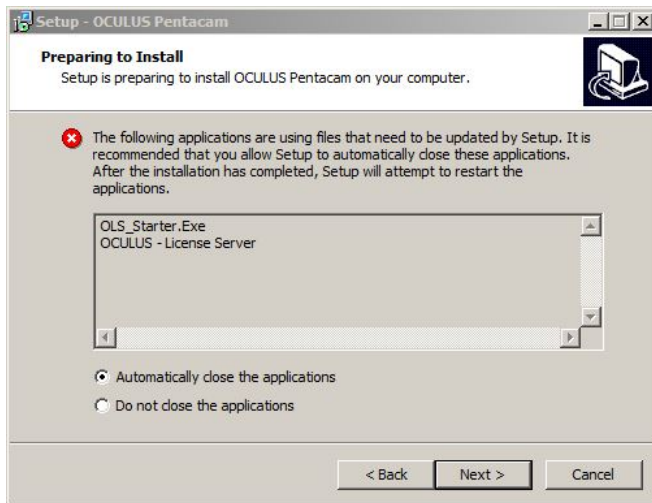
11. Click to the button „Next“ again



12. Click to the button „Install“, the Pentacam® software is now installed on the computer



13. If a floating license key is connected to the respective PC, the following message appears:



14. Click to the button „Next“

15. If no floating license key is connected, no message appears. Continue with step 16.

16. Click to the button „Finish“



17. The OCULUS patient data management opens

18. Depending to the previous installed Pentacam software, the USB driver will be updated. Just follow the instructions on the screen to complete the software update.

19. Click to the button “Finish”



20. Switch-on the Pentacam® head again.