Changes in DentalEye 3.2 from 3.1 – information for users

DentalEye 3.2 is CE marked and some functions are added in order to limit risks for:

- Images captured to the wrong patient
- Images with wrong orientation
- Inferior image quality
- Loss if images or missing information

The workflow has therefore been slightly changed:

- Approval of images is an important certification. Please study the "Instructions for use"!
- Capture images and adjust them first – double-check the patient id – approve when all is ok!
- In 3.1, images were often automatically approved as they were saved. Now, manual approval is needed.
- Moving images to another patient is easier – when done before approval.
- Altering images and image cards after approval is now more difficult.
- Images are displayed in *series* (black icon). Image cards (green icon), can be created as needed.

Improved documentation with clear division of responsibility for users and installers:

- The "Instructions for use" describes the workflow and tools for dental staff, and no technical information.
- The "Instructions for use" is available via the Help menu in DentalEye (or press the F1 key), and printed on paper.
- It is vital that all users study the "Instructions for use". Please take note of all safety precautions!
- The "Installation instructions" is intended for IT technicians. Installation and configuration is not supposed to be performed by the dental staff. Many settings have therefore been removed from the user interface.
- The entire system needs to be properly installed and verified technically and diagnostically, before clinical use.
- A person licensed to capture and diagnose radiographs needs to verify the image quality after installation. A form included in the "Installation instructions" must be filled in and sent to DentalEye AB, see contact info below.

Hints for users with references to the "Instructions for use":

7.1 An **identity label** displays the patient ID during capture to ensure that the right patient is active.

7.3.1 **Green/black** image cards were duplicates in old versions. Normally only the green image cards were visible in the list with black series hidden. Now only series (black icons) are created unless a green image card is created by the user. Read more about the series concept in the Instructions for use.

7.4 The **Save** button is used to **approve** images and save adjustments (images are saved directly when captured). The Save dialog brings up two options: either to Save and approve or Save as not approved. If not approved the image card will be open for changes or additions until approved.
Please do not approve images before everything is ok!

7.5.2 Now you can select two or more images on the image card and perform the same operation for them together.

7.5.3 Move and rotate the images first – then approve!
There is a difference in what can be adjusted before approval and after.

7.5.4 **Delete images:** can only be done before approval.
This requires that special user rights are granted in the security settings.
Caution! It is complicated to rescue a deleted image, this must be done by a DentalEye technician.

| 7.5.6 | As long as an image card is not approved it is easy to move the entire image card or some images to another |
| 7.5.7 | patient. Use the clipboard for images and "**Move series to other patient**" for entire image cards. |

7.5.7 — Make it a habit to double check the patient ID before approving. If images have been approved with the wrong patient it is a much more demanding task to unapprove and move them afterwards.

7.5.8 It is important that images have correct anatomical information. Please make sure that the images are placed in the right frame in the right template before approval!

Templates are included with the system and the installer can create custom templates according to the Installation instructions. Templates shall always be approved by the responsible dentist.

7.5.9 Local image cards (green icon) will be used more seldom. In this part you will also see how to make a **comparison** between two or more image cards.

7.5.10 The **Presentation overview** has been made easier to use.

7.6 **Brightness/contrast** is best adjusted in review mode. In image card mode, the Ctrl key needs to be pressed.

7.6.2 **Measurements** shall always be calibrated.

7.7 **Approval!**

This must only be performed by licensed dental staff – approves that the image is acceptable for diagnosis and that the patient information is correct. Approval can be deferred but is difficult to reverse.

The "Instructions for use" presents situations when it is better to save as unapproved.

7.7.1 A red hollow corner over the image indicates that something has been altered in the image since approval.

The image is still approved and it is usually not necessary to save the changes.

7.7.4 **Change approval** – can be done but only as an emergency.

If the need occurs there might be a flaw in the workflow, which needs to be addressed. Why was the image card approved when it obviously was not ready for approval? To change approval is a task only to be performed by supervisory staff.

7.8 **Export/import** of image files: it is now easier to export to or import from CD:s, the desktop or other folders on

7.9 your computer. Exported image files will be given a unique name containing patient ID and date so they cannot be mixed up or replaced with another file.

DICOM format is recommended, since patient information is stored together with the image. Use the DICOMDIR option when exporting multiple image files.

7.9.1 **CD-recording** is easier in this version. Read more in "Instructions for use".

8 **Incident reporting:**

If a risk for maltreatment or injury to patients or users is identified, a report must be sent to DentalEye AB.

Make sure that the equipment is properly installed in line with the "Installation Instructions". This needs to be verified by the responsible dentist!

There is a tool called "System information" in the Help menu, which sends information to DentalEye AB about configuration and error logs. Please use this tool to send the information to DentalEye AB when support is needed.