May 2nd, 2016

Upgrade to DentalEye 3.2

This information is for dental practitioners using DentalEye 3.1 and for IT technicians and distributors installing DentalEye. The information contains practical and technical advice to prepare the exchange of DentalEye to our CE marked version DentalEye 3.2.

DentalEye, like any other medical software, is now classified as a medical device with strict regulatory requirements. The product must be CE marked to be approved for clinical use, and as manufacturers we must be certified according to the European Medical Directive.

The EC certificate for DentalEye was issued on 2016-04-08. The first CE marked version of the software, **DentalEye 3.2.1**, was released on 2016-04-28.

Please note that the old version DentalEye 3.1 is not CE marked and needs to be replaced with the CE marked version. DentalEye 3.1 will not be supplied in the future.

Recall

This information is only for clinics that have started or expanded their use of DentalEye 3.1 after November 21, 2011. Clinics that have had the product delivered prior to this date are not to be concerned.

Some clinics have had DentalEye 3.1 delivered after a market ban was issued in 2011. The Swedish Medical Products Agency has requested the wrongfully distributed software to be recalled, which means that the distributed systems will be replaced with a CE marked version, or as an alternative, existing systems will be blocked from new patient information entry. A notification of the recall has been confirmed by all of the affected practitioners.

The Swedish Medical Products Agency decided to extend the time of the withdrawal to June 30, 2016. After this date, the old version must not be used. Please upgrade to the CE marked version well in advance!

Manuals, Support and Training

An important part of the regulatory requirements is that both users and installers have clear instructions to follow and that the software is installed and setup correctly before clinical use.

For DentalEye 3.2, we have developed new manuals: **Instructions for use** for healthcare professionals and **Installation instructions** for technicians and installers.

DentalEye 3.2 is not meant to be installed by healthcare professionals, and should be installed by an authorized representative/distributor or an experienced dental-equipment and software IT technician.

The instruction manuals will be delivered with the software and can also be downloaded from our website for preparation. Please observe that the manuals have been recently updated. Download the latest version from the link below.

The manuals can be found at http://www.dentaleye.com/release/DE32/documents/

For Healthcare Professionals

The user interface in DentalEye 3.2 is practically the same as in the previous version, so experienced users will be able to continue to work without any major difference. There are some changes to the workflow and some functions have a new appearance.

This is clearly described in our new **Instructions for use**. It's important that all healthcare professionals read the instructions for use when it's time to change to the new version, and also take note of the changes and all of the safety precautions. The instructions for use will be distributed electronically with the program, and we will also distribute printed paper copies to clinics that upgrade to the new version.

In addition to the instructions for use we of course provide **user support** as usual via e-mail and telephone. Sometime after the upgrade, when the users are more familiar with the program, we do recommend that you contact us to make an appointment for **user training** at the clinic.

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For Installers

It's important that whoever is about to install and adjust settings for DentalEye 3.2 reads the **installation instructions** beforehand.

As always, we provide technical support with installations, but hopefully most of the questions will be covered in the installation guide which consists, amongst other things, of:

- system requirements
- supported equipment
- database connection
- program settings
- configuration of plugins
- calibration of X-ray equipment and monitors

Please note that each installation must be documented by signing a form and submitting it to us. The form can be found on the last page of the installation instructions.

Important Technical Information

Computers, Operating Systems and Network

The first release of the new version, DentalEye 3.2.1, is only supported in Windows 7 and Windows 8.1. For our next release, 3.2.2, we plan to add support for Windows 10. DentalEye works with both 32-bit and 64-bit versions of the operating systems, but the drivers of connected equipment may not. This is specified in the installation guide for each plugin.

Practitioners still using Windows XP or Vista are required to upgrade to a more recent operating system and most likely to newer computers.

For a clinic approaching an upgrade of computers and imaging equipment it may be a good opportunity to change computers in connection with the upgrade to DentalEye 3.2. It might be easier to install the software on a new computer instead of trying to upgrade an old. Additionally, the old computers can be kept operational during and after the installation of the new computers, as a safety precaution.

We strongly recommend that you check servers, backup and networks prior to the upgrade so that they have sufficient performance and storage capacity, and that the network communication is functioning properly. For larger practices (3 or more computers), we recommend that you use a dedicated server and preferably a Windows domain. Please see the installation guide for more detailed system requirements and recommendations.

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Installation

DentalEye 3.2 can't be installed on a computer that has a previous version of the program installed. DentalEye 3.1 and any old plugins must be uninstalled before the installation can run. All of the old settings will disappear with the uninstallation, and it's safest to save or transfer the settings (with a tool, see below) before uninstalling, in case they are needed again.

DentalEye 3.2 is delivered with a set of updated plugins for connection of compatible equipment, such as sensors and cameras. The included plugins cover most sensors and other equipment that currently can be used with DentalEye 3.1, but some plugins are not yet upgraded and will be added to upcoming versions. Some older plugins will not be adapted to DentalEye 3.2. This can for example involve plugins for older equipment that only have Windows XP drivers.

An important preparation before the uninstallation is to find out if the current equipment still supports DentalEye 3.2, i.e. if there is an updated plugin and a driver that will work with newer operating systems. The details can be read in the installation guide, and you can also contact us to find out if the equipment is supported and to discuss how to handle old equipment not supported by DentalEye 3.2.

It's not possible to install any other plugins but the ones included in the installation package – for example it is not possible to install an older plugin from DentalEye 3.1 in the new version. The reason for this is that all of the software components must be CE marked, which is not the case with older plugins.

When connecting equipment, it must be installed with drivers that are of the same version as the plugin was tested with. This is specified for each plugin in the installation guide. Drivers are no longer included in the installation package. The drivers should be provided by the distributor of the equipment, but we will also make them available for download at http://www.dentaleye.com/release/DE32/drivers/

Databases

DentalEye 3.2 is only supported on SQL Server. Clinics still using an MS Access database must convert the database prior to the upgrade. Please contact us well in advance to make an appointment for conversion! DentalEye 3.2 uses the same database format as DentalEye 3.1, and client computers with 3.2 and 3.1 can work in the same database during a transition period before all the computers have been upgraded.

License Keys

DentalEye 3.2 uses new license keys, and a key for 3.1 cannot be used for 3.2 and vice versa. **Please contact us to request license keys prior to installation!** DentalEye's license keys are stored in the database. If you have client computers with both 3.1 and 3.2 connected to the same database, you must add a key for each version.

Tools

We provide you with a few tools so that you in advance can evaluate if the upgrade of DentalEye 3.2 will be successful. Both of the tools can be accessed on our website. Please use the tools as soon as possible and alert us with potential problems, so that there will be enough time to take precautions before the upgrade.

System information is used to create a report of the clinic's database, error logs, and used plugins. The report may also be sent to DentalEye AB.

Run the tool at http://www.dentaleye.com/DESysInfo.exe

DE 3.2 Readiness check evaluates if a computer is ready to be upgraded to DentalEye 3.2, saves a report with old settings, and warns about problems with operating systems, plugins, etc. The tool should be run on all computers before beginning the uninstallation of 3.1, and can also transfer settings to the new installation.

Run the tool at http://www.dentaleye.com/DE32ReadyCheck.exe