



Sirona Dental Systems GmbH • 64625 Bensheim

To all CEREC user

04/15/2018

Important warning in the latest version of the directions for use for CEREC AC / AF / AI with Omnicam

Dear Mr. / Ms. (Dr.),

As part of our proactive approach to risk management, we have incorporated a new warning in the directions for use of the CEREC AC /AF / AI with Omnicam. Since your safety and that of your patients and staff is paramount when using our medical products, we are bringing this retroactive notice to the attention of all existing active users.

On the Dentsply Sirona Portal, there is an update to your directions for use at the address manuals.sirona.com, which has been expanded with a warning in section 7.3. As with lots of other optical impression systems, the CEREC Omnicam uses pulsating light. In rare cases, pulsating light from a CEREC Omnicam may trigger epileptic seizures. For this reason, persons diagnosed with epilepsy are strongly urged to refrain from using the Omnicam. This characteristic prompts us to formulate the warning as follows:

WARNING

Danger of injury in the case of diagnosed epilepsy

Patients who have been diagnosed with epilepsy cannot be treated with the CEREC Omnicam.

Dentists and dental assistants who have been diagnosed with epilepsy cannot work with the CEREC Omnicam.

Dentsply Sirona has installed thousands of CEREC systems on the market which have generated millions of scans and restorations. Given such high rates of use, such incidents are possible even if extremely rare. Rest assured that the CEREC system meets the latest safety standards for a medical product and will continue to do so.

Yours sincerely,

Stefan Leopold

CAD/CAM Quality Management Manager

Christian Schwarze

CAD/CAM Product Management

Sirona Dental Systems GmbH • 64625 Bensheim

Recipient address
Address line 01
Address line 02
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Important warning in the latest version of the directions for use for CEREC AC / AF / AI with Omnicam

Dear customer,

As part of our proactive approach to risk management, we have incorporated a new warning in the directions for use of the CEREC AC /AF / AI with Omnicam. Since the safety of our patients and users is paramount when using our medical products, in conjunction with the relevant authorities competent for us, we are bringing this retroactive notice to the attention of all existing active CEREC AC /AF / AI with Omnicam users. This step cannot be implemented without your active support. It is therefore a requisite that the attached information letter or new directions for use are sent to your registered CEREC AC /AF / AI with Omnicam users by **May 30, 2018** at the latest.

After concluding your complete customer communication action, we ask that you please provide us with written confirmation of this by **June 4, 2018** at the latest. (To the above mentioned e-mail address.)

On behalf of the trading partner cited in the address line, I confirm the sending of the information letter from Sirona Dental Systems GmbH, or the sending of updated directions for use, to our active CEREC AC /AF / AI with Omnicam users.

__ __ __ users have been proactively notified.

Date	Location	Name (plain text)	Signature
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We would like to apologize for any inconvenience caused and thank you in advance for your assistance.

Yours sincerely,

Stefan Leopold
CAD/CAM Quality Management Manager

Christian Schwarze
CAD/CAM Product Management