
Urgent Field Safety Notice

Update of device software and recommended emergency measures

regarding

WO300 OR1 FUSION CONTROL®
200828557
2020-09-28

Sender:

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen/Germany

Addressee:

User, operator

Identification of the medical devices concerned:

WO300 OR1 FUSION CONTROL® software release 1.4.0 / 1.4.1

Intended use:
The OR1 FUSION CONTROL® is designed for use in operation rooms by qualified personnel. The OR1 FUSION CONTROL® is an appliance (consisting of hardware and software) for the documentation of audiovisual data and patient data during diagnostic and therapeutic procedures. It allows the operation to be recorded and described for documentation purposes. The audiovisual data that is recorded and forwarded using the OR1 FUSION CONTROL® is for examination and information purposes but not primarily for making diagnoses. The recorded audiovisual data is not intended to be shown intraoperatively on the operation monitor.

Description of the problem including the identified cause:

In the KARL STORZ OR1 FUSION® software releases 1.4.0 and 1.4.1, it is currently possible with the OR1 FUSION CONTROL® WO300 for image data of one patient to be assigned to the procedure data of another patient.

The following event can lead to this occurrence:
The user triggers a recording during an operation of patient B. If a system error occurs in the capture module, a recorded image from the past, for example, of patient A, which is still in the buffer memory of OR1 FUSION CONTROL®, is assigned to patient B. The image of patient A then appears in the folder of captured images of patient B when the procedure of patient B is competed.

Although analyses have shown that the system does not assign images 100% correctly due to the potential error, there is no risk to the patient if the intended use is observed.

In order to prevent the unexpected occurrence of cross-case misallocation completely, we recommend the following primary measure.

What measures are to be taken by the addressee?

- *Please restart the system after each operation.*

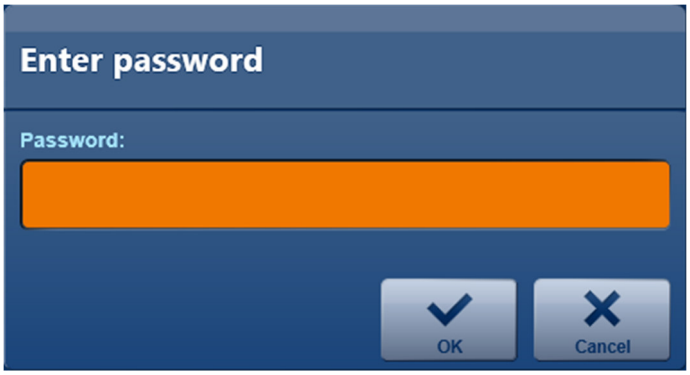
  As a primary measure, each restart causes the buffer memory of OR1 FUSION CONTROL® to be emptied, and as a result, no old images, for example, of patient A, can be loaded to the procedure of patient B.

  To ensure the integrity of all recorded images during the operation itself, we recommend that the image preview also be activated as well. This additional measure helps to detect any images that may occur where the acquired image does not correspond to the current image.

- *Activation of "Picture in picture" capture feedback & configuration of the video outputs*

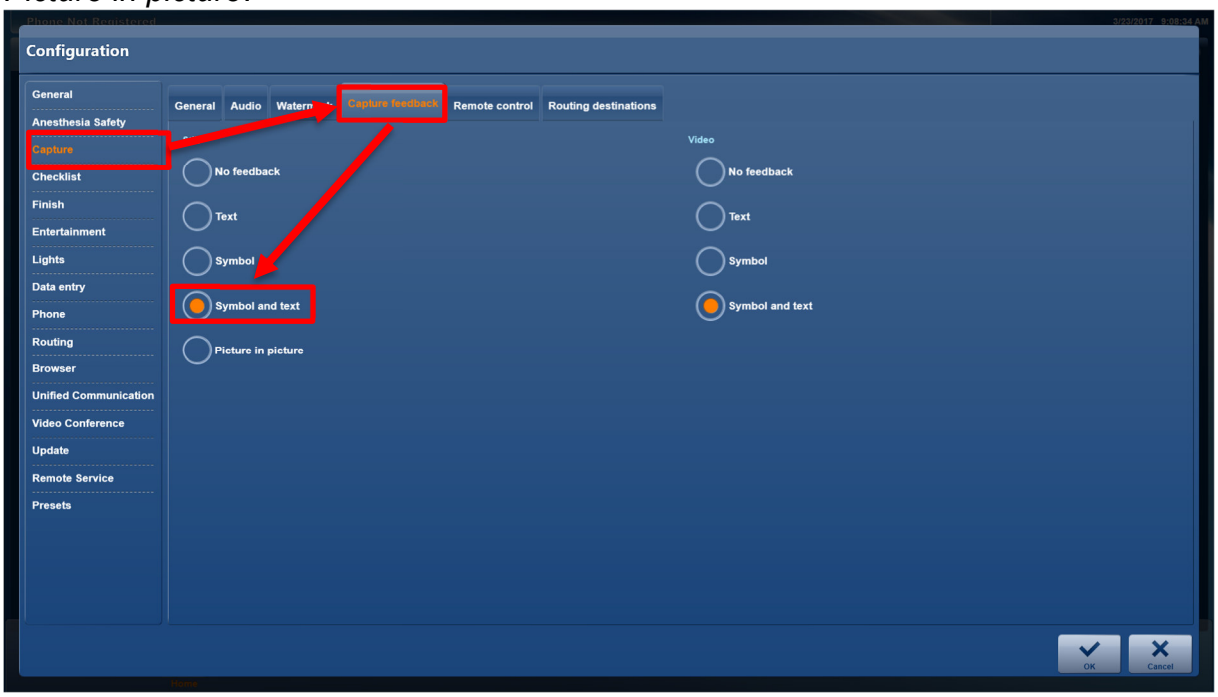
  Start KARL STORZ OR1 FUSION® if this has not already been done and open the configuration area by tapping the tool icon in the header.

  When the login window opens, enter the password (administrator password) and confirm with OK.

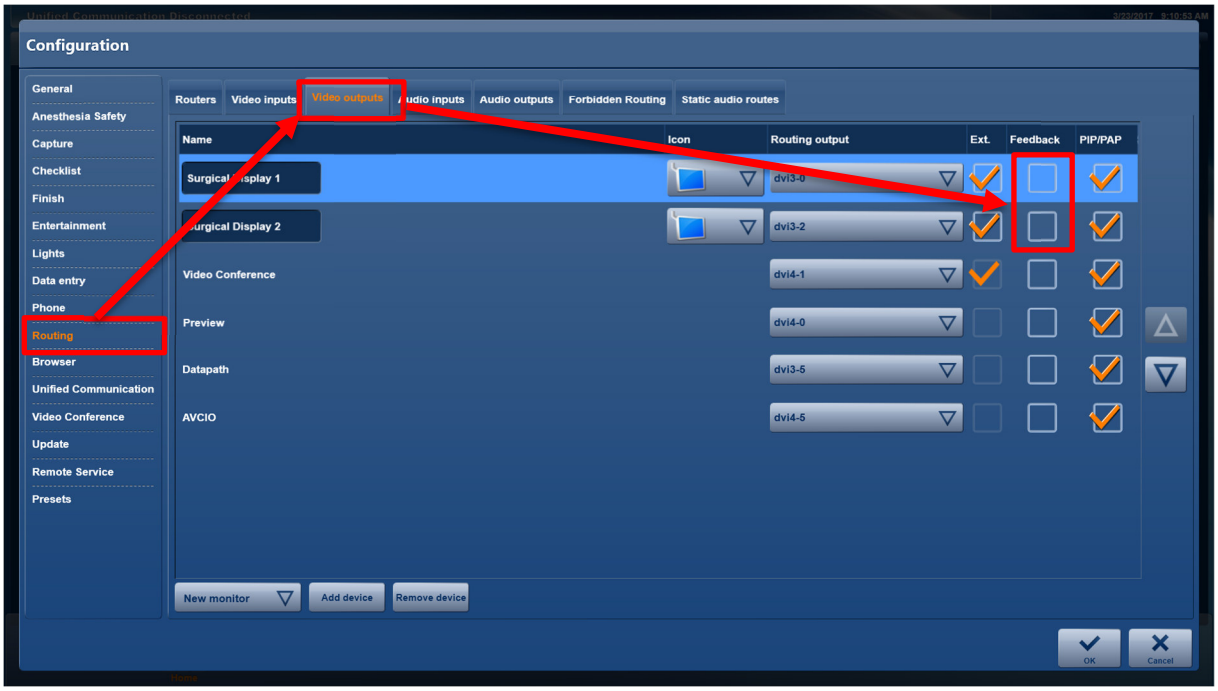


  Proceed in the following order to implement the settings:

Configuration → “*Capture*” module → “*Capture feedback*” tab → mark (still image) *Picture in picture*.



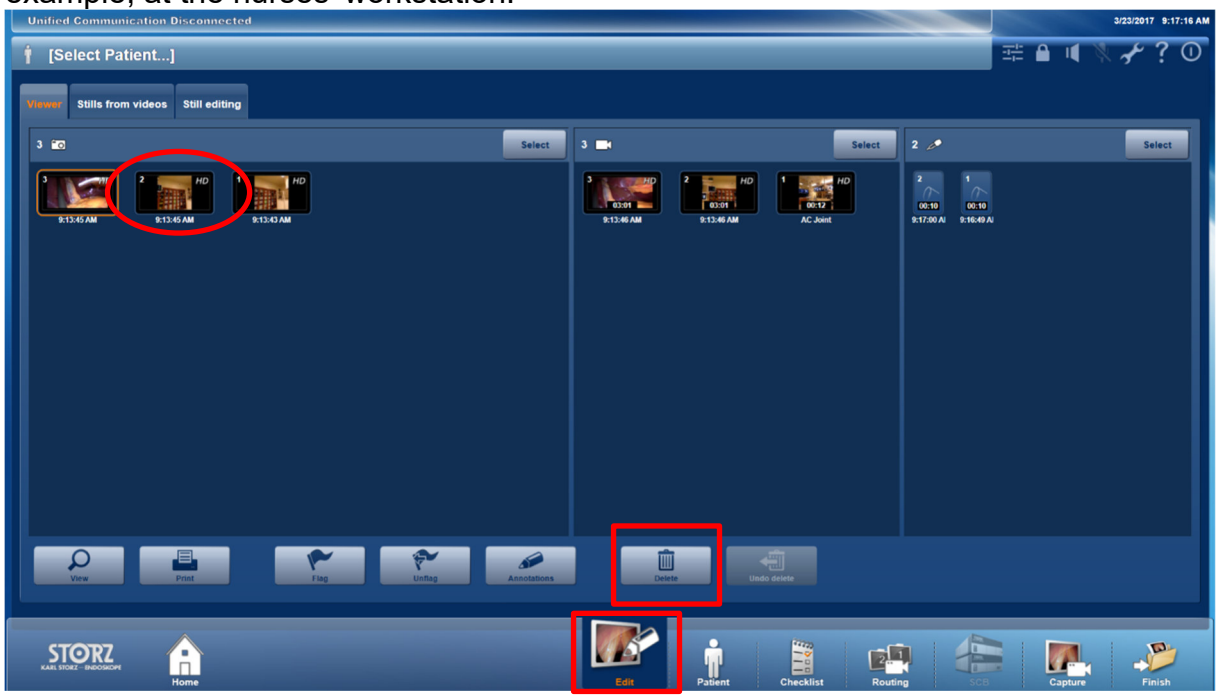
Configuration → “*Routing*” module → “*Video outputs*” tab → Set check for *Feedback* ✓.



In addition, one of the following measures can be applied during an operation:

- *Check the images that have just been captured and displayed on the operation room screen*
- *Check the images that have just been captured using "Preview images" in the right part of the "Capture" module*

In the case of anomalies, additional images must be created.
You also have the option of deleting faulty images after the end of the operation but before the procedure is completed. This can be done in the "*Edit*" module directly via software, for example, at the nurses' workstation.



Recommendation:

- *Check the captured patient images before the end of the operation and only then complete the procedure (Finish / Export) with KARL STORZ OR1 FUSION®.*

Further procedure:

In a further step, an update to the latest software release 1.4.2 will be provided, in which the malfunction is corrected. For this purpose, the respective KARL STORZ service office will contact you to arrange an appointment.

Transmission of the urgent field safety notice:

This urgent field safety notice must be passed on to all users of the products listed above and all other persons who need to be aware within your organization. If you have transferred these products to third parties, please transmit a copy of this notice or alert the contact listed below. Please keep this notice at least until the corrective action has been fully implemented.
The competent supervisory authority has received a copy of this urgent field safety notice.

We thank you for your cooperation and understanding for this measure.

Please respond by October 30, 2020.

Contact:

KARL STORZ SE & Co. KG
Robert Herz
Tel.: +49 07461 708 7348 (during business hours)
Fax: +49 07461 708 45581.

Sincerely,

KARL STORZ SE & Co. KG

Feedback form 200828557

This is not a product recall – please do not return any products!

We hereby confirm that the safety information has been received and, where applicable, passed on.

Please send this form to:
vigilance@karlstorz.com

or

Fax: +49 07461 708 45581

or by post to

KARL STORZ SE & Co. KG
Attn. Robert Herz
- Department Head Vigilance -
Dr. Karl-Storz-Str. 34
78532 Tuttlingen, Germany

Hospital or organization (stamp):

I confirm that I have read and understood the safety instruction and that I have implemented it accordingly.

Name: _____

Title/position: _____

Signature: _____

Date: _____