

IMPORTANT FIELD SAFETY NOTICE

Internal Trium Ref.-Nr.: CTO-420
August 2011

To: Head of Ob/Gyn Department

Subject: **Trium CTG Online – Inconsistent behaviour of display in combination with inappropriate formulation in operators manual**

Dear Customer,

Trium Analysis Online GmbH has become aware that for the software product Trium CTG Online there is the possibility of an inconsistent behaviour of the display, which shows the CTG trace as "frozen" despite the fact that the displayed time and the symbol of a rotating fetus was refreshed. This behaviour can have an impact on patient safety. Other functions of Trium CTG Online are not affected. **Please ensure that all potential users of the system in your institution take notice of this safety information including the recommended actions.**

Safety Issue

The following issue was identified within the application of Trium CTG Online:

1. A technical problem with the Trium CTG Online server can lead to a situation in which the currently recorded CTG traces are not transmitted to the user client.
2. The user client cannot update the CTG trace, which shows sequences of up to 30 minutes of the fetal heart rate and the maternal uterine contractions, because of a technical problem with the server. In parallel the time displayed in the user client is being refreshed continuously, as well as a sequence of images that give the impression of a rotating fetus.
3. The safety information in the corresponding section in the operators manual of Trium CTG Online is therefore inappropriate. The safety information refers only to cases where a joint „freeze“ of CTG display, time and rotating fetus is indicated:



If the time or position of the child does not change over 30 - 45 seconds, there is either a network or server error. In this case, check and/or re-establish the connection. If the error cannot be corrected by reloading the page in your browser, please contact your system administrator and initiate a CTG paper strip check on-site.

Affected Product Details

The technical problem affects versions of Trium CTG Online up to version number 1.8.3.

The version number can be found in the window of data management at "Info" (in version 1.8. by clicking on the Trium logo).

Safety Instructions

The technical problem can be detected by visual controlling if the CTG trace freezes – in addition to visual controlling a freeze of displayed time and the rotating fetus over a time period in the range of 30-45 seconds.

The technical problem can be resolved by restarting the server. In this case it needs to be assured that the CTG paper strip can be controlled at the point of care.

Corrective actions

Trium Analysis Online GmbH has resolved the problem of a partial freeze in the display in an update of the affected software version. This update is offered to affected customers. Please contact during usual office hours:

Trium Analysis Online GmbH

Phone: +49 89 20 60 26 9 ■

Fax: +49 89 20 60 26 9 11

e-mail: support@ctgonline.de

Trium Analysis Online GmbH confirms that this notice has been reported to the appropriate Regulatory Agency.

We would like to emphasize that the maintenance of a high standard in quality and safety of our product is of highest priority. Please don't hesitate to contact us directly in case of any doubts or concerns.

Sincerely

Michael Scholz
Managing Director
Trium Analysis Online GmbH

Dr. Martin Daumer
Managing Director
Trium Analysis Online GmbH