

## Urgent Field Safety Notice

April 24, 2014

Dear Customer,

FertiliTech is issuing this Field Safety Notice for the EmbryoScope time-lapse system to inform you that in connection with cleaning or disinfection, metal clips may short circuit the electronics on the culture dish holder. This may result in elevated temperatures on the culture dish holder.

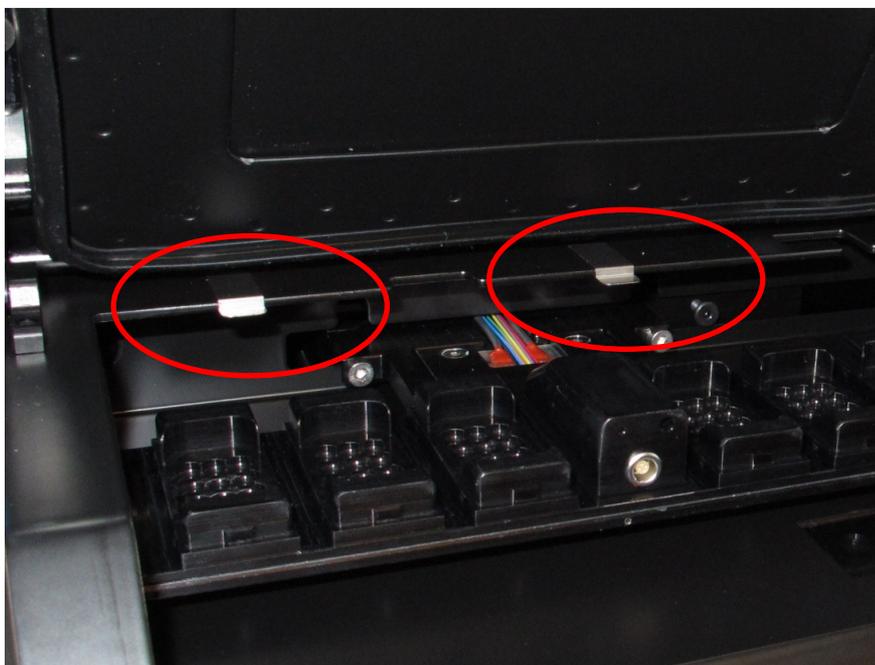
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<b>Products affected</b>	Reference number: ESD20000, ESD20000-EU, ESD20000-JAP Description: EmbryoScope time-lapse incubator
<b>Description of issue</b>	When cleaning or disinfecting parts of the EmbryoScope time-lapse incubator, the metal clips which are attached to the embryo chamber and support the transparent plate positioned over the culture dish holder may come loose.
<b>Hazard</b>	<p>If a metal clip comes loose and comes into contact with the electronics on the culture dish holder, the electronics may be short circuited resulting in an elevated temperature on the culture dish holder.</p> <p>The EmbryoScope time-lapse incubator alarm system will activate an alarm when the temperature on the culture dish holder is 0.5 °C higher than the user-defined set point.</p> <p>If the electronics is short circuited, the heat foil may continue to heat the culture dish holder beyond the 0.5 °C alarm limit.</p>

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EmbryoScope time-lapse incubator with open load door and transparent plastic cover plate in correct position



EmbryoScope time-lapse incubator load area with cover plate removed and metal clips in correct position

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After cleaning or disinfection of the EmbryoScope time-lapse incubator, always confirm that both metal clips are securely fastened at the top of the embryo chamber.

**Action to be taken by user**

If all EmbryoSlide culture dishes need to be removed from the EmbryoScope time-lapse incubator, follow the instructions in the EmbryoScope time-lapse incubator user manual or the Emergency procedure located below the service lid at the top of the EmbryoScope time-lapse incubator.

Please note that FertiliTech does not recommend users to stop using the EmbryoScope time-lapse incubator.

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**Distribution of this Field Safety Notice**

This notice should be passed on to everyone in your organization who operates the EmbryoScope time-lapse incubator.

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**Action planned by FertiliTech**

The user manual for the EmbryoScope time-lapse incubator will be revised with updated instructions, clarifying that the user should confirm the position of the two metal clips after completed cleaning or disinfection.

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**Further information**

If you have any further questions or concerns, do not hesitate to contact the FertiliTech Helpdesk/Hotline at +45 7023 0500 or +1 781 681 9306 or [support@fertilitech.com](mailto:support@fertilitech.com) or [support-usa@fertilitech.com](mailto:support-usa@fertilitech.com).

A copy of this notice can also be found on <http://fertilitech.com/en-GB/Support.aspx> and <http://fertilitech.com/en-US/Support.aspx>

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Yours sincerely



Henrik Wahlgren

QA Manager

Unisense FertiliTech A/S