

Field Safety Notice

Tissue-Tek® AutoSection®, Item# 5000, up to serial number 0297

Safety communication by EUROPEAN REPRESENTATIVE

Date: June 29, 2018

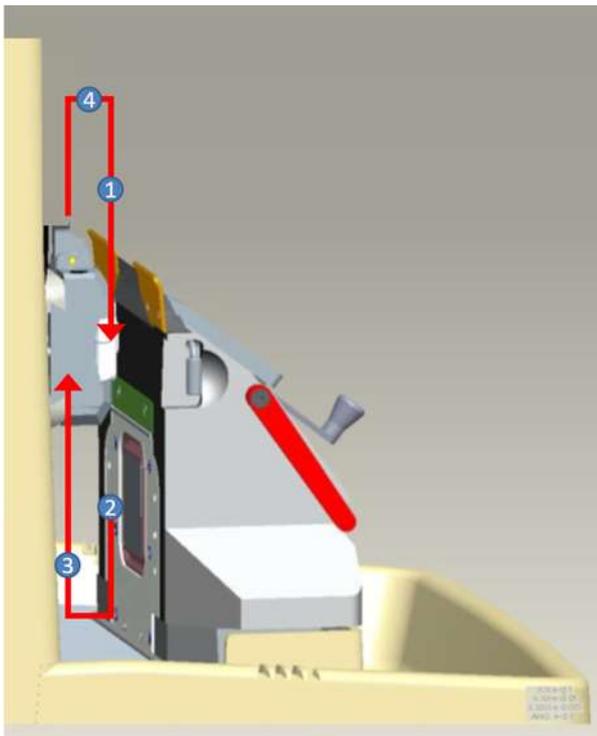
Introduction

Sakura Finetek is continuously looking to improve its products and increase customer safety and satisfaction. Sakura Finetek Europe B.V. herewith informs you that a recent software version of the AutoSection contains a software bug that requires immediate attention.

Description:

When software version 5.89 has been installed on the AutoSection and the emergency button is pressed before the alignment stage has been completed, the AutoSection will start sectioning (or facing) again after releasing the emergency button to reset the system.

The image below shows the AutoSection from the side to provide a detailed overview of the different stages in the alignment protocol.



ALIGNMENT STEPS

- 1) Placement of block and initialising alignment
- 2) Alignment of block
- 3) Bringing the chuck back up
- 4) Start face/section after alignment

Step one describes the user placing a block in the chuck and initialising the alignment by choosing “Align and Face”, “Align and Section” or any programmed protocol that contains a “Align” step.

The second step is the actual alignment of the block followed by a third one in which the chuck is brought back up. The final step starts facing or sectioning the block and resembles also the end of the alignment stage.

Only during the first three steps of the alignment the issue will occur when the emergency button is pressed. The chuck will return to its upper position to reinitiate and will start without further notice after a few seconds.

Since the user will not anticipate the chuck to move at this stage, it is possible that the user is near the chuck (and therefore the blade) when the motion starts again. This poses a risk to user health.

Advise on action to be taken by the user:

In order to ensure our customers safety, making them aware that this software bug exists is going to be the first step in fixing this issue. We ask of you to contact the customers in your region to explain that this bug will only occur when the instrument runs on software version 5.89 and is stopped with the emergency button within its alignment protocol.

Document the date of the communication to your customer in the field safety effectiveness check form.

Software version 5.90a which is expected to be released within 2 weeks, will be a mandatory upgrade in which this software bug is solved.

User advice

An instructed customer can still use the AutoSection in their daily routine while being alert that after an emergency stop within the before mentioned conditions the chuck will start moving again. This movement could simply be stopped by pressing the touchscreen like how one would normally stop the movement of the AutoSection.

Any questions or further advice regarding this subject can be directed at support@sakura.eu

Transmission of this field safety notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation. Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action (if appropriate).