



Product Correction

Immediate Action Required

Date Issued

May 19, 2016

Product

Product Name	List Number	UDI
ACCELERATOR a3600 Centrifuge Module	06P37	Not applicable

Explanation

Abbott Diagnostics has received the attached letter from Inpeco, the supplier of the ACCELERATOR a3600 Centrifuge Module. Inpeco recommends an immediate reduction in the operating speed of the centrifuge not to exceed a maximum of 3500 RPMs. Material changes may have an impact on the strength of the buckets, which could lead to the bucket becoming dislodged in the centrifuge.

There have been no reports from ACCELERATOR a3600 customers of any centrifuge module failures. However, if a centrifuge fails, there is the potential for:

- Operator biohazard exposure (due to broken sample tubes)
- Operator physical hazard (due to broken glass within the centrifuge or the centrifuge moving unexpectedly).

Patient Impact

If a centrifuge failure occurs, processing of patient samples may be delayed.

Necessary Actions

Implement the following immediately:

1. **Do not exceed a maximum of 3500 RPMs.** This corresponds to an RCF (g) value of 2657. This value meets the requirements for the centrifugation of commonly used blood sample tubes:

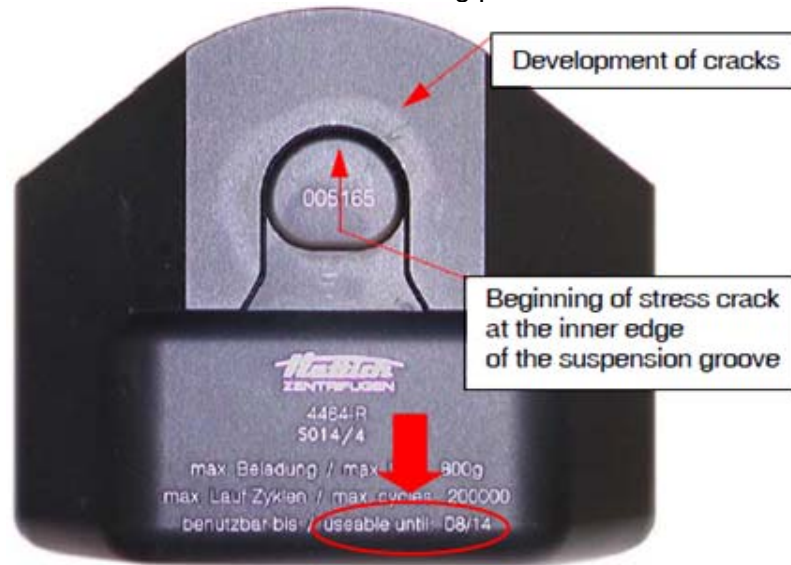
Manufacturer	Type	RCF*	Time (min)*
BD	Vacutainer	1100 – 1300	10
Sarstedt	S-Monovette	1800 – 3000	10 – 15
Greiner	Vacurette	1800 – 2200	10 - 15

*Please reference the instructions for use of the respective tube manufacturer. You may need to adjust configured spin time.

NOTE: Reduction of RPMs may impact overall track workflow and turn around times due to the potential of increased centrifugation time.

2. Per the Hettich Centrifuge operating instructions (AB5680DEENFRIT), when the centrifuge is running, according to EN/IEC 61010-2-020, no persons, dangerous substances or objects may be within the safety margin of 1 foot (300 mm) around the centrifuge.
3. **Visually inspect your centrifuge buckets for cracks**, particularly at the inner edge of the suspension groove. Cracks can be identified more easily using a magnifying glass. **If any cracks are identified OR if the “useable until” date has expired, immediately stop using the centrifuge.** Contact Customer Service to arrange for

replacement buckets. Reference the following picture.



4. Continue to perform **Weekly Maintenance** per the ACCELERATOR a3600 Operations Manual (0U00000141.00, September 2015).

If you have any questions or concerns while performing these steps, please contact Customer Service for assistance.

Contact Information

If you or any of your health care providers you serve have any questions regarding this information, U.S customers should call Abbott Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S. should contact your local area Customer Support.
