HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

ARCHITECT c4000 Mixer
ARCHITECT c8000 Mixer
ARCHITECT c16000 Mixer

Priority 2 – Warning

HPRA Safety Notice: SN2019(14) **Issue Date: 17 May 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Abbott Laboratories	V39936

ISSUE
Abbott has issued a field safety notice (FSN) to raise awareness of the potential for the mixer blade to separate from the mixer of ARCHITECT c4000, c8000 and c16000 analysers. A missing mixer blade will result in inadequate mixing of the reaction mixtures which could potentially lead to incorrect results (failed assay calibration, Quality Control (QC) out of range, and/or incorrect patient results). Abbot advises users of these analysers to inspect the mixer blade as part of routine maintenance. Users who identify a mixer with a detached blade should consult their medical director regarding previously generated results. Please refer to the accompanying FSN for further details.

ACTION OR RECOMMENDATIONS
The HPRA advises that healthcare professionals: 1. Refer to the accompanying FSN and follow the instructions provided.

2. Acknowledge receipt of the FSN if you have not already done so.
3. Forward a copy of this safety notice and the FSN to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred.
4. Report any concerns regarding these devices and this issue to the manufacturer and the HPRA.

TARGET GROUPS

Biochemistry Departments
Clinical Chemistry Departments
Clinical Directors
Hospital Managers / CEOs
Laboratory Managers
Laboratory Staff
Laboratory Technicians
Medical Scientists
Purchasing Managers
Risk Managers
Supplies Managers

BACKGROUND

Abbott has issued an FSN to provide further information to enable users to inspect the mixer blade and identify error codes which signal the need for an immediate inspection of the mixer. A procedure for inspecting the mixer is included alongside further precautions for the weekly maintenance of the mixer

Abbott has indicated that the investigation is ongoing and that updated information on these procedures will be provided once the investigation is completed.

Please refer to the accompanying FSN for further details.

The HPRA is issuing this safety notice to raise awareness of this issue.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Abbott
Max-Planck-Ring 2
Wiesbaden 65205
Germany

Abbott Helpline
Telephone: +353-1-4691568
E-mail: AbbottCareIrl@Abbott.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie