



# Medical Device Alert

MDA/2016/003

Issued: 10 March 2016 at 14:00

Valid until: March 2017

All ZeniPower mercury-free hearing aid batteries – low risk of batteries exploding during use or if depleted.

## Summary

Manufactured by Zhuhai Zhi Li Battery Co Ltd – stop using batteries with certain best before dates.

## Action

- Identify affected batteries (see Device section).
- Do not use batteries with a best before date of '08-2018' and '09-2018'. This date is on the outer blister packaging.
- If in doubt do not use.
- Ensure all cochlear implant and hearing aid patients receive a copy of this medical device alert, that they understand the problem and do not use the batteries.
- Contact your supplier to arrange for replacement batteries and ensure there is a system in place to supply users with these batteries.

### Action by

- Audiology departments and staff responsible for these devices

### Deadlines for actions

Actions underway: 24 March 2016

Actions complete: 22 April 2016

## Device details

Only batteries with best before dates of '08-2018' and '09-2018' are affected. An example of the packaging is shown below:



If you purchased these batteries from NHS Supply Chain, their codes (NPC) are given below:

NPC (England only)	Manufacturer product code	Description	Brand
GHD3582	A675P MF	R44 zinc air size 675 for cochlear implants	ZeniPower
GHD3583	A675 MF	R44 zinc air size 675	ZeniPower
GHD3584	A13 MF	R48 zinc air size 13	ZeniPower
GHD3585	A312 MF	R41 zinc air size 312	ZeniPower
GHD3586	A10 MF	R70 zinc air size 10	ZeniPower

Since 13 January 2016, NHS Supply Chain has received new supplies of batteries, which do not exhibit this problem.

## Problem / background

The problem is caused by excessive gassing, as the zinc electrode reacts with the electrolyte to generate hydrogen. The battery may expand and possibly explode on rare occasions. This issue affects all types of ZeniPower mercury-free batteries listed above.

## Manufacturer contacts

ZeniPower Battery Co. Ltd.

Tel: +86 756 252 6620

Email: [sales@ZeniPower.com](mailto:sales@ZeniPower.com)

## Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

### Trusts (NHS boards in Scotland)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Audiology departments
- Cochlear implant centres
- ENT departments
- ENT medical staff
- ENT services, directors of
- Risk managers

### NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- Community pharmacists
- General practitioners
- General practice managers
- General practice nurses

### Independent distribution

#### Establishments registered with the Care Quality Commission (CQC) (England only)

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

#### Establishments registered with OFSTED

- Children's services
- Educational establishments with beds for children
- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Enquiries

### England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2016/003** or **2015/012/010/401/016**.

### Technical aspects

Yasser Zayni or Andy Marsden, MHRA

Tel: 020 3080 7238 or 7205

Email: [Yasser.zayni@mhra.gsi.gov.uk](mailto:Yasser.zayni@mhra.gsi.gov.uk) or [andy.marsden@mhra.gsi.gov.uk](mailto:andy.marsden@mhra.gsi.gov.uk)

### Clinical aspects

Mark Grumbridge, Senior Clinical Advisor, MHRA

Tel: 020 3080 7128

Email: [mark.grumbridge@mhra.gsi.gov.uk](mailto:mark.grumbridge@mhra.gsi.gov.uk)

### Reporting adverse incidents in England

Through Yellow Card <https://yellowcard.mhra.gov.uk/>

**Northern Ireland**

Alerts in Northern Ireland are distributed via the [NI SABS system](#).

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre  
CMO Group  
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

**Reporting adverse incidents in Northern Ireland**

Please report directly to NIAIC using the [forms on our website](#).

**Scotland**

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre  
Health Facilities Scotland  
NHS National Services Scotland

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

**Reporting adverse incidents in Scotland**

NHS Boards and Local Authorities in Scotland – [report to Health Facilities Scotland](#).

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – [report to Health Facilities Scotland](#).

Private facilities providing care to private clients report to the [Care Inspectorate](#) and [MHRA](#).

**Wales**

Enquiries in Wales should be addressed to:

Healthcare Quality Division  
Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

**Reporting adverse incidents in Wales**

Report to MHRA through Yellow Card <https://yellowcard.mhra.gov.uk/> and follow specific advice for reporting in Wales in [MDA/2004/054 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health  
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