


# Medical Device Alert

Ref: MDA/2013/054R Issued: 23 July 2013 at 16:45

**Amendment: range of ventilator serial numbers affected**

Device	
<p>SLE 4000/5000 ventilator.</p> <p>Power supply unit (PSU) model FP110 – 410.</p> <p>Specific serial numbers.</p> <p>Manufactured by SLE.</p>	

Problem	Action
<p>Potential component failure in the power supply unit (PSU). Failure of the PSU will cause the ventilator to alarm and shut down immediately.</p> <p>The manufacturer issued a <a href="#">technical bulletin</a> to its customers in February 2012, recommending replacing the PSU. However, the MHRA is uncertain whether corrective actions were carried out.</p>	<p>Locate all affected ventilators and inspect them to identify affected PSUs.</p> <p>Contact the manufacturer for a replacement PSU as soon as possible if the original PSU has not already been replaced.</p> <p>Inform SLE when the PSU has been changed or if the ventilator is not affected.</p> <p>Have an alternative ventilator on standby until any faulty PSUs are replaced.</p>
Action by	<p>Check supplies to ensure that any spare PSUs are not affected.</p>
<p>All staff involved in the set-up, maintenance and use of these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 30 July 2013</p> <p>Action complete: 06 August 2013</p> <p><b>Note: These deadlines are for devices to be identified and arrangements made to replace the component.</b></p>	<p><b>Manufacturer</b> Fred Bauer Quality Assurance Manager SLE Ltd Tel: 020 8681 1414 Email: <a href="mailto:service@sle.co.uk">service@sle.co.uk</a></p>

## Device

Affected PSUs can be identified as shown below:



### Affected product

Ventilator model SLE 4000	Serial numbers 42040 and below
Ventilator model SLE 5000	Serial numbers 53164 and below
Power supply unit model FP110-410	Serial numbers from 163746 to 167558 inclusive

Other model FP110-410 PSUs outside the above serial range may be affected if they contain 'tall' capacitors. These can be checked by following the recommendations in the manufacturer's [technical bulletin](#).

## Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (chief executives)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

#### Trusts

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

- A&E departments
- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetists
- EBME departments
- Equipment libraries and stores
- Equipment stores
- In-house maintenance staff
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care, directors of
- Maintenance staff
- Neonatology departments
- Paediatric intensive care units
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

## Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres

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.

## Contacts

### Manufacturer

SLE Ltd  
Twin Bridges Business Park  
232 Selsdon Road  
South Croydon  
CR2 6PL

Tel: 020 8681 1414

Fax: 020 8649 8570

Email: [service@sle.co.uk](mailto:service@sle.co.uk)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/054** or **2013/005/014/601/004**

### Technical aspects

Patrick Sweeney or Mel King  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 6898/7286

Fax: 020 8754 3965

Email: [patrick.sweeney@mhra.gsi.gov.uk](mailto:patrick.sweeney@mhra.gsi.gov.uk)  
[mel.king@mhra.gsi.gov.uk](mailto:mel.king@mhra.gsi.gov.uk)

### Clinical aspects

Jonathan Plumb  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 6648

Fax: 020 8754 3965

Email: [Jonathan.plumb@mhra.gsi.gov.uk](mailto:Jonathan.plumb@mhra.gsi.gov.uk)

## How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

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

Northern Ireland Adverse Incident Centre

Health Estates Investment Group

Room 17

Annex 6, Castle Buildings

Stormont Estate

Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

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

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

### How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

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

Incident Reporting and Investigation Centre

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

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

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team

Medical Directorate

Welsh Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

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