Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/025 Issued: 2 July 2019 at 14:00

IntelliVue MX40 patient-worn monitors – increased power consumption and no visual or audible alarms when batteries are low

Summary

Manufactured by Philips – devices may lose power earlier than expected and users may not realise the loss of monitoring due to no alarm, which could contribute to a delay in emergency treatment.

Action

- Locate all IntelliVue MX40 devices (see manufacturer's updated Field Safety Notice (FSN) issued 19 June 2019)
- Contact the manufacturer to arrange for them to update the software to version B.06.59 if this hasn't already been done.
- Until the software has been upgraded:
  - devices being used in Monitor Mode, with SpO2 measurement (Manual, Continuous and Auto modes) and with AA batteries as the power source, should have their batteries replaced every 2 hours
  - devices used in all other modes and/or with rechargeable battery packs should have their batteries/packs replaced every 8 hours
  - as specified in the instructions for use, all power sources should be fully charged before starting to use the device.
- Report adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by
All medical, nursing and technical staff involved in the use and maintenance of these devices.

Deadlines for actions
Actions underway: 23 July 2019
Actions complete: 13 August 2019

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

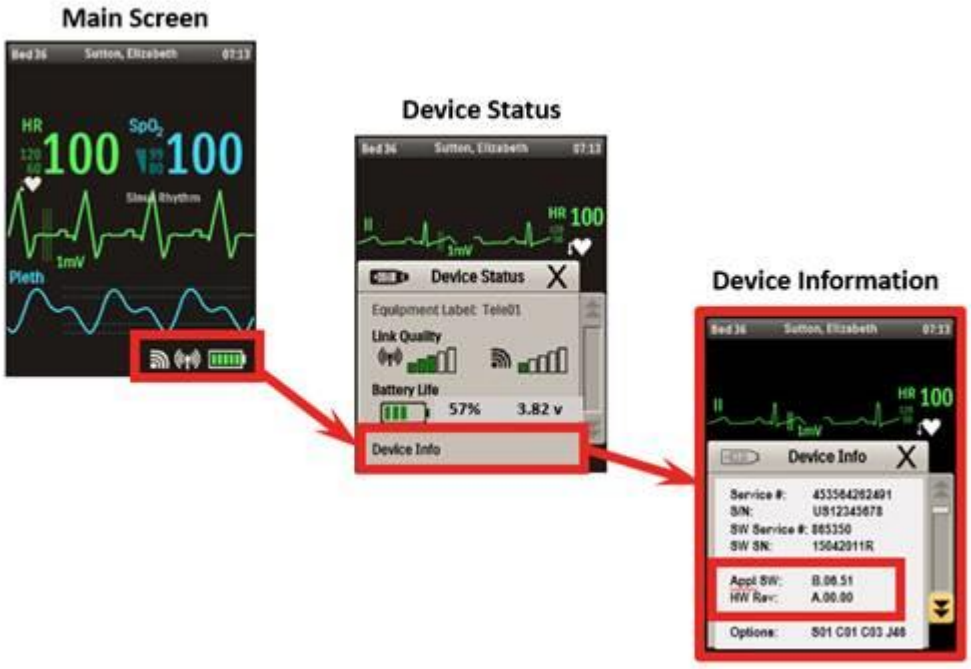
NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

All MX40 units are affected. The original expected battery life can be found in the instructions for use, section 15. This performance will be restored once the software is upgraded.

You can check which software version is installed on each monitor by touching the battery icon on the main screen, then selecting ‘Device Info’. The software version is listed under ‘Appl SW’.



Manufacturer contacts

Philips Customer Care Service Centre
Tel: 0870 532 9741
Email: DeviceVigilanceUKI@Philips.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 NICAS liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Community hospitals
- Coronary care departments
- Coronary care nurses
- Day surgery units
- EBME departments
- Equipment stores
- Equipment libraries and stores
- General surgery
- General surgical units, directors of
- In-house maintenance staff
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Medical directors
- Medical libraries
- Midwifery departments
- Midwifery staff
- MRI units, directors of
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Operating department practitioners
- Ophthalmic nurses
- Outpatient theatre managers
- Outpatient theatre nurses

- Paediatric intensive care units
- Paediatric medicine, directors of
- Purchasing managers
- Radiation & medical oncology departments
- Radiographer superintendents
- Renal medicine departments
- Renal medicine, directors of
- Resuscitation officers and trainers
- Special care baby units
- Theatre managers
- Theatre nurses
- Theatres

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies

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 Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/025** or **2019/004/011/291/024.**

Technical aspects

Phillip Davenport, MHRA
Tel: 020 3080 6000
Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health, Social Services and Public Safety
Tel: 028 9052 3868
Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 250986 / 03000 255510

Email: haz-aic@wales.gov

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).