REF: CC2178

DATE: 28 November, 2019

Urgent Field Safety Notice
SLE6000 Infant Ventilator

For Attention of: Distributors and Healthcare Practitioners

Contact details of local representative (name, e-mail, telephone, address etc.)
Contact Name: Chris Worrell **Company:** SLE Ltd., UK **Address:** Twin Bridges Business Park, 232 Selsdon Road, South Croydon, Surrey, CR2 6PL. United Kingdom. **Email:** CWorrell@sle.co.uk & regulatory@sle.co.uk **Telephone:** +44 (0)20 8681 1414

Urgent Field Safety Notice (FSN)
SLE6000 Infant Ventilator
Risk addressed by FSN

Information on Affected Devices
1. Device Type(s)
The SLE6000 ventilator is a neonatal/infant ventilator.
2. Commercial name(s)
SLE6000 Infant Ventilator
3. Primary clinical purpose of device(s)
The ventilator is designed to administer ventilation to the patient's respiratory system.
4. Device Model/Catalogue/part number(s)
Model = SLE 6000 Part Number = Z6000
5. Software version
1.0.47 or below
6. Affected serial or lot number range
Please refer to "Attachment 1"
7. Associated devices
No other associated device in the context of this Field Safety Corrective Action

Reason for Field Safety Corrective Action (FSCA)
1. Description of the product problem
Through the investigation of a reported incident, SLE Ltd (SLE) has identified that its SLE6000 Infant Ventilators with software version 1.0.47 or below can give rise to a fault condition where the measured oxygen concentration is not the same as that set on the medical device. This fault condition has the potential to occur when the ventilator has been set to administer fraction of inspired oxygen (FiO2) at a concentration of 100% oxygen and the external air supply has been removed then reinserted into the ventilator. The fault condition can also occur when the ventilator has been set to administer FiO2 at a concentration of 21% oxygen initially, the air supply has been removed then reinserted and then the ventilator has been set to FiO2 at a concentration of 100%. In such cases, a "no air supply" alarm would be generated by the ventilator during disconnection of the air supply and, after reconnection, the device will generate High/Low oxygen supply alarm if the measured oxygen concentration differs by more than 5% of the set oxygen concentration. Furthermore, the fault condition does not occur when the ventilator has been set to administer FiO2 at a concentration value between 22% to 99% oxygen, regardless of whether the air supply has been removed then reinserted into the ventilator.
2. Hazard giving rise to the FSCA
The fault condition described above will mean that the measured oxygen concentration is not the same as that set on the medical device. In some instances both the measured oxygen concentration and the set oxygen concentration could be different from the actual delivered concentration. This issue may result in a life-threatening injury to patients requiring 100% oxygen.
3. Probability of problem arising
SLE's risk assessment has estimated that this incident has the probability of occurring at least once in every 500,000 device operating days.
4. Predicted risk to patient/users
There are certain neonates and infants who may require the administration of 100% oxygen to maintain acceptable partial pressure of oxygen (PaO2) and oxygen saturation (SaO2) levels.
5. Further information to help characterise the problem
Ensure external Air and O2 supplies are connected
6. Background on Issue
SLE Ltd (SLE) is conducting a voluntary field safety corrective action (FSCA) for its SLE 6000 range of

SLE Ltd
Twin Bridges Business Park, 232 Selsdon Road, South Croydon, Surrey, CR2 6PL. United Kingdom.
T: +44 (0)20 8681 1414 E: sales@sle.co.uk
F: +44 (0)20 8649 8570 W: www.sle.co.uk

Reg Office as above. Reg No: 1649988 (England and Wales) VAT Reg No. GB 372 5425 52

ventilators with software version 1.0.47 or below.

SLE requests that all affected customers follow instructions noted in this Field Safety Notice (FSN) with immediate effect.

Type of Action to mitigate the risk

1. Action To Be Taken by the User

☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device

☒ On-site device modification/inspection

☐ Follow patient management recommendations

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

Please identify affected units using the list of affected serial numbers provided in "Attachment 1" and the instructions in "Attachment 2" of this FSN. Contact your local representative noted on page 1 of this FSN. Your local representative will arrange for the system update, which will remove the fault condition.

2. By when should the action be completed?	Immediately upon receipt of this FSN.

3. Is follow-up of patients or review of patients' previous results recommended?
No
Long-term patient outcomes are not impacted by the hazard, which has given rise to this FSCA.

4. Is customer Reply Required? (Please complete form appended as "Attachment 3")	Yes

5. Action Being Taken by the Manufacturer

☐ Product Removal ☒ On-site device modification/inspection

☒ Software upgrade ☐ IFU or labelling change

☐ Other ☐ None

SLE is rolling out an upgrade to the system software, which will fix the fault condition that may give rise to the hazard identified in this FSN. Please follow the instructions noted in section 1 above. Once the affected systems held by your facility have been upgraded, please complete and return "Attachment 3" to your local representative identified on page 1 of this FSN.

6. By when should the action be completed?	With immediate effect
7. Is the FSN required to be communicated to the patient /lay user?	No

SLE Ltd
Twin Bridges Business Park, 232 Selsdon Road, South Croydon, Surrey, CR2 6PL. United Kingdom.
T: +44 (0)20 8681 1414 E: sales@sle.co.uk
F: +44 (0)20 8649 8570 W: www.sle.co.uk

Reg Office as above. Reg No: 1649988 (England and Wales) VAT Reg No. GB 372 5425 52

General Information	
1. FSN Type	New
2. Anticipated timescale for follow-up FSN	Not applicable. Please return completed "Attachment 3" (if you are a healthcare practitioner) and "Attachment 4" (if you are a distributor).
3. Manufacturer information **(For contact details of local representative refer to page 1 of this FSN)**	
a. Company Name	SLE Ltd, UK
b. Address	Twin Bridges Business Park, 232 Selsdon Road, South Croydon, Surrey, CR2 6PL. United Kingdom.
c. Website address	www.sle.co.uk
4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
5. List of attachments/appendices:	**Attachment 1:** List of Affected Serial Numbers **Attachment 2:** Instructions for identifying affected system version **Attachment 3:** Customer Reply Form **Attachment 4:** Distributor/Importer Reply Form

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

SLE Ltd
Twin Bridges Business Park, 232 Selsdon Road,
South Croydon, Surrey, CR2 6PL. United Kingdom.
T: +44 (0)20 8681 1414
E: sales@sle.co.uk
F: +44 (0)20 8649 8570
W: www.sle.co.uk

Reg Office as above. Reg No: 1649988 (England and Wales) VAT Reg No. GB 372 5425 52

Attachment 3 - Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	CC2178
FSN Date	28th November, 2019
Product/ Device name	SLE6000 Infant Ventilator
Product Code(s)	Z6000
Batch/Serial Number (s)	Please refer to “Attachment 1”

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to tick box and/or enter further comments in this space
☐	I performed all actions requested by the FSN.	Customer to tick box and/or enter further comments in this space
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to tick box and/or enter further comments in this space
☐	I have identified affected devices using the list of serial numbers noted above and contacted my local representative noted on page 1 of the FSN.	Customer to tick box and/or enter further comments in this space
☐	I do not have any affected devices.	Customer to tick box or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name		
Signature		
Date		

SLE Ltd
Twin Bridges Business Park, 232 Selsdon Road, South Croydon, Surrey, CR2 6PL. United Kingdom.
T: +44 (0)20 8681 1414 E: sales@sle.co.uk
F: +44 (0)20 8649 8570 W: www.sle.co.uk

Reg Office as above. Reg No: 1649988 (England and Wales) VAT Reg No. GB 372 5425 52

4. Return acknowledgement to sender	
Email	regulatory@sle.co.uk
Customer Helpline	+44 (0)20 8681 1414
Postal Address	Twin Bridges Business Park, 232 Selsdon Road, South Croydon, Surrey, CR2 6PL. United Kingdom.
Deadline for returning the customer reply form	4 weeks from receipt of this notice

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Attachment 4 - Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	CC2178
FSN Date	28th November, 2019
Product/ Device name	SLE6000 Infant Ventilator
Product Code(s)	Z6000
Batch/Serial Number (s)	Please refer to “Attachment 1”

2. Distributor/Importer Details	
Company Name	
Account Number	
Address	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Return acknowledgement to Sender	
Email	regulatory@sle.co.uk
Distributor/Importer Helpline	+44 (0)20 8681 1414
Postal Address	Twin Bridges Business Park, 232 Selsdon Road, South Croydon, Surrey, CR2 6PL. United Kingdom.
Deadline for returning the Distributor/Importer reply form	12 weeks from receipt of this notice

4. Distributors/Importers (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to tick box and/or enter further comments in this space
☐	I have checked my stock and quarantined inventory	Distributor/Importer to tick box and/or enter further comments in this space
☐	I have identified customers that received or may have received this device	Distributor/Importer to tick box and/or enter further comments in this space
☐	I have attached a list of affected customers	Distributor/Importer to tick box and/or enter further comments in this space
☐	I have informed the identified customers of this FSN	Distributor/Importer to tick box and enter Date of communication:

☐	I have received confirmation of reply from all identified customers	Distributor/Importer to tick box and/or enter further comments in this space
☐	I have upgraded all affected devices in line with manufacturer's service manual and provided applicable training as related to the upgrade.	Distributor/Importer to tick box. By ticking the box, you confirm that all serial number(s) listed in section 1 of this attachment have been upgraded. Enter further comments in this space.
☐	I have returned the affected devices to SLE.	Enter serial number(s) of returned device(s) or enter N/A
☐	Neither I nor any of my customers has any affected devices in inventory	Distributor/Importer to tick box or enter N/A
Print Name		
Signature		
Date		

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

SLE Ltd

Twin Bridges Business Park, 232 Selsdon Road,
South Croydon, Surrey, CR2 6PL. United Kingdom.

T: +44 (0)20 8681 1414
E: sales@sle.co.uk

F: +44 (0)20 8649 8570
W: www.sle.co.uk

Reg Office as above. Reg No: 1649988 (England and Wales) VAT Reg No. GB 372 5425 52

Attachment 1: List of Affected Serial Numbers

Model	Product Code	Ventilator Serial Number
SLE6000	Z6000	6010100037
SLE6000	Z6000	6010100038
SLE6000	Z6000	6010100039
SLE6000	Z6000	6010100056
SLE6000	Z6000	6010100057
SLE6000	Z6000	6010100058
SLE6000	Z6000	6010100059
SLE6000	Z6000	6010100060
SLE6000	Z6000	6010100061
SLE6000	Z6000	6010100097

Attachment 2 - SLE Technical bulletin

TB191101 issue 1

SLE6000 infant ventilators

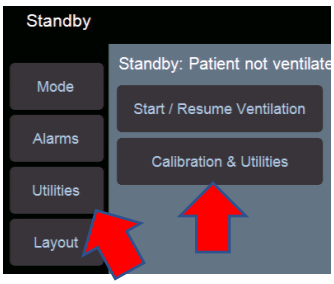
Identification of software version & upgrade procedure

This service information letter is to inform users of the SLE6000 of software upgrade procedure for V2.0.50.

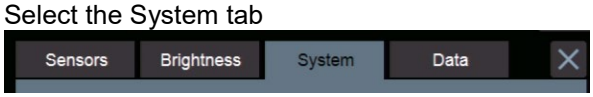
This information is only for user of ventilators running V1.0.43 or V1.0.47 that are required to upgrade to V2.0.50 as part of FSCA reference CC2178.

Confirmation of ventilator software.

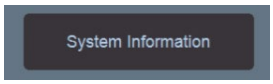
1. Turn on the ventilator.
2. Select the “Utilities” or “Calibration & Utilities” button.



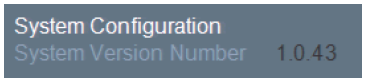
3. Select the System tab



4. Then the System information button



5. Confirm that the System version number is either V1.0.43 or V1.0.47



Caution: For all ventilators upgrading to V2.0.50 the user will have to supply the serial number prior to upgrade so the V2.0.50 licence set can be issued for that unit. Upgrading without the licence USB available will mean that the unit will not be serviceable after the upgrade.

Note 1: For licencing the user must use a SLE approved USB device. If you do not have an approved USB device please order part number G0USB/1GB.

Note 2: For ventilators running version V1.0.12 to 1.0.29 please use the manual software upgrade process detailed in the SLE6000 service manual.

Upgrade procedure warnings.

Warning: Ensure that before you commence the upgrade procedure that all external sensors are disconnected if fitted. The upgrade will fail if a sensor is connected.

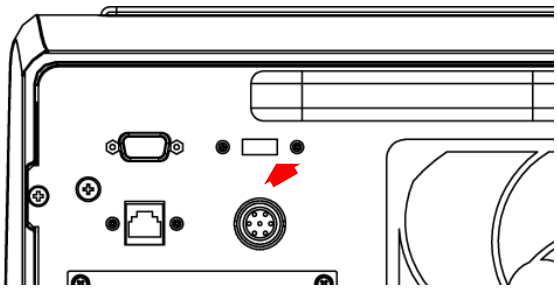
Upgrade procedure equipment

Mandatory – PNº: Z6000/USB/S03 (SLE6000 USB3 System update software – Programmed with V2.0.50.)

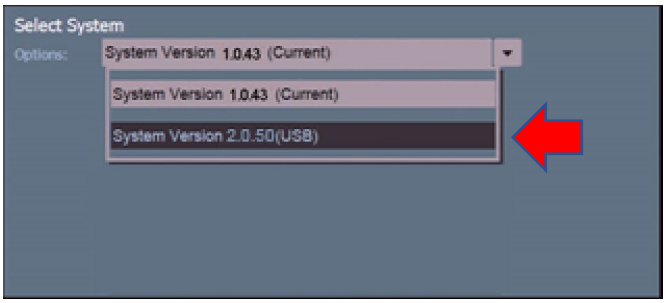
Optional - G0USB/1GB USB stick for software licencing.

Upgrade and licencing procedure

1. Insert the software update firmware USB memory stick into the top USB port of the vent.



2. Power up the ventilator
3. Navigate “Utilities”>”System”
4. Press the “System Update”.
5. Enter the “System Update” PIN (6000) and press confirm.
6. The SLE6000 System Update Utility will now be activated.
7. From the Select system the option pull down menu.
8. Select the 2.0.50 version that has (USB) at the end of System version.



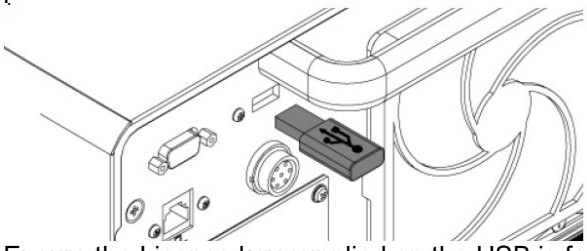
Limited, Twin Bridges Business Park, 232 Selsdon Road, South Croydon, Surrey, CR2 6PL, UK
· (0)20 8681 1414 f +44 (0)20 8649 8570 e service@sle.co.uk w www.sle.co.uk
tered Office as above Reg. No.: 1649988 (England & Wales) VAT Reg. No.: GB 372 5425 52

9. Once selected press the confirm button. This will start the automatic system update process.

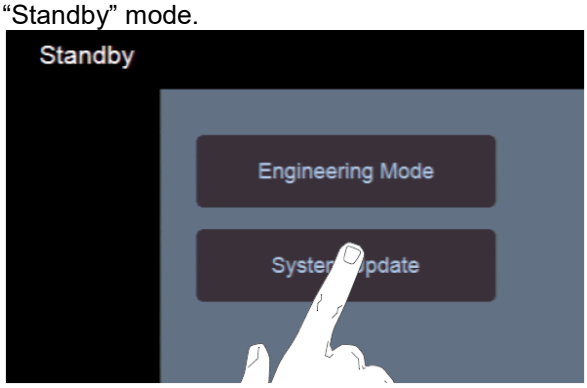
10. The progress bar will indicate the subsystem being updated and the overall progress of the installation.
11. When fully complete the message "**Updates Completed. Restart the ventilator**" will appear.
12. Turn the ventilator OFF.

License application for the upgraded ventilator.

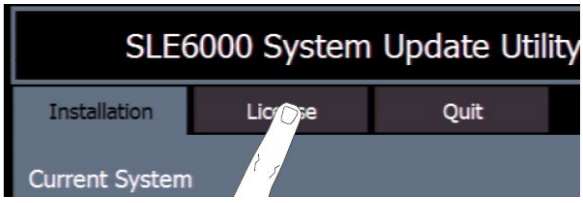
1. Insert the licence key into the “Data export” USB port on the rear of the ventilator.



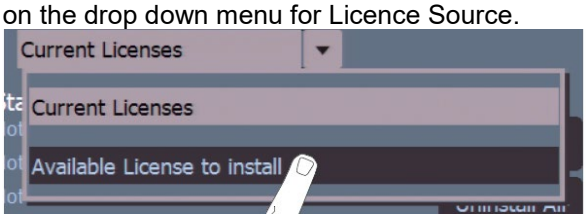
2. Ensure the Licence key supplied on the USB is for the serial number of the vent to be licenced. The ventilator will not recognise Licence keys for any other ventilator.
3. Turn on the ventilator.
4. Press the “System Update“ button from the “Standby” mode.



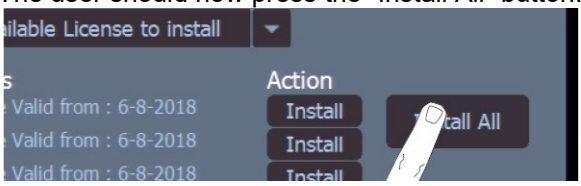
5. Enter the code “6000” and press the confirm button.
6. The SLE6000 System Update Utility. Version 2.0.4 will now become active.
7. Select the “Licence” tab.



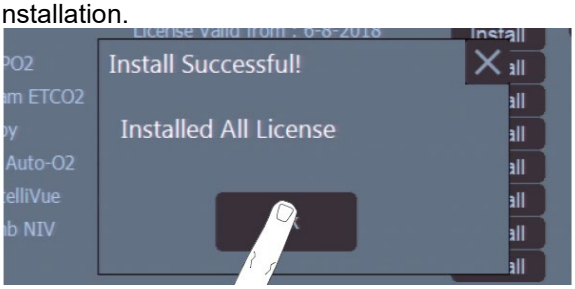
8. From the “Licence” panel press the down arrow on the drop down menu for Licence Source.



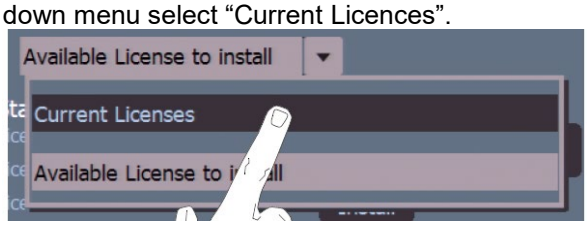
9. They may be a short pause before the "Available Licence to Install” panel appears.
10. The user will now see a list of installable Licences. The user should now press the “Install All” button.



11. When the “Installation Successful” dialog box appears press the “OK” Button to complete the installation.



12. After Installation from the Licence Source drop down menu select “Current Licences”.



13. The user will now see all installed licences.
14. To complete the installation press the quit tab and wait for the Restart ventilator panel to appear. Press and hold the power button for 15 seconds.
15. Remove the Licence USB an restart the ventilator.
16. Check in “System information” panel that the System version number reads 2.0.50

For further information please contact the SLE Service department or your local distributor.