

## Urgent Field Safety Notice

PRODUCT AFFECTED	Statscan VE0 and VE1 models
MANUFACTURER	Lodox Systems (Pty) Ltd
DATE OF NOTICE	2017-10-04
TYPE OF ACTION	Advisory notice
FSN REFERENCE:	LODXFSN-201701

### Attention: Users, Distributors, Service Technicians

Dear Customer:

Lodox Systems (Pty) Ltd have initiated a field safety corrective action on Statscan VE0 and Statscan VE1 model devices. The field safety corrective action addresses a possible malfunction that could potentially occur if the device is used beyond the expected useful life of the device (10 years).

The following device serial numbers have been identified:

STN002, STN003, STN005, STN006, STN007, STN008, STN010, STN011, STN012, STN013, STN014, STN018, STN019, STN020, STN023, STN024, STN025, STN026, STN028, STN029, STN030, STN031, STN032, STN033, STN034, STN035, STN036, STN037, STN038, STN039, STN040, STN041, STN042, STN043, STN044, STN046, STN047, STN048, STN049, STN050, STN053, STN054, STN056, STN057, STN065, STN066, STN071, STN072, STN075, STN076, STN077, STN078, STN079, STN082, STN084, STN087, STN089, STN090, STN094, STN095.

### Description of the problem:

With extensive and prolonged use of a device beyond the expected useful life of 10 years, shaving of the cable loom within the C-arm housing due to movement of the C-arm, can damage the cable loom. The damage could become extensive and then lead to a malfunction.

### Potential risk:

A damaged cable loom can cause a malfunction which could lead to an incident in which either the user, patient or body (forensics) could be injured or damaged.

### Advice on action to be taken by the user:

No action required from the user to address the field safety corrective action. It is required of each user to return the completed FSN notice form below to the nominated representative by 5 November 2017.

### Field Safety Corrective action to be taken by service technicians:

Lodox Systems (Pty) Ltd will contact and plan a preventative service on each of the affected devices. Priority will be given to devices in-use for more than 10 years.

This field safety corrective action shall be addressed at all effected sites by 31 March 2018.

The field safety corrective action includes the following:

1. Add a label that will serve as a reminder for production, installation and service technicians that indicate the correct height of the cable loom to prevent possible damage.
  - a. If the cable loom is found to be below the required levels, the service technician shall adjust the cable loom accordingly.
2. Mount the cover securing screw (button head) from the top of the bracket below the cable loom to prevent sharp edges protruding on the inside of the C-arm.
3. Add a rubber strip over the steel bracket to prevent cable loom damage due to movement.

**Transmission of this Field Safety Notice:**

This notice needs to be passed on to all relevant persons who need to be aware, within your organization, of the field safety corrective action which will include a service from a qualified service technician.

**Nominated Representative:**

Name: Lindie Venter  
Organisation: Lodox Systems (Pty) Ltd  
Address: 7 Dartfield Road  
Kramerville  
Johannesburg  
Gauteng  
South Africa  
2146  
Contact Number: +27 11 444 9118  
Contact email: lindie.venter@lodox.com

On behalf of Lodox Systems (Pty) Ltd we thank you sincerely for your help and support in completing this preventative action within the target date and regret any inconvenience that it may cause. We would like to reassure you that Lodox Systems (Pty) Ltd is committed to ensuring that only conforming and safe devices, meeting our high internal quality standards, remain on the market even beyond the useful life of our devices.

The undersigned confirms that this notice has been notified to the appropriate regulatory agency.

\_\_\_\_\_  
Lindie Venter  
Compliance and Quality Assurance Executive

\_\_\_\_\_  
Date

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## FIELD SAFETY NOTICE (FSN) – **CUSTOMER REPLY FORM**

Immediate action required – PLEASE complete this form and return to Lodox Systems (Pty) Ltd nominated representative as soon as possible.

<b>PRODUCT AFFECTED</b>	<b>Statscan VE0 and Statascan VE1</b>
<b>MANUFACTURER</b>	Lodox Systems (Pty) Ltd
<b>DATE OF NOTICE</b>	5 October 2017
<b>TYPE OF ACTION</b>	Preventative action
<b>FSN REFERENCE:</b>	<b>LODFSN-201701</b>

This receipt provides Lodox Systems (Pty) Ltd and subsequently any regulatory body, with the means to monitor the progress of the field safety corrective action and Field Safety Notice.

It is important that this acknowledgement form is returned for our records and to enable us to meet our obligations to notify the regulators of progress and final close of the field safety notice.

By signing this receipt of notice, it is acknowledged that the receiver has received, read and understood the respective actions that will follow as recommended in the FSN.

### Acknowledgement of Receipt

<b>Name:</b>		<b>Date:</b>	
<b>Signature</b>		<b>Telephone:</b>	
<b>Designation:</b>		<b>Email:</b>	
<b>Company:</b>		<b>Address:</b>	