

Date: April 30th, 2021

Urgent Field Safety Notice

SOLUSCOPE SERIE 4 PA

For Attention of: SOLUSCOPE SERIE 4 PA distributors who initiated the software upgrade to version 1.8.2 before March 26th 2021.

Contact details of local representative
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1. Information on Affected Devices

Device Type	Flexible endoscope reprocessing,
Commercial name	SOLUSCOPE SERIE 4 PA
Primary intended use of the device	Automatic Flexible Endoscope Disinfection
Device Model	SL-V4-PA
Software version	1.8.2

2. Reason for Field Safety Corrective Action (FSCA)

As a Distributor, you have been notified by Soluscope about a new version of **software 1.8.2** to be installed on the **SOLUSCOPE SERIE 4 PA** machines. This latest software upgrade was communicated without sufficiently detailed instructions to ensure its proper implementation.

In some cases, the upgrade has not been performed according to the following protocol:

- Use an empty SD card
- Enter manually the parameters that apply to customer groups
- Do not copy-paste the customer groups data from the previous software version

If the upgrade installation process is not performed properly, the control variables that had been set up for the endoscope customer groups, if any, are by default reset to zero. This leads to the absence of channel control parameters. It means endoscopes are reprocessed but controls will not notify the user in case of disconnection or blockage during the cycle.

The software 1.8.2 performs well. This issue is only related to the software upgrade installation process. This issue could arise if the machine has pre-set customized customer groups parameters and the software upgrade is copy-pasted over the previous version.

If the software upgrade installed has erased pre-set parameters, the machines will still perform the reprocessing of the endoscopes, but automatised control would fail to notify the user in case of disconnection or blockage for endoscopes belonging to Customer Groups

As per good practices required for endoscope reprocessing and as reported in the user manual, blockage and disconnection processes must be checked by a trained healthcare professional. At the end of each endoscope reprocessing cycle, the machine delivers a ticket, that a trained professional has to check and verify to validate the conformity of the cycle.

Therefore, the risk for the patient (infection triggered by an improperly reprocessed endoscope) is low.

3. Actions to mitigate the risk

Action Being Taken by the Distributor

1. As per previous communication sent by Soluscope Technical Support, suspend **immediately** the deployment of the software upgrade, as long as you did not receive the instruction notice explaining the protocol to be followed
2. In case you have initiated the software upgrade implementation at your customer sites, please **immediately** do the following:
 1. Identify the machines and corresponding healthcare facility
 2. Ensure that your Technical Support team proceeded with the upgrade manually (without any copy-paste)
3. In case the implementation has been done by copy-paste,
 - Inform **immediately** the customer with following information
 - In case there are customer groups on the machine:
 - suspend the use of the machine for those endoscopes related to customer groups, until a maintenance visit is done by your technician to proceed with the correct implementation of the software

For an endoscope related to a customer group that has been reprocessed,	
If the endoscope has not been used on a patient	If the endoscope has been used on a patient
<p>the endoscope should not be reused until its reprocessing has not been performed again:</p> <ul style="list-style-type: none"> - manually, - with Soluscope Serie 4 PA, after proper software upgrade of the machine by a technician, or - with another type of AER. 	<p>Please check the conformity of the tickets that were issued after the cycle. In case the ticket displays control values equal to zero, immediately notify the distributor and the National Competent Authority for incident reporting.</p> <p>The endoscope should not be reused until its reprocessing has not been performed again:</p> <ul style="list-style-type: none"> - manually, - with Soluscope Serie 4 PA, after proper software upgrade of the machine by a technician, or - with another type of AER.

- In case there are no customer groups on the machine:
 - do not proceed with any customer group creation if a maintenance visit has not been done by your technician to proceed with the correct implementation of the software
- Schedule an on-site visit to proceed with the correction as soon as possible
- 4. In case of any patient incident reported by Healthcare facility, report immediately the information to Soluscope and the National Competent Authority.
- 5. In case the implementation has been done manually, **no action is needed**,
- 6. Please acknowledge receipt of this communication by returning the duly completed and signed form at your earliest convenience - but no later than **May 14th, 2021**

Action Being Taken by the Manufacturer

A technical notice explaining the software upgrade protocol has been written and will be sent to you as soon as possible, so that your technical support team can proceed with the software upgrade.

Following this incident, Soluscope plans to add an additional feature into the next version of the software, to prevent cycle with control limit values at zero. This will be integrated

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into version 1.8.3 currently under development for compliance with the revision of standard 15883-4 version 2018.

4. General Information

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

FSN Type	New
List of attachments/appendices:	Reply form

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organization or to any relevant third part supporting you in the technical support of Soluscope machines

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.